Grant Agreement number: 101003673 — I-MOVE-COVID-19 — H2020-SC1-PHE-CORONAVIRUS-2020/H2020-SC1-PHE-CORONAVIRUS-2020
Amendment Reference No AMD-101003673-1

EUROPEAN COMMISSION
Directorate-General for Research and Innovation
People
Director

AMENDMENT Reference No AMD-101003673-1

Grant Agreement number: 101003673 — Multidisciplinary European network for research, prevention and control of the COVID-19 Pandemic (I-MOVE-COVID-19)

The parties agree to amend the Grant Agreement as follows ('**Amendment**'):

1 . Addition of a new beneficiary

The following new beneficiaries are added:

- INSTITUT NATIONAL DE LA SANTE ET DE LA RECHERCHE MEDICALE (INSERM) — as from 4 June 2020
- VRIJE UNIVERSITEIT BRUSSEL (VUB) — as from 4 June 2020
- ASSISTANCE PUBLIQUE HOPITAUX DE PARIS (AP-HP) — as from 4 June 2020
- CENTRE HOSPITALIER UNIVERSITAIRE MONTPELLIER (CHUM) — as from 4 June 2020
- CENTRE HOSPITALIER UNIVERSITAIRE DE RENNES (CHU Rennes) — as from 4 June 2020
- HOSPICES CIVILS DE LYON (HCL) — as from 4 June 2020

This implies the **following changes** to the Grant Agreement:

- The new beneficiaries and the 'accession date' are added to the **Preamble**:

  *21. "**INSTITUT NATIONAL DE LA SANTE ET DE LA RECHERCHE MEDICALE (INSERM)**, established in RUE DE TOLBIAC 101, PARIS 75654, France, VAT number: FR31180036048, — as from 4 June 2020"*

  *23. "**VRIJE UNIVERSITEIT BRUSSEL (VUB)**, established in PLEINLAAN 2, BRUSSEL 1050, Belgium, VAT number: BE0449012406, — as from 4 June 2020"*

  *25. "**ASSISTANCE PUBLIQUE HOPITAUX DE PARIS (AP-HP)**, established in 3 AVENUE VICTORIA, PARIS 75000, France, VAT number: FR95267500452, — as from 4 June 2020"*

  *27. "**CENTRE HOSPITALIER UNIVERSITAIRE MONTPELLIER (CHUM)**, established in AVENUE DU DOYEN GASTON GIRAUD 191, MONTPELLIER 34000, France, VAT number: FR80263400160, — as from 4 June 2020"*

  *28. "**CENTRE HOSPITALIER UNIVERSITAIRE DE RENNES (CHU Rennes)**, established in RUE HENRI LE GUILLOUX -HOPITAL 2, RENNES CEDEX 9 35033, France, VAT number: FR01263500076, — as from 4 June 2020"*

*30. "**HOSPICES CIVILS DE LYON (HCL)**, established in QUAI DES CELESTINS 3, LYON 69002, France, — as from 4 June 2020"*

2. Removal of a linked third party

The participation of the following linked third party is ended for:

- FUNDACION PUBLICA MIGUEL SERVET (NBM-FMS), affiliated or linked to ORGANISMO AUTONOMO INSTITUTO DE SALUD PUBLICA Y LABORAL DE NAVARRA - on the day after the submission of the amendment request

This implies the **following changes** to the Grant Agreement:

- The 'end date of the participation' is added, for the linked third party, in **Article 14.1**:

"FUNDACION PUBLICA MIGUEL SERVET (NBM-FMS), affiliated or linked to ORGANISMO AUTONOMO INSTITUTO DE SALUD PUBLICA Y LABORAL DE NAVARRAuntil end date of participation"

The joint and several liability of the linked third party (if any) continues also after the end of its participation.

If the estimated budget in Annex 2 is changed, the maximum amount referred to in Articles 44.1.1(b), 44.1.2(b)(i), and 44 .1.3(b)(i) and in the Declaration on joint and several liability (Annex 3a) is that of the estimated budget before this amendment.

3. Change of Annex 1 (description of the action)

Annex 1 is changed and replaced by the Annex 1 attached to this Amendment.

4 . Change to the Commission/Agency right to object to transfers or licensing

As from 4 June 2020, the Commission may object to a transfer of ownership or the licensing of results.

This implies the **following changes** to the Grant Agreement:

- The option for 5.1.2e in **Article 30.3** becomes applicable.

5 . Changes of Annex 2 (estimated budget)

Annex 2 is changed and replaced by the Annex 2 attached to this Amendment.

6. Change of the maximum grant amount (increase)

The maximum grant amount set out in **Article 5.1** is changed to:

"**EUR 2 808 162.50** (two million eight hundred and eight thousand one hundred and sixty two EURO and fifty eurocents)".

7. Change of the estimated eligible costs

The estimated eligible costs of the action set out in **Article 5.2** are changed to:

"**EUR 2 808 162.50** (two million eight hundred and eight thousand one hundred and sixty two EURO and fifty eurocents)".

8. Changes due to Changes via general manual amendment clause

Change concerning additional exploitation obligations:
The beneficiaries must comply with additional exploitation obligations.
This implies the following changes to the Grant Agreement:
• The option for additional exploitation obligations in Article 28.1 becomes applicable.
Change concerning additional dissemination obligations:
The beneficiaries must comply with additional dissemination obligations.
This implies the following changes to the Grant Agreement:
• The general option for additional dissemination obligations in Article 29.1 becomes applicable.
Change concerning open access to research data for health actions targeting public health emergencies:
The beneficiaries must comply with the open access obligations for health actions targeting public health emergencies.
This implies the following changes to the Grant Agreement:
• The option 1c for health actions targeting public health emergencies in Article 29.3 becomes applicable."

All other provisions of the Grant Agreement and its Annexes remain unchanged.

This Amendment **enters into force** on the day of the last signature.

This Amendment **takes effect** on the date on which the amendment enters into force, except where a different date has been agreed by the parties (for one or more changes).

Please inform the other members of the consortium of the Amendment.

SIGNATURES

For the coordinator

For the Commission

Enclosures:

Annex 1
Annex 2

EUROPEAN COMMISSION
Directorate-General for Research and Innovation

RTD.E – People
E.2 – Combatting Diseases

ANNEX 1 (part A)

Research and Innovation action

NUMBER — 101003673 — I-MOVE-COVID-19

Table of Contents

1.1. The project summary

Project Number [1]	101003673	Project Acronym [2]	I-MOVE-COVID-19

One form per project	
General information	
Project title [3]	Multidisciplinary European network for research, prevention and control of the COVID-19 Pandemic
Starting date [4]	16/03/2020
Duration in months [5]	27
Call (part) identifier [6]	H2020-SC1-PHE-CORONAVIRUS-2020
Topic	SC1-PHE-CORONAVIRUS-2020 Advancing knowledge for the clinical and public health response to the 2019-nCoV epidemic
Fixed EC Keywords	
Free keywords	Primary care/Hospital networks, Pooled epidemiological studies,multidisciplinary network, epidemiological/clinical/virological surveillance, respiratory disease research, vaccines/treatment evaluation

Abstract [7]

I-MOVE-COVID-19 aims to obtain epidemiological, clinical and virological information about COVID-19 and patients infected with SARS-CoV-2, through provision of a flexible surveillance platform (adaptable to the epidemiological situation), research studies, hypothesis-testing and evaluation of public health interventions (e.g. vaccination, antivirals) in order to contribute to the knowledge base, guide patient management, and inform the public health response. This will be achieved through adaptation and expansion of the existing, long-running, Europe-wide influenza surveillance network (I-MOVE) to include COVID-19. The network includes primary care networks, hospitals, national laboratory reference centres in eleven countries.

I-MOVE-COVID-19 priority activities and research projects will be selected based on ECDC/WHO input and the proposal's detailed list. These will be conducted by mobilising an existing large European multidisciplinary network, combining the expertise and resources of groups working in surveillance (epidemiological, clinical, virological), respiratory disease research, and evaluation of vaccines/treatments. Through protocol sharing and pooling European results, questions will be answered which could not be efficiently answered by countries acting alone. I-MOVE-COVID-19 will share study results rapidly and widely with national and international partners and with the wider scientific community and contribute to clinical management of patients and public health preparedness and response to COVID-19.

1.2. List of Beneficiaries

Project Number [1]	101003673	Project Acronym [2]	I-MOVE-COVID-19

List of Beneficiaries

No	Name	Short name	Country	Project entry date[8]	Project exit date
1	EPICONCEPT	EPICONCEPT	France		
2	INSTITUTO DE SALUD CARLOS III	ISCIII	Spain		
3	ORGANISMO AUTONOMO INSTITUTO DE SALUD PUBLICA Y LABORAL DE NAVARRA	ISPLN	Spain		
4	NHS NATIONAL SERVICES SCOTLAND	NHSNS	United Kingdom		
5	INSTITUTO NACIONAL DE SAUDE DR. RICARDO JORGE	INSA	Portugal		
6	STICHTING NEDERLANDS INSTITUUT VOOR ONDERZOEK VAN DE GEZONDHEIDSZORG	NIVEL	Netherlands		
7	Department of Health	DH	United Kingdom		
8	LIETUVOS SVEIKATOS MOKSLU UNIVERSITETAS	LSMU	Lithuania		
9	HEALTH SERVICE EXECUTIVE HSE	HSE	Ireland		
10	FOLKHALSOMYNDIGHETEN	FOHM	Sweden		
11	VIENNA VACCINE SAFETY INITIATIVE EV	VIVI	Germany		
12	INSTITUTUL NATIONAL DE CERCETARE-DEZVOLTARE MEDICO-MILITARA CANTACUZINO	IC	Romania		
13	UNIVERSITE DE CORSE PASCAL PAOLI	UCPP	France		
14	SORBONNE UNIVERSITE	SU	France		
15	AGENCE NATIONALE DE SANTE PUBLIQUE	SPF	France		
16	INSTITUT PASTEUR	IP	France		
17	MINISTERIO DA SAUDE - REPUBLICA PORTUGUESA	MS	Portugal		
18	THE CHANCELLOR, MASTERS AND SCHOLARS OF THE UNIVERSITY OF OXFORD	UOXF	United Kingdom		
19	INSTITUTE OF PUBLIC HEALTH	IPHA	Albania		
20	RIJKSINSTITUUT VOOR VOLKSGEZONDHEID EN MILIEU	RIVM	Netherlands		

1.2. List of Beneficiaries

No	Name	Short name	Country	Project entry date[8]	Project exit date
21	INSTITUT NATIONAL DE LA SANTE ET DE LA RECHERCHE MEDICALE	INSERM	France	04/06/2020	
23	VRIJE UNIVERSITEIT BRUSSEL	VUB	Belgium	04/06/2020	
25	ASSISTANCE PUBLIQUE HOPITAUX DE PARIS	AP-HP	France	04/06/2020	
27	CENTRE HOSPITALIER UNIVERSITAIRE MONTPELLIER	CHUM	France	04/06/2020	
28	CENTRE HOSPITALIER UNIVERSITAIRE DE RENNES	CHU Rennes	France	04/06/2020	
30	HOSPICES CIVILS DE LYON	HCL	France	04/06/2020	

1.3. Workplan Tables - Detailed implementation

1.3.1. WT1 List of work packages

WP Number[9]	WP Title	Lead beneficiary[10]	Person-months[11]	Start month[12]	End month[13]
WP1	Management, scientific coordination, communication	1 - EPICONCEPT	16.70	1	27
WP2	Primary care surveillance networks	6 - NIVEL	112.70	1	27
WP3	Hospital surveillance network	4 - NHSNS	171.60	1	27
WP4	Pooled studies	1 - EPICONCEPT	114.40	1	27
WP5	Ethics requirements	1 - EPICONCEPT	N/A	1	27
		Total	415.40		

1.3.2. WT2 list of deliverables

Deliverable Number[14]	Deliverable Title	WP number[9]	Lead beneficiary	Type[15]	Dissemination level[16]	Due Date (in months)[17]
D1.1	Report kick-off ST-SC Committee meeting	WP1	1 - EPICONCEPT	Report	Public	1
D1.2	Website	WP1	1 - EPICONCEPT	Demonstrator	Public	3
D1.3	Data management plan	WP1	1 - EPICONCEPT	ORDP: Open Research Data Pilot	Public	6
D1.4	First Report Steering-Scientific Committee, scientific meeting	WP1	1 - EPICONCEPT	Report	Public	13
D1.5	Second Report Steering-Scientific Committee, scientific meeting	WP1	1 - EPICONCEPT	Report	Public	25
D1.6	Interim activity Report	WP1	1 - EPICONCEPT	Report	Public	6
D1.7	Report to identify synergies and areas for collaboration	WP1	1 - EPICONCEPT	Report	Public	1
D1.8	Update no1 of Report to identify synergies and areas for collaboration	WP1	1 - EPICONCEPT	Report	Public	12
D1.9	Update no2 of Report to identify synergies and areas for collaboration	WP1	1 - EPICONCEPT	Report	Public	24
D2.1	Report describing current COVID-19 surveillance practices and recommendations	WP2	6 - NIVEL	Report	Public	1
D2.3	Phased surveillance protocol	WP2	6 - NIVEL	Report	Public	3
D2.4	WP2 Surveillance monitoring and evaluation protocol	WP2	6 - NIVEL	Report	Public	4
D2.5	WP2 First surveillance bulletin including data from all sentinel sites	WP2	6 - NIVEL	Report	Public	6
D2.6	WP2 Second surveillance bulletin including data from all sentinel sites	WP2	6 - NIVEL	Report	Public	12

Deliverable Number[14]	Deliverable Title	WP number[9]	Lead beneficiary	Type[15]	Dissemination level[16]	Due Date (in months)[17]
D2.7	WP2 Third surveillance bulletin including data from all sentinel sites	WP2	6 - NIVEL	Report	Public	24
D2.8	WP2 Surveillance evaluation report	WP2	6 - NIVEL	Report	Public	24
D3.1	Report describing current COVID-19 hospital surveillance practices	WP3	4 - NHSNS	Report	Public	1
D3.3	Hospital Phased surveillance protocol	WP3	4 - NHSNS	Report	Public	3
D3.4	Surveillance monitoring and evaluation protocol	WP3	4 - NHSNS	Report	Public	4
D3.5	First surveillance bulletin including data from all sentinel sites	WP3	4 - NHSNS	Report	Public	6
D3.6	Second surveillance bulletin including data from all sentinel sites	WP3	4 - NHSNS	Report	Public	12
D3.7	Third surveillance bulletin including data from all sentinel sites	WP3	4 - NHSNS	Report	Public	24
D3.8	Surveillance evaluation report	WP3	4 - NHSNS	Report	Public	24
D3.9	Pooled database for clinical samples	WP3	4 - NHSNS	Report	Public	12
D4.1	Report describing existing information on COVID-19 and knowledge gaps and recommendations on short-term and longer-term priority studies.	WP4	1 - EPICONCEPT	Report	Public	1
D4.2	Protocols for priority studies early in the epidemic	WP4	1 - EPICONCEPT	Report	Public	3
D4.3	Protocols for priority studies later in the epidemic	WP4	1 - EPICONCEPT	Report	Public	14
D4.4	Study reports on priority studies early in the epidemic	WP4	1 - EPICONCEPT	ORDP: Open Research Data Pilot	Public	12
D4.5	Study reports on priority studies later in the epidemic	WP4	1 - EPICONCEPT	Report	Public	24

Deliverable Number[14]	Deliverable Title	WP number[9]	Lead beneficiary	Type[15]	Dissemination level[16]	Due Date (in months)[17]
D4.6	First draft of Vaccine Effectiveness Protocol	WP4	1 - EPICONCEPT	Report	Confidential, only for members of the consortium (including the Commission Services)	11
D5.1	H - Requirement No. 1	WP5	1 - EPICONCEPT	Ethics	Confidential, only for members of the consortium (including the Commission Services)	6
D5.2	POPD - Requirement No. 2	WP5	1 - EPICONCEPT	Ethics	Confidential, only for members of the consortium (including the Commission Services)	6
D5.3	HCT - Requirement No. 4	WP5	1 - EPICONCEPT	Ethics	Confidential, only for members of the consortium (including the Commission Services)	6
D5.4	EPQ - Requirement No. 6	WP5	1 - EPICONCEPT	Ethics	Confidential, only for members of the consortium (including the Commission Services)	6
D5.5	GEN - Requirement No. 7	WP5	1 - EPICONCEPT	Ethics	Confidential, only for members of the consortium (including the Commission Services)	3
D5.6	GEN - Requirement No. 9	WP5	1 - EPICONCEPT	Ethics	Confidential, only for members of the consortium (including the Commission Services)	12
D5.7	GEN - Requirement No. 10	WP5	1 - EPICONCEPT	Ethics	Confidential, only for members of the consortium (including the Commission Services)	27

1.3.3. WT3 Work package descriptions

Work package number [9]	WP1	Lead beneficiary [10]	1 - EPICONCEPT
Work package title	Management, scientific coordination, communication		
Start month	1	End month	27

Objectives

To implement a project managerial structure that ensures efficient management of the project at financial, administrative and scientific levels
To guarantee that the project is appropriately adapted to the COVID-19 situation and implemented accordingly
To define resources, and tools for ensuring that all expected results are delivered on time, with an adequate level of quality and within budget
To ensure effective communication and coordination of activities between work packages to help drive the whole Consortium as a team towards successful completion
To ensure optimal communication and dissemination of results and knowledge generated by the project to relevant national, European and international stakeholders and other complementary H2020 initiatives
To predict, mitigate and overcome research-related risks
To provide scientific advice and ensure that studies are conducted using robust scientific methods
To facilitate the exchange of experiences and create links with existing initiatives working on public health preparedness, surveillance and response to COVID-19 both in Europe and internationally

Description of work and role of partners

WP1 - Management, scientific coordination, communication [Months: 1-27]
EPICONCEPT
Description of work
WP1 - Management, Scientific Coordination, Communication [Months: 1-26] WP Leader
Epiconcept

Task 1.1. Management [M1- M26], Task leader Epiconcept. Contributors: all WP leaders
1. Establish a work plan; control and update regularly
2. Provide support to and organise communication with the Steering-Scientific Committee and Executive Board
3. Provide support to organise meetings, technical workshops, videoconferences (logistics, minutes, etc.)
4. Financially manage the programme: cost control, budget management and distribution
5. Set up reporting mechanisms for financial and technical reports
6. Be the focal point for the Commission, coordinate the Grant Agreement signature and potential amendments
Task 1.2. – Risk Management (M1-M26), Task leader Epiconcept. Contributors: all partners
A risk review will be a permanent item on the agenda for each Steering-Scientific Committee and Executive Board meeting. The risks identified in this proposal will form the foundation for the project risk register. The risk review will seek to check on the status of already identified risks and discuss necessary mitigation as well as identify any new or emerging risks and how to mitigate them; newly identified risks will be added to the risk register. The periodic risk review process will upgrade or downgrade all risks and consider any new developments for mitigation.
Task 1.3. Internal Network Communication [M1- M26], Task leader Epiconcept. Contributors: WP leaders
Collaborative tools will be established for the communication within the Consortium including a library for documents (protocols, articles, minutes of meetings, reports), a calendar of events, and mailing lists.
The website will include a reserved/protected areas for each work package. In addition, periodical videoconferences (general, work package/scientific group-specific) will be organised.

Task 1.4. Communication outside the network [M1-M26], Task leader Epiconcept. Contributors: all beneficiaries
The Steering-Scientific Committee will establish a communication strategy to disseminate the project results and progress with stakeholders including European Agencies (ECDC, EC, EMA), international agencies (WHO-HQ, WHO/ Europe), national and regional health authorities, and the scientific community. The communication tools will include an external website, study protocols, newsletters, scientific articles, presentations in international congresses, use of repositories, etc. Details on how I-MOVE-COVID-19 will manage research data/results generated and collected during the project are outlined in the draft data management plan (Section 2.2.c).

Each study site will be responsible for the communication of the study site results at national or regional level. The Steering-Scientific Committee will define the overall communication of the network.

Task 1.5. Steering-Scientific Committee and Executive Board meeting implementation [M1- M26] Task co-led by Epiconcept and the Executive Board (WP leaders)
We propose a Steering-Scientific Committee to be implemented with the participation of one expert per beneficiary, Epiconcept, ECDC, and WHO/Europe.
The Chairman will be designated by the Steering-Scientific Committee. The role of the committee will be to:
1. Monitor the project progress
2. Propose corrective measures in case of deviance from the Work Plan
3. Propose and validate a communication plan, including issues related to data access
4. Ensure the coordination and coherence of all work packages and scientific working groups
5. Liaise with each work package

An initial kick-off meeting will be organised for WP leaders to present an update of the COVID-19 situation and define with the Steering-Scientific Committee priority actions. Because a face-to-face meeting is not feasible in the current COVID-19 situation, , a webconference system will be in place for the kick-off meeting. Plenary in-person meetings will be held yearly thereafter and will be rotated between different partners.

The Executive Board will be formed by the WP leaders and the Coordinator of the virology activities (National Centre for Microbiology, ISCIII). The Executive Board will have video conferences every 3 months (maximum) to allow for close monitoring of progress. Every WP leader will present a progress report and next steps for the subsequent period at each meeting. Upcoming deliverables and milestones will be reviewed. Permanent agenda items will include innovations, project risks, and publications.

Task 1.6. Organise scientific meetings and technical workshops [M1-M24] Task leader Epiconcept. Contributors: all beneficiaries
An annual conference will be organised to present the scientific results of the technical work packages, discuss methodological and operational aspects, summarise lessons learnt and share experiences with other European and international initiatives working on COVID-19. To avoid travelling and maximise cost, the scientific conference will be held right after the Steering-Scientific Committee meeting and in the same venue. In addition, restricted technical workshops will be organised to discuss specific questions for each technical work package.
The meetings will be held in English.

For each meeting, the WP1 leader will:
Develop the agenda in agreement with all work package leaders
Propose the list of meeting participants to be accepted by the Steering-Scientific Committee
Ensure the delivery of the full meeting, including:
o Organisation of travel for all participants and coverage of all costs related to the travel of experts (economy class) to attend the meeting;
o Organisation of meals and accommodation and coverage of all costs for all participants;
o Provide the meeting venue as appropriate, ensuring smooth implementation and ideal working conditions; including all relevant material such as personal computers, video projector, screens, flip charts), and coffee breaks during meetings;
o Provide in advance material needed to prepare the meeting;
o Prepare a meeting report including agenda list of participants, summary of discussion points;
o Ensure that all participants sign the participant list for each day of the meeting;
o For participants willing to share their presentation, collect their acceptance on a signed form and make these participant presentations available to the website and other meeting participants.

Participation per Partner

Partner number and short name	WP1 effort
1 - EPICONCEPT	16.70
Total	16.70

List of deliverables

Deliverable Number[14]	Deliverable Title	Lead beneficiary	Type[15]	Dissemination level[16]	Due Date (in months)[17]
D1.1	Report kick-off ST-SC Committee meeting	1 - EPICONCEPT	Report	Public	1
D1.2	Website	1 - EPICONCEPT	Demonstrator	Public	3
D1.3	Data management plan	1 - EPICONCEPT	ORDP: Open Research Data Pilot	Public	6
D1.4	First Report Steering-Scientific Committee, scientific meeting	1 - EPICONCEPT	Report	Public	13
D1.5	Second Report Steering-Scientific Committee, scientific meeting	1 - EPICONCEPT	Report	Public	25
D1.6	Interim activity Report	1 - EPICONCEPT	Report	Public	6
D1.7	Report to identify synergies and areas for collaboration	1 - EPICONCEPT	Report	Public	1
D1.8	Update no1 of Report to identify synergies and areas for collaboration	1 - EPICONCEPT	Report	Public	12
D1.9	Update no2 of Report to identify synergies and areas for collaboration	1 - EPICONCEPT	Report	Public	24

Description of deliverables

D1.1 : Report kick-off ST-SC Committee meeting [M1]
A kick-off meeting will be organised with the participation of all beneficiaries. During this first meeting, the Steering-Scientific Committee will review the COVID-19 epidemiological situation and identify priority research questions to respond to. If some of the beneficiaries are unable to travel due to their implication in the COVID-19 response, Epiconcept will provide web conference facilities for them to join.
D1.2 : Website with different access levels and tools for internal collaboration, communication [M2]
A website will be available with three levels of access: restricted to the beneficiaries, accessible to partner institutions, and open to the public. Beneficiaries will exchange results using the restricted website area. Preliminary results will be shared among relevant study sites during periodic videoconferences. The website will include a library of documents (protocols, articles, training material, videoconference minutes, etc).
D1.3: Data management plan [M6] The draft data management plan (section 2.2.c) will be reviewed and adapted according to input from the Steering-Scientific Committee and partners, noting that this deliverable will evolve during the lifetime of the project in order to present the status of the project's reflections on data management.
D1.4 : First Report Steering-Scientific Committee, scientific meeting [M13] Report including agenda, participants, summary of the presentations and main points discussed
D1.5 : Second Report Steering-Scientific Committee, scientific meeting [M25] Report including agenda, participants, summary of the presentations and main points discussed

D1.1 : Report kick-off ST-SC Committee meeting [1]

A kick-off meeting will be organised (by VC) with the participation of all beneficiaries. During this first meeting, the Steering-Scientific Committee will review the COVID-19 epidemiological situation and identify priority research questions to respond to. Epiconcept will provide web conference facilities for participants to join.

D1.2 : Website [3]

with different access levels and tools for internal collaboration, communication [M3] A website will be available with three levels of access: restricted to the beneficiaries, accessible to partner institutions, and open to the public. Beneficiaries will exchange results using the restricted website area. Preliminary results will be shared among relevant study sites during periodic videoconferences. The website will include a library of documents (protocols, articles, training material, videoconference minutes, etc).

D1.3 : Data management plan [6]

The draft data management plan (section 2.2.c) will be reviewed and adapted according to input from the Steering-Scientific Committee and partners, noting that this deliverable will evolve during the lifetime of the project in order to present the status of the project's reflections on data management.

D1.4 : First Report Steering-Scientific Committee, scientific meeting [13]

Report including agenda, participants, summary of the presentations and main points discussed

D1.5 : Second Report Steering-Scientific Committee, scientific meeting [25]

Report including agenda, participants, summary of the presentations and main points discussed

D1.6 : Interim activity Report [6]

Short report early update on the work

D1.7 : Report to identify synergies and areas for collaboration [1]

Report on virtual meeting with the leadership of other thematically relevant SARS-CoV2 projects funded under the Expression of Interest SC1-PHE-CORONAVIRUS-2020 to identify synergies and areas for collaboration. Description of the deliverable This report will include: 1) Plan for regular (follow up) meetings to update on each other's progress 2) Concrete plan to ensure the use of common study protocols and harmonised data collection, such as for case management in primary and hospital care facilities. 3) Plan to ensure coordinated modelling 4) Set up of inter-project working groups, where relevant, to align efforts throughout the projects lifetime 5) Ensure the integration of social sciences capacities across projects, as well as collaboration and coordination of activities 6) Share any research finding with relevance for public health policy on the dedicated platform (Health Policy Platform/research for policy action)

D1.8 : Update no1 of Report to identify synergies and areas for collaboration [12]

Update of deliverable D1.7

D1.9 : Update no2 of Report to identify synergies and areas for collaboration [24]

Update of deliverable D1.8

Schedule of relevant Milestones

Milestone number[18]	Milestone title	Lead beneficiary	Due Date (in months)	Means of verification
MS1	Kick-off meeting	1 - EPICONCEPT	3	Kick-off meeting report
MS2	Website used	1 - EPICONCEPT	3	Website used for information sharing
MS3	Presentation of first year results at ST-SC meeting	1 - EPICONCEPT	13	Report first scientific meeting
MS4	Presentation of second year results at ST-SC meeting	1 - EPICONCEPT	25	Report second scientific meeting

Work package number [9]	WP2	Lead beneficiary [10]	6 - NIVEL
Work package title	Primary care surveillance networks		
Start month	1	End month	27

Objectives

To enhance hospital surveillance in seven countries to rapidly detect and report severe (hospitalised) COVID-19 cases
To develop/adapt generic hospital surveillance protocols (including follow up of patients until hospital discharge) that are flexible to rapidly adapt to the epidemiological context (e.g. increased severe disease incidence)
To describe suspected and confirmed cases with severe disease
To identify early transmission in the community by detecting cases not identified previously as contacts of confirmed cases
To strengthen preparedness to respond to COVID-19 through hospital surveillance
To implement appropriate protocols to collect data for relevant clinical, epidemiological, and virological studies in WP4
To implement relevant protocols to collect virological, clinical and epidemiological data from patients with severe disease according to international guidelines

Description of work and role of partners

WP2 - Primary care surveillance networks [Months: 1-27]
NIVEL, ISCIII, ISPLN, NHSNS, INSA, DH, HSE, FOHM, UCPP, SU, SPF, IP, MS , UOXF, RIVM
Description of work
WP2 [Months: 1-24] WP leader NIVEL
Preparedness phase
Task 2.1. Review of existing COVID-19 surveillance activities in EU and UK primary care sentinel systems [M1-M24], Task leader NIVEL. Contributors: WP2 beneficiaries
WP2 will compile information on COVID-19 surveillance activities conducted in primary care sentinel systems, including laboratories. Participating sentinel networks will create an inventory, then meet (tele/video-conferences or face-to-face if feasible) to identify strengths and challenges and recommend how the systems could be reinforced in the different phases of the epidemic. The review will be updated over the project duration.
Task 2.2. Capacity strengthening [M2-M24], Task leader NIVEL Contributors: WP2 beneficiaries.
Based on the results of task 2.1, WP2 will identify and conduct priority activities (in consultation with ECDC) to strengthen preparedness, virological and epidemiological surveillance, infection control and case management in participating sentinel networks: training of clinical, administrative and laboratory staff (e.g. webinars). This will also include the immediate sharing of laboratory protocols for whole genome sequencing (WGS) for different platforms.
Task 2.3. Phased surveillance protocol [M2-M3], Task leader NIVEL. Contributors: WP2 beneficiaries
WP2 will develop or adapt existing surveillance protocols for the different phases of the epidemic. The protocols will include the recruitment strategy, inclusion and exclusion criteria, process of obtaining informed consent, case definition, study population, exposures, risk/preventive factors, random or systematic selection of cases for laboratory diagnostics in case of high incidence, samples and tests to be performed (e.g. RT-PCR, rapid tests/self-swabbing, if available - viral genetic characterisation), laboratory procedures (WGS), safety measures when taking/handling/processing of samples, data flow, case management, and monitoring indicators. The surveillance protocol will take into account the case definitions and other surveillance recommendations at national, European (ECDC) and international (WHO) levels. Scripts for automatic analysis will be developed. The protocols will be harmonised, so data can be pooled into a multicentre study.
Task 2.4. Surveillance monitoring and evaluation protocol [M4], Task leader Epiconcept. Contributors: WP2 beneficiaries
WP2 will develop a surveillance monitoring and evaluation protocol with key indicators to monitor data collection, performance and surveillance attributes adapted to the different phases of the epidemic.
Implementation phase
Task 2.5. Surveillance [M3- 24], Task leaders NIVEL and Epiconcept. Contributors: WP2 beneficiaries.
Surveillance will be reinforced according to the priorities identified in Task 2.1. Participant sentinel sites will adapt the generic protocols to the epidemiological situation in each country. Data collected will be shared with ECDC and other actors. Participating sentinel networks will produce automatic (based on analytical scripts developed by Epiconcept) epidemiological and virological reports (frequency depending on the phase of the epidemic) describing cases by clinical,

virological and epidemiological characteristics. Epiconcept will make tables and graphs available on the I-MOVE-COVID-19 website, and archive them in another repository for longevity.
Task 2.6. Provide data to WP4 to conduct pooled studies according to priority questions and following the scientific protocols [M3- 24], Task leaders NIVEL and Epiconcept. Contributors: WP2 beneficiaries.
Many of the epidemiological studies proposed in WP4 are based on pooled surveillance data from WP2 and WP3. WP2 will provide to the WP4 leader the data needed to conduct pooled analyses to respond to the relevant priority questions (following WP4 protocols). WP2 beneficiaries will provide inputs on the epidemiological study protocols developed by WP4 (See WP4 description).
Task 2.7. Sequence and isolate viruses from respiratory samples from acute SARS-CoV-2 positive cases [M2- 24], Task leader ISCIII, Contributors: WP2 beneficiaries
Specimens from WP2 SARS-CoV-2 positive patients will be used for virus isolation and sequencing; results will be pooled and sequencing results shared in GISAID. Dedicated bioinformatics pipelines will be used for analysis of viral sequencing data. These data will be provided to WP4 for epidemiological and modelling studies.

Participation per Partner

Partner number and short name	WP2 effort
2 - ISCIII	12.60
FIBAO	3.00
IACS	3.00
3 - ISPLN	13.60
4 - NHSNS	3.60
UNI. STRATHC.	1.00
5 - INSA	6.50
6 - NIVEL	12.70
7 - DH	4.60
9 - HSE	9.80
10 - FOHM	10.00
13 - UCPP	7.20
14 - SU	9.60
15 - SPF	1.00
16 - IP	1.00
17 - MS	6.50
18 - UOXF	5.00
20 - RIVM	2.00
Total	112.70

List of deliverables

Deliverable Number[14]	Deliverable Title	Lead beneficiary	Type[15]	Dissemination level[16]	Due Date (in months)[17]
D2.1	Report describing current COVID-19	6 - NIVEL	Report	Public	1

List of deliverables

Deliverable Number[14]	Deliverable Title	Lead beneficiary	Type[15]	Dissemination level[16]	Due Date (in months)[17]
	surveillance practices and recommendations				
D2.3	Phased surveillance protocol	6 - NIVEL	Report	Public	3
D2.4	WP2 Surveillance monitoring and evaluation protocol	6 - NIVEL	Report	Public	4
D2.5	WP2 First surveillance bulletin including data from all sentinel sites	6 - NIVEL	Report	Public	6
D2.6	WP2 Second surveillance bulletin including data from all sentinel sites	6 - NIVEL	Report	Public	12
D2.7	WP2 Third surveillance bulletin including data from all sentinel sites	6 - NIVEL	Report	Public	24
D2.8	WP2 Surveillance evaluation report	6 - NIVEL	Report	Public	24

Description of deliverables

D2.1 Report describing current COVID-19 surveillance practices and recommendations on how to strengthen preparedness and surveillance. [M1]
D2.2 Capacity strengthening plan [M2]
Based on the results of task 2.1, and together with the Steering-Scientific Committee, WP2 will develop a capacity strengthening plan defining the priority activities and a calendar for their implementation.
D2.3 Phased surveillance protocol [M3]
D2.4 Surveillance monitoring and evaluation protocol [M4]
D2.5 First surveillance bulletin including data from all sentinel sites [M6]
The periodic bulletins will compile and summarise data from all sites (at least three bulletins during the duration of the project, frequency will depend on the phase of the epidemic). However, from the beginning of the project, weekly automatic reports (graphs, tables) will be available on the I-MOVE-COVID-19 website.
D2.6 Second surveillance bulletin including data from all sentinel sites [M12]
D2.7 Third surveillance bulletin including data from all sentinel sites [M24]
D2.8 Surveillance evaluation report [M24]. The report will include recommendations on how to adapt existing sentinel systems to rapidly support surveillance in case of public health emergency.

D2.1 : Report describing current COVID-19 surveillance practices and recommendations [1]

on how to strengthen preparedness and surveillance.

D2.3 : Phased surveillance protocol [3]

Surveillance protocols

D2.4 : WP2 Surveillance monitoring and evaluation protocol [4]

Surveillance monitoring and evaluation protocol

D2.5 : WP2 First surveillance bulletin including data from all sentinel sites [6]

The periodic bulletins will compile and summarise data from all sites (at least three bulletins during the duration of the project, frequency will depend on the phase of the epidemic). However, from the beginning of the project, weekly automatic reports (graphs, tables) will be available on the I-MOVE-COVID-19 website.

D2.6 : WP2 Second surveillance bulletin including data from all sentinel sites [12]
Second surveillance bulletin including data from all sentinel sites

D2.7 : WP2 Third surveillance bulletin including data from all sentinel sites [24]
Third surveillance bulletin including data from all sentinel sites

D2.8 : WP2 Surveillance evaluation report [24]
Surveillance evaluation report

Schedule of relevant Milestones

Milestone number[18]	Milestone title	Lead beneficiary	Due Date (in months)	Means of verification
MS5	Current surveillance practices and recommendations	6 - NIVEL	1	Report describing current practices
MS6	Capacity strengthening plan	6 - NIVEL	2	Capacity strengthening plan
MS7	Surveillance protocol	6 - NIVEL	3	Surveillance protocol
MS8	Monitoring and evaluation protocol	6 - NIVEL	4	Monitoring and evaluation protocol
MS9	Surveillance in place	6 - NIVEL	6	Surveillance bulletin report

Work package number [9]	WP3	Lead beneficiary [10]	4 - NHSNS
Work package title	Hospital surveillance network		
Start month	1	End month	27

Objectives

To enhance hospital surveillance in seven countries to rapidly detect and report severe (hospitalised) COVID-19 cases
To develop/adapt generic hospital surveillance protocols (including follow up of patients until hospital discharge) that are flexible to rapidly adapt to the epidemiological context (e.g. increased severe disease incidence)
To describe suspected and confirmed cases with severe disease
To identify early transmission in the community by detecting cases not identified previously as contacts of confirmed cases
To strengthen preparedness to respond to COVID-19 through hospital surveillance
To establish severity indicators in order to facilitate international comparisons of COVID-19 severity assessment
To implement appropriate protocols to collect data for relevant clinical, epidemiological, and virological studies in WP4
To implement relevant protocols to collect virological, clinical and epidemiological data from patients with severe disease according to international guidelines

Description of work and role of partners

WP3 - Hospital surveillance network [Months: 1-27]
NHSNS, ISCIII, ISPLN, INSA, DH, LSMU, VIVI, IC, MS , IPHA, VUB, AP-HP, CHUM, CHU Rennes, HCL
Description of work
WP3 [Months: 1-26], LEADER: NHSNSS
Preparedness phase
Task 3.1. Review of existing COVID-19 surveillance activities in EU and UK hospital surveillance systems [M1], Task leader NHSNSS. Contributors: WP3 beneficiaries
WP3 will compile information on COVID-19 surveillance activities conducted in hospitals. Participating hospitals will create an inventory then meet (via tele/video-conferences or face-to-face if feasible) to identify strengths and challenges and recommend how the surveillance could be reinforced in the different phases of the epidemic.
Task 3.2. Capacity strengthening [M2-24], Task leader NHSNSS. Contributors: WP3 beneficiaries.
Based on the results of task 3.1, WP3 will identify and conduct priority activities (in consultation with ECDC) to strengthen preparedness, surveillance, laboratory procedures, infection control and case management in participating hospitals: training of clinical, administrative and laboratory staff (e.g. webinars). This will also include immediate sharing of lab protocols for whole genome sequencing (WGS) for different platforms.
Task 3.3. Phased surveillance protocol [M2-3], Task leader NHSNSS. Contributors: WP3 beneficiaries
WP3 will develop or adapt existing surveillance protocols for the different phases of the epidemic. The protocols will include the recruitment strategy, inclusion and exclusion criteria, process of obtaining informed consent case definition, study population, exposures, risk/preventive factors, random or systematic selection of cases for laboratory diagnostics in case of high incidence, samples and tests to be performed (e.g. RT-PCR, rapid tests (if available), viral genetic characterisation), laboratory procedures (WGS), safety measures when taking/handling/processing of samples, data flow, case management, severity and monitoring indicators. The surveillance protocol will take into account the case definitions and other surveillance recommendations at national, European (ECDC) and international (WHO) level and, where possible, align with the WHO/ISARIC protocols. Scripts for automatic analysis will be developed. The protocols will be harmonised, so data can be pooled into a multicentre study.
Task 3.4. Surveillance monitoring and evaluation protocol [M4], Task leader NHSNSS and Epiconcept. Contributors: WP3 beneficiaries
WP3 will develop a surveillance monitoring and evaluation protocol with key indicators to monitor data collection, performance and surveillance attributes adapted to the different phases of the epidemic.
Implementation phase
Task 3.5. Surveillance [M3- 24], Task leader NHSNSS and Epiconcept. Contributors: WP3 beneficiaries.
Surveillance will be reinforced according to the priorities identified in Task 3.1. Generic protocols will be adapted to the epidemiological situation in each country, either by participant hospital sites or centrally. Data collected will be shared with ECDC and other actors. Participating hospitals will produce automatic (based on the analytical scripts developed by Epiconcept) epidemiological and virological reports (frequency depending on the phase of the epidemic) describing

cases by clinical, virological and epidemiological characteristics. Epiconcept will make tables and graphs available on the I-MOVE-COVID-19 website, and archived in another repository for longevity.
Task 3.6. Provide data to WP4 to conduct pooled studies according to priority questions and following the scientific protocols [M2- 24], Task leader NHSNSS and Epiconcept. Contributors: WP3 beneficiaries.
Many of the epidemiological studies proposed in WP4 are based on pooled surveillance data from WP2 and WP3. WP3 will provide to the WP4 leader the data needed to conduct pooled analyses to respond to the relevant priority questions (following the WP4 protocols). WP3 beneficiaries will provide inputs on the epidemiological study protocols developed by WP4.
Task 3.7 Sequence and isolate viruses from respiratory samples from mild, severe and fatal SARS-CoV-2 positive cases [M2- 24], Task leader ISCIII. Contributors: WP3 beneficiaries.
Respiratory samples from WP3 mild, severe and fatal SARS-CoV-2 positive patients will be collected to allow cross-comparison within different European countries. Specimens will be used for virus isolation and sequencing; results will be pooled and sequencing results shared in GISAID. These data will be provided to WP4 for potential epidemiological and modelling studies.

Participation per Partner

Partner number and short name	WP3 effort
2 - ISCIII	22.30
3 - ISPLN	16.40
4 - NHSNS	9.20
5 - INSA	10.50
7 - DH	7.40
8 - LSMU	14.00
11 - VIVI	10.00
12 - IC	38.00
17 - MS	6.50
19 - IPHA	6.00
23 - VUB	5.40
25 - AP-HP	17.50
27 - CHUM	3.20
28 - CHU Rennes	2.60
30 - HCL	2.60
Total	171.60

List of deliverables

Deliverable Number[14]	Deliverable Title	Lead beneficiary	Type[15]	Dissemination level[16]	Due Date (in months)[17]
D3.1	Report describing current COVID-19 hospital surveillance practices	4 - NHSNS	Report	Public	1
D3.3	Hospital Phased surveillance protocol	4 - NHSNS	Report	Public	3

List of deliverables

Deliverable Number[14]	Deliverable Title	Lead beneficiary	Type[15]	Dissemination level[16]	Due Date (in months)[17]
D3.4	Surveillance monitoring and evaluation protocol	4 - NHSNS	Report	Public	4
D3.5	First surveillance bulletin including data from all sentinel sites	4 - NHSNS	Report	Public	6
D3.6	Second surveillance bulletin including data from all sentinel sites	4 - NHSNS	Report	Public	12
D3.7	Third surveillance bulletin including data from all sentinel sites	4 - NHSNS	Report	Public	24
D3.8	Surveillance evaluation report	4 - NHSNS	Report	Public	24
D3.9	Pooled database for clinical samples	4 - NHSNS	Report	Public	12

Description of deliverables

Deliverables (brief description and month of delivery)
D3.1. Report describing current COVID-19 hospital surveillance practices and recommendations on how to strengthen preparedness and surveillance of severe disease. [M1]
D 3.2. Capacity strengthening plan [M2]
Based on the results of task 3.1, and together with the Steering-Scientific Committee, WP3 will develop a capacity strengthening plan defining priority activities and a calendar for their implementation.
D 3.3 Phased surveillance protocol [M3]
D 3.4 Surveillance monitoring and evaluation protocol [M4]
D 3.5 First surveillance bulletin including data from all sentinel sites [M6]
The periodic bulletins will compile and summarise data from all sites (at least three bulletins during the project; frequency will depend on the phase of the epidemic). However, weekly automatic reports (graphs, tables) will be available on the I-MOVE-COVID-19 website.
D 3.6 Second surveillance bulletin including data from all sentinel sites [M12]
D 3.7 Third surveillance bulletin including data from all sentinel sites [M24]
D 3.8 Surveillance evaluation report [M24]. The report will include recommendations on how to adapt existing hospital networks to rapidly support surveillance in case of public health emergency
D 3.9 Pooled database for clinical samples at time of admission from WP3, virus isolates and sequences [M12]

D3.1 : Report describing current COVID-19 hospital surveillance practices [1]

Report describing current COVID-19 hospital surveillance practices and recommendations on how to strengthen preparedness and surveillance of severe disease.

D3.3 : Hospital Phased surveillance protocol [3]

Phased surveillance protocol

D3.4 : Surveillance monitoring and evaluation protocol [4]

Surveillance monitoring and evaluation protocol

D3.5 : First surveillance bulletin including data from all sentinel sites [6]

The periodic bulletins will compile and summarise data from all sites (at least three bulletins during the project; frequency will depend on the phase of the epidemic). However, weekly automatic reports (graphs, tables) will be available on the I-MOVE-COVID-19 website.

D3.6 : Second surveillance bulletin including data from all sentinel sites [12]

Second surveillance bulletin including data from all sentinel sites

D3.7 : Third surveillance bulletin including data from all sentinel sites [24]

Third surveillance bulletin including data from all sentinel sites

D3.8 : Surveillance evaluation report [24]

Surveillance evaluation report The report will include recommendations on how to adapt existing hospital networks to rapidly support surveillance in case of public health emergency

D3.9 : Pooled database for clinical samples [12]

Pooled database for clinical samples at time of admission from WP3, virus isolates and sequences

Schedule of relevant Milestones

Milestone number[18]	Milestone title	Lead beneficiary	Due Date (in months)	Means of verification
MS10	WP3 Current Surveillance practices and recommendations	4 - NHSNS	1	Report describing current practices
MS11	WP3 Capacity strengthening plan	4 - NHSNS	2	Capacity strengthening plan
MS12	WP3 Surveillance protocol	4 - NHSNS	3	Surveillance protocol
MS13	WP3 Monitoring and evaluation protocol	4 - NHSNS	4	Monitoring and evaluation protocol
MS14	WP3 Surveillance in place	4 - NHSNS	6	Surveillance bulletin report

Work package number [9]	WP4	Lead beneficiary [10]	1 - EPICONCEPT
Work package title	Pooled studies		
Start month	1	End month	27

Objectives

Objectives
Main aim: To conduct studies contributing to priority questions and knowledge gaps on the epidemiology of COVID-19 and specific virological characteristics of SARS-CoV-2
To develop/modify existing epidemiological study protocols that are easily adaptable to the epidemiological context and setting
To utilise existing sentinel networks (WP2 and WP3) to rapidly implement studies responding to priority questions and knowledge gaps
To pool data from WP2 and WP3 to achieve a high sample size and robustness of results
To share findings rapidly and widely among the scientific community and all stakeholders, including national and international organisations and institutes
Specific objectives depend on the epidemiological situation, knowledge, studies conducted or planned by other groups and include studies to
describe the incubation period for mild and severe cases
model disease transmission (effective and basic reproduction numbers)
compare transmission dynamic estimates over a number of European settings
identify preventive and risk factors for SARS-CoV-2 transmission in the community and hospital settings
identify preventive and risk factors for severity and death
obtain timely estimates of case fatality among hospitalised cases by severity level, age and risk group, and over time (changes with the epidemiological situation of COVID-19)
measure the effectiveness of preventive and treatment strategies
measure post-authorisation vaccine effectiveness, once candidate vaccines are available
conduct sero-epidemiological studies in community and hospital settings when relevant
measure (survey) the proportion of the population complying with preventive measures
sequence the full viral genome and describe the genomic diversity of SARS-CoV-2 in (WP2) mild, and in severe (hospitalised) and fatal cases (WP3)
study viral genotype over time and region
identify transmission chains during hospital outbreaks (HCW) using WGS-NGS
identify viral genetic determinants involved during progression of disease

Description of work and role of partners

WP4 - Pooled studies [Months: 1-27]
EPICONCEPT, ISCIII, ISPLN, NHSNS, INSA, NIVEL, DH, LSMU, HSE, FOHM, VIVI, IC, SU, UOXF, IPHA, VUB, AP-HP, CHUM, CHU Rennes, HCL
Description of work
WP4- [Months: 1-26]
Leader: Epiconcept
Preparedness phase
Task 4.1. Defining priority studies through review of existing epidemiological information on COVID-19 and virological information on SARS-CoV-2 and addressing knowledge gaps [M1]. Task leader: Epiconcept. Contributors: WP4 beneficiaries, Steering-Scientific Committee
WP4 will compile information on COVID-19 epidemiological knowledge and gaps together with partners in WP2 and WP3. The Steering-Scientific Committee (W2, WP3, WP4 partners, ECDC, WHO) will meet during the kick-off meeting (tele/video-conference or face-to-face meeting if feasible) to identify priority studies for the short-term and longer term, in conjunction with other actors at national, European and international levels. Criteria to define the studies needed will include:
responding to key knowledge gaps
contributing to the diagnosis and clinical management of patients infected withSARS-CoV-2
contributing to the public health preparedness and response to the epidemic of COVID-19
feasible in the timeframe of the project

results rapidly available
no duplication with other initiatives
complementarity with other initiatives

Task 4.2. Protocols for the priority studies early in the epidemic [M2-3], Task leader Epiconcept. Contributors: WP4 beneficiaries
WP4 will develop or adapt existing surveillance protocols for studies identified in task 4.1 as priority studies in the short-term. These could include description of natural history of infection, modelling disease transmission and the course of the epidemic, identifying preventive and risk factors for SARS-CoV-2 transmission in the community and hospital settings, identifying preventive and risk factors for severity and death, measuring the effectiveness of preventive and treatment strategies and studying viral genotype over time and region and outbreaks among close contacts.
The protocols will include the recruitment strategy, inclusion and exclusion criteria, process of obtaining informed consent, study design, study population, case definitions, control selection (if relevant), samples and tests to be performed (e.g. RT-PCR, rapid tests - if available, viral genetic characterisation), laboratory procedures, safety measures when taking/handling/processing of samples, safety measures when taking/handling/processing of samples, data flow and management plan (including data security), and plan of analysis (including pooling).
The protocols will be adapted/developed in collaboration with other actors to ensure harmonisation of data collection globally. Draft data management and analysis scripts, including automatic reporting, will be developed. Protocols and draft scripts will be shared via the I-MOVE-COVID-19 website and archived in another repository for longevity.
Task 4.3. Protocols for the priority studies later in the epidemic [M2-6], Task leader Epiconcept Contributors: WP4 beneficiaries
WP4 will develop or adapt existing surveillance protocols for studies identified in task 4.1 as priority studies in the longer-term. These could include measuring post-authorisation vaccine effectiveness once candidate vaccines are available, and conducting sero-epidemiological studies in community and hospital settings when relevant.
The protocols will include the recruitment strategy, inclusion and exclusion criteria, process of obtaining informed consent, study design, study population, case definitions, control selection (if relevant), samples and tests to be performed (e.g. RT-PCR, rapid tests - if available, viral genetic characterisation), laboratory procedures, data flow and management plan (including data security), and plan of analysis (including pooling).
The protocols will be adapted/developed in collaboration with other actors to ensure harmonisation of data collection globally. Data management and analysis scripts, including automatic reporting will be developed. Protocols and scripts will be shared via the I-MOVE-COVID-19 website and archived in another repository for longevity.
Implementation phase
Task 4.4. Conducting the studies [M2-20], Task leader Epiconcept. Contributors: WP4 beneficiaries
Many of the studies will be carried out within the WP2 and WP3 primary care and hospital networks, see task 2.6 and 3.6. As part of capacity strengthening (task 2.2/3.2), training will be carried out for conducting the studies, where appropriate.
Task 4.5. Analysis and reports [M4-22], Task leader Epiconcept Contributors: WP4 beneficiaries
Study data will be collected using secure file transfer protocols or secure data entry tools (e.g. Zenodo or Voozanoo), anonymised and shared with the wider scientific community as appropriate, according to FAIR principles and in compliance with EU general data protection regulations (GDPR). Draft scripts will be finalised and data analysis will be carried out according to the analysis plans, as outlined in tasks 4.2 and 4.3. Analysis will be done at regional, national, European and international pooled level, as appropriate. Modelling studies will be carried out by I-MOVE-COVID-19 partner mathematical modelling teams.
Shared data from other studies using harmonised protocols may be pooled as well, depending on data quality and homogeneity of settings.
Results and reports will be shared as rapidly and widely as possible with regional, national, European and international stakeholders.

Participation per Partner

Partner number and short name	WP4 effort
1 - EPICONCEPT	2.00
EPIUK	9.50
2 - ISCIII	10.00

Partner number and short name	WP4 effort
3 - ISPLN	15.10
4 - NHSNS	6.00
5 - INSA	19.80
6 - NIVEL	3.20
7 - DH	1.50
8 - LSMU	6.30
9 - HSE	2.80
10 - FOHM	5.00
11 - VIVI	3.10
12 - IC	11.60
14 - SU	4.90
18 - UOXF	1.60
19 - IPHA	3.50
23 - VUB	2.30
25 - AP-HP	3.90
27 - CHUM	0.90
28 - CHU Rennes	0.70
30 - HCL	0.70
Total	114.40

List of deliverables

Deliverable Number[14]	Deliverable Title	Lead beneficiary	Type[15]	Dissemination level[16]	Due Date (in months)[17]
D4.1	Report describing existing information on COVID-19 and knowledge gaps and recommendations on short-term and longer-term priority studies.	1 - EPICONCEPT	Report	Public	1
D4.2	Protocols for priority studies early in the epidemic	1 - EPICONCEPT	Report	Public	3
D4.3	Protocols for priority studies later in the epidemic	1 - EPICONCEPT	Report	Public	14
D4.4	Study reports on priority studies early in the epidemic	1 - EPICONCEPT	ORDP: Open Research Data Pilot	Public	12

List of deliverables

Deliverable Number[14]	Deliverable Title	Lead beneficiary	Type[15]	Dissemination level[16]	Due Date (in months)[17]
D4.5	Study reports on priority studies later in the epidemic	1 - EPICONCEPT	Report	Public	24
D4.6	First draft of Vaccine Effectiveness Protocol	1 - EPICONCEPT	Report	Confidential, only for members of the consortium (including the Commission Services)	11

Description of deliverables

D4.1. Report describing existing information on COVID-19 and knowledge gaps and recommendations on short-term and longer-term priority studies. [M1]
D4.2. Protocols for priority studies early in the epidemic [M3]
D4.3. Protocols for priority studies later in the epidemic [M6]
D4.4. Copies of opinions/approvals by ethics committees and/or competent authorities for the protocols proposed [M8]
D4.5. Study reports on priority studies early in the epidemic [M12]
These study reports will also be available on the I-MOVE-COVID-19 website.
D4.6. Study reports on priority studies later in the epidemic [M24]
These study reports will also be available on the I-MOVE-COVID-19 website.

D4.1 : Report describing existing information on COVID-19 and knowledge gaps and recommendations on short-term and longer-term priority studies. [1]

Report describing existing information on COVID-19 and knowledge gaps and recommendations on short-term and longer-term priority studies.

D4.2 : Protocols for priority studies early in the epidemic [3]

Protocols for priority studies early in the epidemic

D4.3 : Protocols for priority studies later in the epidemic [14]

Protocols for priority studies later in the epidemic

D4.4 : Study reports on priority studies early in the epidemic [12]

Study reports on priority studies early in the epidemic

D4.5 : Study reports on priority studies later in the epidemic [24]

Study reports on priority studies later in the epidemic These study reports will also be available on the I-MOVE-COVID-19 website.

D4.6 : First draft of Vaccine Effectiveness Protocol [11]

With regard to the delay of the Deliverable 4.3, from recent conversations that we participated in with ECDC and different Member States, it seems that countries are getting ready for vaccine effectiveness trials for early 2021.

Schedule of relevant Milestones

Milestone number[18]	Milestone title	Lead beneficiary	Due Date (in months)	Means of verification
MS15	List of priority research questions	1 - EPICONCEPT	1	Report describing existing epidemiological information

Schedule of relevant Milestones

Milestone number[18]	Milestone title	Lead beneficiary	Due Date (in months)	Means of verification
				on COVID-19 and knowledge gaps
MS17	Protocols for priority studies later in the epidemic	1 - EPICONCEPT	12	Protocols for studies to be conducted later in the epidemic

Work package number [9]	WP5	Lead beneficiary [10]	1 - EPICONCEPT
Work package title	Ethics requirements		
Start month	1	End month	27

Objectives

The objective is to ensure compliance with the 'ethics requirements' set out in this work package.

Description of work and role of partners

WP5 - Ethics requirements [Months: 1-27]
EPICONCEPT
This work package sets out the 'ethics requirements' that the project must comply with.

List of deliverables

Deliverable Number[14]	Deliverable Title	Lead beneficiary	Type[15]	Dissemination level[16]	Due Date (in months)[17]
D5.1	H - Requirement No. 1	1 - EPICONCEPT	Ethics	Confidential, only for members of the consortium (including the Commission Services)	6
D5.2	POPD - Requirement No. 2	1 - EPICONCEPT	Ethics	Confidential, only for members of the consortium (including the Commission Services)	6
D5.3	HCT - Requirement No. 4	1 - EPICONCEPT	Ethics	Confidential, only for members of the consortium (including the Commission Services)	6
D5.4	EPQ - Requirement No. 6	1 - EPICONCEPT	Ethics	Confidential, only for members of the consortium (including the Commission Services)	6
D5.5	GEN - Requirement No. 7	1 - EPICONCEPT	Ethics	Confidential, only for members of the consortium (including the Commission Services)	3
D5.6	GEN - Requirement No. 9	1 - EPICONCEPT	Ethics	Confidential, only for members of the consortium (including the Commission Services)	12

List of deliverables

Deliverable Number[14]	Deliverable Title	Lead beneficiary	Type[15]	Dissemination level[16]	Due Date (in months)[17]
D5.7	GEN - Requirement No. 10	1 - EPICONCEPT	Ethics	Confidential, only for members of the consortium (including the Commission Services)	27

Description of deliverables

The 'ethics requirements' that the project must comply with are included as deliverables in this work package.

D5.1 : H - Requirement No. 1 [6]

1. The procedures and criteria that will be used to identify/recruit research participants must be submitted as a deliverable. 2. The informed consent procedures that will be implemented for the participation of humans must be submitted as a deliverable. 3. Templates of the informed consent/assent forms and information sheets (in language and terms intelligible to the participants) must be kept on file. 4. Copies of opinions/approvals by ethics committees and/or competent authorities for the research with humans must be submitted as a deliverable.

D5.2 : POPD - Requirement No. 2 [6]

1. The beneficiary must check if special derogations pertaining to the rights of data subjects or the processing of genetic, biometric and/or health data have been established under the national legislation of the country where the research takes place and submit a declaration of compliance with respective national legal framework(s). 2. The host institution must confirm that it has appointed a Data Protection Officer (DPO) and the contact details of the DPO are made available to all data subjects involved in the research. For host institutions not required to appoint a DPO under the GDPR a detailed data protection policy for the project must be submitted as a deliverable. 3. A description of the technical and organisational measures that will be implemented to safeguard the rights and freedoms of the data subjects/research participants must be submitted as a deliverable. 4. A description of the security measures that will be implemented to prevent unauthorised access to personal data or the equipment used for processing must be submitted as a deliverable. 5. Description of the anonymysation/pseudonymisation techniques that will be implemented must be submitted as a deliverable. 6. In case personal data are transferred from a non-EU country to the EU (or another third state), confirmation that such transfers comply with the laws of the country in which the data was collected must be submitted as a deliverable. 7. In case of further processing of previously collected personal data, an explicit confirmation that the beneficiary has lawful basis for the data processing and that the appropriate technical and organisational measures are in place to safeguard the rights of the data subjects must be submitted as a deliverable. 8. The beneficiary must evaluate the ethics risks related to the data processing activities of the project. This includes also an opinion if data protection impact assessment should be conducted under art.35 General Data Protection Regulation 2016/679. The risk evaluation and the opinion must be submitted as a deliverable.

D5.3 : HCT - Requirement No. 4 [6]

1. In case human cells/tissues are obtained within the project, details on cell/tissue types must be kept on file. 2. Copies of relevant documents for using, producing or collecting human cells or tissues (e.g., ethics approval, import licence, accreditation/designation/authorisation/licensing) must be kept on file. 3. In case human cells/tissues are obtained from a biobank, details on the cell/tissue types and on the biobank and access to it must be kept on file.

D5.4 : EPQ - Requirement No. 6 [6]

1. Copies of authorisations for relevant facilities (e.g., security classification of laboratory, GMO authorisation) must be kept on file. 2. The applicant must demonstrate that appropriate health and safety procedures conforming to relevant local/national guidelines/legislation are followed for staff involved in this project. This must be kept on file.

D5.5 : GEN - Requirement No. 7 [3]

1. An independent Ethics Advisor must be appointed to monitor the ethics issues involved in this project and how they are handled.

D5.6 : GEN - Requirement No. 9 [12]

1. A report by the independent Ethics Advisor must be submitted as a deliverable at the end of the 1st reporting period.

D5.7 : GEN - Requirement No. 10 [27]

1. A report by the independent Ethics Advisor must be submitted as a deliverable at the end of the final reporting period.

Schedule of relevant Milestones

Milestone number[18]	Milestone title	Lead beneficiary	Due Date (in months)	Means of verification

1.3.4. WT4 List of milestones

Milestone number[18]	Milestone title	WP number[9]	Lead beneficiary	Due Date (in months)[17]	Means of verification
MS1	Kick-off meeting	WP1	1 - EPICONCEPT	3	Kick-off meeting report
MS2	Website used	WP1	1 - EPICONCEPT	3	Website used for information sharing
MS3	Presentation of first year results at ST-SC meeting	WP1	1 - EPICONCEPT	13	Report first scientific meeting
MS4	Presentation of second year results at ST-SC meeting	WP1	1 - EPICONCEPT	25	Report second scientific meeting
MS5	Current surveillance practices and recommendations	WP2	6 - NIVEL	1	Report describing current practices
MS6	Capacity strengthening plan	WP2	6 - NIVEL	2	Capacity strengthening plan
MS7	Surveillance protocol	WP2	6 - NIVEL	3	Surveillance protocol
MS8	Monitoring and evaluation protocol	WP2	6 - NIVEL	4	Monitoring and evaluation protocol
MS9	Surveillance in place	WP2	6 - NIVEL	6	Surveillance bulletin report
MS10	WP3 Current Surveillance practices and recommendations	WP3	4 - NHSNS	1	Report describing current practices
MS11	WP3 Capacity strengthening plan	WP3	4 - NHSNS	2	Capacity strengthening plan
MS12	WP3 Surveillance protocol	WP3	4 - NHSNS	3	Surveillance protocol
MS13	WP3 Monitoring and evaluation protocol	WP3	4 - NHSNS	4	Monitoring and evaluation protocol
MS14	WP3 Surveillance in place	WP3	4 - NHSNS	6	Surveillance bulletin report
MS15	List of priority research questions	WP4	1 - EPICONCEPT	1	Report describing existing epidemiological information on COVID-19 and knowledge gaps
MS16	Protocols for priority studies in the early phase of the epidemic		1 - EPICONCEPT	6	Protocols for studies to be conducted early in the epidemic
MS17	Protocols for priority studies later in the epidemic	WP4	1 - EPICONCEPT	12	Protocols for studies to be conducted later in the epidemic

1.3.5. WT5 Critical Implementation risks and mitigation actions

Risk number	Description of risk	WP Number	Proposed risk-mitigation measures
1	Challenges in coordinating/ managing many beneficiaries from different countries (LOW)	WP1, WP2, WP3, WP4, WP5	Scientific aspect: Restricted number of action oriented work packages. Managerial aspects: all managerial activities run from WP1 with standard administrative procedures and minimum delays based on experience acquired with H2020/I-MOVE+ project Coordination: overall managerial and scientific coordination within a single Steering-scientific committee.
2	Non availability of I-MOVE partners and WP leaders due to heavy workload with COVID-19 response Medium likelihood	WP2, WP3, WP4	Large number of study sites and networks allowing for some drop out Co-leadership for each work package
3	Rapid ending of current COVID-19 epidemic Low likelihood	WP2, WP3, WP4	Protocols available and adaptable to other Coronavirus /other respiratory disease epidemics of international magnitude
4	Delays in obtaining ethical approvals for research studies Low/Medium likelihood	WP4, WP5	Rapid development of protocols and submission to relevant bodies. Studies based on surveillance data prioritised. Feasibility within the time frame of the project is a criteria for study selection. Network already in place with experience in submitting protocols for ethical approval.

1.3.6. WT6 Summary of project effort in person-months

	WP1	WP2	WP3	WP4	WP5	Total Person/Months per Participant
1 - EPICONCEPT	16.70	0	0	2	✓	18.70
· EPIUK	0	0	0	9.50	✓	9.50
2 - ISCIII	0	12.60	22.30	10	✓	44.90
· FIBAO	0	3	0	0	✓	3
· IACS	0	3	0	0	✓	3
3 - ISPLN	0	13.60	16.40	15.10	✓	45.10
· NBM-FMS	0	0	0	0	✓	0
4 - NHSNS	0	3.60	9.20	6	✓	18.80
· UNI. STRATHC.	0	1	0	0		1
5 - INSA	0	6.50	10.50	19.80	✓	36.80
6 - NIVEL	0	12.70	0	3.20	✓	15.90
7 - DH	0	4.60	7.40	1.50	✓	13.50
8 - LSMU	0	0	14	6.30	✓	20.30
9 - HSE	0	9.80	0	2.80	✓	12.60
10 - FOHM	0	10	0	5	✓	15
11 - VIVI	0	0	10	3.10	✓	13.10
12 - IC	0	0	38	11.60	✓	49.60
13 - UCPP	0	7.20	0	0	✓	7.20
14 - SU	0	9.60	0	4.90	✓	14.50
15 - SPF	0	1	0	0	✓	1

	WP1	WP2	WP3	WP4	WP5	Total Person/Months per Participant
16 - IP	0	1	0	0	✓	1
17 - MS	0	6.50	6.50	0	✓	13
18 - UOXF	0	5	0	1.60	✓	6.60
19 - IPHA	0	0	6	3.50	✓	9.50
20 - RIVM	0	2	0	0	✓	2
21 - INSERM	0	0	0	0		0
23 - VUB	0	0	5.40	2.30		7.70
25 - AP-HP	0	0	17.50	3.90		21.40
27 - CHUM	0	0	3.20	0.90		4.10
28 - CHU Rennes	0	0	2.60	0.70		3.30
30 - HCL	0	0	2.60	0.70		3.30
Total Person/Months	16.70	112.70	171.60	114.40		415.40

1.3.7. WT7 Tentative schedule of project reviews

No project reviews indicated

1. Project number

The project number has been assigned by the Commission as the unique identifier for your project. It cannot be changed. The project number **should appear on each page of the grant agreement preparation documents (part A and part B)** to prevent errors during its handling.

2. Project acronym

Use the project acronym as given in the submitted proposal. It can generally not be changed. The same acronym **should appear on each page of the grant agreement preparation documents (part A and part B)** to prevent errors during its handling.

3. Project title

Use the title (preferably no longer than 200 characters) as indicated in the submitted proposal. Minor corrections are possible if agreed during the preparation of the grant agreement.

4. Starting date

Unless a specific (fixed) starting date is duly justified and agreed upon during the preparation of the Grant Agreement, the project will start on the first day of the month following the entry into force of the Grant Agreement (NB : entry into force = signature by the Commission). Please note that if a fixed starting date is used, you will be required to provide a written justification.

5. Duration

Insert the duration of the project in full months.

6. Call (part) identifier

The Call (part) identifier is the reference number given in the call or part of the call you were addressing, as indicated in the publication of the call in the Official Journal of the European Union. You have to use the identifier given by the Commission in the letter inviting to prepare the grant agreement.

7. Abstract

8. Project Entry Month

The month at which the participant joined the consortium, month 1 marking the start date of the project, and all other start dates being relative to this start date.

9. Work Package number

Work package number: WP1, WP2, WP3, ..., WPn

10. Lead beneficiary

This must be one of the beneficiaries in the grant (not a third party) - Number of the beneficiary leading the work in this work package

11. Person-months per work package

The total number of person-months allocated to each work package.

12. Start month

Relative start date for the work in the specific work packages, month 1 marking the start date of the project, and all other start dates being relative to this start date.

13. End month

Relative end date, month 1 marking the start date of the project, and all end dates being relative to this start date.

14. Deliverable number

Deliverable numbers: D1 - Dn

15. Type

Please indicate the type of the deliverable using one of the following codes:

R	Document, report
DEM	Demonstrator, pilot, prototype
DEC	Websites, patent fillings, videos, etc.
OTHER	
ETHICS	Ethics requirement
ORDP	Open Research Data Pilot
DATA	data sets, microdata, etc.

16. Dissemination level

Please indicate the dissemination level using one of the following codes:

PU	Public
CO	Confidential, only for members of the consortium (including the Commission Services)
EU-RES	Classified Information: RESTREINT UE (Commission Decision 2005/444/EC)
EU-CON	Classified Information: CONFIDENTIEL UE (Commission Decision 2005/444/EC)
EU-SEC	Classified Information: SECRET UE (Commission Decision 2005/444/EC)

17. Delivery date for Deliverable

Month in which the deliverables will be available, month 1 marking the start date of the project, and all delivery dates being relative to this start date.

18. Milestone number

Milestone number:MS1, MS2, ..., MSn

19. Review number

Review number: RV1, RV2, ..., RVn

20. Installation Number

Number progressively the installations of a same infrastructure. An installation is a part of an infrastructure that could be used independently from the rest.

21. Installation country

Code of the country where the installation is located or IO if the access provider (the beneficiary or linked third party) is an international organization, an ERIC or a similar legal entity.

22. Type of access

TA-uc	if trans-national access with access costs declared on the basis of unit cost,
TA-ac	if trans-national access with access costs declared as actual costs, and
TA-cb	if trans-national access with access costs declared as a combination of actual costs and costs on the basis of unit cost,
VA-uc	if virtual access with access costs declared on the basis of unit cost,
VA-ac	if virtual access with access costs declared as actual costs, and
VA-cb	if virtual access with access costs declared as a combination of actual costs and costs on the basis of unit cost.

23. Access costs

Cost of the access provided under the project. For virtual access fill only the second column. For trans-national access fill one of the two columns or both according to the way access costs are declared. Trans-national access costs on the basis of unit cost will result from the unit cost by the quantity of access to be provided.

Technical annex

I-MOVE-COVID-19

Multidisciplinary European network for research, prevention and control of the COVID-19 Pandemic

table of contents

Comparison table of the modifications made from the DOA dated 19 March 2020 and the DOA for the amendment no AMD-101003673-1

Comparison table of the modifications made from the DOA dated 19 March 2020 and the Amendment no101003673-1

<table>
<tr><th>Version (date)</th><th>Changes</th></tr>
<tr><td></td><td>Annex1 Part A (online forms)</td></tr>
<tr><td>Amendment noAMD-101003673-1</td><td>Beneficiaries
Addition of 6 new partners: the consortium goes from 20 to 26 beneficiaries and from 10 to 11 countries:

- Institut national de la santé et de la recherche médicale (INSERM), PIC number 999997833, France
- Assistance Publique - Hôpitaux de Paris (AP-HP), PIC number 999645432, France
- CHU de Montpellier (CHUM), PIC number 999609348, France
- CHU de Rennes (CHU RENNES), PIC number 988378009, France
- Les Hospices Civiles de Lyon (HCL), PIC number 999469765, France
- Vrije Universiteit Brussel (VUB), PIC number 999902094, Belgium
These two beneficiaries will be part of WP3 and WP4.

Removal of Miguel Servet Public Foundation as linked third party of beneficiary 3, ISPLN</td></tr>
<tr><td rowspan="2">Amendment noAMD-101003673-1</td><td>Financial information</td></tr>
<tr><td>
<u>1/ Additional budget of 260,000 euros</u>
<table>
<tr><th>No participant</th><th>PIC number</th><th>Legal name</th><th>Total requested</th><th>WP1</th><th>WP3</th><th>WP4</th></tr>
<tr><td>new partner 21</td><td>999997833</td><td>INSERM</td><td>2500</td><td></td><td>2500</td><td></td></tr>
<tr><td>new partner 23</td><td>999645432</td><td>AP-HP</td><td>81500</td><td></td><td>81500</td><td></td></tr>
<tr><td>new partner 24</td><td>999609348</td><td>CHU-MONTPELLIER</td><td>22000</td><td></td><td>22000</td><td></td></tr>
<tr><td>new partner 25</td><td>988378009</td><td>CHU-RENNES</td><td>22000</td><td></td><td>22000</td><td></td></tr>
<tr><td>new partner 26</td><td>999469765</td><td>HOSPICES CIVILS DE LYON</td><td>22000</td><td></td><td>22000</td><td></td></tr>
<tr><td>16</td><td>9999930</td><td>Institut Pasteur</td><td>20000</td><td></td><td>20000</td><td></td></tr>
<tr><td>new partner 22</td><td>999902094</td><td>Universitair Ziekenhuis Brussel (</td><td>30000</td><td></td><td>30000</td><td></td></tr>
<tr><td>1</td><td>952870383</td><td>EPICONCEPT</td><td>10000</td><td>10000</td><td></td><td></td></tr>
<tr><td></td><td></td><td>to be distributed among partners involved in WP4</td><td>50000</td><td></td><td></td><td>50000</td></tr>
<tr><td></td><td></td><td></td><td>260000</td><td>10 000</td><td>200 000</td><td>50000</td></tr>
</table>
</td></tr>
</table>

Amendment noAMD-101003673-1

2/ Budget transfer

No participant	Legal name	Total	WP2	WP3
4	NHSNSS	**-17 000**		-17 000
6	NIVEL	**-5000**	-5000	
1	EPICONCEPT	**22000**	5000	17 000

3/ WP4 Budget distribution from Epiconcept (€521,000) and additionnal budget (€50,000)

No participant	Legal name	Total WP4	HR	Other direct costs	Subcontracting	Indirect cost	WP4 person/month
1	EPICONCEPT	120450	96360			24090	11,50
2	ISCIII	45250	36200			9050	10,00
3	ISPL	45250	36200			9050	15,10
4	NHSNSS	45250	36200			9050	6,00
5	INSA	57150	37280	8440		11430	19,80
6	NIVEL	20350	16280			4070	3,20
7	DH	12850	10280			2570	1,50
8	LSMU	24900	15920		5000	3980	6,30
9	HSE	20350	16280			4070	2,80
10	PHAS	20350	15000	1280		4070	5,00
11	ViVI	24900	19920			4980	3,10
12	IC	24900	17120	2800		4980	11,60
14	SU	20350	16280			4070	4,90
18	UOXF	14000	11200			2800	1,60
19	IPHA	24900	19920			4980	3,50
23	AP-HP	18200	14560			3640	3,90
24	CHU-MONTPELLIER	6200	4960			1240	0,90
25	CHU-RENNES	6200	4960			1240	0,70
26	HOSPICES CIVILS DE LYON	6200	4960			1240	0,70
22	VUB	13000	10400			2600	2,30
	TOTAL	**571 000,00**	**440280**	**12520**	**5000**	**113200**	**114,40**

Version (date)	Changes
Amendment noAMD-101003673-1	**Deliverables** **A. Deadline extension** **WP2 –D2.3 (D9) Phased surveillance protocol** Extension of the deadline of deliverable to M3 (15 June 2020) ***Explanations:*** Error in the online entry of the deadline but delivery correctly scheduled in DoA (M3, 15 June 2020) **WP4 - D4.3. (D15) Protocols for priority studies later in the epidemic** Extension of the deadline of deliverable to M14 (15 May 2021) ***Explanations:*** Therefore, in order to have more realistic protocols, we require to postpone the delay for this deliverable to May 2021. In July 2020, several vaccines are starting phase III trials. It does not seem realistic to have phase IV trials in Europe early 2020. We will start developing the vaccine effectiveness protocols as soon as information on phase IV studies in Europe would be available: vaccines used, priority target groups, organisation of the vaccination programmes in participating countries. We will share the early draft of the protocol with the European Commission, ECDC, EMA and other research groups but we believe it is more realistic to have a final protocol including all information needed in May 2021.
Amendment noAMD-101003673-1	**B. Deliverables cancellation** **WP2 - D2.2. (D8) Primary care Capacity strengthening plan** **WP3 – D3.2. (D11): Hospital capacity strengthening plan** ***Explanations:*** In the current situation, all countries have already defined their surveillance strengthening plan to generate indicators useful to monitor the pandemic and guide the deescalation. Each country has different de-escalation measures with resources allocated to them. Therefore, those two deliverables are not useful anymore as each country has a plan adapted to its epidemiological situation. Not having these deliverables will not affect the implementation of the DoA.
Amendment noAMD-101003673-1	**C. Deliverables addition** **WP4 - D4.6. (D39) 1st Draft of Vaccine Effectiveness Protocol - Month 11 (February 2021)** ***Explanations:*** With regard to the delay of the Deliverable 4.3, from recent conversations that we participated in with ECDC and different Member States, it seems that countries are getting ready for vaccine effectiveness trials for early 2021.

Version (date)	Changes
	Annex1 Part B
Amendment noAMD-101003673-1	Addition of **2 new partners**: the consortium goes from 20 to 22 beneficiaries and from 10 to 11 countries
	Section 2.2a, text addition: **"Additional exploitation obligations:** Beneficiaries must take all measures aiming to ensure that their results or resulting products/services will be broadly available and accessible, as soon as possible and at fair conditions. In this respect, they must grant non-exclusive licences to their results under fair and reasonable conditions to any legal entities that commit to rapidly and broadly exploit the resulting products and services at fair conditions. Beneficiaries must indicate the owner(s) of the results (results ownership list) in the final report. Beneficiaries must use the Horizon Results Platform to find interested parties to exploit those results."
Amendment noAMD-101003673-1	**Table of section 3.4.b** Other direct cost' items modification for Institut Pasteur - partner no16
Amendment noAMD-101003673-1	**Section 4: Members of the consortium** **Addition of beneficiaries** 4.1. Participants (applicants) 4.1.1 Partner name: Inserm - France - participant no21 4.1.1 Partner name: Vrije Universiteit Brussel (VUB) - Belgium - participant no22 4.1.1 Partner name: AP-HP - France - participant no23 4.1.1 Partner name: CHU-MONTPELLIER - France - participant no24 4.1.1 Partner name: CHU-RENNES - France - participant no25 4.1.1 Partner name: HOSPICES CIVILS DE LYON - France - participant no26 **Text correction** 4.2. Third parties involved in the project 4.2.1 Partner name: ISPLN , Spain - participant no3: Miguel Servet Public Foundation (Fundación Pública Miguel Servet – FMS) is not a linked third party but a third party providing in-kind contribution under Article 11 of the GA

Comparison table of the modifications made from the DOA dated 13 February 2020 and the DOA dated 13 March 2020

Additions are noted in blue and deletions in red

Version (date)	Changes
13/03/2020	**Annex1 Part A** Beneficiary modification: remove Partner no7 (MINISTERIE VAN VOLKSGEZONDHEID, WELZIJN EN SPORT - NLNA) and add Partner no 20 (National Institute for Public Health and the Environment (RIVM))
13/03/2020	**Annex1 Part B** **Section 1** Physical data (addition) **1.3** Will you re-use any existing data and how? Several years of I-MOVE data may be used to compare ILI/SARI cases with COVID-19 cases. These data have been collected and processed according to GDPR and are anonymised.
13/03/2020	"4. Data security More details on the data security measures will be added to the data management plan as a priority. This will include descriptions of the anonymysation techniques."
13/03/2020	"7. Ethical aspects The I-MOVE-COVID-19 project has appointed an external ethics advisor, who will oversee all aspects of ethics in this project. There will be an evaluation of the ethics risks related to the data processing activities of the project. This includes also an opinion if data protection impact assessment should be conducted under art.35 General Data Protection Regulation 2016/679. The risk evaluation and the opinion will be submitted as part of this plan and included as deliverable.. Templates of the informed consent/assent forms and information sheets will be included in the data management plan."
13/03/2020	Delete deliverable **Table 3.1b: Work package description WP2** "D2.9 Pooled database for clinical samples from WP2, virus isolates and sequences [M12]"
13/03/2020	Delete objective **Table 3.1b: Work package description WP3** "Objective no6. To establish severity indicators in order to facilitate international comparisons of COVID-19 severity assessment Objective no8. To establish a European collection of SARS-CoV-2 virological information from samples from severe (hospitalised) patients according to international guidelines"
13/03/2020	Addition text "Task 3.3 "the recruitment strategy, inclusion and exclusion criteria, process of obtaining informed consent" "safety measures when taking/handling/processing of samples,""
13/03/2020	Addition text **Table 3.1b: Work package description WP4** "Task 4.2. Protocols for the priority studies early in the epidemic "the recruitment strategy, inclusion and exclusion criteria, process of obtaining informed consent," and "safety measures when taking/handling/processing of samples,"

Version (date)	Changes
13/03/2020	Addition text **Table 3.1b: Work package description WP4** "Task 4.3.Protocols for the priority studies later in the epidemic The protocols will include "the recruitment strategy, inclusion and exclusion criteria, process of obtaining informed consent,"
13/03/2020	Deletion of DELIVERABLE Table 3.1b: Work package description WP4 "D4.4. First study reports on priority epidemiological studies early in the epidemic [M6] These study reports will also be available on the I-MOVE-COVID-19 website."
13/03/2020	Addition deliverable Table 3.1c: List of Deliverables D4.4.First study reports on priority epidemiological or laboratory studies early in the epidemic
13/03/2020	Section 4: Members of the consortium Addition 4.2.1 Partner name: ISCIII - participant no2
13/03/2020	Section 5 - Ethics and security Completion: 5.1.2.1 Ethical approval - paragraph "Informed consent procedures" paragraph "5.1.4 Incidental findings policy" paragraph 5.1.5 Protection of personal data and data handling

Comparison table of the modifications made from the DOA dated 13 March 2020 and the DOA modified following the requests of the Legal & Financial officer received on 19/03/2020 (all requests were not processed by this date)

Additions are noted in blue and deletions in red

Version (date)	Changes
	Annex1 Part a
19/03/0202	Start date on 16 March 2020
19/03/0202	Financial estimation on-line for Santé Publique France
19/03/0202	Add Deliverable D1.6 Interim activity report (M6)
19/03/0202	Add Deliverable D1.7 Report to identify synergies and areas for collaboration (M1)
19/03/0202	Add Deliverable D1.8 Update of Report to identify synergies and areas for collaboration (M12)
19/03/0202	Add Deliverable D1.9 Update of Report to identify synergies and areas for collaboration (M24)
	Annex1 Part B
19/03/0202	Remove tables 3.1a, 3.1b, and 3.1c from section 3.1. They are included in Part A. on-going Remove tables 3.2a and 3.2b from section 3.2. They are included in Part A. on-going Remove table 3.4a from section 3.4. It is included in Part A.
19/03/0202	Delete p16
19/03/0202	Add Table 3.4b for Participant 2 (ISCII)
19/03/0202	Add Table 4.2.1 for Participant 4 (NHSS)
19/03/0202	Move Section 2, 2.2 c/ Data Management Plan moved to the end of Part B as Section 6 Data Sharing

Section 1. Excellence

Your proposal must address a work programme topic for this call for proposals. .
The I-MOVE-COVID-19 Consortium partners have worked together for more than a decade in the I-MOVE (ECDC) and I-MOVE+ (H2020) projects aiming at measuring the impact and effectiveness of influenza and other vaccines. This consortium has established a strong European network of general practitioners, hospitals, public health institutes, universities, reference laboratories and a Small or Medium Enterprise (SME) to perform post marketing evaluation of existing and new vaccines and delivery programmes independently from commercial interests.

The strength of this consortium was acknowledged in 2019 by the French Ministry of Higher Education and Research, which awarded I-MOVE+ (coordinated by Epiconcept and with the participation of the current I-MOVE-COVID-19 partners) the "Stars of Europe" award for project coordination work and European commitment.

The work conducted by the Consortium partners has raised new hypotheses and questions about clinical endpoints signifying severe and fatal acute respiratory infection that require a better understanding of host factors and host-pathogens interactions influencing these outcomes. Together this network has published more than 100 scientific articles.

The Consortium comprises multidisciplinary experts (clinicians, virologists, immunologists, mathematical modellers, epidemiologists) in respiratory diseases who were involved in responses to pandemic influenza, SARS and MERS outbreaks, and are currently in the frontline of the European response to the COVID-19 epidemic.

Partners in the I-MOVE (influenza) network currently identify, recruit, interview, and test individuals presenting with influenza-like illness (ILI) at primary care level (sentinel primary care practitioners participating in influenza surveillance) and patients hospitalised with severe acute respiratory infection (SARI), using a common protocol across ten countries (ten primary care networks and more than 20 hospitals) in the EU, UK and Albania. In the last influenza season (2018/19), the I-MOVE primary care multicentre study recruited over 10,000 participants across nine EU/EEA countries, while the I-MOVE hospital network recruited 2,315 participants from 17 hospitals across seven European countries. A key strength of the consortium is our experience in harmonising protocols, pooling and analysing data across Europe, and communicating results.

In most of the I-MOVE-COVID-19 partners' national and regional institutes, public health scientists involved in influenza activities are also leading the response to COVID-19 epidemic. Four of the eight European expert laboratories for coronaviruses are part of the Consortium. Therefore, the ongoing network can and is already easily expanding its scope of work and is immediately active in COVID-19 clinical, virological and epidemiological enhanced surveillance and research projects.

1.1 Objectives

We aim to obtain epidemiological, clinical and virological information about COVID-19 and patients infected with SARS-CoV-2, through provision of a flexible surveillance network (adaptable to the epidemiological situation), to perform research studies, test hypotheses and evaluate public health

interventions (e.g. vaccination, antivirals) in order to contribute to the knowledge base, guide patient management, and inform the public health response. This will be done through adaptation and expansion of the existing, long-running (12 years), Europe-wide influenza surveillance network (I-MOVE) to include COVID-19.

Objective 1: Preparedness

- To reinforce preparedness for COVID-19 in the EU, UK and Albania through strengthening capacities for surveillance, case management, and infection control in both sentinel primary care networks and hospitals.

Objective 2: Enhanced surveillance

- To develop a real-time adaptation of existing or develop new surveillance protocols for primary care, hospital and laboratory surveillance systems for this novel coronavirus in order to reinforce preparedness for COVID-19 across European countries
- To implement and adapt existing primary care, hospital and laboratory surveillance systems to the epidemiological context of COVID-19, in order to
  - describe disease patterns and identify trends, incidence, risk factors for severe disease, and case fatality by age- and risk-groups
  - identify early transmission of COVID-19 in the community
  - provide authorities with the necessary information to update / adapt case definition(s) (depending on disease occurrence and early interventions)
  - provide authorities with information for risk assessment
- To investigate cases occurring in health care workers (HCWs) in order to
  - Describe COVID-19 cases in HCWs
  - measure HCW compliance with preventive measures and early interventions

Objective 3: Clinical

- To describe clinical, laboratory, case management and treatment characteristics of COVID-19 cases identified through primary care practice and hospital surveillance networks and to disseminate this information through use/adaption of WHO and ECDC tools in order to
  - rapidly expand on the existing global knowledge base for COVID-19 through the immediate sharing of data
  - inform and improve on clinical case management through rapid data dissemination and sharing of the experiences of those in the network
  - provide an infrastructure which is ready to monitor future coronavirus outbreaks

Objective 4: Virology

- To test all suspected COVID-19 cases identified in the network for laboratory confirmation, in order to
  - confirm diagnosis and define positivity rate over time
  - carry out representative viral genome sequencing (sequencing all viruses in the early phase of the epidemic and a representative sample when higher viral circulation) to identify trends in viral change
  - describe viral genotype over time and region

- inform and improve on virological tests by sharing of protocols between the network

Objective 5: Pooled epidemiological and virological studies

- To develop new or adapt existing protocols (WHO, ECDC) and rapidly implement epidemiological and virological studies responding to priority questions in order to disseminate findings of COVID-19 throughout the international community in the shortest time possible.

The I-MOVE-COVID-19 Steering/Scientific Committee will define the priority protocols and select the studies based on the epidemiological situation, current knowledge, and on studies being conducted by other groups, to avoid duplication and reinforce complementarity. ECDC and WHO recommendations will be taken into account (e.g. Conclusions of the WHO meeting '2019 novel Coronavirus global research and innovation forum: towards a research roadmap'). Studies conducted by I-MOVE-COVID-19 may include any or all of the studies listed below. Settings for the studies will be the I-MOVE-COVID-19 primary care practitioners network, hospitals and laboratories, and may also include the community and specific cohorts in the countries/regions participating (e.g. health care workers). Studies will be selected from the following list according to the epidemiological situation over time:

- model disease transmission (effective and basic reproduction numbers)
- describe the incubation period for mild and severe cases
- measure (survey) the proportion of the population complying with preventive measures and early interventions
- identify preventive and risk factors for COVID-19 transmission in the community and in hospital settings
- identify preventive and risk factors for severity and death
- conduct sero-epidemiologic studies in primary and hospital settings, when relevant
- measure the effectiveness of preventive and treatment strategies (cohort or case control studies)
- measure post authorisation vaccine effectiveness, once candidate vaccines are available
- study viral load over time
- develop and implement WGS on MinION platform for rapid sequencing
- sequence the full viral genome and describe the genomic diversity of SARS-CoV-2 in mild, severe and fatal cases
- identify host characteristics that may influence severity
- study viral persistence in host over time
- support sero-epidemiologic studies in the community and hospital settings to complement existing initiatives (e.g. ECDC group)
- study resistance to antivirals once they come available through genotypic and phenotypic assays

1.2 Relation to the work programme

I-MOVE-COVID-19 brings together experts from 20 European institutions representing national and regional public health institutes, virology reference centres, Directorate General of Public Health, associations, Small and Medium Enterprise-based research institutes, and universities. The European Centre for Disease Prevention and Control (ECDC) and WHO Regional Office for Europe (WHO/Europe) are partners of I-MOVE (influenza) and will be invited to be members of the I-MOVE-COVID-19 Steering-Scientific Committee. The multicentre programme currently conducts independent influenza research and innovative evaluation of influenza vaccines in the EU/EEA, the UK and Albania.

The H2020 funding will allow the network to expand the current recruitment and testing of patients (patients presenting with influenza-like illness, acute respiratory infection or SARI who are tested for influenza) to include SARS-CoV-2, therefore gaining a better understanding of transmission of infection and the clinical and public health measures required to improve patients' health, in the following ways:

- I-MOVE-COVID-19 will utilise an existing network currently recruiting and testing patients at primary care and hospital levels presenting with viral respiratory infection.
- By using an efficient and productive European multidisciplinary collaboration which is already in place, I-MOVE-COVID-19 will be immediately active, adapted to the epidemiological context in each participating country (e.g. exhaustive vs sentinel surveillance, active vs passive surveillance) and providing rapid results.
- By mobilising a large European multidisciplinary network, I-MOVE-COVID-19 will combine the expertise and resources of different groups working in epidemiological, clinical and virological surveillance, research into respiratory diseases, and evaluation of vaccines/treatments.
- Through multicentre studies sharing the same protocols and pooling results across Europe, I-MOVE-COVID-19 will maximise added value by focusing on objectives and activities (large sample sizes, pooled analyses, comparisons between countries/regions) which could not be efficiently realised by individual countries acting alone.
- By linking public-public partnerships and international organisations (e.g. as already achieved in the first phase of I-MOVE: European Commission, ECDC, EMA, WHO, national public health institutes, USA, Canada, Australia, New Zealand, and Latin America), I-MOVE-COVID-19 will maintain and further develop synergies and complementarities through this large collaborative transnational project.
- I-MOVE-COVID-19 will make their protocols publicly available early, as well as harmonising them as much as possible with other actors; specifically ECDC, WHO, and representatives of other complementary H2020 projects (e.g. focusing on immunology or mathematical modelling). Data will be shared via ECDC and WHO tools, Global Initiative on Sharing All Influenza Data (GISAID) and other publicly available platforms. I-MOVE-COVID-19 will share interim and final research data, as rapidly and widely as possible, including with the above-mentioned institutes and organisations.

1.3 Concept and methodology

(a) Concept

A key recommendation in the 'Guide to revision of national pandemic influenza preparedness plans: Lessons learned from the 2009 A(H1N1) pandemic – ECDC/WHO', is that existing systems should be strengthened rather than developing new ones. This is exactly what the present proposal is about. We will build on an existing primary care, hospital, laboratory surveillance and applied research network. The 12-year experience of I-MOVE multicentre studies allows for rapid adaptation of existing generic protocols, and efficient pooling of data, resulting in key clinical, epidemiological, and virological data on COVID-19.

The setting for the studies will be the existing multidisciplinary network of European primary care practices, hospitals and laboratories, already recruiting patients presenting with acute respiratory infections. Through this multi-country, multidisciplinary platform we will describe clinical and epidemiological characteristics of COVID-19, and virological characteristics of SARS-CoV-2, identify risk

factors and evaluate preventive and control measures that will contribute to improve the management of patients and guide the implementation of prevention and control measures. Our approach is to offer a flexible surveillance and research platform able to adapt to the evolving COVID-19 epidemiological and knowledge situation. During the kick-off meeting, the Steering-Scientific committee will define the studies to be conducted based on public health priorities and knowledge gaps. The participation of public health institutes, European expert coronavirus laboratories, ECDC and WHO/Europe in the Steering-Scientific Committee will ensure that new knowledge will be integrated, that I-MOVE-COVID-19 studies are in line with public health priorities and complement the international research agenda.
To address the host, pathogen and host-pathogen interactions, we will work in an inter-disciplinary team including public health experts, clinicians, epidemiologists, virologists, immunologists, and modellers. This combined expertise will allow integration of all elements needed to understand essential features of COVID-19.

I-MOVE-COVID-19 includes four work packages encompassing (1) overall administration/ management/scientific coordination of the networks (including dissemination of information to relevant stakeholders), (2) strengthening and coordination of the primary care surveillance network, (3) strengthening and coordination of the hospital surveillance network for severe disease, and (4) preparation and implementation of studies using pooled data, to address clinical, virological and epidemiological aspects of the COVID-19 response. The primary care and hospital networks together provide a platform for preparedness, surveillance, clinical, virological and epidemiological activities. We propose a phased approach, in which the network will adapt its activities to the evolving epidemiological situation.

Phase I: Preparedness (first 1-2 months)

- WP1 (Coordination): Adaptation of the work plan to public health priorities. Development of a communication and information dissemination strategic plan. Linking with other COVID-19 initiatives.
- WP2 (Primary care network) and WP3 (Hospital network): Strengthening and monitoring preparedness activities (within relevant WP)
- WP4 (Pooled epidemiological, clinical, virological studies)
    - Identification of research priorities by the Steering-Scientific Committee
    - Adaptation/preparation of research protocols and sharing of data analysis scripts and automatised reports for individual national and pooled analyses
    - Identification/implementation of a platform for data sharing

Phase II: Implementation (months 2 onwards, depending on the epidemiological situation)

- WP2 (Primary care network): Conduct timely enhanced surveillance of suspected and laboratory-confirmed COVID-19
    - Primary care networks to
        - identify and describe cases attending primary care practices using laboratory confirmed and clinical endpoints
        - measure incidence by age group, time
- WP3 (Hospital network): Conduct timely enhanced surveillance of suspected and laboratory-confirmed COVID-19
    - Participating hospital networks to
        - identify and describe severe (hospitalised) laboratory-confirmed cases of COVID-19

    - measure incidence by age group, time, professional categories (health care workers)
- WP4 (Pooled clinical, virological, epidemiological studies) with WP2 and WP3: Conduct studies (depending on priorities, existing knowledge and studies planned by other groups)

Phase III (month n: end of the project)

- WP1-4 will:
    - Ensure sustainability of the network by identifying additional funding if needed
    - Evaluate the performances of the surveillance system (case definition, sensitivity, representativeness, timeliness, usefulness, etc.)
    - Review generic COVID-19 protocols, to include lessons learned from this epidemic, for use in any future viral respiratory epidemic(s)

Positioning of the project

Over the past 20 years we have faced the emergence of three major epidemics/pandemics due to beta-coronaviruses (SARS, MersCoV and now COVID-19). Coronaviruses now represent one of the major infectious diseases threats at the global level, requiring coordinated surveillance, management and research activities during and after the epidemic.

In this context, the I-MOVE-COVID-19 project is perfectly positioned to ensure the identification of patients to provide a detailed description of clinical, virological and epidemiological characteristics, identification of preventive measures and risk factors, and a platform to conduct necessary effectiveness studies (evaluation research). Existing and updated WHO, ECDC COVID-19 protocols or I-MOVE protocols (cohort, case-control, cluster investigation) can be rapidly adapted for descriptive or analytical studies to be performed through this new project.

Prior to starting the project, all partners will contribute to update current knowledge on coronavirus and related epidemics and priority areas of research will be compiled through a rapid review of the literature including WHO/ECDC technical documents, expert meeting recommendations, and surveillance reports.

We will organise a kick-off meeting including all stakeholders at the beginning of the project to identify priority research areas based on existing knowledge for each of the work packages, and the current epidemiological situation. Based on these priorities, we will develop, or adapt already existing protocols to make them appropriate for the study context and address the various questions in the clinical, virology, and epidemiology areas. There will also be a wrap-up meeting including all stakeholders at the end of the project to discuss lessons learned, archiving of material/tools developed in a way that is accessible, and to develop a preparedness plan for the next outbreak.

Linkage with international research initiatives

The I-MOVE-COVID-19 partners already work closely with ECDC and WHO/Europe in the framework of I-MOVE (influenza), as the network is currently funded by ECDC, WHO/Europe and Epiconcept. ECDC and WHO/Europe are part of the I-MOVE steering committee. In addition, there are strong links with national public health institutes of USA (CDC), Canada (British Columbia CDC, Quebec public health institute, public health Ontario), Australia (WHO Collaborating Centre for Reference and Research on Influenza), Hong Kong (University of Hong Kong), and WHO-Panamerican Health Organization. The I-MOVE network

meets annually with all these European and international partners to share results, discuss methodological aspects and identify priority research areas. We aim to continue working with all these partners in the area of COVID-19. We will organise annual meetings with European and international teams to review current knowledge and existing knowledge gaps, and to update the research agenda.

(b) Methodology

- Preparedness

In the very early stages of the epidemic in Europe (Phase I of the project), partners will review the current knowledge and epidemiological situation of COVID-19, identify knowledge gaps, define priority questions that the network should address, prepare or adapt surveillance and research protocols (clinical, epidemiological, virological), analysis scripts, train staff, and enhance preparedness within the existing I-MOVE network. In this phase, we will ensure to align I-MOVE-COVID-19 activities with the priorities set up by national authorities, ECDC, and WHO, so as to contribute to rapidly increase knowledge, preparedness and response to COVID-19.

- Enhanced surveillance

As soon as COVID-19 is detected in participating sites, I-MOVE-COVID-19 will pool data collected from participating primary care surveillance networks and from each of the hospitals participating in the network.

In case of a dramatic increase of incidence, as was observed in China, the strategy in countries will change from containment to monitoring. Surveillance will move to sentinel surveillance to follow trends, identify potential epidemiological changes and collect detailed information on key preventive or risk factors for research purposes. As per I-MOVE (influenza) protocols, the selection of patients to be included in the sentinel system will ensure representativeness.

Standards for RT-PCR will be shared between participating laboratories and used to confirm COVID-19 infection in clinically suspected cases. Participating laboratories will participate in European or international external quality assessments (EQAs) to monitor the performance of the implementation of different formats.

Depending on the incidence, all or a random sample (age, sex and time representative) of laboratory confirmed COVID-19 specimens will be sequenced.

Specimen processing will be performed in accordance with relevant national biological safety regulations and following the recommended WHO guidelines on biosafety and biosecurity. A secured laboratory clinical specimen database will be set up.

- Studies to respond to priority public health questions

During the epidemic (Phase II of the project), I-MOVE-COVID-19 will respond to priority questions through multicentre studies:

a) preventive and risk factor epidemiological studies using different study designs including ad-hoc cohort studies, various types of case-control studies (e.g. test negative design), and modelling. Prevention and control evaluation research studies using European multicentre cohort and case control studies to measure the effectiveness and impact of preventive and treatment measures (cf ECDC and WHO guidelines).

b) virological studies: whole-genome sequencing (WGS) to describe viral mutation over time, description of viral loads among mild and severe cases, definition of viral persistence over time (cohort of cured cases). If and as needed, measure the performance of rapid diagnostic tests (sensitivity, specificity, positive and negative predictive values) to ease and accelerate identification of cases. Complement existing initiatives (e.g. ECDC seroepidemiology group) by implementing studies (if needed) or providing a platform to conduct seroepidemiological studies in the community and hospital settings.

Gender dimension

Analyses will be stratified and results presented by sex to evaluate possible differences in individual and group (e.g. pregnant women)-specific risks of disease and performance of prevention and treatment.

1.4 Ambition

Based on an existing clinical, surveillance, epidemiological and virological research network, I-MOVE-COVID-19 will rapidly provide results by conducting studies that can be adapted to the evolving situation of the COVID-19. From active case-finding in participating primary care and hospital networks in case of low incidence in participating countries to adaptation of influenza-like illness (ILI) surveillance in case of high incidence, the network can rapidly respond to the changing epidemiology of the disease.

The I-MOVE-COVID-19 Steering/Scientific Committee (that includes I-MOVE-COVID-19 public health institutes and laboratories, ECDC, and WHO) will ensure that the network addresses priority clinical, virological and epidemiological questions and integrates new knowledge.

Based on harmonised protocols, we will pool data from participating countries to reach a European sample size able to provide robust description of the clinical, virological and epidemiological characteristics of cases and generate hypotheses that we will be able to test within the network. Through recruitment of reference group(s), we will identify risk and preventive factors, and evaluate preventive and control measures. If relevant, the availability of several years of influenza data from I-MOVE could be an opportunity to compare ILI/SARI cases (e.g. influenza A(H1N1)pdm09 from the 2009/10 season) with COVID-19 cases.

Our results will be available immediately to national public health authorities, ECDC, EMA, European Commission, and WHO. We will share protocols and data gathered through public health platforms.

Consortium beneficiaries have a long history of multidisciplinary collaboration and can rapidly respond to new needs, integrate new concepts and approaches. This is demonstrated by the capacity to adapt the I-MOVE network activities during the A(H1N1)pdm09 pandemic in 2009/10[1],[2], and to integrate new research questions in the area of influenza vaccines every year: vaccine effectiveness against different

[1] Valenciano M et al. Estimates of Pandemic Influenza Vaccine Effectiveness in Europe, 2009-2010: Results of Influenza Monitoring Vaccine Effectiveness in Europe (I-MOVE) Multicentre Case-Control Study. Plos Med8(1):e10000388.doi;10.1371/journal.pmed.1000388

[2] Hardelid P et al. Effectiveness of pandemic and seasonal influenza vaccine in preventing pandemic influenza A(H1N1)2009 infection in England and Scotland 2009-2010. Euro Surveill. 2011;16(2):pii=19763. Available online: http://www.eurosurveillance.org/ViewArticle.aspx?ArticleId=19763

outcomes, effect of yearly repeated vaccination[3], waning of immunity during and between seasons[4], vaccine effectiveness against specific clades by integrating sequencing of a random selection of viruses[5], effect of the use of statins, birth cohort effect[6], cost-effectiveness of vaccinating children[7].

The current increased workload of European public health institutes (many of them being part of I-MOVE) as a result of additional surveillance and control activities due to the COVID-19 epidemic means that most would not be in a position to also coordinate the I-MOVE-COVID-19 project. Epiconcept is coordinating the I-MOVE network, which covers influenza surveillance, but is not yet involved in the current public health response to the COVID-19 epidemic. Epiconcept is therefore well-placed to take on the coordination of the project, perform pooled European studies, and conduct their analyses with the real-time scientific communication of results. Epiconcept will bring its expertise on Consortium coordination (including H2020 Consortium) and methodological expertise in pooling and analysing European data.

The network will ensure provision of new knowledge needed to guide public health response by integrating as beneficiaries national and regional public health institutes, and reference laboratories across Europe, as well as including ECDC and WHO/Europe in the Steering/Scientific Committee.

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[3] Valenciano M, Kissling E, Larrauri A, Nunes B, Pitigoi D, O Donnell J, et al, I-MOVE primary care multicentre case-control team. Exploring the effect of previous inactivated influenza vaccination on seasonal influenza vaccine effectiveness against medically-attended influenza: results of the European I-MOVE multicentre test-negative case-control study, 2011/12-2016/17. Influenza Other Respir Viruses. 2018;1-15.doi: 10.1111/irv.12562.

[4] Kissling E, Nunes B, Robertson C, Valenciano M, Reuss A, Larrauri A, et al, I-MOVE case–control study team. I-MOVE multicentre case–control study 2010/11 to 2014/15: Is there within-season waning of influenza type/subtype vaccine effectiveness with increasing time since vaccination? Euro Surveill. 2016;21(16):pii=30201. DOI: http://dx.doi.org/10.2807/1560-7917.ES.2016.21.16.30201

[5] Kissling E, Pozo F, Buda S, Vilcu AM, Rizzo C, Gherasim A, et al. Effectiveness of influenza vaccine against influenza A in Europe in seasons of different A(H1N1)pdm09 and the same A(H3N2) vaccine components (2016-17 and 2017-18). Vaccine X. 2019;3:100042.

[6] Kissling E, Pozo F, Buda S, Vilcu AM, Gherasim A, et al. Low 2018/19 vaccine effectiveness against influenza A(H3N2) among 15–64-year-olds in Europe: exploration by birth cohort. Euro Surveill. 2019;24(48):pii=1900604. https://doi.org/10.2807/1560-7917.ES.2019.24.48.1900604

[7] Hodgson D, Baghuelin M, [redacted] E, Panavoska-Griffiths J, et al. Effect of mass paediatric influenza vaccination on existing influenza vaccination programmes in England and Wales: a modelling and cost-effectiveness analysis. Lancet Public Health. 2017 Feb;2(2):e74-e81. doi: 10.1016/S2468-2667(16)30044-5.

Section 2. Impact

2.1 Expected impacts

We will contribute to the public health preparedness and response in the context of the ongoing epidemic of COVID-19 by achieving the following:

Infrastructural and preparedness impact

- Rapid adaptation and preparation of primary care network, hospital network and laboratory infrastructure in 11 countries will enhance the response to this epidemic, while setting the stage for the next.
- Detection of transmission in the community (new cases not identified previously as contacts) to inform risk assessment.
- Preparedness reinforcing to respond to different phases of the COVID-19 epidemic.

Research impact

- A detailed list of research priorities for I-MOVE-COVID-19 to be updated over time and shared with the international community will allow for cross-validation and avoid unnecessary duplication of studies.
- Rapid dissemination of pooled European clinical, epidemiological and virological results will improve the knowledge base for COVID-19.
- Powerful (large sample size from European multicentre studies) results of studies of preventive and risk factors will provide robust interpretation of results and allow for better prevention and control of the epidemic and reduction in case fatality.
- I-MOVE-COVID-19 ready to measure vaccine effectiveness (once a vaccine is developed and available) as the network is already measuring influenza vaccine effectiveness. I-MOVE-COVID-19 and will develop protocols for this in advance, incorporating different designs.

Impact on patient health

- Primary care practitioner and hospital-based surveillance will allow, in the early phase of the epidemic, detection and testing of all suspected mild and severe cases in participating hospitals and primary care networks for confirmation, with contact identification and finding to limit the spread of the disease.
- Monitoring delays between disease onset in cases and date of detection will allow measurement of and improvement in any deficit in timeliness of case identification and management.
- Measuring the proportion of cases not identified through contact tracing will allow early identification of local transmission and measurement of the effectiveness of and modification in the case-finding strategy during the early stage of the epidemic.
- Evaluation of the performances of current diagnostic tests (RT-PCR) will allow improvement in the sensitivity and specificity of case detection and contribute to the diagnosis and early clinical management of patients infected by COVID-19.
- Monitoring case management, treatment procedures, identification and evaluation of new drugs and procedures (e.g. new antivirals) will allow reduction in length of hospital stay and case fatality.
- Identification of viral mutation(s) associated with severity will provide vital information to guide treatment strategies.

Impact on policy and policy-makers

- In the event of high incidence, implementing alternative (sentinel) surveillance (similar to what is done for influenza) to allow detailed monitoring of trends will provide the latest and most thorough data to inform changes in/updates to policy
- Monitoring the effect of different treatment strategies through in-hospital case fatality estimation and risk of severe disease will inform policy.
- Evaluation of public health measures (e.g. vaccination, antivirals) will inform policy

Other impacts

- I-MOVE-COVID-19 will further strengthen a powerful, existing, multidisciplinary, collaborative surveillance and research network able to rapidly respond to emerging pathogens. The high number of primary care practitioners, hospitals, public health institutes, universities, and reference laboratories participating in the network together with Epiconcept (an SME) constitutes a network which remains independent from industry. This is particularly important to increase public acceptance of the results and recommendations when evaluating commercially produced treatment, or prevention strategies such as vaccination.

The proposed workforce currently already responds to emergencies in public health institutes, laboratories, the primary care setting, and hospitals. Funds for the project will be used to strengthen these teams, and to develop additional tools to facilitate preparedness and surveillance tasks. The coordinator of the project is not currently involved in the COVID-19 response and therefore can coordinate the scientific and managerial aspects, identify risks and implement mitigation measures.

In most participating countries, surveillance activities and studies using surveillance data do not require approval by ethical committees, obviating potential regulatory barriers.

Study sites will transfer anonymised data to Epiconcept (coordinating hub), respecting the European general data protection regulations (GDPR) for pooled data analysis using a secured data transfer application for exchanging health-related files among health professionals.

Protocols for surveillance of influenza already exist and are in use by the network, allowing their rapid adaptation to COVID-19 using a standardised methodology from the start.

2.2 Measures to maximise impact

a) Dissemination and exploitation of results

We will disseminate results to share knowledge beyond the project (e.g. other research groups, scientific community), to provide results allowing evidence-based decisions to policy-makers, to the industry and to the public. The Executive Board will ensure that scientific results are translated into clear and transparent messages to the public, patient associations and specialised media. We will exchange, share and discuss results with other COVID-19 research initiatives to maximise their impact and to prioritise research areas. As per the EC declaration, we will make our research data available, at the latest within 30 days after it has been generated. **Please also see our draft data management plan** (section 6) **for further information on data/results sharing.**

We will develop a website that will address three categories of viewers:

- I-MOVE-COVID-19 study sites (to access network documents, recruitment tables and preliminary results)
- I-MOVE-COVID-19 partners, public health authorities (national, ECDC, EMA, EC, WHO); to access all existing adapted or newly developed protocols, training material, and published results validated by the scientific committee. All general practitioners, paediatricians, hospitals, regional epidemiologists, and laboratories involved in the studies will receive interim and final reports as approved by the I-MOVE-COVID-19 Steering-Scientific Committee.
- the public and other healthcare professionals; to access interim results (when relevant), final results and specific scientific evidence and information. This will be done in collaboration with risk analysis and public communication experts.

Post-project longevity will be ensured by copying protocols and reports to a public domain repository, chosen in consultation with the Steering-Scientific Committee and other actors, and which ensures long-term archiving.

Exploitation of results

Viral sequences will be shared through the GISAID platform

I-MOVE-COVID-19 evidence-based results will be shared with:

- European agencies and EU/EEA Member States, to guide their recommendations through sharing periodic reports and teleconferences;
- Industry, to inform them of the effect of their products (if relevant) through reports shared with EMA ;
- National Health authorities, to adjust the national/local policies and recommendations;
- WHO/Europe, through reports, participation in the Steering-Scientific Committee, teleconferences;
- Public and associations of health care consumers and patient advocacy groups through the website or specific meetings with I-MOVE-COVID-19 partners if needed.

Annual technical meetings

The Steering-Scientific Committee of the project will facilitate the review of yearly results during two annual 3-5 day workshops for all participating study sites, ECDC, EMA, WHO, EC and selected external experts. These meetings will allow for an exchange between international partners to improve studies and maximise their impact. They will identify the next research and public health questions to be answered and the best method to respond to them. The meeting reports will present the main findings, lessons learnt and recommendations. The meeting reports will be shared rapidly with all meeting participants including ECDC, EMA, EC, and WHO.

Reports of the two annual meetings and technical workshops will be made available to the scientific committee, study sites and authorities upon request.

Publications

Based on previous experience from I-MOVE, from five to 10 national or EU/EEA pooled study publications are expected each year in journals with high impact factors. Any scientific publications will be "Gold" Open Access with a pre-print made publicly available.

- Each study site will be encouraged to publish its own part of the I-MOVE-COVID-19 results in national or international open-source, peer-reviewed journals.
- I-MOVE-COVID-19 will facilitate publication of pooled multicentre study results and lessons learnt from the project in relevant, open-source, international, peer-reviewed journals with high impact factors. Investigators will be listed by order of contribution (sample size) in the pooled analyses. Remaining authorships will be in reference to methods, laboratory, digital or other significant contributions in line with ICMJE guidance.

Other dissemination of results

At national level, the dissemination of results will be defined by the partners conducting the studies.

At pooled level:

- Publications policy A generic publications policy will be developed and implemented by all network members as part of the research agenda
- Conferences I-MOVE-COVID-19 will facilitate the presentation and discussion of national and EU/EEA pooled results at international conferences (e.g. ISIRV, EID, ESCAIDE, ESPID, EPH, etc.).
- Standards Generic protocols, models, guidelines, training material, scripts for data analysis that are developed in the context of the project will be public domain. They will be placed on the I-MOVE-COVID-19 website and made available to ECDC, EMA and WHO. Additionally, they will be placed on a repository, such as ZENODO, to ensure post-project longevity. Please see the draft data management plan for more information (section 2.2.c).

Proposed measures and their contribution to the expected impact of the project.

- Results of clinical, virological, and epidemiological findings, as well as treatment benefits/risks from a public health perspective, all independent from commercial interests, will have a high acceptability for regulatory bodies, public health agencies, public health professionals, and patient organisations.
- Results from burden and risk factors studies and the effects of treatment and new vaccines will guide health topics for public health decision-makers and industries towards new treatments and prioritisation of vaccine investments.
- Results available at European and country levels will guide the selection of the preventive and curative strategies and help with tailoring interventions.
- Generic protocols will be adaptable by other European countries regions or other regional networks outside of the EU.

- I-MOVE-COVID-19 annual meetings and workshops will contribute to answering current questions at international level
- I-MOVE-COVID-19 members are part of institutional/international committees on respiratory infections, vaccination strategies
- Continuing a 12-year collaboration with I-MOVE, ECDC will be part of the Steering-Scientific Committee and will be able to immediately put into action the evidence gathered, as well as rapidly adapt EU guidance (vaccination, strategies, antiviral treatment, rapid diagnostic tests)
- I-MOVE-COVID-19 will support EMA and the respective national regulatory agencies for drugs and biologicals address the pre- and post-authorisation requirement it places on manufacturers of anti-infective and future vaccines.
- The critical involvement of multiple national public health institutes will support policy-making and public health guidance and assist in the provision of information to patients and prescribers.
- Detailed evaluation of risk and preventive factors will help to guide funding allocation to public health programmes and research activities at the national and European levels.
- The Steering-Scientific Committee, with the support of WP1 leader, will identify funding opportunities to continue the activities of the Consortium or to scale them up if needed.

I-MOVE-COVID-19 is committed to the principles set out in the 2016 Statement on data sharing in public health emergencies, as well as the EC recommendation of 25/4/2018 "On access to and preservation of scientific information" and EC Guidelines on FAIR data management in H2020. Details on how I-MOVE-COVID-19 will manage research data generated and collected during the project are outlined in the draft data management plan (section 6). In summary:

Data collected will comply with each participating country's anonymisation regulations (GDPR) and will be collected and stored according to standard good clinical and epidemiological practices. Individual patient data are needed to reach clinical, epidemiological and virological objectives.

Anonymised data will be transmitted to the I-MOVE-COVID-19 coordination level when needed for pooled EU analysis, following a strict, secured data transfer procedure. Cost of data transfer and pooled storage will be organised and covered by Epiconcept. Epiconcept is certified by the data protection agency of the French Government (ASIP) as a "personal health data host" with ISO 27001 accreditation.

Surveillance and study protocols will be submitted (if relevant) for approval to each respective national scientific/ethical committee.

Data collected will include

- Demographics (anonymised unique ID number, age, sex, presence of chronic disease)
- Clinical signs and symptoms and onset date
- Exposures (travel history, contacts)
- Potential risk factors (co-morbidity, immuno-suppressed, etc.)
- Preventive and treatment measures used (e.g. antivirals, vaccination, when available)

- Outcomes: severe disease, death
- Laboratory results including viral characteristics, sequencing, relative viral load.
- In-hospital death

All the above information will be collected by I-MOVE-COVID-19 partners at the community, primary care and hospital settings using epidemiologists and clinical research investigators.

Information collected will be used for analysing surveillance data (distributions, trends, time series); risk factors and effectiveness studies (retrospective and prospective cohort studies, case control studies including the test negative design as used for influenza); modelling studies (disease transmission dynamics, predictive studies) random sample community surveys; laboratory database studies (performance of diagnosis tests, magnitude of viral mutation).

Potential vaccine and antiviral related studies will be discussed with EMA that will link with the producers.

Sequencing information will be rapidly uploaded to GISAID's new BetaCoV 2019-2020 platform, which is open access. Appropriate repositories (such as ZENODO) will be used for data, results and protocols/reports, to ensure longevity and safety of outputs after the end of the project. Meta-data using appropriate standards will be stored alongside the data. Where possible, Creative Commons licenses will be used, however licenses and access will be determined in conjunction with the Steering-Scientific Committee on a case-by-case basis.

Consortium Agreement

- Based on the model used during the H2020 I-MOVE+ project, a document stating principles of scientific collaboration and decision-making procedures between I-MOVE-COVID-19 partners is in preparation and following the frame provided by H2020 (DESCA Model Consortium Agreement). It will be completed by the Steering-Scientific Committee and approved by all study sites.
- This document will include, among other things: information about and procedures for data ownership, data exchange, data storing, sharing of results, principles of authorship for publications, rules for deciding in case of scientific disagreement (e.g. through the Steering-Scientific Committee), etc. **The draft data management plan** (section 2.2.c) will be finalised and included in the consortium agreement.
- The consortium agreement will describe the internal organisation of the Consortium, its decision-making process and management arrangements.

Strategy for knowledge management and protection. Measures to provide open access to peer-reviewed scientific publications resulting from the project include:

- Articles presenting our results will be published in peer-reviewed scientific publications with gold open access with a satisfactory impact factor such as Lancet Infectious Diseases, Eurosurveillance, Plos One, BMC Public Health, International Journal of Infectious Diseases and others.
- Real-time information and annual technical reports (surveillance, epidemiological studies) will be available in the public area of the website.
- The list of all publications and the link giving access to publications and reports will be available in the public area of the website.

Additional exploitation obligations:

Beneficiaries must take all measures aiming to ensure that their results or resulting products/services will be broadly available and accessible, as soon as possible and at fair conditions.

In this respect, they must grant non-exclusive licences to their results under fair and reasonable conditions to any legal entities that commit to rapidly and broadly exploit the resulting products and services at fair conditions.

Beneficiaries must indicate the owner(s) of the results (results ownership list) in the final report.

Beneficiaries must use the Horizon Results Platform to find interested parties to exploit those results.

b) Communication activities

The proposed communication measures for promoting the project and its findings include:

- The source of funding (H2020) of the project will be mentioned in all communications and documents (website, articles, presentations, protocols).

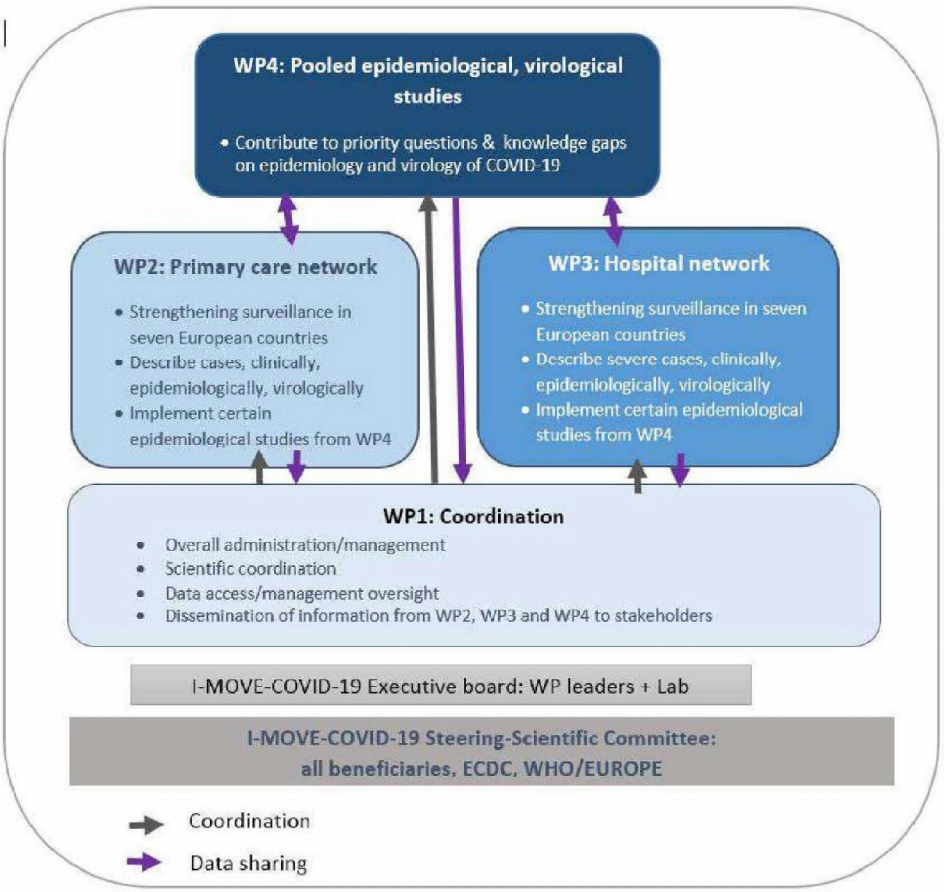
- The website will include an open area with the generic protocols, news, list of publications, list of presentations at conferences and congresses, and links to specific articles from and outside of the network. This open area will target the public and the scientific community.
- Study sites will be encouraged to publish their own results in peer-reviewed journals or national bulletins and to present them at international and national conferences.
- The annual meetings will be a communication platform to which external participants will be invited. They will come from EU institutions (EMA, EC, ECDC), international agencies (WHO) and other non-EU MS involved in similar studies (US-CDC, Australian and Canadian provinces and ministries of health, Latin American research networks, Honk Kong SAR CHP, etc).
- Results will be presented during national and international conferences.
- Results will be shared with national and international regulatory agencies and public health authorities.
- Upon approval of the executive board, the main results will be disseminated also onto selected social media sites (Facebook, Twitter)

Section 3. Implementation

We propose to divide the work plan into four work packages (WP):

- WP1: Management, Scientific Coordination and Communication
- WP2: Primary care sentinel networks
- WP3: Hospital network
- WP4: Pooled epidemiological and virological studies

Graphical presentation of the I-MOVE-COVID19 components showing how they interrelate



3.3 Consortium as a whole

The core of the project and budget are the work packages 2-4, in which enhanced surveillance and studies are conducted. We propose to have a work package for each of the two surveillance components (primary care sentinel networks, hospital studies) and one for the implementation of priority studies. All technical WPs will contribute to better understand and evaluate clinical, virological and epidemiological aspects of SARS-CoV-2/COVID-19. Each technical WP includes epidemiologists, clinicians, virologists, biostatisticians, modellers and public health experts, ensuring that all expertise needed to reach the objectives are covered. These technical packages (WP2, WP3, WP4) include the following core activities: development of generic/standard protocols, adapting the protocols to the sites conducting the studies, conducting the studies, and communicating the results.

Coordination: The overall coordination will be provided by Epiconcept through WP1. We propose to regroup the management, scientific coordination and communication under WP1, to minimise the costs of management/coordination and devote more resources to the conduction of studies. WP1 will ensure that stakeholders and scientists work together effectively, will monitor the progress of all work packages, and ensure that deadlines are made while delivering the anticipated results. Epiconcept will be responsible for contract monitoring and deliverable scheduling and will submit the deliverables to the Commission after having verified their completeness and correctness. Epiconcept will also lead the creation of periodic reports and the final report (these will of course include input and material from all partners). All partners have a role in contributing to reports and reviewing them before submission. Work package leaders manage their own work packages. Effort for work package management is allocated at the WP level, not in this (management) work package; hence only Epiconcept has effort budgeted for this WP. All logistical and administrative aspects related to meetings will be Epiconcept's responsibility and therefore, budgets for meetings are included in WP1.

WP1 will support the conduction of studies in all other work packages and ensure the complementarity of the tasks conducted. Epiconcept will co-lead WP3, led by Health Protection Scotland, to ensure that the activities continue in case of non-participation of HPS due to Brexit. Epiconcept will also provide back-up to any WP leaders who could face difficulties in coordinating WP activities in case of high workload due to COVID-19.

The laboratory aspects in WP2-4 will be coordinated by the National Centre for Microbiology, ISCIII, Spain.

Steering-Scientific Committee: The I-MOVE-COVID-19 coordination will respond to the Steering-Scientific Committee of the project. The Steering-Scientific Committee will be composed of all beneficiaries, the European Centre for Disease Prevention and Control (ECDC) and WHO/Europe as advisor. The Steering-Scientific Committee, comprised of scientists from participating institutes, is also the Scientific Committee of the project. In its scientific role, the Steering-Scientific Committee may call upon advice from external scientific expertise. The Steering-Scientific Committee will define the studies to be conducted within WP4 and the budget allocated to each beneficiary participating in the

studies. WP4 holds the budget for these studies and will distribute it to participating beneficiaries following the Steering-Scientific Committee's decision.

Executive board: An executive board (all WP leaders and the Coordinator of the virology component, Centro Nacional de Microbiología, ISCIII) will help the coordination team for real-time decision-making and advice as necessary. It will comprise each of the work package leaders and the Centro Nacional de Microbiología- ISCIII that will coordinate the laboratory activities.

Role of the Steering-Scientific Committee:

- Managerial aspects: the Steering-Scientific Committee will
    - based on the epidemiological situation at the start of the project, and the knowledge gaps, define priority activities for each WP.
    - monitor the development and the application of principles of collaboration including ethical issues and their approval by all participants
    - review once a year the compliance with the planned budget, its allocation under EC regulations and the overall achievement of deliverables within the required timelines
- Scientific aspects: the Steering-Scientific Committee will
    - meet face-to-face once a year and as needed by videoconferences (at least once every 6 months) to review and make decisions to approve or comment on:
        - development of study protocols and their adaptation to country-specific contexts, the conduct of the specific studies in each participating country, and the compliance with the protocol
        - respect of ethical rules as prescribed by country-specific authorities
        - respect of good scientific practice
        - the process of secured and anonymous data transmission, sharing, and storing
        - appropriate analysis of data
        - reporting and dissemination of results to study sites, national, European, and international authorities
        - publication of results in peer-reviewed journals
        - provision of scientific advice upon request from study sites
        - development of complementary funding proposals

Tables for section 3.4

Table 3.4b: 'Other direct cost' items (travel, equipment, other goods and services, costs of internally invoiced goods and services, large research infrastructure)

1 EpiConcept	Cost (€)	Justification
Travel	177930	Travel & Daily meeting allowances for all participants and invited scientists for all meetings and site visits organised by the project. Travel & Daily allowances for all participants and invited scientists for participation of international conferences. air plane tickets and insurance 71400 Meals meeting allowance 52210 Meeting & conferences acccomodation 54320
Equipment		
Other goods and services	47800	Meeting expenses, scientific and communication for publication fees, international congress registration and other direct costs connected to the coordination of the project meetings, site-web hosting and set-up, logo and costs for the issuance of a certificate of financial statement (3000€) small supplies and organizational costs 34000 Publication fees 10000 Website hosting costs 800 CFS audit cost 3000
Total	225730	

2 ISCII	Cost (€)	Justification
Travel		
Equipment		
Other goods and services	20800	Laboratory tests (hospital expenses for laboratory) distributed as follows between: €16,000 for ISCII budget €2,400 for FIBAO (linked 3rd party) €2,400€ for IACS (linked 3rd party) ========= €20,800
Total	20800	

4 NHS National Services Scotland	Cost (€)	Justification
Travel		
Equipment		
Other goods and services	40000	Laboratory tests
Total	40000	

5 Instituto Nacional de Saúde Dr. Ricardo Jorge	Cost (€)	Justification
Travel		
Equipment		
Other goods and services	80440	Laboratory tests by INSA Hospital expenses for laboratory diagnosis of 2019-nCoV and clinical data collection
Total	80440	

7 Public Health England	Cost (€)	Justification
Travel		
Equipment		
Other goods and services	16000	consumables in the lab.
Total	16000	

8 Lietuvos Sveikatos Moksiu Universitetas	Cost (€)	Justification
Travel		
Equipment		
Other goods and services	21300	Laboratory testing, dry ice, transportation expences
Total	21300	

10 The Public Health Agency of Sweden	Cost (€)	Justification
Travel		
Equipment		
Other goods and services	19280	Laboratory tests
Total	19280	

13 UNIVERSITE DE CORSE PASQUALE PAOLI	Cost (€)	Justification
Travel		
Equipment		
Other goods and services	8000	Reagents for test laboratory over the two years
Total	8000	

16 Institut Pasteur	Cost (€)	Justification
Travel		
Equipment		
Other goods and services	48 000	Consumables (kits, reagents for tests)
Total	48 000	

19 IPH (ISHP)	Cost (€)	Justification
Travel		
Equipment		
Other goods and services	30 000	Laboratory testing, dry ice, transportation expences
Total	30 000	

20 RIVM	Cost (€)	Justification
Travel		
Equipment		
Other goods and services	17 000	Laboratory tests
Total	17 000	

21 INSERM	Cost (€)	Justification
Travel		
Equipment		
Other goods and services	2 000	administrative expenses
Total	2 000	

3.4.c Other sources of funding for the tasks described in the Description of the Action (DoA) and covered by this H2020 grant.

No funding from any other third party for the tasks described in this Description of Action has been received at the time of grant agreement preparation.
In the event that this changes during the implementation of the action , the consortium will inform the Commission services.

3.4.d Other sources of funding for any complementary tasks closely related to the work covered by this H2020 grant."

No funding from any other third party for any complementary tasks closely related to the work covered by this H2020 grant has been received at the time of grant agreement preparation. In the event that this changes during the implementation of the action , the consortium will inform the Commission services.

Section 4: Members of the consortium

4.1. Participants (applicants)

4.1.1 Partner name: EPICONCEPT - France - participant no1

1.1.1 Description of the legal entity

Epiconcept is a Small and Medium Enterprise, specialised in epidemiology and health information systems.

The epidemiology department has a strong expertise in coordinating European vaccine research networks:

- Since 2007, coordination of I-MOVE (influenza monitoring vaccine effectiveness network)
- 2015- 2018, coordination of I-MOVE+ (Integrated Monitoring of Vaccines in Europe) a consortium of 26 partners that measures the effectiveness, impact and cost-effectiveness of pneumococcal and influenza vaccines among the population aged 65 years or more. For the influenza component, I-MOVE+ includes a network of 26 hospitals, a GP network and studies based on electronic databases in six countries.
- Since 2015, coordination of PERTINENT, a European hospital network to measure the incidence of pertussis in infants less than one year of age, as well as the vaccine effectiveness and impact of different pertussis vaccination strategies in the EU/EEA.
- Since 2012, coordination of SpIDnet project (Streptococcus pneumoniae Invasive Disease network), a European surveillance network comprising ten institutions from eight countries measuring the impact and effectiveness of pneumococcal conjugate vaccines in children < 5 years in Europe.

Epiconcept has developed generic protocols for impact and effectiveness of influenza, pneumococcal, pertusiss, rotavirus, HPV vaccines. Epiconcept conducts pooled analysis of multicentre studies in Europe. The epidemiology department conducts other activities in the area of evaluation of surveillance systems (e.g. evaluation of European surveillance systems for ECDC), biostatistics (e.g. development of data quality indicators for ECDC surveillance systems), training in epidemiology.

Epiconcept is certified by the data protection agency of the French government (ASIP) as a "personal health data host" for his Voozanoo platform. The technical requirements relating to 19 security, risk analysis and the establishment of an ISSP (Information Systems Security Policy) for obtaining this accreditation are very similar to those for the ISO 27001 standard.

For I-MOVE-COVID-19 Epiconcept will lead WP1 and WP4 and participate in WP2 and WP3 (development/review of protocols, support for data analysis). Epiconcept will be a member of the Steering-Scientific Commitee and Executive Board.

1.1.2 Personnel involved

1.1.3 5 relevant publications/services/achievements

Rose, AMC, Kissling, E, Gherasim, A, et al; I-MOVE Hospital study team. Vaccine effectiveness against influenza A(H3N2) and B among laboratory-confirmed, hospitalised older adults, Europe, 2017-18: A season of B lineage mismatched to the trivalent vaccine. *Influenza Other Respi Viruses*. 2020; 00: 1– 9. https://doi.org/10.1111/irv.12714

Kissling E, Pozo F, Buda S, Vilcu AM, Gherasim A, Brytting M, Domegan L, Gómez V, 5.1.2e, Lazar M, Vučina VV, Dürrwald R, van der Werf S, Larrauri A, Enkirch T, O'Donnell J, Guiomar R, Hooiveld M, Petrović G, Stoian E, Penttinen P, Valenciano M, I-Move Primary Care Study Team. Low 2018/19 vaccine effectiveness against influenza A(H3N2) among 15-64-year-olds in Europe: exploration by birth
cohort. Euro Surveill. 2019 Nov;24(48). doi:10.2807/1560-7917.ES.2019.24.48.1900604.

Rondy Marc, Kissling Esther, Emborg Hanne-Dorthe, Gherasim Alin, 5.1.2e, 5.1.2e 5.1.2e, 5.1.2e, Larrauri Amparo,McMenamin Jim, 5.1.2e, I-MOVE/I-MOVE+ group. Interim 2017/18 influenza seasonal vaccine effectiveness: combined results from five European studies. Euro Surveill. 2018;23(9):pii=18-00086

Kissling E, Nunes B, Robertson C, Valenciano M, Reuss A, Larrauri A, Cohen JM, Oroszi B, Rizzo C, Machado A, Pitigoi D, Domegan L, Paradowska-Stankiewicz I, Buchholz U, Gherasim A, Daviaud I, Horváth JK, Bella A, Lupulescu E, O Donnell J, Korczyńska M, Moren A; I-MOVE case–control study team. I-MOVE multicentre case-control study 2010/11 to 2014/15: Is there within-season waning of influenza type/subtype vaccine effectiveness with increasing time since vaccination?. Euro Surveill. 2016 Apr 21;21(16). doi: 10.2807/1560-7917.ES.2016.21.16.30201.

Valenciano M, Kissling E, Cohen JM, Oroszi B, et al. Estimates of pandemic influenza vaccine effectiveness in Europe, 2009-10: results of I-MOVE multicentre case-control study, Plos Med 2011 Jan;8(1):e1000388.

1.1.4 5 previous projects

I-Move+ Integrated Monitoring of Vaccine Effectiveness in Europe: a platform to measure and compare effectiveness and impact of influenza and pneumococcal vaccines and vaccination strategies in the elderly. Horizon 2020. EU project 634446. 2015-2018.

Monitoring vaccine effectiveness during seasonal and pandemic influenza in EU/EEA, ECDC tender (OJ/16/07/2014-Proc/2014/024). 2016-2017

Assessing the impact of vaccination with conjugate vaccines on the epidemiology of invasive pneumococcal disease in EU/EEA. SpIDnet network, ECDC tender ECDC/2015/031

Set-up a hospital based enhanced surveillance sentinel system for whooping cough in order to assess the burden of disease IN eu:eea, PERTINENT network, ECDC tender ECDC/2015/017

Measure the impact of rotavirus vaccination on incidence of hospitalisation for acute gastroenteritis due to Rotavirus Infections - ECDC/09/041OJ/2009/09/24-PROC/2009/043

1.1.5 Significant infrastructure and/or any major items of technical equipment relates to the proposal

Various generic protocols for evaluation of vaccine effectiveness and impact.

Standard procedures for management and financial follow up of European projects

Scripts developed in R and Stata for multicentre studies

Certification to host personal healthcare data by the French Accreditation Committee for personal healthcare data hosting services.

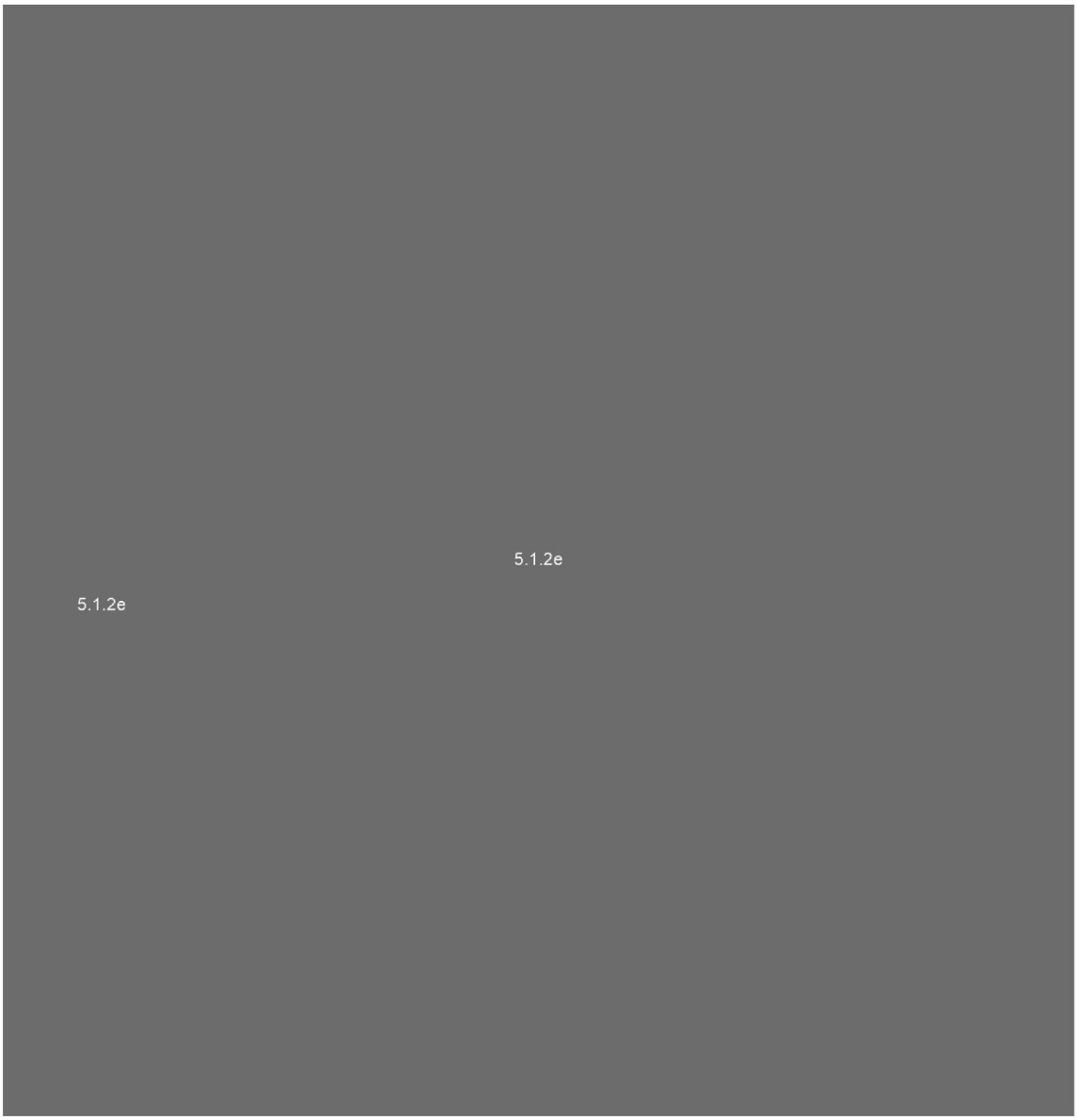
4.1.1 Partner name: ISCIII - Spain - participant no2

1.1.1 Description of the legal entity

The Instituto de Salud Carlos III (ISCIII) mission is to promote scientific and technological research and innovation, as well as to provide scientific and technical high quality services in the field of public health, biomedicine and sciences health, aimed to the General State Administration, the Autonomous Communities and the National Health System. The ISCIII is the leading Public Research Institution which funds, administers, and performs biomedical research in Spain and hosts, among other, the Microbiology National Centre for Microbiology and the National Centre of Epidemiology . The National Influenza Center Spain is part of the National Center for Microbiology (Centro Nacional de Microbiología, CNM) and the National Reference Laboratory for Influenza in Spain. The CNM's specific function is the control of infectious diseases, for which it offers diagnostic and reference services, also maintaining research programs, both basic and applied, related to the prevention, diagnosis and treatment of these illnesses. It has a quality management system which complies with the UNE-EN ISO 9001 standard, certified by AENOR, for the reception of biological samples, as well as a number of techniques and services accredited by ENAC, according to the UNE-EN ISO 15189 standard. The Department of Communicable Diseases (Departamento de Enfermedades Transmisibles, DET), within the National Centre of Epidemiology (CNE) has a double legal mandate. On the one hand, the management of the National Epidemiological Surveillance Network (RENAVE) and, on the other, to exercise scientific advice on issues related to surveillance and applied research in epidemiology of communicable diseases. These tasks are carried out in the field of public health competences for which the national and regional health administrations are responsible. The DET close collaborate with the Health Ministry in the preparedness and response for management of public health event of international relevance, and with the Spanish Agency of Medicine and Health Care Products (AEMPS) in the fields of Benefit/Risk of vaccine preventable diseases.

For I-MOVE-COVID-19, ISCIII will participate in WP2 (including data from the Spanish sentinel system), WP3 (including data from two hospitals), WP4 and coordinate the laboratory tasks of WP2 and WP3. ISCIII will be a member of the Steering-Scientific Committee and, as laboratory coordinator, of the Executive Board.

1.1.2 Personnel involved



1.1.3 5 relevant publications/services/achievements

-Pérez-Sautu U, Wiley MR, Iglesias-Caballero M, Pozo F, Prieto K, Chitty JA, García-García ML, Calvo C, Casas I, Palacios G. Target-independent high-throughput sequencing methods provide evidence that already known human viral pathogens play a main role in respiratory infections with unexplained etiology. Emerg Microbes Infect. 2019;8(1):1054-1065. doi: 10.1080/22221751.2019.1640587. IF: 3.84, Q1.

High-throughput sequencing methods used directly in respiratory clinical samples from children in order to find virus which play a role in infections from patients negative by real time RT-PCRs used in the diagnosis.

-Garcia-Garcia ML, Calvo C, Ruiz S, Pozo F, del Pozo V, Remedios L, Exposito N, Tellez A, Casas I. Role of viral coinfections in asthma development. PLoS ONE 2017 12(12): e0189083. IF: 2,766, Q1.

Coinfections are very common and they are an accessory difficulty for associating the etiological virus found in children with asthma. Causality is a difficult characteristic in these type of cases.

-Vasilijevic J, Zamarreño N, Oliveros JC, Rodriguez-Frandsen A, Gomez G, Rodriguez G, Perez-Ruiz M, Rey S, Barba I, Pozo F, Casas I, Nieto A, Falco A. Reduced accumulation of defective viral genomes contributes to severe outcome in influenza virus infected patients. PLoS Pathog 2017 13(10): e1006650. IF:7,003, D1, Q1.

Defective viral genomes studied by different approaches and the relation with the high pathogenicity of influenza virus directed study in clinical samples from severe infection.

Delgado-Sanz C, Mazagatos-Ateca C, Oliva J, Gherasim A, Larrauri A. Illness Severity in Hospitalized Influenza Patients by Virus Type and Subtype, Spain, 2010–2017. Emerg Infect Dis. 2020;26(2):220-228. https://dx.doi.org/10.3201/eid2602.181732 IF:5.993, D1, Q1.

Machado Ausenda, Mazagatos Clara, Dijkstra Frederika, Kislaya Irina, Gherasim Alin, McDonald Scott A, Kissling Esther, 5.1.2e, Meijer Adam, 5.1.2e 5.1.2e, Nunes Baltazar, Larrauri Amparo. Impact of influenza vaccination programmes among the elderly population on primary care, Portugal, Spain and the Netherlands: 2015/16 to 2017/18 influenza seasons. Euro Surveill. 2019;24(45):pii=1900268. https://doi.org/10.2807/1560-7917.ES.2019.24.45.1900268 IF: 7,421, D1, Q1.

Gherasim A, Martinez-Baz I, Castilla J, Pozo F, Larrauri A, the cycEVA working group (2017) Effect of previous and current vaccination against influenza A(H1N1)pdm09, A(H3N2), and B during the post-pandemic period 2010-2016 in Spain. PLoS ONE 2017, 12(6): e0179160. https://doi.org/10.1371/journal.pone.0179160 IF: 2,776, Q1.

1.1.4 5 previous projects

- Health Research Foundation (ISCIII - PI18CIII/00009) The respiratory virus in the ARIs of the new-born and pediatric patients: association with severity of the acute episode and asthma and weething development. 5.1.2e 2019-2021

- Health Research Foundation (ISCIII - PI15CIII/00028): Viral Metagenomics applied to the study of the severe acute infection in the low respiratory tract of pediatrc patients 5.1.2e, 2016-2018

-Health Research Foundation (PI12/01291; MPY-997/13): 'Viral microbiome from pediatric patients with acute and severe low respiratory tract infection' 5.1.2e 2013-2015.

- Health Research Foundation (FIS PI13/02123). Implementation of a sustainable strategy for the evaluation of a generalized public health intervention: influenza vaccination in Spain. (5.1.2e 5.1.2e , 5.1.2e , 2015-2017.

- Horizon 2020 (EU project 634446). I-Move+ Integrated Monitoring of Vaccine Effectiveness in Europe: a platform to measure and compare effectiveness and impact of influenza and pneumococcal vaccines and vaccination strategies in the elderly. (5.1.2e 5.1.2e Spanish component) 2015-2018.

- PREVICET. Ciber de Epidemiología y Salud Pública (CIBERESP). Study of the severity of influenza in recommended vaccination risk groups. Protective value and impact of influenza vaccine. (5.1.2e 5.1.2e , 2017-2019.

1.1.5 Significant infrastructure and/or any major items of technical equipment relates to the proposal

The National Influenza Center at the CNM-ISCIII operates 15 Scientific Services, including a Bioinformatics Initiative, which include computational genomics, sequence analysis & structure prediction, scientific computing or computational proteomics. Other relevant facilities are confocal microscopy, proteomics, genomics, protein tools, flow cytometry, and electron microscopy. The animal facility provides a mouse embryo cryopreservation service and a transgenesis service allowing for the generation of knock-out mice e.g. for specific host risk-factors for severe influenza virus infection as well as cryopreservation of their embryos for future studies. Furthermore, NIC-CNM hosts a biosafety level 3 laboratory which comprises 6 independent laboratories for working in different human infectious agents. NIC-CNM also has a number of management support units, covering areas such as: quality assurance, biosafety, technical and scientific support, secretarial support and stores.

The Influenza and other respiratory virus surveillance Group at the CNE is responsible for the coordination of the epidemiological part of the Spanish Influenza Surveillance System that encompass several surveillance systems and information sources, in order to provide timely and precise information on the evolution of the diseases caused by these viruses among the population. They are responsible for the surveillance of the suspected and confirmed cases of COVID-19 in Spain, in close collaboration with the Alert and Emergency Coordination Center at the MoH, and for the timely notification of the evolution of the disease activity to the ECDC/WHO. The Group has been collaborating since its beginning in 2007 with I-MOVE. It is also responsible of the Spanish contribution to the EuroMoMo and FluMoMo aimed to monitor of excess mortality for public health action and to obtain associated influenza mortality estimates for Europe.

4.1.1 Partner name: Instituto de Salud Pública y Laboral de Navarra – Spain - participant no3

1.1.1 Description of the legal entity

The Public Health Institute of Navarra (Instituto de Salud Pública y Laboral de Navarra, ISPLN) is the scientific institution to be included in the proposal as partner. Due to the legal structure of the Navarra Public Health Service, Miguel Servet Foundation needs to come on board in order to receive the funds. The Miguel Servet Public Foundation (Fundación Pública Miguel Servet, FMS) will manage the financial and administrative part of ISPLN's participation.

The ISPLN is an autonomous organism depending on the Navarra Government, aiming at public health protection for all the population in the region. This institute coordinates the immunization programmes and the epidemiological and microbiological surveillance for the entire region.
This Institute has developed research activities on chronic and infectious diseases for more than thirty years, is member of the two following networks:
- the Research Network on Epidemiology and Public Health in Spain (CIBERESP),
- the Navarra Institute for Health Research (IdiSNA)
under the research lines on effectiveness and impact of vaccines and vaccination programmes.
For viral diagnosis in clinical samples the ISPLN is supported by the Clinical Microbiology Service of the Navarra Hospital Complex.
ISPLN will participate in WP2 (sentinel network), in WP3 (three hospitals) and will contribute if relevant to WP4 (studies). ISPLN will be member of the Steering-Scientific Committee.

1.1.2 Personnel involved

5.1.2e

The staff members described are employed by the beneficiary.

1.1.3 5 relevant publications/services/achievements

Articles on different respiratory viral infections:

Navascués A, Casado I, Pérez-García A, Aguinaga A, Martínez-Baz I, Floristán Y, Ezpeleta C, Castilla J. Detection of Respiratory Viruses in Deceased Persons, Spain, 2017. Emerg Infect Dis. 2018 Jul;24(7):1331-1334.
This article is especially relevant because we found 7% of coronavirus positivity in post-mortem samples of people who died regardless of the cause.

Casado I, Domínguez Á, Toledo D, Chamorro J, Astray J, Egurrola M, Fernández-Sierra MA, Martín V, Morales-Suárez-Varela M, Godoy P, Castilla J. Repeated influenza vaccination for preventing severe and fatal influenza infection in older adults: a multicentre case-control study. CMAJ. 2018 Jan 8;190(1):E3-E12.

Viguria N, Martínez-Baz I, Moreno-Galarraga L, Sierrasesúmaga L, Salcedo B, Castilla J. Respiratory syncytial virus hospitalization in children in northern Spain. PLoS One. 2018 Nov 15;13(11):e0206474.

Martínez-Baz I, Casado I, Navascués A, Díaz-González J, Aguinaga A, Barrado L, Delfrade J, Ezpeleta C, Castilla J. Effect of Repeated Vaccination With the Same Vaccine Component Against 2009 Pandemic Influenza A(H1N1) Virus. J Infect Dis. 2017 Mar 15;215(6):847-855.

Castilla J, Navascués A, Fernández-Alonso M, Reina G, Albéniz E, Pozo F, Álvarez N, Martínez-Baz I, Guevara M, García-Cenoz M, Irisarri F, Casado I, Ezpeleta C. Effects of previous episodes of influenza and vaccination in preventing laboratory-confirmed influenza in Navarre, Spain, 2013/14 season. Euro Surveill. 2016 Jun 2;20(22).

1.1.4 5 previous projects

- I-MOVE+, Integrated Monitoring of Vaccines Effects in Europe: a platform to measure and compare effectiveness and impact of influenza and pneumococcal vaccines and vaccination strategies in the elderly. Horizon 2020 Program. Consortium Agreement # 634446. 2015-2018. 236.250 €.

- EU-JAV # 801495. European Joint Action on Vaccination, CHAFEA. 2018-2021.

- ISCIII- PI17/00868. Prevalence of infection by respiratory viruses in deceased persons. Instituto de Salud Carlos III. 2018-2020. Funds: 123.420 €.

- I-MOVE. Monitoring influenza vaccine effectiveness (seasonal and pandemic) in EU/EEA. ECDC framework contract ECDC/2018/029. Period 2009-2020.

- SpidNet2 ECDC OJ/15/06/2015- PROC/2015/020. Assessing the impact of vaccination with conjugate vaccines on the epidemiology of the invasive pneumococcal disease in Europe- European Centre for Disease Control. 2015-2020.

1.1.5 Significant infrastructure and/or any major items of technical equipment relates to the proposal

Excellent collaboration among public health professionals, epidemiological surveillance, vaccination programmes, virologists, general practitioners and hospital clinicians. This collaboration has been demonstrated in the real time monitoring of influenza epidemics, and influenza vaccine effectiveness.

Enhanced surveillance systems on infectious diseases covering a population of 650.000 inhabitants.

Population-based vaccination register.

Clinical microbiology laboratory with high quality standards. This laboratory analyses annually over 4000 patients for respiratory viruses RT-PCR including influenza, RSV, coronavirus, enterovirus, adenovirus, metapneumovirus, parainfluenza, bocavirus and/or rhinovirus. Subtyped is available for influenza, RSV, parainfluenza and coronavirus. The RT-PCR test for detection the COVID-19 is already available. Viral culture techniques are also available.

4.1.1 Partner name: Health Protection Scotland – Scotland - participant no4

1.1.1 Description of the legal entity

Health Protection Scotland (HPS) is a division of NHS National Services Scotland which works at the very heart of the health service across Scotland, delivering services critical to frontline patient care and supporting the efficient and effective operation of NHS Scotland. On April 1st 2020 HPS will be subsumed within a new public body, Public Health Scotland (PHS), but will continue within the Board Clinical and Protecting Health Directorate to deliver health protection for the National Health Service in Scotland.

Health Protection Scotland (HPS) was established by the Devolved Administration Scottish Government in 2005 to strengthen and co-ordinate health protection in Scotland. HPS plan and deliver effective and specialist national services which co-ordinate, strengthen and support activities aimed at protecting all the people of Scotland from infectious and environmental hazards. They do this by providing advice, support and information to health professionals, national and local government, the general public and a number of other bodies that play a part in protecting health. HPS is a division of NHS National Services. HPS is organised into three specialist groups with expertise provided by a multi-disciplinary workforce, which includes doctors, nurses, scientists and information staff, all of whom are supported by core business and IM&T teams. The specialist groups are:

- Healthcare Associated Infections and Infection Control;
- Blood Borne Viruses and Sexually Transmitted Infections,
- Immunisation, and Respiratory and Vaccine Preventable Diseases;
- Gastrointestinal and Zoonoses, Travel, and Environmental Public Health.

HPS carry out surveillance to monitor the extent and impact of infections and other risks to Scotland's health and help prepare plans to manage incident or outbreaks, particularly those, like pandemic flu, that may stretch the resources of the NHS in Scotland. They co-ordinate the management of incidents and outbreaks which affect the whole country and are responsible for taking forward specific health protection programmes like healthcare associated infections (HAI), vaccine preventable diseases and prevention of sexually transmitted infections. They promote a consistent Scotland-wide approach to health protection, including developing information and knowledge management systems to reduce the risks to the people of Scotland.

HPS also contributes surveillance information at a UK and international level through close collaboration with these specialist agencies. HPS is responsible for commissioning the NHS specialist microbiology and laboratory services.

HPS will contribute to the following I-MOVE-COVID-19 Work packages

- **WP1**: Member of the Steering-Scientific Committee and of the Executive Board
- **WP2**: Provide sentinel practices data to reach WP2 objectives

- **WP3**: WP Leader. Provide hospital data to reach WP3 objectives. Participate in discussions, review documents, coordinate inputs from national partners. Identify partners to participate in workshops, meetings.
- **WP4**: Contribute to pooled analyses through provision of pooled data or analysis outputs of data as agreed with coordinators.

1.1.2 Personnel involved

Key experts experience (profile, gender)	
1	5.1.2e 5.1.2e
2	5.1.2e 5.1.2e

3	5.1.2e 5.1.2e
4	5.1.2e

1.1.3 5 relevant publications/services/achievements

1	5.1.2e 5.1.2e 5.1.2e 5.1.2e 5.1.2e 5.1.2e 5.1.2e
2	5.1.2e 5.1.2e 5.1.2e 5.1.2e
3	5.1.2e 5.1.2e

4	[redacted]
5	5.1.2e 5.1.2e 5.1.2e 5.1.2e 5.1.2e

1.1.4 5 previous projects

Up to five relevant previous projects or activities connected with the proposal	
1	EU Horizon 2020 IMOVE+ project
2	SPIDNET, ECDC
3	EuroMOMO
4	IMOVE, ECDC

1.1.5 Significant infrastructure and/or any major items of technical equipment relates to the proposal

Description of any significant infrastructure and/or any major items of technical equipment, relevant to the proposed	
	Hospital network (including ICU network – HPS/SICSAG)
	GP network

	Medical Electronic records, vaccination registry

4.1.1 Partner name: INSA – Portugal - participant no5

1.1.1 Description of the legal entity

INSA is a public organization of the Portuguese Ministry of Health, endowed with scientific, technical, administrative, financial and property of its own. Founded in 1899 as the laboratory of the Portuguese Health System, INSA´s main goal is to contribute to achieving public health gains, fulfilling a triple role as State Laboratory in the Health Sector, National Reference Laboratory and National Health Observatory. INSA accomplishes its mission through research and development, epidemiological surveillance, health registry and monitoring, consultancy and service provision, training and promotion of public awareness of science.

INSA had an important role in the surveillance during the 2009 influenza pandemic, and supported preparedness and response for the infectious disease emergencies of SARS, influenza A(H5N1) and MERS-CoV at national level, and Ebola in Guiné-Bissau. INSA also participates in WHO PISA (Pandemic Influenza Severity Assessment) project.

During the new coronavirus (COVID-19) public health emergency, INSA will have a cornerstone role at national level. The role of INSA will include the coordination of all the operation related with the laboratory diagnosis and virology research (including the coordination of national network of laboratories for the COVID-19 diagnosis). Assuring the epidemiological surveillance through its GP sentinel network and participatory surveillance systems, design and conduct studies on the effectiveness of a potential COVID-19 vaccine, and the development of mathematical models to design scenarios COVID-19 population impact.

INSA will participate in this project through the Department of Epidemiology and the Department of Infectious Diseases. The Department of Epidemiology (DEP) has long track of participating in several national and international epidemiological studies during public health emergencies. DEP manages several monitoring and surveillance systems at population level (national surveys, participatory surveillance) and at the health care level (GP and hospital networks). The DEP staff provides expertise in several key areas, including, public health medicine, epidemiology, biostatistics, mathematical modelling and social sciences. The Department of Infectious Diseases (DDI) support the national surveillance of infectious diseases in close cooperation with Health Authorities, other agencies of the Ministry of Health and European Surveillance Networks. It includes in its structure the National Reference Laboratory for Influenza and Other Respiratory Virus. DDI has a dedicated bioinformatics team in the field of infectious diseases, which has been actively involved in implementing/applying WGS/Bioinformatics for public health surveillance of several human pathogens in Portugal.

For I-MOVE-COVID-19 INSA will be a member of the Steering-Scientific Committee. INSA will participate actively in the adaptation of current surveillance and research protocols in place for the GP (sentinel network providing data to WP2) and Hospital I-MOVE networks (two hospitals included in WP3). At national level, INSA will implement the studies and data collection standard procedures, assuring high quality data, in close collaboration with the National Health Authority (DGS). All the laboratory diagnosis of specimens collected within the networks will be performed

or coordinated by INSA. Regarding WGS of COVID-19, INSA is currently capable of performing continuous genome-based surveillance through both an already implemented upstream wet-lab procedure and downstream bioinformatics pipeline.

According to the identified needs, INSA will contribute to the design, implementation, analysis and results interpretation of the studies described in WP4.

1.1.2 Personnel involved

1.1.3 5 relevant publications/services/achievements

1. Borges V, Pinheiro M, Pechirra P, Guiomar R, Gomes JP. INSaFLU: an automated open web-based bioinformatics suite "from-reads" for influenza whole-genome-sequencing-based surveillance. Genome Medicine 2018; 10:46.

This study describes INSaFLU (https://insaflu.insa.pt/), which is a surveillance-oriented online bioinformatics framework for genome-based characterization of pathogens

(especially viruses) evolution during seasonal epidemics and pandemics. In a user-friendly manner, it allows performing complex next-generation sequencing (NGS) data analyses, from raw reads to consensus sequences, (minor) variants analysis, alignments, trees and metadata visualization, thus fitting well to the first-line needs for rapid and continuous genome-based laboratory surveillance of COVID-19.

2. Guiomar R, Pereira da Silva S, Conde P, Cristóvão P, Maia AC, Pechirra P, Rodrigues AP, Nunes B; Portuguese Laboratory Network for the Diagnosis of Influenza Infection, Milho L, Coelho AP, Fernandes A, Caseiro P, Rodrigues F, Correia L, Pereira-Vaz J, Almeida S, Branquinho P, Côrte-Real R, Viseu R, Peres MJ, Sanches R, Dantas F, Freitas L, Andrade G, Maurílio M, Caldeira F, Cabral Veloso R, Mota-Vieira L, Soares M, Couto AR, Bruges-Armas J, Pinto RM, Sobrinho Simões J, Costa MDR, Guimarães JT, Martins L, Cunha M. Cross-protection to new drifted influenza A(H3) viruses and prevalence of protective antibodies to seasonal influenza, during 2014 in Portugal. Vaccine. 2017 Apr11;35(16):2092-2099. doi: 10.1016/j.vaccine.2017.02.019. Epub 2017 Mar 18. PubMed PMID: 28318771.

This article describes the results of a seroepidemiological study developed in Portugal aiming at evaluating the cross-protection to a new A(H3) viruses and also the seroprevalences for the circulating influenza virus during the 2013-14 season. The study shows the capacity of INSA and the hospital network to develop community seroepidemiological studies.

3. Nunes B, Machado A, Guiomar R, Pechirra P, Conde P, Cristovão P, Falcão I. Estimates of 2012/13 influenza vaccine effectiveness using the case test-negative control design with different influenza negative control groups. Vaccine. 2014 Jul 31;32(35):4443-9. doi: 10.1016/j.vaccine.2014.06.053. Epub 2014 Jun 21. PubMed PMID: 24962756.

This article describes the results of an influenza vaccine effectiveness study in Portugal, using a test-negative design based on the GP sentinel network. With this study we show INSA capacity do design, conduct, analyse and report results of epidemiological studies

aimed at measuring vaccine effectiveness, a potential relevant topic if a candidate 2019 nCoV vaccine becomes available.

4. Portuguese Laboratory Network for the Diagnosis of Influenza Infection Collective. Contribution of the Portuguese Laboratory Network for the Diagnosis of Influenza A(H1N1)pdm09 Infection during the 2009/10 and 2010/11 influenza seasons . Euro Surveill. 2012;17(27):pii=20211. https://doi.org/10.2807/ese.17.27.20211-en

This article describes the contribution of a laboratory network to the study of the A(H1N1)pdm09 pandemic in 2009-2011. It shows the capacity of INSA and its networks to collected, analyse and interpret high quality data during public health emergencies. During 2019 nCoV emergency this same network was assembled and it will be a very relevant platform to provide data on epidemiological characteristics such as viral genotype and pathogenicity.

5. Flasche S, Hens N, Boëlle PY, Mossong J, van Ballegooijen WM, Nunes B, Rizzo C, Popovici F, Santa-Olalla P, Hrubá F, Parmakova K, Baguelin M, van Hoek AJ, Desenclos JC, Bernillon P, Cámara AL, Wallinga J, Asikainen T, White PJ, Edmunds WJ. Different transmission patterns in the early stages of the influenza A(H1N1)v pandemic: a comparative analysis of 12 European countries. Epidemics. 2011 Jun;3(2):125-33. doi: 10.1016/j.epidem.2011.03.005. Epub 2011 Apr 13. PubMed PMID: 21624784.

This study results from an international collaboration coordinated by Public Health England, that aimed at describing the different transmission patterns of the first EU cases of A(H1N1)pdm09 during the summer of 2009. It seeks to identify relevant predictors of transmission in several EU countries. The study shows the ability of INSA to participate in international collaborations, sharing data on the first pandemic cases and knowledge for the early estimation basic and effective reproduction numbers.

1.1.4 5 previous projects

- **IMOVE+:** Integrated Monitoring of Vaccines Effects in Europe: a platform to measure and compare effectiveness and impact of influenza and pneumococcal vaccines and

vaccination strategies in the elderly. (http://www.i-moveplus.eu/). At national level, this project allowed establish a General Practitioner network and a Hospital network to conduct studies to monitor the influenza vaccine effectiveness.

- **INSEF:** Improvement of epidemiological health information to support public health decision and management in Portugal. Towards reduced inequalities, improved health, and bilateral cooperation. This project allowed to perform a National Health and Examination Survey and to organize a national biobank (http://www.insef.pt/English/Pages/Inicio.aspx).

- **EPHESUS**: Evaluation of whether EU/EEA infectious disease surveillance systems meet their objectives, provide information for public health action, in order to strengthen the systems collecting, analysing, interpreting and disseminating infectious disease surveillance data at European Union (EU) and European Economic Area (EEA) level. INSA coordinated the evaluation of Anthrax, Botulism and Cholera. (https://sites.google.com/a/epiconcept.fr/ephesus/)
- **Platform INSaFLU** (https://insaflu.insa.pt/), which is an influenza-oriented platform (https://doi.org/10.1186/s13073-018-0555-0) that can be adapted to handle any amplicon-based NGS schema for any pathogen, which may be specially relevant for: i) genome-based investigation/surveillance of viral pathogens in the context of both seasonal epidemics or pandemics; ii) targeted typing or gene panels survey for diagnosis or characterization of bacteria and parasites. Although INSaFLU can currently be used for COVID-19, this tool is being upgraded on behalf of TELE-Vir project, which is ongoing EU funded project that aims to develop a very fast point-of-incidence toolbox for identification and characterisation of emerging virus threats for humans. This further development will bring expected benefits for the activities of these project.

- **The Global Influenza B Study (GIBS)** (https://nivel.nl/en/international-projects/gibs)The Global Influenza B Study (GIBS) was launched in 2012 and its aim is to collect information on the epidemiology and burden of disease of influenza B in the world during the past 10-15 years, in order to support prevention policies in the coming

years. The GIBS is part of the Global Influenza Initiative (GII), an expert scientific forum that aims to address ongoing problems related to influenza worldwide.

- **Influenza sero-epidemiological study.** The seroepidemiological study was established since 2014 in the scope of influenza surveillance aims to assess the cross-protection for the influenza viruses and determine the prevalence of seasonal influenza protective antibodies by age, gender, and region.

- **Immune response in health care workers after influenza vaccine uptake.** To access the vaccine induced immune response and waning immunity was established a cohort study on a group of vaccinated of health care workers during 3 influenza seasons (between 2017 and 2020). Was measure the vaccine induced immune response and the duration of the immunity (before vaccine uptake, 30 days and 6 months after vaccination).

1.1.5 Significant infrastructure and/or any major items of technical equipment relates to the proposal

- INSA has in-house capacities for delivering surveillance data from the integrated clinical and laboratorial Influenza surveillance system managed by INSA [including General Practitioners Sentinel Influenza medically attended incidence estimates, influenza laboratorial confirmed cases, influenza-like illness (ILI) consultations].
- Influenza surveillance system (GRIPENET – member of INFLUENZANET), ECOS (a house-survey of 1 000 families), National Health and Examination Survey are being coordinated by INSA. Those projects allow getting estimates of ILI, vaccine coverage, health care seeking behaviour.
- INSA coordinates the Mortality Surveillance System VDM, that is part of the EuroMOMO network. VDM system and the EurMOMO network have already shown their installed capacity to detect and estimate the impact (excess mortality) during pandemic periods.
- INSA has in-house capacity to swiftly launch web-based surveys.
- INSA has access to map shapes (from statistics Portugal, SNIG), population data, data from the National Health Service Portal, hospital admissions data and medication sales data and environmental data and might get access to school absenteeism.

- The National Influenza Reference Laboratory (NIRL) of the national Institute of Health is recognized by the WHO as the National Influenza Centre, meeting the criteria of the WHO NIC terms of reference.The NIRL is also the ECDC Portuguese Operational Contact Point for Virology for the Influenza and other respiratory virus surveillance.
- The NIRL has the capacity to perform the diagnosis of influenza and other respiratory viruses including the avian influenza, SARS, MERS and COVID-19.
- The NIRL has in place methodologies to perform the genetic characterization of influenza (whole genome sequencing), respiratory syncytial virus, Enterovirus-D68 and rhinovirus. For influenza, is also performed antigenic characterization and antiviral susceptibility assays.
- Serological assays to evaluate antibodies against influenza virus are established at NIRL
- NIRL coordinates the Portuguese laboratory network for influenza diagnosis: 20 hospital laboratories members of the network have the capacity to perform RT-PCR for influenza and other respiratory viruses.
- INSA has access to all infrastructure resources needed for large-scale WGS-based typing, namely 3 Next-generation-sequencing apparatus (NextSeq, MiSeq, Minion) and to vast strain collections of clinical isolates and associated pheno and genotyping data.
- Availability of bioinformatics pipelines for integrative analysis of genomic and epidemiological data (at cross sectoral level) on behalf of routine surveillance and outbreak detection and investigation of multiple microbial pathogens, from virus to bacteria or parasites.
- INSA has close working contacts with General Directorate of Health and Regional Health Authorities in the field of communicable diseases, cluster analysis, epidemics and pandemics and Health Surveys.
- INSA is an associated member of several national and international bodies and networks, e.g., ECDC, EFSA, European Science Advisory Network for Health, and the IANPHI, and cooperates with WHO.

4.1.1 Partner name: NIVEL – Netherlands - participant no6

1.1.1 Description of the legal entity

Nivel – the Netherlands institute for health services research – is the national institute for health services research in the Netherlands. It is an independent organization with the formal structure of a (not-for-profit) foundation. Its domain is applied and applicable health services research. Health services research is the multidisciplinary field of scientific investigation that examines how social factors, financing systems, organisational structures and processes, health technologies, and personal behaviours affect access to health care, the quality and costs of health care, and ultimately our health and well-being. Nivel's mission is to carry out high quality research which has a demonstrable impact upon society. Starting in 1965 as the scientific institute of the Dutch College of General Practitioners, Nivel's domain has expanded gradually to primary care, secondary care and hospital care. Nowadays, Nivel's research covers the entire 'somatic' health care. Stakeholders are policy makers, patient organisations, health care organisations, professional associations, as well as the international scientific community. Nivel has a full ISO-9001 accreditation for its research activities since 1999. Nivel is part of the knowledge infrastructure of the Ministry of Health. One of the activities is the maintenance of several national databases and information systems which are utilized not only by Nivel itself but also by other research groups. One of these databases is Nivel Primary Care Database (Nivel Zorgregistraties Eerste Lijn), collecting routinely recorded data from health care providers to monitor health and utilisation of health services in a representative sample of the Dutch population. Currently, the database holds information from about 450 general practices with about 1.7 million enlisted patients, representing 10% of the Dutch population. Some 40 general practices participating in the Sentinel Practices, report patients with clinically diagnosed ILI (since 1970) and take nose- and throat swabs for virological analyses (since 1992, collaboration with RIVM). As of February 6, 2020, the virological analyses will include testing on novel coronavirus. A syndromic surveillance system has been established in 2013 to complement the sentinel ILI surveillance system, collecting automatically daily information on all morbidity once a week from about 400 general practices covering 8 percent of the Dutch population. Until 2009, Nivel was coordinator of the European Influenza Surveillance Scheme (EISS), after which it moved over to ECDC.

Nivel will lead the I-MOVE-COVID-19 WP2 (primary care network) and participate if relevant to WP4 studies. Nivel will be member of the Executive Board and Steering-Scientific Committee.

1.1.2 Personnel involved

5.1.2e

5.1.2e

1.1.3 5 relevant publications/services/achievements

1. Kissling E, Pozo F, Buda S, Vilcu AM, Gherasim A, Brytting M, Domegan L, Gómez V, 5.1.2e, Lazar M, Vučina VV, Dürrwald R, van der Werf S, Larrauri A, Enkirch T, O'Donnell J, Guiomar R, Hooiveld M, Petrović G, Stoian E, Penttinen P, Valenciano M, I-Move Primary Care Study Team. Low 2018/19 vaccine effectiveness against influenza A(H3N2) among 15-64-year-olds in Europe: exploration by birth cohort. Euro Surveill. 2019 Nov;24(48).

   Nivel is partner in the I-MOVE network since 2015.

2. Vos LM, Teirlink AC, Lozano JE, Vega T, Donker GA, Hoepelman AI, Bont LJ, Oosterheert JJ, 5.1.2e. Use of the moving epidemic method (MEM) to assess national surveillance data for respiratory syncytial virus (RSV) in the Netherlands, 2005 to 2017. Euro Surveill. 2019 May;24(20).

   The joint influenza surveillance system by Nivel and RIVM (Sentinel practices) has proven to provide useful results for the surveillance of other respiratory infections.

3. Hooiveld M, Groep T van de, Essen GA van, Tacken MAJB, Sande MAB van der, Verheij RA, Verheij TJM. Prescription of oseltamivir by general practitioners during the influenza A(H1N1)2009 pandemic. BMC Pharmocology and Toxicology 2013;14(1):55.

   The routine data collection of Nivel Primary Care Database was used to evaluate antiviral prescriptions during the 2009 influenza pandemic.

4. Paget Wj, Balderston C, Casas I, Donker G, Edelman L, Fleming D, Larrauri 5.1.2e, Puzelli S, Rizzo C, Simonsen L; and all EPIA collaborators. Assessing the burden of paediatric influenza in Europe. Eur J Pediatr. 2010 Mar 13.

   Existing weekly virological and age-specific influenza-like illness (ILI) data from surveillance networks across Europe were used for the paediatric influenza burden in European countries.

5. Nivel and the French Sentinelles network (Inserm – Sorbonne University) recently organised a workshop on "Sentinel surveillance networks in primary care" at the conference of the European Forum for Primary Care, Nanterre, 2019. The aim of the workshop was to encourage exchanges between sentinel surveillance networks and EFPC members. During the workshop, data collected within the Sentiworld project (Sorbonne), a global inventory of existing sentinel surveillance networks in general practice, was shared with the audience, followed by brief presentations from several participating European sentinel networks and interactive discussions on their missions and experiences on monitoring of one or more specific illness

problems on a regular or continuous basis. Following this workshop, several initiatives have been launched on collaborative project proposals.

1.1.4 5 previous projects

1. ECDC: Monitoring vaccine effectiveness during seasonal and pandemic influenza in EU/EEA (I-MOVE). 2018 – present.
   The overall project builds on existing European collaboration of the I-MOVE network, coordinated by EpiConcept.
2. H2020: Integrated Monitoring of Vaccines Effects in Europe: a platform to measure and compare effectiveness and impact of influenza and pneumococcal vaccines and vaccination strategies in the elderly (I-MOVE+). 2015 – 2018.
   The I-MOVE network has proven to be able to expand from influenza to other respiratory outcomes.
3. Sanofi Pasteur: RSV ComNet, development and testing of a generic protocol to assess the burden of RSV in young children in primary care in Italy and the Netherlands. 2019 – present.

Development of a generic protocol for RSV burden of disease, based on existing sentinel general practitioner and paediatrician respiratory surveillance systems. Preliminary results will be useful to the overall project.

4. Nivel participates in numerous other international projects and is work-package leader in some of them. Some examples: COMPAR-EU (comparing effectiveness and cost-effectiveness of self-management interventions in 4 high priority chronic diseases in Europe – H2020), GIBS (Global Influenza B Study - Sanofi Pasteur), CHORDIS (Joint Action on Chronic Diseases). A full list of international projects can be found on the Nivel website: https://nivel.nl/en/international-projects
5. IMI: RESCEU, aims to develop robust evidence on RSV disease burden and economic impact; create a sustainable Europe-wide multidisciplinary, multi-stakeholder community from academia, public health, scientific societies, patient organisations, regulatory agencies and industry; and provide infrastructure to perform future pivotal trials for RSV vaccines and therapeutics.

Nivel contributes to WP2 'Consolidation of health care systems data from large surveillance, registry, observational and health care system datasets' and WP3 'Retrospective resource use analyses from existing databases / networks'.

1.1.5 Significant infrastructure and/or any major items of technical equipment relates to the proposal

Nivel Primary Care Database (PCD) uses routinely recorded data from health care providers to monitor health and utilisation of health services in a representative sample of the Dutch population. The aim of Nivel PCD is to do research on developments in health and the use of primary health services in the Netherlands. The infrastructure of Nivel PCD is funded by the Ministry of Health, Welfare and Sports.

4.1.1 Partner name: Public Health England, UK - participant no7

1.1.1 Description of the legal entity

We are the public health institute of England. We are part of the IMove influenza vaccine effectiveness network and have worked on influenza serology, sentinel swabbing, vaccine effectiveness and cohort analyses with RCGP-RSC data for over 15 years including the 2009 H1N1 pandemic. We have experienced Virologists, Epidemiologists and Statisticians with many years of experience working on Respiratory viruses such as Influenza.

WP2: Help with development of protocols, case-definitions, and other standardised practices. Developing ideas for how to best use Primary care data. Analysis of RCGP RSC swabbing data from ~100 practices which is sent, along with surveillance forms to the PHE laboratory. Potentially analysis of serology data taken at GPs (RCGP - RSC). Collaborating with RCGP-RSC on analysis of cohort data.

WP3: Help with protocols and setting up a swabbing system for undiagnosed pneumonia ICU admissions in 22 sentinel hospitals in England. Analysis by the Laboratory at PHE, Colindale and by epidemiologist and statistician at PHE. This includes database management.

WP4: Help with commenting on protocols and analytical approaches. Contribute to pooled analyses through provision of pooled data or analysis outputs as data as agreed with coordinators. Run analyses and write scripts for analysis of data from England to enable sharing as agreed and as possible based on data sharing agreements.

Member of the I-MOVE-COVID-19 Steering-Scientific Committee.

1.1.2 Personnel involved

1.1.3 5 relevant publications/services/achievements

These publications show experience in using GP swabbing data, Immunogenicity data and sero-epidemiological data to assess influenza. This includes during the 2009 Pandemic.

1. Pebody RG, Whitaker H, Ellis J, Andrews N, Marques DFP, Cottrell S, Reynolds AJ, Gunson R, Thompson C, Galiano M, Lackenby A, Robertson C, O'Doherty MG, Owens K, Yonova I, Shepherd SJ, Moore C, Johnston J, Donati M, McMenamin J, Lusignan S, Zambon M. (2020). End of season influenza vaccine effectiveness in primary care in adults and children in the United Kingdom in 2018/19. Vaccine. 2020 Jan 16;38(3):489-497. doi: 10.1016/j.vaccine.2019.10.071. Epub 2019 Nov 1.
2. Höschler K, Southern J, Thompson C, Warburton F, Andrews NJ, Miller E, Zambon M (2018). Responses to live attenuated influenza vaccine in children vaccinated previously with Pandemrix (ASO3B adjuvanted pandemic A/H1N1pdm09). Vaccine. 2018(36): 3034-3040.pii: S0264-410X(18)30486-9. doi: 10.1016/j.vaccine.2018.04.01.
3. Andrews, N., Waight, P., Yung, C.-F., & Miller, E. (2011). Age-specific effectiveness of an oil-in-water adjuvanted pandemic (H1N1) 2009 vaccine against confirmed infection in high risk groups in England. The Journal of infectious diseases, 203(1), 32–9.
4. Kissling E, Rose A, Emborg HD, Gherasim A, Pebody R, Pozo F, Trebbien R, Mazagatos C, Whitaker H, Valenciano M, European Ive Group (inc Andrews NJ) (2019). Interim 2018/19 influenza vaccine effectiveness: six European studies, October 2018 to January 2019. Euro Surveill. 2019 Feb;24(8). doi: 10.2807/1560-7917.ES.2019.24.1900121.
5. Miller, E., Hoschler, K., Hardelid, P., Stanford, E., Andrews, N., & Zambon, M. (2010). Incidence of 2009 pandemic influenza A H1N1 infection in England: a cross-sectional serological study. Lancet, 375(9720), 1100–8.

1.1.4 5 previous projects

Below are relevant European funded projects.

2013-2019: Horizon 20-20 Grant for assessing interventions in the Elderly (Flu and Pneumo Vaccines). (EURO 2,500,000). European project called IMove+. I am involved in assessing the VE of PPV23 as well as indirect impact of childhood vaccination on the elderly.

2009-2012: Vaccine safety in Europe: Improving Systems for reporting and Evaluating Potential Adverse Events following Immunization (AEFI) in EU/EEA/EFTA countries. With the Brighton Collaboration.

1.1.5 Significant infrastructure and/or any major items of technical equipment relates to the proposal

We work closely with RCGP-RSC who will also partner on this proposal and run the sentinel GP swabbing scheme and RCGP cohort database. We have extensive experience in analysis of GP cohort data, swabbing data, immunogenicity data and serology data. The Virus Reference Dept at Public Health England develop assays and test both swabs and serology samples. This department is carrying out coronavirus testing in England.

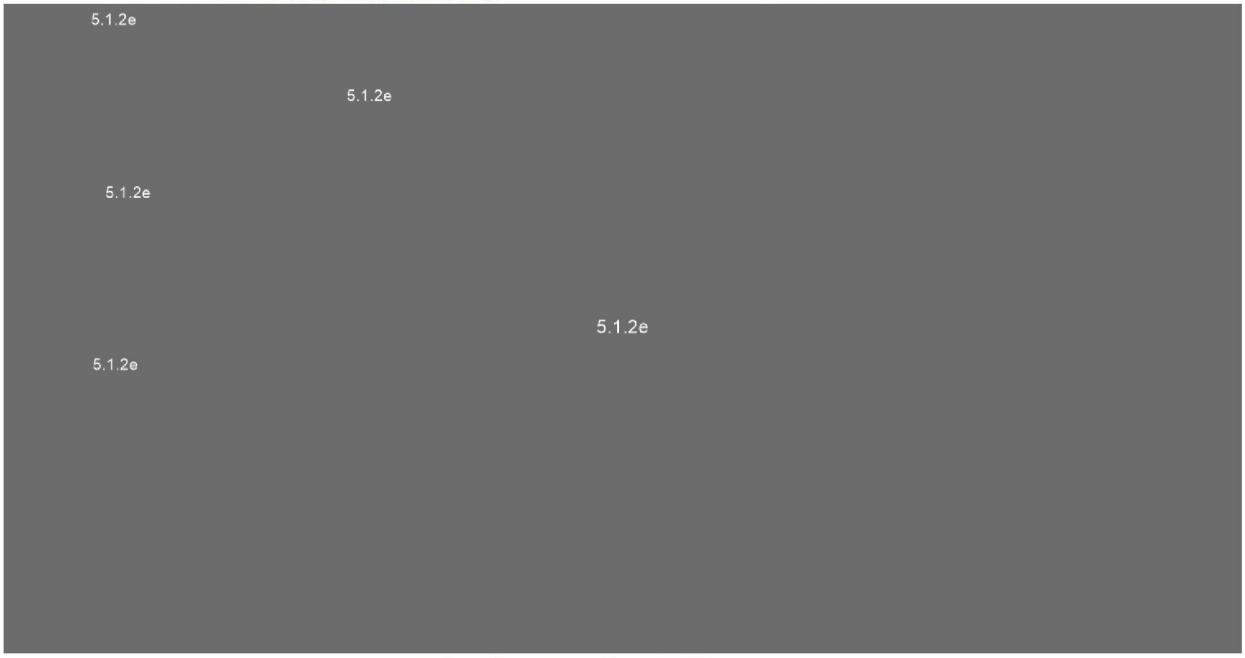
4.1.1 Partner name: LSMU, Lithuania - participant no8

1.1.1 Description of the legal entity

Lithuanian University of Health Sciences (LSMU) is the largest specialised institution providing university degrees, training and research in biomedical science in Lithuania, Kaunas. University's Hospital is the largest hospital in Lithuania providing specialized services and it includes 34 preventive clinics and 39 inpatient departments. The Department of Infectious Diseases carries out clinical work and research in the Faculty of Medicine at LSMU. The main directions of the scientific activity of the Department includes central nervous system infections with a special interest in tick-borne encephalitis and Lyme disease, and clinical research in vaccinology. Among others, the Department of Infectious Diseases was one of the study centers for PRIDE (Post-pandemic Review of anti-Influenza Drug Effectiveness) study and Tailoring Immunization Programmes for seasonal influenza (TIP FLU) in pregnant women project by WHO Regional Office for Europe. Since 2012, the Department has been collaborating on and since 2015 has been leading routine assessments of seasonal influenza vaccine effectiveness in risk groups and older people funded by the Lithuanian Research Council and H2020, in close collaboration with the I-MOVE in Europe (Influenza - Monitoring Vaccine Effectiveness) network. The Department is one of the five national centers in response to the novel coronavirus.

LSMU will contribute to I-MOVE-COVID-19 through **WP3** (two hospitals participating in the hospital surveillance network) and potentially to **WP4** (depending on the research projects defined by the Steering-Scientific Committee). LSMU will be a member of the Steering-Scientific Committee.

1.1.2 Personnel involved



1.1.3 5 relevant publications/services/achievements

1: 5.1.2e Estimating burden of influenza-associated influenza-like illness and severe acute respiratory infection at public healthcare facilities in Romania during the 2011/12-2015/16 influenza seasons. Influenza Other Respir Viruses. 2018 Jan;12(1):183-192. doi: 10.1111/irv.12525. Epub 2017 Dec 15.

- This publication proves expertise in infectious diseases hospital surveillance on the national level, as well as assessment of disease burden. Such context knowledge is essential for strengthening surveillance, as well as analysing the data of (newly) emerging infectious diseases.

2: 5.1.2e 5.1.2e Seasonal influenza vaccine effectiveness against laboratory-confirmed influenza in 2015-2016: a hospital-based test-negative case-control study in Lithuania. BMJ Open. 2017 Oct 10;7(10):e017835. doi: 10.1136/bmjopen-2017-017835.

- This publication is based on the independently conducted study on influenza vaccine effectiveness among the hospitalized SARI cases in Lithuania, showing that Lithuanian collaborators are well organized, competent and independent. The data derived from this study were shared with the IMOVE+ project as part of a collaboration with the IMOVE network ongoing since 2011.

3: 5.1.2e 5.1.2e Predictors of influenza in the adult population during seasonal and A(H1N1)pdm09 pandemic influenza periods. Epidemiol Infect. 2014 May;142(5):950-4. doi: 10.1017/S0950268813002434. Epub 2013 Sep 30. PubMed PMID: 24073672.

- This publication demonstrates methodological expertise is assessment of the predictors of seasonal vs pandemic influenza. Consideration of the predictors and their comparison across the patients with different respiratory infections is necessary when considering and assessing cases of the novel coronavirus as well.

4: 5.1.2e 5.1.2e After adjusting for bias in meta-analysis seasonal influenza vaccine remains effective in community-dwelling elderly. J Clin Epidemiol. 2014 Jul;67(7):734-44. doi: 10.1016/j.jclinepi.2014.02.009. Epub 2014 Apr 24.

- This study proves expertise in quantitative data analysis concerning bias in influenza vaccination effectiveness research. This expertise is rather unique in I-MOVE-nCoV Consortium, and therefore gives the potential for a more theoretical discussion and view on the methodologies to be utilized in the described work packages.

5: 5.1.2e 5.1.2e 5.1.2e 5.1.2e I-MOVE+ hospital working group. Low 2016/17 season vaccine effectiveness against hospitalised

influenza A(H3N2) among elderly: awareness warranted for 2017/18 season. Euro Surveill. 2017 Oct;22(41). doi: 10.2807/1560-7917.ES.2017.22.41.17-00645.

- This publications proves collaboration with the I-MOVE+ network.

1.1.4 5 previous projects

1. **Tailoring immunization programme for seasonal influenza (TIP FLU)/ WHO Regional Office for Europe/ FLU pilot project for pregnant women in Kaunas, Lithuania 2014-2016.**

- *During this project, there has been a lot of collaboration with public health centers and various other stakeholders, which equipped AM, GG and MK with an extensive network among the infectious diseases professionals, patient organizations, media channels that might be useful for connections and communications about the current project.*

2. **Seasonal influenza vaccine effectiveness in hospitalized elderly patients in Lithuania in 2015-2017. Funded by the Research Council of Lithuania under the framework of Healthy ageing (SEN-03/2015).**

- This project proves the capacity to conduct good quality vaccine effectiveness monitoring, as well as scientific competence in sharing the results through (inter)national presentations and publications.

3. **European Network for Collaboration on Encephalitis Investigations & Follow-up (multicentre study led by Grenoble University, France) 2017-2020.**
4. **„I-MOVE+: Hospital-based test negative case control studies to measure seasonal influenza vaccine effectiveness against influenza laboratory confirmed SARI hospitalisation among the elderly across the European Union and European Economic Area Member States", The European Union Framework Programme for Research and Innovations Horizon 2020 /Fighting infectious diseases and global epidemics / Grant Agreement 634446.**

- This project proves that Am, GG and MK are collaborators and part of the I-MOVE+ network.

5. **PRIDE (Post-pandemic Review of anti-Influenza Drug Effectiveness) study 2009-2011**

1.1.5 Significant infrastructure and/or any major items of technical equipment relates to the proposal

Lithuanian University of Health Sciences will provide the project with data and expertise on respiratory disease monitoring in one of the Baltic States, ensuring their representation in this European project as well as generalization of the findings at the later stages. The skilled project team (AM, GG, MK) with over 8 years of experience of working with I-MOVE network, also has expertise and hands on experience in other infectious diseases control related projects on municipal level, including science communication to the patient groups, the public and the professionals. The two hospitals participating in I-MOVE-COVID-2019 are part of the I-MOVE network.

4.1.1 Partner name: Health Protection Surveillance Centre (HSE-HSPC), Ireland - participant no9

1.1.1 Description of the legal entity

The Health Service Executive-Health Protection Surveillance Centre (HSE-HPSC) is the Irish national infectious disease surveillance institute. HSE-HPSC is a public body.

The HPSC mission statement is as follows: To improve the health of the Irish population by provision of the best possible information on infectious diseases through surveillance and independent advice, epidemiological investigation, research and training.

HSE-HPSC has six main areas of responsibility as follows:

1. Surveillance of some of the major communicable diseases. Surveillance in this context includes:
   i. Collecting data
   ii. Collating it
   iii. Analysing it and
   iv. Communicating information to those who need to know
2. Operational support - providing expert advice to, and responding to requests for support from, departments of public health or hospitals;
3. Training for professionals working in communicable disease control;
4. Research - identifying and developing best practice in communicable diseases;
5. Policy advice - providing advice to government departments and appropriate agencies in relation to the development of standards, guidelines and practices, and promoting the adoption of best practice by different agencies;
6. Public information - providing information on infectious diseases to the public and the media.

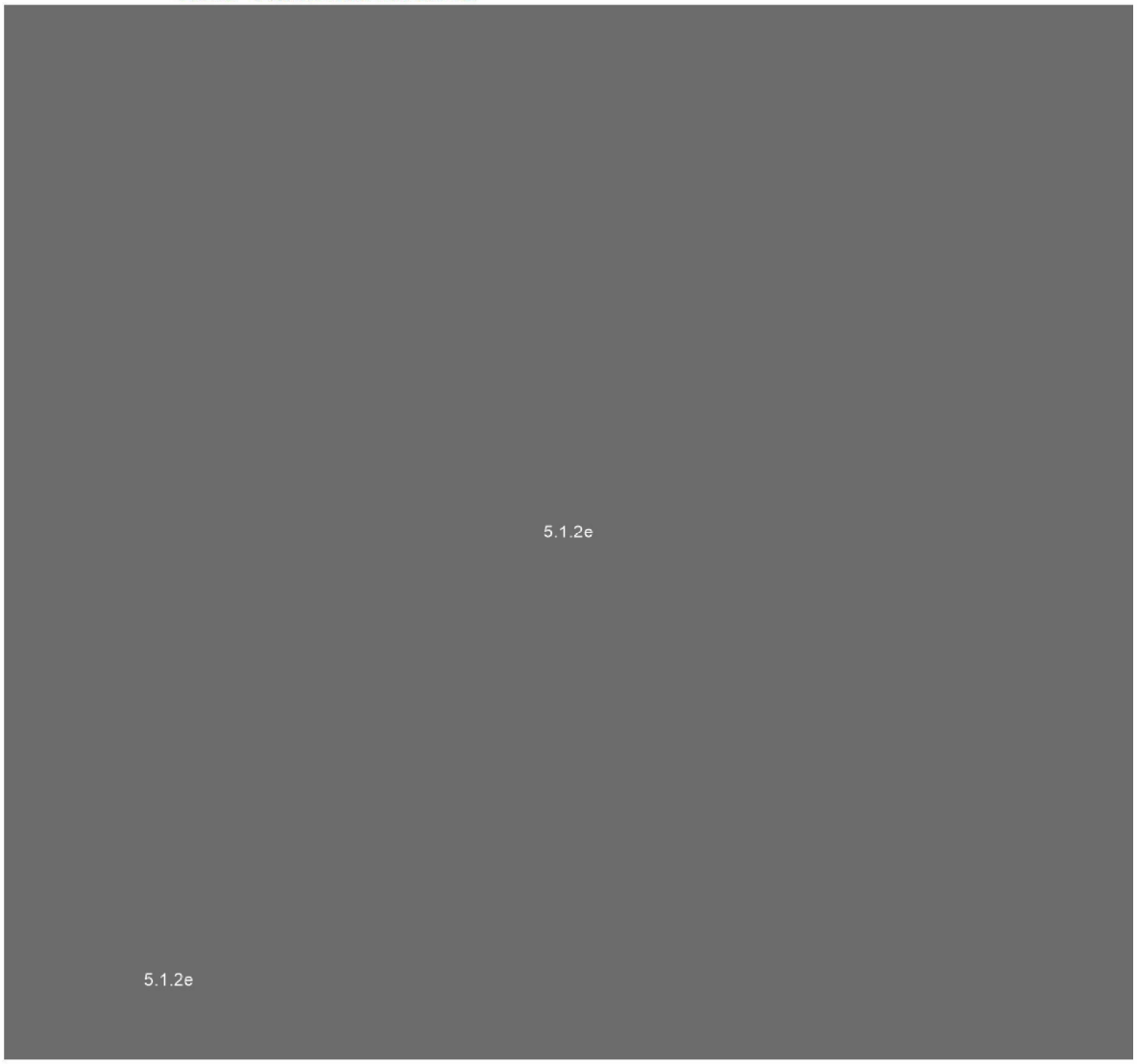
A multidisciplinary team works at HSE-HPSC comprising medical epidemiologists, medical microbiologists, surveillance scientists, health protection and infection prevention and control nurses, IT staff and administration staff.

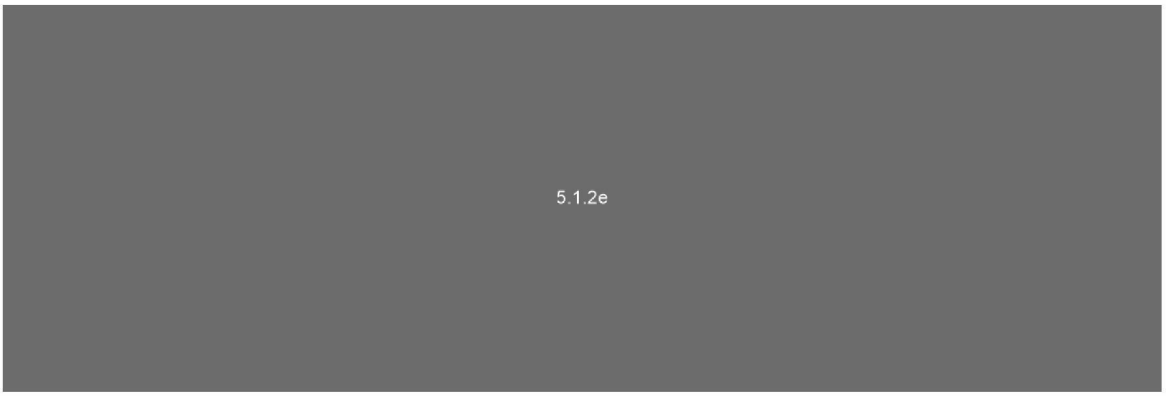
The divisions within HPSC include:

- Bloodborne infections (Hepatitis B, C as well as Hepatitis A and E)
- Emergency Planning and Preparedness,
- Gastroenteric/vector borne,
- HIV and STIs,
- Microbiology including hospital acquired infections,
- Respiratory division (influenza including influenza vaccine effectiveness studies, TB, Legionellosis, other respiratory viruses e.g. MERS, EVD-68, adenovirus etc) and
- Vaccine Preventable Diseases.

The respiratory division at HPSC has been a member of the IMOVE network since 2009, participating each influenza season in the primary care test negative design case control influenza vaccine effectiveness (VE) studies and also participated in the IMOVE+ project (funded by H2020 grant). The primary care influenza VE study is a collaboration between the Irish College of General Practitioners (ICGP), the National Virus Reference Laboratory (NVRL) and HPSC. HPSC takes the lead co-ordinating role. The surveillance of the newly identified 2019-novel coronavirus also comes under the remit of the respiratory team who have already developed a case and contact surveillance system in this regard.
HSE-HPSC will be a member of the I-MOVE-COVID-19 Steering- Scientific committee and will participate in WP2 through the network of primary care practitioners and to WP4 if studies proposed can be conducted within our infrastructure.

1.1.2 Personnel involved





1.1.3 5 relevant publications/services/achievements

Rebolledo, J; Igoe, D; O'Donnell, J; Domegan, L; Boland, M; Freyne, B; McNamara, A; Molloy, E; Callaghan, M; Ryan, A; O'Flanagan, D. Influenza in hospitalized children in Ireland in the pandemic period and the 2010/2011 season: risk factors for paediatric intensive-care-unit admission. 2013:1-10 Epidemiol. Infect.

Beauté J, Broberg E, Plata F, Bonmarin I, O'Donnell J, Delgado C, Boddington N, Snacken R. Overrepresentation of influenza A(H1N1)pdm09 virus among severe influenza cases in the 2011/12 season in four European countries. Euro Surveill. 2012;17(9):pii=20105. Available online: http://www.eurosurveillance.org/ViewArticle.aspx?ArticleId=20105

Martin J, O'Donnell J, Igoe D, O'Hora A, Thornton L, Murphy N, Cullen G, Fitzgerald M, Cotter S, McKeown P, O'Flanagan D, in conjunction with the National Public Health Outbreak Response Team. Enhanced surveillance of initial cases of pandemic H1N1 2009 influenza in Ireland, April - July 2009. Euro Surveill. 2009;14(38):pii=19337. Available online: http://www.eurosurveillance.org/ViewArticle.aspx?ArticleId=19337

Cullen G, Martin J, O'Donnell J, Boland M, Canny M, Keane E, McNamara A, O'Hora A, Fitzgerald M, Jackson S, Igoe D, O'Flanagan D. Surveillance of the first 205 confirmed hospitalised cases of pandemic H1N1 influenza in Ireland, 28 April – 3 October 2009. Euro Surveill. 2009;14(44):pii=19389. Available online: http://www.eurosurveillance.org/ViewArticle.aspx?ArticleId=19389

1.1.4 5 previous projects

I-Move+ Integrated Monitoring of Vaccine Effectiveness in Europe: a platform to measure and compare effectiveness and impact of influenza and pneumococcal vaccines and vaccination strategies in the elderly. Horizon 2020. EU project 634446. 2015-2018.

Monitoring vaccine effectiveness during seasonal and pandemic influenza in EU/EEA" ECDC tender (OJ/16/07/2014-Proc/2014/024). 2016-2017

EuroMOMO: mortality surveillance in Europe

1.1.5 Significant infrastructure and/or any major items of technical equipment relates to the proposal

For the IMOVE and IMOVE+ studies measuring influenza vaccine effectiveness (IVE), HPSC works with a network of sentinel GPs who undertake clinical and virological surveillance of influenza as well as partaking in the TND studies for influenza vaccine effectiveness. HPSC also works closely on with the National Virus Reference Laboratory (NVRL) at University College Dublin (UCD) on these IVE studies. NVRL undertake routine influenza testing using RT-PCR and also genetic analysis on a selection of the study specimen.The University College Dublin will not participate in the project.

4.1.1 Partner name: The Public Health Agency of Sweden - participant no10

1.1.1 Description of the legal entity

The Public Health Agency of Sweden (PHAS) has the overall national responsibility for protecting the population against communicable diseases and coordinates communicable disease control on a national level. We develop regulations, recommendations and guidance for healthcare professionals to ensure effective communicable disease control. Some of the agency's responsibilities include vaccination programmes, emergency preparedness for health. In addition, we coordinate national efforts concerning infection control and healthcare-associated infections.

The Department of Microbiology at PHAS performs microbiological laboratory analysis including diagnostics and supports quality and method development at laboratories engaged in diagnostics of communicable disease pathogens. Our high containment laboratories have round-the-clock preparedness every day of the year to conduct microbiological diagnostics of high-consequence infectious agents that pose a particular danger to human health. One important task is to provide expert support to investigations of suspected or confirmed outbreaks of communicable diseases and to maintain laboratory preparedness needed for effective communicable disease control in the country.

Our tasks in this project will be to contribute to WP2 (Primary care sentinel networks) and WP4 (Epidemiological pooled studies). Regarding WP2, we will contribute with sharing experience of the COVID-19 surveillance activities conducted in Sweden. We will produce epidemiological and virological reports describing cases by clinical, virological and epidemiological characteristics. We will adapt our existing sentinel network for different phases of the epidemic and harmonize our efforts with participating countries and institutions of this project. We will use the data generated in WP2 to contribute to the epidemiological studies conducted in WP4. Furthermore, we will use our existing sentinel network to implement studies on relevant objectives such as identification of COVID-19 risk factors, effectiveness of preventive and treatment strategies, and others (depending on the epidemiological situation).

We have several years of experience in collaborating with IMOVE and contribute yearly with data from the National Influenza Sentinel surveillance. We will use that expertise and our existing infrastructure to address relevant questions regarding COVID-19 virology and epidemiology.

PHA will contribute to WP2 of I-MOVE-COVID-19 (sentinel network and laboratory) and be a member of the Steering-Scientific Committee.

1.1.2 Personnel involved

There will be 3 main researchers involved in the project: 5.1.2e 5.1.2e , 5.1.2e 5.1.2e 5.1.2e 5.1.2e 5.1.2e .

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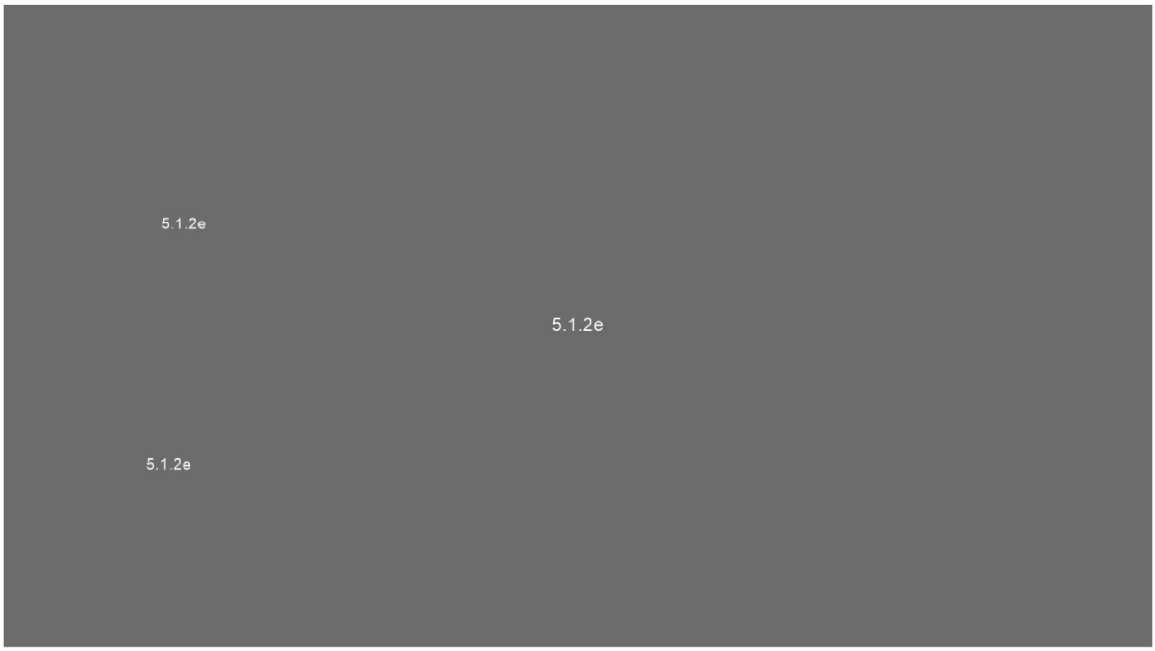


1.1.3 5 relevant publications/services/achievements

These should be relevant to the call/project. If appropriate, add one or two sentences which describes the content of the publication, and how this is relevant to the project.

1.) Low 2018/19 vaccine effectiveness against influenza A(H3N2) among 15-64-year-olds in Europe: exploration by birth cohort. 5.1.2e 5.1.2e 5.1.2e I-Move Primary Care Study Team. Euro Surveill. 2019 Nov;24(48). doi: 10.2807/1560-7917.ES.2019.24.48.1900604.

2.) Interim 2018/19 influenza vaccine effectiveness: six European studies, October 2018 to January 2019. Kissling E, Rose A, Emborg HD, Gherasim A, Pebody R, Pozo F, Trebbien R, Mazagatos C, Whitaker H, Valenciano M; European Ive Group (5.1.2e 5.1.2e , 5.1.2e 5.1.2e). Euro Surveill. 2019 Feb;24(8). doi: 10.2807/1560-7917.ES.2019.24.1900121.

- the publications listed under 1.) and 2.) describe our most recent contributions to IMOVE

3.) Novel influenza A(H1N2) seasonal reassortant identified in a patient sample, Sweden, January 2019. Wiman Å, Enkirch T, Carnahan A, Böttiger B, Hagey TS, Hagstam P, Fält R, Brytting M.

- this publications describes the identification of a novel reassortant and demonstrates our capacity and strength to detect and characterise rare viral strains on a molecular level

4.) Evaluation of the national laboratory-based surveillance system for respiratory syncytial virus in Sweden, 2015-2016. Harvala H, Carnahan A, Axelsson S, Brytting M. J Clin Virol. 2018 Jul;104:11-15. doi: 10.1016/j.jcv.2018.04.004. Epub 2018 Apr 10.

- this publications describes the evaluation of the national laboratory-based surveillance system for RSV and includes concepts what we can also apply for the surveillance of COVID-19

5.) As National Reference Laboratory for SARS-CoV, MERS-CoV and Influenza, we provide service and support to other laboratories in Sweden.

1.1.4 5 previous projects

The Public Health Agency of Sweden is actively engaged in public health work within organisations including the EU and the WHO. We are also a national focal point for these organisations, in areas such as the protection and management of international health threats. We are part of the IMOVE network for several years and actively contribute to yearly vaccine effectiveness studies. We will apply the expertise and infrastructure we gained through I-MOVE to the new project.

Furthermore, our department is member of the Nordic Biopreparedness Forum, a network based on a cooperation agreement between the authorities of Sweden, Finland, Denmark, Norway and Iceland and the Nordic Biosafety Network, which includes the national agencies and microbiological laboratories in the Nordic countries. On the European level, we participate in EVD-LabNet, the European expert laboratory network for emerging viral diseases.

1.1.5 Significant infrastructure and/or any major items of technical equipment relates to the proposal

We will use our existing Influenza sentinel infrastructure for this project, which includes contacts to primary care facilities such as general practitioners. At the Swedish Public Health Agency we have several laboratories with biosafety level 2, two biosafety level 3 laboratories and one high containment laboratory with biosafety level 4. Our department has a well-equipped NGS platform using Ion Torrent and MinIon Nanopore single-molecule sequencing technology which we can access for this project

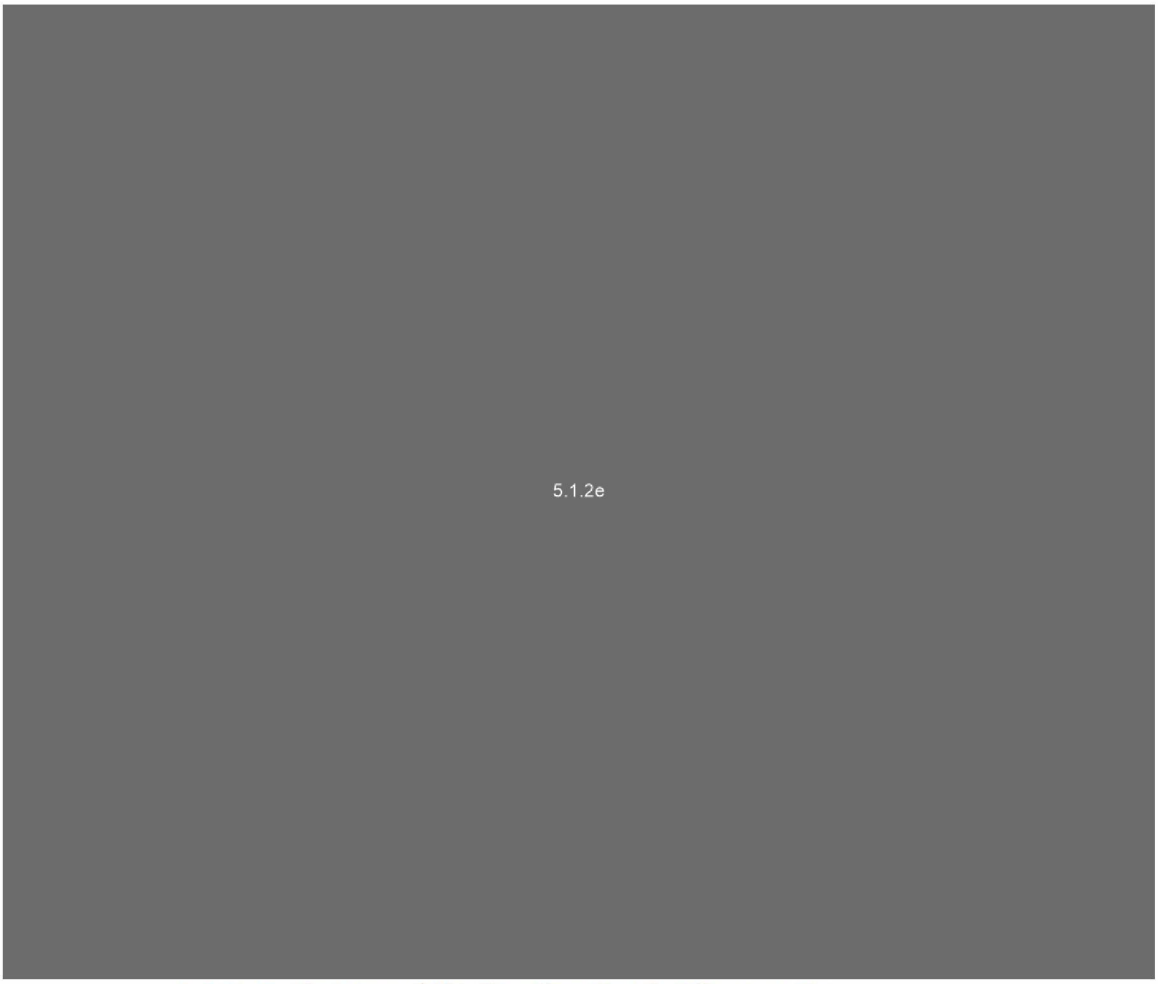
4.1.1 Partner name: - The Vienna Vaccine Safety Initiative (ViVI), Germany - participant no11

1.1.1 Description of the legal entity

The Vienna Vaccine Safety Initiative (ViVI) is an international non-profit organization focused on the prevention, treatment, and communication of infectious diseases and vaccines. Members of the ViVI Scientific Think Tank are **subject matter experts** in human anthropology, paediatrics, infectious diseases, risk communication, linguistics, infectious diseases and epidemiology, regulatory science and bioethics as well as machine learning/AI and data security. The ViVI team developed and validated clinical and virologic endpoints and mobile applications or clinical trials and observational settings. The goal is to individualize the management of influenza and other respiratory viral infections though integration of infectious disease epidemiology with data standardization, e-health, biomarker research and advanced diagnostic capabilities. **Eleven years of successful collaboration resulted in 15 joint projects and 30 peer-reviewed articles**. ViVI was recently joined by experts in data security and new **frameworks for Artificial Intelligence model development** that can be distributed over millions of mobile devices, allowing citizens to own their data and benefit from highly personalized models without compromising user privacy.(Rath, 2018)

In the I-Move-COVID-2019 project, ViVI will contribute to WP3 (Hospital Network). ViVI will be part of the Steering-Scientific Committee. The budget will cover the coordination work of ViVI ; UBFC and CDSIC are not involved as paid participants

1.1.2 Personnel involved



1.1.2 5 relevant publications/services/achievements

Research conducted using the ViVi Score mobile application:

-> Development and validation of the score

Rath, B., Conrad, T., Myles, P., Alchikh, M., Ma, X., Hoppe, C., Obermeier, P., Kisler, B. & Schweiger, B. 2017a. Influenza and other respiratory viruses: standardizing disease severity in surveillance and clinical trials. *Expert Review of Anti-infective Therapy,* 15(6), pp 545-568.

-> Use in the ICU setting

Karsch, K., Chen, X., Miera, O., Peters, B., Obermeier, P., Francis, R. C., Amann, V., Duwe, S., Fraaij, P., Heider, A., de Zwart, M., Berger, F., Osterhaus, A., Schweiger, B. & Rath, B. 2016. Pharmacokinetics of Oral and Intravenous Oseltamivir Treatment of Severe Influenza B Virus Infection Requiring Organ Replacement Therapy. Eur J Drug Metab Pharmacokinet, 42(1), pp 155-164.

-> Validation in a European multi-center setting

Rath, B., Maltezou, H. C., Papaevangelou, V., Papagrigoriou-Theodoridou, M. A., Alchikh, M., Myles, P. & Schweiger, B. 2019. Partnering for enhanced digital surveillance of influenza-like disease and the effect of antivirals and vaccines (PEDSIDEA). Influenza Other Respir Viruses, 13(4), pp 309-318.

-> Identification of clinical features related diagnostic testing for RV in routine care

Alchikh, M., Conrad, T., Hoppe, C., Ma, X., Broberg, E., Penttinen, P., Reiche, J., Biere, B., Schweiger, B. & Rath, B. 2019. Are we missing respiratory viral infections in infants and children? Comparison of a hospital-based quality management system with standard of care. Clin Microbiol Infect, 25(3), pp 380.e9-380.e16.

-> Identification of clinical patterns

Ma, X., Conrad, T., Alchikh, M., Reiche, J., Schweiger, B. & Rath, B. 2018. Can we distinguish respiratory viral infections based on clinical features? A prospective pediatric cohort compared to systematic literature review. Rev Med Virol, 28(5), pp e1997.

1.1.4 5 previous projects

1. **NGO with 11-year track record in successful management of international vaccine and VPD research and communication projects**. The ViVI Scientific Think Tank includes international experts in infectious diseases and vaccines, public health, medical anthropology, paediatrics, innovation and digital health, risk communication, linguistics, gamification and mobile health, data standards, cybersecurity, regulatory science, epidemiology, machine learning and big data analytics. The think tank has issued 30+ per reviewed publications in biomedical journals in the field of vaccination. From this pool of experts, we draw the right expertise for each project.
2. ViVI is part of the **EU-JAV Stakeholder Forum and a member of the EU Coalition for Vaccination (EU-CfV)** working to improve patient-provider interactions from a user-centered viewpoint.
3. ViVI developed and validated scientifically, four mobile health tools, including a user-centered digital immunisation record empowering parents to better understand the vaccination status of their children. For this work, ViVI was shortlisted for the EU Health Award in 2017.
4. In 2019, ViVI completed a tender on **Added value of EU action on EU Health Programme and Vaccination** by the EU Directorate for Impact Assessment and European Added Value; European Added Value Unit (EAVA), and the DG for Parliamentary Research Services; European Parliament's Committee on the Environment, Public Health and Food Safety (ENVI): analysing the state of play and future benefit of EU action in vaccination and the EU health programme
5. ViVI collaborates and shares data with several **EU, EU-Euro, and CIHR funded international networks (RescEU, RSVGold, PRIDE, iMove, FluGold, RepAIR, Monarch**

Collaboration,and others) and regularly participates in expert panels at the **IPA Vaccine Trust Project,** EMA, the ECDC and other EU institutions.

1.1.4 Significant infrastructure and/or any major items of technical equipment relates to the proposal

ViVI has **successfully developed, validated and published four innovative mobile applications supporting precision medicine and human centered care**.(Rath, 2017; Rath et al., 2019; Hoppe et al., 2016; Obermeier et al., 2016) ViVI apps are **multilingual,** currently in use in English, German, French and Spanish for iOS or Android (https://score.vi-vi.org). Another mobile app helping migrants to assess their health needs, was translated into Farsi, Arab and Russian languages.(Rath et al., 2018) ViVI is part of the **EU-JAV Stakeholder Forum** and a member of the **EU Coalition for Vaccination (EU-CfV)** working with the **European Academy of Paediatrics** to improve patient-provider interactions from a user-centered viewpoint. ViVI has a **strong track-record of data sharing with several EU, WHO-Euro and CIHR- funded international networks** (RescEU, RSVGold, PRIDE, iMove, FluGold, RepAIR, Monarch Collaboration and others) and regularly participates in expert panels at the **EMA**, the **ECDC** and other EU institutions. Collaborating with ISARIC/GloPID-R in clinical research.

See also: Rath, B. 2018. Vienna Vaccine Safety Initiative. Hum Vaccin Immunother, 14(5), pp 1038-1041. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6007970/

4.1.1 Partner name: "Cantacuzino" National Military Medical Institute for Research and Development - Romania - participant no12

1.1.1 Description of the legal entity

"Cantacuzino" National Military Medical Institute for Research and Development was created as a strategic institution to perform research in all domains of microbiology and related sciences in order to develop the production of therapeutic sera and vaccines. In present the main fields of activity consist of research in immunology and immune mediated diseases, microbiology, virology, parasitology and other infectious diseases. The Microbiology Laboratories functioning in Cantacuzino Institute are supporting surveillance and control of infectious diseases by covering the reference functions; they are playing a central role in detecting epidemics, monitoring prioritized infectious diseases, providing microbiological data for public health response and scientific evidence for infectious diseases prevention and control.

Due to experience and expertise gain in I-MOVE projects the same national public health scientists involved in influenza from the national network will respond to COVID-19 epidemic and also can participate to the WPs from the proposed project: WP3 (hospital surveillance network) and possible in WP4 (depending on priority studies as defined by the Steering-Scientific Committee).

1.1.1 Personnel involved

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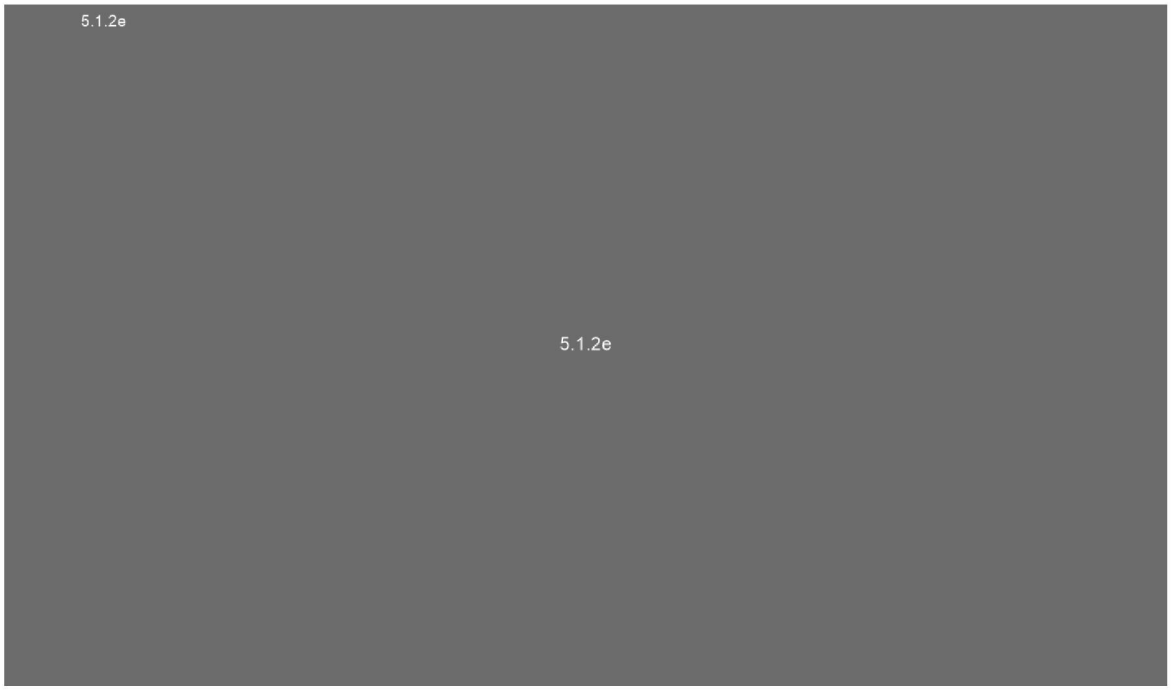


1.1.2 5 relevant publications/services/achievements

1. Lazar M, Stănescu A, Penedos A, Pistol A. *Characterisation of measles after the introduction of the combined measles-mumps-rubella (MMR) vaccine in 2004 with focus on the laboratory data, 2016 to 2019 outbreak,* Romania. Euro Surveill. 2019;24(29):pii=1900041. https://doi.org/10.2807/1560-7917.ES.2019.24.29.1900041 (IF 7.4). A combination of epidemiological data and molecular characterizations enabled the team to trace the spread of wild measles virus genotype in the country.
2. Lazăr M, Perelygina L, Martines R, Greer P, Paddock CD, Peltecu G, Lupulescu E, Icenogle J, Zaki SR. *Immunolocalization and Distribution of Rubella Antigen in Fatal Congenital Rubella Syndrome*, EBioMedicine. 2015 Nov 27;3:86-92. doi: 10.1016/j.ebiom.2015.11.050. eCollection 2016. http://www.ncbi.nlm.nih.gov/pubmed/26870820 ISSN-L: 2352-3964 (IF 6.6) Twenty-eight cases of congenital rubella syndrome (CRS) (including 11 neonatal deaths and one stillbirth) identified after the Romanian rubella outbreak, lead to the nominee of project leader as responsible for the project financial sustained by CDC (Centers for Disease Control and Prevention) Atlanta, "Cellular and Molecular mechanisms of Pathogenesis in Congenital Rubella Syndrome" (2012-2014). Research performed on paraffin-embedded autopsy tissues from three fatal case-patients aimed to identify target cells of rubella virus persistence in congenitally infected foetuses and newborns and to reveal cellular genes specifically regulated in response to rubella infection. The novel findings of this study consisting in *the identification for the first time of rubella virus antigen in progenitor cells of outer granular layer of the brain and the identification of capillary endothelial cells and the basal plate as the primary targets in the placenta* (with consequences on capillary necrosis and blockage, thus impacting placenta functions and leading to growth retardation of the fetus)

3. Popescu C. P., Florescu S.A., Lupulescu E., Zaharia M., Tardei G., Lazăr M, Ceausu E. Ruta S. *Neurologic complications of influenza B virus infection in adults: A case series from a tertiary facility in Romania,* Emerging Infectious Diseases ISSN:1080-6059, April 2017, Volume 23, Nr 4. DOI: http://dx.doi.org/10.3201/eid2304.161317 (IF 8.22). The results from a collaborative study with "Victor Babes" hospital *concluded that infection with influenza B virus should be considered as an etiologic factor for encephalitis*
4. Lazăr M, Abernathy E, Chen M, Icenogle J, Janta D, Stanescu A, Pistol A, Santibanez S, Mankertz A, Hübschen JM, Mihaescu G, Necula G, Lupulescu E. *Epidemiological and molecular investigation of a rubella outbreak, Romania, 2011 to 2012*. Euro Surveill. 2016;21(38):pii=30345. DOI: http://dx.doi.org/10.2807/1560-7917.ES.2016.21.38.30345 ISSN 1560-7917 (IF 7.2). The Romanian rubella outbreak (2011-2012) was also described in terms of time, place and person, with a focus on laboratory and molecular analysis. Genetic information obtained by the project leader revealed that it was driven by two 2B lineages with an average of 3.5% nucleotide difference, which overlapped both temporally and geographically.
5. **Necula G, Lazăr M, Stanescu A, Pistol A, Santibanez S, Mankertz A, Lupulescu E. Transmission and molecular characterisation of wild measles virus in Romania, 2008 to 2012. Euro Surveill. 2013;18(50):pii=20658. Article DOI:** http://dx.doi.org/10.2807/1560-7917.ES2013.18.50.20658 The authors contributed equally to this article. ISSN 1560-7917(IF 6,15) A combination of epidemiological data and molecular characterizations enabled the team to trace the spread of wild measles virus genotype in our country from 2008 to 2012, demonstrating *D4-Manchester and its descendants as new endemic strains in Romania that circulated continuously for almost two years.*

1.1.3 5 previous projects

Grant of the Romanian Ministries of Research and Innovation, CCCDI - UEFISCDI, project number PN-III-P1-1.2-PCCDI-2017-052 / 62PCCDI / 2018, PNCDI III (2018-2021), ConVac, https://www.convac.ro/en/partners/partner-2.html

OBJECTIVE OF THE PROJECT

This consortium provides the framework for developing a vaccine by:

- studies that will ensure the development of the antigen;

- studies on optimizing the formulation of this antigen;

- developing the characterization of antigen-adjuvant complexes;

- evaluation of protection given by antigen-adjuvant complexes;

- elaboration of non-clinical studies documentation according to pharmaceutical regulations.

As the sole national vaccine manufacturer, the institute was involved in projects regarding the advancement of capacity for influenza vaccine production (WHO project Pandemic Preparedness). The **DG-SANCO** project, **Fast VAC** has as main objective to put into effect a comprehensive set of predictive rules enabling accelerated development, evaluation, production and release of emergency vaccines. "Combating flu in a combined action between the industry and the public sector in order to secure adequate and fast intervention in Europe" was the subject of **Flu Secure**, a DG-SANCO project developed during 2006-2010, a collaborative action between NIRDMIC and NIBSC aimed at technological transfer, immunogenicity evaluation of H5N1 influenza vaccines in animal models and building a reagent bank for the multiplication of seed strains in cell culture. Another direction for research is the eco-epidemiology of vector-borne diseases in the hanging European environment which has been developed in the framework of FP6 and FP7 projects: **EDEN** (2005-2009) and **EDENext** (2011-2014).

1.1.4 Significant infrastructure and/or any major items of technical equipment relates to the proposal

Starting 2019 new sequencing platforms can be used in INCDMM "Cantacuzino". The platforms allow for a previously unprecedented view into complex mixtures of RNA and DNA samples:

- MiSeq Illumina - an integrated instrument that performs clonal amplification, genomic DNA sequencing, and data analysis with base calling, alignment, variant calling, and reporting in a single run.

- The NovaSeq Sequencing System from Illumina - unleashes groundbreaking innovations that leverage our proven technology. Now you can get scalable throughput and flexibility for virtually any sequencing method, genome, and scale of project.

- PacBio – Pacific Biosciences long-read sequencing sequencing provides the most comprehensive view of genomes, transcriptomes and epignomes.

Other equipment useful for the project activities:

- RealTime PCR thermocycler (Stratagene Mx3005P) for diagnosis of influenza.
- Conventional thermocycler PCR (Bio-Rad DNA Engine Dyad and Corbett Research) to obtain DNA libraries.
- Traditional Sanger sequencing: PRISM 3100-Avant Genetic Analyzer (Applied Biosystems).
- Ion Torrent Next Generation Sequencing (NGS): Ion PGM (Personal Genome Machine) System (ThermoFisher Scientific), which is typically used to investigate a few to several hundred genomic regions across multiple samples,
- Sequencher DNA analysis software for Sanger or NGS data sets.

- Biosafety hoods (Class 2), refrigerators, freezers (-20°C and -80°C), conventional electrophoresis agarose gel with transilluminator UVP used for PCR products analysis and identification, Qubit for fluorometric quantitation (rapid *quantification* of *DNA*, oligos, *RNA*, microRNA).
- The BSL3 room is under development in the final steps (tests, training people).

4.1.1 Partner name: The University of Corsica Pasquale Paoli - France - participant no13

1.1.1 Description of the legal entity

The University of Corsica Pasquale Paoli is a **multidisciplinary institution** which counts 8 faculties, institutes and schools. The University of Corsica has a strong interest in several scientific domains concerning sustainable development and environmental issues, legal aspects of scientific research as well as public health. **The research unit EA7310 of the University of Corsica Pasquale Paoli coordinates the Mediterranean *Sentinelles* network (Corsica and PACA).**

The Mediterranean *Sentinelles* network has been established in 2007 by the University of Corsica in collaboration with the Faculty of Medicine of Sorbonne University and contributes to the real-time epidemiological surveillance system, based on the participation of 138 general practitioners and 11 paediatricians, who collect real-time epidemiologic data on 10 health indicators.

The Mediterranean *Sentinelles* network contributes:

- to provide timely epidemiological information on influenza like illness (ILI) all year long and virological information on circulating respiratory viruses in Corsica and PACA regions during winter seasons.
- to analyse the respiratory viruses circulating during the wither season, thanks to the virology laboratory at the University of Corsica. The collected specimens are analysed through real-time RT-PCR tests for the detection of influenza virus (IV, type and subtype are searched), respiratory syncytial virus (RSV), human metapneumovirus (HMPV) and human rhinovirus (HRV).
- to serological analyses of infectious diseases in the general population and in the general practitioners (GP) population.

Considering the previous experience in the area of surveillance of respiratory infections and of emerging diseases such as vector-borne diseases, the EA7310 has the capacity of contributing to the ensemble of tasks described in WP2 and WP4 (if relevant for the priority studies defined by the Steering-Scientific Committee). University of Corsica will be a member of the Steering-Scientific Committee.

1.1.2 Personnel involved

5.1.2e

5.1.2e

5.1.2e

1.1.3 5 relevant publications/services/achievements

1. 5.1.2e
   5.1.2e Risk factors for seasonal influenza virus detection in stools of patients consulting in general practice for acute respiratory infections in France, 2014-2016. Influenza Other Respir Viruses. 2019 Jul;13(4):398-406.

Acute respiratory infection (ARI) patients were enrolled by general practitioners (GP) during two winter seasons (2014-2016). Nasopharyngeal swabs, stool specimens, and clinical data were collected. Samples were tested for 12 respiratory pathogen groups (nasopharyngeal and stool specimens) and for 12 enteric pathogens (stool specimens).

2. 5.1.2e
   5.1.2e Estimation of seasonal influenza vaccine effectiveness using data collected in primary care in France: comparison of the test-negative design and the screening method. Clin Microbiol Infect. 2018 Apr;24(4):431.e5-431.e12.

We discussed which method between the test-negative design (TND) and the screening method (SM) could provide more robust real-time and end-of-season vaccine effectiveness (VE) estimates using data collected from routine influenza surveillance in primary care.

3. 5.1.2e
   Circulation of Toscana Virus in a Sample Population of Corsica, France. Viruses. 2019 Sep 4;11(9).

Sandfly-borne phleboviruses pathogenic to humans, such as Toscana virus (TOSV) and Sandfly Fever Sicilian virus (SFSV), are endemic in the Mediterranean region. In this cross-sectional study, participants were enrolled (i) from a medical staff at the University of Corsica and (ii) from general practitioners of the Corsican Sentinelles Network. The seroprevalence study was based on a virus microneutralization assay.

4. 5.1.2e
   5.1.2e Baseline characteristics and clinical symptoms related to respiratory viruses identified among patients presenting with influenza-like illness in primary care. Clin Microbiol Infect. 2019 Sep;25(9):1147-1153.

In this study we aimed to identify patients' clinical characteristics associated with respiratory viruses identified among patients presenting with influenza-like illness (ILI).

5. 5.1.2e
   5.1.2e 5.1.2e
   5.1.2e

I-Move Primary Care Study Team. Low 2018/19 vaccine effectivenessagainst influenza A(H3N2) among 15-64-year-olds in Europe: exploration by birth cohort. Euro Surveill. 2019 Nov;24(48).

Study sites in nine European countries took part in the primary care-based I-MOVE multicentre study in the 2018/19 influenza season: Croatia, France, Germany, Ireland, the Netherlands, Portugal, Romania, Spain and Sweden. General practitioners (GPs) or paediatricians systematically selected patients with influenza-like illness (ILI) or acute respiratory infection (ARI) to interview and swab.

1.1.4 5 previous projects

1) Since 2015, the EA7310 has been part of the **I-MOVE project** (Monitoring Influenza Vaccine Effectiveness) whose main objective is to conduct research on influenza vaccine effectiveness, in the overall population and for the population at risk for influenza complications.
2) During 2014/15, we coordinated the project **GrippeNet.fr in Corsica (a GrippeNet project)**, which is a participatory surveillance system collecting voluntary reports of influenza-related symptoms within the French population, through a dedicated website (https://www.grippenet.fr) where individuals also provide profile information.
3) Since 2007, the Mediterranean *Sentinelles* network contributes to a real real-time epidemiologic surveillance system based on the voluntary participation of 138 general practitioners and 11 paediatricians, located throughout Corsica and PACA regions, who collect real-time epidemiologic data on 10 health indicators. The health indicators monitored have evolved over time, the network being flexible and able to respond to public health emergencies.
4) Since 2018/2019, we coordinate a regional project with 14 national partners about the epidemiology of emerging disease (such as Hepatitis E) or vector borne-diseases (such as Toscana virus).
5) Since 2018-2019, we coordinate a regional project with 4 partners about a mobile application development for monitoring public health studies.

1.1.5 Significant infrastructure and/or any major items of technical equipment relates to the proposal

The EA7310 has BSL1 and BSL2+ laboratories which allow to standard molecular biology/immunology/cellular biology analysis.

4.1.1 Partner name: Sorbonne Université - France - participant no14

1.1.1 Description of the legal entity

Sorbonne Université is involved in numerous European and International partnership agreements and has France's largest scientific library and infrastructures bringing together the best talent in a wide array of these disciplines. With 8,500 publications per year (approx. 10% of all publications in France), Sorbonne Université is a major player in international knowledge and innovation economy, offering transversal academic and research programs. Following its tradition in hosting excellent researchers from around the world, Sorbonne Université is engaged into the adoption of the European Charter for Researchers and the Code of Conduct for the Recruitment of Researchers.

The Research and Innovation office, which is in charge of the EU projects at the university, has managed so far 150 FP7 and more than 110 H2020 projects. The office will manage all the financial, administrative and legal aspects for the participation of Sorbonne Université in this project.

The French *Sentinelles* network (http://www.sentiweb.fr) has been established in 1984 by the Medical faculty of Sorbonne Université and the French National Institute for Medical Research (INSERM, not involved in the project), in collaboration with the French Public Health Institute (Santé publique France). It has obtained a research authorisation from the French independent administrative authority protecting privacy and personal data (CNIL), n°471 393.

This network is a real-time epidemiologic surveillance system based on the voluntary participation of 500 general practitioners (GPs) (approximately 0.8% of all French GPs) and 100 paediatricians, located throughout metropolitan France, who collect real-time epidemiologic data on 10 health indicators. One of the main objectives of the French *Sentinelles* network has been to provide timely epidemiological information on ILI all year long and virological information on the main respiratory viruses circulating in France during winter seasons. Surveillance of the main circulating respiratory viruses is carried out in partnership with the French National Influenza Reference Center (CNR, Paris and Lyon), the virology laboratory at the University of Corsica, and Santé publique France. Starting with season 2017-18, acute respiratory infections (ARI) in the elderly population (65 years or older) are included among the health indicators monitored by the Sentinelles network.

Within the ILI and ARI clinical surveillance, the participating sentinel GPs report the weekly number of cases seen in consultation and clinically describe each case. The virological surveillance consists in collecting nasopharyngeal specimens from a systematic sample of ILI and elderly ARI patients along with additional clinical information. Currently, the collected specimens are analysed through real-time RT-PCR tests for the detection of influenza virus (IV, type and subtype are searched), respiratory syncytial virus (RSV), human metapneumovirus (HMPV) and human rhinovirus (HRV).

Considering the previous experience in the area of surveillance of respiratory illnesses, the Sentinelles network has the capacity of contributing to the ensemble of tasks described in I-MOVE-COVID-19 work packages (WP) 2 and 4 of the current project. Additionally, an ongoing project of our institute consisted in establishing a global inventory of existing sentinel surveillance networks in general practice in Europe and worldwide (http://sentiworld.sentiweb.fr/), which allows us to gain a better understanding of their activities and may facilitate international collaborations. The knowledge acquired, the contacts established, and the infrastructure developed within this project could additionally contribute to the realisation of the tasks described in WP2.

Sentinelles will be member of the Steering-Scientific Committee.

1.1.2 Personnel involved

Staff members of Sorbonne University:

1.1.3 5 relevant publications/services/achievements

1) *Souty C, Masse S, Valette M, Behillil S, Bonmarin I, Pino C, Turbelin C, Capai L, Vilcu AM, Lina B, van der Werf S, Blanchon T, Falchi A, Hanslik T. Baseline characteristics and clinical symptoms related to respiratory viruses identified among patients presenting with influenza-like illness in primary care. Clin Microbiol Infect. 2019 ; 2019;25(9):1147-1153 30703528 doi:10.1016/j.cmi.2019.01.014*

This study allowed the identification of symptoms associated with several viral aetiologies in patients presenting influenza-like illness (ILI), based on routine data collected by general practitioners participating at the French *Sentinelles* network. This expertise could be helpful in the achievement of the tasks included in WP 2 and 4 of this project, from a both statistical and epidemiological point of view. A proper knowledge and understanding of these clinical signs may improve the medical management of patients.

2) Souty C, Amoros P, Falchi A, Capai L, Bonmarin I, van der Werf S, Masse S, Turbelin C, Rossignol L, Vilcu AM, Lévy-Bruhl D, Lina B, Minodier L, Dorléans Y, Guerrisi C, Hanslik T, Blanchon T. Influenza epidemics observed in primary care from 1984 to 2017 in France: A

decrease in epidemic size over time. Influenza Other Respir Viruses. 2019 ; 2019;13(2):148-157 30428158 HAL hal-02343449 doi:10.1111/irv.12620 pmc:PMC6379635

Epidemiological analysis of past influenza epidemics remains essential to understand the evolution of the disease and optimize control and prevention strategies. In this study, we used data collected by a primary care surveillance system over the last three decades to study trends in influenza epidemics and describe epidemic profiles according to circulating influenza viruses.

3) Guerrisi C, Turbelin C, Souty C, Poletto C, Blanchon T, Hanslik T, Bonmarin I, Levy-Bruhl D, Colizza V. The potential value of crowdsourced surveillance systems in supplementing sentinel influenza networks: the case of France. Euro Surveill. 2018 ; 2018;23(25): 29945696 HAL hal-01832885 doi:10.2807/1560-7917.ES.2018.23.25.1700337 pmc:PMC6152237

This study discusses the potential of a crowdsourced surveillance system as a complementary source for syndromic surveillance of ILI. Thanks to its flexibility, the GrippeNet platform, here discussed, could represent an important complementary resource to carry research on other health topics, including emerging infectious diseases like the coronavirus.

4) Vilcu AM, Souty C, Enouf V, Capai L, Turbelin C, Masse S, Behillil S, Valette M, Guerrisi C, Rossignol L, Blanchon T, Lina B, Hanslik T, Falchi A. Estimation of seasonal influenza vaccine effectiveness using data collected in primary care in France: comparison of the test-negative design and the screening method. Clin Microbiol Infect. 2018 ; 2018;24(4):431.e5-431.e12 28899840 HAL hal-01911031 doi:10.1016/j.cmi.2017.09.003

In this paper, we discussed which method between the test-negative design (TND) and the screening method (SM) could provide more robust real-time and end-of-season vaccine effectiveness (VE) estimates at a country level, using data collected from routine influenza surveillance in primary care.

5) Ariza M, Guerrisi C, Souty C, Rossignol L, Turbelin C, Hanslik T, Colizza V, Blanchon T. Healthcare-seeking behaviour in case of influenza-like illness in the French general population and factors associated with a GP consultation: an observational prospective study. BJGP Open.2018;1(4):bjgpopen17X101253, 30564694, doi:10.3399/bjgpopen17X101253 pmc:PMC6181105

This study allowed the identification of specific factors associated with GP consultation for an ILI episode. These findings may help to coordinate health information campaigns and to raise awareness, especially among individuals at risk of influenza complications.

1.1.4 5 previous projects

1) Since 1984, the Sentinelles network has developed a real real-time epidemiologic surveillance system based on the voluntary participation of 500 general practitioners (GPs) (approximately 0.8% of all French GPs) and 100 paediatricians, located throughout metropolitan France, who collect real-time epidemiologic data on 10 health indicators. The health indicators monitored have evolved over time, the network being flexible and able to respond to public health emergencies.

2) Since 2015, the Sentinelles network has been part of the **I-MOVE project** (Monitoring Influenza Vaccine Effectiveness) whose main objective is to conduct research on influenza vaccine effectiveness, in the overall population and for the population at risk for influenza complications.

3) Since 2012/13, our institute coordinates the project **GrippeNet.fr** (part of the InfluenzaNet network), which is a participatory surveillance system collecting voluntary reports of influenza-related symptoms within the French population, through a dedicated website (https://www.grippenet.fr) where individuals also provide profile information. Data are collected on a weekly basis through a symptoms survey. GN is an online participatory system providing flexibility and a richness of data offering several opportunities to track and analyse epidemics due to pathogens causing respiratory symptoms.

4) A recent study called **Sentiworld** (http://sentiworld.sentiweb.fr/) has built a global inventory of existing sentinel surveillance networks in general practice. The aim of this project was to provide a better understanding of their activities and to facilitate international collaborations. A better knowledge of each sentinel network's activities and their specificities will create a framework for further exchanges and collaborations, in order to improve health monitoring and infectious disease surveillance in primary care in Europe.

5) Since 1999, the *Sentinelles* network maintains a scientific partnership with IQVIA France, which has enabled us to use drug dispensing data as a complementary source for the epidemiological surveillance of infectious diseases, such as influenza-like-illness and acute gastroenteritis. The research projects carried out within this partnership allowed us to develop epidemic detection and activity forecast models based on drug sales data, but also to conduct observational studies investigating the association between exposure to a drug class and the occurrence of an infectious event.

1.1.5 Significant infrastructure and/or any major items of technical equipment relates to the proposal

Through the participation in projects such as GrippeNet (InfluenzaNet), Sentiworld, and I-MOVE, the Sentinelles network has developed a solid network of contacts in the field of epidemiological surveillance in primary care, which could enhance collaboration and facilitate coordinated actions in situations of emerging diseases.

From a logistic point of view, our lab disposes of the infrastructure required for the collection, storage, security and treatment of the data collected.

4.1.1 Partner name: Santé Publique France - France - participant no15

1.1.1 Description of the legal entity

Santé publique France (SpF), the National Public Health Agency (previously Institut de Veille Sanitaire, InVS) is a governmental institution reporting to the Ministry of Health. SpF is responsible for surveillance and alert in all domains of public health. The Unit for Infectious Diseases and Vaccination conducts activities to monitor diseases preventable by vaccination, allowing the epidemiological impact of vaccination programs implemented in the framework of the immunisation schedule to be evaluated.
SpF has been involved and has supported the development of sustainable European networks to monitor the effectiveness and impact of vaccines in the population (I-Move for influenza vaccine effectiveness, SpidNet for conjugate pneumococcal vaccine impact, Pertinent for pertussis vaccine effectiveness). SpF can provide the expertise needed to expand and build new networks and to facilitate the implementation of epidemiological and microbiological studies in France thanks to an excellent network of partners including hospitals, laboratories, and research teams working on vaccination.
SPF will participate in I-MOVE-COVID-19 WP2, WP3 and WP4 by providing scientific advice on protocols, data analysis and interpretation of results. SPF will be member of the Scientific-Steering Committee

1.1.2 Personnel involved

5.1.2e

5.1.2e

5.1.2e

1.1.3 5 relevant publications/services/achievements

Lepoutre A, Varon E, Georges S, Dorleans F, Janoir C, Gutmann L, Lévy-Bruhl D; Microbiologists of Epibac; ORP Networks. Impact of the pneumococcal conjugate vaccines on invasive pneumococcal disease in France, 2001-2012. Vaccine. 2015;33(2):359-66.

Bonmarin I, Belchior E, Lévy-Bruhl D. Impact of influenza vaccination on mortality in the French elderly population during the 2000-2009 period. Vaccine. 2015 Feb 25;33(9):1099-101.

Tubiana S, Belchior E, Guillot S, Guiso N, Lévy-Bruhl D; Renacoq Participants. Monitoring the Impact of Vaccination on Pertussis in Infants Using an Active Hospital-based Pediatric Surveillance Network: Results from 17 Years' Experience, 1996-2012, France. Pediatr Infect Dis J. 2015 Aug;34(8):814-20.

Belchior E, Lévy-Bruhl D, Le Strat Y, Herida M. Cost-effectiveness of a herpes zoster vaccination program among the French elderly people. Hum Vaccin Immunother. 2016 Sep;12(9):2378-82.

Kissling E, Valenciano M, Cohen JM, Oroszi B, Barret AS, et al. (2011) I-MOVE Multi-Centre Case Control Study 2010-11: Overall and Stratified Estimates of Influenza Vaccine Effectiveness in Europe. PLoS ONE 6(11): e27622.

1.1.4 5 previous projects

Coordination of the surveillance of VPD in France and the annual estimation of vaccine coverage
Contribution to vaccine policy-making (introduction of new vaccines in the population, assessment of vaccine effectiveness and impact, annual revision of the national immunization schedule, national guidelines for the prevention of VPD
Existing collaborations with various partners in France and in other countries involved in vaccine research and surveillance (e.g. sentinel GP network, national reference centres, research institute working on modelling the transmission of VDP and impact of vaccines, network of clinicians…)
Participation to European networks and the implementation of multicentre studies to estimate the impact and effectiveness of vaccines in the population (I-MOVE since 2014, I-MOVE + since 2015, SPID-Net since 2012, Pertinent since 2016) and to monitor vaccine strategy in Europe as work package leader in the VENICE project since 2006.

1.1.5 Significant infrastructure and/or any major items of technical equipment relates to the proposal

High expertise in respiratory infections surveillance and response including SARS, A(H1N1)pdm09, MERS-Cov.

4.1.1 Partner name: Institut Pasteur - France - participant no16

1.1.1 Description of the legal entity

Institut Pasteur (IP) is a non-for-profit private foundation dedicated to biological research. Widely recognized as the birthplace of microbiology, the Institut Pasteur has also helped lay the foundations of immunology and molecular biology. Pasteurian research has now extended to neuroscience, developmental and stem cell biology, genomics and computational biology, placing the Institut Pasteur among the most prestigious institutions in Biomedical Research worldwide. IP core missions are Research, Public health, Teaching and Valorization of scientific research via technology transfer and industrial partnerships. IP has a critical mass of about 2600 people including approximately 600 tenured scientists, several hundred PhD students and post-doctoral fellows, dedicated engineers and technicians, as well as administrative staff. Composed of 11 departments of research, 134 research units and Hosting 3 "laboratories of excellence" (LabEx), and along with his network of 32 associated institutes worldwide (the Institut Pasteur International Network - IPIN), Institut Pasteur represents a unique international multidisciplinary research organization.

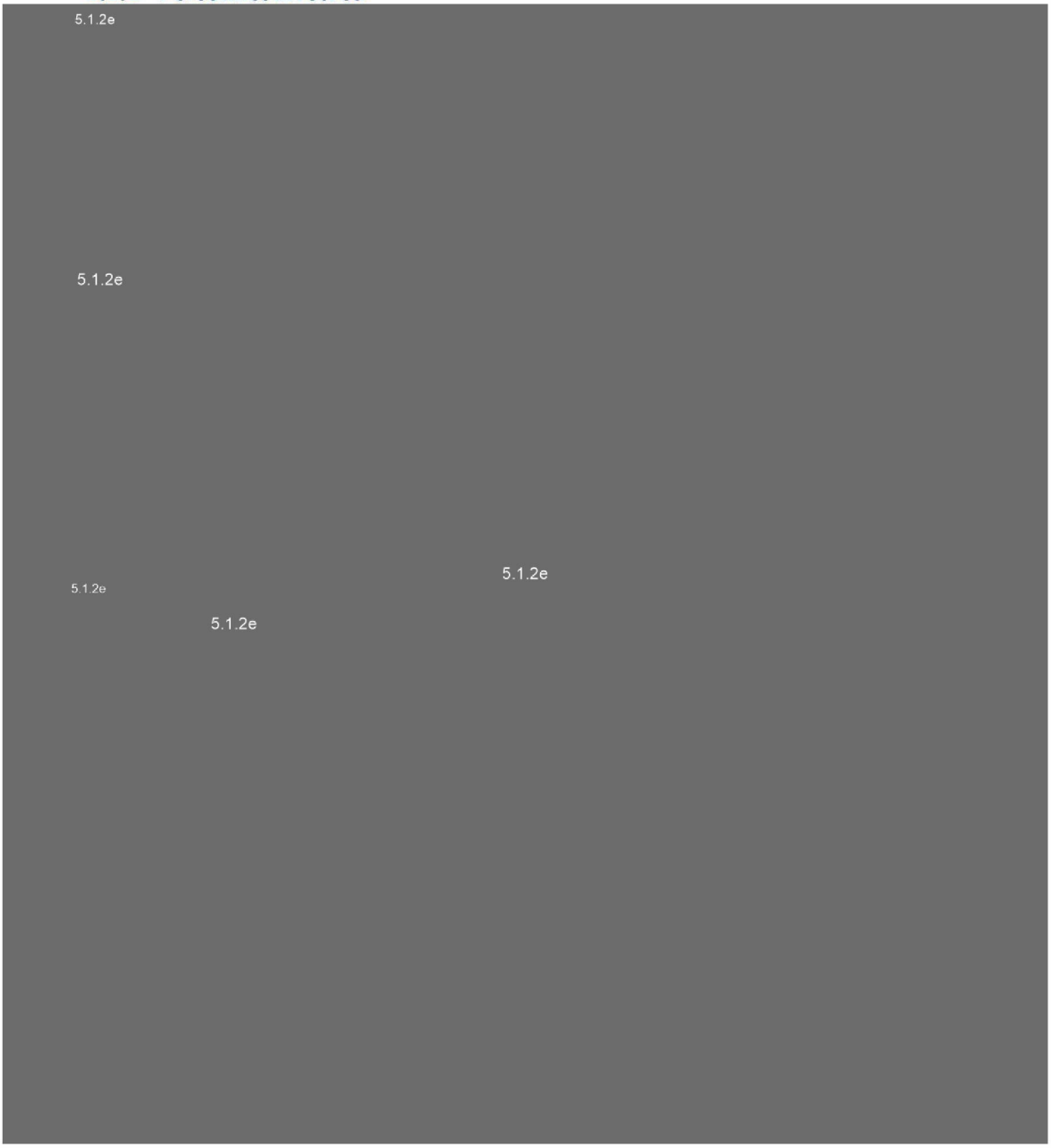
About 300 scientists work in the integrative biology of emerging infectious diseases. Public health being one its core missions, IP hosts 14 National Reference Centers (NRC) for human infectious diseases and 5 WHO collaborating centers (WHOCCs), as well as 2 World Organization for Animal Health (OIE) reference laboratories and 1 OIE Collaborating Center (OIECC) for the detection and identification in humans of emerging animal pathogens. This collaborative work between the OIECCs, CNRs and WHOCCs enables a "One Health" approach".

The National Reference Center (CNR) for Respiratory Viruses at the Institut Pasteur in Paris is one of WHO's reference laboratories for coronavirus COVID-19. The CNR is in charge of monitoring respiratory viruses, relying on the network of hospital laboratories, RENAL, and the network of general practitioners and paediatricians Sentinelles. The laboratory develops its own detection methods by RT-qPCR so that it is never caught off guard and can always respond to the emergence of new viruses. The viruses detected are then isolated, amplified, if possible, to be able to better study them by serological and molecular biology methods. Sequencing of the viral genome can be carried out on the initial sample or viral culture and a cDNA production method allows DNA to be prepared without initial amplification. NGS sequencing is performed on the Mutualized Platform of Microbiology of Institut Pasteur (P2M) and data analysis is performed by the CNR. For this purpose, we have developed specific workflows for respiratory viruses using the CLC Genomics Workbench software (Qiagen). These workflows are routinely used to determine the presence or not of mutations of interest within the framework of the CNR but also in the more advanced analysis requested by a clinician (search for antiviral resistance) or a researcher (interfering defective particles). The consensus sequences resulting from these analyses and the tables of mutations are shared on the international GISAID database. The establishment of phylogenetic trees makes it possible to assess the genetic evolution of viruses and to relate this information to antigenic analyses. The CNR was the first laboratory to detect,

isolate and sequence the new COVID-19 coronavirus in Europe thanks to its know-how and the tools made available to researchers by the Institut Pasteur.

In I-MOVE-COVID-19, IP will participate in WP2, WP3 providing laboratory data from the French participants and potentially in WP4 according to the Steering-Scientific Committee decision on priority studies. IP will be a member of the Steering-Scientific Committee.

1.1.2 Personnel involved



1.1.4 5 previous projects

I-Move (ECDC)

Prepare (FP7)

Global Initiative on Sharing All Influenza Data (GISAID) platform

1.1.5 Significant infrastructure and/or any major items of technical equipment relates to the proposal

Scientists at Institut Pasteur benefit from the availability of high-biosafety level laboratories (BSL2/3), animal resources and cutting-edge technological facilities, with equipment for (meta)genomics, proteomics, nanoimaging, high-throughput screening, high performance computing and access to a bioinformatics center. The Microbiology Mutualised Platform (P2M) is open to all the reference laboratories of the Institut Pasteur, in Paris and within the International Network (RIIP). In a spirit of technological mutualisation, P2M gathers all the requests and thus allows the previously not possible routine use of innovative techniques such as next generations multi-pathogenic sequencing, automated extraction of nucleic acids and MALDI-TOF. The sequencing is made according to a unique library manufacturing protocol whatever the pathogen (bacteria, viruses, mushrooms or parasites). This choice allows to optimise the deadlines and, so, to integrate the technology into the panel of microbiological public health surveillance tools. Bio-IT specialists commissioned by the C3BI realize the tests of quality of the sequences generated by the sequencer and can also help laboratories, if needed, to implement routine sequence analyses. We work with the Illumina technologies. The platform follows the quality approach of the Institut Pasteur and joins in the scope of activity of the LREMS (Laboratory of Reference and Expertise Multi-site, a structure including, within a single entity, all the CNR, CCOMS and CIBU).

4.1.1 Partner name: The Directorate-General of Health (DGS) - Portugal - participant no17

1.1.1 Description of the legal entity

The Directorate-General of Health (DGS) is a central agency of the Portuguese Ministry of Health with administrative autonomy. Since its inception, DGS has dedicated itself to epidemiological surveillance and disease control and prevention, in order to protect and improve the health and well-being of citizens. Through evidence-based interventions, inequities are tackled under quality and safety standards to reach their health potential. In addition, DGS coordinates and leads the preparation and management of public health emergencies; issues clinical and organizational guidelines for the health sector; and provides technical input for health-related political decision making.

DGS has its headquarters in Lisbon with approximately 100 staff, including public health consultants, physicians, nurses, psychologists, senior officers and trainees. As the National Health Authority, the Director-General of Health coordinates a network of public Health Authorities. This network is a pillar to protect population's health throughout risk detection, risk management and risk communication.

DGS has a vital and leading role in public health emergencies and national outbreaks. The latest examples include the 2009 influenza pandemic, SARS, Ebola, Zika virus, MERS-CoV and measles.

Since January 2020, DGS has established a national coordination mechanism to respond to the 2019-novel coronavirus (COVID-19) public health emergency, ensuring scaling up operations for early detection, effective diagnosis and efficient implementation of public health measures. DGS has strengthen the national surveillance system for COVID-19 and it will need to continue adapt its systems to properly adapt to the evolution of the COVID-19.

The Division of Epidemiology and Statistics within the Department of Information and Analysis [Divisão de Epidemiologia e Estatística da Direção de Serviços de Informação e Análise (DEE/DSIA)] develops, maintains and evaluates the national surveillance system for infectious diseases in Portugal; and monitors, analyses and disseminates infectious disease trends. DGS has a national comprehensive electronic surveillance system, SINAVE (Sistema Nacional de Vigilância Epidemiológica). This system aims to interconnect hospitals, laboratories, physicians and public health authorities of all levels. The DES is also part of the national crisis management team, providing surveillance experts to assist with epidemiological investigations of national, regional or local outbreaks. DES collaborates with other entities and experts to design and implement public health emergency plans for public health threats, including the 2019-novel coronavirus. Due to its expertise on the area, the main researchers are part of DEE/DSIA.

At the national level, DGS will actively participate in the I-MOVE-COPID-19 WP2, WP3 and WP4, mainly through implementation of activities to strengthen preparedness, surveillance, infection control and case management at primary care and hospital networks. Furthermore, we will also

support the adaptation of the surveillance protocols, collaborating in their monitoring process. Even though all laboratory diagnosis of specimens collected within the networks will be performed or coordinated by INSA, DGS will gather all the information within the system, linking clinical and laboratory data. DGS will also collaborate in WP4 through the design, implementation, analysis and interpretation of epidemiological studies. DGS will be a member of the Steering-Scientific Committee.

1.1.2 Personnel involved

1.1.3 5 relevant publications/services/achievements

Sentís A, Vasconcelos P, Machado RS, et al. Failure to complete treatment for latent tuberculosis infection in Portugal, 2013-2017: geographic-, sociodemographic-, and medical-associated factors [published online ahead of print, 2019 Dec 3]. Eur J Clin Microbiol Infect Dis. 2019;10.1007/s10096-019-03765-y. doi:10.1007/s10096-019-03765-y

Augusto Gonçalo Figueiredo, Cruz Diogo, Silva Andreia, Pereira Natália, Aguiar Bárbara, Leça Ana, Serrada Elisabete, Valente Paula, Fernandes Teresa, Guerra Fernando, Palminha Paula, Vinagre Elsa, Lopo Sílvia, Cordeiro Rita, Sáez-López Emma, Neto Maria, 5.1.2e Jorge, Freitas Graça. Challenging measles case definition: three measles outbreaks in three Health Regions of Portugal, February to April 2018. Euro Surveill. 2018;23(28):pii=1800328.

Citation style for this article: Augusto Gonçalo Figueiredo, Silva Andreia, Pereira Natália, Fernandes Teresa, Leça Ana, Valente Paula, Calé Etelvina, Aguiar Bárbara Andreia, Martins António, Palminha Paula, Vinagre Elsa, Cordeiro Rita, Lopo Sílvia, 5.1.2e Jorge. Report of simultaneous measles outbreaks in two different health regions in Portugal, February to May 2017: lessons learnt and upcoming challenges. Euro Surveill. 2019;24(3):pii=1800026.

Duarte G, Williams CJ, Vasconcelos P, Nogueira P. Capacity to report on mortality attributable to chronic hepatitis B and C infections by Member States: An exercise to monitor progress towards viral hepatitis elimination. J Viral Hepat. 2018;25(7):878–882. doi:10.1111/jvh.12882

Ndumbi P, Freidl GS, Williams CJ, et al. Hepatitis A outbreak disproportionately affecting men who have sex with men (MSM) in the European Union and European Economic Area, June 2016 to May 2017. Euro Surveill. 2018;23(33):1700641. doi:10.2807/1560-7917.ES.2018.23.33.1700641

1.1.4 5 previous projects

EU Joint Action InfAct (Information for Action) – This JA aims to build a sustainable solid infrastructure on EU HI through improving the availability of comparable, robust and policy-relevant health status data and health system performance information. Through country collaboration, the JA streamlines health information activities, reduces the data collection burden and works for a sustainable and robust data collection in Europe that facilitates and supports country knowledge, health research and policy making.

EU Joint Action Health Equity Europe (JAHEE) – JAHEE improve health and well-being of European citizens and achieve greater equity in health outcomes across all groups in society in all participants countries and in Europe at large. In addition, JAHEE will also include a specific focus on both vulnerable groups and migrants. DEE/DSIA collaborates in WP7 in monitoring and evaluation of migrant's health in Portugal.

EU Joint Action SHARP - The EU JA SHARP (Strengthened International HeAlth Regulations and Preparedness in the EU) is a Joint Action to strengthen preparedness in the EU against serious cross-border threats to health and support the implementation of the International Health Regulations. It is financed through EU DG Sante.

RICA – The Project RICA (Repositório de Informação Clínica Anonimizada, Anonymized Repository of Clinical Information) is a joint Project of SPMS (Shared Services of the Ministry of health) and ACSS (Central Administration of the Health System) that aims to gather anonymized clinical health information of every patient in order to link data from different databases in one virtual place. This will bring a more secure and integrated process.

BI MH – DEE/DSIA is part of a working group that aims to improve the outputs of BIMH. Hospital morbidity (BDMH) database, run by Central Administration of the Health System (Administração Central do Sistema de Saúde, ACSS), which includes demographic and administrative data on all admissions and discharges from all National Health Service hospitals in Portugal, including Autonomous Regions and social sector. Data of BDMH describes hospital morbidity, supports

health institutions regarding financing, contracting and billing, and can be used to support epidemiological or economic research.

1.1.5 Significant infrastructure and/or any major items of technical equipment relates to the proposal

DGS plays a central role in preparedness and response to potential health threats, national epidemiological surveillance and the implementation of prevention and control measures. DGS connects the whole Health System for public health purposes, produces and disseminates technical guidelines and gathers information for epidemiological surveillance matters. The Director-General of Health is the National Health Authority.

DGS owns a mortality surveillance system (eVM, vigilância diária da mortalidade) and a communicable disease system (SINAVE). DGS is well associated and actively participates in communicable diseases networks in Europe, including ECDC, WHO and EFSA.

4.1.1 Partner name: THE CHANCELLOW, MASTERS AND SCHOLARS OF THE UNIVERSITY OF OXFORD (UOXF) - UK - participant no18

1.1.1 Description of the legal entity

Oxford is a world-leading centre of learning, teaching and research and the oldest university in the English-speaking world.

UOFX will participate in I-MOVE-COVID-19 WP2 by providing data from RCGP and will be member of the Steering-Scientific Commitee.

1.1.2 Personnel involved

5.1.2e

1.1.3 5 relevant publications/services/achievements

1. Pebody RG, Whitaker H, Ellis J, Andrews N, Marques DFP, Cottrell S, Reynolds AJ, Gunson R, Thompson C, Galiano M, Lackenby A, Robertson C, O'Doherty MG, Owens K, Yonova I, Shepherd SJ, Moore C, Johnston J, Donati M, McMenamin J, Lusignan S, Zambon M. End of season influenza vaccine effectiveness in primary care in adults and children in the United Kingdom in 2018/19. Vaccine. 2019 Nov 1. pii: S0264-410X(19)31460-4. doi: 10.1016/j.vaccine.2019.10.071.
2. de Lusignan S, Borrow R, Tripathy M, Linley E, Zambon M, Hoschler K, Ferreira F, Andrews N, Yonova I, Hriskova M, Rafi I, Pebody R. Serological surveillance of influenza in an English sentinel network: pilot study protocol. BMJ Open. 2019 Mar 8;9(3):e024285. doi: 10.1136/bmjopen-2018-024285.
3. de Lusignan S, Correa A. Opportunities and challenges of a World Serum Bank. Lancet. 2017 Jan 21;389(10066):250-251. doi: 10.1016/S0140-6736(17)30046-6.

4. de Lusignan S, Correa A, Pebody R, Yonova I, Smith G, Byford R, Pathirannehelage SR, McGee C, Elliot AJ, Hriskova M, Ferreira FI, Rafi I, Jones S. Incidence of Lower Respiratory Tract Infections and Atopic Conditions in Boys and Young Male Adults: Royal College of General Practitioners Research and Surveillance Centre Annual Report 2015-2016. JMIR Public Health Surveill. 2018 Apr 30;4(2):e49. doi: 10.2196/publichealth.9307.
5. de Lusignan S, Correa A, Smith GE, Yonova I, Pebody R, Ferreira F, Elliot AJ, Fleming D. RCGP Research and Surveillance Centre: 50 years' surveillance of influenza, infections, and respiratory conditions. Br J Gen Pract. 2017 Oct;67(663):440-441. doi: 10.3399/bjgp17X692645.

1.1.4 5 previous projects

Below are relevant European funded projects.

Title: HealthPros
Funder: H2020, Marie Skłodowska-Curie actions
Period 2017-21

Title: I-Move+
Funder: H2020
Period 2013-19

Title MOCHA - Models of Child Health Appraised
Awarding body EU Horizon 2020
Period 2015-18

Other relevant funded project:

Title: Royal College of General Practitioners (RCGP), Research and Surveillance Centre (RSC) quinquagenarian (QQG) practice network. Creating a longitudinal linked sentinel database of 50 years clinical and virology data and prospective research platform.
Awarding body: Wellcome Trust - Biomedical Resources
Period: 2019-22

Title: Serological and virological surveillance of influenza in older adults
Awarding body: HPRU NIHR
Period: 2019-2020

1.1.5 Significant infrastructure and/or any major items of technical equipment relates to the proposal

The RCGP Research and Surveillance Centre (RSC) is an internationally renowned source of information, analysis and interpretation of primary care data. Established in 1957, the RSC is an active research and surveillance unit that collects and monitors data, in particular influenza, from over 500 practices across England. In 2017 the RSC celebrated 50 years of weekly influenza surveillance and reporting, a landmark anniversary. The dataset is nationally representative, having only small differences with the national population, which have now been quantified and can be assessed for clinical relevance for specific studies. With twice weekly data extractions, the dataset is one of the most up to date in the UK. The University of Surrey (now in University of Oxford) is the data processing hub for the RCGP RSC, receiving a weekly data upload of routinely collected data from practices in the network. This is held in a secure server, compliant with the UK's Department of Health information governance policies and standards, and only accessed by approved researchers.

The live-attenuated influenza vaccination (LAIV) project - The RSC works with Public Health England and the University of Surrey (now University of Oxford) on the pilot of a universal childhood (LAIV) programme. The UK initiated a universal childhood immunisation programme with a newly licensed intransally-administered trivalent LAIV in the 2013/14 influenza season.

Flu virology scheme - Some RSC practices are included in the flu virology specimen scheme. These practices provide nasal and throat specimens during the flu season each year from patients clinically suspected of having flu. This helps to establish which strain of the flu is dominant in the current season and likely to be dominant the following flu season and how the flu vaccine can be improved to target these specific strains

Serology pilot - The RSC is working with Public Health England and the University of Surrey (now University of Oxford) to pilot a method for provision of nationally representative serum samples and associated patient data to measure sero-positivity and seroincidence due to seasonal influenza and other infections of public health importance, and create a population- based serology bank for investigation of other important infections. Rapidly undertaken age-stratified serology studies can produce valuable data about a new emerging infection including back-ground population immunity and seroincidence during an influenza pandemic.

Variable	Count (N)
Currently registered patients	4,154,924
Patients ever registered	10,139,172
Events (consultations or other interactions with patients)	3,037,072,232
Prescriptions	1,348,184,434
BMI Measurements	28,151,807
Blood Pressure Readings	57,988,047
HbA1c measures	9,804,470
Excluded Patients (opted out of record sharing , not analysed)	250,351
Current registered patients 90+yrs	38,418
Current registered patients 65+yrs	755,494
Patients ever registered 90+yrs	623,212
Patients ever registered 65+yrs	2,305,408

4.1.1 Partner name: Institute of Public Health (Instituti i Shendetit Publik) - Albania - participant no19

1.1.1 Description of the legal entity

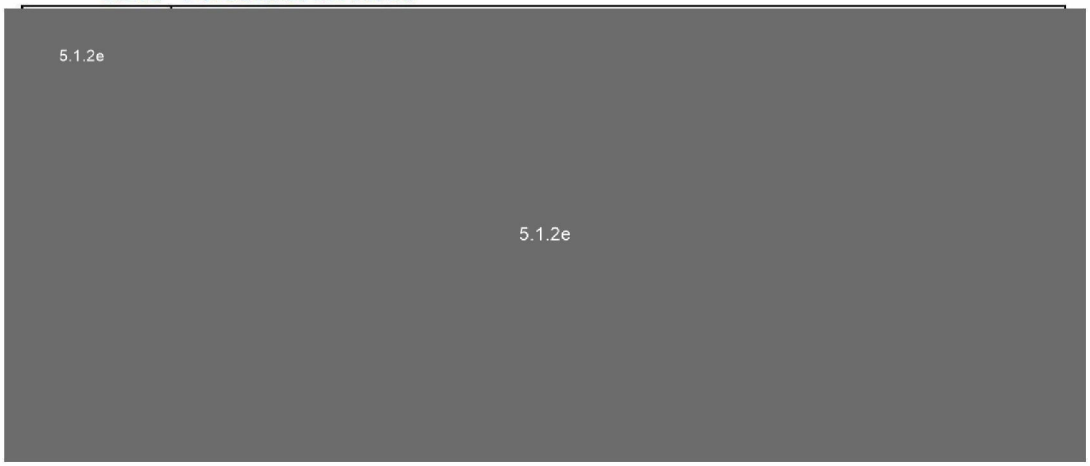
IPH is the only coordinating center on public health in Albania aiming to protect the Albanian population from infectious agents, hazards and disability. Department of Epidemiology and Control of Infectious Diseases (DECID) of the Institute of Public Health, pilotes the national coordination center on surveillance and control of infectious diseases including also the unit of emerging pathogens virological surveillance and virology laboratory , where the National Reference Centre for influenza and other respiratory viruses is established.

DECID is the national center for surveillance, outbreak investigation and control of emerging respiratory viruses including coronaviruses. It is coordinating the South East European (SEE) network on Influenza surveillance and control and pandemic preparedness. In 2009 a hospital-based sentinel Severe Acute Respiratory Infection Surveillance was established and strengthened in 2013 -2017. DECID is the leading department to coordinate preparedness to COVID-19 infection in Albania.

DECID will participate in Work Package 3 and will:

1. Contribute show on how to adapt and strengthen SARI and Pneumonia surveillance to rapidly detect and report severe (hospitalized) 2019-nCoV cases.
2. Contribute to the adaptation of generic SARI and Pneumonia hospital surveillance protocols and test how flexible they are to rapidly adapt to a new epidemiological context (e.g. increased severe disease incidence.
3. Contribute to the description of suspected and confirmed severe disease cases
4. In collaboration with sentinel hospitals will contribute to strengthen their preparedness and hospital surveillance to respond to 2019-nCoV.

1.1.2 Personnel involved



5.1.2e

1.1.3 5 relevant publications/services/achievements

1. 5.1.2e Under detection of laboratory-confirmedinfluenza-associated hospital admissions among infants: a multicentre, prospective study. Lancet Child and Adolescent Health 2019 Nov;3(11):781-794
2. 5.1.2e Program cost analysis of Influenza vaccination of health care workers in Albania. Vaccine. 2020 Jan 10;38(2):220-227.
3. 5.1.2e 5.1.2e Influenza and respiratory syncytial virus in infants study (IRIS) of hospitalized and non-ill infants aged <1 year in four countries: study design and methods.BMC Infectious Diseases 2017 Mar 22;17(1):222
4. 5.1.2e 5.1.2e Southeastern European Health Network (SEEHN) communicable disease surveillance; a decade of bridging trust and collaboration. Emerg Health Threats J. 2013;6.. Epub 2013 Jan 25.
5. 5.1.2e 5.1.2e 5.1.2e Surveillance for severe acute respiratory infections (SARI) in hospitals in the WHO European region – an exploratory analysis of risk factors for a severe outcome influenza- positive SARI cases.BMC Infect Dis. 2015 Jan 8;15:1. doi: 10.1186/s12879-014-0722-x.

1.1.4 5 previous projects

1. Crimean Congo Hemorrhagic Fever;Modern Approaches to Diagnostics,Surveillance, Prevention, Therappy and Preparedness Grant agreement number no:260427
2. EDENext (Biology and control of vector-borne infections in Europe) a major research project in the 7th Framework Programme for Research and Technological Development (FPRT).
3. Surveillance and Response to Avian and Pandemic Influenza by National Health Authorities outside the United States funded by Centers for Disease Control and Prevention. 2013 -2019. And in collaboration with South East European Center for Infectious Diseases Surveillance and Control (SECID)
4. Surveillance and Response to Avian and Pandemic Influenza by National Health Authorities outside the United States funded by Centers for Disease Control and Prevention. 2019 -2021. And in collaboration with South East European Center for Infectious Diseases Surveillance and Control (SECID). SARI surveillance activities including sample collection and data management are included in this project.

5. Timeliness of detection and response in selected diseases and countries of South East Europe. 2016- 2018. And in collaboration with South East European Center for Infectious Diseases Surveillance and Control (SECID). A web based system developed to be used for SARI surveillance and other surveillance systems
6. Part of the MediLabSecure project aiming at consolidating a Laboratory Network on the emerging viruses that are pathogens for humans and/or animals. The project ensures quality assurance for different coronaviruses.

1.1.5 Significant infrastructure and/or any major items of technical equipment relates to the proposal

Laboratory capacities

The laboratory is hosting three BSL-2 units and one BSL- 2 plus with a BSL3 hood and it is well equipped with PCR machines other equipments. The lab is dedicated to diagnosis of human infectious diseases caused mainly by emergent viral diseases and undergoes quality assurance for various coronaviruses, influenza and other respiratory viruses.

4.1.1 Partner name: National Institute for Public Health and the Environment (RIVM), Netherlands - participant no20

1.1.1 Description of the legal entity

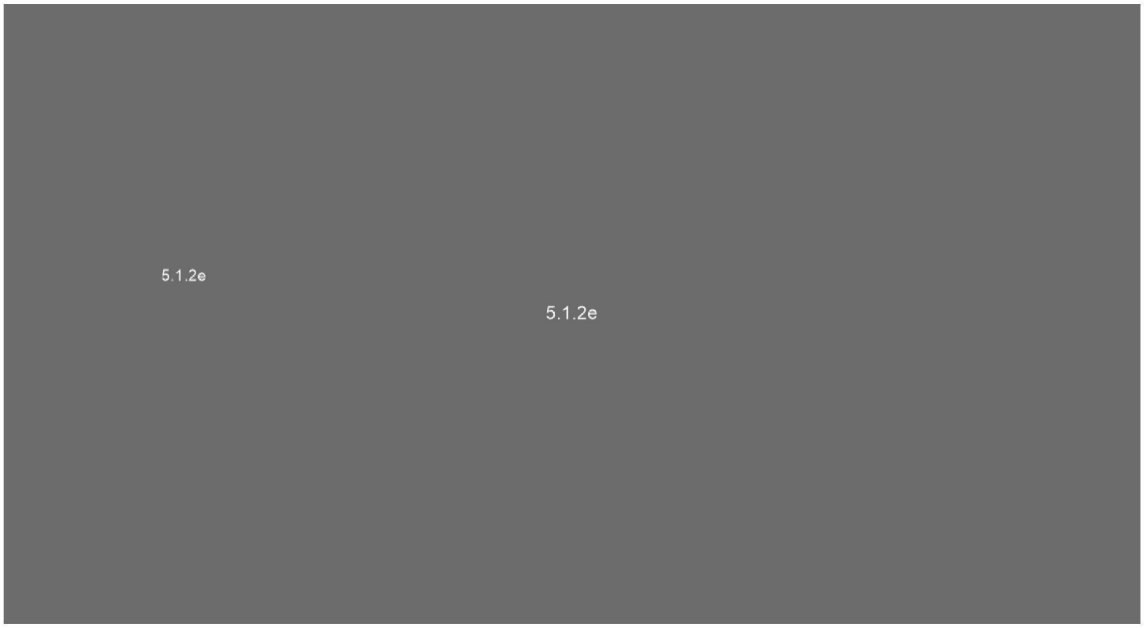
The National Institute for Public Health and the Environment (RIVM) is an agency under the Ministry of Health, Welfare and Sports with a central role in infectious disease control and national prevention and population screening programmes. RIVM conducts independent (scientific) research in the field of Public Health, Health Services, Environmental Safety and Security. This is organised in 12 centres. Three of the RIVM centres are actively involved in the response to the novel coronavirus COVID-19. The National Coordination Centre for Communicable Disease Control is responsible for rapid and efficient communication about COVID-19, scientific advice on control measures to the government and for implementation by health professionals. The Centre for Epidemiology and Surveillance of Infectious Diseases analyses and monitors the occurrence and trends in COVID-19 in the Netherlands and worldwide and is responsible for studies on the effectiveness and cost-effectiveness of control measures. The Centre for Infectious Diseases Research, Diagnostics and Laboratory Surveillance (IDS) is the only laboratory, together with the Erasmus Medical Centre (Rotterdam) (EMC), that carries out patient diagnostics of COVID-19 in the Netherlands in the current phase of the epidemic. IDS coordinates a network of Outbreak Assistance Laboratories that is being prepared for COVID-19 testing when the epidemic hits the Netherlands and the demand for testing exceeds the capacity of the central labs.

As a national health institute, RIVM is actively involved in assessing and evaluating case definitions for national as well as international surveillance, i.e. with ECDC, and WHO. RIVM (co-)coordinates several European research and surveillance projects on respiratory infections, including influenza and RSV.

RIVM will participate in I-MOVE-COVID-19 WP2 (Primary care surveillance network) and in WP4 (studies based on pooled analysis). The Dutch primary care (influenza) surveillance network is one of the oldest in the world, existing for more than 50 years. It is an effective collaboration between RIVM, NIVEL Netherlands institute for health services research, and the EMC (RIVM and EMC together being the National Influenza Centre for WHO). RIVM will participate in the project with top international expertise in the fields of virology, epidemiology, and mathematical modelling. RIVM will be a member of the I-MOVE-COVID-19 Steering-scientific committee.

1.1.2 Personnel involved

5.1.2e



1.1.3 5 relevant publications/services/achievements

Backer JA, Wallinga J, 5.1.2e, Donker GA, van der Hoek W, van Boven M (2019). The impact of influenza vaccination on infection, hospitalisation and mortality in the Netherlands between 2003 and 2015. Epidemics, 26, 77-85.

Corman VM, Landt O, Kaiser M, Molenkamp R, 5.1.2e, Chu DK, Bleicker T, Brünink S, Schneider J, Schmidt ML, Mulders DG, Haagmans BL, van der Veer B, van den Brink S, Wijsman L, Goderski, Romette JL, Ellis J, Zambon M, Peiris M, 5.1.2e, Reusken C, Koopmans MP, Drosten C. Detection of 2019 novel coronavirus (COVID-19) by real-time RT-PCR. Euro Surveill. 2020 Jan;25(3). doi: 10.2807/1560-7917.ES.2020.25.3.2000045.

5.1.2e, Beerens A, Claas E, Hermans 5.1.2e A, Molenkamp R, Niesters H, Overduin P, Rossen J, Schuurman R, Wolffs P, Fouchier R, Osterhaus A, Schutten 5.1.2e M. Preparing the outbreak assistance laboratory network in the Netherlands for the detection of the influenza virus A(H1N1) variant. J Clin Virol. 2009 Jul;45(3):179-84. doi: 10.1016/j.jcv.2009.06.003.

5.1.2e, Swaan CM, Voerknecht M, Jusic E, van den Brink S, Wijsman LA, Voordouw BC, Donker GA, Sleven J, Dorigo-Zetsma WW, Svraka S, van Boven M, Haverkate MR, Timen A, van Dissel JT, Koopmans MP, Bestebroer TM, Fouchier RA (2018). Case of seasonal reassortant A(H1N2) influenza virus infection, the Netherlands, March 2018. Euro Surveillance, 23(15). doi: 10.2807/1560-7917.ES.2018.23.15.18-00160.

Teirlinck AC, de Gier B, 5.1.2e, Donker G, de Lange M, Koppeschaar C, van der Hoek W, Kretzschmar ME, McDonald SA (2018). The incidence of symptomatic infection with influenza

virus in the Netherlands 2011/2012 through 2016/2017, estimated using Bayesian evidence synthesis. Epidemiology and Infection, https://doi.org/10.1017/S095026881800273X.

Zhang L, Pan Y, Hackert V, van der Hoek W, 5.1.2e, Yang P, Wang Q (2018). The 2015-2016 influenza epidemic in Beijing, China: unlike elsewhere, circulation of influenza A(H3N2) with moderate vaccine effectiveness. Vaccine, 36: 4993-5001.

1.1.4 5 previous projects

RIVM, 5.1.2e have been involved in:

1. I-MOVE: RIVM is participating in the I-MOVE programme since its inception some 10 years ago.
2. 'Integrated monitoring of vaccine effects in Europe: a platform to measure and compare effectiveness and impact of influenza and pneumococcal vaccines and vaccination strategies in the elderly (I-MOVE-plus)', a Horizon2020 project, in which RIVM actively participated in primary care and hospital-based studies, and impact assessments.
3. 'REspiratory Syncytial virus Consortium in Europe (RESCEU)', a Horizon2020 IMI project coordinated by the University of Edinburgh, in which RIVM is responsible for the task of improving RSV surveillance in Europe, together with SSI Denmark and ECDC.
4. 'Accelerated Development of VAccine beNefitrisk Collaboration in Europe (ADVANCE)', also an IMI project in which RIVM was leading the task on inventory, appraisal and extension of vaccine effectiveness assessment methods to make results more rapidly available.
5. 'Vaccines and InfecTious diseases in the Ageing popuLation (VITAL)', an ongoing IMI project with the University Medical Center (UMC) Utrecht as the managing entity and 5.1.2e 5.1.2e of RIVM 5.1.2e

1.1.5 Significant infrastructure and/or any major items of technical equipment relates to the proposal

5.1.2e

5.1.2e Currently all samples submitted for COVID-19 analysis in the Netherlands are split and simultaneously tested at RIVM and at Erasmus University Rotterdam. 5.1.2e

5.1.2e

5.1.2e (see publication under 1.2.3). The Erasmus Medical Centre (Rotterdam) (EMC) is not involved in the project.

4.1.1 Partner name: Institut national de la santé et de la recherche médicale (Inserm), France - participant no21

1.1.1 Description of the legal entity

Created in 1964, INSERM is a public scientific and technological establishment, placed under the dual supervision of the Ministry of Health and the Ministry of Research. Dedicated to biological, medical and human health research, it is positioned on the entire journey from the research laboratory to the patient's bed. On the international scene, it is the partner of the largest institutions engaged in the challenges and scientific progress of these fields.

INSERM brings together 15,000 researchers, engineers, technicians and administrative staff, with a common objective: improving the health of all by advancing knowledge of living things and diseases, innovation in treatments and public health research.

The Clinical Research Department of INSERM assists researchers to ensure the feasibility, quality and correct implementation of their research, that regulatory texts are complied with and research participants are protected. To achieve this, as a sponsor INSERM:

a. Evaluates the clinical and health research projects that researchers present to it.

b. Prepares the necessary documents for submitting the project to the health authorities (Ethical Research Committee and Competent Authorities).

c. Takes out civil liability insurance to protect and possibly compensate participants in the research, prepares the information documents on the research and consent that all participants in clinical and health research must sign, together with patients' associations.

d. Records and possibly declares any adverse events that arise during a research project to the health authorities.

e. Directly or by delegation ensures the proper implementation and quality of the research through regular visits to the investigation sites.

f. Ensures the implementation of its commitments in terms of transparency policy.

INSERM participates in I-MOVE-COVID-19 on the WP3 and WP4 (hospital studies) through the scientific coordination of the five structures in France:

- **CIC 1417 Cochin Pasteur**, located in Cochin Hospital (Assistance Publique – Hôpitaux de Paris)
- **CIC 1425 Bichat**, located in Bichat-Claude Bernard hospital (Assistance Publique – Hôpitaux de Paris)
- **CIC Montpellier**, located in Montpellier University Hospital
- **CIC Rennes**, located in Rennes University Hospital
- **Department of Hygiene, Epidemiology and Prevention**, located in Hospices Civils of Lyon

The data to be collected for the I-MOVE-COVID-19 project are provided in the amendment of the FLUVAC study, sponsored in France by INSERM since 2011.

The 5 sites are selected following several criteria:

- Ø Strong experience in participation in I-MOVE+ project,
- Ø High representation on French territory of the patients hospitalized for COVID-19,
- Ø Efficient screening strategy by their participation to FLUVAC studies since 2011,
- Ø Implication of the physicians and other staff,
- Ø Involvement of several departments for recruitment of patients in each of hospitals.

The strengths and the values offered by the 5 sites are an expertise in designing, implementing and regulating phase 1-4 clinical studies in the fields of vaccinology including influenza and other respiratory pathogens, or HIV.

These 5 sites are part of the **I-REIVAC network** (Innovative clinical research network in vaccinology). The REIVAC, created in 2007 by INSERM, became I-REIVAC in 2014 following its certification by the infrastructure F-CRIN (French Clinical Research Infrastructure Network).

I-REIVAC is a strong network of clinicians in 27 French hospital departments with high expertise in vaccination, vaccine coverage and in human and social science to understand levers and breaks of vaccination. I-REIVAC coordinated more 81 academic and industrial studies from phase I to IV and managed the regulatory and financial aspects.

Since 2011, the I-REIVAC and the CIC 1417 coordinate **FLUVAC** studies on influenza vaccine effectiveness whose sponsor is INSERM. This is a Phase IV study evaluating the efficacy of seasonal influenza vaccination against hospitalized flu. 7 centres have participated the first year with 239 patients enrolled and the combined analysis of the data was carrying out by EPICONCEPT. In 2012/2013, this study has been enlarged to an international level, and involved 5 REIVAC centres for France. These studies complement the already existing framework for influenza surveillance in France and could not be achieved without the co- ordination by the I-REIVAC. French data are shared in France with « Santé Publique France » institute and also with « WHO ».

Also, these studies are conducted within the framework of a European and international surveillance networks using a generic protocol. Furthermore, these data are pooled with European data for the vaccine effectiveness evaluation at European level.

1.1.2. Personnel involved

5.1.2e

1.1.3. 5 relevant publications/services/achievements

1 FLUVAC Study Group. Non-**influenza** respiratory viruses in adult patients admitted with **influenza**-like illness: a 3-year prospective multicenter study. Infection. 2020 Feb 13. doi: 10.1007/s15010-019-01388-1.

2 I-MOVE Hospital study team. Vaccine effectiveness against influenza A(H3N2) and B among laboratory-confirmed, hospitalised older adults, Europe, 2017-18: A season of B lineage mismatched to the trivalent vaccine. Influenza Other Respir Viruses. 2020 Feb 5. doi: 10.1111/irv.1271

3. InNHOVE/I-MOVE+working group, Moren A. Repeated seasonal influenza vaccination among elderly in Europe : Effects on laboratory confirmed hospitalised influenza.Vaccine. 2017 Aug 3;35(34):4298-4306. doi: 10.1016/j.vaccine. 2017.06.088. Epub 2017 Jul 11

4. I-MOVE+ hospital working group, 2015/16 seasonal vaccine effectiveness against hospitalisa- tion with influenza A(H1N1)pdm09 and B among elderly people in Europe: results from the I-MOVE+ project Eurosurveillance. 2017 Jul 27;22(30). pii: 30580. doi: 10.2807/1560-7917.ES.2017.22.30.30580.

5 FLUVAC Study Group. J Clin Virol. **2016** Jun;79:68-73.do i: 10.1016/j.jcv. **2016**.04.005. Epub **2016** Apr 12.

1.1.4. 5 previous projects

1. Project FLUVAC EV-01/02/03: Efficiency in Population of Influenza Vaccination for Seasonal 2011-2012/ 2012-2013/ since 2013 for Flu Prevention of the Hospitalized Adults: an Observational Study.

2. Randomized phase II study evaluating the immunogenicity and tolerance of influenza vaccine (H1N1) adjuvanted and v influenza A (H1N1) v non-adjuvanted in patients infected with HIV, HIFLUVAC Study.
3. Phase II study evaluating the immunogenicity and safety of a vaccine inactivated non-adjuvanted against influenza A (H1N1) v in pregnant women, PREFLUVAC Study.
4. A randomized, placebo controlled trial evaluating the efficacy and safety of influenza vaccination in subjects treated with immunosuppressants for chronic inflammatory bowel disease (IBD), MICIVAX Study.
5. Cohort study evaluating the clinical expression and impact Maternal-fetal influenza A/H1N1survenant during the pregnancy, COFLUPREG Study.

1.1.5. Significant infrastructure and/or any major items of technical equipment relates to the proposal

Through the participation in projects such as FLUVAC and I-MOVE since several years, CIC 1417 has developed an expertise and hands on experience in several infectious diseases projects.

The project will be performed in collaboration with all clinical departments including emergency, intensive care units and virological departments.
The CIC 1417 will provide the project with clinical, vaccine, … data and expertise on respiratory disease monitoring.

From a logistic point of view, our laboratory works with quality assurance procedures in the respect of good laboratory practice or GLP.
Our laboratory refers to a control quality system for research laboratories to ensure the uniformity, consistency, reliability, reproducibility, quality, and integrity of tests. It undertakes routine influenza and other respiratory virus testing using RT-PCR technique.

4.1.1 Partner name: Vrije Universiteit Brussel (VUB), Belgium - participant no22

1.1.1 Description of the legal entity

Vrije Universiteit Brussel (VUB) is a competitive, high-quality, socially committed and internationally oriented university located in Brussels, Belgium. It counts 4 campuses in Brussels, 8 faculties and 193 research groups around 9 strategic research clusters: 1) big data, 2) brain & behaviour, 3) city dynamics, 4) environmental issues, 5) fighting diseases, 6) small particles, 7) smart engineering, 8) societal challenges, and 9) the circle of life. In 2018, VUB ranked #47 in Reuters' Most Innovative Universities Top 100 in Europe, it has 127 active patent families and disclosed 40 inventions. VUB accommodates 3 doctoral schools (Human Sciences, Natural Sciences and (Bioscience) Engineering, and Life Sciences and Medicine) that cater to the needs of its more than 1,600 PhD students (2017: 1,677). Additionally, the university provides high-quality education in all academic fields to more than 16,000 BA and MA students (2017: 16,094). VUB is an active participant in European R&I projects, Horizon 2020 in particular. There are currently about 120 running R&I projects at VUB.

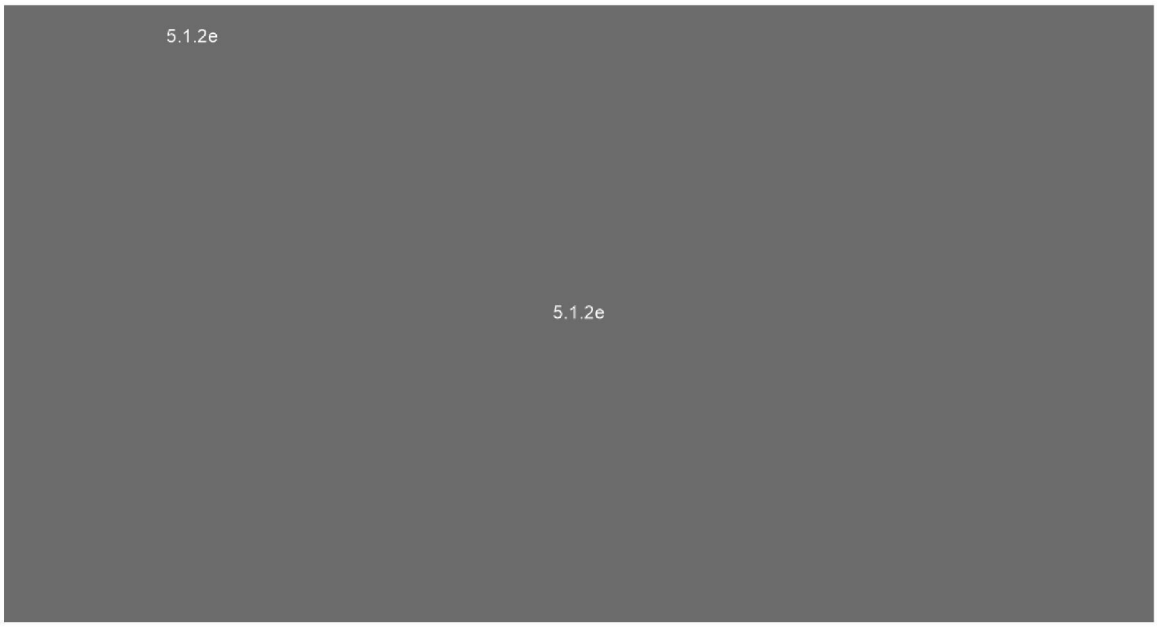
Our center, **the UZ Brussel hospital**, is a university hospital linked to the VUB (Vrij Universiteit Brussel) university, in Brussels. It is a clinical centre of secondary and tertiary level. Our department of internal medicine includes one of the Belgian HIV-reference centres, a centre for Travel Medicine, and an infectiology clinic. We work very closely with the Department of Microbiology of our hospital. Our team of infectiologists have been leading the management of the COVID-19 pandemic at the level of our hospital, hand in hand with other acute units such as the Intensive Care department and the Emergency department, and the hospital laboratories.

Since 2014, our hospital's ethics committee has acted as the central committee for the Belgian surveillance study on influenza, of which we are one of the sentinelle hospitals, and which is coordinated by 'Sciensano', the Belgian Public Health Institute.

Being at the frontline of the COVID-19 epidemic at the hospital level, we are also well placed to collect the clinical data needed for I-MOVE-COVID 19 network, within work packages 3 and 4.

1.1.2. Personnel involved

5.1.2e



1.1.3. 5 relevant publications/services/achievements

Local Principal investigator for the 'DAWN-plasma' clincial trial: 'Donated antibodies working against nCoV'. EudraCT Nbr: 2020-001918-38

Sub-investigator for the 'SARPAC' clinical trial: A prospective, randomized, open-label, interventional study to investigate the efficacy of sargramostim (LeukineR) in improving oxygenation and short- and long-term outcome of COVID-19 patients with acute hypoxic respiratory failure. EudraCT n° 2020-001254-22

Sub-investigator for the 'COV-AID' clinical trial: A prospective, randomized, factorial design, interventional study to compare the safety and efficacy of combinations of blockade of interleukin-6 pathway and interleukin-1 pathway to best standard of care in improving oxygenation and short- and long-term outcome of COVID-19 patients with acute hypoxic respiratory failure and systemic cytokine release syndrome. EudraCT n° 2020-001500-41

Our centre is sentinelle hospital for the surveillance of influenza in Belgian, coordinated by Sciensano (Belgian Public health institute). The transmission of UZ Brussel Hospital data is coordinated by our infectious diseases team.

5.1.2e Federal pilote project on OPAT (outpatient parenteral antibiotic therapy), which is currently being investigated in Belgium, before its formal introduction into the health system. 5.1.2e
5.1.2e

1.1.4. 5 previous projects

Running projects:

Our centre is sentinelle hospital for the surveillance of influenza in Belgian, coordinated by *Sciensano* (Belgian Public health institute). Since 2014, our hospital has been the coordinating Ethics committee for this Belgian federal project. The transmission of UZ Brussel Hospital data is coordinated by our infectious diseases team, 5.1.2e The link with the ECDC is made through *Sciensano*.

5.1.2e Federal pilot projects on OPAT (outpatient parenteral antibiotic therapy), which is currently being investigated in Belgium before its formal introduction into the health system. This was a competitive application process, and gives an example of working with partners from different institutions and backgrounds.

The infectiology department of the UZBrussel hospital is one of the centers for the TANGO Study, a phase III, randomized, multicenter, parallel-group, non-inferiority study evaluating the efficacy, safety, and tolerability of switching to dolutegravir plus lamivudine in HIV-1 infected adults who are virologically suppressed. 5.1.2e 5.1.2e

1.1.5. Significant infrastructure and/or any major items of technical equipment relates to the proposal

Our hospital is JCI accredited, and has an accredited (NEN-EN-ISO 15189) microbiology laboratory, which performs PCR tests for COVID-19. No molecular characterisation or culture of SARS-CoV-2 virus is performed.

Our hospital's clinical research is coordinated by the Clinical Trial Center @UZBrussel, offering support and follow-up of clinical studies, such as the I-MOVE-COVID-19 project.

We will be the first Belgian hospital to participate in this network of European hospitals and public health institutes. We will bring input from an extra country in Europe, and will hopefully encourage other partners in Belgium to join in the future if at all possible. This can only add to the pool of European data to be able to reach critical numbers and publish meaningful and useful data for the scientific community.

4.1.1 Partner name: Assistance Publique – Hôpitaux de Paris, France - participant no23

1.1.1 Description of the legal entity

Created in 1849, Assistance Publique – Hôpitaux de Paris (APHP) is the largest university hospital center in Europe, federating 39 different hospitals and hospital groups, mainly located in Paris and its suburban area. It has more than 19,000 medical staff, 3000 hospital physicians including 1000 professors and more than 6000 residents and medical students. Moreover, APHP's 39 hospitals treat 8 million people every year, and cover all the major medical specialties, including rare diseases.
As a public health institution, APHP pursues 3 main missions: healthcare delivery, medical and paramedical teaching, and biomedical and clinical research. The group develops high-quality research activities, including European and International Research Projects.

Two sites belonging to APHP will participate:

- **CIC 1417 Cochin-Pasteur, located in Cochin Hospital**
- **CIC Bichat, located in Bichat-Claude Bernard Hospital**

CIC Cochin Pasteur

The CIC (Clinical research center) Cochin-Pasteur is a department of the APHP for the management of clinical studies in the fields of vaccinology and biotherapy in the field of infectious disease, internal medicine and oncology. It is the first and currently the only full-service public Research Organization in France dedicated to vaccinology. The CIC is a center of I-REIVAC (Innovative clinical research network in vaccinology). I-REIVAC is a network of 50 partners whose 20 hospitals that has objective to promote the excellence of the clinical research in vaccinology.

Since 2011, the I-REIVAC and the CIC coordinate FLUVAC studies (EV-01 pilot study in 2011/2012, EV-02 in 2012/2013 and EV-03 in 2013/2014) on influenza vaccine effectiveness whose sponsor is INSERM. These studies are conducted within the framework of a European surveillance network (I-move). This is a Phase IV study evaluating the efficacy of seasonal influenza vaccination against hospitalized flu. These studies complement the already existing framework for influenza surveillance in France and could not be achieved without the coordination by the REIVAC. 7 centres have participated the first year with 239 patients enrolled and the combined analysis of the data by EPICONCEPT. In 2012/2013, this study has been enlarged to an international level, and involved 5 REIVAC centres for France with 447 patients enrolled. In 2013/2014, 6 centres have participated with 420 patients enrolled. The REIVAC network has coordinated the French part of the study and the analysis of French data has been managed by the INSERM unit 770. The French data are pooled with all European data and analyzed by EPICONCEPT.

The CIC Cochin-Pasteur team is made up 6 physicians, 4 clinical study coordinators, 6 clinical research associates, 2 clinical research nurses and 2 secretaries. All the staff has years of expertise in the field of clinical research in vaccinology.

CIC Bichat

The multi-thematic CIC Bichat is implemented in a hospitalization department entirely dedicated to clinical research and translational research. The structure mostly works on five therapeutic areas: oncology, cardiology, diabetology, pneumology and infectious diseases, including influenza.

CIC Bichat is also a member of the I-REIVAC network, and participates in FLUVAC studies. It is located within Bichat-Claude Bernard Hospital (Paris), which is covering a catchment area of more than 800,000 persons and 340,000 consultations. Bichat Hospital has a total of 961 in about 45 services, including a highly developed emergency ward.

The CIC Bichat team is made up of a team of 18 people, including clinical study physicians, clinical research associates, clinical study technicians, clinical study nurses, health managers, project managers and quality managers. The whole staff has received an advanced training on good clinical research practices.

Involved in WP3 and hospital studies of the WP4, the AP-HP will recruit a large number of patients with COVID 1 and will provide data collection for the project and clinical research and translational research expertise.

1.1.2. Personnel involved

1.1.3. 5 relevant publications/services/achievements

Publications - More than 150 peer-rewieved articles and 32 with impact factor >5

Top ten papers (2009-2013) out of publications:

- 5.1.2e 5.1.2e 2011-12 seasonal influenza vaccines effectiveness against confirmed A (H3N2) influenza hospitalisation: pooled analysis from a European network of hospitals. A pilot study. PLoS One. 2013;8(4):e59681.
- 5.1.2e 5.1.2e Factors associated with humoral immune response to pandemic A/H1N1(v) 2009 influenza vaccine in cystic fibrosis.
- 5.1.2e 5.1.2e Inserm COFLUPREG Study Group. Low rate of pandemic A/H1N1 2009 influenza infection and lack of severe complication of vaccination in pregnant women: a prospective cohort study. PLosOne 2012; 7(12):e52303.
- 5.1.2e 5.1.2e Inserm C09-33 PREFLUVAC study group. Strong Immune Response of a Monovalent 2009 non-Adjuvanted Influenza A/H1N1v vaccine in pregnant women. Ann Intern Med 2011; 155(11):733-41.
- 5.1.2e 5.1.2e Safety and Immunogenicity of a Monovalent 2009 Influenza A/H1N1v Vaccine Adjuvanted with AS03A or Unadjuvanted in HIV-infected Adults: A Randomized, Controlled Trial. J Infect Dis 2011;204(1):124-134.

1.1.4. 5 previous projects

- Project FLUVAC EV-01/02/03: Efficiency in Population of Influenza Vaccination for Seasonal 2011-2012/ 2012-2013/ 2013-2014 for Flu Prevention of the Hospitalized Adults: an Observational Study.
- Cohort study evaluating the clinical expression and impact Maternal-fetal influenza A/H1N1survenant during the pregnancy, COFLUPREG Study.
- Phase II study evaluating the immunogenicity and safety of a vaccine inactivated non-adjuvanted against influenza A (H1N1) v in pregnant women, PREFLUVAC Study.
- Randomized phase II study evaluating the immunogenicity and tolerance of influenza vaccine (H1N1) adjuvanted and v influenza A (H1N1) v non-adjuvanted in patients infected with HIV, HIFLUVAC Study.

- Cohort study evaluating the clinical efficacy, tolerability and immunogenicity of the pandemic influenza vaccination in patients with cystic fibrosis and, where appropriate, the clinical expression of the influenza A (H1N1) and the factors associated with the occurrence severe forms in this population, Study MUCOFLU.

4.1.1 Partner name: CIC St Eloi - Centre Hospitalier Universitaire de Montpellier - France - participant no24

1.1.1 Description of the legal entity

The **Centre Hospitalier Universitaire Montpellier (CHUM)** is structured around 13 university-medical departments, closely connected with organisational services that allow the whole institution to carry out its 3 essential missions: health care, education and medical research.

The CHUM ranks 6 th amongst French hospitals for medical research productivity (SIGAPS' rank) : 1803 on-going clinical trials with 341 promoted by CHUM, 5 339 papers, 46 active patents, 17 technological infrastructures, 7 rare disease reference networks and 6 spin-off companies which recently emerged from its research activities.

The CIC (Clinical research center) of Montpellier is a department of ''Centre Hospitalier Universitaire de Montpellier'' for the management of clinical studies in several fields, particularly diabetes & metabolism, neurosciences, infectious diseases and pediatrics. It has a particular interest in research in vaccinology. The CIC has been a member of REIVAC then I-REIVAC (Innovative clinical research network in vaccinology) since their creation in 2008. I-REIVAC is a network of 50 partners whose 20 hospitals aim at promoting the excellence of clinical research in vaccinology.

Since 2011, the I-REIVAC and the CIC have been coordinating FLUVAC studies (EV-01 pilot study in 2011/2012, EV-02 in 2012/2013 and EV-03 in 2013/2014) on influenza vaccine effectiveness whose sponsor is INSERM. These studies are conducted within the framework of a European surveillance network (I-move). They are Phase IV studies evaluating the efficacy of seasonal influenza vaccination against hospitalized influenza. These studies complement the already existing framework for influenza surveillance in France and could not be achieved without the coordination by the REIVAC. Seven centers have participated the first year with 239 patients enrolled and the combined analysis of the data by EPICONCEPT. In 2012/2013, this study has been enlarged to an international level, and involved 5 REIVAC centers for France with 447 patients enrolled. In 2013/2014, 6 centers have participated with 420 patients enrolled. The REIVAC network has coordinated the French part of the study and the analysis of French data has been managed by the INSERM unit 770. The French data are pooled with all European data and analyzed by EPICONCEPT.

The research team of Montpellier CIC includes 3 physicians, 5 projects managers and 4 clinical research nurses. All the staff has expertise and training in the field of clinical research in vaccinology.

Involved in WP3 and hospital studies of the WP4, the CHUM will recruit a large number of patients with COVID 1 and will provide data collection for the project.

1.1.2. Personnel involved

5.1.2e

5.1.2e

1.1.3. 5 relevant publications/services/achievements

- Loulergue P, Galtier F, Valette M, Lenzi N, Postil D, Tattevin P, Lucht F, Laurichesse H, Duval X, Lina B, Launay O. Low influenza vaccine effectiveness during 2011-2012 season and mismatch between circulating virus, and vaccine strains: a Fluvac virological sub study. Submitted in J Clin Virol.
- Falsey AR, McElhaney JE, Beran J, van Essen GA, Duval X, Esen M, Galtier F, Gervais P, Hwang SJ, Kremsner P, Launay O, Leroux-Roels G,McNeil SA, Nowakowski A, Richardus JH, Ruiz-Palacios G, St Rose S, Devaster JM, Oostvogels L, Durviaux S, Taylor S. Respiratory syncytial virus and other respiratory viral infections in older adults with moderate to severe influenza-like illness. J Infect Dis. 2014 Jun 15; 209(12):1873-81.
- McElhaney JE, Beran J, Devaster JM, Esen M, Launay O, Leroux-Roels G, Ruiz-Palacios GM, van Essen GA, Caplanusi A, Claeys C, Durand C, Duval X, El Idrissi M, Falsey AR, Feldman G, Frey SE, Galtier F, Hwang SJ, Innis BL, Kovac M, Kremsner P, McNeil S, Nowakowski A, Richardus JH, Trofa A, Oostvogels L; Influence65 study group. AS03-adjuvanted versus non-adjuvanted inactivated trivalent influenza vaccine against seasonal influenza in elderly people: a phase 3 randomised trial. Lancet Infect Dis. 2013 Jun;13(6):485-96.
- Launay O, Paul S, Servettaz A, Roguet G, Rozenberg F, Lucht F, Lambert C, Presles E, Goulvestre C, Méritet JF, Galtier F, Dubray C, Lebon P, Weill B, Batteux F. Control of humoral immunity and auto-immunity by the CXCR4/CXCL12 axis in lupus patients following influenza vaccine. Vaccine. 2013 Aug 2;31(35):3492-501.

1.1.4. 5 previous projects

- Project FLUVAC EV-01/02/03: Efficiency in Population of Influenza Vaccination for Seasonal 2011-2012/ 2012-2013/ 2013-2014 for Flu Prevention of the Hospitalized Adults: an Observational Study.
- International Phase III multicentric study to demonstrate the higher efficacy of FLU NG influenza vaccine (adjuvanted vaccine) in the prevention of A and/or B influenza, to be confirmed by RT-PCR, compared to Fluarix, in adults aged of 65 years old or more.
- Role of CXR4/CXCL12 axis the control of humoral immunity and autoimmunity in lupus patients after vaccination anti-influenza: CXCR4-GRIPLUP.
- Safety and Immunogenicity of a Quadrivalent Influenza Vaccine Administered via the Intramuscular Route in Adult and Elderly Subjects.

4.1.1 Partner name: CHU de Rennes, France - participant no25

1.1.1 Description of the legal entity

PIC no
988378009
Legal name
CENTRE HOSPITALIER UNIVERSITAIRE DE RENNES
Short name
CHU RENNES
Contact person
5.1.2 5.1.2e
Email of the contact person
5.1.2e @chu-rennes.fr
Department name
Infection Diseases and Medical Reanimation

The clinical Investigation Center (CIC) Inserm 1414 of The CHU of Rennes (Pr Laviolle) is composed of a Multi-theme unit and a Technological Innovation Unit.

The CIC of Rennes is certified ISO 9001 for the Methodology, management, and analysis of clinical studies since 2016 and was the first CIC in France to be certified ISO 9001.

It provides research support teams including methodologists, data managers, biostatisticians, pharmacovigilance officers, and a 10 beds clinical investigation with study coordinators and study nurses.

The Clinical Investigation Center has participated in the FLUVAC project since 2011.

Involved in WP3 and hospital studies of the WP4, the CHU of Rennes will recruit a large number of patients with COVID 1 and will provide data collection for the project.

1.1.2. Personnel involved

1.1.3. 5 relevant publications/services/achievements

1. Tsatsaris V, Capitant C, Schmitz T, Chazallon C, Bulifon S, Riethmuller D, et al. Maternal immune response and neonatal seroprotection from a single dose of a monovalent nonadjuvanted 2009 influenza A(H1N1) vaccine: a single-group trial. Ann Intern Med. 2011 Dec 6;155(11):733–41.
2. Loubet P, Lenzi N, Valette M, Foulongne V, Krivine A, Houhou N, et al. Clinical characteristics and outcome of respiratory syncytial virus infection among adults hospitalized with influenza-like illness in France. Clin Microbiol Infect. 2017 Apr;23(4):253–9.
3. Bénézit F, Le Bot A, Jouneau S, Lemaître F, Pronier C, Lentz PA, Patrat-Delon S, Revest M, Thibault V, Tattevin P. COVID-19 in Patient with Sarcoidosis Receiving Long-Term Hydroxychloroquine Treatment, France, 2020. Emerg Infect Dis. 2020;26(10)
4. Bénézit F, Le Turnier P, Declerck C, Paillé C, Revest M, Dubée V, Tattevin P; RAN COVID Study Group. Utility of hyposmia and hypogeusia for the diagnosis of COVID-19. Lancet Infect Dis. 2020:S1473-3099(20)30297-8.
5. Bénézit F, Loubet P, Galtier F, Pronier C, Lenzi N, Lesieur Z, Jouneau S, Lagathu G, L'Honneur AS, Foulongne V, Vallejo C, Alain S, Duval X, Houhou N, Costa Y, Vanhems P, Amour S, Carrat F, Lina B, Launay O, Tattevin P; FLUVAC Study Group. Non-influenza respiratory viruses in adult patients admitted with influenza-like illness: a 3-year prospective multicenter study. Infection. 2020;48(4):489-495. doi: 10.1007/s15010-019-01388-1.

1.1.4. 5 previous projects

The clinical Investigation Center (CIC) Inserm 1414 of The CHU of Rennes 5.1.2e is composed of a Multi-theme unit and a Technological Innovation Unit

5.1.2e multiple clinical studies on COVID-19, including:
- Discovery
- French COVID cohort
- Covidaxis
- Coronado
- Recover

4.1.1 Partner name: HOSPICES CIVILS DE LYON, France - participant no26

1.1.1 Description of the legal entity

PIC no
999 469 765
Legal name
HOSPICES CIVILS DE LYON
Short name
HCL
Contact person
5.1.2e 5.1.2e
Email of the contact person
5.1.2e @chu-lyon.fr
Department name
Infection Control and Epidemiology Unit

As a Public Centre of Excellence, the «Hospices Civils de Lyon» (HCL) make up the second-largest University Hospital Network in France.

For over 200 years, as a network providing expertise in all disciplines – both medical and surgical – HCL have offered a wide range of human, technical and logistical resources to ensure that they provide care, training, research, medical innovation as well as disease prevention and health education. Today, the HCL comprise 14 multidisciplinary or specialised establishments providing a diverse range of services.

HCL also make up a world-class network for the fight against cancer, and are ranked amongst the 25 best hospitals in the world. They are key establishments particularly in neurosciences, genetics and rare diseases.

With an annual budget allocation of 1.6 billion Euros, more than 5,300 beds and spaces and over 23,000 professionals, of which 5,000 are internationally recognised doctors with access to the latest equipment, the network devotes itself daily to its mission: contributing towards the constant improvement of the health of the French and Europeans.

More particularly, our department, the department of Hygiene, Epidemiology and Prevention, belongs to the university-affiliated Edouard Herriot hospital (Hospices Civils de Lyon-France). The latter is the largest hospital in the Rhône-Alpes region with 1100 beds and 102 units located in 32 buildings.

5.1.2e

5.1.2e At the early phase of the COVID19 pandemic, the department set-up a prospective hospital-based international study to assess the nosocomial transmission of COVID-19. The trial is ongoing and so far, more than 2000 patients and health care workers were enrolled. The department has been involved in the EU funded project ASSET "Action plan in Science in Society in Epidemics and Total pandemics", 2014-2017. Since the start of the COVID-19 pandemic, the department has initiated an international multi-center study on nosocomial transmission of this emerging virus. Extensive involvement of the department in infection control activities/research during the COVID-19 pandemic together with the expertise in the surveillance and outbreak investigation of infectious diseases match well with our involvement in the different WPs.

Besides, the department has been involved for many years in the surveillance of nosocomial infections and outbreak investigations. A surveillance of nosocomial influenza since more than 10 years provided a good expertise on the risk of spread of respiratory viruses at hospital. The department was strongly involved in the production of guidelines and reference documents. So far, the research team has developed a network of HCP with extensive experience in the detection, management and follow-up of nosocomial cases and consequences on the care organization (excess of hospital stay, decrease of quality of care, loss of chance, etc.)

Involved in WP3 and hospital studies of the WP4, the HCL will recruit a large number of patients with COVID 1 and will provide data collection for the project.

1.1.2. Personnel involved

5.1.2e

5.1.2e

1.1.3. 5 relevant publications/services/achievements

1. Saadatian-Elahi M, Picot-Sanchez V, Hénaff L, et al. Protocol for a multicentre study of nosocomial SARS-CoV2 transmission: The NOSO-COR Project. MedRxiv 2020.04.08.20057471; doi: https://doi.org/10.1101/2020.04.08.20057471.

2. Caussy C, Pattou F, Wallet F, Simon C, Chalopin S, Telliam C, Mathieu D, Subtil F, Frobert E,

Alligier M, Delaunay D, Vanhems P, Laville M, Jourdain M, Disse E; COVID Outcomes HCL

Consortium and Lille COVID–Obesity Study Group. Prevalence of obesity among adult inpatients with COVID-19 in France. Lancet Diabetes Endocrinol. 2020 May 18:S2213-8587(20)30160-1. doi:10.1016/S2213-8587(20)30160-1.

3. Etard JF, Vanhems P, Atlani-Duault L, Ecochard R. Potential lethal outbreak of coronavirus disease (COVID-19) among the elderly in retirement homes and long-term facilities, France, March 2020. Euro Surveill. 2020 Apr;25(15):2000448. doi: 10.2807/1560-7917.ES.2020.25.15.2000448. PMID: 32317051; PMCID: PMC7175651.

4. Vanhems P, Saadatian-Elahi M, Chuzeville M, et al. Fast nosocomial spread of SARS-CoV2 in a French geriatric unit Lyon Study Group on Covid-19 infection. Infect Control Hosp Epidemiol. 2020 Mar 30:1-4. doi: 10.1017/ice.2020.99. Epub ahead of print.

5. Vanhems P, Bénet T, Munier-Marion E. Nosocomial influenza: encouraging insights and future challenges. Curr Opin Infect Dis. 2016 Aug;29(4):366-72.

1.1.4. 5 previous projects

1.ECDC project: Support to HAI (Hospital acquired infection) Net coordination and analysis of HAI-Net data.

2. Eighth Joint Transnational Call For Networks Within The Joint Programming Initiative On Antimicrobial Resistance "Building the Foundation of the JPIAMR Virtual Research Institute" inCreasing cOmmunicatioN, awareNEss and data sharing in a global approaCh against resistance (CONNECT project) 5.1.2e 5.1.2e 5.1.2e -National Institute for Infectious Diseases 5.1.2e, IRCCS, Rome, Italy

3. Asymptomatic Flu Project (AFP), Multicentric research project, grant from French Ministry of health (PHRC)

4. I-REIVAC: Innovative Clinical Research Network in Vaccinology.; I-REIVAC is the only French clinical research network in vaccinology. Under the supervision of the ITMO Public Health (AVIESAN), it has been labelled "network of excellence" within the framework of the F-CRIN project. The network is part of the Vaccinology Research Consortium (CoReVac) created by the Institute of Microbiology and Infectious Diseases (IMMI).

5. Action plan on Science-in-Society related issues in Epidemics and Total pandemics (http://www.asset-scienceinsociety.eu/)

4.2. Third parties involved in the project (including use of third party resources)

Please complete, for each participant, the following table (or simply state "No third parties involved", if applicable):

4.2.1 Partner name: EPICONCEPT - participant no1

Does the participant plan to subcontract certain tasks (please note that core tasks of the project should not be sub-contracted)	Y
If yes, please describe and justify the tasks to be subcontracted - Web site development and graphic designer services (3K€) - Independant Ethics auditor (10 K€) Subcontracts will be awarded ensuring the best value for money or, if appropriate, the lowest price, ensuring there is no conflict of interests and that all applicable internal and/or national procurement rules have been followed	
Does the participant envisage that part of its work is performed by linked third parties[8]	Y
If yes, please describe the third party, the link of the participant to the third party, and describe and justify the foreseen tasks to be performed by the third party - EpiConcept UK is a wholly owned subsidiary of EpiConcept. Part of the work in relation with all Work Packages will be performed by 5.1.2e 5.1.2e 5.1.2e from EpiConcept UK.	
Does the participant envisage the use of contributions in kind provided by third parties (Articles 11 and 12 of the General Model Grant Agreement)	N
If yes, please describe the third party and their contributions	
Does the participant envisage that part of the work is performed by International Partners[9] (Article 14a of the General Model Grant Agreement)?	N
If yes, please describe the International Partner(s) and their contributions	

[8] A third party that is an affiliated entity or has a legal link to a participant implying a collaboration not limited to the action. (Article 14 of the Model Grant Agreement).

[9] 'International Partner' is any legal entity established in a non-associated third country which is not eligible for funding under Article 10 of the Rules for Participation Regulation No 1290/2013.

4.2.1 Partner name: ISCIII - participant no2

Does the participant plan to subcontract certain tasks (please note that core tasks of the project should not be sub-contracted)	N
If yes, please describe and justify the tasks to be subcontracted	
Does the participant envisage that part of its work is performed by linked third parties[10]	Y
If yes, please describe the third party, the link of the participant to the third party, and describe and justify the foreseen tasks to be performed by the third party The participation of two linked third parties is foreseen within the project. On the one hand, **Fundación Instituto de Investigación Sanitaria Aragón (IIS Aragón)**, (PIC code: 932533266) and on the other hand **Fundación para la Investigación Biosanitaria de Andalucía Oriental – Alejandro Otero (FIBAO)** (PIC 998986317) Both entities are linked to ISCIII through RENAVE the Spanish network for epidemiological surveillance. 1. RENAVE is a network created by law according to the Spanish Royal Decree 2210/1995 https://www.boe.es/buscar/pdf/1996/BOE-A-1996-1502-consolidado.pdf 2. This Royal decree is promoted by the Spanish Ministry of Health (on that time called Health and Consumers), with rights and obligation for the Ministry but also for the Regions (Comunidades Autónomas). In order to manage this network among many other issues that are on behalf the Central Government and the Regions there is the interregional board called 'Consejo Inter-territorial Del Sistema Nacional de Salud' . The function, roles and governance of this board is due to the Spanish Law: Ley 16/2003 de Cohesión y Calidad del Sistema Nacional de Salud, and in particular Chapter X (pages 17 to 19)of this law is the one that develop these contents. 3. This board, as management body approved by19th of June and 23 July, the attached guide for the vigilance of Flu, and among this decision they approve the regions and reference labs (page 33) for the Flu Vigilance in Spain (approved), marked in red are the relevant for this action:http://vgripe.isciii.es/documentos/20182019/InformesAnuales/Informe_Vigilancia_GRIPE_2018-2019_22julio2019.pdf 4. Within both hospitals, the Hospital Virgen de las Nieves (Granada) and the Hospital Miguel Servet (Zaragoza), the autonomic reference laboratories for influenza in Andalucía and Aragón, respectively, are working. They participate actively in the influenza surveillance in Spain at primary and secondary care level integrated in the Spanish Influenza Surveillance System. These labs have not legal personality by them self, but they belong to IIS Aragón and FIBAO respectively, that are the entities with legal personality that run the labs.	
Does the participant envisage the use of contributions in kind provided by third parties (Articles 11 and 12 of the General Model Grant Agreement)	N
If yes, please describe the third party and their contributions	
Does the participant envisage that part of the work is performed by International Partners[11] (Article 14a of the General Model Grant Agreement)?	N
If yes, please describe the International Partner(s) and their contributions	

[10] A third party that is an affiliated entity or has a legal link to a participant implying a collaboration not limited to the action. (Article 14 of the Model Grant Agreement).

[11] 'International Partner' is any legal entity established in a non-associated third country which is not eligible for funding under Article 10 of the Rules for Participation Regulation No 1290/2013.

4.2.1 Partner name: Instituto de Salud Pública y Laboral de Navarra – Spain - participant no3

Does the participant plan to subcontract certain tasks (please note that core tasks of the project should not be sub-contracted)	N
If yes, please describe and justify the tasks to be subcontracted	
Does the participant envisage that part of its work is performed by linked third parties[1]	N
If yes, please describe the third party, the link of the participant to the third party, and describe and justify the foreseen tasks to be performed by the third party	
Does the participant envisage the use of contributions in kind provided by third parties (Articles 11 and 12 of the General Model Grant Agreement)	Y
If yes, please describe the third party and their contributions According the Article 11 of the General Model Grant Agreement, the in-kind contribution provided by Miguel Servet Public Foundation (FMS) against payment will be devoted to the costs declared to EC under the budget lines of the beneficiary, Instituto de Salud Pública y Laboral de Navarra (ISPLN). As mentioned in the specific cases, FMS will manage and operate the beneficiary's budget received by the EC without requesting any financial compensation for these administrative and financial services.	

4.2.1 Partner name: Health Protection Scotland – Scotland - participant no4

Does the participant plan to subcontract certain tasks (please note that core tasks of the project should not be sub-contracted)	N
If yes, please describe and justify the tasks to be subcontracted	
Does the participant envisage that part of its work is performed by linked third parties[12]	Y
If yes, please describe the third party, the link of the participant to the third party, and describe and justify the foreseen tasks to be performed by the third party *The University of Strathclyde will act as a linked third part to NSS Health Protection Scotland.* 5.1.2e 5.1.2e 5.1.2e 5.1.2e *A memorandum of understanding between the University of Strathclyde and NSS Health Protection Scotland provides the contractual framework for the joint appointment of* 5.1.2 5.1.2e *in both institutes and* 5.1.2e 5.1.2e *and his Department of the University of Strathclyde contribute to NSS Health Protection Scotland.* *It is envisaged that* 5.1.2 5.1.2e 5.1.2e *will contribute to the protocols to be developed for database and data linkage studies associated with surveillance and research during the Covid-19 epidemic.* 5.1.2e *will also be involved in adapting the protocols for the Scottish setting and carrying out the periodic statistical analysis of the Scottish Data.* 5.1.2e *will also contribute to the statistical modelling and development of statistical models associated with the work packages.*	
Does the participant envisage the use of contributions in kind provided by third parties (Articles 11 and 12 of the General Model Grant Agreement)	N
If yes, please describe the third party and their contributions	
Does the participant envisage that part of the work is performed by International Partners[13] (Article 14a of the General Model Grant Agreement)?	N
If yes, please describe the International Partner(s) and their contributions	

[12] A third party that is an affiliated entity or has a legal link to a participant implying a collaboration not limited to the action. (Article 14 of the Model Grant Agreement).

[13] 'International Partner' is any legal entity established in a non-associated third country which is not eligible for funding under Article 10 of the Rules for Participation Regulation No 1290/2013.

4.2.1 Partner name: Lietuvos Sveikatos Mokslu Universitetas - participant no8

Does the participant plan to subcontract certain tasks (please note that core tasks of the project should not be sub-contracted)	Y
If yes, please describe and justify the tasks to be subcontracted - *Recruitment of the eligible hospitalized patients.* *Justification: to ensure a large enough sample size, the Lithuanian University of Health Sciences will subcontract another Infectious Disease Unit in one of the major hospitals in the country where screening for coronavirus could be implemented, if necessary. The core managerial and scientific tasks will be with the participant.* Subcontracts will be awarded ensuring the best value for money or, if appropriate, the lowest price, ensuring there is no conflict of interests and that all applicable internal and/or national procurement rules have been followed	
Does the participant envisage that part of its work is performed by linked third parties[1]	N
If yes, please describe the third party, the link of the participant to the third party, and describe and justify the foreseen tasks to be performed by the third party	
Does the participant envisage the use of contributions in kind provided by third parties (Articles 11 and 12 of the General Model Grant Agreement)	N
If yes, please describe the third party and their contributions	

[1] A third party that is an affiliated entity or has a legal link to a participant implying a collaboration not limited to the action. (Article 14 of the Model Grant Agreement).

4.3. Financial support to third parties

⚠ *For detailed specific info on terms and conditions: see General Annex K of the Horizon 2020 Work Programme published in the reference documents section of the H2020 Participants Portal (http://ec.europa.eu/research/participants/data/ref/h2020/other/wp/2018-2020/annexes/h2020-wp1820-annex-ga_en.pdf)*

Financial support in the form of a grant

Where this possibility is indicated under the relevant topic in the action, proposals which foresee a financial support to third parties, shall:

1. clearly detail the objectives and the results to be obtained and
2. contain the following specifications (as a minimum):
    a) a closed list of activities that qualify for financial support; please check in the action for the list of activities for which financial support to third party is allowed;
    b) the definition of persons or categories of persons that may receive financial support;
    c) the criteria for awarding financial support;
    d) the criteria for calculating the exact amount of the financial support;
    e) the maximum amount of financial support per third party, which must not exceed EUR 60 000, unless a higher amount is necessary to achieve the objectives of the action, and the criteria for determining it.

Please check in the action if there are other conditions that apply and, if so, include them in the specifications or in any other element of the proposal as appropriate.

Section 5: Ethics and security

5.1 Ethics

I-MOVE-COVID-19 study sites will comply with country-/region-specific ethical approval regulations. In most sites, specimens collected for surveillance or for routine patient care do not need ethical approval. Partners are public health institutes complying with national ethical approval regulations.

5.1.1 Study population

I-MOVE-COVID-19 will include patients from participating countries, presenting respiratory symptoms (suspected COVID-19 cases) either at the primary care or hospital level.

5.1.2 Ethical approval and informed consent procedures

5.1.2.1 Ethical approval

Surveillance activities (WP2, WP3)

Most national/regional surveillance systems (clinical or laboratory-based) in the EU, UK, and Albania have been implemented after governmental decisions (e.g. Commission Informatique et Liberté in France) or have received approval by an ethics committee. We will provide copies of all relevant documents before contract signature or within the first 5 months of the project. Extracted data will be anonymised.

Primary care surveillance network
Surveillance activities are based on data collected in the context of clinical practice and routine epidemiological surveillance. The project includes patients recruited in national or regional surveillance systems. Each national surveillance network obtains annual ethical approval or a governmental decision to implement specific disease surveillance.

Hospital surveillance network

For hospitals, the surveillance protocols will be submitted to respective regional or national ethical approval bodies. All included hospitals are already participating in I-MOVE (influenza), and have received ethical approval to conduct SARI surveillance. Specimen collection occurs in the context of routine patient management.

For each study site, a list of already available regional/national approval documents will be provided before the contract signature. For countries without a formal ethical approval/clearance mechanism, an official document will be required from the respective Ministries of Health or any other accredited authority.

Research projects (WP4)

Priority research projects will be identified and approved by the Steering-Scientific Committee as described in the proposal. Each site participating in the studies will submit the country-specific protocol to the corresponding local/regional/national ethics committee. The project coordinator will keep a copy of the ethical clearance in the project repository.

Informed consent procedures

Study sites will comply with regional/national regulations. According to our experience from I-MOVE studies, some countries may require oral informed consent and others written consent.

A copy of the respective national regulations will be provided before grant signature or before starting the study.

Information about the study and the consent to be signed by patients or families (for patients not able to provide informed consent or children), will be included in I-MOVE-COVID-19 country-specific protocols

The consent of the legal representatives (and assent, when applicable) for both of the above categories will be acquired in advance of the study, by the treating physician. In the hospital network, the participant's legal representative will be informed in the same way in which the adult patients are; this process will be outlined in detail in the surveillance and in each study protocol. Note that for surveillance, in some countries participating in the network, informed consent is not required.

Both of these categories of patients will be included in the surveillance (WP2, WP3) and research (WP4) arms of the proposal as it is important to understand the clinical characteristics and epidemiology of the disease in both of these populations. Specifically, it is important to understand incidence and risk factors in children as one of the current research questions is the proportion of symptomatic and asymptomatic children infected with SARS-CoV-2. It is also important to include and obtain such information on severe cases (e.g. ICU patients, or those with underlying conditions) as we aim to identify factors associated to severe disease; often, adults in this category may not be able to provide informed consent.

5.1.3 Type of cells/tissues used in the research and invasive physical procedures

Naso-pharyngeal swabs for SARS-CoV-2 testing (RT-PCR and culture) will be performed by sentinel practitioners or clinicians in hospitals. Swabbing procedures are approved in the context of surveillance system approval. Relevant authorisations and ethical approvals will be provided before contract signature; if not available at that time, then by month 2 of the project and definitively before starting data collection and analysis.
Other specimens may be obtained for diagnostic purposes in the context of routine patient care.

5.1.4 Incidental findings policy

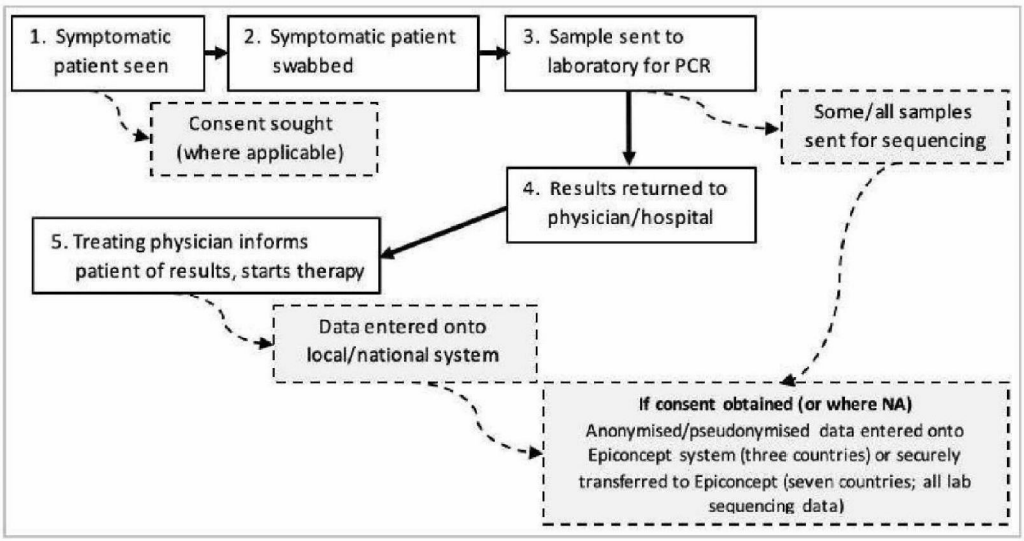
The project is not a clinical trial.
In case of abnormal findings, relevant results will be communicated in an appropriately timely manner to EU authorities (EMA, ECDC, EC and WHO) by the respective EU member states (ministries or general directorates of health) participating in the project.
This policy concerns any incidental findings, whether anticipated (known to be associated with a test/procedure) or not, which may occur during (a) the surveillance or (b) any of the research projects within this proposal. These are described in turn below.

(a) Surveillance

Within the COVID-19 primary care (WP2) and hospital (WP3) surveillance networks, in all participating countries, annual or other regular ethical approvals are required and will be obtained at national level. Individual subject consent for some countries is not required, as the study falls under the umbrella of routine surveillance/patient care. In others, only verbal, and in a few, written consent is required and obtained. In all of these instances, the generic study protocol (used/adapted by all participating countries/sites) mandates that the symptomatic patient is swabbed and then tested for COVID-19. As these sites are all also part of the I-MOVE network, the patients will all also be tested for influenza. In most countries, no other viruses will be tested for,

hence there will be no other potential findings. The process of routine RT-PCR testing for COVID-19 in some sites may also include other respiratory viruses, as multiplex PCR is used. It is also possible that subsequent genetic sequencing of some/all samples could reveal an unanticipated finding (e.g. a more virulent, or highly transmissible, strain of the new virus).

As each included patient is already under clinical care (for both the primary care and hospital network), it is the responsibility of the treating physician to share sample results with the patient. Patient results are not shared with the network in advance. Each participating site collates and anonymises/pseudonymises all of their patient data *before* sending it to the network's central data point (Epiconcept) for pooling and analysis (see below).



(b) Research projects

For research projects, the process will be different and will depend on the individual research study. Each research project will pursue ethical approval and will have to make provisions for incidental findings (both anticipated and unanticipated) as recommended by the I-MOVE-COVID-19 Ethical Advisor on a study-by-study basis. Briefly, the incidental findings policy will be revised for each research study after discussion with ethical expert(s) regarding the best procedure for each study.

5.1.5 Protection of personal data and data handling

Informed consent procedures are described in the draft data management plan (section 6).

Third countries:

Eight of the 10 included countries are within the EU and all research which will be proposed will have to be legal within all EU Member States. The studies conducted outside the EU in the two non-EU participating countries (the UK and Albania) will also be legal within the EU.

5.2 Security

The I-MOVE-COVID-19 project does not involve:

- activities or results raising security issues
- 'EU-classified information' as background or results

Section 6: Data sharing

I-MOVE-COVID-19 is committed to the principles set out in the 2016 Statement on data sharing in public health emergencies, as well as the European Commission (EC) recommendation of 25/4/2018 "On access to and preservation of scientific information" and EC Guidelines on FAIR data management in H2020.

I-MOVE-COVID-19 will make available their research data, as soon as possible, but at the latest within 30 days after it has been generated, to third parties that need the research data to address the public health emergency. The mechanisms for this data sharing, and adherence of I-MOVE-COVID-19 to FAIR principles, can be found in the draft "Data management plan".

Due to short deadlines, not all members of the Scientific Steering Committee have reviewed this draft "Data management plan". This early draft will be reviewed and updated (where relevant) by the Scientific Steering Committee, with project partners and with their Information and communications technology departments.

c) Draft data management plan

1. Data Summary

This section aims to review the scope of I-MOVE-COVID-19 (purpose and objectives) in order to clarify the relation between it and the data generation, collection, processing and sharing envisaged in I-MOVE-COVID-19.

1.1 The purpose of data collection

We collect data in I-MOVE-COVID-19 in order to enable us to contribute to the knowledge base, to guide patient management, and to inform the public health response on COVID-19. Specifically we collect data to obtain epidemiological, clinical, and virological information about COVID-19 and patients infected with SARS-CoV-2.

1.2 What types and formats of data will the project collect?

The types and formats of data include:

Electronic data

- Protocols; Word format
- Clinical, demographic, risk/preventive factor, exposures, treatments, outcome (e.g. deaths); csv
- Specimen information; csv
- Virological information; FASTA format, metadata in csv
- Serology information; csv (where appropriate; e.g.if serology studies are selected to be performed by the Scientific Steering committee)

Physical data

- Paper questionnaires; paper
- Specimens: swabs, blood tests; laboratory specimens

1.3 Will you re-use any existing data and how?

Several years of I-MOVE data may be used to compare ILI/SARI cases with COVID-19 cases. These data have been collected and processed according to GDPR and are anonymised.

1.4 What is the origin of the data?

The data from WP2 and WP3 will originate from patients consulting physicians at primary care and hospital levels in the I-MOVE-COVID-19 surveillance network; through interviews, physical examinations, test results, specimen collection (swabbing/blood samples), through extraction of medical records, and extraction of data from registries (e.g. vaccination registries, death registries).

Epidemiological study data (WP4) will originate from WP2 and WP3, but also from surveys in the general population, and cohorts of health care workers through face-to-face or online questionnaires.

1.5 What is the expected size of the data?

The size of the data will depend on the epidemiological situation and thus number of cases. Nevertheless, the electronic data collected is unlikely to exceed 1GB.

1.6 To whom might it be useful ('data utility')?

The data itself and the processed outputs will be useful to the I-MOVE-COVID-19 network, regional, national and international public health bodies and the general public, including the broader scientific community worldwide.

2. FAIR data

I-MOVE-COVID-19 is committed to the principles set out in the 2016 Statement on data sharing in public health emergencies, as well as the commission recommendation of 25/4/2018 "On access to and preservation of scientific information" and EC Guidelines on FAIR data management in H2020. Protocols and results generated by I-MOVE-COVID-19 and data as much as is possible within security, privacy and ethical constraints, will be made available in an anonymised and open access mode in order to enable wide and rapid data sharing, including with public health and research communities and the WHO.

2. 1. Making data findable, including provisions for metadata

A series of information, such as: description, short name, long name, data author, data maintainer, data of creation, data of revision, dissemination licence, are all typical metadata needed to be FAIR principles compliant. This selection of metadata choice is planned to be discussed and further developed in the future data management plan updates along with a cooperative effort with project partners and in particular their Information Communication and Technology (ICT) departments. The Metadata Standards Directory within the Research data Alliance will be used to search for relevant standards and associated tools.

I-MOVE-COVID-19 data will be archived in the relevant database using a unique identifier. The metadata information will be stored alongside the data.

In general, I-MOVE-COVID-19 data will conform to best epidemiological practices and standards in naming conventions and versioning.

2.2. Making data openly accessible

While I-MOVE-COVID-19 remains committed to an open access approach in general, a case by case decision will need to be adopted in terms of data that is made freely available. Personal data will be processed according to the applicable EU and national law and international
standards. Individual patient/study participant information twill not be shared with the general public o However, critical information will be shared with WHO and other scientific partners rapidly, via a more restricted platform.

Freely available data include:

- All protocols, including this data management plan, will be made publicly available on the I-MOVE-COVID-19 website. Solutions for longevity (availability after end of project) of uploaded protocols will be sought, in consultation of international partners and other actors (examples of repositories could include Zenodo, GitHub, OSF, OBiba and others).
- Sequencing information will be rapidly uploaded to GISAID's new BetaCoV 2019-2020 platform, which is open access.
- All surveillance bulletins will be made publicly available on the I-MOVE-COVID-19 website and be shared with international and other actors.
- Any scientific publications will be Open Access with a pre-print made publicly available.
- Relevant statistical scripts will be made available either on the I-MOVE-COVID-19 website and to ensure longevity on repositories such as GitHub.

I-MOVE-COVID-19 plans to use a specific open science platform such as Zenodo, REDCap or B2Share for individual and aggregated patient data, in order to disseminate this information to a wider audience while following the FAIR principles. Further decisions and details will follow in the next version of this draft data management plan, upon consultation with all partners and when arrangements with the identified repository(ies) have been sought. GDPR guidelines will be followed.

Any publications resulting from the project will be made in "Gold" open access.

The Scientific Steering committee will be central to decisions for data access. If needed a separate data access committee will be created.

2.3. Making data interoperable

I-MOVE-COVID-19 will make available data interpretable to third parties without link to the project. This means that each dataset will be accompanied with a description of methodology, sources, definitions and scope.

To ensure interoperability of data, metadata generated will be in open format (e.g. .xls, .odt, etc.).

I-MOVE-COVID-19 will adhere to existing standards (e.g. within FAIRSHARE.org and others) and vocabularies in order to make data interoperable. This may be a collaborative "work in process" together with other actors working on COVID-19.

2.4. Increase data re-use (through clarifying licences)

I-MOVE-COVID-19's Scientific Committee/data access committee will choose a repository for their data, ideally with an inbuilt mechanism for selecting the appropriate license.

Creative Commons licenses will be used for protocols, using the Attribution-ShareAlike (**CC BY-SA**) license, which lets others remix, tweak, and build upon your work even for commercial purposes, as long as they credit you and license their new creations under the identical terms. Protocols will be shared immediately after finalisation on the open I-MOVE-COVID-19 website and post-project longevity will be ensured by copying protocols to a repository, chosen in consultation with the Scientific Steering Committee and other actors, and which ensures long-term archiving.

Sequencing data of the viral genome will be shared through GISAID's new EpiCoV platform, which shares the same sharing mechanisms as GISAID's Epiflu platform. Data are shared with anyone who positively identifies himself or herself, and agrees to respect the inherent rights of contributors. Sequencing data will be shared as soon as possible. Sequences available on GISAID are ensured long-term archiving.

For individual and aggregate patient data, the license will be decided on a case-by-case basis by the Scientific Steering Committee/Data access committee, ensuring that rapid sharing is in place for those who need to know. An appropriate repository will be used with different tiers of licenses for data sharing, as well as long-term archiving.

The WP leader will have overall responsibility of data quality. To ensure quality of data/datasets uploaded to repositories, extensive review by contributing partners should be carried out, including review of scripts of any data cleaning processes applied onto raw data. To ensure that individual datasets are clear to third parties, the accompanying documentation (see section 2.3 "making data inter-operable") will be reviewed by one senior partner, not involved in the preparation or processing of the dataset.

3. Allocation of resources

Project staff time has been allocated to the approved budget for data management related tasks. Any costs in relation to Open Access publications and repositories will be covered within the approved budgets of the relevant WP.

The WP leader has the overall responsibility for the data management within her/his WP.

The Scientific-Steering Committee/Data Access Committee, in collaboration with international partners and other actors, about the best practices for long term data preservation.

4. Data security

I-MOVE already complies with GDPR data security standards and I-MOVE-COVID-19 will continue in this way. All data will be transferred using secure systems and are stored on secure servers. The EpiFiles system is used preferentially for secure data transfer and is part of the Voozanoo platform, which is certified by the French Ministry of Health to legally hold personal health information.

Any repositories used for sensitive digital data (in terms of privacy, ethics or security) will be certified for data safety.

Information in paper format will be stored in a locked cabinet or office, where only a restricted, known number of people have access to it. Once the information has been processed and the raw data is no longer needed, appropriate long-term storage or destruction measures will be taken.

More details on the data security measures will be added to the data management plan as a priority. This will include descriptions of the anonymysation techniques.

4.1 Data protection policy

As the project progresses a detailed data protection policy will be included as part of this data management plan and enforced by the appointed data protection officer.

This will also include confirmations that data transfer from non-EU countries to the EU or any other state will comply with laws of the country in which the data was collected.

5. Human cells/tissues

Not only electronic data will be collected as part of this project, but also human cells/tissues as part of swabbing of patients and potential blood taking if a sero-epidemiology study is deemed priority. All details on cell/tissue types will be kept on file. I-MOVE-COVID-19 will create documents for using, producing or collecting human cells or tissues (e.g., ethics approval, import licence, accreditation/designation/authorisation/licensing), which will be part of the data management plan and also part of study site-specific protocols if relevant. We will ensure that all procedures at primary care, hospitals and laboratory level are performed in accordance with relevant national biological safety

regulations and following the recommended WHO guidelines on biosafety and biosecurity. Virus isolation will be done in accredited laboratories.

No human cells/tissues from biobanks will be used.

6. Environmental protection and safety

We will update this section on environmental protection and safety as the project progresses. This will include security classification of laboratories, health and safety procedures for clinical, laboratory and other staff. These procedures will conform to relevant local/national guidelines/legislation It will also be part of the protocols if relevant.

7. Ethical aspects

Ethical approval of studies will be sought through the appropriate ethics board within each country. I-MOVE countries have experience of seeking appropriate ethical approval for their primary care and hospital network data. Some of the tasks within WP2 can be carried out within the framework of general surveillance, which in most participating countries do not require approval by ethical committees, obviating potential regulatory barriers.
Verbal or written informed consent will be sought from each participant as needed. For participants not able to provide informed consent, parents (for children) or relatives will be asked to provide consent.
The I-MOVE-COVID-19 project has appointed an external independependent ethics advisor, who will oversee all aspects of ethics in this project. There will be an evaluation of the ethics risks related to the data processing activities of the project. This includes also an opinion if data protection impact assessment should be conducted under art.35 General Data Protection Regulation 2016/679. The risk evaluation and the opinion will be submitted as part of this plan and included as deliverable..

Templates of the informed consent/assent forms and information sheets will be included in the data management plan.

ESTIMATED BUDGET FOR THE ACTION

	Estimated eligible[1] costs (per budget category)											EU contribution			Additional information		
	A. Direct personnel costs				B. Direct costs of subcontracting	[C. Direct costs of fin. support]	D. Other direct costs		E. Indirect costs[2]	F. Special unit costs	Total costs	Reimbursement rate %	Maximum EU contribution[3]	Maximum grant amount[4]	Information for indirect costs	Information for auditors	Other information
	A.1 Employees (or equivalent) A.2 Natural persons under direct contract A.3 Seconded persons [A.6 Personnel for providing access to research infrastructure]		A.4 SME owners without salary A.5 Beneficiaries that are natural persons without salary				D.1 Travel D.2 Equipment D.3 Other goods and services D.4 Costs of large research infrastructure	D.5 Costs of internally invoiced goods and services		F.1 Costs for clinical studies[5]					Estimated costs of in-kind contributions not used on premises	Declaration of costs under Point D.4	Estimated costs of beneficiaries/ linked third parties not receiving funding/ international partners
Form of costs[6]	Actual	Unit[7]	Unit[8]		Actual	Actual	Actual	Unit[9]	Flat-rate[10] 25%	Unit[12]							
	a	Total b	No hours	Total c	d	e	f	Total g	h = 0,25 x (a +b+c+f+g +[i1][13]-[i2][13]-n)	Total i1	j = a+b+c -d-[e]+f+g +h-[i1]+[i2]	k	l	m	n	Yes/No	
1. EPICONCEPT	185 160.00	0.00	0.00	0.00	13 000.00	0.00	225 730.00	0.00	102 722.50	0.00	526 612.50	100.00	526 612.50	526 612.50	0.00	No	n/a
- EPIUK	80 000.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	20 000.00	0.00	100 000.00	100.00	100 000.00	100 000.00	0.00	No	n/a
Σ beneficiary	265 160.00	0.00	0.00	0.00	13 000.00	0.00	225 730.00	0.00	122 722.50	0.00	626 612.50		626 612.50	626 612.50	n/a	n/a	0.00
2. ISCIII	124 200.00	0.00	0.00	0.00	0.00	0.00	16 000.00	0.00	35 050.00	0.00	175 250.00	100.00	175 250.00	175 250.00	0.00	No	n/a
- FIBAO	29 600.00	0.00	0.00	0.00	0.00	0.00	2 400.00	0.00	8 000.00	0.00	40 000.00	100.00	40 000.00	40 000.00	0.00	No	n/a
- IACS	29 600.00	0.00	0.00	0.00	0.00	0.00	2 400.00	0.00	8 000.00	0.00	40 000.00	100.00	40 000.00	40 000.00	0.00	No	n/a
Σ beneficiary	183 400.00	0.00			0.00	0.00	20 800.00	0.00	51 050.00	0.00	255 250.00		255 250.00	255 250.00	n/a	n/a	0.00
3. ISPLN	124 200.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	31 050.00	0.00	155 250.00	100.00	155 250.00	155 250.00	0.00	No	n/a
- NBM-FMS	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	0.00
Σ beneficiary	124 200.00	0.00			0.00	0.00	0.00	0.00	31 050.00	0.00	155 250.00		155 250.00	155 250.00	n/a	n/a	0.00
4. NHSNS	75 400.00	0.00	0.00	0.00	0.00	0.00	40 000.00	0.00	28 850.00	0.00	144 250.00	100.00	144 250.00	144 250.00	0.00	No	n/a
- UNL STRATHC.	45 600.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	11 400.00	0.00	57 000.00	100.00	57 000.00	57 000.00	0.00	No	n/a
Σ beneficiary	121 000.00	0.00			0.00	0.00	40 000.00	0.00	40 250.00	0.00	201 250.00		201 250.00	201 250.00	n/a	n/a	0.00
5. INSA	69 280.00	0.00	0.00	0.00	0.00	0.00	50 440.00	0.00	37 430.00	0.00	187 150.00	100.00	187 150.00	187 150.00	0.00	No	n/a
6. NIVEL	112 280.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	28 070.00	0.00	140 350.00	100.00	140 350.00	140 350.00	0.00	No	n/a
7. DH	94 280.00	0.00	0.00	0.00	0.00	0.00	16 000.00	0.00	27 570.00	0.00	137 850.00	100.00	137 850.00	137 850.00	0.00	No	n/a
8. LSMU	51 420.00	0.00	0.00	0.00	14 000.00	0.00	21 300.00	0.00	18 180.00	0.00	104 900.00	100.00	104 900.00	104 900.00	0.00	No	n/a
9. HSE	72 280.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	18 070.00	0.00	90 350.00	100.00	90 350.00	90 350.00	0.00	No	n/a
10. POHM	53 000.00	0.00	0.00	0.00	0.00	0.00	19 280.00	0.00	18 070.00	0.00	90 350.00	100.00	90 350.00	90 350.00	0.00	No	n/a
11. VIVI	83 920.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	20 980.00	0.00	104 900.00	100.00	104 900.00	104 900.00	0.00	No	n/a
12. IC	73 120.00	0.00	0.00	0.00	0.00	0.00	10 800.00	0.00	20 980.00	0.00	104 900.00	100.00	104 900.00	104 900.00	0.00	No	n/a
13. UCPP	0.00	0.00	0.00	0.00	0.00	0.00	8 000.00	0.00	2 000.00	0.00	10 000.00	100.00	10 000.00	10 000.00	0.00	No	n/a
14. SU	48 280.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	12 070.00	0.00	60 350.00	100.00	60 350.00	60 350.00	0.00	No	n/a
15. SPF[14]	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	41 265.82
16. IP	0.00	0.00	0.00	0.00	0.00	0.00	48 000.00	0.00	12 000.00	0.00	60 000.00	100.00	60 000.00	60 000.00	0.00	No	n/a
17. MS	32 000.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	8 000.00	0.00	40 000.00	100.00	40 000.00	40 000.00	0.00	No	n/a
18. UOXF	47 200.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	11 800.00	0.00	59 000.00	100.00	59 000.00	59 000.00	0.00	No	n/a
19. IPHA	53 920.00	0.00	0.00	0.00	0.00	0.00	30 000.00	0.00	20 980.00	0.00	104 900.00	100.00	104 900.00	104 900.00	0.00	No	n/a
20. RIVM	19 000.00	0.00	0.00	0.00	0.00	0.00	17 000.00	0.00	9 000.00	0.00	45 000.00	100.00	45 000.00	45 000.00	0.00	No	n/a
21. INSERM	0.00	0.00	0.00	0.00	0.00	0.00	2 000.00	0.00	500.00	0.00	2 500.00	100.00	2 500.00	2 500.00	0.00	No	n/a
23. VUB	34 400.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	8 600.00	0.00	43 000.00	100.00	43 000.00	43 000.00	0.00	No	n/a

ESTIMATED BUDGET FOR THE ACTION

	Estimated eligible[1] costs (per budget category)											EU contribution			Additional information		
	A. Direct personnel costs				B. Direct costs of subcontracting	[C. Direct costs of fin. support]	D. Other direct costs		E. Indirect costs[2]	F. Special unit costs	Total costs	Reimbursement rate %	Maximum EU contribution[3]	Maximum grant amount[4]	Information for indirect costs	Information for auditors	Other information
	A.1 Employees (or equivalent) A.2 Natural persons under direct contract A.3 Seconded persons [A.6 Personnel for providing access to research infrastructure]		A.4 SME owners without salary A.5 Beneficiaries that are natural persons without salary				D.1 Travel D.2 Equipment D.3 Other goods and services D.4 Costs of large research infrastructure	D.5 Costs of internally invoiced goods and services		F.1 Costs for clinical studies[5]					Estimated costs of in-kind contributions not used on premises	Declaration of costs under Point D.4	Estimated costs of beneficiaries/ linked third parties not receiving funding/ international partners
Form of costs[6]	Actual	Unit[7]	Unit[8]		Actual	Actual	Actual	Unit[9]	Flat-rate[10] 25%	Unit[12]							
	a	Total b	No hours	Total c	d	e	f	Total g	h = 0,25 x (a +b+c+f+g +[i1][13]+[i2][13]+n)	Total i1	j = a+b+c +d+[e]+f+g +h+[i1]+[i2]	k	l	m	n	Yes/No	
25. AP-HP	79 750.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	19 940.00	0.00	99 700.00	100.00	99 700.00	99 700.00	0.00	No	n/a
27. CHUM	22 560.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	5 640.00	0.00	28 200.00	100.00	28 200.00	28 200.00	0.00	No	n/a
28. CHU Rennes	22 560.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	5 640.00	0.00	28 200.00	100.00	28 200.00	28 200.00	0.00	No	n/a
30. HCL	22 560.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	5 640.00	0.00	28 200.00	100.00	28 200.00	28 200.00	0.00	No	n/a
Σ consortium	1 685 580.00	0.00		0.00	27 000.00	0.00	539 350.00	0.00	556 232.50		2 808 162.50		2 808 162.50	2 808 162.50			41 265.82

[1] See Article 6 for the eligibility conditions.
[2] Indirect costs already covered by an operating grant (received under any EU or Euratom funding programme; see Article 6.5.(b)) are ineligible under the GA. Therefore, a beneficiary/linked third party that receives an operating grant during the action's duration cannot declare indirect costs for the year(s)/reporting period(s) covered by the operating grant, unless it can demonstrate that the operating grant does not cover any costs of the action (see Article 6.2.E).
[3] This is the theoretical amount of EU contribution that the system calculates automatically (by multiplying all the budgeted costs by the reimbursement rate). This theoretical amount is capped by the 'maximum grant amount' (that the Commission/Agency decided to grant for the action) (see Article 5.1).
[4] The 'maximum grant amount' is the maximum grant amount decided by the Commission/Agency. It normally corresponds to the requested grant, but may be lower.
[5] Depending on its type, this specific cost category will or will not cover indirect costs. Specific unit costs that include indirect costs are: costs for energy efficiency measures in buildings, access costs for providing trans-national access to research infrastructure and costs for clinical studies.
[6] See Article 5 for the forms of costs.
[7] Unit : hours worked on the action; costs per unit (hourly rate) : calculated according to the beneficiary's usual accounting practice.
[8] See Annex 2a 'Additional information on the estimated budget' for the details (costs per hour (hourly rate)).
[9] Unit and costs per unit : calculated according to the beneficiary's usual accounting practice.
[10] Flat rate : 25% of eligible direct costs, from which are excluded: direct costs of subcontracting, costs of in-kind contributions not used on premises, direct costs of financial support, and unit costs declared under budget category F if they include indirect costs.
[11] See Annex 2a 'Additional information on the estimated budget' for the details (units, costs per unit).
[12] See Annex 2a 'Additional information on the estimated budget' for the details (units, costs per unit, estimated number of units, etc).
[13] Only specific unit costs that do not include indirect costs.
[14] See Article 9 for beneficiaries not receiving funding.
[15] Only for linked third parties that receive funding.

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