AD HOC WORKING GROUP (ACTION 1) & SUB-GROUPS

MANDATE & TERMS OF REFERENCE

Background document for the 4th DG R&I VC | 14 May 2020

In the context of Action 1 (Coordination of R&I funding against the Coronavirus) of the ERAvsCorona Action Plan an Ad-hoc group of experts was set up upon nomination by the Member States[1].

The first meeting took place on 17 April 2020 with the participation of DG R&I, DG SANTE, Member States, (10)(2a) (10)(2a), the European Medicines Agency, the European Centre for Disease Prevention and Control and the European Investment Bank. At this meeting, the group decided to split into four sub-groups to discuss (1) Clinical trials, (2) Manufacturing, (3) Testing, and (4) Financing.

- The proposed **mandate for the Ad hoc working group** can be found in **Annex I**.
  The DGs are asked **to endorse the mandate of the Ad-hoc working group**.

- The draft **Terms of Reference of the four sub-groups** can be found for information in **Annex II**.

[1] Three associated countries were also invited: Norway, Iceland and Switzerland; when referring to the Member States in the rest of this document, these three associated countries are included.

ERAvsCORONA Action plan - *Ad hoc* Working Group

Mandate 14 May 2020

Background

The aim of the Ad hoc working group is to strengthen the operational coordination of R&I funding, and funded activities, against the Coronavirus covering the whole pipeline (from pre-clinical research to products being available to citizens) for vaccines, treatments and testing. This group should enable public funders of research and innovation to work better together in a coordinated and more efficient manner in the immediate need to tackle the current Covid-19 pandemic. It will look at the complete vaccine, treatment and testing pipelines from research to deployment, from a very pragmatic and operational aspect. The work of the ad-hoc group will prepare the ground for operational decisions to be taken by the R&I DGs.

Purpose and objective

The group will identify the key challenges that need to be overcome to ensure efficient pipelines and will identify and propose solutions to face them. It will also help in having a collective overview of combined efforts to develop therapies, vaccines and diagnostics in view of the Coronavirus Global Response. Proposed solutions will be presented for decision to the appropriate decision making forums depending on their nature.

The Ad hoc group can set up specific sub- groups to address identified challenges to ensure the competencies needed to develop adequate solutions. The subgroups will report to the Ad-hoc group on regular basis.

Membership.

The Ad hoc group, and its sub-groups, will be composed by appointed representatives of the Member States, Commission Services and Agencies (e.g. EMA, ECDC), and as appropriate EIB.

Functioning and timeframe

The Ad Hoc Working Group will convene (virtually) and will be informed by the four sub-groups (clinical trials, manufacturing, testing, financing) about their discussions and recommendations. A document sharing platform may be made available.

The Ad Hoc Working Group will report to the R&I DGs on a regular basis, information provided to the R&I DGs should facilitate their discussions and operational decision-making. Any political decisions should be referred to the Council and its preparatory bodies.

The Ad hoc Working Group and its sub-groups are established for the duration of the COVID-19 pandemic response.

Annex II – Terms of Reference of the four sub-groups of the Ad hoc group on Action 1

(1) Clinical Trials

ERAvsCORONA Action plan - *Ad hoc* working group: Clinical trials sub-group

Terms of Reference

Background

On 7 April 2020, the first ERAvsCorona Action Plan, supported by the Ministers responsible for research and innovation, was published. The Action Plan identifies 10 short-term priority actions, based on dialogues between the Commission services and National Ministries.[2] Priority number two aims at "extending and supporting large EU-wide clinical trials for clinical management of Coronavirus patients". It is in this context that the *ad hoc* working group of MS agreed on a "clinical trials sub-group"; other sub-groups will address issues related to manufacturing, testing and financing.

Purpose and objectives

The overall purpose of this clinical trials sub-group is to support the implementation of large-scale, multi-centric clinical trials across Europe, using harmonised protocols, in order to obtain robust results that can benefit patients and the healthcare systems in a timely manner. In this regard, the following specific objectives are defined:

- To facilitate an updated overview of the COVID-19 clinical trials that are planned, ongoing and finalised in EU/EEA, as well as updated information on preliminary or final results of the finalised trials;
- To facilitate the creation of an EU-wide network on clinical trials, organised on the concept of adaptive platform trials, and advise on therapeutic compounds and/or vaccine candidates to be assessed;
- To advise on addressing the political, ethical, administrative, regulatory and logistical (PEARL) hurdles that may hamper the rapid implementation or adaptation of clinical trials run within the network and in general on the EU territory.

Membership

Members of the clinical trials sub-group are appointed representatives from the Member States; national competent authorities (NCAs) will be represented by the two co-chairs of the clinical trials facilitation group (HMA) and committee members bringing ethics expertise by two experts from the European Commission clinical trials expert group (CTEG). Representatives from DG R&I, DG SANTE, EMA and ECDC are included.

[2] https://ec.europa.eu/info/sites/info/files/research_and_innovation/research_by_area/documents/ec_rtd_era-vs-corona_0.pdf

The clinical trials sub-group is coordinated by DG Research & Innovation.

Functioning and timeframe

The clinical trials sub-group will communicate mainly through e-mail exchange; a document sharing platform may be made available. As relevant, (virtual) meetings will be organised. The sub-group will report to the *ad hoc* working group on regular basis. Coordination with the WHO R&D Blueprint will be ensured.

The clinical trial sub-group is established for the duration of the COVID-19 pandemic response.

(2) Manufacturing

ERAvsCORONA Action plan - *Ad hoc* working group: Manufacturing sub-group

Draft Terms of Reference

Background

On 7 April 2020, the first ERAvsCorona Action Plan, supported by the Ministers responsible for research and innovation, was published. The action plan identifies 10 short-term priority actions, based on dialogues between the Commission Services and National Ministries.[3] Priorities number three and four aim at "innovative and rapid health-related approaches to respond to coronavirus and deliver quick results relevant to society and a higher level of preparedness of health systems" and "increasing support to innovative companies". In this context, the *ad hoc* working group of MS agreed on a "manufacturing sub-group"; other sub-groups will address issues related to clinical trials, testing and financing.

Membership

Members of the manufacturing sub-group are appointed representatives from the Member States as well as representatives from the Commission (DG SANTE, R&I, GROW and COMP) and from industry associations in the EU. The sub-group is coordinated by DG Health and Food Safety (SANTE).

Purpose and objectives

The overall aim of this manufacturing sub-group is to identify and propose actions to accelerate the production of effective diagnostics, treatments and vaccines for COVID-19, including the scale-up of the capacity for their manufacturing and distribution. In this regard, the following specific objectives are defined:

1. To map and determine the existing manufacturing capacity in Europe, both in publicly and privately owned facilities.
2. To determine the required degree of scale-up in manufacturing capacity: what is urgently needed in the short-term and what is also needed in the long-term to maintain adequate manufacturing capacity for resilience and other use after COVID-19.
3. To define the associated investment needs, both for (a) repurposing, upgrading and expanding existing manufacturing facilities, as well as (b) building new facilities.
4. To identify relevant national investment initiatives, the contributions that the current and future EU funding instruments can make, and to explore complementarities among all these.

Functioning and timeframe

The manufacturing sub-group will communicate mainly through e-mail exchange; a document sharing platform may be made available. As relevant, (virtual) meetings will be organised. The sub-group will report to the *ad hoc* working group on regular basis and liaise closely with the three other sub-groups. The sub-group is established for the duration of the COVID-19 pandemic response.

[3] https://ec.europa.eu/info/sites/info/files/research_and_innovation/research_by_area/documents/ec_rtd_era-vs-corona_0.pdf

(3) Testing

ERAvsCORONA Action plan - *Ad hoc* working group: Testing sub-group

Draft Terms of Reference

Background

The ad hoc Working Group on Testing of the Member States Research Network is set up in the context of

1. the ERAvsCorona action plan[4] which lays out 10 priority short-term coordinated actions to tackle coronavirus and
2. the Communication from the Commission[5] on "Guidelines on COVID-19 in vitro diagnostic tests and their performance" adopted on 15 April 2020.

Purpose and objectives

The activities of this sub-group are in line with the following action listed in the Commission Communication[2] on testing kits:

"The Commission, together with Member States, will put efforts into the development of tools to enable evaluation of device performance and align approaches across the Union, such as reference materials and methods for standardised comparison. This will require close cooperation between regulators, health technology assessment bodies, the ECDC, the COVID-19 reference laboratory network, research organisations and industry to ensure the most optimal outcome. The Commission will consider which funding opportunities will provide support for these activities."

Its activities will also feed into the following action:

"The Commission, supported by the ECDC, health technology assessment experts and in vitro diagnostics competent authorities, will assist Member States with a centralised overview of available information on test performance and act as a single point of contact for management of this information."

The following items should be addressed by the Working Group:

- Identify most needed research and development goals for advancing and broadening the testing techniques and equipment for both direct SARS-CoV-2 detection and the detection of antibodies actively involved in the immunological defence towards this virus. Although a holistic view on the whole process is required - including proof of concept, development for the market, introduction in clinical use – the focus should be on the research and innovation part.
- Give advice on the setting-up of a strategic R&I agenda on COVID-19 diagnostics, to be endorsed by the R&I DGs
- Map national research and development activities
- Coordinate/cluster national research and development activities

[4] https://ec.europa.eu/info/sites/info/files/research_and_innovation/research_by_area/documents/ec_rtd_era-vs-corona_0.pdf
[5] https://ec.europa.eu/info/sites/info/files/testing_kits_communication.pdf

- Monitor scientific/research developments
- Serve as a forum to discuss the centralised overview of information on performance

Regulatory aspects of COVID-19 diagnostics fall outside the remit of this group.

Membership

Members of the testing sub-group are appointed representatives from the Member States and from DG R&I, JRC, SANTE, GROW, ECDC, EMA; it is coordinated by DG R&I and JRC.

Functioning and timeframe

The testing sub-group will communicate mainly through e-mail exchange; a document sharing platform may be made available. As relevant, (virtual) meetings will be organised. The sub-group will report to the *ad hoc* working group on regular basis and liaise closely with the three other sub-groups.

The sub-group is established for the duration of the COVID-19 pandemic response.

(4) Financing

ERAvsCORONA Action plan - *Ad hoc* working group: Financing sub-group

Terms of Reference

Background

On 7 April 2020, the first ERAvsCorona Action Plan, supported by the Ministers responsible for research and innovation, was published. The action plan identifies 10 short-term priority actions, based on dialogues between the Commission Services and National Ministries.[6] Several of the actions refer to the need to increase the funding dedicated to e COVID-19 projects. It is in this context that the ad hoc working group of MS agreed to create a "Financing sub-group". The remaining three sub-groups will address issues related to clinical trials, manufacturing, and testing.

Membership

Members of the Financing sub-group are appointed representatives from the Member States. In addition, representatives from DG R&I, DG SANTE and the European Investment Bank are included.

National Promotional Banks and Institutions may be invited to participate in the sub-group meetings and discussions as observers.

The Financing sub-group is coordinated by DG R&I.

Purpose and objectives

The overall purpose of the Financing sub-group is to ensure an increased support to innovative companies developing COVID-19 related solutions, in particular for the development of vaccines and production facilities. In this regard, the following specific objectives are defined:

- To identify the possibilities to expand the use of R&I financial instruments addressing COVID-19 related issues;
- To examine the possibilities enabled by the Temporary State Aid Framework and other flexible arrangements for dedicating other funding sources to R&I COVID-19 actions;
- To explore avenues for joint COVID-19 response between the EU and national level vis-à-vis funding the development of vaccines and production facilities.

Functioning and timeframe

The Financing sub-group will communicate mainly through e-mail exchange; a document-sharing platform may be made available. As relevant, (virtual) meetings will be organised. The sub-group will report to the *ad hoc* working group on regular basis.

As needed, external experts may be consulted to provide support for specific issues.

The financing sub-group is established for the duration of the COVID-19 pandemic response.

[6] https://ec.europa.eu/info/sites/info/files/research_and_innovation/research_by_area/documents/ec_rtd_era-vs-corona_0.pdf