



EUROPEAN COMMISSION  
HEALTH AND FOOD SAFETY DIRECTORATE-GENERAL

Directorate Public health, country knowledge, crisis management  
Crisis management and preparedness in health Unit

**SENSITIVE\***

*RELEASABLE TO: Need to know basis*

## EVALUATION REPORT

### 1. Contract references

**Title of contract:** Call for tenders for the development, production, priority-purchasing options and supply of COVID-19 vaccines for EU Member States

**Reference:** SANTE/2020/C3/042

**Contracting authority:**

The contract with the winning tenderer (“Contractor”) shall be concluded by the European Commission on behalf and in the name of the following EU Member States (hereinafter referred to as “the Contracting authorities”):

Republic of Austria (AT)  
 Kingdom of Belgium (BE)  
 Republic of Bulgaria (BG)  
 Republic of Croatia (HR)  
 Republic of Cyprus (CY)  
 Czech Republic (CZ)  
 Kingdom of Denmark (DK)  
 Republic of Estonia (EE)  
 Republic of Finland (FI)  
 French Republic (FR)  
 Federal Republic of Germany (DE)  
 Hellenic Republic (EL)  
 Hungary (HU)  
 Ireland (IE)  
 Italian Republic (IT)  
 Republic of Latvia (LV)  
 Republic of Lithuania (LT)  
 Grand Duchy of Luxembourg (LU)  
 Republic of Malta (MT)  
 Kingdom of the Netherlands (NL)  
 Republic of Poland (PL)  
 Portuguese Republic (PT)  
 Romania (RO)  
 Republic of Slovakia (SK)

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Republic of Slovenia (SI)  
 Kingdom of Spain (ES)  
 Kingdom of Sweden (SE)

**Type of procedure:** negotiated procedure without prior publication of a contract notice according to Article 164(l)(d) as well as Annex I, Point 11.1(c) of the Financial Regulation. The justification on the type of procedure and selection of the candidate is the following :

As mentioned in the Commission Decision<sup>1</sup> adopted on 18 June 2020, the Council of Ministers for Health agreed 12 June 2020 on the need for joint action to support the development and deployment of a safe and effective vaccine against COVID-19 by securing rapid, sufficient and equitable supplies for Member States. In order to implement such action, the Commission has offered to run a single central procurement procedure on behalf of all Member States and with a view to signing EU level Advance Purchase Agreements (“APAs”) with vaccine manufacturers.

The development of an effective and safe vaccine against the virus COVID-19 will save many lives, jobs and billions of euros. Conversely to the normal practice, where vaccine producers make investments in their production capacity only when they are sure of a viable product, given the current situation of global emergency, investments need to be made now in order to ensure that vaccines will be produced at the scale required as early as possible.

The reasons for extreme urgency are outside the sphere of influence of the European Commission and participating contracting authorities. Therefore, individual negotiated procedures with preselected economic operators invited to submit a tender within the shortest possible, yet reasonable time limit is the most appropriate procedure in the context of the ongoing COVID-19 outbreak.

Consequently, in compliance with Article 164(l)(d) as well as Annex I, Point 11.1(c) of the Financial Regulation, the Commission will apply, for each identified economic operator, a **negotiated procedure without prior publication of a contract notice for the procurement for the development, production, priority-purchasing options and supply of COVID-19 Vaccines for EU Member States.**

## 2. Working method

The evaluation was performed by an evaluation committee appointed by the responsible authorising officer (Ares(2020)4243830- 10/08/2020 amended on 18/08/2020 with Ares(2020)4298230).

The evaluation committee comprised of 20 people with two observers, of whom seven from the Member States, that are part of the Steering Board.

The evaluators split into two teams. One team of evaluators evaluated the exclusion and selection criteria. A second team verified compliance with the minimum technical requirements and applied the award criteria.

Due to the exceptional time-constraints in the context of the ongoing coronavirus outbreak, the evaluation was carried out and the requests for additional information were made for the non-exclusion, selection, technical conformity and award criteria in parallel.

<sup>1</sup> COMMISSION DECISION C(2020) 4192 final of 18.6.2020 approving the agreement with Member States on procuring Covid-19 vaccines on behalf of the Member States and related procedures: <http://www.ec.ecc/sg/vista/home?documentDetails&DocRef=C/2020/4192&ticket=ST17143962zblJo8Dzx1XIfoFzzulImqsqqezePkRe5xwdQGwbZ5d8dlGgEoYZEdXRlBkagiqsbEMk3zXSm128sazMhV25gjpJZscgsw0KXA5S7qlcMNcumPg4RUQs3RsQSYumzTKqvrBbAwLzVxs1fvJhbRFRKOJY53oVXOhVj2CYjo3GOiuYpCVeYk98E5q201XDvLQ9>

It has to be noted that due to the complexity and importance of the contract, additional experts from DG BUDG and Legal Service have been involved in the drafting of contract. Specific technical discussions were organised to address complexities.

All evaluators approved the final outcome of the evaluation of the exclusion, selection and award criteria and final contract resulting from subsequent contract negotiations.

The members of the evaluation committee held meetings according to the following schedule:

Date	Place	Topic discussed
18/08/2020	WebEx	General assessment of the tender. Exchange on the draft contract.
20/08/2020	Skype meeting	Evaluation of the exclusion, selection and award criteria.
26/08/2020- 28/08/2020	WebEx	Specific discussions on the draft contract.
07/09/2020	WebEx	Final meeting of the evaluation committee

And agreed by writing on the evaluations.

### 3. Access to market

The evaluation committee examined whether the tenderer has access to the market of the European Union pursuant to Articles 176 and 177 of the Financial Regulation.

The invited tenderer was found to have access to EU public procurement contracts. The results of the verification are as follows:

No	Name	Place of establishment or domicile	Access to market	Comments
1	Sanofi Pasteur SA (Leader)	FR	Yes	
	Glaxosmithkline Biologicals SA	BE	Yes	

### 4. Verification of exclusion criteria (declaration)

The provision of declarations on honour, dated and signed, stating that the tenderers are not in one of the exclusion or rejection situations referred to in Articles 136 to 141 of the Financial Regulation, has been verified.

The check of the Early Detection and Exclusion System has been performed.

The results of the verification of exclusion criteria are as follows:

No	Name	Declaration received in due form	Further request (date + ARES reference)	Accepted, rejected or excluded	Comments
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<b>1</b>	Sanofi Pasteur SA (Leader)	Yes	Evidence requested on 19-08-2020: Ares(2020)4339 961 Evidence received on 26-08-2020: Ares(2020)4434 267.	Accepted	
	Glaxosmithkline Biologicals SA	Yes		Accepted	

### 5. Verification of selection criteria (declaration)

The results of the verification of selection criteria are as follows:

No	Name	Declaration received in due form	Further request (date + ARES reference)	Accepted, rejected or excluded	Comments
<b>1</b>	Sanofi Pasteur SA (Leader)	Yes		Accepted	
	Glaxosmithkline Biologicals SA	Yes		Accepted	

Detailed evaluation comments per criterion:

No	Criterion	Documents to be submitted regarding criterion	Evidence provided	Comments
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F1	<p>The tenderer must prove to be financially viable to fulfil its obligations under the APA during the project development phase of the next twelve months. Financial viability of the tenderer will be checked by calculating a survival ratio as per explanations below.</p>	<ul style="list-style-type: none"> <li>- Reasoned assessment for each involved entity of the projected quarterly cash needs for the period up to December 2021, starting with the current quarter (mix of actual and projection), taking into account at least cash flows from operations, cash outflows from planned investments and cash outflows from maturing debt, and</li> <li>- Cash balance available at the end of the previous quarter and the date at which the information is requested, and</li> <li>- Copy of the profit and loss accounts, cash flow statements (if available) and balance sheet for the last two years for which accounts have been closed from each concerned involved entity, or, failing that,</li> <li>- Appropriate statements from banks. The most recent year must have been closed within the last 18 months, or</li> <li>- Any other document allowing to calculate the ratio below.</li> </ul>	Yes	<p>The survival ratio is below 1 however the cashflow expected for the next 12 months is positive (January 2020-December 2020). We understand that Sanofi uses a cashpooling system to centralize money in one entity and can rely on this entity in case of cash need. General financial situation is acceptable (see explanation on ratings and availability of credit lines)</p>
T1	<p>The tenderer must have implemented, within the company, Good manufacturing practice (hereafter, GMP) or GMP equivalent standards in its production processes.</p>	<ul style="list-style-type: none"> <li>- Copy of a valid EU GMP certificate issued by a competent authority; or failing that,</li> <li>- Confirmation by an authorised body of the country where production takes place that it conforms to GMP standards equivalent to those in the EU.</li> </ul>	Yes	<p>GSK: Copy of Certificates of GMP compliance from BE, FR, IT, UK national Agency for Medicines and health products safety</p> <p>Sanofi: Declaration + Copy of Certificates of GMP compliance from FR, DE, IT national Agency for Medicines and health products safety + statement that 2 extra Certificates of GMP compliance for the Marcy L'Etoile manufacturing site from FR are extended until 2021</p> <p>+ Manufacturer's authorisation for 3 sites: FR, IT, DE</p>
T2	<p>The tenderer must have implemented, within the company, a Quality Management System, based on ISO 9001 or equivalent, in respect of the activities subject of this call for tender.</p>	<ul style="list-style-type: none"> <li>- Copy of valid ISO 9001 certificate or equivalent; or, failing that,</li> <li>- Document demonstrating that the tenderer has implemented a Quality Management System for the services within its company based on ISO 9001 or equivalent.</li> </ul>	Yes	<p>GSK Quality Management System (QMS) replaces ISO 9001.</p> <p>SANOFI: "Pharmacien responsable" declaration equivalent to QMS</p>
T3	<p>The tenderer must have an activity related to the development of a</p>	<ul style="list-style-type: none"> <li>- Notification by a competent authority of any development activity taking place; development of or manufacturing of clinical trials; or failing that,</li> </ul>	Yes	<p>Sanofi: EMA Rapid Scientific Advice CoV-2 preS dTM (549)</p>

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## 5. Compliance with technical specifications

Compliance of tenders with the tender specifications was checked.

The results of the compliance check are as follows:

No	Name	Compliant	Comments
1	Sanofi Pasteur SA (Leader)	Yes	
	Glaxosmithkline Biologicals SA	Yes	

Overall, the minimum requirements for this tender appear to be met, taking into account that certain elements are not yet available and certain parameters are still unknown. Commitment from company may need to be ascertained regarding some aspects, e.g. full regulatory compliance, production and delivery timeline, etc.

### Detailed evaluation comments

#### a) Technical requirements for vaccine characteristics

- Formulation: liquid containing recombinant protein, separate adjuvant to be mixed at time of vaccination. Vaccination by injection.
- Injectable
- Packaging as multi-dose vials (10 doses).
- The minimum requirements regarding the information on the packaging in accordance with the European law (prospect with adverse reactions, etc.)
- Certificates of GMP compliance submitted for the various Sanofi Pasteur and GSK production sites.

#### b) Regulatory requirements

The Contractor shall demonstrate compliance with all relevant legislation and regulatory requirements and fulfil necessary licencing requirements particular to the supply of vaccines in the European Union.

The Contractor shall hold a marketing authorisation for a COVID-19 vaccine ahead of placing on the EU market. The vaccine shall be manufactured, controlled and distributed in compliance with Directive 2001/83/EC of the European Parliament and of the Council on the Community code relating to medicinal products for human use.

During the course of the contract, the Contractor enables the Contracting authorities to carry out a GMP/GDP-inspection at all times. The Contractor shall provide full cooperation during these inspections as long as the inspections are related to this tender. The costs of the inspection are for the account of the Contracting authorities, unless the inspection results in proof of default. In the latter case, all costs are for the account of the Contractor.

- Project presented to EMA (March 2020) and several national regulatory agencies in Europe (ANSM, March 2020; AEMPS, April 2020 ; PEI, June 2020). Interactions with EMA and official Scientific Advice procedures are ongoing (second Scientific Advice planned for September 2020).
- c) Other requirements that might be used to guide the purchase of the vaccine
- a. **Immunogenicity (incl. pre-clinical data)** - Magnitude and quality (e.g. neutralising antibodies)/nature of immune response that is likely to confer protection.
  - Non-clinical and clinical studies ongoing but no results or evidence of immunogenicity presented at moment.
    - b. **Safety** - Reactogenicity profile in line with what seen with licensed vaccines and no significant serious adverse events (at least 100 subjects). Occurrence of unexpected serious adverse events allowing a positive risk-benefit profile. No signs of vaccine dependent enhancement from either preclinical or clinical studies.
  - The candidate vaccine is composed of Sanofi Pasteur's recombinant Covid-19 Spike protein antigen – based on Baculovirus Expression System Technology - and GSK's squalene-based Adjuvant. S Antigen expression system is FDA-approved and under EMA review for the flu vaccine (Supemtek) using the same technology; GSK's Adjuvant, AS03, is FDA/EMA approved. Non-clinical and clinical studies ongoing.
    - c. **Safety and immunogenicity** in different populations, notably the elderly - Immune response comparable to younger adults (with potential adjustment of posology) and no emerging safety concerns.
  - Phase I/II and Phase III clinical trials ongoing/ planned with healthy adults volunteers 18 years of age and older.
    - d. **Efficacy** (NB- It is a critical aspect but it is understood that data will not be available by end of 2020) - Pre-clinical infection models showing protection after challenge. Any emerging evidence from clinical studies (if available).

- Non-clinical and clinical studies ongoing but no results presented at the moment.

## 6. Evaluation of award criteria

### Detailed evaluation comments per criterion:

Tender was evaluated according to the best price-quality ratio in accordance with the formula announced in the Technical Specification of the call, and on the basis of the following award criteria and their weighting:

#### 1. Price - 10%

The price considered for evaluation was be the total price of the tender, covering both: the upfront costs and the total price of the vaccines (calculated by multiplying the proposed number of doses by the estimated unit price per dose of vaccine).

#### 2. Quality - 90%

The quality evaluation (Q) of tenders was scored out of 100 points and based on the criteria set out in the tables below.

If the tender do not score the minimum quality threshold of 40% of points for all the criteria combined, it should be eliminated as stated in the Technical Specifications.

### Detailed evaluation comments per criterion:

The price (P) has been evaluated using the following formula :

Cost of development and production of one dose of vaccine :  $Pr = (UI + TPV) / QP$

Where:

- P is the score for the price of the tender in question
- UI is the total amount of the upfront payments (or investments)
- TPV is the total price of vaccines
- QP is the proposed number of doses

As per financial offer received :

UI = EUR 324.000.000,00

TPV = EUR 2.268.000.000,00 = EUR 8,64 x 300.000.000 doses

QP = 300.000.000 doses

Pr = EUR 8,64

No	Criterion	Documents to be submitted regarding criterion	Methodology of scoring points	Maximum points	Points	COMMENTS
	PRICE			$\Sigma$ 100		
	<b>Cost of development and production of one dose of vaccine</b>		<ul style="list-style-type: none"> <li>- <b>20 points</b> will be scored if Pr is above 30 EUR</li> <li>- <b>40 points</b> will be score if Pr is between 20 EUR and 30 EUR</li> <li>- <b>60 points</b> will be scored if Pr is between 12 EUR and 20 EUR</li> <li>- <b>80 points</b> will be score if Pr is between 8 EUR and 12 EUR</li> <li>- <b>100 points</b> will be score if Pr is below 8 EUR.</li> </ul>	100	80	See calculation above
	QUALITY			$\Sigma$ 100		
1.1	Roadmap towards starting clinical trials plans by in 2020	Technical offer demonstrating: <ul style="list-style-type: none"> <li>- Clinical trials plans.</li> <li>- If studies have started, the Clinical trial study descriptions.</li> </ul>	<ul style="list-style-type: none"> <li>- <b>10 points</b> will be scored to a tender that will demonstrate plans to enter clinical trials by end of October 2020</li> <li>- <b>5 points</b> will be scored to a tender that will demonstrate plans to enter clinical trials by end of December 2020</li> <li>- <b>0 points</b> will be scored to a tender that will demonstrate plans to enter clinical trials after end of December 2020</li> </ul>	10	10	Although no exact date indicated, timeline provided has Phase I/II clinical trials starting in Q3 2020 (i.e. before Oct 2020). Phase III to start before end of 2020 (Q4).
1.2	Capacity for the development of successful Covid-19	<p>The organization should demonstrate the scientific approach used in the development of the vaccine, including the research and development activities related to the application of the vaccine, the safety and efficacy studies, the manufacturing process, the distribution and the management of the vaccine.</p>	<ul style="list-style-type: none"> <li>- <b>20 points</b> will be scored to a tender that will demonstrate the organization's ability to develop a successful safe vaccine</li> </ul>	20	20	Vaccine incorporating Sanofi Pasteur's recombinant SARS-CoV-2 spike protein antigen (Baculovirus Expression System Technology) and GSK's AS03

1.3	Capacity to produce at scale required capacities for the EU	Technical offer indicating clearly the planned steps to produce and deliver the proposed number of doses of COVID-19 vaccines for the duration of the contract (indicated in column D of Annex 6, "Financial offer"), including, e.g.: - Production plan, batch size, and measures put in place to guarantee the production of the specified quantities including contingency plans, e.g. supplies and production parameters. - Guaranteed production capacity, maximum capacity of initial production (after the vaccine candidate approval) and subsequent maximum capacity per week. - A declaration on the percentage of the foreseen production capacity that will be reserved to the fulfilment of orders placed under the APA.	- <b>20 points</b> will be scored to a tender that will demonstrate capacity to produce at scale by end of by end of December 2020. - <b>10 points</b> will be scored to a tender that will demonstrate capacity to produce at scale by end of June 2021 - <b>0 points</b> will be scored to a tender that will not demonstrate capacity to produce at scale after end of June 2021.	20	10	Planned steps for production, detailed manufacturing timeline and overview of planned technology transfers / ramp-ups have been submitted. Timeline for availability of Adjuvanted Pandemic Vaccine is anticipated as follows: • Start full scale S Antigen Drug Substance production early Q1 2021 • First doses of final Drug Product Adjuvanted Pandemic Vaccine shipped as early as Q2 2021 (pending Union marketing authorisation) • Union marketing authorisation anticipated June 2021
1.4	Response capacity (With this criterion the evaluation committee will assess	- Financial offer indicating the maximum number of doses of vaccines that could potentially be delivered per quarter (3 calendar months) for one or more orders not exceeding one twelfth (1/12) of the total amount indicated in column C (Desired number of units for the duration	- <del>100% of the target of the proposed capacity per quarter confirmed based on the provided supporting evidence:</del> - 100% of the target of the proposed capacity per quarter confirmed based on the provided supporting evidence:	15	15	Proposal to deliver half of the amount (150 million doses) in first quarter (3 months), thus exceeding percentage of capacity per quarter if calculated (calculation 300 M / 12 = 25 M). However, final delivery schedule to be confirmed in December 2020 / January 2021 once key parameters are known (incl. final antigen dosage, manufacturing yield, etc...). No information

1.5	Speed of delivery supplies	<p>Delivery plan, indicating clearly the proposed speed of delivery of products taken into account the following parameters:</p> <ul style="list-style-type: none"> <li>- The delivery time is to be calculated from the actual order of vaccines to the time the goods will actually reach the premises of the Contracting authority.</li> <li>- The speed of delivery must apply to the quantities indicated in the response capacity (criterion 1.4).</li> <li>- It is not allowed to split the amount declared under criterion 1.4 according to the speed (ex. if the quantity indicated under response capacity above is 1 500 doses per quarter, the speed of delivery must take into account the whole amount. For instance, split offers like "500 doses in 2 weeks and the rest in 4 weeks" will be awarded 0 points).</li> <li>- A declaration on the percentage of the foreseen production capacity that will be reserved to the fulfilment of orders placed under the APA.</li> </ul>	<p>First delivery within 12 weeks will be scored <b>0 points</b>. For each reduction by one week the tender shall be scored <b>3 additional points</b>, up to a maximum of <b>12 points</b>.</p>	12	0	<p>No information supplied regarding speed of delivery. Interaction with EMA and official Scientific Advice procedures ongoing (second Scientific Advice planned for September 2020).</p>

1.6	Intention to seek EU marketing authorization	Technical offer demonstrating that the tenderer has engaged with EU regulators at the early stage with the intention to apply for an EU marketing authorisation for the candidate vaccine(s).	- <b>10 points</b> will be scored to a tenderer that has engaged with EU regulators with the intention to seek future EU marketing authorization at the time for submitting the tender. - <b>0 points</b> will be scored to a tenderer that has not engaged with the EU regulators with the intention to seek future EU authorization at the time for submitting the tender.	10	10	Project presented to EMA (March 2020) and several national regulatory agencies in Europe (ANSM, March 2020; AEMPS, April 2020 ; PEI, June 2020). Interactions with EMA and official Scientific Advice procedures are ongoing (second Scientific Advice planned for September 2020).
1.7	Production capacity in the EU (linked to COVID-19 vaccine)	Technical offer outlining: - Any production sites (e.g., active substances, or adjuvants, or finished product) in the EU; or - Any research and development sites in the EU; or - Any fill-and-finish capacity in the EU; or other.  (Including supporting evidence, e.g.: - Certificate of approval for an activity related to the subject of this call for tenders for the relevant site; or, failing that, - Confirmation by an authorised body of the country where the activity takes place; or equivalent, or - Document demonstrating that the tenderer has production capacity in the EU.)	- <b>13 points</b> will be scored to a tenderer that has at least one production site and research and development site and fill-and-finish capacity in the EU. - <b>6 points</b> will be scored to a tenderer that has at least one production site or research and development site or fill-and-finish capacity in the EU. - <b>0 points</b> will be scored to a tenderer that has no production capacity in the EU.	13	13	Manufacture predominantly at GSK and Sanofi Pasteur sites in the EU. 1- Production sites (antigen production, adjuvant production) in FR, BE, DE, IT; 2- Research and development sites in EU: FR and BE; 3- Fill-and-finish capacity in the EU : FR, IT, BE.
<b>TOTAL QUALITY SCORE:</b>				<b>78</b>	<b>Minimum quality threshold = 40</b>	
<b>FINAL SCORE = (P * 10%) + ( Q * 90%)</b>				<b>78.2</b>	<b>Final score minimum threshold = 45</b>	

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### 7. Abnormally low tender(s)

Not applicable.

### 8. Score

The final score of the tender was calculated following the formula indicated in the tender specifications:

$$R = (Q * 0,9) + (P * 0,1)$$

where:

- R is the final score of the tender in question;
- Q is the quality evaluation score awarded;
- P is the score for the price of the tender in question;

The contract shall be awarded to the tender which complies with the Tender Specifications and is submitted by a tenderer having access to procurement, not in an exclusion situation and fulfilling the selection criteria, and the offer it submitted has a total score above 40 in relation to the quality award criteria (Q) and the final score (R) is above 45.

	Price score	Quality score	$R = (Q * 0,9) + (P * 0,1)$	Minimum threshold reached
Sanofi - GSK	80	78	78,2	YES

### 9. Award

Considering the results of the evaluation as described above, the Evaluation Committee proposes to award the contract to the following tenderers:

Sanofi Pasteur SA (Leader)  
14 Espace Henry Vallée  
69007 Lyon  
FRANCE

Glaxosmithkline Biologicals SA  
89 Rue de l'Institut,  
1330 Rixensart  
BELGIUM

**Total contract value:** 2.592.000.000,00

The above-mentioned tender is compliant with the tender specifications and offers the best price quality ratio.

The check of the Early Detection and Exclusion System has been checked.

Name, date and signature of the evaluation committee members:

Name	Department	Date	Signature
5.1.2e	SANTE.C3	Ares date	In ARES workflow
5.1.2e	SANTE.C3	Ares date	In ARES workflow
5.1.2e	SANTE.C3	Ares date	In ARES workflow
	SANTE.A3	Ares date	In ARES workflow
5.1.2e	SANTE.A3	Ares date	In ARES workflow
5.1.2e	SANTE.DDG2	Ares date	In ARES workflow
5.1.2e	SANTE.DDG2	Ares date	In ARES workflow
5.1.2e	SG DSG2 D3	Ares date	In ARES workflow
5.1.2e	COMP B1	Ares date	In ARES workflow
5.1.2e	SJ H	Ares date	In ARES workflow
5.1.2e	SJ H	Ares date	In ARES workflow
5.1.2e 5.1.2e 5.1.2e	SJ H	Ares date	In ARES workflow
	SANTE.C3	Manual	
5.1.2e	IT representative	Manual	
	ES representative	Manual	
5.1.2e	FR representative	Manual	
	DE representative	Manual	
	SE representative	Manual	
	PL representative	Manual	
	NL representative	Manual	

\* Steering Board MS representatives