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CONSUMERS, HEALTH, AGRICULTURE AND FOOD EXECUTIVE AGENCY

Health and Food Safety Unit

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Call for Tenders CHAFEA/2019/Health/07

Service contract for the provision of options and recommendations for an EU citizens' vaccination card

TENDER SPECIFICATIONS

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1. INFORMATION ON TENDERING

1.1. Purpose of the contract

The Consumers, Health, Agriculture and Food Executive Agency (henceforth "CHAFEA" or "the Contracting Authority"), acting under the powers delegated by the European Commission (henceforth "the Commission"), is launching the present invitation to tender for the conclusion of a service contract (henceforth "the contract").

The purpose of this contract is to examine the feasibility of developing a common vaccination card for EU citizens[1]. Based on a mapping of existing vaccination cards (work package 1), the contractor shall develop, test and evaluate proposals for an EU citizens' vaccination card that takes into account potentially different national vaccination schedules; that is interoperable with EU Member States' Immunisation Information Systems (IIS); and that is common to all EU Member States and usable across borders (work package 2).

The contract shall result in a Final Report on options and recommendations on an EU citizens' vaccination card based on a legal, operational and financial evaluation, outlining the added value of such an EU citizens' vaccination card in view of increasing vaccination coverage, facilitating movements of EU citizens across borders and taking EU Member States' different technical environments into account.

The requested service is further detailed in the technical specifications (Section 2).

1.2. Background information and Context

CHAFEA was created on 1 January 2005 (formerly named PHEA from 2005 to 2008 and EAHC[2] from 2008 to 2014). In 2013[3], CHAFEA replaced and succeeded the executive agency EAHC, which was established by Decision 2004/858/EC. CHAFEA's mandate was prolonged until 2024 and extended in order to cover management of new actions and programmes (in the field of health, consumer protection and food safety). In 2016, the mandate was extended to manage the reformed EU agricultural products information and promotion.

Currently, CHAFEA implements the Promotion of Agriculture Products, the EU Health Programme, the Consumer Programme, and the Better Training for Safer Food initiative (BTSF).

The Agency provides professional services in performing the tasks and activities entrusted to it by the Commission and works closely with the DG Health and Food Safety, DG Justice and Consumers and DG Agriculture and Rural Development.

[1] For ease of reference, the term "EU citizens" is used throughout the document but encompasses EU residents in general.

[2] Commission Decision of 15 December 2004 setting up an executive agency, the 'Executive Agency for the Public Health Programme', for the management of Community action in the field of public health - pursuant to Council Regulation (EC) No 58/2003.

[3] Commission Implementing Decision of 17 December 2013 establishing the Consumers, Health and Food Executive Agency and repealing Decision 2004/858/EC.

1.3. Participation in the tendering procedure, access to market

Participation in this procurement procedure is open on equal terms to all natural and legal persons coming within the scope of the Treaties, as well as to international organisations.

Procurement procedures launched by CHAFEA are open to all natural and legal persons established in EEA countries and countries under the Stabilisation and Association Agreements.

For British candidates or tenderers:

Please be aware that after the UK's withdrawal from the EU, the rules of access to EU procurement procedures of economic operators established in third countries will apply to candidates or tenderers from the UK, depending on the outcome of the negotiations. In case such access is not provided by legal provisions in force, candidates or tenderers from the UK could be rejected from the procurement procedure.

The rules of access to the market apply to all members of a joint tenderer, but do not apply to subcontractors.

1.4. Contractual Conditions

The tenderer should bear in mind the provisions of the draft contract, which specifies the rights and obligations of the contractor, particularly those on payments, performance of the contract, confidentiality, and checks and audits.

1.5. Compliance with Applicable Law

The tender must comply with applicable environmental, social and labour law obligations established by Union law, national legislation, collective agreements or the international environmental, social and labour conventions listed in Annex X to Directive 2014/24/EU.[4]

1.6. Joint Tenders

A joint tender is a situation where a tender is submitted by a group of economic operators (natural or legal persons). Joint tenders may include subcontractors in addition to the members of the group.

In case of joint tenders, all members of the group assume joint and several liability towards the Contracting Authority for the performance of the contract as a whole, i.e. both financial and operational liability. Nevertheless, tenderers must designate one of the economic operators as a single point of contact for the Contracting Authority (the leader). The leader shall be authorised to submit the tender on behalf of the group and act on behalf of its members in connection with the tender.

After the award, the Contracting Authority will sign the contract either with all members of the group, or with the leader on behalf of all members of the group, authorised by the other members via powers of attorney.

[4] Directive 2014/24/EU of the European Parliament and of the Council of 26 February 2014 on public procurement and repealing Directive 2004/18/EC (OJ L 94, 28.3.2014, p. 65).

The tender must identify the participating operators (members) by filling in the relevant points of Annex Ia (tender submission form). The tender shall clearly specify the role and tasks of each member within the tender.

For information on how the exclusion, selection and award criteria are applied to joint tenders (with or without subcontracting) please refer to section 4 of the tender specifications.

1.7. Subcontracting

Subcontracting is permitted but the contractor will retain full liability towards the Contracting Authority for performance of the contract as a whole. The Contracting Authority will not have any direct legal commitment with the subcontractor(s).

Tenderers are required to identify subcontractors whose share of the contract is above 10 % and those subcontractors whose capacity is necessary to fulfil the selection criteria (hereinafter referred to as "identified subcontractors").

The tender must provide all the necessary information related to the above mentioned subcontractor(s) by filling in the Annex Ia (identity, role, specific tasks). All identified subcontractors should provide a written statement declaring their undertaking to collaborate with the tenderer in case of award of the contract and the resources that the subcontractor will put at the tenderer s disposal (see Annex Ic - letter of intent for subcontractors).

During the execution of the contract, the change of any subcontractor identified in the tender or any additional subcontracting will be subject to prior written approval of the Contracting Authority.

For information on how the exclusion, selection and award criteria are applied to subcontractors please refer to section 4 of the tender specifications.

1.8. Structure and Content of the Tender

The tenders must be presented as follows:

A: Administrative offer

The administrative offer must include documents issued by the tenderers /members of the joint tender/identified subcontractors and provide information in relation to the identification of the tender, its access to the market and compliance with the exclusion and selection criteria.

The Administrative offer must include the following documents:

Document to be provided	Form to use (if applicable)	Reference to the Tender specifications' chapter
Cover letter	n.a.	1.9
Tender submission form	Annex Ia – included in the published PDF form	1.9

Power of attorney (for members of the Joint Tender)	Annex Ib – included in the published PDF form	1.9
Letters of intent (for subcontractors)	Annex Ib – included in the published PDF form	1.9
Legal entity forms (and its supporting documents)	Annex II – The form is available via a link within the Tender Submission Form that is included in the published PDF form	1.9
Financial identification form (and its supporting documents)	Annex III – The form is available via a link within the Tender Submission Form that is included in the published PDF form	1.9
Declaration of Honour on exclusion and selection	Annex IV – included in the published PDF form	4.1 and 4.2
Check-list	Annex VI	

Additional administrative documents should be provided upon request by the successfully evaluated tenders. If necessary for the assessment of the tenders, CHAFEA is reserving the right to request further administrative documents in duly justified cases.

B: Technical offer

The technical offer must cover all aspects and assignments required in the technical specifications and provide all the information needed to apply the award criteria. More specifically, the technical offer must include a detailed description on how the tenderer(s) are planning to provide the requested service, as defined in the technical specifications covering all aspects and tasks described therein (see section 3 below). The tender should provide all the information needed to appraise the award criteria presented in point 4.3 of the present tender specifications.

Technical offers that do not cover all minimum requirements may be rejected on the basis of non-compliance with the tender specifications and will not be further evaluated.

C: Financial offer

The price for the tender must be quoted in Euro. Tenderers from countries outside the euro zone have to quote their prices in euro. The price quoted may not be revised in line with exchange rate movements. It is for the tenderer to bear the risks or the benefits deriving from any variation.

Prices must be quoted free of all duties, taxes and other charges, including VAT, as the European Union is exempt from such charges under Articles 3 and 4 of the Protocol on the privileges and immunities of the European Union. The amount of VAT may be shown separately.

The quoted price must be a fixed amount which includes all charges (including travel and subsistence). Travel and subsistence expenses are not refundable separately.

1.9. Identification of the tenderer - legal status

The tender must include a **cover letter** signed by an authorised representative together with the administrative offer (A) of the tender presenting the name of the tenderer (including all entities in case of joint tender) and identified subcontractors, if applicable, as well as the name of the single contact point (leader) in relation to this procedure.

In case of joint tender, the cover letter must be signed either by an authorised representative for each member, or by the leader authorised by the other members with the power of attorney (see Annex Ib).

As evidence, **all tenderers** (including all members of the group in case of joint tender and identified subcontractors if any) shall fill in the data requested in the appropriate PDF Tender submission form (Main form for the tenderer or the Leader, and Sub-form for all the others) and provide all the supporting documents requested for each specific annex. In order to generate the appropriate Sub-forms and Annexes, the tenderer (or the leader in case of joint tender) should follow the technical instructions.

Please note that there are particularities for some of the annexes contained in the PDF Tender submission form:

- Annex Ia (Tender submission form):

  All tenderers (including all members of the group in case of joint tender and identified subcontractors if any) should fill in the Tenderer's composition and Member detailed information.

  Additionally, the tenderer (or the leader in case of joint tender) should fill in and sign the Statement page.

  The tenderer (and each member of the group in case of joint tender) must declare whether it is a Small or Medium Size Enterprise in accordance with Commission Recommendation 2003/361/EC by selecting the relevant option in the Member detailed information part of Annex Ia. This information will be used by the contracting authority for statistical purposes only.

- Annex Ib (Power of attorney):

  In case of Joint Tender, all members of the group should provide the Power of attorney document counter-signed by the leader of the Joint Tender (see point 1.5 of the present tender specifications).

- Annex Ic (Letter of intent):

  Identified subcontractors must provide the letter of intent signed by an authorised representative (see point 1.6 of the present tender specifications.

- Annex IIa / IIb / IIc (Legal entity form) - the link to access the forms is included in the PDF Tender Submission Form

The tenderer (and each member of the group in case of joint tender) must provide a signed Legal Entity Form with its supporting evidence. No form is required for subcontractors.

Tenderers that are already registered in the Contracting Authority's accounting system (i.e. they have already been direct contractors) must provide the form but are not obliged to provide the supporting evidence.

- Annex III: Financial identification form - the link to access the form is included in the PDF Tender Submission Form

The tenderer (or the leader in case of joint tender) must provide a Financial Identification Form with its supporting documents. Only one form per tender must be submitted. No form is required for subcontractors and other members of the group in case of joint tender.

2. TECHNICAL SPECIFICATIONS

2.1. Description of the requested service and deliverables

Work package 1 — Mapping of existing vaccination cards

General background

On 7 December 2018, EU Health Ministers adopted a Council Recommendation on strengthened cooperation against vaccine-preventable diseases (https://ec.europa.eu/health/sites/health/files/vaccination/docs/14152_2018_en.pdf). The Recommendation was accompanied by a Commission Communication (https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=COM:2018:245:FIN). While the organisation of vaccination programmes are the responsibility of EU Member States and programmes, for this reason, present variations, the Recommendation and the Communication call for a multitude of actions to cooperate at EU level to fight vaccine-preventable diseases.

One of these actions is to examine the feasibility of developing a common EU citizens' vaccination card/passport with the main purpose of improving vaccination coverage by addressing the issues caused by cross-border movement of people, and differences in vaccination programmes across the EU.

Such a common EU citizens' vaccination card/passport is also in line with the "participatory approach" in the way individuals engage in health-related decisions and with the citizen-centred approach adopted in the European Commission's eHealth Action Plan 2012-2020 (https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1550061597950&uri=CELEX:52012DC0736).

As a policy initiative, the Council Recommendation and the Commission Communication are complemented by a Joint Action of Vaccination (https://eu-jav.com), launched in September 2018 and co-funded by the EU Health Programme.

General objective

The purpose of this mapping exercise is to examine and compare **form** and **content** of existing vaccination cards with a view to identifying features which have the capacity to be taken up in an EU citizens' vaccination card.

Tasks of the contractor

Concerning the **form** of existing vaccination cards, the mapping exercise shall focus on physical design and appearance as well as on functional features. This includes material, size and format, colour, layout, use of graphics and images, protective cover option etc. It also includes elements related to the way existing vaccination cards present themselves as official public health documents, e.g. via an overview of the applicable vaccination programme and/or messaging on the importance of vaccination.

This part of the mapping exercise shall pay special attention to whether existing vaccination cards are in physical form, electronic form (owned by citizens or by the healthcare system), including an application for mobile devices, or both. In relation to this, the way existing vaccination cards are linked to Immunisation Information Systems (IIS) must be examined and compared.

It is here to be noted that some countries have advanced IIS in operation that can be used to monitor vaccination coverage in the population but also to keep track of citizens' vaccination status and, on the basis of this, generate vaccination cards. Other countries are piloting IIS and still others have no IIS in operation or being piloted. To this regard, the European Centre for Disease Prevention and Control (ECDC), in 2017, performed a **survey** on the implementation and system characteristics of immunisation information systems in the EU and EEA (https://ecdc.europa.eu/sites/portal/files/documents/immunisation-systems.pdf) and, in 2018, published a **handbook for those involved in the design, implementation or management of IIS** (https://ecdc.europa.eu/en/publications-data/designing-and-implementing-immunisation-information-system-handbook).

Concerning the **content** of existing vaccination cards, the mapping exercise shall focus on the dataset provided. This includes basic patient identification information (e.g. the individual's name, date of birth and/or unique identification number), vaccine provider's contact information, names, types and batch number of vaccines and the diseases the individual should be protected against, date of receipt for each vaccine/each dose, expiry of the protection provided, vaccines received outside of the routine vaccination programme, vaccine provider's notes, e.g. concerning known allergies and adverse reactions to vaccination, vaccine provider's signature and/or stamp etc.

Concerning both **form** and **content** of existing vaccination cards, the mapping exercise must focus on vaccination cards in all EU Member States, including, if applicable, regional vaccination cards in countries (e.g. Belgium and Spain) where vaccination programmes are managed regionally.

In addition, the mapping exercise shall cover the following:

a) national or regional vaccination cards from EEA countries, the USA, Canada, and Australia (the inclusion of these countries is a minimum requirement – tenderers can propose additional countries)
b) vaccination cards/formats for cross-border use, i.e. the **International Certificate of Vaccination or Prophylaxis** (https://www.who.int/ihr/IVC200_06_26.pdf?ua=1), issued by the World Health Organisation and the vaccination field of the **patient summary** of the eHealth digital service infrastructure, an electronic EU public health document allowing exchange of health data between EU Member States (see also work package 2)

c) other common EU documents, for instance the driving licence.

The following deliverables (D) are linked to work package 1:

D2 — Mapping of form and content of existing vaccination cards and other relevant public health documents
D3 — Interim Progress Report

Work package 2 — Development, testing and evaluation of templates for an EU citizens' vaccination card

General background

The variations presented by EU Member States' vaccination programmes can pose practical problems when EU citizens move between Member States. A key issue is difficulties regarding the ability to continue vaccinations where citizens, in particular children, move from one Member State to another while being in the middle of a vaccination course that is part of the vaccination programme in the Member State of departure but not of that of the Member State of destination, or to catch up with the vaccination programme in the opposite situation. An EU citizens' vaccination card could help to improve vaccination coverage by empowering citizens to get the vaccinations they need when moving between Member States and help to prevent cross-border health threats by having a document easily recognisable in all EU Member States.

Specific objective

Based on the mapping of existing vaccination cards in all EU Member States, this work package shall **develop**, **test** and **evaluate** 3 (three) different templates for an EU citizens' vaccination card. In completing the work, the contractor shall make sure that the templates proposed take into account applicable EU legislation on data protection.

Tasks of the contractor

1) *Development of templates*

Concerning the **form** of the 3 templates for an EU citizens' vaccination card, it must be **dual**. For the purpose of this work package, a "template" shall thus be understood as a vaccination card in electronic form as well as its physical counterpart.

The templates must take into account the fact that the EU citizens' vaccination card should be usable across borders in EU Member States and that it should carry the European Union logo; have the potential to be used as a widely recognised EU document; and be updatable, both when the cardholder is vaccinated and in case new vaccines are introduced.

The templates must also take into account the fact that the EU citizens' vaccination card should be a **citizen's self-care tool**. The templates should give vaccine providers and other health professionals valuable information about the individual's vaccination history but they should first of all empower citizens to get the vaccinations they need. The vaccination card, as a lifelong document, should be **portable** in the sense that citizens should be able to easily store it or carry it with them, be it in paper/booklet form or as a "vaccination app" for smartphones, or both. Likewise, the vaccination card should be

easily readable for citizens. It should thus provide information not just in English but also in citizens' national language(s).

Concerning the **content**, the templates must take into account the fact that Member States' vaccination programmes present variations, for instance in terms of timing of vaccines and whether certain vaccines are mandatory or only recommended. It could thus be considered what **minimal dataset** the vaccination card should provide, e.g. names, types and batch of vaccines and the diseases the individual should be protected against, date of receipt for each vaccine/each dose and expiry of the protection provided.

The provision of the expiry of the protection provided is important. Since the EU citizens' vaccination card should first of all empower citizens to get the vaccinations they need, they would have to know when to be vaccinated again. It could thus also be considered how the vaccination card could remind citizens of their next vaccination, be it by a reminder function (vaccination card in electronic form – different reminder functions could be proposed) or by the simple indication of the date from which the individual is no longer protected (vaccination card in physical form).

Concerning **both form and content**, the templates should take the following **compatibility/interoperability needs** into account:

a) compatibility with Member States' IIS
b) interoperability between Member States' IIS and with the eHealth Digital Service Infrastructure.

Concerning these compatibility/interoperability needs, the templates should also take into account activities and achievements of the Joint Action of Vaccination (https://eu-jav.com), in particular Work Package 5 (Immunization Information Systems to strengthen surveillance and increase vaccination coverage).

Experience with existing electronic EU public health documents, in particular the patient summary of the eHealth Digital Service Infrastructure, a system that will allow cross-border exchange of ePrescriptions, patient summaries and, with the set-up of an European Electronic Health Record exchange format (see https://ec.europa.eu/digital-single-market/en/news/recommendation-european-electronic-health-record-exchange-format), electronic health records, should be taken into account and interoperability should be ensured. Finally, ythe proposed methodology should also take into account experiences to develop other EU wide common documents, such as passport or driving licence.

To this end, the Contracting Authority and DG SANTE, unit C3 and/or other units, will, at the kick-off meeting and throughout the duration of the contract, provide the contractor with additional information on the Joint Action of Vaccination and the patient summary, as well as on all relevant deliverables.

2) *Testing of templates*

The work package must test the 3 dual templates in at least 10 volunteering EU Member States with different IIS status. The purpose of this testing exercise is to determine the uptake, the operability and to what extent each of the templates helps to improve

vaccination coverage by empowering EU citizens in different technical environments to get the vaccinations they need.

The testing exercise is the most complex and time-consuming activity of the requested service. It consists in testing the templates in a cross-border setting and should be prepared by the development of an adequate **test design** taking the above-mentioned purpose into account, in particular by addressing the **user-friendliness** of the templates.

The test design must allow for an **adjustment and re-testing phase** if necessary.

In their description of the proposed methodology, the tenderers must provide the rationale behind the choice of Member States according to their IIS status. The EDCD survey on the implementation and system characteristics of immunisation information systems in the EU and EEA (https://ecdc.europa.eu/sites/portal/files/documents/immunisation-systems.pdf) and the ECDC handbook for those involved in the design, implementation or management of IIS (https://ecdc.europa.eu/en/publications-data/designing-and-implementing-immunisation-information-system-handbook) could be referred to in this respect.

The test design proposed will be assessed according to the following criteria:

a) involvement of EU Member States with different IIS status

b) involvement of EU Member States with different geographical location

c) involvement of EU Member States with different population size (small, medium, large)

d) involvement of national and/or regional competent authorities

e) involvement of at least 10 000 individuals per country, to ensure that the test results have the statistical power to show the potential of each of the templates to contribute to higher vaccination coverage

f) focus on at least two different vaccines, one being a childhood vaccine and the other a life-course vaccine.

Evaluation of templates – Final Report

Based on the testing on the templates in Member States, the 3 dual templates must be compared and evaluated in terms of their potential to serve the cardholder and to contribute to higher vaccination coverage. This evaluation must address legal, operational and financial issues, as well as outline the added value of an EU citizens' vaccination card in view of increasing vaccination coverage. It must also feed into the end goal of the work package, namely a **Final Report on options and recommendations for an EU citizens' vaccination card**, taking Member States' different IIS status into account.

The following deliverables (D) are linked to work package 2:

D4 — 3 templates for an EU citizens' vaccination card
D5 — Identification, in view of the testing of templates, of at least 10 volunteering EU Member States with different IIS status

D6 — Outline of Test design D7 — State of play of testing D8 — Test report D9 — Draft Final report on options and recommendations for an EU citizens' vaccination card D10 — Final report on options and recommendations for an EU citizens' vaccination card

Timeline

MONTH	**ACTIVITY/DELIVERABLE**
M1	Kick-off meeting (Luxembourg or Brussels)
M2	D1 — Inception Report
M6	D2 — Mapping of form and content of existing vaccination cards and other relevant public health documents Interim progress meeting 1 (Luxembourg or Brussels) D3 — Interim Progress Report
M7	D4 — 3 templates for an EU citizens' vaccination card
M9	D5 — Identification, in view of the testing of templates, of at least 10 volunteering Member States with different IIS status D6 — Outline of Test design
M9-18 M12	Testing of templates in the 10 volunteering Member States D7 — State of play of testing
M20	D8 — Test report Interim progress meeting 2 (Luxembourg or Brussels) D9 — Draft Final Report on options and recommendations for an EU citizens' vaccination card
M24	D10 — Final Report on options and recommendations for an EU citizens' vaccination card[5]

[5] The four months between the draft and final reports are necessary for all the necessary iterations, consultations and adjustments that the contracting authority and DG SANTE may need.

A more detailed timeline, including the breakdown of the key tasks in phases, should be provided in the submitted offer.

2.2 Meetings

As indicated in the table under section 2.1.6., the contractor will meet the responsible unit (Crisis management and preparedness in health) of DG SANTE of the European Commission and contracting authority (Chafea) at the kick-off meeting (M1); prior to the submission of the Interim Progress Report (M6); and at the time of submission of the Draft Final Report (M20).

The 3 meetings will take place in Luxembourg or Brussels. If necessary, further meetings could be organised as audio and/or video conferences.

Travel expenses shall be included in the global price offered by the tenderer. Separate reimbursement of travel costs is not possible.

2.3 Estimated value of the purchase

The estimated total value for the implementation of the contract, is **EUR 2 600 000**.

2.4 Duration of the tasks

Without prejudice to the time needed by the contracting authority to approve the final deliverables, the duration of the tasks to be performed by the contractor (contract performance) in execution of the requested service is **24 months**. This duration should be taken into account by the tenderer when preparing its offer.

3 CONTENT, STRUCTURE AND GRAPHIC REQUIREMENTS OF THE DELIVERABLES

The contractor must provide the deliverables as indicated below.

DELIVERABLE	TITLE AND DESCRIPTION	MONTH
D1	Inception report: in 3 hard copies and in electronic form, in English The inception report must include: • Work programme for work package 1 • Strategy for the data collection and analysis in view of the mapping of form and content of existing vaccination cards	M2
D2	Mapping of form and content of existing vaccination cards and other relevant public health documents: in 3 hard copies	M6

	and in electronic form, in English The mapping must be supported by visual elements and info-graphics as appropriate.	
D3	Interim Progress Report: in 3 hard copies and in electronic form, in English The Interim Progress Report must include: • State of play of the work programme for work package 1 • Work programme for work package 2 The Interim Progress Report must by supported by visual elements and info-graphics as appropriate.	M6
D4	3 templates for an EU citizens' vaccination card: to be presented/demonstrated according to their dual electronic and physical form	M7
D5	Identification, in view of the testing of templates, of at least 10 volunteering Member States with different IIS status: list in 3 hard copies and in electronic form, in English	M9
D6	Outline of Test design: in 3 hard copies and in electronic form, in English	M9
D7	State of play of testing: in 3 hard copies and in electronic form, in English	M12
D8	Test report: in 3 hard copies and in electronic form, in English. The test report must include: • Application of Test design: Which problems were encountered and how were they solved? • Test results: To what extent does each of the templates help to improve vaccination coverage by empowering EU citizens in different technical environments to get the vaccinations they need? • Limitations of test results: Which	M20

	factors should be taken into account? The test report must by supported by visual elements and info-graphics as appropriate.	
D9	Draft Final Report on options and recommendations for an EU citizens' vaccination card	M20
D10	Final Report on options and recommendations for an EU citizens' vaccination card: in 3 hard copies and in electronic form, in English. See also point 3.2 ("Content"). The Final Report must be supported by visual elements and info-graphics as appropriate.	M24

3.1 Content

Final Report

The Final Report must include:

- an abstract of no more than 200 words and an executive summary of maximum 6 pages, both in English and French;
- specific identifiers which must be incorporated on the cover page provided by the Contracting Authority;
- the following disclaimer (both in English and French as mentioned below):

"This report was produced under the EU Health Programme (2014-2020) under a service contract with the Consumers, Health, Agriculture and Food Executive Agency (CHAFEA) acting under the mandate from the European Commission. The information and views set out in this report are those of the author(s) and do not necessarily reflect the official opinion of the Commission/ Executive Agency. The Commission/Executive Agency does not guarantee the accuracy of the data included in this study. Neither the Commission /Executive Agency nor any person acting on the Commission's / Executive Agency's behalf may be held responsible for the use which may be made of the information contained therein."

«Les informations et points de vue exposés dans le présent rapport n'engagent que leur auteur (ou leurs auteurs) et ne sauraient être assimilés à une position officielle de la Commission/Agence Exécutive. La Commission/ Agence Exécutive ne garantissent pas l'exactitude des données figurant dans la présente étude. Ni la Commission/ Agence Exécutive ni aucune personne agissant au nom de la Commission/ Agence Exécutive n'est responsable de l'usage qui pourrait être fait des informations contenues dans le présent texte.»

Publishable executive summary

The publishable executive summary must be provided in both English and French and must include:

-specific identifiers which must be incorporated on the cover page provided by the Contracting Authority;

-the following disclaimer:

"This report was produced under the EU Health Programme (2014-2020) under a service contract with the Consumers, Health, Agriculture and Food Executive Agency (CHAFEA) acting under the mandate from the European Commission. The information and views set out in this report are those of the author(s) and do not necessarily reflect the official opinion of the Commission/ Executive Agency. The Commission/ Executive Agency do not guarantee the accuracy of the data included in this study. Neither the Commission /Executive Agency nor any person acting on the Commission's / Executive Agency's behalf may be held responsible for the use which may be made of the information contained therein."

3.2 Requirements for publication on Internet

The Commission/ Executive Agency is committed to making online information as accessible as possible to the largest possible number of users including those with visual, auditory, cognitive or physical disabilities, and those not having the latest technologies. The Commission supports the Web Content Accessibility Guidelines 2.0 of the W3C.

For full details on the Commission policy on accessibility for information providers, see: http://ec.europa.eu/ipg/standards/accessibility/index_en.htm.

For the publishable versions of the study, abstract and executive summary, the contractor must respect the W3C guidelines for accessible pdf documents as provided at: http://www.w3.org/WAI/.

3.3 Structure

All reports should have numbered paragraphs and pages and a clear identification, containing:

- the contract number (not the call number),
- the acronym,
- the version (draft, revision or final) and
- the date.

The reports and the deliverables shall be in English, unless otherwise indicated in these tender specifications.

3.4 Graphic requirements

The contractor must deliver the study and all publishable deliverables in full compliance with the corporate visual identity of the European Commission, by applying the graphic rules set out in the European Commission's Visual Identity Manual, including its logo. The graphic rules, the Manual and further information are available at:

http://ec.europa.eu/dgs/communication/services/visual_identity/index_en.htm

The contractor must apply the rules set out in Visual Identity Manual for the graphic design of both the cover page and the internal pages of the study. The professional font (EC Square Sans Pro) to be used for the study will be made available to the contractor free of charge upon acceptance of the terms and conditions of its use after contract signature. The use of templates for studies is exclusive to European Commission's/ CHAFEA's contractors. No template will be provided to tenderers while preparing their tenders.

4 EVALUATION AND AWARD

The evaluation is based solely on the information provided in the submitted tender, after access to the market is verified. It involves the following:

- Verification of non-exclusion of tenderers on the basis of the exclusion criteria
- Selection of tenderers on the basis of selection criteria
- Verification of compliance with the minimum requirements set out in the tender specifications
- Evaluation of tenders on the basis of the award criteria.

The contracting authority may reject abnormally low tenders, in particular if it established that the tenderer or an identified subcontractor does not comply with applicable obligations in the fields of environmental, social and labour law.

The tenders will be assessed in the order indicated above. Only tenders meeting the requirements of one step will pass on to the next step.

4.1 Verification of non-exclusion and evidence

All tenderers must provide a declaration on honour (Annex IV), signed and dated by their authorised representative, stating that they are not in one of the situations of exclusion listed in the declaration on honour as part of the tender. Annex IV is part of the tender submission form as part of the Administrative offer.

In case of a **joint tender**, each member of the group must provide a declaration on honour signed by its authorised representative, as exclusion criteria apply separately to each legal entity of the group.

In case of subcontracting, all identified subcontractors must provide a declaration on honour signed by an authorised representative.

The successful tenderer must provide the documents mentioned as supporting evidence in the declaration on honour before signature of the contract and within a deadline given by the contracting authority. This requirement applies to each member of the group in case of joint tender and to all identified subcontractors.

The obligation to submit supporting evidence **does not** apply to international organisations.

A tenderer (or a member of the group in case of joint tender, or a subcontractor if applicable) is not required to submit the documentary evidence if it has already been submitted for another procurement procedure and provided the documents were issued not more than one year before the date of their request by the contracting authority and are still valid at that date. In such cases, the tenderer must declare on its honour that the documentary evidence has already been provided in a previous procurement procedure, indicate the reference of the procedure and confirm that that there has been no change in its situation.

A tenderer (or a member of the group in case of joint tender, or an identified subcontractor) is not required to submit a specific document if the contracting authority can access the document in question on a national database free of charge. In such a case the tenderer shall inform the contracting authority how the said document can be accessed the national database.

4.2 Verification of selection criteria and evidence

The purpose of the selection criteria is to determine whether the tenderer has the capacity to implement the contract. Aspects of this capacity include the economic and financial capacity and the technical and professional capacity.

Each selection criterion consists of three elements: (i) the criterion itself, (ii) a minimum level/minimum requirement and (iii) the supporting documents. The selection criteria *are not scored* by the contracting authority. They are subject to a pass or fail assessment.

If not otherwise indicated, selection criteria are applied to the tenderer as a whole including the members of a joint tender and identified subcontractors on which the tenderer may rely to fulfil some of the selection criteria.

4.2.1 Declaration and evidence

The tenderers (and each member of the group in case of joint tender) and subcontractors whose capacity is necessary to fulfil the selection criteria must provide the declaration on honour (see Annex IV), signed and dated by an authorised representative, stating that they fulfil the selection criteria applicable to them individually. For the criteria applicable to the tenderer as a whole the tenderer (sole tenderer or leader in case of joint tender) must provide the declaration on honour stating that the tenderer, including all members of the group in case of joint tender and including subcontractors if applicable, fulfils the selection criteria for which a consolidated assessment will be carried out.

This declaration is part of the declaration used for exclusion criteria (see section 1.8 and Annex IV) so only one declaration covering both aspects should be provided by each concerned entity.

The Contracting Authority will evaluate selection criteria on the basis of the declarations on honour. Nevertheless, it reserves the right to require evidence of the legal and regulatory, financial and economic and technical and professional capacity of the tenderers at any time during the procurement procedure and contract performance. In such case the tenderer must provide the requested evidence without delay. The Contracting Authority may reject the tender if the requested evidence is not provided in due time.

The successfully evaluated tenderer will be required to provide the evidence mentioned below before signature of the contract and within a deadline given by the contracting

authority. This requirement applies to each member of the group in case of joint tender and to subcontractors whose capacity is necessary to fulfil the selection criteria.

A tenderer (or a member of the group in case of joint tender, or a subcontractor) is not required to submit the documentary evidence if it has already been submitted for another procurement procedure and provided the documents were issued not more than one year before the date of their request by the contracting authority and are still valid at that date. In such cases, the tenderer must declare on its honour that the documentary evidence has already been provided in a previous procurement procedure, indicate the reference of the procedure and confirm that that there has been no change in its situation.

A tenderer (or a member of the group in case of joint tender, or a subcontractor) is not required to submit a specific document if the contracting authority can access the document in question on a national database free of charge.

4.2.2 Legal and Regulatory capacity

Not applicable.

4.2.3 Economic and Financial capacity.

The tenderer must have the necessary economic and financial capacity to perform this contract until its end. In order to prove their capacity, the tenderer must comply with **both of** the following criteria:

Criterion 1: The sum of turnover and/or other operating income for each of the last two closed financial years is above EUR 2 400 000. This criterion applies to the tenderer as a whole, i.e. the combined capacity of all members of a group in case of joint tenders.

Criterion 2: The indicators of liquidity and solvency have a result "acceptable" after their assessment as detailed below. This criterion applies to at least one member of the group in case of joint tenders.

The tenderer's liquidity and solvency ratios demonstrating its economic and financial capacity shall be calculated as follows:

Purpose	**Indicators**	**Ratios**
Liquidity	Current Ratio[1]	Current Assets (3)[2] / Trade and Other Debts (6)
Solvency	Financial Autonomy Ratio[3]	Capital and Reserves (4) / Total Liabilities (4 + 5 + 6)

Thresholds

[1] For the last year for which accounts have been closed

[2] The figures mentioned between brackets refer to the respective accounts listed in Annex VII

[3] For the last year for which accounts have been closed

According to the results obtained for each of the abovementioned ratios, the following marks are given:

Purpose	Indicators	Weak	Acceptable
Liquidity	Current Ratio	i < 1,00	1,00 ≤ i
Solvency	Financial Autonomy Ratio	i < 0,20	0,20 ≤ i

Evidence:

The successfully evaluated tenderer shall provide the evidence on the above criteria by submitting:

- Copy of the **profit and loss accounts and balance sheet** or extracts of balance sheet for the last two years for which accounts have been closed from each concerned legal entity;

- Failing that, appropriate statements from banks.

If, for an exceptional reason which the Contracting Authority considers justified, a tenderer is unable to provide one or other of the above documents, it may prove its economic and financial capacity by any other document which the Contracting Authority considers appropriate. In any case, the Contracting Authority must at least be notified of the exceptional reason and its justification. The Contracting Authority reserves the right to request any other document enabling it to verify the tenderer's economic and financial capacity.

4.2.4 Technical and professional capacity criteria

Tenderers (in case of a joint tender, the combined capacity of all members of the group and identified subcontractors) must comply with the criteria listed below.

a. Criteria relating to the tenderer(s) delivering the service:

- **Criterion A1**: The tenderer must prove experience in the field of public health and eHealth as well as in project management and data collection.

Evidence A1: The tenderer must provide references for relevant services/projects, provided and coordinated during the last 7 years with a minimum overall budget for each service or project of at least EUR 1 000 000.

- **Criterion A2**: The tenderer must prove its capacity to cover all EU Member states

Evidence A2: The tenderer must provide references for 3 projects delivered in the last 7 years. The combination of projects must cover the required geographical scope (i.e. all EU Member states) or the tenderer must prove that it has contacts in the EU Member states not covered by its project experience in order to ensure the required geographical

coverage (e.g. by including in the proposed tender team reference persons that have worked in similar studies in a given EU Member state).

- **Criterion A3:** The tenderer must prove capacity to draft reports in English and French.

Evidence A3: The tenderer must provide one document of at least 10 pages (report, study, etc.) in both English and French that it has drafted and published or delivered to a client in the last two years. The verification will be carried out on 5 pages of the document.

- **Criterion A4**: The tenderer must prove experience in the field of large scale testing of information system templates (for WP2 tasks: Development, testing and evaluation of templates for an EU citizens' vaccination card)

Evidence A4: The tenderer must provide references for 3 projects delivered in the last 7 years which demonstrate the capacity of carrying out the WP2 tasks and more particularly the large scale testing of templates in 10 EU Member states.

b. Criteria relating to the team delivering the service:

The team delivering the service should include, as a minimum, the following profiles.

B1 - Project Manager: The project manager shall have:

- University degree in public health.

- At least 7 years of experience in project management, including overseeing project delivery, quality control of delivered service, client orientation and conflict resolution experience in project of a similar size (at least EUR 1 000 000) and coverage (at least 10 countries covered),

- Experience in management of team of at least 15 people.

- Level C2 in English.

Evidence B1: CV

B2 - Expert in development, testing and implementation of eHealth solutions. Relevant higher education degree (e.g. computer science or information technology, business administration, life sciences, public health) and at least 5 years of professional experience in the field. Level C2 in English.

Evidence B2: CV

B3 - Team for data collection: Collectively, the team of at least 5 people should have proven experience of 5 years in data collection techniques, as well as level C2 in English.

Evidence B3: CV

4.3 Award Criteria

The contract will be awarded based on the most economically advantageous offer, according to the 'best price-quality ratio' award method. The maximum total quality score is 100 points.

Tenders must score minimum 60 % for each criterion and in total. The tenders that do not reach the minimum quality levels will be rejected and will not be ranked.

The quality of the tender will be evaluated based on the following criteria:

1. **Quality of the proposed methodology** (70 points – minimum score 60 %)

    - Sub-criterion 1.1. Quality of the proposed methodology for work package 1 (30 points – minimum score 60 %)

      This criterion will assess the methodology proposed for the mapping of the form and content of existing vaccination cards. It will, in particular, assess the method(s) suggested for data collection and analysis, including its/their appropriateness for the purpose, in particular in relation to the required geographical coverage.

    - Sub-criterion 1.2. Quality of the proposed methodology for work package 2 (40 points – minimum score 60 %)

      This criterion will assess the methodology proposed for the development, testing and evaluation of templates for an EU citizens' vaccination card. It will, in particular, assess the method(s) suggested for the testing of each of the 3 dual templates in at least 10 volunteering Member States with different IIS status, including its/their appropriateness for the purpose, in particular in relation to its/their capacity to ensure that test results will have the statistical power to show the potential of each of the templates to contribute to higher vaccination coverage. It will also be assessed whether the testing of the 3 dual templates allows for an adjustment and re-testing phase in necessary.

2. **Organisation of the work and resources** (15 points – minimum score 60 %)

    This criterion will assess how the roles and responsibilities of the proposed team and of the different economic operators (in case of joint tenders), including subcontractors (if applicable) are distributed for each activity or deliverable. It also assesses the global allocation of time and resources to the project and to each activity or deliverable, and whether this allocation is adequate for the work. The tender must provide details on the allocation of time (timetable) and human resources (clear division of activities or deliverables among team members and possible subcontractors) and the rationale behind the choice of this allocation. Details must be provided as part of the technical offer.

3. **Quality control measures** (15 points – minimum score 60 %)

    This criterion will assess the measures proposed for risk assessment, monitoring and quality control applied to the service foreseen in these tender specifications concerning the quality of the deliverables and of the language

quality check, and the service continuity in case of absence of a team member. The quality system must be detailed in the tender and specific to the tasks; a generic quality system will result in a low score.

4.4 Price and Award Method

Only the tenders that have reached the technical quality thresholds announced for the quality award criteria will be subject to best price-quality assessment.

Prices must be presented using the standard format announced with the tender specifications. Tenderers are required to use Annex V to submit their financial offer. Every offer that successfully passes the evaluation of the quality award criteria will be assessed on the price offered.

The tenderers shall propose a total price that shall include all the costs pertaining to the provision of the requested service, in particular:

- staff costs (including every cost aspect bearable by the tenderer as employer e.g. social contributions and taxes);
- data purchase;
- travel, hotel and subsistence costs for the internal meetings of the contractor; for the meetings with the Contracting Authority; and for visits to Member States as appropriate in relation to the proposed methodology;
- translation costs.
- all other costs the tender considers necessary to provide the requested service.

Ranking of tenders

Only the tenders that have reached the technical quality thresholds announced for the quality award criteria will be subject to best price/quality assessment.

The tender with the lowest price will be awarded 100 points. The other tenders will be awarded points on the basis of the following formula:

Points = (lowest price/price of the bid in question) x 100

Calculation of the most economically advantageous tender on the basis of the best price/quality method:

In order to determine the most economically advantageous tender for the award of the contract, a quality/price ratio of 70/30 will be applied to each tender in the following way:

The points awarded for technical quality multiplied by 0.7.

The points awarded for the price multiplied by 0.3.

The points for technical quality and those for price will then be added together, the tenderers will be ranked according to their total number of points and the contract will be awarded to the tenderer achieving the highest score.

Contracts may not be awarded to tenderers who, during the procurement procedure:

(a) are in an exclusion situation established in accordance with article 136 of the Financial Regulation;

(b) have misrepresented the information required as a condition for participating in the procedure or have failed to supply that information;

(c) were previously involved in the preparation of procurement documents where this entails a distortion of competition that cannot be remedied otherwise.

This assessment will be carried out based on all the documents and information provided. If necessary (e.g. in case of doubt), the Executive Agency will ask the economic operator to submit observations on the issue.

Administrative and financial penalties

Without prejudice to the application of contractual penalties laid down in the contract, the contracting authority may impose regulatory administrative sanctions on tenderers including: exclusion from receiving Union funding for certain duration (Articles 135 to 145 Financial Regulation) and financial penalties, as an alternative or in addition to a decision of exclusion depending on the cases (Article 138(1) Financial Regulation). Administrative sanctions can be imposed on economic operators who are in a specific situation of exclusion listed in Article 136 Financial Regulation.

ANNEXES

- **Annex Ia**: Tender submission form - Statement
- **Annex Ib**: Power of attorney for members of joint tender
- **Annex Ic**: Letter of intent for subcontractors
- **Annex IIa**: Legal entity form for public entities
- **Annex IIb**: Legal entity form for private entities
- **Annex IIc**: Legal entity form for individuals
- **Annex III**: Financial identification form
- **Annex IV**: Declaration on honour on exclusion and selection
- **Annex V:** Financial offer form
- **Annex VI**: Checklist

Please note that Annexes Ia, Ib, Ic, IIa, IIb, IIc, III and IV are contained in one single document: "PDF Tender Submission Form".