

Tender Specifications

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IMI.2019.OP.01**

**Supporting Regulatory
Acceptance of IMI Results**

1 Overview of this Tender	2
1.1 Introduction to the IMI2 JU.....	2
1.2 Description of the Contract	3
1.3 Timetable	3
1.4 Eligibility - Participation in the Tender Procedure.....	3
1.5 Joint Tenders - Participation of Consortia.....	4
1.6 Sub-contracting	5
1.7 Submission of Tenders.....	5
1.8 Environmental & Social Considerations	7
1.9 Period during which tenders are binding.....	8
1.10 Contacts between the IMI2 JU and Tenderers	8
1.11 Visits to the IMI2 JU Premises	9
1.12 Variants	9
1.13 Contract Provisions	9
2 Technical Specifications	9
2.1 Introduction: Background to the Invitation to Tender	9
2.2 Outline of the Services Required	9
2.3 Description of the Framework Contract	10
3 Evaluation of Tenders & Contract Award	14
3.1 Exclusion Criteria.....	15
3.2 Selection Criteria.....	16
3.3 Award Criteria	18
ANNEX I - TENDER SUBMISSION FORM.....	21
ANNEX II - DECLARATION OF HONOUR (ON EXCLUSION CRITERIA & SELECTION CRITERIA) .	24
ANNEX III – SUB-CONTRACTORS DECLARATION	29
ANNEX IV.a – SELECTION CRITERIA – 3.2.2 ECONOMIC & FINANCIAL CAPACITY	30
ANNEX IV.b – SELECTION CRITERIA – 3.2.3 TECHNICAL & PROFESSIONAL CAPACITY – EXPERIENCE OF THE TENDERER].....	31
ANNEX IV.c – TECHNICAL & PROFESSIONAL CAPACITY - OVERVIEW OF [PROJECT TEAM / PROPOSED PERSONNEL]	32
ANNEX V - MODEL FINANCIAL OFFER	33

1 Overview of this Tender

1.1 Introduction to the IMI2 JU

The goal of IMI, particularly in its second phase (IMI2, 2014-2020), is to develop next generation vaccines, medicines and treatments, such as new antibiotics. Our projects will provide Europeans, including the increasing numbers of older people, with more efficient and effective medicines and treatments. Greater coordination across industry sectors will result in more reliable and faster clinical trials, and better regulation. Our research and innovation efforts will also open new commercial

possibilities based on new services and products. The research, industry and societal sectors involved in IMI2 will benefit from the cooperation and knowledge sharing which take place in these projects.

Further information can be found on [the IMI2 JU's website](#).

1.2 Description of the Contract

The services required by the IMI2 JU under the contract to be potentially awarded as a result of this call for tender are described in the **Technical Specifications in Section 2** of the present tender specifications.

1.3 Timetable

Summary timetable	Date	Comments
Launch date	11 October	
Deadline for addressing requests for clarification to the IMI2 JU	25 November 2019 at 17:00	
Last date on which clarifications are issued by the IMI2 JU	29 November 2019 at 17:00	Tenderers are advised to check the IMI2 JU's website on a regular basis for possible updates and/or clarifications.
Deadline for Submission of Tenders	6 December 2019	Tenders delivered by hand shall be submitted not later than 17:00*
Opening Session	13 16 December 2019 at 10:00 *	Maximum two representatives per participating tenderer may attend the opening session. Tenderers shall inform the IMI2 JU of their intention to attend, at least 5 working days prior to the opening session.
Completion Date for Evaluation of Tenders	20 December 2019	Estimated
Signature of Framework Contract	15 January 2020	Estimated

* Brussels Local Time

1.4 Eligibility - Participation in the Tender Procedure

This procurement procedure is open to any natural or legal person wishing to bid for the assignment and established in any of the European Union Member States, Norway, Iceland, Liechtenstein or Switzerland. Under the Stabilisation and Association Agreements (SAA) economic operators from Albania, the Former Yugoslav Republic of Macedonia (FYROM), Montenegro, Serbia, Bosnia & Herzegovina and Kosovo are also eligible to submit a tender.

Tenderers must not be in any situation of exclusion under the exclusion criteria indicated in Section 3.1 / Annex II of these tender specifications and must have the legal & regulatory capacity to allow them to participate in this tender procedure (see Section 3.2.1).

Moreover, the tenderers 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 the Public Procurement Directive.¹

Please note that any attempt by a tenderer to obtain confidential information, enter into unlawful agreements with competitors or influence the evaluation committee or the IMI2 JU during the process of examining, clarifying, evaluating and comparing tenders will lead to the rejection of his tender and may result in administrative penalties.

Note for British 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 tenderers from the UK depending on the outcome of the negotiations. In case such access is not provided by legal provisions in force tenderers from the UK could be rejected from the procurement procedure.

1.5 Joint Tenders - Participation of Consortia

Consortia may submit a tender on the condition that they comply with the rules of competition including satisfying the requirements under the exclusion criteria (see Section 3.1) applicable to the award of the contract.

A consortium may be a permanent, legally-established grouping or a grouping which has been constituted informally for a specific tender procedure, complying with the eligibility requirements (Section 1.4). All members of a consortium (i.e. the leader and all other members) are jointly and severally liable to the Contracting Authority.

For each consortium member, the tenderer must, at the time of tender submission²:

- ✓ Specify the company or person heading the project (the leader) and submit, a copy of the document authorising this company or person to submit a tender on behalf of the consortium (e.g. power of attorney) – *alternatively, if already available at the time of tender submission, a duly signed and dated (by each member) consortium agreement.*
- ✓ Submit the required declaration of honour on the exclusion (Section 3.1) and selection (Section 3.2) criteria – Annex II.

In case of successful award & before contract signature: the tenderer to whom the contract is to be awarded shall provide, at the latest, within 15 days following notification of award and preceding the signature of the contract, a duly signed and dated (by each of the consortium members) consortium agreement specifying the company or person heading the project and authorised to submit a tender on behalf of the consortium (unless already submitted at the time to tender submission).

¹ Directive 2014/24/EU of the European Parliament and of the Council of 26 February 2014: <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:32014L0024>

² See also Section 1.7 and Annex I – Tender Submission Form – for a summary / overview of documents to be submitted as part of the tender.

The participation of an ineligible person will result in the automatic exclusion of that person. In particular, if that ineligible person belongs to a consortium, the whole consortium will be excluded.

1.6 Sub-contracting

Sub-contractors (including freelancers) must satisfy the requirements under the exclusion criteria (see Section 3.1) applicable to the award of the contract.

If the identity of the intended sub-contractor(s) is already known at the time of submitting the tender, **for each sub-contractor**, the tenderer must, **at the time of tender submission**³:

- ✓ Indicate clearly **which parts of the work will be sub-contracted** (including freelance consultants, experts etc.) and **to what extent** (proportion in %). The sub-contractor must not sub-contract further.
- ✓ **Submit a duly signed and dated (by the sub-contractor) ‘Sub-contractors Declaration’ – Annex III** - confirming that they are not in any of the situations of exclusion / conflict of interest (see Section 3.1) and pledging their irrevocable undertaking to collaborate with the tenderer, should he win the contract and that they will put all appropriate and necessary resources from their part at the tenderer’s disposal for the performance of the contract.

****Important Note:** If the identity of the sub-contractor(s) is not known at the time of submitting the tender, the tenderer who is awarded the contract will have to seek the IMI2 JU’s prior written authorisation before entering into a sub-contract. Where no sub-contracting is indicated in the tender the work will be assumed to be carried out directly by the bidder.*

1.7 Submission of Tenders

It is strictly required that tenders be presented in the correct format and include all documents necessary to enable the evaluation committee to assess them. Failure to respect these requirements will constitute a formal error and may result in the rejection of the tender. As a result, tenders must comply with the following conditions for submission.

1.7.1 Presentation of the Tender

Tenders must be submitted in accordance with the **double envelope system**:

Outer Envelope: The outer envelope or parcel should be sealed with adhesive tape, signed across the seal and carry the following information as shown in the diagram in 1.7.4 below:

- ✓ the ref. number of the invitation to tender: **IMI.2019.OP.01**
- ✓ the project title: **Supporting Regulatory Acceptance of IMI Results**
- ✓ the name of the tenderer
- ✓ the indication **“Tender - Not to be opened by the internal mail service”**
- ✓ the address for submission of tenders (*as indicated in the tender docs*)
- ✓ the date of posting (*if applicable*) should be legible on the outer envelope

³ See also Section 1.7 and Annex I – Tender Submission Form – for a summary / overview of documents to be submitted as part of the tender.

Inner Envelopes: The outer envelope must contain **three inner envelopes**, namely, Envelopes A, B and C. The content of each of these three envelopes must be as follows:

ENVELOPE A – ADMINISTRATIVE DOCUMENTS <i>(One signed original)</i>
✓ Tender Submission Form (front page of administrative documents) – using template in Annex I .
✓ Declaration of Honour (Section 3.1 Exclusion Criteria) – using template in Annex II .
✓ <i>In case of sub-contracting (Section 1.6):</i> Sub-contractors Declaration – Annex III .
✓ Financial Identification Form – using the template downloadable from the European Commission’s Website: http://ec.europa.eu/budget/contracts_grants/info_contracts/index_en.cfm
✓ Legal Entity Form (Section 3.2.1 Legal & Regulatory Capacity) – using template from link below and the supporting documents requested in Section 3.2.1: http://ec.europa.eu/budget/contracts_grants/info_contracts/legal_entities/legal_entities_en.cfm
✓ <i>In case of consortia (Section 1.5):</i> Consortium agreement (if already available), or, powers of attorney issued by the consortium members empowering the representative of the consortium leader (tenderer) to submit a tender of their behalf.
ENVELOPE B – TECHNICAL DOCUMENTS <i>(One signed original and 3 copies* of signed originals)</i>
✓ Technical Offer providing all information requested in Section 3.3.1 .
ENVELOPE C - FINANCIAL DOCUMENTS <i>(One signed original and 3 copies* of signed originals)</i>
✓ Financial Offer (Section 3.3.2) using the template found in Annex V .

*The original tender must be marked “ORIGINAL”, and the copies (identical in full to the original) marked “COPY”.

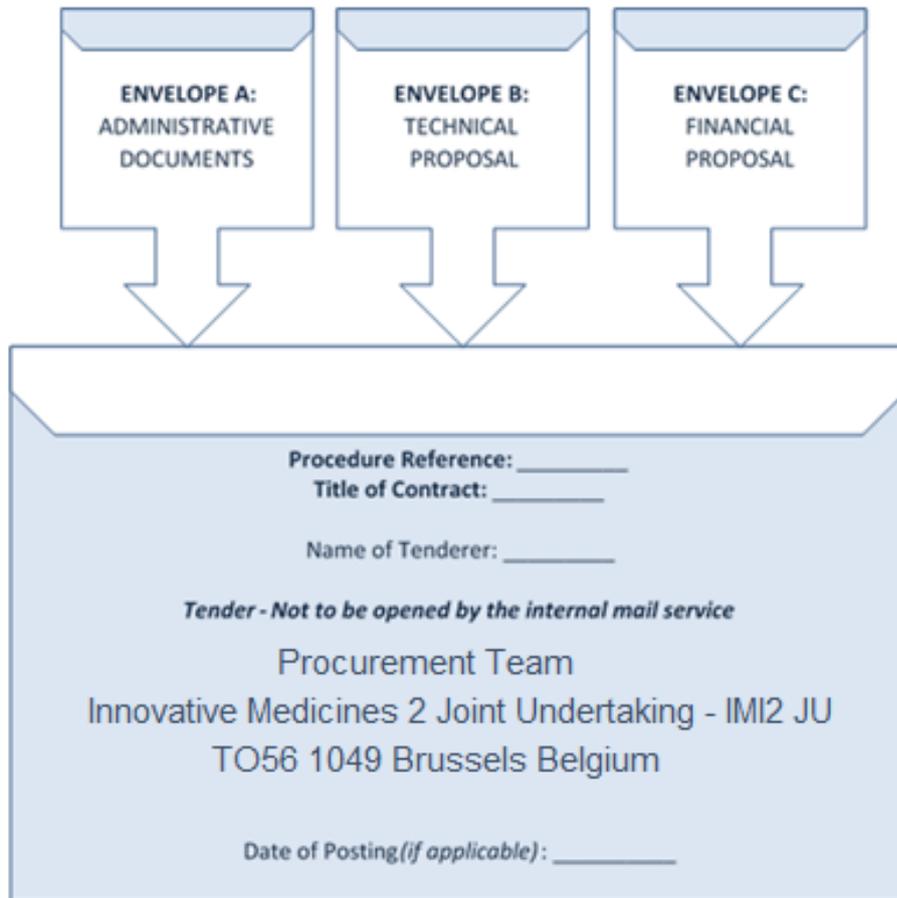
1.7.2 Language of the Tender

Tenders should be drafted in one of the official languages of the European Union, **preferably English**.

1.7.3 Division into Lots

This tender is not divided into lots. The tenderer must be in a position to provide all the services requested.

1.7.4 Tender Submission - Envelope Diagram



1.7.5 Submission modalities

Tenders must be submitted no later than the deadline for submission of tenders indicated in Section 1.3 – Timetable, (Part II - tender specifications), either by:

- Post (registered mail recommended) or Courier: In this case, the evidence of the date of dispatch shall be constituted by the postmark or the date of the deposit / posting slip, or,
- Hand Delivered / Delivered in Person: In this case, the tenderer must obtain a proof of receipt, signed and dated (including the time of submission) by the person who took delivery at the IMI2 JU's Reception desk. Please note that the IMI2 JU's Reception desk is open Monday to Friday, 08.00 – 18:00 (Brussels local time) except for public holidays.

Address for Submission by Post, Courier or in Person

Procurement Team
 Innovative Medicines 2 Joint Undertaking the IMI2 JU
 Ave de la Toison d'Or 56-60 • 1060 Brussels • Belgium

**Important Note: Please inform the IMI2 JU whether you intend to submit a tender, by writing to the address indicated above or sending an e-mail to the following e-mail address:*
procurement@imi.europa.eu

1.8 Environmental & Social Considerations

The IMI2 JU is committed to minimising the environmental impact of its everyday business activities, including, promoting an eco-friendly approach in its purchasing activity. Therefore, contractors of the

IMI2 JU should also follow / adopt such environmental considerations and strive to be eco-friendly (i.e. reduce water, energy and waste consumption, actively recycle, using reusable / recyclable materials etc.) in their related business operations.

In addition, the contractor shall ensure compliance with any European and national rules on environmental protection, safety and health as well as, as already described in Section 1.4 above, the applicable environmental, social and labour law obligations.

It is strongly recommended that tenders be submitted in an environmentally friendly way, e.g. by choosing a simple and clear structure (list of contents and consecutive page numbering), double-sided printing, limiting attachments to what is required in the tender specifications (no additional material) and avoiding plastic folders or binders.

1.9 Period during which tenders are binding

The period of validity of tenders, during which tenderers may not modify the terms of their tenders in any respect is 4 months after the deadline for the submission of tenders. In exceptional cases, before the period of validity expires, the IMI2 JU may ask tenderers to extend the period for a specific number of days, which shall not exceed 40.

The selected tenderer must maintain its tender for a further 60 days from the date of notification that his tender has been recommended for the award of the contract. The further period of 60 days is added to the initial period of 4 months irrespective of the date of notification.

1.10 Contacts between the IMI2 JU and Tenderers

Contacts between the IMI2 JU and tenderers are prohibited throughout the procedure save in exceptional circumstances and under the following conditions only:

Before the final date for submission of tenders:

- At the request of the tenderer, the IMI2 JU may provide additional information solely for the purpose of clarifying the procurement documents.
- Any request for clarification must be made in writing by e-mail to procurement@imi.europa.eu and should indicate the reference number and the title of the tender.
- Requests for clarification received by the IMI2 JU after the deadline for such requests for clarification as specified in Section 1.3 – Timetable may not be processed.
- The IMI2 JU may, on its own initiative, inform interested parties of any error, inaccuracy, omission or any other clerical error in the text of the procurement documents.
- Any clarifications including that referred to above will be posted on the IMI2 JU's Procurement Webpage: <https://www.imi.europa.eu/work-for-us/procurement> - please ensure that you visit regularly the site for updates.

After the opening of tenders:

- If, after the tenders have been opened, some clarification is required in connection with a tender, or if obvious clerical errors in the submitted tender must be corrected, the the IMI2 JU may contact the tenderer, provided this does not lead to any substantial changes to the terms of the submitted tender.

1.11 Visits to the IMI2 JU Premises

No site visits at the IMI2 JU's premises are deemed necessary for this procedure.

1.12 Variants

Variants are not permitted.

1.13 Contract Provisions

In drawing up your tender, you should bear in mind the provisions of the draft contract (see Part III of the Procurement Documents). In particular, the draft contract indicates the method and the conditions for payments to the contractor.

****Important Note: Submission of a tender implies acceptance of all the terms and conditions set out in the Procurement Documents (Contract Notice, Procurement Documents - Part I - invitation to tender, Part II - tender specifications and Part III - draft contract) and, where appropriate, waiver of the tenderer's own general or specific terms and conditions. It is binding on the tenderer to whom the contract is awarded for the duration of the contract.***

In this respect every tenderer is also required to sign a declaration to this effect in as part of the tender submission form in Annex I.

2 Technical Specifications

These Technical Specifications (TS) will become an integral part of the contract that may be awarded as a result of the tender.

2.1 Introduction: Background to the Invitation to Tender

The Innovative Medicines Initiative 2 Joint Undertaking (IMI2 JU) intends to establish a framework service contract to provide a central support system which will capitalise on IMI project results generated by maximising their impact and securing sustainability through their regulatory acceptance. The objective is to ensure that the key results generated by IMI projects are acceptable in a research and development (R&D) context (non-clinical or clinical studies), and are therefore implemented in the regulatory practices.

The results include novel biomarkers, endpoints, outcomes, tools/ methodologies, recommendations that would support development of regulatory guidance documents. This may cover different disease areas or axes of research as per the IMI Strategic Research Agenda.

2.2 Outline of the Services Required

The Contractor will be required to:

— **identify and prioritise the relevant project results:**

The service provider will map the IMI projects to identify the regulatory project results and prioritise those which should be subject to engaging regulatory acceptance. This mapping will cover IMI1 and IMI2 projects that have ended or will end by 30 April 2020, with the exception of IMI 1 education and training projects, projects focusing on early drug development.

To carry out this mapping, the service provider will have access to the project description of work as well as final /periodic reports and any other relevant information.

Based on this mapping and agreement of the IMI Programme Office on the selection and of the concerned consortia, the service provider will support consortia (for ongoing projects) or result owners (for finished projects) to further define regulatory relevant project results that should be subject to engaging regulatory acceptance processes and define the most appropriate regulatory pathway (selection of the process like qualification procedure, etc.)

— **identify information/ data gaps that need to be addressed to complete the submission:**

The service provider will analyse data available and make recommendations for the course of action, depending on whether the project has ended or is still ongoing; Depending on whether the results would be mature enough to form a basis to implement changes in regulatory practice this may include support to defining further development and research work needed and the strategy to generate the missing evidence.

— **preparation of the dossier for interaction with the regulatory agencies**

The Contractor will support the preparation of the required documentation to be submitted to the EMA and FDA, to support the regulatory acceptance of the results. In addition the service provider will support the preliminary engagement with the agencies.

— **develop a framework**

The service provider will develop a framework that could be replicated across all projects, etc. to secure efficiency, consistency and quality for engaging planning and implementation of regulatory acceptance processes: the service provider will deliver a framework document which will guide IMI ongoing and future projects and provide best practices on planning regulatory strategy into the research workplan and implementing engagement with regulatory processes.

Deliverables:

Set-up phase. identify and prioritise the relevant project results

- Indicative timeline: 2 months
- Deliverable – report to the IMI2 JU - Mapping and prioritisation of results suitable for regulatory acceptance processes.

Work phase: Implementation phase. Concrete actions and results

- Indicative timeline : 15-18 months
- The level of achievement of the 3 deliverables below for the selected project results will depend on the maturity of the results. Regular report to IMI on the status of progression is key.

- 1) Recommendation on the regulatory pathway for acceptance of the selected results;
- 2) Gaps data analysis and strategy to generate them;
- 3) File for selected results and selected process ready for submission to regulatory agencies.

- Final report to IMI covering all actions carried out, and their outcome.
- Regulatory acceptance framework to guide other projects in the planning and project implementation phases.

The work phase will entail active interaction with consortia (for ongoing projects) and result owners (for finished projects).

2.3 Description of the Framework Contract

A framework contract is a legal agreement between two parties - in this case, the IMI2 JU and the contractor. It acts as the legal basis for the possible future purchase of services/supplies by the IMI2

JU. The framework contract defines, amongst others, the scope of services/supplies that can be purchased, methodology for implementation, timing and fees to be respected by the contractor etc.

Important Note: The framework contract itself is not an order for services or supplies and does not constitute a financial commitment.

2.3.1 Implementation of the Framework Contract

Services are requested (i.e. ordered) under “specific contracts” (or “order forms”) linked to particular activities, over a given period.

The IMI2 JU intends to issue individual and successive specific contracts over the period of validity of the framework contract. These shall take the form of one of the documents provided under Annexes III.a (specific contract) and III.b (order form) to the draft framework contract (Part III of the Procurement Documents). Either format may be used for implementation of the framework contract indiscriminately, depending on the IMI2 JU’s needs.

Important Note: No legal or financial commitment exists on behalf of either party until the specific contract/order form is signed by both parties.

2.3.2 Ordering Process

2.3.2.1 Specific Contract Issuance

The IMI2 JU will draft a specific contract covering its anticipated needs for the relevant period, based on the estimated volumes and prices in the framework contract. Payment shall be subsequently made against actual services delivered.

The IMI2 JU will inform the contractor about the upcoming project by submitting a “request for services” outlining the scope of the project, deadlines, deliverables etc. Within 5 working days of receipt of the official request for services (or alternatively the period defined within the request), the contractor shall submit an offer, including, at least the following:

- Proposed Project Team;
- Description of the methodology for project implementation;
- Financial offer including a budget breakdown;
- Work schedule time-frame for the completion of the assignment.

Once the offer is accepted, the IMI2 JU will prepare a specific contract and send it to the contractor for signature.

Within five working days of a specific contract being sent by the IMI2 JU to the contractor, the IMI2 JU should have received it back, duly signed and dated. The period allowed for the execution of the tasks shall start to run on the date the contractor signs the specific contract, unless a different date is indicated therein.

It is foreseen that the Contracting Authority will start contract implementation by issuing a standalone specific contract to cover the set-up phase described in Section 2.2, and a subsequent specific contract to cover the ensuing work phase. Should budget consumption permit it, and needs require it, this contractual sequence may be repeated at least once, over the lifetime of the framework contract.

2.3.2.2 Types of Specific Contract

Specific contracts shall be drafted using one of the methods defined below. Any combination or variant of the methods shall be possible over the duration of the framework contract:

- **Time & Means (TM):** Orders shall correspond to a number of man-days/hours. Invoicing shall subsequently be based on the number of man-days/hours performed and duly substantiated by timesheets.
- **Quoted Time & Means (QTM):** Orders shall correspond to a number of man-days/hours for defined sub-tasks. The IMI2 JU specifies the different tasks and sub-tasks to be executed and a total number of man-days/hours. Only agreed costs for the specified sub-tasks are chargeable, after acceptance by the IMI2 JU.

2.3.2.3 Payment Formalities

Payment formalities will be prescribed in the ensuing framework and specific contracts.

2.3.3 Reporting, Documents & Deliverables

Any reports, documents and/or deliverables to be produced will be specified in each specific contract. Such reports/documents could consist of:

- Minutes of Meetings;
- Mission Reports;
- Updates on progress of the contract implementation;
- Potential difficulties/obstacles to sort out;
- Final / Interim Reports;
- Etc.

2.3.4 Duration of the Contract

The framework contract will be signed for an initial period of two years, and shall be renewable up to two times, for a one-year period, for a total maximum duration of four years, under the same conditions.

2.3.5 Volume of the Contract

The total maximum value of the framework contract is € 250 000.

2.3.6 Place of Delivery/Execution

The main place of execution shall be the IMI2 JU's premises in Brussels, Belgium.

2.3.7 Quality Management

2.3.7.1 Project Team & Management

The tenderer should appoint / propose a suitable project team for the contract implementation. A project manager / focal point should be appointed for the entire contract duration and shall ensure the overall management of the contract including timely completion of the activities, ensuring the required level of quality is met.

Furthermore, notwithstanding any remedies outlined in the draft contract, please note that the IMI2 JU reserves the right to request replacement of any project team member found not satisfactory and after repeated notification as such.

2.3.7.2 Performance Indicators

Without prejudice to the IMI2 JU's rights or any other remedies / measures available under the contract or at law in the case that the contractor does not meet the quality expectations of the IMI2 JU they shall be contacted (in writing) by the IMI2 JU and informed of the shortcomings/complaint. Upon such request the contractor is expected to take immediate measures to address and resolve such problems.

2.3.7.3 Monitoring Quality

- **Reporting Milestones:** For each specific contract the contractor will have to report to the IMI2 JU the completion status of the assignment at defined reporting milestones i.e.: at 30% / 60% / 100% of time of assignment elapsed.
- **Status Report:** At any of the reporting milestones, if the assignment is not progressing as expected, the contractor shall indicate the reasons for this. If the reasons are elements not foreseen by or outside the control of the IMI2 JU at the time the original request for services was agreed on, an appropriate extension of time / means may be agreed with the contractor.
- **Satisfaction:** At the above reporting milestones the IMI2 JU will, upon receipt of the contractor's report, express a satisfaction level with the quality of the work-in-progress achieved at that moment, on a scale from 0 to 5 where 5 represents the maximum possible satisfaction. In case the satisfaction level at a particular reporting milestone is less than <4/5> the IMI2 JU will discuss with the contractor possible improvements to be applied.
- **Final Approval:** Should the satisfaction score at the final reporting milestone not reach <4/5>, the contractor shall diligently carry out the necessary improvements without impact on the agreed cost of the order. Only after such satisfaction score is reached may the contractor present the invoice.

2.3.7.4 Annual Quality Performance Review

- **Annual Review:** On each framework contract anniversary date, an overall analysis of quality performance of the services delivered will be carried out.
- **Average Satisfaction Levels:** The quality performance will be measured by the initial satisfaction levels expressed by the IMI2 JU (satisfaction level before the remedial actions are taken by the contractor) at intermediate reporting milestones and at final reporting milestones for all closed or on-going specific contracts during the last contractual year. **The annual average of these satisfaction levels shall be calculated by the contractor and submitted to the IMI2 JU at each framework contract anniversary date.**

- **Corrective Actions:** If the annual average referred to above is below <4/5> the contractor shall propose effective corrective actions aimed at improving the quality of its performance under framework contract.
- **Right to Terminate:** In addition, in such cases the IMI2 JU also reserves the right to terminate the framework contract.

3 Evaluation of Tenders & Contract Award

The criteria for selecting a contractor are divided into the following categories:

Section / Criteria	Evaluation
Section 1.4 - Eligibility	Verified on a pass/fail basis in light of eligibility criteria defined in Section 1.4.
Section 3.1 - Exclusion Criteria	Verified on a pass/fail basis in light of exclusion criteria defined in Section 3.1 and Annex II.
Section 3.2 - Selection Criteria	Defines minimum capacities (legal & regulatory, economic & financial, technical & professional) to be met by all tenderers. Verified on a pass/fail basis.
Tender Specifications (All Sections)	Review of relevance and compliance of the tender (proposal) with the minimum requirements (i.e. subject matter, scope, location, timeline, format, etc.) of the tender specifications. Verified on a pass/fail basis.
Section 3.3 - Award Criteria (Technical & Financial)	Method to allow a ranking of the tenders according to their merits – most economically advantageous tender

In order to evaluate the tenders received under this procedure the criteria will be applied in the following order: I. Exclusion, II. Selection & III. Award. Therefore if a tenderer does not pass the exclusion and selection criteria categories, it will not be evaluated technically or financially.

3.1 Exclusion Criteria

Nr.	<u>Criteria:</u>	<u>Evidence Required (from main tenderer including consortia members [and/or subcontractors]):</u>
	<p>Participation in this tender is only open to tenderers (including, in the case of, all consortia members and/or sub-contractors) who are not in any of the situations of exclusion listed in Article 136 of the Financial Regulation (FR)⁴ and outlined in Annex II.</p>	<p>✓ At the time of Tender Submission: Tenderers shall provide a declaration on their honour (see model in Annex II) in accordance with Article 137(1) FR, in original, duly signed and dated.</p> <p>✓ In case of successful award & before contract signature: The tenderer(s) to whom the contract is to be awarded shall in accordance with Article 137(2) and (3) FR provide, within 15 calendar days following notification of award and preceding the signature of the contract*, the following documentary evidence in original to confirm the declaration referred to above:</p> <ul style="list-style-type: none"> - For situations (1)(a), (c), (d),(f), (g) or (h) of ‘Annex II – Declaration of honour and as stated in Article 136(1) (FR) , a recent⁵ extract from the judicial record or, failing that, an equivalent document recently⁶ issued by a judicial or administrative authority in the country of establishment showing that those requirements are satisfied. - For situations (1)(a) and (1)(b) of ‘Annex II – Declaration of honour’ and as stated in Article 136(1) (FR) , a recent⁷ certificate issued by the competent authorities of the State concerned. These documents must provide evidence covering all taxes and social security contributions for which the person is liable, including for example, VAT, income tax (natural persons only), company tax (legal persons only) and social security contributions. <p>Further information is provided in ‘eCertis’ - an information system that helps to identify the requested document or certificate across the EU. It can be accessed under the following link: https://ec.europa.eu/growth/tools-databases/ecertis/ Where any document or certificate referred to above is not issued in the country concerned, it may be replaced by a sworn or, failing that, a solemn statement made before a judicial or administrative authority, a notary or a qualified professional body in his country of establishment.</p> <p>* Important note: Tenderers are recommended to compile all listed documentary evidence before contract award in order not to delay the contract signature in case of successful award. Only in case all requested documentary evidences have been submitted to the Agency, the contract can be signed.</p>

**Note: If the tenderer has already submitted such evidence for the purpose of another procurement procedure, its issuing date does not exceed one year and it is still valid, the tenderer shall declare on its honour that the documentary evidence has already been provided and confirm that no changes have occurred in its situation.*

⁴ Regulation (EU, Euratom) No 1046/2018 of the European Parliament and of the Council of 18 July 2018 on the financial rules applicable to the general budget of the Union, repealing Regulation (EC, Euratom) No 966/2012 (OJ L 193 of 30.07.2018, p. 1), as amended.

⁵ Not more than one year old.

⁶ Not more than one year old.

⁷ Not more than one year old.

3.2 Selection Criteria

The purpose of the selection criteria is to determine whether a tenderer has the capacity necessary to implement the contract.

Tenderers must submit evidence of their legal & regulatory, economic & financial and technical & professional capacity to perform the contract.

3.2.1 Legal & Regulatory Capacity

Nr	<u>Criteria:</u>	<u>Evidence Required (from main tenderer including consortia members):</u>
a.	Tenderers (including consortium members) are asked to prove that they are authorised to perform the contract under the national law as evidenced by inclusion in a trade or professional register, or a sworn declaration or certificate, membership of a specific organisation, express authorisation or entry in the VAT register.	<ul style="list-style-type: none"> ✓ A duly filled in and signed Legal Entity Form, in original, to be downloaded, depending on the tenderer's nationality and legal form (i.e. individual, private/public company), from the following website: http://ec.europa.eu/budget/contracts_grants/info_contract_s/legal_entities/legal_entities_en.cfm; ✓ Supporting documents: <ul style="list-style-type: none"> - a copy of any official document (i.e. official gazette, register of companies etc.) showing the individual's / contractor's name and address and the registration number given to it by the national authorities. - A copy of the VAT registration document (if applicable) should be submitted <i>if the VAT number does not appear on the official document referred to above.</i>

**Note: If the tenderer has already submitted the legal entity file for the purpose of another procurement procedure, its issuing date does not exceed one year and it is still valid, the tenderer may not be obliged to submit a new file. The tenderer shall declare on its honour that the legal entity file has already been provided and confirm that no changes have occurred in its situation.*

3.2.2 Economic & Financial Capacity

Nr	<u>Criteria:</u>	<u>Evidence Required (from main tenderer including consortia members):</u>
a.	The tenderer must be in a stable financial position and have the economic and financial capacity to perform the contract. The yearly overall turnover must not have fallen below 100 000 EUR.	<ul style="list-style-type: none"> ✓ Provision of completed Annex IV.a – Economic & Financial Capacity, and, balance sheets / financial statements or their extracts for the last two years for which accounts have been closed (where publication of the balance sheet is required under the company law of the country in which the economic operator is established). <p><i>*Note: if, for some exceptional reason which the IMI2 JU considers justified, the tenderer is unable to provide the evidence requested they may prove their economic and financial capacity by any other means which the IMI2 JU considers appropriate.</i></p>

b.	Tenderers must possess an appropriate level of professional risk indemnity insurance ⁸	✓ Provision of completed Annex IV.a – Economic & Financial Capacity , and, appropriate evidence of relevant professional risk indemnity insurance.
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**Note: If the tenderer has already submitted the evidences for the purpose of another procurement procedure, the tenderer may not be obliged to submit them again. In such cases, the tenderer shall declare on its honour that the evidences have already been provided and confirm that no changes have occurred in its situation.*

3.2.3 Technical & Professional Capacity

Nr.	Criteria:	Evidence:
a.	Experience of Tenderer: Tenderer must have at least 2 years' experience working with regulatory agencies, including regulatory submissions.	An detailed description of the services performed within the past five years with a description of the activities performed by completing the table in Annex IV.b – Experience of the Tenderer. References, e.g. letters/emails of recommendations, from previous clients with whom similar contracts were concluded during the past 10 years.
b.	Tenderer must have successfully managed at least one comparable projects/contracts during the past 5 years to the project to be performed under this contract .	Detailed description of the projects/contracts performed including any research, analysis, reports, presentations etc. delivered.
c.	Project Team/Expertise Tenderer must have a good knowledge of the available regulatory pathways for regulatory acceptance of novel methods/methodologies. i. Project Team: Tenderers must have a competent and experienced project team for the performance of the contract. All staff involved in the execution of the contract should possess at least 3 years of experience in a similar role, an adequate educational background and expertise relevant to the tasks that they shall perform, as well as a good level of English language competency.	<ul style="list-style-type: none"> - Overview of the project team (using the template provided in Annex IV.c), and, - CVs of the key experts to carry out the study (using the EU CV format available at: http://europass.cedefop.europa.eu/en/home) covering education and training, organisational, technical and work experience including any relevant supporting documentation i.e. accreditations, certificates etc.

⁸ Or any other type of insurance considered appropriate
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infodesk@imi.europa.eu • www.imi.europa.eu

	<p>ii. Project Team leader: a suitable project team leader should be designated, with at least 5 years of experience in a similar role with experience in at least 1 other comparable project in the team leader role and a very good level of English language competency.</p>	
d.	<p>Environmental Considerations: The tenderer shall have / adopt a suitable environmental policy.</p>	<p>A description or copy of the tenderer's environmental policy (specifying the status of implementation).</p>
e.	<p>The tenderer shall not be in any situation which could give rise to a professional conflicting interest in what concerns the performance and/or implementation of the contract.</p>	<p>Provision of duly signed tender submission form (Annex I) including declaration on "professional conflicting interest" (Section 7).</p> <p>Please note that the IMI2 JU reserves the right to reject any tenderer that is found to be in a situation of professional conflicting interest, in relation to this tender / contract.</p>
f.	<p>The tenderer must have in place a quality management system (QMS).</p>	<p>Proof of a quality management system in place such as DIN EN ISO 9001 or equivalent system.</p>

***Important Note:** the IMI2 JU reserves the right to ask for clarification or further material in the case that the documents submitted are not found as adequate evidence that the tender fulfils the exclusion and/or selection criteria.

3.3 Award Criteria

The award of the contract is based on the most economically advantageous tender. Only the tenderers satisfying the minimum requirements of the technical specifications and fulfilling the requirements of the exclusion and selection criteria are eligible for contract award.

The contract will be awarded to the tenderer offering the best-value-for-money (best price-quality ratio).

3.3.1 Assessment of Technical Quality

Technical Offer & Evaluation

The quality of technical offers reaching this stage will be evaluated in accordance with the technical award criteria and the associated weighting as detailed in the evaluation grid below. The technical offer shall contain all necessary information to allow evaluation of the tender (according to the technical award criteria), be consistent with the technical specifications and be signed by the tenderer.

Tenderers' technical offers should include a detailed description of how they intend to implement the required tasks as described in Section 2.2, and any additional relevant information, and should permit exhaustive assessment against the technical award criteria listed below.

Technical Quality Threshold: Only tenders scoring **70 points or more** (of a maximum of 100 points) against the technical award criteria will have their financial offer evaluated.

Additionally, tenders must score at least **50%** on each individual technical award criterion to be considered further for financial evaluation.

No.	TECHNICAL AWARD CRITERIA	MAX POINTS
1	Rationale & Strategy: Strategy, approach, quality of the methodology to meet the objectives of the framework contract, reference list of activities, related inputs and outputs, a description of the input from each of the consortium members (in case of consortia), description of the support facilities, sub-contracting arrangements foreseen, reasonable/credible response time & strategy to requests for services etc.)	40
2	Timetable: Timing, sequence and duration of the proposed activities, identification and timing of major milestones in execution of the contract etc. Tenderers should specify how they intend to adhere to prescribed deadlines.	30
3	Organisation of work, expertise and composition and functioning of the proposed team: Organisation of work, availability and involvement of key personnel, specific role of each individual expert within the project team, interaction and coordination of tasks etc.	30
	TOTAL	100

3.3.2 Assessment of Price

Financial Evaluation

The financial evaluation will be made on the basis of the prices offered in the model financial offer (Annex V).

Financial scores will be calculated based on the following formula:

$$\text{Financial Score for Tender X} = (P(A1)_{\min} / P(A1)_x) + (P(A2)_{\min} / P(A2)_x) + (P(A3)_{\min} / (A3)_x) + (P(A4)_{\min} / (A4)_x) + (P(B1)_{\min} / P(B1)_x) + (P(B2)_{\min} / P(B2)_x) + (P(B3)_{\min} / (B3)_x) + (P(B4)_{\min} / (B4)_x)$$

Where:

(A1) = Person-day rate (A) for Senior Expert (1)

$P(A1)_{\min}$ = Cheapest Price for (A1)

$P(A1)_x$ = Price for (A1) proposed by Tenderer X

The financial evaluation will be made on the basis of the prices offered in the financial offer (Annex V). The financial offer must be presented strictly in the format provided in **Annex V**.

Financial Offer

- The financial offer must be presented in the format provided in **Annex V**.
- Every tenderer is required to verify that the results of all data entered in the model financial offer are correct and ensure that all averages, sub-totals, totals etc. are correct and consistently provided.
- A price shall be indicated for each category and must not amount to zero. Failure to comply with this requirement may lead to rejection of the tender.
- Please note that the prices indicated are maximum prices, and will be binding on the contractor throughout the contract implementation.
- Prices must be quoted in **EURO** and include all expenses necessary to perform the contract, except any travel and subsistence expenses incurred by experts in the performance of the contract which shall be reimbursed in accordance with Article I.5.3. and Article II.22. of the contract.
- Prices shall be fixed and not subject to revision for the first year of performance of the Contract. From the beginning of the second year of performance of the Contract, prices may be subject to revision. The revision shall be solely done as stipulated in the draft contract (Part III of the Procurement Documents).
- Prices must be quoted free of any duties, taxes (such as VAT) and/or other charges, as the IMI2 JU is exempt from such charges under Articles 3 and 4 of the Protocol on the privileges and immunities of the European Union.
- Costs incurred in preparing and submitting tenders are borne by the tenderer and shall not be reimbursed.

3.3.3 Contract Award - Choice of the Selected Tender

The most economically advantageous tenders are established by weighing technical quality against price on a **70/30** basis.

The consolidated score for each tenderer will be calculated as follows:

$$\text{Consolidated score} = (\text{Technical score} \times 0,7) + (\text{Financial score} \times 0,3)$$

The framework contract will be awarded to the best-ranked tender.

ANNEX I - TENDER SUBMISSION FORM

1. SUBMITTED by (i.e. the identity of the tenderer)	
Tenderer (Legal Name)	
Legal Address	
Postal Address for Tender (if different from above)	
Nationality (country of registration)	
VAT Registration Number	

2. CONTACT PERSON for this Tender (to act as focal point for all communication which may take place between the IMI2 JU and the tenderer)	
Name	
Organisation	
Address	
Telephone	
E-mail	

3. AUTHORISED SIGNATORY for this Tender (i.e. legally authorised representative of the tenderer)	
Name	
Position	
Address	
Documentary Evidence Attached	<input type="checkbox"/> Supporting documents providing evidence that above-mentioned signatory is legally empowered to represent / sign on behalf of the tenderer attached.

4. INFORMATION ON JOINT TENDERS			
Tender is submitted on behalf of a Consortium (indicate as applicable) YES <input type="checkbox"/> / NO <input type="checkbox"/>			
Role	Name(s) of legal entity or entities submitting this tender	SME (small or medium-sized enterprise ⁹)	Nationality
Leader (as above)		YES <input type="checkbox"/> / NO <input type="checkbox"/>	
Member 1		YES <input type="checkbox"/> / NO <input type="checkbox"/>	

⁹ <http://eur-lex.europa.eu/legal-content/EN/LSU/?uri=CELEX%3A32003H0361>

Member 2		YES <input type="checkbox"/> / NO <input type="checkbox"/>	
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Add / delete additional lines for consortium members as appropriate. **Please note that a sub-contractor IS NOT considered to be a consortium member.**

5. INFORMATION ON SUB-CONTRACTING		
Tenderer shall make use of sub-contractors (<i>indicate as applicable</i>) YES <input type="checkbox"/> / NO <input type="checkbox"/>		
In line with Section 1.6 we/I undertake to guarantee the eligibility of the sub-contractor(s) for the parts of the contract for which we have stated our intention to sub-contract in the technical offer.		
Name	Nationality	% Sub-contracted

Add / delete additional lines for sub-contractors as appropriate.

6. SUBMISSION CHECKLIST (i.e. content of the offer) - Our tender is made up of the following documents, duly signed and dated:			
ENVELOPE A – ADMINISTRATIVE DOCUMENTS			
	Single Tenderer / Consortium Leader	Consortium Members	Sub-contractors
✓ Tender Submission Form (front page of admin docs) – using template in Annex I.	<input type="checkbox"/>	N/A	N/A
✓ Declaration of Honour (Section 3.1 Exclusion Criteria) – using template in Annex II.	<input type="checkbox"/>	<input type="checkbox"/>	N/A
✓ <i>In case of sub-contracting (Section 1.6):</i> Sub-contractors Declaration – Annex III.	N/A	N/A	<input type="checkbox"/>
✓ Financial Identification Form – using the template downloadable from the European Commission's Website: http://ec.europa.eu/budget/contracts_grants/info_contracts/index_en.cfm	<input type="checkbox"/>	N/A	N/A
✓ <i>In case of consortia (Section 1.5):</i> Consortium agreement (if already available), or, powers of attorney issued by the consortium members empowering the representative of the consortium leader (tenderer) to submit a tender on their behalf.	<input type="checkbox"/>	<input type="checkbox"/>	N/A
ENVELOPE B – TECHNICAL DOCUMENTS (one signed original & 3 copies)			
✓ Technical Offer (Section 3.3.1 of the specifications).		<input type="checkbox"/>	
ENVELOPE C - FINANCIAL DOCUMENTS (one signed original & 3 copies)			
✓ Financial Offer (Section 3.3.2) - using the template in Annex V		<input type="checkbox"/>	

7. DECLARATION

I, the undersigned, **being the authorised signatory** of the above tenderer (including all consortium members, in the case of a consortium), hereby declare that we have examined and accept without reserve or restriction the entire contents of the tender specifications for the tender procedure referred to above.

Furthermore we hereby solemnly declare that:

- **In the case of consortium:** We are fully aware that, in the case of a consortium, the composition of the consortium cannot be modified in the course of the tender procedure except with the prior written authorisation of the IMI2 JU. We are also aware that the consortium members would have joint and several liability towards the IMI2 JU concerning participation in both the above procedure and any contract awarded to us as a result of it.
- We accept the **validity period** stipulated in Section **1.9** of the Tender Specifications.
- We declare and confirm our unconditional and irrevocable **acceptance of all the terms and conditions** set out in the Procurement Documents (Contract Notice, Procurement Documents - Part I - invitation to [tender/negotiate], Part II - tender specifications and Part III - draft contract) and, where appropriate, waiver of our own general or specific terms and conditions. *Please note that this acceptance shall be fully binding on the tenderer as of submission of the tender and, in case of successful contract award, for the entire duration of the contract.*
- **Professional Conflicting Interest:**
 - We are not and shall not be in any situation which could give rise to a professional conflicting interest in what concerns the performance and/or implementation of the contract.
 - We also declare that in the case that we are found to be in a situation of professional conflicting interest, in relation to this tender / contract, we understand that our tender shall be rejected.
 - In the event of the contract being awarded to us, we undertake to act with complete impartiality and in good faith in what concerns its performance and outcome and to immediately declare to the IMI2 JU in writing any situation that might raise concerns with respect to professional conflicting interest, impartiality or otherwise affect our position/ability to duly and appropriately perform the contract.
- We are aware that there is **no possibility of negotiating the contract** and, should the contract be awarded to us hereby undertake to duly sign it with the same terms and conditions and substantially in the form enclosed in the procurement documents.
- We are also aware and agree that **non-acceptance of terms and/or conditions** as cited above **may lead to the exclusion of our tender** for non-compliance with the tender conditions.

Name	
Date & Signature	

ANNEX II - DECLARATION OF HONOUR (ON EXCLUSION CRITERIA & SELECTION CRITERIA)

(To be completed by tenderer and (in the case of joint tenders) by each consortium member)

Name of the individual:	
ID or Passport number:	
Representing* [himself/herself][the following legal person]:	
Full official name:	
Official legal form	
Full official address:	
Statutory registration number:	
VAT registration number:	

**Please choose adequate form and delete as appropriate – individual representing themselves (i.e. freelance consultant, expert etc.) or individual representing a legal body (i.e. compancy, organisation etc.)*

(1) Declares whether the above-mentioned person is in one of the following situations or not (PLEASE TICK YES OR NO) :		
SITUATION OF EXCLUSION CONCERNING THE PERSON	YES	NO
(a) it is bankrupt, subject to insolvency or winding up procedures, its assets are being administered by a liquidator or by a court, it is in an arrangement with creditors, its business activities are suspended or it is in any analogous situation arising from a similar procedure provided for under national legislation or regulations;	<input type="checkbox"/>	<input type="checkbox"/>
(b) it has been established by a final judgement or a final administrative decision that the person is in breach of its obligations relating to the payment of taxes or social security contributions in accordance with the law of the country in which it is established, with those of the country in which the contracting authority is located or those of the country of the performance of the contract;	<input type="checkbox"/>	<input type="checkbox"/>
(c) it has been established by a final judgement or a final administrative decision that the person is guilty of grave professional misconduct by having violated applicable laws or regulations or ethical standards of the profession to which the person belongs, or by having engaged in any wrongful conduct which has an impact on its professional credibility where such conduct denotes wrongful intent or gross negligence, including, in particular, any of the following:		
(i) fraudulently or negligently misrepresenting information required for the verification of the absence of grounds for exclusion or the fulfilment of selection criteria or in the performance of a contract;	<input type="checkbox"/>	<input type="checkbox"/>
(ii) entering into agreement with other persons with the aim of distorting competition;	<input type="checkbox"/>	<input type="checkbox"/>
(iii) violating intellectual property rights;	<input type="checkbox"/>	<input type="checkbox"/>
(iv) attempting to influence the decision-making process of the contracting authority during the award procedure;	<input type="checkbox"/>	<input type="checkbox"/>

(v) attempting to obtain confidential information that may confer upon it undue advantages in the award procedure;	<input type="checkbox"/>	<input type="checkbox"/>
(d) it has been established by a final judgement that the person is guilty of any of the following:		
(i) fraud, within the meaning of Article 1 of the Convention on the protection of the European Communities' financial interests, drawn up by the Council Act of 26 July 1995;	<input type="checkbox"/>	<input type="checkbox"/>
(ii) corruption, as defined in Article 3 of the Convention on the fight against corruption involving officials of the European Communities or officials of EU Member States, drawn up by the Council Act of 26 May 1997, and in Article 2(1) of Council Framework Decision 2003/568/JHA, as well as corruption as defined in the legal provisions of the country where the contracting authority is located, the country in which the person is established or the country of the performance of the contract;	<input type="checkbox"/>	<input type="checkbox"/>
(iii) participation in a criminal organisation, as defined in Article 2 of Council Framework Decision 2008/841/JHA;	<input type="checkbox"/>	<input type="checkbox"/>
(iv) money laundering or terrorist financing, as defined in Article 1 of Directive 2005/60/EC of the European Parliament and of the Council;	<input type="checkbox"/>	<input type="checkbox"/>
(v) terrorist-related offences or offences linked to terrorist activities, as defined in Articles 1 and 3 of Council Framework Decision 2002/475/JHA, respectively, or inciting, aiding, abetting or attempting to commit such offences, as referred to in Article 4 of that Decision;	<input type="checkbox"/>	<input type="checkbox"/>
(vi) child labour or other forms of trafficking in human beings as defined in Article 2 of Directive 2011/36/EU of the European Parliament and of the Council;	<input type="checkbox"/>	<input type="checkbox"/>
(e) the person has shown significant deficiencies in complying with the main obligations in the performance of a contract financed by the Union's budget, which has led to its early termination or to the application of liquidated damages or other contractual penalties, or which has been discovered following checks, audits or investigations by an Authorising Officer, OLAF or the Court of Auditors;	<input type="checkbox"/>	<input type="checkbox"/>
(f) it has been established by a final judgment or final administrative decision that the person has committed an irregularity within the meaning of Article 1(2) of Council Regulation (EC, Euratom) No 2988/95;	<input type="checkbox"/>	<input type="checkbox"/>
(g) for the situations of grave professional misconduct, fraud, corruption, other criminal offences, significant deficiencies in the performance of the contract or irregularity, the applicant is subject to: <ul style="list-style-type: none"> (i) facts established in the context of audits or investigations carried out by the Court of Auditors, OLAF or internal audit, or any other check, audit or control performed under the responsibility of an authorising officer of an EU institution, of a European office or of an EU agency or body; (ii) non-final administrative decisions which may include disciplinary measures taken by the competent supervisory body responsible for the verification of the application of standards of professional ethics; (iii) decisions of the ECB, the EIB, the European Investment Fund or international organisations; (iv) decisions of the Commission relating to the infringement of the Union's competition rules or of a national competent authority relating to the infringement of Union or national competition law; or (v) decisions of exclusion by an authorising officer of an EU institution, of a European office or of an EU agency or body. 	<input type="checkbox"/>	<input type="checkbox"/>

[Only for legal persons other than Member States and local authorities, otherwise delete this table]

(2) Declares whether a natural person who is a member of the administrative, management or supervisory body of the above-mentioned legal person, or who has powers of representation, decision or control with regard to the above-mentioned legal person (this covers the company directors, members of the management or supervisory bodies, and cases where one natural person holds a majority of shares) is in one of the following situations or not (PLEASE TICK YES OR NO):

SITUATIONS OF EXCLUSION CONCERNING NATURAL PERSONS WITH POWER OF REPRESENTATION, DECISION-MAKING OR CONTROL OVER THE LEGAL PERSON	YES	NO
Situation (c) above (grave professional misconduct)	<input type="checkbox"/>	<input type="checkbox"/>
Situation (d) above (fraud, corruption or other criminal offence)	<input type="checkbox"/>	<input type="checkbox"/>
Situation (e) above (significant deficiencies in performance of a contract)	<input type="checkbox"/>	<input type="checkbox"/>
Situation (f) above (irregularity)	<input type="checkbox"/>	<input type="checkbox"/>

(3) Declares whether a natural or legal person that assumes unlimited liability for the debts of the above-mentioned legal person is in one of the following situations or not (PLEASE TICK YES OR NO OR N/A):

SITUATIONS OF EXCLUSION CONCERNING NATURAL OR LEGAL PERSONS ASSUMING UNLIMITED LIABILITY FOR THE DEBTS OF THE LEGAL PERSON	YES	NO	N/A
Situation (a) above (bankruptcy)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Situation (b) above (breach in payment of taxes or social security contributions)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

(4) Declares whether the above-mentioned person is in the following situation or not (PLEASE TICK YES OR NO):

GROUNDS FOR REJECTION FROM THIS PROCEDURE	YES	NO
(h) Has distorted competition by being previously involved in the preparation of procurement documents for this procurement procedure;	<input type="checkbox"/>	<input type="checkbox"/>

(5) Acknowledges that the above-mentioned person may be subject to rejection from this procedure and to administrative sanctions (exclusion or financial penalty) if any of the declarations or information provided as a condition for participating in this procedure prove to be false.

(6) Declares whether the above-mentioned person complies with the selection criteria as provided in the tender specifications (PLEASE TICK YES OR NO):

SELECTION CRITERIA	YES	NO
(a) It has the legal and regulatory capacity to pursue the professional activity needed for performing the contract as required in Section 3.2.1 of the tender specifications;	<input type="checkbox"/>	<input type="checkbox"/>
(b) It fulfills the applicable economic and financial criteria indicated in Section 3.2.2 of the tender specifications;	<input type="checkbox"/>	<input type="checkbox"/>
(c) It fulfills the applicable technical and professional criteria indicated in Section 3.2.3 of the tender specifications.	<input type="checkbox"/>	<input type="checkbox"/>

(7) The above-mentioned person as legal representative of the tenderer or legal representative of the leader of the consortium in case of joint tender, declares that:			
	YES	NO	N/A
the tenderer, including all members of the group in case of joint tender and including subcontractors if applicable, complies with all the selection criteria for which a consolidated assessment will be made as provided in the tender specifications.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

(8) Declares that the above-mentioned person will be able to provide the necessary supporting documents listed in the relevant Sections of the tender specifications and which are not available electronically upon request and without delay.

(9) Declares that the above-mentioned person complies 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 the Public Procurement Directive¹⁰.

***IMPORTANT NOTES:**

✓ **Remedial Measures:**

If the person declares one of the situations of exclusion listed above, it should indicate the measures it has taken to remedy the exclusion situation, thus demonstrating its reliability. They may include e.g. technical, organisational and personnel measures to prevent further occurrence, compensation of damage or payment of fines. The relevant documentary evidence which appropriately illustrates the remedial measures taken should be provided in annex to this declaration. This does not apply for the situations referred in point (1)(d) of this declaration.

✓ **Evidence upon request:**

Upon request, the tenderer(s) to whom the contract is to be awarded **shall provide, within 15 days following notification of award and preceding the signature of the contract, the following documentary evidence in original to confirm the declaration:**

- For situations described in (1)(a), (c), (d) or (f), production of a recent extract from the judicial record is required or, failing that, an equivalent document recently issued by a judicial or administrative authority in the country of establishment of the person showing that those requirements are satisfied.
- For the situation described in point (1)(a) or (1)(b), production of recent certificates issued by the competent authorities of the State concerned are required. These documents must provide evidence covering all taxes and social security contributions for which the person is liable, including for example, VAT, income tax (natural persons only), company tax (legal persons only) and social security contributions.

Where any document described above is not issued in the country concerned, it may be replaced by a sworn statement made before a judicial authority or notary or, failing that, a solemn statement made before an administrative authority or a qualified professional body in its country of establishment.]

**Note: If the tenderer has already submitted such evidence for the purpose of another procurement procedure, its issuing date does not exceed one year and it is still valid, the person shall declare on its honour that the documentary evidence has already been provided and confirm that no changes have occurred in its situation.*

¹⁰ Directive 2014/24/EU of the European Parliament and of the Council of 26 February 2014: <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:32014L0024>

Name	
Date & Signature	

ANNEX III – SUB-CONTRACTORS DECLARATION

(To be completed by each sub-contractor including freelance consultants)

<Letterhead of the sub-contractor or other entity on whose resources to rely>

Name of Tenderer:	
Name of the individual (<i>authorised signatory</i>)	
representing the following legal person: (<i>only if the economic operator is a legal person</i>)	
Name of Company / Organisation:	
Legal address:	
Registration number/ID Card No.:	
VAT number:	

DECLARATION OF INTENT
I, the undersigned, being the authorised signatory of the above company hereby solemnly declare and confirm our irrevocable undertaking to collaborate with the above named tenderer should they win the contract and that all appropriate and necessary resources from our part shall be put at the tenderer's disposal for the performance of the contract.
DECLARATION OF HONOUR (ON EXCLUSION CRITERIA)
Furthermore, declares on oath that the above-mentioned natural/legal person is not in one of the situations of exclusion/professional conflicting interest listed in Articles 136 and 141(1) of the Financial Regulation (FR) ¹¹ .

Name	
Date & Signature	

¹¹ Regulation (EU, Euratom) No 1046/2018 of the European Parliament and of the Council of 18 July 2018 on the financial rules applicable to the general budget of the Union, repealing Regulation (EC, Euratom) No 966/2012 (OJ L 193 of 30.07.2018, p. 1), as amended, as amended (<http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32015R1929>).

ANNEX IV.a – SELECTION CRITERIA – 3.2.2 ECONOMIC & FINANCIAL CAPACITY

Name of Tenderer:	
<i>(In case of consortia: Name of Consortium Member:)</i>	

In line with Section 3.2.2 – Economic & Financial Capacity (Selection Criteria) please complete the table below with the information and supporting documents requested.

a. Statement of Annual Turnover [concerning the services/supplies covered by the contract]		
Year	Annual Turnover in EUR	Balance Sheets or Extracts from Balance Sheets Provided / Attached to Offer
2018	<complete>	<input type="checkbox"/>
2017	<complete>	<input type="checkbox"/>
2017	<complete>	N/A

b. [Statement of Professional Risk Indemnity Insurance]		
Type	Level of Insurance (<i>indicating currency</i>)	Evidence Provided / Attached to Offer
<>	<complete>	<input type="checkbox"/>
<>	<complete>	<input type="checkbox"/>
<>	<complete>	N/A

Name	
Date & Signature	

ANNEX IV.b – SELECTION CRITERIA – 3.2.3 TECHNICAL & PROFESSIONAL CAPACITY – EXPERIENCE OF THE TENDERER]

Name of Tenderer:	
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In line with Section 3.2.3 – Technical & Professional Capacity (Selection Criteria) please complete the table below with the information and supporting documents requested.

	Client /Company Name**	Project / Contract Start – End Date	Description of Services	Financial Volume of Services (EUR)***	Reference Included in Tender (minimum <X>)
1.					<input type="checkbox"/>
2.					<input type="checkbox"/>
3. *					<input type="checkbox"/>

*More rows/columns can be added by the tenderer where necessary

** Where this cannot be disclosed, please indicate company type or equivalent

*** Where this cannot be disclosed other means to verify the scope/volume shall be presented i.e. range

Name	
Date & Signature	

ANNEX IV.c – TECHNICAL & PROFESSIONAL CAPACITY - OVERVIEW OF [PROJECT TEAM / PROPOSED PERSONNEL]

Name of Tenderer:	
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In line with Section 3.2.3 – Technical & Professional Capacity (Selection Criteria) please complete the table below with the information and supporting documents requested.

	Name	Role / Main Responsibilities in [Project Team/Contract Implementation]	Employment Status (<i>i.e. employed, sub-contracted, staff member of consortium partner etc.</i>)	CV included in offer
1.				<input type="checkbox"/>
2.				<input type="checkbox"/>
3.				<input type="checkbox"/>
4.				<input type="checkbox"/>
5.				<input type="checkbox"/>

**More rows/columns can be added by the tenderer where necessary*

Name	
Date & Signature	

ANNEX V - MODEL FINANCIAL OFFER

Name of Tenderer:	
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PRICE LIST

	Expert Category	Person-day in EURO (A)	Hourly rate in EURO (B)
(1)	Senior Expert	€	€
(2)	Intermediate Expert	€	€
(3)	Junior Expert	€	€
(4)	Secretarial/ administrative support	€	€

Note:

- **Please note that the prices indicated in Part A, are maximum prices, and will be binding on the contractor throughout contract implementation.**
- Prices must be quoted in **EURO** and include all expenses necessary to perform the contract, except any travel and subsistence expenses incurred by experts in the performance of the contract which shall be reimbursed in accordance with Article I.5.3. and Article II.22. of the contract.
- A price shall be indicated for each category and must not amount to zero. Failure to comply with this requirement may lead to rejection of the tender.
- Every tenderer is required to verify that the results of all data entered in the model financial offer are correct and ensure that all averages, sub-totals, totals etc. are correct and consistently provided.
- The price quoted is fixed and shall be subject to **NO revision**.

Name	
Date & Signature	

Procurement Documents

Part III

Draft Contract

