Enabel
Implementing on behalf of #TEAMEUROPE

Tender Specifications RWA21001-10055

Public service contract for:

"DEVELOPMENT OF A PHARMACEUTICAL TRACK AND TRACE SYSTEM COMPLIANT WITH EPCIS STANDARDS"

Direct Negotiated Procedure with Prior Publication

Country: RWANDA

Navision code: RWA2100111

KWIGIRA PROJECT

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1 General provisions

1.1 Derogations from the General Implementing Rules

Section 4, '*Specific contractual and administrative conditions*' of these Tender Specifications (CSC/Cahier Spécial des Charges) holds the specific administrative and contractual provisions that apply to this public procurement contract as a derogation of the Royal Decree of 14.01.2013 or as a complement or an elaboration thereof.

1.2 Contracting authority

The contracting authority of this public procurement contract is Enabel, the Belgian Agency for international cooperation, public-law company with social purposes, with its registered office at Rue Haute 147, 1000 Brussels in Belgium (enterprise number 0264.814.354, RPM/RPR Brussels).

This tender is organised by Enabel in Rwanda, acting under a mandate from the European Union to implement projects in health, agriculture, agroforestry, and urbanisation, thereby contributing to Rwanda's socio-economic development. All activities and commitments described in this document are undertaken within the framework of that mandate.

For the purpose of this procurement contract, Enabel shall be represented by Ms. Virginie HALLET, Country Director of Enabel in Rwanda, or, where applicable, by any other person(s) duly mandated in accordance with Enabel's mandate structure to represent Enabel vis-à-vis third parties and to award public procurement contracts.

1.3 Institutional setting of Enabel

The general framework of reference in which Enabel operates is:

- The Belgian Law on Development Cooperation of 19 March 2013[1];
- The Belgian Law of 21 December 1998 establishing the Belgian Technical Cooperation as a public-law company2;
- The Belgian Law of 23 December 2017 changing the name of the Belgian Technical Cooperation and defining the missions and functioning of Enabel, the Belgian development agency, published in the Belgian Official Gazette on 11 December 2017.

The following initiatives are also guiding Enabel in its operations: We mention as main examples:

- In the field of international cooperation: the United Nations Sustainable Development Goals and the Paris Declaration on the harmonisation and alignment of aid;
- In the field of the fight against corruption: the Law of 8 May 2007 approving the United Nations Convention against Corruption, adopted in New York on 31 October 20033, as well as the Law of 10 February 1999 on the Suppression of Corruption transposing the Convention on Combating Bribery of Foreign Public Officials in International Business Transactions;
- In the field of Human Rights: the United Nations' Universal Declaration of Human Rights (1948) as well as the 8 basic conventions of the International

[1] Belgian Official Gazette of 30 December 1998, of 17 November 2001, of 6 July 2012, of 15 January 2013 and of 26 March 2013.

[2] Belgian Official Gazette of 1 July 1999.

[3] Belgian Official Gazette of 18 November 2008.

Labour Organisation4 on Freedom of Association (C. n°87), on the Right to Organise and Collective Bargaining (C. n°98), on Forced Labour (C. n°29 and 105), on Equal Remuneration and on Discrimination in Respect of Employment (C. n°100 and 111), on Minimum Age for Admission to Employment (C. n°138), on the Prohibition of the Worst Forms of Child Labour (C. n°182);

- In the field of environmental protection: The Climate Change Framework Convention in Paris, 12 December 2015;
- The first Management Contract concluded between Enabel and the Belgian federal State (approved by the Royal Decree of 17.12.2017, Belgian Official Gazette 22.12.2017) that sets out the rules and the special conditions for the execution of public service tasks by Enabel on behalf of the Belgian State.
- Enabel's Code of Conduct of January 2019, Enabel's Policy regarding sexual exploitation and abuse of June 2019 and Enabel's Policy regarding fraud and corruption risk management of June 2019;

1.4 Rules governing the procurement contract

- The following, among other things, applies to this public procurement contract:
- The Law of 17 June 2016 on public procurement contracts5;
- The Law of 17 June 2013 on justifications, notification and legal remedies for public procurement contracts and certain procurement contracts for works, supplies and services6;
- The Royal Decree of 18 April 2017 on the award of public procurement contracts in the classic sectors7;
- Royal Decree of 14 January 2013 establishing the General Implementing Rules for public procurement contracts and for concessions for public works8;
- Circulars of the Prime Minister with regards to public procurement contracts.
- Enabel's Policy regarding sexual exploitation and abuse – June 2019;
- Enabel's Policy regarding fraud and corruption risk management – June 2019;
- Legislation with regards to sexual harassment at the workplace or equivalent;
- Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data (General Data Protection Regulation – 'GDPR'), and repealing Directive 95/46/EC:
- Law of 30 July 2018 on the protection of natural persons with regard to the processing of personal data.

All Belgian regulations on public contracts can be consulted onwww.publicprocurement.be; Enabel's Code of Conduct and the policies mentioned above can be consulted on Enabel's website via https://www.enabel.be/content/integrity-desk.

1.5 Definitions

The following definitions apply to this procurement contract:

[4] http://www.ilo.org/ilolex/french/convdisp1.htm.
[5] Belgian Official Gazette 14 July 2016.
[6] Belgian Official Gazette of 21 June 2013.
[7] Belgian Official Gazette 9 May 2017.
[8] Belgian Official Gazette 27 June 2017.

The tenderer: An economic operator submitting a tender;

The contractor/ service provider: The tenderer to whom the procurement contract is awarded;

The contracting authority: Enabel, represented by the Country Director of Enabel in Rwanda and/or any other person(s) duly mandated in accordance with Enabel's mandate structure to represent Enabel vis-à-vis third parties;

The tender: Commitment of the tenderer to perform the procurement contract under the conditions that he has submitted;

Days: In the absence of any indication in this regard in the Tender Specifications and the applicable regulations, all days should be interpreted as calendar days;

Procurement documents: Tender Specifications including the annexes and the documents they refer to;

Technical specifications: A specification in a document defining the characteristics of a product or a service, such as the quality levels, the environmental and climate performance levels, the design for all needs, including accessibility for people with disabilities, and the evaluation of conformity, of product performance, of the use of the product, safety or dimensions, as well as requirements applicable to the product as regards the name by which it is sold, terminology, symbols, testing and test methods, packaging, marking or labelling, instructions for use, the production processes and methods at every stage in the life cycle of the supply or service, as well as the evaluation and conformity procedures;

Variant: An alternative method for the design or the performance that is introduced either at the demand of the contracting authority, or at the initiative of the tenderer;

Option: A minor and not strictly necessary element for the performance of the procurement contract, which is introduced either at the demand of the contracting authority, or at the initiative of the tenderer;

Inventory: The procurement document which splits up the performance in different items and specifies the quantity or the method to determine the price for each of them;

General Implementing Rules (GIR): Rules laid down in the Royal Decree of 14.01.2013 establishing the General Implementing Rules for public procurement contracts and for concessions for public work;

The Tender Specifications (Cahier spécial des charges/CSC): This document and its annexes and the documents it refers to;

Corrupt practices: The offer of a bribe, gift, gratuity or commission to any person as an inducement or reward for performing or refraining from any act relating to the award of a procurement contract or performance of a procurement contract already concluded with the contracting authority;

Litigation: Court action;

Subcontractor in the meaning of public procurement regulations: The economic operator proposed by a tenderer or contractor to perform part of the contract. The subcontractor is understood as the economic operator with the capacity which the applicant or tenderer relies upon or to whom he entrusts all or part of his engagements;

Controller in the meaning of the GDPR: the natural or legal person, public authority, agency or other body which, alone or jointly with others, determines the purposes and means of the processing of personal data;

Sub-contractor or processor in the meaning of the GDPR: a natural or legal person, public authority, agency or other body which processes personal data on behalf of the controller;

Recipient in the meaning of the GDPR: a natural or legal person, public authority, agency or another body, to which the personal data are disclosed, whether a third party or not;

Personal data: any information relating to an identified or identifiable natural person ('data subject'); an identifiable natural person is one who can be identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data, an online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that natural person.

1.6 Processing of personal data by the contracting authority and confidentiality

1.6.1 Processing of personal data by the contracting authority

The contracting authority undertakes to process the personal data that are communicated to it in response to the Call for Tenders with the greatest care, in accordance with legislation on the protection of personal data (General Data Protection Regulation, GDPR). Where the Belgian law of 30 July 2018 on the protection of natural persons with regard to the processing of personal data contains stricter provisions, the contracting authority will act in accordance with said law.

1.6.2 Confidentiality

The tenderer or contractor and Enabel are bound to secrecy vis-à-vis third parties with regards to any confidential information obtained within the framework of this public contract and will only divulge such information to third parties after receiving the prior written consent of the other party. They will disclose this confidential information only among appointed parties involved in the assignment. They guarantee that said appointed parties will be adequately informed of their obligations in respect of the confidential nature of the information and that they shall comply therewith.

PRIVACY NOTICE OF ENABEL: Enabel takes your privacy serious. We undertake to protect and process your personal data with due care, transparently and in strict compliance with privacy protection legislation.

See also: https://www.enabel.be/content/privacy-notice-enabel

1.7 Deontological obligations

Any failure to comply with one or more of the deontological clauses may lead to the exclusion of the candidate, tenderer or contractor from other public procurement contracts for Enabel.

For the duration of the procurement contract, the contractor and his staff respect human rights and undertake not to go against political, cultural or religious customs of the beneficiary country. The tenderer or contractor is bound to respect fundamental labour standards, which are internationally agreed upon by the International Labour Organisation (ILO), namely the conventions on union freedom and collective bargaining, on the elimination of forced and obligatory labour, on the elimination of employment and professional discrimination and on the abolition of child labour.

In accordance with Enabel's Policy regarding sexual exploitation and abuse, the contractor and his staff have the duty to behave in an irreproachable manner towards the beneficiaries of the projects and towards the local population in general. They must abstain from any acts that could be considered a form of sexual exploitation or abuse and they must abide by the basic principles and guidelines laid down in this policy.

Any attempt of a candidate or a tenderer to obtain confidential information, to proceed to illicit arrangements with competitors or to influence the evaluation committee or the contracting authority during the investigation, clarification, evaluation and comparison of tenders and candidates procedure will lead to the rejection of the application or the tender.

Moreover, in order to avoid any impression of risk of partiality or connivance in the follow-up and control of the performance of the procurement contract, it is strictly forbidden to the contractor to offer, directly or indirectly, gifts, meals or any other material or immaterial advantage, of whatever value, to agents of the contracting authority who are concerned, directly or indirectly, by the follow-up and/or control of the performance of the procurement contract, regardless of their hierarchical rank.

The contractor of the procurement contract commits to supply, upon the demand of the contracting authority, any supporting documents related to the performance conditions of the contract. The contracting authority will be allowed to proceed to any control, on paperwork or on site, which it considers necessary to collect evidence to support the presumption of unusual commercial expenditure. Depending on the gravity of the facts observed, the contractor having paid unusual commercial expenditure is liable to have its contract cancelled or to be permanently excluded from receiving funds.

In accordance with Enabel's Policy regarding sexual exploitation and abuse of June 2019 and Enabel's Policy regarding fraud and corruption risk management complaints relating to issues of integrity (fraud, corruption, etc.) must be sent to the Integrity desk through the https://www.enabelintegrity.be website.

1.8 Applicable law and competent courts

The procurement contract must be performed and interpreted according to Belgian law.

The parties commit to sincerely perform their engagements to ensure the good performance of this procurement contract.

In case of litigation or divergence of opinion between the contracting authority and the contractor, the parties will consult each other to find a solution.

If agreement is lacking, the Brussels courts are the only courts competent to resolve the matter.

2 Subject-matter and scope of the procurement contract

2.1 Type of procurement contract

This procurement contract is a services procurement contract.

2.2 Subject-matter of the procurement contract

This services procurement contract concerns the "**Development of a pharmaceutical track and trace system compliant with EPCIS standards**", in accordance with the conditions set out in these Tender Specifications.

2.3 Lots

The procurement contract consists of a single, indivisible lot, since the services and components are interdependent and require seamless integration, consistent technical and quality standards, and a single point of accountability to ensure efficiency, quality, and cost-effectiveness.

A tender for part of a lot is inadmissible.

2.4 Items

The procurement contract consists of one single item with the tasks described in the technical specifications (See also below **section 5 of the tender documents**).

These tasks are pooled and form one single procurement contract.

2.5 Term of the procurement contract[9]

The contract shall enter into force upon notification of the award decision and shall have a total duration of ten (10) months.

In addition, the Contractor shall provide post-implementation services for a period of six (6) months **(See art. 5.7 and 5.8)**.

2.6 Variants

Variants are not permitted.

2.7 Option

Options are not permitted.

2.8 Quantity

Quantities (person days) are determined in the technical specifications (**See section 5 of the tender specifications**).

[9] Please note: term of the procurement contract not to be confused with performance period.

3 Subject-matter and scope of the procurement contract

3.1 Award procedure

Direct Negotiated Procedure with Prior Publication in application of Article 41 of the Law of 17 June 2016.

3.2 Publication

3.2.1 Official publication

This procurement contract is officially advertised in the Belgian Public Tender bulletin.

3.2.2 Further notification

These Tender Specifications are published on the Enabel website (www.enabel.be).

This procurement contract is officially published on the OECD website.

3.3 Information

The awarding of this procurement contract is coordinated **by Mr. Evariste SIBOMANA**, evariste.sibomana@enabel.be.

Throughout this procedure all contacts between the contracting authority and the (prospective) tenderers about this procurement contract will exclusively pass through this service / this person. (Prospective) tenderers are prohibited to contact the contracting authority in any other way with regards to this contract, unless otherwise stipulated in these Tender Specifications.

Until 10 calendar days before the final date for receipt of the tenders, candidate-tenderers may ask questions about these Tender Specifications and the procurement contract.

Questions will be in writing to:

Mr. Evariste SIBOMANA

(evariste.sibomana@enabel.be)

with copy to

Mrs. Oliver UWANTEGE (oliver.uwantege@enabel.be)

and

Mr. Réal NIMPAGARITSE

(real.nimpagaritse@enabel.be)

and they will be answered in the order received. The complete overview of questions asked will be available at the address mentioned above at the latest 7 days before the deadline for submission of bids

Until the notification of the award decision no information will be given about the evolution of the procedure.

The procurement documents can be consulted free of charge at the following internet address: www.enabel.be. To be able to submit a tender in full knowledge of the facts, the tenderer may visit the website.

The tenderer is supposed to submit his tender after reading and taking into account any corrections made to the contract notice or the Tender Specifications that are published in the Belgian Public Tender bulletin or that are sent to him by e-mail. To do so, when the tenderer has downloaded the Tender Specifications, it is strongly advised that he gives his coordinates to the public procurement administrator mentioned above and requests information on any modifications or additional information.

In accordance with Article 81 of the Royal Decree of 18 April 2017, the tenderer is required

to report immediately any gap, error or omission in the procurement documents that precludes him from establishing his price or compare tenders, within ten days at the latest before the deadline for receipt of tenders.

3.4 Tender

3.4.1 Data to be included in the tender

The tenderer must use the tender form in annexe. In case he does not use this form, he is fully responsible for the perfect concordance between the documents he has used and the form.

The tender and the annexes to the tender form are drawn up in English.

By submitting a tender, the tenderer automatically renounces to his own general or specific sales conditions, even if these are mentioned in any of the annexes to his tender.

The tenderer clearly designates in his tender which information is confidential and/or relates to technical or business secrets and may therefore not be divulged by the contracting authority.

3.4.2 Period the tender is valid

The tenderers are bound by their tender for a period of 120 days from the deadline for the receipt date.

The validity of the tender will be negotiated, if the deadline stated above is overrun.

3.4.3 Determination of prices

All prices given in the tender form must obligatorily be quoted in EUROS (**see also below art. 6.2 – Price Form**).

This procurement contract is a price-schedule contract, i.e. a contract in which only the unit prices are lump-sum prices. The price to be paid will be obtained by applying the unit prices mentioned in the inventory to the quantities actually performed.

In accordance with Article 37 of the Royal Decree of 18 April 2017, the contracting authority may for the purpose of verifying the prices carry out an audit of any and all accounting documents and an on-site audit to check the correctness of the indications supplied.

3.4.3.1 Elements included in the price

The service provider is deemed to have included in his unit and global prices any charges and taxes generally applied to services.

The following are in particular included in the prices (non-exhaustive list):

• Expert cost including: fees, the per diems, accommodation costs, local transport costs, insurance costs, security costs, communication costs (including the internet), administrative and secretariat costs, photocopy and printing costs, costs for documentation of the services that can be required by the contracting authority, the production and delivery of documents or records linked to the performance of the services, the customs and excise duties for materials and products used, the packaging costs, the acceptance costs, all costs, staff and material and logistics expenses needed to perform the present contract, where applicable, the measures imposed by occupational safety and worker health legislation, the intellectual property right fees, the purchase or leasing of third party services needed for the performance of the contract, and the applicable Withholding taxes.

• Reimbursable Costs: (paid based upon presentation of justification documents, up to the maximum budget set and accepted in financial proposal): only international travel costs and

visa costs (if any) are accepted as reimbursable costs.

• International travel days are not reimbursed by Enabel.

3.4.4 How to submit tenders?

The tenderer may only submit one tender as follows:

- **The tender will be drawn up in 3 copies, one of them being the original and two copies.**
- **Soft Copy (Exactly identical to the hard copy) must be submitted in one or more PDF files on a USB stick. Bidders who do not submit the required copies (hard and the soft copies), might be rejected.**

The tender and all accompanying documents have to be numbered and signed by the tenderer or his/her representative. The same applies to any alteration, deletion or note made to this document.

The representative of the bidder must clearly state that he/she is authorised to commit the tenderer. If the tenderer is a company / association without legal body status, formed by separate natural or legal persons (temporary group or temporary partnership), the tender must be signed by each of these persons.

The signed and dated original (including the soft copy on the key) will be sent in a sealed enveloped mentioning:

"TENDER RWA21001-10055"

The tender must be **received before 16/04/2026 at 04:00 PM Kigali time**.

It must be sent to:

Mr. Réal NIMPAGARITSE

ECA - Enabel in Rwanda

Belgian agency for international cooperation

KN 67 Street, plot N° 10 SORAS Towers,

Wing A, 6th Floor Opposite St Michel Catholic Church

B.P. 6089 KIYOVU

Any request for participation or tender must arrive before the final submission date and time. Requests for participation or tenders that arrive late will not be accepted[10].

Attention points:

- *the bids sent by email will be rejected!*
- *Kindly refer also to the Section. 7 – Document to be included in the proposal/Offer.*

3.4.5 Change or withdrawal of a tender that has already been submitted

When a tenderer wants to change or withdraw a tender already sent or submitted this must be done in accordance with the provisions of Articles 43 and 85 of the Royal Decree of 18 April 2017.

To change or withdraw a tender already sent or submitted, a written statement is required, which will be correctly signed by the tenderer or his representative. The subject-matter and the scope of the changes must be indicated in detail. Any withdrawal must be pure and simple.

The withdrawal may also be communicated by electronic means, provided that it is confirmed by registered letter deposited at the post office or against acknowledgement of receipt at the latest the day before the tender acceptance deadline.

[10] Article 83 of the Royal Decree Award

When the submission report drawn up following the modifications or withdrawal set out in clause 1 does not bear the signature referred to in paragraph 1, the modification or withdrawal is automatically deemed null and void. This nullity applies only to the modifications or withdrawal, not to the tender itself.

3.4.6 Opening of Tenders

The tender must be in the possession of the contracting authority before the final submission date and time **specified in point 3.4.4**. The tenders will be opened behind closed doors.

3.4.7 Selection of tenderers

3.4.7.1 Exclusion grounds

The mandatory and optional exclusion grounds are given in the Declaration on honour enclosed to these Tender Specifications.

By submitting this tender, the tenderer certifies that he is not in any of the cases of exclusion listed in the Articles 67 to 70 of the Law of 17 June 2016 and the Articles 61 to 64 of the Royal Decree of 18 April 2017.

The contracting authority will verify the accuracy of this Declaration on honour for the tenderer with the best tender.

For that purpose, the contracting authority will ask the tenderer concerned to provide information or documents allowing the contracting authority to verify the tenderer's personal situation by the fastest means and within the term set by the contracting authority.

The contracting authority will itself ask for information or documents that it can obtain free of charge by digital means from the instances that manage the information or documents.

3.4.7.2 Selection criteria

Moreover, by means of the documents requested in the 'Selection file (see points 5.9, 6.6.), the tenderer must prove that he is sufficiently capable, from an economic and financial as well as from a technical point of view, to successfully perform this public procurement contract.

The minimum required profile for the consulting firm and keys experts will be analysed at the selection stage.

The bidders who will not meet the minimum technical requirements will not be selected for the award stage.

3.4.7.3 Overview of the procedure

In a first phase, the tenders submitted by the selected tenderers will be evaluated as to formal and material regularity. Irregular tenders will be rejected.

The contracting authority reserves the right to have the irregularities in the tenderers' tender regularised during the negotiations.

In a second phase, the formally and materially regular tenders will be evaluated as to content by an evaluation commission.

This evaluation will be conducted on the basis of the award criteria given in these Tender Specifications and aims to setting a shortlist of tenderers with whom negotiations will be conducted. The contracting authority may decide to include a maximum of three tenderers in the shortlist.

Then, the negotiation phase follows. In view of improving the contents of the tenders, the contracting authority may negotiate with tenderers the initial tenders and all subsequent tenders that they have submitted, except final tenders. The minimum requirements and the award criteria are not negotiable. However, the contracting authority may also decide not to negotiate. In this case, the initial tender is the final tender.

When the contracting authority intends to conclude the negotiations, it will so advise the remaining tenderers and will set a common deadline for the submission of any BAFOs. Once negotiations have closed, the BAFO will be compared with the exclusion, selection and award criteria. The tenderer whose BAFO shows the best value for money (obtaining the best score based on the award criteria given below) will be designated the contractor for this procurement contract.

3.4.7.4 Award criteria

The contracting authority will choose the regular BAFO that it finds to be most advantageous, taking account of the following criteria:

2. Technical proposal 60%

Technical proposal will be evaluated based on the following criterion and scoring:

Criteria N°	Criteria for methodology evaluation	Maximum score
1	Detailed Methodology including the details on how all activities and sub-activities will be performed, understanding of ToRs and overall strategy to be used, risk assessment and mitigation measures. • Detailed Methodology (**20 Pts**) • Understanding of ToRs overall strategy to be used (**10 Pts**). • Risk assessment and mitigation measures (**10 Pts**)	**40**
2	Relevance of the proposed work plan & timetable of activities/ sub-activity and work distribution between the team members Work plan • Relevant work plan (**10 pts**) • Relevant work distribution between the team members (**10pts**)	**20**
	TOTAL	**60**

3. Price: 40%

With regards to the 'price' criterion, the following formula will be used:

$$\textbf{Score of Bid A} = \frac{\text{amount of lowest bid price} * 40}{\text{Bid price A}}$$

The lowest price will get the maximum point.

3.4.7.5 Final score

The scores for the award criteria will be added up. The procurement contract will be awarded to the tenderer with the highest final score, after the contracting authority has verified the accuracy of the Declaration on honour of this tenderer and provided the control shows that the Declaration on honour corresponds with reality.

3.4.7.6 Awarding the procurement contract

the procurement contract will be awarded to the tenderer who has submitted the most economically advantageous tender.

Notice though that in accordance with Art. 85 of the Law of 17 June 2016, there is no obligation for the contracting authority to award the procurement contract.

The contracting authority may either decide not to award the procurement contract; either redo the procedure, if necessary, through another award procedure.

3.4.8 Concluding the procurement contract

In accordance with Art. 88 of the Royal Decree of 18 April 2017, the procurement contract occurs through the notification to the selected tenderer of the approval of his tender.

Notification is via digital platforms, e-mail or fax.

So, the full contract agreement consists of a procurement contract awarded by Enabel to the chosen tenderer in accordance with:

- These Tender Specifications and its annexes;
- The approved BAFO of the contractor and all of its annexes;
- The notification of the award decision;
- Any later documents that are accepted and signed by both parties, as appropriate.

In an objective of transparency, Enabel undertakes to publish each year a list of recipients of its contracts. By introducing his tender, the successful tenderer declares that he agrees with the publication of the title of the contract, the nature and object of the contract, its name and location, and the amount of the contract.

4 Specific contractual conditions

This chapter of these Tender Specifications holds the specific provisions that apply to this public procurement contract as a derogation of the 'General Implementing Rules for public procurement contracts and for public works concessions' of the Royal Decree of 14 January 2013, hereinafter referred to as 'GIR', or as a complement or an elaboration thereof. The numbering of the articles below (between brackets) follows the numbering of the GIR articles. Unless indicated, the relevant provisions of the General Implementing Rules (GIR) apply in full.

These Tender Specifications derogate from Art.25-33 of the General Implementing Rules.

4.1 Managing official (Art. 11)

The managing official is **Mrs. Oliver UWANTEGE, Business Analyst eHealth, e-mail: oliver.uwantege@enabel.be**

Once the procurement contract is concluded, the managing official is the main contact point for the service provider. Any correspondence or any questions with regards to the performance of the procurement contract will be addressed to her, unless explicitly mentioned otherwise in these Tender Specifications.

The managing official is responsible for the follow-up of the performance of the contract.

The managing official is fully competent for the follow-up of the satisfactory performance of the procurement contract, including issuing service orders, drawing up reports and states of affairs, approving the services, progress reports and reviews. She may order any modifications to the procurement contract with regards to its subject-matter provided that they remain within its scope.

However, the signing of amendments or any other decision or agreement implying derogation from the essential terms and conditions of the procurement contract are not part of the competence of the managing official. For such decisions the contracting authority is represented as stipulated under 'The contracting authority'.

Under no circumstances is the managing official allowed to modify the terms and conditions (e.g. performance deadline) of the contract, even if the financial impact is nil or negative. Any commitment, change or agreement that deviates from the conditions in the Tender Specifications and that has not been notified by the contracting authority, will be considered null and void.

4.2 Subcontractors (Art. 12 to 15)

The fact that the contractor entrusts all or part of his commitments to subcontractors does not relieve him of liability to the contracting authority. The latter does not recognise any contractual relation with third parties.

The contractor remains, in any case, solely liable to the contracting authority.

The service provider commits to having the procurement contract performed by the key experts/persons indicated in the tender, except for force majeure. The persons mentioned or their replacements are all deemed to effectively be involved in the performance of the procurement contract. Any replacements must be approved by the contracting authority.

When the contractor uses a subcontractor to carry out specific processing activities on behalf of the contracting authority, the same data protection obligations as those of the contractor are imposed on that subcontractor by contract or any other legal act.

In the same way, the contractor will respect and enforce to his subcontractors, the provisions of Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data (General Data Protection Regulation, GDPR). The

contracting authority may conduct an audit of the processing carried out in order to validate compliance with this legislation.

4.3 Confidentiality (art. 18)

The knowledge and information gathered by the tenderer under the framework of this public contract is strictly confidential.

Under no circumstances can the information collected, regardless of its origin and nature, be transferred to third parties in any form.

The tenderer is therefore bound by the duty of discretion.

In accordance with Article 18 of the Royal Decree of 14 January 2013 establishing the general rules for public procurement, the tenderer undertakes to consider and process in a strictly confidential manner any information, all facts, any documents and/or any data, whatever their nature and support, which have been communicated to him, in any form and by any means, or to which he has access, directly or indirectly, in the context or on the occasion of this public contract. Confidential information covers, in particular, the very existence of this public contract, without this list being limited.

Therefore, he undertakes to:

•Respect and enforce the strict confidentiality of these elements and to take all necessary precautions in order to preserve their secrecy (these precautions cannot in any case be inferior to those taken by the tenderer for the protection of his own confidential information);

•Consult, use and/or exploit, directly or indirectly, all of the above elements only to the extent strictly necessary to prepare and, if necessary, to carry out this public contract (particularly in accordance with the privacy legislation with respect to personal data processing);

•Not reproduce, distribute, disclose, transmit or otherwise make available to third parties the above elements, in whole or in part, and in any form, unless having obtained prior and written consent of the contracting authority;

•Return, at the first request of the contracting authority, the above elements;

•In general, not disclose directly or indirectly to third parties, whether for advertising or any other reason, the content of this public contract.

4.4 Protection of personal data

4.4.1 Processing of personal data by the contracting authority

The contracting authority undertakes to process the personal data that are communicated to it in response to the call for tenders with the greatest care, in accordance with legislation on the protection of personal data (General Data Protection Regulation, GDPR). Where the Belgian law of 30 July 2018 on the protection of natural persons with regard to the processing of personal data contains stricter provisions, the contracting authority will act in accordance with said law.

4.4.2 PROCESSING OF PERSONAL DATA

During contract performance, the contractor may process personal data of the contracting authority exclusively in the name and on behalf of the contracting authority, for the sole purpose of performing the services in accordance with the provisions of the Tender Specifications or in execution of a legal obligation.

For any processing of personal data carried out in connection with this public contract, the contractor is required to comply with Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data (GDPR) and the Belgian law of 30 July 2018 on the protection of natural persons with regard to the processing of personal data.

By simply participating in the contracting process, the tenderer certifies that he will strictly comply with the obligations of the GDPR for any processing of personal data conducted in connection with that public contract.

Given the public contract, it is to be considered that the contracting authority and the contractor will each be responsible, individually, for the processing.

4.5 Intellectual property (Art. 19 to 23)

The contracting authority acquires the intellectual property rights created, developed or used during performance of the contract.

Without prejudice to clause 1 and unless otherwise stipulated in the procurement documents, when the subject-matter of the procurement contract consists of the creation, manufacture or the development of designs or of logos, the contracting authority acquires the intellectual property thereof, as well as the right to trademark them, to have them registered and to have them protected.

For domain names created under the procurement contract, the contracting authority also acquires the right to register and protect them, unless otherwise stipulated in the procurement documents.

4.6 Performance bond (Art. 25 to 33)

The performance bond is set at 5 % of the total value, excluding VAT, of the procurement contract. The value thus obtained is rounded up to the nearest 10 euros.

In accordance with the legal and regulatory provisions, the performance bond may be constituted either of cash or of public funds or may take the form of a joint performance bond.

The performance bond may also take the form of a surety bond issued by a credit institution meeting the requirements of the law on the statute and control of credit institutions (Bank Guarantee).

As a derogation from Article 26, the performance bond may be posted through an establishment that has its registered office in one of the countries of destination of the services. The contracting authority maintains the right to accept or refuse the posting of the bond through that institution. The tenderer shall mention the name and address of this institution in the tender.

This derogation is founded on the idea of providing possible local tenderers with an opportunity to submit a tender.

The contractor must, within 30 calendar days from the day of procurement contract conclusion, furnish proof that he or a third party has posted the bond in one of the ways set out below:

1° in the case of cash, by transfer of the amount to the bpost account number of the Deposit and Consignment Office Fill out the form https://finances.belgium.be/sites/default/files/01_marche_public.pdf as completely as possible and return it to the e-mail address: info.cdcdck@minfin.fed.be

After reception and validation of said form, an agent of Belgium's Deposit and Consignment Office (Caisse des Dépôts et Consignations) will communicate to you the payment instructions (account number + communication) for posting the bond in cash;

2° in the case of public funds, by depositing such funds, for the account of the Deposit and Consignment Office, with the State Cashier at the head office of the National Bank in Brussels or at one of its provincial agencies or with a public institution with an equivalent function;

3° in the case of a joint surety, by deposit via an institution that lawfully carries out this activity of a deed of joint surety with the Deposit and Consignment Office or with a public institution with an equivalent function;

4° in the case of a guaranty, by the deed of undertaking of the credit institution or the insurance company.

This proof must be provided as applicable by submission to the contracting authority of:

1° the deposit receipt of the Deposit and Consignment Office or of a public institution with an equivalent function; or

2° a debit notice issued by the credit institution or the insurance company; or

3° the deposit certificate issued by the State Cashier or public institution with an equivalent function; or

4° the original copy of the deed of joint surety stamped by the Depot and Consignment Office or by a public institution with an equivalent function; or

5° the original copy of the deed of undertaking issued by the credit institution or the insurance company granting a guaranty.

These documents, signed by the depositor, must state why the performance bond was posted and its precise usage, consisting of a concise indication of the subject-matter of the procurement contract and a reference to the procurement documents, as well as the name, first name and full address of the contractor and, where relevant, that of the third party that made the deposit on the contractor's account, bearing the statement 'lender' or 'mandatory', as appropriate.

Ideally, the performance bond shall not have an expiry date. However, the Contracting Authority may accept a performance bond with an expiry date. In such cases, the contractor shall ensure that the performance bond is renewed as necessary in order to ensure continuous coverage of the entire contractual term.

The period of 30 calendar days specified above is suspended during the period of closure of the contractor's business for paid annual holidays and the days off in lieu stipulated by regulation or by a collective binding labour agreement.

Proof that the required performance bond has been posted must be sent to the address that will be mentioned in the contract conclusion notification.

Request by the contractor for the acceptance procedure to be carried out:

1° For the provisional acceptance: This is equal to a request to release the first half of the performance bond;

2° For the final acceptance: This is equal to a request to release the second half of the performance bond, or, in case no provisional acceptance applied, to release the whole of the performance bond.

4.7 Conformity of performance (Art. 34)

The services must comply in all respects with the procurement documents. Even in the absence of technical specifications in the procurement documents, the services must comply in all aspects with good practice.

4.8 Changes to the procurement contract (Art. 37 to 38/19)

4.8.1 Replacement of the contractor (Art. 38/3)

Provided that he meets the selection and exclusion criteria set out in this document, a new contractor may replace the contractor with whom the initial procurement contract was agreed in cases other than those provided for in Art. 38/3 of the General Implementing Rules (GIR).

The contractor submits his request as quickly as possible by registered post, stating the reasons for this replacement and providing a detailed inventory of the state of supplies and services already performed, the new contractor's contact details and the documents and certificates which the contracting authority cannot access free of charge.

The replacement will be recorded in an amendment dated and signed by all three parties. The initial contractor remains liable to the contracting authority for the performance of the remainder of the procurement contract.

4.8.2 Adjusting the prices (Art. 38/7)

For this procurement contract, price reviews are not permitted.

4.8.3 Indemnities following the suspensions ordered by the contracting authority during performance (Art. 38/12)

The contracting authority reserves the right to suspend the performance of the procurement contract for a given period, mainly when it considers that the procurement contract cannot be performed without inconvenience at that time.

The performance period is extended by the period of delay caused by this suspension, provided that the contractual performance period has not expired. If it has expired, the return of fines for late performance will be agreed.

When activities are suspended, based on this clause, the contractor is required to take all necessary precautions, at his expense, to protect the services already performed and the materials from potential damage caused by unfavourable weather conditions, theft or other malicious acts.

The contractor has a right to damages for suspensions ordered by the contracting authority when:

- The suspension lasts in total longer than one twentieth of the performance time and at least ten working days or two calendar weeks, depending on whether the performance time is expressed in working days or calendar days;
- The suspension is not due to unfavourable weather conditions;
- The suspension occurred during the contract performance period.

Within thirty days of their occurrence or the date on which the contractor or the contracting authority would normally have become aware of them, the contractor reports the facts or circumstances succinctly to the contracting authority and describes precisely their impact on the progress and cost of the procurement contract.

4.8.4 Unforeseen circumstances

As a rule, the contractor is not entitled to any modification of the contractual terms due to circumstances of which the contracting authority was unaware.

A decision of the Belgian State to suspend cooperation with a partner country is deemed to be unforeseeable circumstances within the meaning of this article. Should the Belgian State break off or cease activities which implies therefore the financing of this procurement contract, Enabel will do everything reasonable to agree a maximum compensation figure.

4.9 Preliminary technical acceptance (Art. 42)

The contracting authority reserves the right to demand an activity report at any time of the assignment to the service provider (meetings held, persons met, institutions visited, summary of results, problems encountered and unresolved issues, deviations from the planning and deviations from the ToR...).

4.10 Performance modalities (Art. 146 et seq.)

4.10.1 Deadlines and terms (Art. 147)

See art. 2.5 above.

4.10.2 Place where the services must be performed and formalities (Art. 149)

Implementation activities will be conducted both remotely and onsite at the Rwanda FDA Headquarters in Nyarutarama, 32 KG 9 Ave, Kigali, as outlined in **section 5 below.**

4.11 Inspection of the services (Art. 150)

If during contract performance irregularities are found, the contractor will be notified about this immediately by fax or e-mail, which will be confirmed consequently by official letter. The contractor is bound to perform the non-complying services again.

The service provider advises the managing official by registered post or e-mail showing the exact date of dispatch, at which date the services can be controlled.

4.12 Liability of the service provider (Art. 152-153)

The service provider takes the full responsibility for mistakes and deficiencies in the services provided.

Moreover, the service provider indemnifies the contracting authority against damages for which it is liable towards third parties due to late performance of the services or due to failure of the service provider.

4.13 Zero tolerance Sexual exploitation and abuse

In application of Enabel's Policy regarding sexual exploitation and abuse of June 2019 there will be zero tolerance towards any misconduct that could impact the professional credibility of the tenderer.

4.14 Means of action of the contracting authority (Art. 44-51 and 154-155)

The service provider's default is not solely related to services as such but also to the whole of the service provider's obligations.

In order to avoid any impression of risk of partiality or connivance in the follow-up and control of the performance of the procurement contract, it is strictly forbidden to the service provider to offer, directly or indirectly, gifts, meals or any other material or immaterial advantage, of whatever value, to the employees of the contracting authority who are concerned, directly or indirectly, by the follow-up and/or control of the performance of the procurement contract,

regardless of their hierarchical rank.

In case of violation, the contracting authority may impose a lump-sum fine to the service provider for each violation, which can be to up to three times the amount obtained by adding up the (estimated) values of the advantage offered to the employee and of the advantage that the contractor hoped to obtain by offering the advantage to the employee. The contracting authority will decide independently about the application and the amount of this fine.

This clause is without prejudice to the possible application of other measures as of right provided in the GIR, namely the unilateral termination of the procurement contract and/or the exclusion of procurement contracts of the contracting authority for a determined duration.

4.14.1 Failure of performance (Art. 44)

§1 The contractor is considered to be in failure of performance under the procurement contract:

1° when the delivery is not carried out in accordance with the conditions specified in the procurement documents;

2° at any time, when the delivery has not progressed in such a way that it can be fully completed on the due dates;

3° when he does not observe written orders, which are given in due form by the contracting authority.

§2 Any failure to comply with the provisions of the procurement contract, including the non-observance of orders of the contracting authority, is recorded in a report ('process verbal'), a copy of which will be sent immediately to the contractor.

The contractor must repair the defects without any delay. He may assert his right of defence by letter addressed to the contracting authority within fifteen days from the date of dispatch of the report (process verbal). Silence on his part after this period shall be deemed as acknowledgement of the reported facts.

Any defects detected that can be attributed to the contractor render him liable to one or more of the measures provided for in Articles 45 to 49, 154 and 155.

4.14.2 Fines for delay (Art. 46 and 154)

The fines for delay differ from the penalties referred to in Article 45. They are due, without the need for notice, by the mere lapse of the performance term without the issuing of a report and they are automatically applied for the total number of days of delay.

Without prejudice to the application of fines for delay, the contractor continues to guarantee the contracting authority against any damages for which it may be liable to third parties due to late performance of the procurement contract.

4.14.3 Measures as of right (Art. 47 and 155)

§1 When, upon expiry of the term given in Article 44, §2, the contractor has not taken action or has presented means deemed unjustified by the contracting authority, the contracting authority may apply the measures as of right described in paragraph 2.

However, the contracting authority may apply measures as of right without waiting for the expiry of the term given in Article 44, §2, when the contractor has explicitly recognised the defects found.

§2 The measures as of right are:

1° Unilateral termination of the procurement contract. In this case the entire performance bond, or if no bond has been posted an equivalent amount, is acquired as of right by the contracting authority as lump sum damages. This measure excludes the application of any fine for delay in

performance in respect of the terminated part;

2° Performance under regie of all or part of the non-performed procurement contract;

3° Conclusion of one or more replacement procurement contracts with one or more third parties for all or part of the procurement contract remaining to be performed.

The measures referred to in 1°, 2° and 3° will be taken at the expense and risk of the defaulting contractor. However, any fines or penalties imposed during the performance of a replacement procurement contract will be borne by the new contractor.

4.15 End of the procurement contract

4.15.1 Acceptance of the services performed (Art. 64-65 and 156)

The managing official will closely follow up the services during performance.

The services will not be accepted until after fulfilling audit verifications, technical acceptance and prescribed tests.

The contracting authority disposes of a verification term of thirty days starting on the final or partial end date of the services, set in conformity with the modalities in the procurement documents, to carry out the acceptance formalities and to notify the result to the service provider. This term commences provided that the contracting authority possesses, at the same time, the list of services delivered or the invoice. Upon expiry of the thirty-day term following the date stipulated for completion of the entirety of the services, depending on the case, an acceptance report or a refusal of acceptance report will be drawn up.

Where the services are completed before or after this date, it is the responsibility of the service provider to notify the managing official by registered letter, and at the same time to ask for the acceptance procedure to be carried out. Within thirty days after the date of receipt of the service provider's request, an acceptance or a refusal of acceptance report will be drawn up, depending on the case.

The acceptance specified above is final.

4.15.2 Invoicing and payment of services (Art. 66 to 72 – 160)

The service provider sends (one copy only of) the invoices and the contract acceptance report (original copy) to the following :

Mr. Antoine GATERA – antoine.gatera@enabel.be – Strategy Expert/Project Manager – Health Care & Pharmaceutical Regulation with copy to Mrs. Oliver UWANTEGE (oliver.uwantege@enabel.be).

Only services that have been performed and approved correctly may be invoiced.

The contracting authority disposes of a verification term of thirty days starting on the end date for the services, set in conformity with the modalities in the procurement documents, to carry out the technical acceptance and provisional acceptance formalities and to notify the result to the service provider.

The amount owed to the service provider must be paid within thirty days with effect from the expiry of the verification term or with effect from the day after the last day of the verification term, if this is less than thirty days. And provided that the contracting authority possesses, at the same time, the duly established invoice and any other documents that may be required.

When the procurement documents do not provide for any separate debt claim, the invoice will constitute the debt claim.

No advance may be asked by the contractor.

Payments may be made in instalments (progress payments) as follow:

No	Deliverable	Payment Modalities	
1	Upon Approval of the inception report	1st Instalment	10% of the contract amount
2	Upon completion and approval of the development of the Track and Trace System, accompanied by the submission of the following documentation a. Requirements gathering, technical design & interoperability documentation. b. Testing, Deployment & Validation (UAT sign-off) report	2nd Instalment	40% of the contract amount
3	Upon presentation and approval of Capacity Building report and the successful system Go-Live	3rd Instalment	30% of the contract amount
4	After the presentation and approval of the System Documentation (Source code documentation, user manuals) and system hand-over report	4th Instalment	20% of the contract amount

4.16 Litigation (Art. 73)

The competent courts of Brussels have exclusive jurisdiction over any dispute arising from the performance of this procurement contract. French or Dutch are the languages of proceedings.

The contracting authority will in no case be held liable for any damage caused to persons or property as a direct or indirect consequence of the activities required for the performance of this procurement contract. The contractor indemnifies the contracting authority against any claims for compensation by third parties in this respect.

In case of 'litigation', i.e. court action, correspondence must (also) be sent to the following address:

Enabel, public-law company

Legal unit of the Logistics and Acquisitions service (L&A)

To the attention of Mrs Laura Jacobs

rue Haute 147

1000 Brussels

Belgium

5 Terms of Reference

5.1 BACKGROUND

The Rwanda FDA is the government agency with the mandate to protect public health by regulating human and veterinary medicines, vaccines and other biological products, processed foods, poisons, medicated cosmetics, medical devices, household chemical substances, tobacco and tobacco products, and the conduct of clinical trials. The vision of Rwanda FDA is to become a world class regulatory Authority effectively protecting and promoting public health. Its mission is to regulate medical products, processed foods, household products, and tobacco and tobacco products to ensure their quality and safety to protect the population of Rwanda from defective, falsified, and substandard products.

Despite having a strong legal and regulatory foundation, Rwanda's pharmaceutical supply chain still faces challenges particularly in achieving full traceability from manufacturing or importation to the point of care. Product movement data such as inventory levels, authenticity, and distribution status remains fragmented across various government systems, distributors, and private stakeholders. This lack of integration limits the ability to monitor distribution effectively, conduct timely recalls, and prevent fraudulent activities like the infiltration of counterfeit medicines.

To address these gaps, Rwanda FDA is implementing a comprehensive Pharmaceutical Track and Trace System Electronic Product Code Information Services (EPCIS) standards compliant an interoperable digital platform designed to deliver end-to-end visibility across the entire pharmaceutical supply chain. The system will enable tracking of products from manufacturers and importers, through distributors, to pharmacies and healthcare facilities.

It aims to solve critical challenges, including:

1. End-to-End Traceability: Ensuring complete tracking of pharmaceuticals at every supply chain stage.
2. Fraud and Counterfeit Prevention: Detecting and removing counterfeit or substandard products.
3. Efficient Recall Management: Enabling rapid identification and removal of affected products.
4. Supply Chain Transparency: Improving oversight to prevent diversion and distribution inefficiencies.
5. Regulatory Compliance: Supporting adherence to national and international pharmaceutical regulations.

The system will integrate stakeholders across Rwanda's pharmaceutical ecosystem, including manufacturers, importers, distributors, retail pharmacies, public and private health facilities, and regulatory bodies such as Rwanda FDA, the Ministry of Health, and Rwanda Medical Supply.

Additionally, the platform will generate real-time analytics to support data-driven decision-making, improve planning, and optimize resource management. By centralizing and standardizing pharmaceutical data, it will strengthen Rwanda FDA's ability to enforce regulations, monitor compliance, and uphold public health standards.

5.2 OBJECTIVES OF THE ASSIGNMENT

5.2.1. General Objectives

The objective of this assignment is to design, develop, deploy, and operationalize an integrated EPCIS compliant Pharmaceutical Track and Trace System that enables full end to end visibility of pharmaceutical products from manufacturing or importation, through distribution, to last-mile dispensing. The system shall strengthen national supply chain oversight, support regulatory

functions such as recall management, diversion and fraud prevention, and enhance data driven decision making across health sector in Rwanda.

The solution is expected to capture, store, and exchange standardized alignment with the broader GS1 architecture, including product and location identification and serialization standards (e.g., GTIN, GLN), across approximately 1,200 pharmacies nationwide. These include 853 human retail pharmacies, 168 human wholesale pharmacies, two central distributor outlets, and local pharmaceutical manufacturers. Additionally, the system will cover around 950 public and private health facilities, including 57 public hospitals, 533 health centers, and 360 private clinics. With this broad coverage, the platform shall ensure nationwide traceability, strengthen interoperability among key stakeholders, and support a fully integrated pharmaceutical ecosystem in Rwanda.

5.2.2. Specific Objectives

1. **Develop a Centralized EPCIS Compliant Track and Trace system**
    - Design, develop, and deploy a centralized pharmaceutical track and trace system fully compliant with GS1 EPCIS standards, ensuring seamless operation within the national digital health and pharmaceutical traceability ecosystem.
2. **Integrate with Core National Systems and Master Data Sources**
    - Integrate the system with the National Product Catalogue (NPC) to synchronize product master data, including GTIN, NDC, descriptions, packaging hierarchies, and manufacturer details.
    - Ensure interoperability with other Government systems:
        - Rwanda Medical Supply (RMS) ERP system for inventory, stock movements, dispatch/receipt events, and automated reconciliation of logistics and traceability records.
        - Integrated Regulatory Information Management System (IRIMS) for regulatory approvals, inspection results, recalls, licensing, and regulatory workflow automation.
        - Rwanda Social Security Board (RSSB) Refund System for real-time pack validation and reimbursement claim verification.
        - Electronic Medical Records (EMR) systems (OpenMRS, eBuzima, e-Fiche, HPEMR, Medsoft) to ensure continuity between clinical systems and pharmaceutical traceability.
        - Customs system (Rwanda Electronic Single window)
3. **Ensure Robust Interoperability and Multi-Channel Data Exchange**
    - Develop an API that will enable an integration with warehouse, logistics, and supply-chain systems to exchange EPCIS events representing product movements.
    - Enable hybrid operations by supporting manual data entry, paper-based processes, and reconciliation tools for generating compliant EPCIS events.
    - Provide offline data capture and later synchronization for facilities with limited connectivity.
    - Support standardized data-exchange mechanisms and configurable workflows to accommodate varying levels of digital maturity across stakeholders.
4. **Support Multi-Actor Participation Across the Supply Chain**
    - Provide configurable role-based access controls tailored to manufacturers, importers, distributors, regulatory bodies, healthcare facilities, and other authorized actors.
    - Support workflows that reflect actual supply chain and regulatory procedures.
    - Ensure scalability for onboarding new stakeholders without requiring major architecture changes.
    - Develop and recommend a nationwide roll-out plan and onboarding guidelines.

5. **Provide Reporting, Analytics, and System Performance Monitoring**
    - Offer configurable dashboards and reports to visualize product movements, system usage, traceability coverage, and supply-chain health.
    - Include analytics and audit features to detect anomalies, incomplete traceability chains, or compliance gaps.
    - Provide documentation and configuration tools to support continuous improvement, future scaling, and alignment with evolving regulatory requirements.
6. **Deliver Capacity Building and Knowledge Transfer**
    - Provide comprehensive training for administrators, super-users, and end-users.
    - Provide full technical documentation, including system architecture, APIs, integration guides, and operational manuals.
    - Conduct train-the-trainer programs for national teams to support decentralized onboarding and system expansion.
    - Ensure knowledge transfer on system maintenance, upgrades, trouble shooting, and operational continuity.
7. **Ensure Compliance with Data Protection and Security Regulations**
    - Implement robust data-protection controls, including secure access management, audit trails, and strong encryption.
    - Align with national data-protection and privacy frameworks to ensure confidentiality, integrity, and ethical use of sensitive data.

Promote public trust through adherence to security best practices and transparent data governance.

5.3 TASK TO BE PERFORMED

In alignment with the objectives of the assignment, the bidder is expected to conduct the following tasks and deliver all related technical, functional, and operational outputs necessary for the full operationalization of the EPCIS-compliant Pharmaceutical Track and Trace System:

5.3.1. Requirements Analysis and System Specification

The Requirements Analysis and System Specification phase establishes the foundation of the system. It involves assessing the current pharmaceutical traceability environment, consulting key stakeholders to understand workflows, data needs, and compliance issues, and identifying gaps and inefficiencies. The goal is to enhance end-to-end visibility, strengthen accountability, and ensure alignment with national and international traceability standards. The bidder will perform the following activities.

- The bidder will engage key stakeholders to assess operational workflows, data needs, and compliance challenges, identifying gaps in the current system to improve traceability and accountability.
- The bidder will map critical pharmaceutical supply chain processes, define tracking and tracing touchpoints, and outline roles and responsibilities at each stage.
- The bidder will specify requirements for key system functionalities, including product serialization, real-time traceability, inventory monitoring, recall management, alerts, and audit trails for regulatory reporting.
- The bidder will define user roles (e.g., manufacturers, regulators, healthcare providers) and implement role-based access controls to ensure security and data integrity.

- The bidder will define technical specifications for integrating the track and trace system with national health systems, regulatory databases, and international standards (e.g., GS1).
- The bidder will define data structure, formats (e.g., JSON, XML), validation protocols, and master data management for consistency across the system.
- The bidder will design user-friendly interfaces for various user types and ensure accessibility, multilingual support, and functionality in low-connectivity environments.
- The firm will establish security protocols, including data encryption, role-based access control, and compliance with Rwanda's data protection regulations and international standards.
- The bidder will define system performance metrics, including response time, uptime, and scalability requirements to accommodate future growth in users, facilities, and transactions.

5.3.2. System Architecture and Technical Design

The design and architecture of the system are pivotal to ensuring the system's successful implementation and long-term functionality. The bidder will play a crucial role in defining and designing the EPCIS architecture, ensuring that it meets national requirements, adheres to regulatory standards, and integrates with existing systems. The following outlines the key tasks that the bidder will undertake as part of this critical phase, from system architecture to data security and scalability, to ensure a robust and future-proof solution

- System Architecture Design: The bidder will define flexible, scalable, and secure architecture for the EPCIS, ensuring modularity and considering centralized or decentralized designs.
- User Interface (UI) Design and Experience: The firm will design customizable, multilingual, and low-connectivity accessible user interfaces with role-based dashboards for various stakeholders.
- Data Flow and Integration Design: The firm will map end-to-end data flows across the pharmaceutical supply chain and integrate the EPCIS with national systems and GS1 traceability standards.
- Data Storage and Management: The bidder will design secure, distributed data storage with encryption, ensuring data integrity and compliance with relevant regulations.
- Security and Privacy Considerations: The firm will implement robust security features, including role-based access controls, two-factor authentication, and audit trails to protect sensitive pharmaceutical data.
- Scalability and Future-Proofing: The firm will ensure the system is scalable to accommodate future growth in transactions and users, incorporating features like load balancing, elasticity, and modular expansion.

5.3.3. System Development and customization

The bidder will be responsible for developing, deploying, and operationalizing the system while ensuring full compliance with the Security and Interoperability standards described in the Technical specifications (notably section 5.4.2). This system will be designed to meet the needs of stakeholders across the pharmaceutical supply chain while complying with national and international regulations. Key components of the system will include:

- Track and Trace System API Services: The bidder will develop the API to handle requests, log transactions, and facilitate integration with various stakeholders and systems, ensuring smooth operations across the supply chain.
- Management Portal: The firm will develop a portal for regulatory administrators to manage user roles, monitor system transactions, and oversee traceability data, ensuring effective system control.
- Management Dashboard: The bidder will design a dashboard that provides real-time monitoring and visualization of transaction statuses, trends, and overall system performance, offering administrators insights into system health.
- Stakeholder Operation Portal: The bidder will develop a portal for stakeholders to manage user roles, track packages, and access support services, ensuring efficient traceability and operation across product movements and cancellations.
- Stakeholder Management Portal: The firm will develop a portal for managing stakeholder branches and administrative users, generating compliance reports and helping stakeholders monitor their activities.
- Notification Portal: The firm will build a notification portal to send alerts about product movements, recalls, and compliance issues, ensuring stakeholders are kept informed in real-time.
- Notification Engine: The bidder will develop a notification engine to send email and SMS alerts based on predefined triggers, ensuring timely notification of critical events.
- Reporting Module: The firm will build a reporting module to generate customized reports on transactions, drug movements, and traceability status, supporting monitoring and auditing activities.
- Integration Engine: The bidder will create an integration engine for data exchange with other national systems (e.g., registration systems and data management platforms), ensuring system interoperability.
- Monitoring Component: The firm will implement a monitoring component to track system performance, response times, and resource utilization, allowing administrators to identify and resolve issues proactively.

5.3.4. System Integration and Interoperability

- Design and implement Application Programming Interfaces (APIs) and secure data exchange mechanisms to integrate the Pharmaceutical Track and Trace System with existing national systems and relevant stakeholder platforms, including regulatory, customs, health, and supply chain systems.
- Ensure interoperability and data sharing in alignment with Rwanda's National Data Integration and Interoperability Framework and applicable government ICT standards, enabling standardized exchange of GS1 EPCIS traceability events across all supply chain actors.
- Ensure compliance with security and privacy policies during all data exchange processes.
- Ensure integration with third-party systems including the Rwanda Electronic Single Window (customs), Rwanda Medical Supply (RMS) system, the regulator's IRIMS platform, the RSSB reimbursement system, and the national Electronic Medical Records (dispensing data) to ensure data exchange and real-time, end-to-end pharmaceutical traceability from importation through to the point of care

5.3.5. Testing and Quality Assurance

- Develop and execute a comprehensive testing plan covering unit testing, integration testing, user acceptance testing (UAT), and performance testing.
- Conduct pilot implementation and collect user feedback to fine-tune system functionalities.

- Verify that the system meets all specified functional, technical, and performance requirements prior to rollout.
- Document all test results, issues identified, and corrective actions undertaken.

5.3.6. System Deployment and Go-Live

- Deploy the approved Pharmaceutical Track and Trace System to a secure production environment hosted at a Government of Rwanda–approved data Center or accredited cloud infrastructure, in compliance with national ICT and cybersecurity standards.
- Migrate existing relevant data into the new system following standard data migration procedures and validation.
- Conduct a soft launch and subsequent official go-live in coordination with the Rwanda FDA and Ministry of Health (National health Intelligence Center) Team

5.3.7. Capacity building and knowledge transfer plan

The bidder will deliver a comprehensive training and knowledge-transfer program to ensure smooth adoption and long-term sustainability of the system within Rwanda FDA, enabling users to operate and manage it independently while strengthening the ICT Unit's capacity for support, maintenance, and future enhancements.

- Develop user manuals, training guides, and standard operating procedures (SOPs) for all user categories.
- Conduct comprehensive training sessions for administrators, technical staff, and end-users across national and sub-national levels.
- Build internal capacity of the Rwanda FDA ICT Unit to provide first-level support, routine maintenance, and system enhancements after project closure.

5.3.8. Documentation

- Provide detailed technical documentation, including system architecture, database schema, API documentation, installation guides, and configuration manuals.
- Submit user documentation, training materials, and maintenance guidelines to support ongoing system management

5.3.9. Post-Implementation Support and Maintenance

To ensures the system remains functional, secure, and efficient after deployment, the bidder shall provide post-deployment technical support for the period of 6 months following system acceptance. All defects, errors, or malfunctions arising from the implementation must be corrected at no additional cost. Key activities include:

- Provide technical support for 6 months after system Go-live, including Correcting errors and defects reported by users.
- The bidder shall provide a dedicated Single Point of Contact (Service Desk such email, or support portal) for logging all incidents and system errors. The Service Desk must include functionality to classify incidents by priority level (Critical, High, Medium, or Low) based on impact and urgency.
- The bidder shall acknowledge each incident within 15–30 minutes and ensure timely resolution according to the following requirements:
  - Critical issues: resolved within 2–4 hours
  - High priority issues: resolved within 6–12 hours
  - Medium priority issues: resolved within 2–3 business days
  - Low priority issues: resolved within 3–5 business days

- Conduct at least quarterly performance reviews, security audits, and system optimization during the support period. Prepare a comprehensive handover report with recommendations for sustainability, scalability, and long-term management of the track and trace system.

5.4 SYSTEM REQUIREMENTS SPECIFICATIONS

The system shall enable the effective use of information to support health and healthcare service delivery related to pharmaceutical product tracking and tracing, as well as the safe use of medicines. The solution shall support the secure, efficient, and timely exchange of data between the Track and Trace system and external systems, including Customs Information Management Systems, Warehouse Management Systems, Pharmacy Information Management Systems, Health Information Systems, and other relevant platforms.

Data exchange shall be implemented using recognized interoperability standards, messaging protocols, and integration tools to ensure data accuracy, consistency, security, and reliability across all participating stakeholders.

5.4.1. Functional requirements

- The system must provide comprehensive Track and Trace Server functionalities to support the complete lifecycle of serialized pharmaceutical or regulated products. These capabilities shall ensure end-to-end visibility, accountability, and traceability across all authorized actors in the supply chain. The system must support the following core functions.
    1) The system shall allow manufacturers and importers to generate and register unique serialized identifiers for each product unit, batch, or shipment. It must support EPCIS compliant event creation (Commissioning events) and transmit production or importation records to the central Track & Trace Server.
    2) The system shall allow manufacturers and importers to generate and register unique serialized identifiers for each product unit, batch, or shipment. It must support EPCIS compliant event creation (Commissioning events) and transmit production or importation records to the central Track & Trace Server.
    3) The system shall enable recording of product sales or transfers between authorized supply chain actors. Sales events must capture sender information, receiver information, product identifiers, timestamps, and associated documentation such as invoices.
    4) The system shall allow receiving entities to validate and confirm incoming serialized products. Acceptance events must verify product authenticity, integrity, and match the corresponding outbound transaction.
    5) The system shall support product return workflows by enabling entities to initiate return events when products are being sent back to the supplier. All returned products must be validated and logged for full traceability.
    6) The system must allow authorized entities to reverse or cancel previously recorded sales transactions under predefined conditions. Sale cancellation events should restore product status to “available for sale” and update related inventory.
    7) The system shall allow pharmacies to record product sales to end users. Pharmacy sales events must capture product identifiers, dispense dates, and dispensing entity information to complete the final supply chain trace.

8) The system must provide functionality to cancel pharmacy sales transactions when needed (e.g., incorrect entry, prescription change). The system shall update product status accordingly.
9) For products used internally by health facilities or designated consumption centers, the system shall record consumption events. This ensures the system reflects accurate stock levels and prevents unused items from re-entering the supply chain.
10) The system shall enable authorized actors to declare products intended for export. Export events must deregister serialized items from the domestic market and provide traceability for international shipment.
11) The system shall provide a query mechanism to verify the most recent status of any serialized product. Users shall be able to confirm authenticity, movement history, and ownership status using product identifiers.
12) The system must allow authorized actors to deactivate serialized products under specific conditions (e.g., damage, expiry, loss, recall). Deactivation events must update system records and restrict further movement or sale of deactivated items

- The system must support Web Portal functionalities, on which all Rwanda Food and Drugs Authority and stakeholders' online operations are executed, such as:
    1) Dashboard, Showing valuable statistics such as system transactions, trends of Drug movements
    2) Reporting, reporting module on different transactions, status, entities and required views and queries.
    3) Notification Engine platform, Engine to manage e-mail, SMS notifications.
- The system must have the capability to effectively use information for managing and responding to supply chain controls, monitoring utilization, ensuring the quality and availability of pharmaceutical products, and supporting comprehensive monitoring and reporting of all supply chain movements.
- The system must have functionality supporting initiating and responding to Trace Requests across all Supply Chain stakeholders
- The system shall provide Inventory visibility functionality that enables tracking drug availability periodically, across different stakeholder types, and by geographic location. System must have mobile and device integration for handheld scanners which support the GTIN + Serial Number serialization.
- System must have adverse events management and reporting, recalls and destruction at the National level and from Pharmacy levels.
- Web Portal and all forms and reports must be available in English language.
- The web portal must support screen resolutions, must be scalable and support the most common Internet browsers (e.g., Microsoft Edge, Mozilla Firefox, Google Chrome, Safari, etc…), and Bidder must list any limitations regarding screen resolutions or browsers in display content or services.
- Any item, which needs to be tracked forward or traced back, must be uniquely identified (e.g. GTIN + Serial number). This applies to any level of the Product Hierarchy, for example, Consumer Unit or a traceable Item not crossing the point of sale. The identification carrier must remain on or attached to the traceable item when it is packed in an upper level of packaging, for unique identification of the traceable item throughout the packaging hierarchy.

5.4.2. Non - functional requirements

5.4.2.1. Performance requirements of the information system

- Demand periods (e.g., regulatory reporting deadlines, national compliance submissions), without performance degradation, data loss, or service interruption.
- The system should be able to render its layout to different screen sizes. Along with automatic adjustment of font size and image rendering.
- The system must grow efficiently to support increasing numbers of users, and transactions.
- System should be platform independent, especially for the front-end devices i.e. mobile phones (smartphones).

5.4.2.2. General IT security requirements

- The system shall conform to all security requirements for web applications listed in the Open Worldwide Application Security Project (OWASP) security framework.
- The system shall support the use of Internet Protocol Security (IPSec) to secure communication between systems.
- The system shall employ the latest official version of the Transport Layer Security (TLS) protocol to secure web communication between the system and systems that utilize a web-enabled device such as a web browser on desk workstations and mobile devices.
- The system shall hash and securely store user authentication credentials using industry-acceptable hashing algorithms and standards.
- The system shall time stamp all information uploaded onto the system upon saving the information onto the system Database
- The system shall maintain a complete audit trail of all write access events that include creation, modification and deletion of records.
- The system shall store all records of all activities on a secure centralized logging server and within the system with access restrictions put in place.
- The system shall have a transactional audit trail that maintains the identification and a record of authorization, utilization (transactions), and changes related to all users.
- The system shall provide audit trails of scheduled events and results of scheduling activity.
- The system shall capture the following minimum details in order to adequately track events performed in the system:
    1) Identification of the event (the module and function accessed).
    2) Type of access (create, modify, delete, read).
    3) User ID performing the event.
    4) Date and time the event was performed.
    5) Last updated date
    6) Last User ID that updated

The terminal ID/location from where the event was executed (indication of physical location).

- The system shall restrict the viewing of the audit logs and audit trails to only authorized users. Authorized users will be able to review the logs and search/filter logs by a variety of parameters that may include user ID, specific date and time ranges, procurement activity, etc.
- The system shall restrict system administrators from having access to/deleting audit logs.

- The system shall have an authority matrix against which different authority levels for carrying out specific activities e.g. data entry and authorization of data entered.
- The system shall assign each user access privileges in the form of roles.
- The system shall restrict users to performing tasks only through the system services to which he/she has access.
- The system should auto-log off users if the account is dormant for a configurable duration of time.
- The system should have a mechanism for protecting the confidentiality of personal records or personally identifiable information (PII).
- The system shall support input validation for all user information
- The system shall be accessible on both the LAN, WAN and the internet
- The system shall support software patches and updates aimed at reducing vulnerabilities or enhancing features and or performance

5.4.2.3. Login /Authentication controls

- The system shall allow for authorized users to define the user level access rights and specify the functions (read/ write) that could be performed by a specified user within each specified module.
- The system shall allow for the definition of the maximum number of unsuccessful login attempts per user at a given time. If a user exceeds the maximum number of unsuccessful log-in attempts at a given instance, the system shall lock out the user from the system for a definable amount of time.
- The system shall allow for the system administrator to temporarily and/or permanently lock out a user.
- The system shall allow for the system Administrator to release a locked-out user.
- The system shall prevent a user from having more than one active login session.
- The system shall allow for the System Administrator to define the maximum amount of idle time before a logged-in user is automatically signed out. This time should be definable by role to enable a variation of different idle times depending on the responsibilities held by the user.
- The system shall display the last log-in time and date should be displayed for the benefit of the user on a successful log-in and provide provisions for users to view previous successful and unsuccessful login attempts to enable them to verify that an unauthorized attempt against their credentials has not been made. Additional details of activities/responsibilities performed on the system should also be included.
- The system shall log all successful and unsuccessful login attempts of a user with the following (minimum) details:
    1) User ID.
    2) Login/logout date and time up to seconds.
    3) IP of the computer and geographical access point.
    4) Web page URL. Actions performed on corresponding system functions, such as add, delete, update, and view.
- The system shall provide a secure facility to allow users to reset their passwords. Users who will have access to this feature should be definable to enable users with non-critical roles to easily reset their passwords.
- The system shall allow system administrators to define the criterion for passwords used in the system and enforce the set criteria. Such criteria would include at least:
    a. Password lengths.
    b. Acceptable range of characters from the Unicode Character set, such as upper case, lower case, special characters, numbers, unique symbols, etc.

c. Number of unique passwords required before old passwords can be re-used. Number of days before a mandatory change of password is enforced.

- When storing authentication credentials, the system shall encrypt and hash them before storing them in a configuration file. The system shall not hard code database connection strings, passwords, or cryptographic keys in clear text in the code or configuration files.
- The system shall allow authorized users to define the user-level access rights and specify the functions (read/ write) that could be performed by a specified user within each specified module.

5.4.2.4. Integration requirements

- The system shall securely integrate with existing and upcoming stakeholders' systems using internationally recognized technologies e.g. REST and SOAP web services.
- Upgrades made to the system and/or interfaced stakeholders' systems should not affect the integration requirements and disrupt data exchange.
- The system shall log all successful and unsuccessful interface transactions, and these should be clearly identified in the audit logs.
- The system shall be able to consume available web services from other systems and publish any of its functionalities as web services/APIs using simple procedures.

5.4.2.5. Backup and restore requirements

- The system shall have inbuilt backup and recovery procedures that can be scheduled to facilitate simple and intuitive recovery from system corruption or failure.
- The System shall provide mechanisms to define and monitor the status of the backup schedule and guarantee no data loss.

5.5 DELIVERABLES

The bidder will be required to deliver all capabilities, functionalities and solutions set forth as requirements within the tender document. As such these requirements will be tied to appropriate milestones and deliverables that will be considered to measure successful implementation and outcomes. The expected deliverables list comprising of documentation and artefacts include the following:

S/No	Deliverables and Activities	Estimated Duration (Calendar days)	Work Arrangement (Person-Days)
D1	**Inception Report** The bidder shall submit a comprehensive **Inception Report** within **fifteen (15) calendar days** of receiving the award notification, The report shall include: 1. A clear understanding of the assignment objectives, scope, and expected outcomes. 2. The proposed methodology and approach to system design and development. 3. A refined implementation roadmap, including timelines, milestones, and dependencies. 4. Stakeholder engagement strategy, data collection methods, and validation processes. 5. Risk assessment and mitigation plan. 6. Detailed resource allocation and project management structure. The Inception Report will serve as the baseline reference document for monitoring project performance, progress tracking, and deliverable compliance throughout the implementation period	15	10 days with a minimum of *3 days onsite*

D2	**Requirements Gathering, Technical Design and Interoperability documentation Report** Following requirements analysis and stakeholder consultations, the bidder shall develop and submit a comprehensive set of Functional and Technical Design Documentation within sixty (60) calendar days from the date of submission and approval of the Inception Report. The documentation shall include: 1. System Requirements Specification (SRS): Detailed functional and non-functional requirements, business rules, user roles, and workflows. 2. System Design Document (SDD): Description of system architecture, modules, interfaces, data structures, database schema, and integration points. 3. Security and Privacy Plan: Data protection measures, user authentication and authorization frameworks, and alignment with the Data Protection and Privacy. 4. Hosting and Deployment Architecture: Infrastructure specifications, environment setup (staging, production), and hosting options (e.g., National Data Centre). 5. Interoperability and Integration Framework: API structures and data exchange protocols to connect with other MIS platforms. The report and documents shall be presented and approved before commencement of the development phase.	65	42 days with a minimum of *15 days onsite*

D3	**Development, Configuration and Integration Report** The bidder shall design, develop, and deploy the fully functional track and trace system based on the approved system specifications. The solution shall include all agreed-upon modules, integration points, and analytics features. The bidder shall complete the system development within 130 calendar days from the date of submission and approval of the Requirements and Technical Design documentation. Deliverables for this stage shall include: 1. Developed Track and Trace system compliant with EPCIS standard: Incorporating modules for case management, treaty tracking, document repository, analytics dashboards, and user administration. 2. Integration with Other Systems: Operational APIs and data exchange with relevant government MIS platforms and partner institutions. 3. Testing and Quality Assurance Reports: Results of system testing (unit, integration, security, and user acceptance testing), including issues identified, resolved, and validated. 4. Data Migration Report: Documentation of migrated datasets, data verification, and integrity validation. Upon satisfactory testing and approval, the system will be deployed to the production environment for official launch.	130	90 days with a minimum of *15 days Onsite*
D4	**Testing, Deployment and Validation Report** This phase will cover all testing and deployment activities, including the testing strategy, execution of test plans, EPCIS conformance checks, security and performance testing, and production deployment. The bidder shall complete all testing and quality-assurance activities within 45 calendar days following the completion of system development and integrations. Deliverables under this phase shall include 1. Develop and execute a comprehensive testing plan covering unit testing, integration testing, user acceptance testing (UAT), and performance testing. 2. Conduct pilot implementation and collect user feedback to fine-tune system functionalities. 3. Verify that the system meets all specified functional, technical, and performance requirements prior to roll-out. 4. Document all test results, issues identified, and corrective actions undertaken.	45	33 days with a minimum *of 10 days Onsite*

D5	**Capacity Building, Knowledge Transfer and Go-Live Report** To ensure sustainability and effective use of the system, the bidder shall within 35 days after the approval of the deliver 4, develop and deliver comprehensive user documentation and training materials, including: 1. User Manuals: Step-by-step guides for administrators, case managers, analysts, and general users. 2. Technical Manuals: System administration, maintenance, and troubleshooting instructions for ICT personnel. 3. Training Modules: Presentations, exercises, and reference materials for different user categories. 4. Conduct comprehensive training sessions for approximately 10 administrators from Rwanda FDA and the Ministry of Health (National Health Intelligence) team to enable them to independently operate, maintain, and support the system after handover, as well as provide training to 60 end-users. 5. Training Report: Summary of training sessions conducted, participants reached, and post-training evaluations. 6. Go-Live Report: Documentation of system launch activities, user onboarding, and immediate post-deployment performance. 7. A comprehensive nationwide roll-out plan and onboarding guidelines. System Documentation (Source code documentation, user manuals) and system hand-over report	35	25 days with a minimum of *10 days onsite*

5.6 OWNERSHIP

All deliverables produced under this contract—including, but not limited to, the system, source code, intellectual property rights, technical documentation, system architecture and design, data reports, and training materials—shall be the exclusive property of the Contracting Authority.

The Contractor hereby assigns (or shall ensure the assignment of) all related intellectual property rights to the Contracting Authority, free of charge, for the entire duration of protection and for all territories, unless otherwise specified in the contract.

All deliverables shall be fully accessible, usable, and modifiable by the Contracting Authority and its designated beneficiaries, without restriction.

5.7 DURATION

The service and the listed tasks and deliverables should be performed within a **period of 10 months**, with a maximum of **200 Person-days** starting from the date of the contract notification letter.

This period includes the design, development, document, implementation, and operationalize a system fully compliant with EPCIS standards and the submission and validation of all the required deliverables.

5.8 POST-IMPLEMENTATION SERVICES

Following the successful deployment of the system, the bidder shall support the go-live process and provide post-implementation services for a period of **6 months** from the date on which the system functionality is formally approved in the production environment.

These services shall include, but are not limited to:

- Continuous system monitoring
- Bug/defect identification and resolution
- User support and incident handling
- Performance optimisation and stability improvements

Deliverables under this phase shall include:

1. Post-Implementation Support Report

   A consolidated report detailing all support activities undertaken, issues logged and resolved, system performance metrics (including uptime), and key lessons learned.

2. Sustainability and Handover Plan

   A comprehensive plan outlining recommendations for long-term system maintenance, capacity-building needs, enhancement roadmap, and proposed institutional ownership and governance arrangements.

5.9 Minimum Required technical profile of the consulting firm and the proposed key experts (to be analysed at selection stage).

5.9.1. The minimum required profile of the firm

To perform this assignment the firm is required to meet the following minimum requirements:

- The firm should be **legally registered by the competent authority** (proof of company registration is required).

- The firm must have a **minimum of 7 years of experience** undertaking software development and deployment tasks.
- The firm must have successfully completed **at least three (3) similar assignments** related to the development of health systems or supply chain systems (to be supported by certificates of good completion or any other relevant documents demonstrating this experience).

5.9.2. The minimum required profile of the key experts

The consultancy firm is required to present a multidisciplinary team of **at least seven (7) key experts, as detailed in the table below.**

Key positions	**Min. Qualification requirements (cv, copy of degree/certification and other supporting documents to be provided)**
1. **Senior Project Manager**	• At least a **bachelor's degree in computer sciences, Software Engineering, Data Sciences, Information and Communications Technologies or related fields** • with a **minimum of 7 years of experience in IT project management, planning, and service delivery.** • **a valid certification in project management framework** (e.g., , Scrum Master, PMBOK, ITL, Prince 2, etc.). • With **at least 3 similar assignments as a project manager** responsible **for developing Software/IT Solutions projects.** Additional skills - considered as desirable but will not be subject to separate scoring and will not constitute grounds for exclusion. ● Excellent leadership abilities, experience coaching and management of an IT Team ● Experience in designing or implementing major government IT solutions and applications ● Familiarity with public sector data environments Experience in gathering requirements, business analysis, and documentation. ● Working knowledge of market-leading data management, business intelligence, enterprise-scale data analytics projects, AI Technologies and Data Interoperability Platforms ● Strong interpersonal communication, presentation and management skills ● Strong skills in designing the capacity building and knowledge transfer plan
2. **Business Analyst**	● A **bachelor's degree in computer science, software engineering, Information Technology, Information Systems, Software Engineering or Computer Science or related fields**. ● At **least 3 years of experience in system analysis, Systems architectural design and enterprise systems integration.** Additional skills considered as desirable but will not be subject to separate scoring and will not constitute grounds for exclusion. ● Experience with business process modelling notation, technical documentation, user-centered design and running technical workshops is an added advantage. ● Experience in environments with complex stakeholder structures is especially valuable. ● Ability in designing and implementing scalable, secure, and resilient system architectures that accommodate real-time data processing and integration with existing and emerging technologies.

	● Extensive experience with API-driven integration, facilitating interoperability among diverse systems and platforms. ● Advanced problem-solving skills to understand and decompose complex issues, translating user and business needs into strategic technological solutions. ● Experience working on governance, human rights, equity, social protection, or public- sector information systems.
3. **Senior System Interoperability and Integration Expert**	• At least **a bachelor's degree** in **Computer Sciences, Software Engineering, Data Sciences, Information and Communications Technologies or related field** • with a minimum of **7 years of experience as an Interoperability and Systems Integration Engineer or similar role.** • At least **2 years of experience** in system integration or interoperability roles or in System Architecture design and specifications ● **at least one relevant professional certification** (eg HL7 (v2/v3, C-CDA, or FHIR certification), IHE certification, Vendor-specific middleware or API integration certifications, Cloud vendor certifications (AWS, Azure, or GCP)) issued by recognized system or technology vendors. Additional Skills - considered as desirable but will not be subject to separate scoring and will not constitute grounds for exclusion. ● Understand Networking Concepts, Connectivity, Systems Architecture, Disaster Recovery ● Extensive knowledge of industry leading interoperability platforms (Hardware and Software), data integration platforms and interoperability protocols, middleware and enterprise application integration ● Extensive experience in Service Oriented Architecture, Microservices Architecture, APIs design and Management, Electronic Data Interchange, Service Oriented Architecture, Enterprise Service Bus, Web Services, and RESTFul Services, virtualization, and cloud computing. ● Experience in training and transmitting knowledge
4. **Front-end Engineer/Developer**	• At least a **bachelor's degree in computer sciences, IT, information security, Software Engineering or related field.** • with a minimum of **5 years of experience in software development.** • At least **1 certification in front-end development in any of the latest technologies or frameworks**. • With at least **2 years of experience as a front-end software developer.** Additional Skills - considered as desirable but will not be subject to separate scoring and will not constitute grounds for exclusion. • Experience integrating with RESTful APIs or GraphQL and implementing authentication (OAuth2/JWT). • Experience with testing (Jest/Cypress), build tools (Webpack/Vite), and CI/CD. • Experience working in Agile teams, using Git, and collaborating in client-facing or consultancy roles.

5. **Back-end Engineer/Developer**	• At least a **bachelor's degree in computer sciences, IT, information security or related field** • with a **minimum of 5 years of experience in software development.** • At least **1 certification in back-end development in any of the latest technologies or frameworks.** • at least **2 years of experience as a back-end software developer** Additional skills - considered as desirable but will not be subject to separate scoring and will not constitute grounds for exclusion. • Proficiency in backend Programming Languages: Mastery of languages such as Python, Java and PHP. Experience in API design and integration. • Experience with distributed systems and microservices. • Strong CI/CD and DevOps experience (Docker, Kubernetes).
6. **Database Administrator**	• At least a **bachelor's degree in computer sciences, IT, information security or related field** • with a **minimum of 5 years of experience in Database development and/or administration.** • At least **1 recognized certification in database management in any Database Management System Software** • With at least **2 years of previous experience as a Database Administrator or developer** Additional skills - considered as desirable but will not be subject to separate scoring and will not constitute grounds for exclusion. ● Deep PostgreSQL Expertise: In-depth understanding of PostgreSQL internals, installation, configuration, and version upgrades. ● Performance Tuning & Query Optimization: Ability to analyze query performance, fine-tune indexes, and optimize execution plans. ● Backup, Recovery, & High Availability: Experience with reliable backup strategies, point-in-time recovery, and setting up replication (streaming or logical) for high availability. ● Security & Compliance: Proficient in configuring authentication, access controls, encryption, and ensuring compliance with data governance policies. ● Automation & Scripting: Skilled in automating routine tasks using SQL, PL/pgSQL, and shell scripting. ● Monitoring & Troubleshooting: Familiarity with PostgreSQL monitoring tools (e.g., pg_stat_statements, pgAdmin) and best practices for diagnosing and resolving performance issues
7. **IT Systems Architect**	• At least a **bachelor's degree in computer sciences, Software Engineering, IT, information security, or related field** • with a minimum of **7 years of experience in system architecture or system design** • With **at least 2 years of experience as a system architecture and design or Software Development** • At least **one recognized certification for Enterprise and Systems architects or similar enterprise systems** (e.g., DHIS2, OpenLMIS, SAP) is required.

5.10 Contract management and reporting arrangement

The bidder will report to the managing official - **Mrs. Oliver UWANTEGE**, **Business Analyst eHealth, e-mail:** **oliver.uwantege@enabel.be**, who will work in close collaboration with the Rwanda FDA designated team.

The Rwanda FDA will cooperate fully with the Bidder and provide a Focal Point to facilitate necessary introductions to stakeholders, provide available documentation, data, and reports and provide timely feedback on deliverables.

The Bidder may be required to present progress, results, and deliverables to relevant stakeholders including but not limited to Rwanda FDA, the Ministry of Health, Rwanda Medical Supply (RMS), Rwanda Social Security Boards (RSSB) through virtual or face-to-face meetings/workshops.

6 Forms

6.1 Identification forms

6.1.1 Legal person entity private/public legal body

OFFICIAL NAME ②			
ABREVIATION			
MAIN REGISTRATION NUMBER③			
SECONDARY REGISTRATION NUMBER (if applicable)			
PLACE OF MAIN REGISTRATION	**CITY**		**COUNTRY**
DATE OF MAIN REGISTRATION	**DD**	**MM**	**YYYY**
VAT NUMBER			
OFFICIAL ADDRESS			
POSTCODE	**P.O. BOX**		**CITY**
COUNTRY			**PHONE**
E-MAIL			

DATE	**STAMP**
SIGNATURE OF AUTHORISED REPRESENTATIVE	

① **Public law body WITH LEGAL PERSONALITY, meaning a public entity being able to represent itself and act in its own name, i.e. being capable of suing or being sued, acquiring and disposing of property, entering into contracts. This legal status is con- firmed by the official legal act establishing the entity (a law, a decree, etc.).**

② **National denomination and its translation in EN or FR if existing.**

③ **Registration number in the national register of the entity.**

6.1.2 Public law entity

OFFICIAL NAME①					
BUSINESS NAME (if different)					
ABREVIATION					
LEGAL FORM					
ORGANISATION TYPE	**FOR PROFIT**				
	NOT FOR PROFIT		**NGO②**	**YES**	**NO**
MAIN REGISTRATION NUMBER③					
SECONDARY REGISTRATION NUMBER (if applicable)					
PLACE OF MAIN REGISTRATION		**CITY**		**COUNTRY**	
DATE OF MAIN REGISTRATION					
		DD	**MM**	**YYYY**	
VAT NUMBER					
ADDRESS OF HEAD OFFICE					
POSTCODE	**P.O. BOX**			**CITY**	
COUNTRY				**PHONE**	
E-MAIL					

DATE	**STAMP**
SIGNATURE OF AUTHORISED REPRESENTATIVE	

① National denomination and its translation in EN or FR if existing.
② NGO = Non Governmental Organisation, to be completed if NFPO is indicated.
③ Registration number in the national register of companies. See table with corresponding field denomination by country.

6.1.3 Subcontractors (if applicable)

Name and legal form	Address / Registered office	Object

6.2 Tender Forms – prices

By submitting this tender the tenderer commits to performing this public contract in conformity with the provisions of the Tender Specifications/ – and explicitly declares accepting all conditions listed in the Tender Specifications and renounces any derogatory provisions such as his own general sales conditions.

The unit prices and the global prices for each item in the inventory are established relative to the value of these items in relation to the total value of the tender. All general and financial costs as well as the profits are distributed between the various items in proportion to their weight.

The value-added tax is a special item of the inventory, to be added to the tender value. The tenderer commits to performing the public contract in accordance with the provisions of the Tender Specifications for the following prices, given in euros and inclusive of VAT:

	Unit	**Unit price incl. WHT excl. VAT[11],[12]**	**Quantity (max 227 person days)**	**Total incl. WHT excl. VAT**
1. Expert Fees				
Senior Project Manager	Person-days	€		€
Business Analyst	Person-days	€		€
Senior System Interoperability and Integration Expert	Person-days	€		€
Front-end Engineer /Developer	Person-days	€		€
Back-end Engineer /Developer	Person-days	€		€
Database Administrator	Person-days	€		€
IT Systems Architect	Person-days	€		€
SUB-TOTAL: incl. WHT and excl. VAT **(A)**				**€**
WHT[12] to be retained at source: 15% of (A) for international bidders or DTA rates. **(B)**				**€**
NET to be paid to the bidder (C) = (A-B)				**€**
VAT of 18% to be added on (A); for international bidders[13] refer to the footnote **(D)**				**€**
SUB-TOTAL: incl. WHT and VAT **(E) = (A+D)**				**€**
2. Reimbursable Fees (if applicable)				
International travel costs		€		€

[11] Refer to the Rwanda Revenue Authority (RRA) link, publishing the double taxation agreements (DTA) for international bidders: https://www.rra.gov.rw/en/publications?tx_news_pi1%5Baction%5D=detail&tx_news_pi1%5Bcontroller%5D=News&tx_news_pi1%5Bnews%5D=11105&cHash=f71e9bc7ede752e64679f8c39e73871c

[12] Refer to article 63 of the law Nº 027/2022 of 20/10/2022, establishing taxes on income in Rwanda. A tax of 15% shall be withheld on public tenders if the recipient is not registered with the Tax Administration or is registered but does not have his/her previous income tax declaration.

[13] Refer to article 14 of the law Nº 049/2023 of 05/09/2023, For international bidders a reverse VAT of 18% to international bidders which will be retained and paid by Enabel will be applied.

Visa costs	€		€
SUB-TOTAL (F)			**€**
GRAND TOTAL (G) = (E+F)			**€**

Should the bidder be registered in Rwanda, EBM invoice will be required for payments.

Should this tender be approved, the performance bond will be constituted under the conditions and deadlines stipulated in the Tender Specifications.

The confidential information and/or the information relating to technical or business secrets is indicated clearly in the tender.

The tenderer declares on honour that the information given is accurate and correct and that it has been established while fully aware of the consequences of misrepresentation.

Certified true and sincere,

Name and signature (s): .....

Done at ....., on .....

6.3 Financial identification

ACCOUNT NAME (1)			
ADDRESS			
TOWN/CITY		**POST CODE**	
COUNTRY			
CONTACT			
TELEPHONE		**TELEFAX**	
E - MAIL			

BANK (2)

NAME OF BANK			
ADDRESS (OF BRANCH)			
TOWN/CITY		**POST CODE**	
COUNTRY			
ACCOUNT NUMBER			
IBAN (3)			
NAME OF SIGNATORIES	**NAME & FORENAME**	**FUNCTION**	

STAMP of BANK + SIGNATURE of BANK'S REPRESENTATIVE (both are obligatory)	**DATE + SIGNATURE OF ACCOUNT HOLDER(Obligatory)**

(1) The name or title under which the account was opened and not the name of the authorised representative.

(2) It is preferable to attach a copy of a recent bank statement. Please note that the bank statement must provide all the information indicated above under "ACCOUNT NAME" and "BANK". In this case, the bank's stamp and the signature of its representative are not required. The signature of the account holder is obligatory in all cases.

(3) If the IBAN code (international bank account number) is applicable in the country where your bank is situated.

6.4 Declaration on honour – exclusion criteria

Hereby, I / we, acting as legal representative(s) of above-mentioned tenderer, declare that the tenderer does not find himself in one of the following situations :

1) The tenderer or one of its 'directors[1]' was found guilty following a conviction by final judgement for one of the following offences:
   1° involvement in a criminal organisation
   2° corruption
   3° fraud
   4° terrorist offences, offences linked related to terrorist activities or incitement to commit such offence, collusion or attempt to commit such an offence
   5° money laundering or terrorist financing
   6° child labour and other trafficking in human beings
   7° employment of foreign citizens under illegal status
   8° creating a shell company.
2) The counterparty which fails to fulfil his obligations relating to the payment of taxes or social security contributions for an amount in excess of EUR 3 000, except if the counterparty can demonstrate that a contracting authority owes him one or more unquestionable and due debts which are free of all foreseeable liabilities. These debts are at least of an amount equal to the one for which he is late in paying outstanding tax or social charges.
3) The counterparty who is in a state of bankruptcy, liquidation, cessation of activities, judicial reorganisation or has admitted bankruptcy or is the subject of a liquidation procedure or judicial reorganisation, or in any similar situation resulting from a procedure of the same kind existing under other national regulations;
4) When Enabel can demonstrate by any appropriate means that the counterparty or any of its directors has committed serious professional misconduct which calls into question his integrity.
   Are also considered such serious professional misconduct:
   a. A breach of Enabel's Policy regarding sexual exploitation and abuse – June 2019
   b. A breach of Enabel's Policy regarding fraud and corruption risk management – June 2019
   c. A breach of a regulatory provision in applicable local legislation regarding sexual harassment in the workplace
   d. The counterparty was seriously guilty of misrepresentation or false documents when providing the information required for verification of the absence of grounds for exclusion or the satisfaction of the selection criteria, or concealed this information
   e. Where Enabel has sufficient plausible evidence to conclude that the counterparty has committed acts, entered into agreements or entered into arrangements to distort competition
   The presence of this counterparty on one of Enabel's exclusion lists as a result of such an act/agreement/arrangement is considered to be sufficiently plausible an element.
5) When a conflict of interest cannot be remedied by other, less intrusive measures;
6) When significant or persistent failures by the counterparty were detected during the execution of an essential obligation incumbent on him in the framework of a previous contract, a previous contract placed with another contracting authority, when these failures have given rise to measures as of right, damages or another comparable sanction.

Also failures to respect applicable obligations regarding environmental, social and labour rights, national law, labour agreements or international provisions on environmental, social and labour rights are considered 'significant'.
The presence of the counterparty on the exclusion list of Enabel because of such a failure serves as evidence.

7) Restrictive measures have been taken vis-à-vis the counterparty with a view of ending violations of international peace and security such as terrorism, human-rights violations, the destabilisation of sovereign states and de proliferation of weapons of mass destruction.
The counterparty or one of its directors are on the lists of persons, groups or entities submitted by the United Nations, the European Union and Belgium for financial sanctions:
For the United Nations, the lists can be consulted at the following address:
https://finances.belgium.be/fr/tresorerie/sanctions-financieres/sanctions-internationales-nations-unies
For the European Union, the lists can be consulted at the following address:
https://finances.belgium.be/fr/tresorerie/sanctions-financieres/sanctions-europ%C3%A9ennes-ue
https://eeas.europa.eu/headquarters/headquarters-homepage/8442/consolidated-list-sanctions_en
https://eeas.europa.eu/sites/eeas/files/restrictive_measures-2017-01-17-clean.pdf
For Belgium:
https://finances.belgium.be/fr/sur_le_spf/structure_et_services/administrations_generales/tr%C3%A9sorerie/contr%C3%B4le-des-instruments-1-2
8) << If Enabel executes a project for another funder or donor, other grounds for exclusion may be added.

The tenderer formally declares being able, when asked and without delay, to provide the relevant certificates and other kinds of supporting documents, except if:

a. Enabel can directly obtain the supporting documents concerned by consulting a national database in a Member State that is accessible for free, provided the tenderer has given the required information (website address, responsible authority for providing the information, specific reference of the documents) so Enabel can obtain these, with concomitant permission to access them;

b. Enabel already has said documents.

The tenderer formally agrees with Enabel accessing the supporting documents substantiating the information provided in this document.

Date
Location
Signature

6.5 Integrity statement for the tenderers

Hereby, I / we, acting as legal representative(s) of above-mentioned tenderer, declare the following:

3. Neither members of administration or employees, or any person or legal person with whom the tenderer has concluded an agreement in view of performing the public contract, may obtain or accept from a third party, for themselves of for any other person or legal person, an advantage appreciable in cash (for instance, gifts, bonuses or any other kind of benefits), directly or indirectly related to the activities of the person concerned for the account of Enabel.
4. The board members, staff members or their partners have no financial or other interests in the businesses, organisations, etc. that have a direct or indirect link with Enabel (which could, for instance, bring about a conflict of interests).
5. I have / we have read and understood the articles about deontology and anti-corruption included in the Tender Documents (see 1.7.), as well as *Enabel's Policy regarding sexual exploitation and abuse* of June 2019 and *Enabel's Policy regarding fraud and corruption risk management* of June 2019 and I / we declare fully endorsing and respecting these articles.

If above-mentioned public contract is awarded to the tenderer, I/we declare, moreover, agreeing with the following provisions:

4. In order to avoid any impression of risk of partiality or connivance in the follow-up and control of the performance of the public contract, it is strictly forbidden to the public contractor (i.e. members of the administration and workers) to offer, directly or indirectly, gifts, meals or any other material or immaterial advantage, of whatever value, to the employees of Enabel who are concerned, directly or indirectly, by the follow-up and/or control of the performance of the public contract, regardless of their hierarchical rank.

5. Any (public) contract will be terminated, once it appears that contract awarding or contract performance would have involved the obtaining or the offering of the above-mentioned advantages appreciable in cash.

6. Any failure to comply with one or more of the deontological clauses will be considered as a serious professional misconduct which will lead to the exclusion of the contractor from this and other public contracts for Enabel.

7. The public contractor commits to supply, upon the demand of the contracting authority, any supporting documents related to the performance conditions of the contract. The contracting authority will be allowed to proceed to any control, on paperwork or on site, which it considers necessary to collect evidence to support the presumption of unusual commercial expenditure.

Finally, the tenderer takes cognisance of the fact that Enabel reserves the right to lodge a complaint with the competent legal instances for all facts going against this statement and that all administrative and other costs resulting are borne by the tenderer.

Signature preceded by 'read and approved', in writing, and indication of name and function

of the person signing:

.....

Place, date

6.6 Selection file – economic and financial capacity

Service provider will need to provide a signed statement indicating the total turnover achieved during each of the past five financial years, demonstrating that the cumulative turnover is at least equal to 100,000 €.

2025	2024	2023	2022	2021	Total

Certified true and sincere,

Name and signature (s): .....

Done at ....., on .....

7 DOCUMENT TO BE INCLUDED IN THE PROPOSAL/OFFER

1. **LEGAL IDENTIFICATION FORMS – ART. 6.1**
2. **FINANCIAL IDENTIFICATION FORM – ART. 6.2**
3. **COMPANY AND KEY EXPERTS REQUIREMENTS AND SUPPORTING DOCUMENTS – ART. 3.4.7 AND 5.9**
4. **TECHNICAL OFFER – ART. 5**
5. **SUBCONTRACTOR FORM IF APPLICABLE – ART. 6.1.3**
6. **TENDER FORM -PRICES – ART. 6.2**
7. **DECLARATION ON HONOUR – EXCLUSION CRITERIA – ART. 6.4**
8. **INTEGRITY STATEMENT– ART. 6.5**
9. **ECONOMIC AND FINANCIAL CAPACITY – ART. 6.6**
10. **POWER OF ATTORNEY**

The Tenderer shall include in his tender the **power of attorney empowering the person signing the bid** on behalf of the company, joint venture or consortium.

In case of a **consortium** or a **temporary association**, the joint bid must specify the role of each member of the consortium. A group leader must be designated, and the power of attorney must be completed accordingly.

11. **CRIMINAL RECORD CERTIFICATE FOR THE PERSON MANDATED TO COMMIT FOR THE FIRM**
12. **CERTIFICATION OF CLEARANCE WITH REGARDS TO THE PAYMENTS OF SOCIAL SECURITY CONTRIBUTIONS**

At the latest before award, the Tenderer must provide a certification from the competent authority stating that he is **in order with the obligations with regard to the payments of social security contributions** that apply by law in the country of establishment. The Tenderer registered in Belgium must be in order for the **4th term of 2025.**

13. **TAX CLEARANCE CERTIFICATE.**

At the latest before award, the Tenderer must provide a valid **recent certification** (up to 6 months) from the competent authority stating that the Tenderer is **in order with the payment of applicable taxes** that apply by law in the country of establishment.