#	Questions	UNICEF Answers
	General Questions	
1	Please advise if the technical volume and price volume may be submitted in the same email or if they should be sent in separate emails.	The question is unclear. However, the UNICEF requirement is that no price proposal should be in the technical proposal. Vendors are respectfully advised that the RFP clearly states that the technical evaluation will be concluded before the commercial/financial proposals are opened. Therefore, under no circumstances should the price information be in the technical proposal. Failure to follow this requirement will lead to disqualification. Separate emails should be sent for the technical and price submissions respectively.
2	Please indicate where in the proposal response UNICEF would like vendors to address the Legal Requirements outlined in Appendix B2 - Proposer Self-Checklist (Legal Action, Ts&Cs, any comments to SLA requirements, if needed)	These can be on a separate document.
3	Please advise if vendors are expected to execute Annex B - Non-Disclosure Agreement as part of our proposal response.	Yes, confirm this is correct. There are boxes to be check marked.
4	We see references to requiring PaaS offerings in the RFPS. It is our understanding that SaaS offerings are an acceptable solution, please confirm.	Software as a Service (SAAS) does not fulfill the requirements of the RFPS. In addition to provision of the software, a complete managed service is expected. Therefore, we have quoted this as Platform as a Service (PAAS). Many of the service requirements can be found in Table C of the "Requirements Compliance Sheet– Appendix B3".

		Note: Many of these are mandatory and so a proposer will not progress past the process described in 9.2.1 of the ToR (Annex B), if they cannot provide these services. They also need to achieve a minimum mark of 754/1300 for table C.
5	Please confirm that profiles for key personnel are not required as part of this response. Section 2.3 of the RFPS states they are only needed "if so required in the Terms of Reference/Statement of Work" and we do not see reference to this requirement in that document.	Profiles for key personnel are not required at this point, however, be aware that the team which presents the demonstration will be scored against their relevant experience and knowledge. See Appendix B4 “Demo” in “Annex B – Global Trust Repository – TOR"
6	Please confirm if UNICEF will require Proposer to follow their Quality assurance / Validation procedure to signoff phase based approach for delivery of GTR solution or will this be performed independently by the Proposer? If yes, could you please share some details on your validation procedures?	This should be performed by the proposer with participation from UNICEF staff. We expect the proposer to provide the process for this, the management and documentation, this is covered in the requirements e.g. GTR-REQ-181.
7	Will UNICEF be responsible for nominating and supporting the alignment with key stakeholders, i.e., Manufacturer, 3rd Parties in local country (i.e. Distributor, wholesaler, Inspectors, pharmacy, etc..), or is it expected for the proposer to lead all conversations with involved stakeholders?	The participation and agreement to use the GTR does not rest with the proposer, this will be managed by UNICEF and its partners through the project governance. The proposer should be prepared to lead the conversations with the manufacturers regarding establishing interfaces, setting up master data and uploading batch serialization data, with some support from UNICEF. This is referred to in GTR-REQ-184 and GTR-REQ-185. There is expected to be some level of in country champions to locally management the design and deployment of the system at a national level. The proposer will be expected to work with these

		in country champions to support them design, plan and deliver deployment of the verification capability at a country level. A key focus of this work will include establishing the verification tools, providing training, and setting up dashboard users. This is referred to in GTR-REQ-189
Contractual Questions		
1	In Annex B, TOR, Section 5 Contractual Approach, it states that, "Proposers must guarantee maintenance and support services of the Proposed Solution including for a minimum of 2 years, plus access to data maintained in the system for an additional 7 years from the last batch upload." Please clarify what is meant by "an additional 7 years from the last batch upload"? Does this statement mean that the Contractor is to store UNICEF Data for 7 years after termination of the contract?	The data held in the GTR could be considered as GxP related data, for that reason we have set the requirement that data must be retained for three years (expected shelf life) + an additional four years, which gives a total of seven years. If the last batch were uploaded on the last day of the contract, then yes, this would imply that this data should be accessible for seven years. This does not imply that the data must be retained in the system for this period, vendors should explain how this will be achieved if not held in the system.
2	Reference Annex B, TOR, Section 6.6 Testing/QA, a SaaS Solution would not be subject to acceptance testing and formal sign-offs since it is a subscription-based solution. In addition, the second paragraph of the section would not be applicable to commercial software provided on a subscription basis under a SaaS agreement. Please confirm your agreement.	Since this is a managed service with expected configuration/setup performed to comply with UNICEF's requirements, UNICEF expects proposer's solution to undergo requisite QA/validation tests and acceptance tests on customized solution.
3	In reference to Section 6.8 Documentation of the TOR, please confirm that in support of Contractor's SaaS solution the Contractor's commercial documentation is sufficient to meet this requirement.	For the purposes of responding to the UNICEF RFPS and the subsequent evaluation, the commercial version of documentation will be adequate. In addition, under the same section6.8 of the TORs, there is the following statement:

		"..includes "*provide one complete set of technical documentation of the verification solution as it is set up and configured/customized (where applicable) for UNICEF."* Please note that the above statement would be applicable after the product is customized/configured for UNICEF.
4	Reference Annex A – General Terms and Conditions, Section 2.11, can you please define the term "institutional subcontractors"?	The term "institutional sub-contractor" is to be understood as a legal entity (whether company, association, partnership, or other form of legal entity) rather than an individual/natural person.
Price question		
1	Section 5 -> Contractual Approach -> "The Proposer shall also provide free of cost a one (1) year warranty to UNICEF to cover the implemented Solution and all Services rendered in connection to it." -> When will this 1 year of warranty to UNICEF period be applicable?	The one year starts once the application is operational and in "go-live" status. The warranty period will kick in once the solution is in production mode.
Technical Questions		
1	Section 6.2 of the TOR states: # of local versions of the GTR App: 15 states. We interpret this to mean that there should be 15 languages supported from the verification app. Which languages need to be supported?	Language is not the only driver which will result in a local version of the GTR App. Other aspects of the app may vary from country to country. Please refer to GTR-REQ-225 "Several tools should be made available to allow verification: Tool B – Local App 1 - This is a version of the GTR app but customized for a specific country e.g. local language, branding, contact information, etc." The specific language requirements have not been established at this point.
2	Regarding Scalability/Development, is there preference from UNICEF team about the deployment of GTR solution for other countries apart from the first 3 countries in 4 months. Is there already a plan or should we prepare a high level one?	There is not a defined plan in place at this point, this will be worked up in parallel to the development of the GTR. Providing a high-level plan covering country deployment would be valuable and count toward the scoring of the project plan, see Annex B – Global Trust Repository – TOR, Appendix B4, Project Plan.

3	What external systems are in scope to exchange Master or location data with GTR system? Could UNICEF confirm if we need to integrate with any UNICEF database system?	There is no need to integrate with any UNICEF systems. Interfaces to the manufacturers will be expected to receive batch level serialization data. GTR-REQ-150 specifies the GTR must support import of Product master data records from an external system via an automated interface. Product Master Data will be provided by the manufacturers. Product Master Data should also be able to be provided via a Web UI, see GTR-REQ-148. Location Master Data is not expected to be required where the GTR is used for verification. Location Master Data will most likely only become necessary once full traceability is implemented in future.
4	What would be the business process to handle Returns in GTR? Who will initiate the returns process back to Manufacturer?	The GTR will be used as a verification system. Product returns is not a process which needs to be support be the GTR at this point as this this more usually associated with full traceability processes.
5	What will be the business process for GTR system to receive data from existing Regulatory formats to capture traceability data ? When will the regulatory format data triggered and send to GTR system?	The GTR is not expected to be used as a traceability system initially and will therefore will not be receiving traceability event data from national regulatory systems. Verification will occur using the tools described in GTR-REQ-224,255, 226. The only possible capture of data from national systems will be where the GTR has an interface to a national system to facilitate the verification of products, see GTR-REQ-227.
6	What are the expectations for non-EPCIS event query interface with GTR system? Could you please share more details?	The GTR is not expected to be used as a traceability system initially and will therefore will not be receiving traceability event data. In

		future the GTR may need to interface to traceability systems which do not send and receive EPCIS based messages. We cannot be more specific at this point as these systems are not in operation in LMIC countries. GTR-REQ-103 and 104 require the GTR to be able to manage the receipt of non-EPCIS messages, so that we are able manage this situation in future if, and when it arises.
7	Please confirm how Pharmacovigilance ID value will be received in GTR system which needs to be queried later on with Dashboard Reporting.	The use of Pharmacovigilance ID will not be used initially, it should however be included in the data model.
8	Could you please confirm number of users for Verification Tool with Baseline and Scaled up scope for GTR?	The number of unique verification tool users has not been estimated. There are however 4-5 million verification requests in the baseline scope and 25 million in the Scaled scope. If you need to convert this to the number of unique verification users, then please do so and state your assumptions.
9	As per requirement "GTR-REQ-025" which other services are expected on verification tool / app ? Are other services limited to existing or new roles?	The mobile verification application does not need to segregate services by role, the user simply has the ability access services which are displayed on the application. The two services which will be available initially are: 1) Verification as per Appendix B6: Use Cases for GTR, Scenario #1. Verification request – App 2) Access to electronic content as per Appendix B6: Use Cases for GTR, Scenario #5. Access to Electronic/ Online Content It is only the GTR itself which will have roles to manage system access, reporting etc.

10	Could you please provide more details for Verification Local App 2 which should provide the app SDK to other app developers to allow integration of the GTR verification service to other prevalent applications in specific countries.	With reference to GTR-REQ-226. In some countries there may be a local application already widely used for other purposes other than verification. It may therefore be more effective to modify that application to provide the ability to verify using the GTR, rather than deploy a new application in that country. In this instance the vendor should be able to work with the developer of that local application and provide the relevant coding/ SDK/ API so that it can scan the 2D DataMatrix and verify using the GTR. We do not expect that this is a very common scenario, but it is likely in at least one country that we are aware of.
11	Are maintenance and support services required in any other language than English? If yes, please share the list accordingly.	We have not defined a requirement for this, if you are able to provide support in languages other than English then please state. Please note GTR-REQ-214 which does request French language for the GTR Dashboard.
12	Is Project documentation (Functional or Technical specifications, Configuration guide, etc..) required in any other language then English? If yes, please share the details accordingly.	There is not requirement to provide project documentation, specification etc. in other languages other than English.
13	Is Training material and key user of trainings required in any other language then English? If yes, please share the details accordingly.	Given GTR-REQ-214 requires the Dashboard in French and English it would be advantageous if training and user materials could be made available in both languages, but not a requirement.

14	Although the system will not record decommissioning of unique identifiers within the supply chain or at the points of sale or dispense, manufacturers may alter the status of unique identifiers after packs have entered the supply chain. For example, they may recall a batch or withdraw a product. In addition, batches may pass their expiry date. Will the GTR report the status to end users when a unique identifier is verified but its status indicates that it is not available to be supplied? Should the GTR simply report that the unique identifier is valid in this case?	The current specification of the GTR does not require this, however if the proposed system has capability to manage status such as recalled or withdrawn then please explain this within the proposal and demonstration. It is important that the GTR can be configured to function without the use of these other status as the processes and capability to maintain theses may not be available from all manufacturers. Also providing recall status through the GTR may have implications for the quality assessment of the system which could impact the ability to rapidly develop and deploy a verification only tool.
15	We understand that the envisaged system will support geo-location (e.g., via the mobile app), but will not be tied to well-defined locations such as licensed or operational premises within a given market. However, the pre-RFP information also suggests that dashboard users will be able to identify products that appear 'in the wrong location'. Does this imply that the GTR must hold target market information – i.e., a list of one or more markets for which the product is intended? If so, how will this information be provided under the COVAX Facility and who will provide it?	It is not intended that the GTR hold target market information at this stage. Currently neither the GTIN or Batch can necessarily be tied to a target country as the same GTIN will be used across countries and Batches can be split and shared across countries. As per Appendix B6: Use Cases for GTR Scenario #3. Suspect Activity. Step SA-120 sets the first country in which the GTIN + Serial Number is scanned as the primary country. SA-160 then checks if that GTIN + Serial Number has been scanned in a different country. This allows the GTR to flag packs which have been scanned in different countries which could be an indication of product diversion. The working assumption is that COVID-19 vaccines are very unlikely to be verified prior to arrival in the destination country, therefore the first country in which as GTIN + Serial Number is scanned is a proxy for "target market". If the proposed system can receive target market by batch, etc. then please state this as this functionality could be of use in future as GTR is expanded to encompass other products etc.

16	Are there any requirements to handle the re-packaging or re-labelling of COVAX vaccines? We have experience of LMIC countries in which the government intends to implement re-packaging or labelling of imported medicinal products at the port of entry. Would this apply to COVAX vaccines? Is there any requirement to support parallel distribution for COVAX vaccines?	This is not a process which has currently been considered, however if this was to take place then the re-packer would be treated like a manufacturer and batch serialization data could be uploaded to allow verification to take place. There is no intention to operate parallel distribution type processes as operated in the European EU FMD system (the EMVS).
17	Is there a requirement to limit the use of the mobile application – e.g., to prevent it being used by members of the public? If so, how is it envisaged that this will be enabled? If an AMC country cannot support reliable verification of intended users or legal entities in their market, how can use of the mobile application be restricted?	Currently we do not plan to limit the use of the mobile application.
18	With regard to requirement GTR-REQ-051, can you please confirm that the dashboard should only provide manufacturers with access to information for the serial numbers they have uploaded. Will government officials only have access to data associated with their own countries?	This is correct.
19	Is there a preference for using an existing Data Link Resolver service (e.g., the GS1 service) or a dedicated service for the GTS?	There is no preference, please state the options available and your preference.
20	With regard to requirement GTR-REQ-020, incorrectly formatted data may be an indication of falsification. Assuming it detects correct symbology and data elements representing a serialised identifier, should the mobile app report incorrectly formatted or encoded data values to the GTR to provide	It would be beneficial if incorrectly formatted or encoded data values could be provided to the GTR by the verification tool (app) and flagged in the Dashboard, as this is a potential sign of a falsified product.

	greater visibility of potentially falsified medicines, or should it avoid reporting this data to prevent the GTR from returning negative verification responses?	
21	Requirement GTR-REQ-026 states that verification can occur at either a batch level or serial number level. Could you please clarify what is meant by 'batch level' verification? Is this verification of a list of unique identifiers associated with a given batch?	Some manufacturers may not be able to provide serialization batch data, however they may be able to provide a list of the batches which they have manufactured. In this instance the verification tool could carry out a verification against the GTIN, Batch and Expiry only. Although this is not as ideal as using the Serial Number is will still provide some level of verification and visibility within the Dashboard.
22	Requirement GTR-REQ-028 states that the GTR must be able to tell which GTINs it has data for so that it does not provide a bad response for packs for which it has no data. What would be considered to be a 'bad response'? Should the GTR report a 'green' (OK) verification response in this case, or report that the data is unrecognized?	There are likely to be three categories of products. 1) COVAX COVID-19 product GTINs which the GTR holds serialized batch data or batch data for. 2) COVAX COVID-19 product GTINs which the GTR does not hold serialized batch data or batch data for. 3) All other GTINs. It is expected that the list of GTINs for (1) and (2) will be known as UNICEF will be procuring the COVAX vaccines. Any other serialized product GTIN which is scanned should not receive a verification failure as it can be assumed to be within (3), however it should return a response of product not within the scope of the system, rather than a Green OK, as we cannot make any assumption for products not in the system.
23	Requirement GTR-REQ-163 states that the Proposer should offer the GTR as "Platform as a Service" (PaaS). Could you please explain the expectations for this requirement? Does this simply mean that the GTR must be deployed on a PaaS	The RFPS refers to the GTR as Platform as a Service (PaaS) as we expect this to be a fully managed service, both the provision of the hosted system and the service elements covered in Table C of the requirements, Appendix B3.

	platform, or is there some expectation that the GTR will itself serve as a cloud platform for other applications?	
24	Requirement GTR-REQ-207 states that "the verification application must only collect the geo-location information which the scan occurred". Does this mean that no geolocation information must be collected for any other purpose except to support verification scans? If not, how should we interpret this requirement?	This is correct, the application must only capture the geo-location against the verification event and at no other time.
25	Requirement GTR-REQ-225 envisages a version of the GTR app but customized for a specific country e.g. local language, branding, contact information, etc. Is there an expectation that the mobile app will be offered as a white-label product with separate, independently managed versions for each of the 25-30 countries (see GTR-REQ-038), or will it be sufficient to provide localized content (including logos, contact details, etc.,) within a single application?	It is envisaged that the mobile app will be offered as "white-label" product with up to 15 managed versions - IOS and Android (as stated in the price schedule, Appendix C). Wherever possible the same mobile app will be used in several countries, it is not the intension to have a different app in every country. It is only where there are national requirements which drive the need for localization that an additional version will be created.
26	Who are the members of the 2020 COVID-19 Vaccine and Therapeutics Traceability Expert Advisory Board?	This question has no relevancy and does not provide additional information pertinent and material in submitting a response to the RFP.