

Sl. No	Question	UNICEF Answers
1.	Technical requirement GTR-REQ-203 states “Proposer must have ISO 27001 certification and maintain services as may be required by ISO 27001 (or equivalent standard).” In the case of bidding in a consortia, is the compliance with the requirement filled and lowest passable score reached, if one of the partners in the bid have ISO 27001 certification and the other one is in the process of getting the certification in 6 months period?	The scoring allocation cannot be discussed, please state the situation clearly against GTR-REQ-203 and this will be taken into account during the evaluation and scoring process.
2.	We are bidding as a consortium of two organizations. We would like to confirm if Past Experiences can be provided by individual consortium members and this would reflect on the consortium as a whole. (ref. RFPS-NYH_ 4.2 joint venture or consortium)	Yes. Please clearly indicate the party/embers of the consortium for which the references are for.
3.	Would the financial status of all organizations in the consortium be considered for the qualification criteria or only the prime bidder? (ref. RFPS-NYH_ 4.2 joint venture or consortium)	The financials for both will be considered.
4.	Is there a preferred cloud service infrastructure provider? (Ref. Annex -B_ 6.3 Platform and Infrastructure)	No - Since it is a PAAS, any cloud service provider who can provide service at scale should be good.
5.	Is there any preference/restrictions on the cloud hosting region? (Ref. Annex -B_ 6.3 Platform and Infrastructure)	Hosting in EU may have a slight advantage given that more users will be based in Africa than in Latin America.
6.	Please provide details on the expected time of helpdesk service and timezone of service expected ? (Ref. Annex-B_11.3 service levels)	<p>Service times and time zones - We have assumed that verification would occur during normal business hours and therefore we need to cover 9am – 5pm support, locally.</p> <p>Most countries which are expected to adopt the GTR for verification will fall into the time zones UTC through to UTC + 8. Please base your proposal on these working assumptions.</p>
7.	Is UNICEF purchasing Covid-vaccines from existing producers / Brand owners or CMOs? Who are those? (e.g. Biontech/Pfizer, Moderna, J&J, AstraZeneca, Sputnik V, etc.)	<p>UNICEF is unable to give information on its suppliers. Please see links below to W.H.O website with pre-qualified vaccines manufacturers.</p> <p>https://extranet.who.int/pqweb/vaccines/covid-19-vaccines</p> <p>https://extranet.who.int/pqweb/sites/default/files/documents/Status_of_COVID-19_Vaccines_within_WHO_EUL-PQ_evaluation_process-16June2021_Final.pdf</p>

Sl. No	Question	UNICEF Answers
8.	Who else will/should provide Covid-vaccines? (Curevac, Sanofi, etc.)	UNICEF is not able to provide a list of potential suppliers of COVID-19 vaccines as this information is commercially sensitive.
9.	Are all the manufacturers already equipped with serialization and aggregation? a. According to which regulation? (GS1, etc.) b. According to which legislation? (EU, USA, China, Russia, Brazil, etc.)	<p>Serialization of COVAX COVID-19 vaccines is not mandated; however, it is a preferred characteristic as defined in Annex E of the COVID-19 Vaccine tender. https://www.ungm.org/public/Notice/117711</p> <p>We expect many, but not all suppliers, to be able to serialise the secondary packaging. The pandemic has driven new suppliers, CMOs and production lines to be used for the supply of COVAX COVID-19 vaccines. As a result, there will be some products supplied which will not be serialised. Over time we hope and expect that the level of serialization will increase.</p>
10.	What shall be verified by UNICEF (DMC, Barcode, OCV/OCR)?	<p>Verification can either be undertaken using:</p> <ol style="list-style-type: none"> 1) The serialization batch data (GTIN and Serial Number + Batch and Expiry) – held in a 2D DataMatrix 2) Just the batch data (GTIN, Batch and Expiry) - where the pack is not serialised – held in a 2D DataMatrix 3) Just the batch data (SSCC, Batch and Expiry) – where the pack is not serialised – held in either a Linear barcode e.g. GTIN-128 or a 2D DataMatrix.
11.	Is the GTR system expected to ingest serialized code information from existing producers? Or will it be a mix of ingestion and generation?	UNICEF will not be generating any serial numbers. Serialised batch data will be uploaded from the manufacturers, as per GTR-REQ-001.

Sl. No	Question	UNICEF Answers
12.	<p>GTR must employ an architecture which simplifies upgrades required to support modified External messaging output file formats per regulation or supply chain partner requirement changes</p> <p>What are the types of file format to create output?</p>	<p>GTR-REQ-054 relates to new market regulations in future which may require the GTR to send serialization batch data and EPCIS event data.</p> <p>We cannot be more specific regarding the messaging output file formats as this would be specified by the regulatory agency which introduced the legislation.</p> <p>File formats are likely to be like those required by existing traceability legislation, in countries such as Turkey, Argentina, Europe etc.</p>
13.	<p>Annex B - Page 5</p> <p>Many of the vaccines being supplied to the COVAX Facility are now serialised in accordance with these labelling specifications using GS1 Standards. In 2021, UNICEF will procure 2 billion doses of COVID-19 vaccines on behalf of the COVAX facility...</p> <p>Page 35</p> <p>The verification can occur at either a batch level or serial number level.</p> <p>For clarification, will we only receive serialized products from manufacturers? Or will there also be a requirement to track non-serialized products?</p>	<p>The GTR will initially only be used for verification and not to track products.</p> <p>The data received from manufacturers will depend on the capabilities they have in place i.e. A) Serialised batch data, B) Batch data or c) no data at all.</p> <p>Verification can either be undertaken using:</p> <ol style="list-style-type: none"> 1) The serialization batch data (GTIN and Serial Number + Batch and Expiry) – held in a 2D DataMatrix 2) Just the batch data (GTIN, Batch and Expiry) - where the pack is not serialised – held in a 2D DataMatrix 3) Just the batch data (SSCC, Batch and Expiry) – where the pack is not serialised – held in either a Linear barcode e.g. GTIN-128 or a 2D DataMatrix.

Sl. No	Question	UNICEF Answers
14	<p>Annex B - Page 16</p> <p>3. Dashboard with analytics across all the user profiles including access segmentation across user profiles and countries.</p> <p>The Requirements Compliance Sheet identify three different types of user roles/profiles.</p> <ul style="list-style-type: none"> • Verification User (page 35) • Dashboard User (page 37) • System Administrator (page 41) <p>Are these all of the expected user roles/profiles or will there be more?</p>	<p>The GTR and the Dashboard is not a publicly available platform. Only users who have been granted access and have been set up with a user profile will be able to use the system.</p> <p>We envisage these users being broken down into two types:</p> <ol style="list-style-type: none"> 1) Dashboard users, who can log into the GTR Dashboard and view verification activity relating to their specific role and privileges. 2) System administrators, who help operate and maintain the system. <p>If the system you are proposing has additional roles (mandated, recommended, or optional), then please state this within your proposal.</p> <p>Please note: The “Verification user” has no access to the GTR or Dashboard. The only interface they have is via the verification tools covered in requirements GTR-REQ-224, 225 and 226.</p>
15	<p>UNICEF Security Requirements Appendix D</p> <p>CLASS II SYSTEM UNICEF SECURITY REQUIREMENTS</p> <p>Is this document provided for informational purposes or do we need to confirm our compliance with each of the security requirements as stated in this document?</p>	<p>Please confirm compliance with all of the security requirements.</p>
16	<p>Requirements Compliance Sheet - GTR-REQ-116</p> <p>GTR must provide a non-EPCIS event query interface</p> <p>Can you provide examples of “non-EPCIS” events for querying?</p>	<p>In future the GTR may need to interface to traceability systems which do not send and receive EPCIS based messages.</p> <p>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.</p>

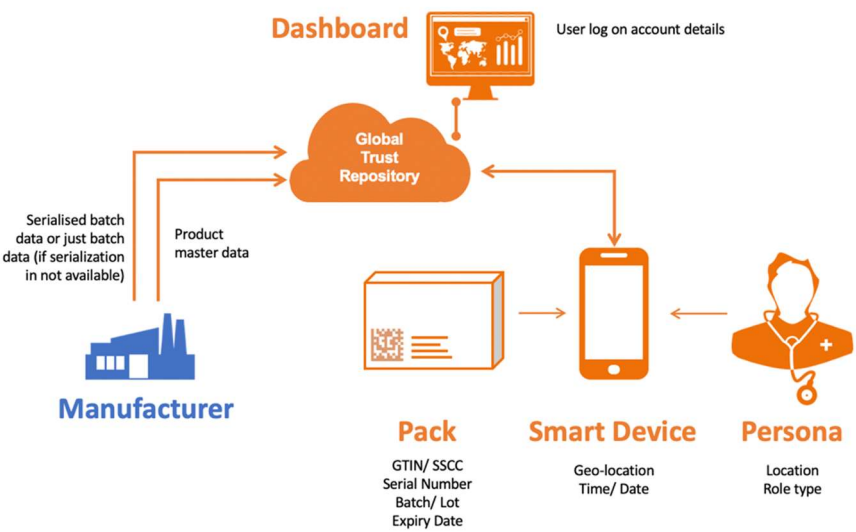
Sl. No	Question	UNICEF Answers
17	<p>Requirements Compliance Sheet - GTR-REQ-167</p> <p>User Administration should support Single Sign On (SSO)</p> <p>Is SSO required for initial GO LIVE within the 4-month target?</p>	<p>Within the Requirements Compliance Sheet – Appendix 3, GTR-REQ-167 classified is a low priority, optional requirement.</p> <p>Not being able to meet this requirement will lose the proposer 7 marks out of a possible 5045.</p> <p>If it is not possible to meet this requirement against the initial go live timelines, then please state this in your proposal and refer to this against GTR-REQ-167.</p>
18	<p>Requirements Compliance Sheet - GTR-REQ-225</p> <p>Several tools should be made available to allow verification:</p> <p>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.</p> <p>Are “customizations” intended only for localization needs? Will there be any functional “customizations” required?</p> <p>Page 12 of Annex B indicates that there are 15 “local versions of the GTR App”. Can we infer that this means there will be 15 “Tool B – Local App 1”?</p>	<p>Correct – customisations are intended only for localization needs and not to provide any additional functionality.</p> <p>The baseline scope (page 12 of Annex B – Global Trust Repository – ToR), does refer to 15 local version of the GTR app i.e., as per GTR-REQ-225</p>
19	<p>GTR must meet 21 CFR Part 11 requirements or other relevant international requirements for IT auditability and security.</p> <p>At what stage will 21 CFR Part 11 be used in the application ?</p>	<p>Regarding GTR-REQ-125. We would expect the proposer to understand the requirements of 21 CFR Part 11 and other relevant international requirements relating to the IT auditability and security aspects of their system.</p> <p>Given we do not have knowledge of your system or verification tools we cannot be more specific, however please consider aspects such as audits, system validation, audit trails, electronic signatures, and the documentation for the proposed software/ systems.</p>

Sl. No	Question	UNICEF Answers
20	<p>GTR must support Parent/Child hierarchies among Products</p> <p>Could you explain in more detail about the hierarchies of products?</p>	<p>GTR-REQ-155 refers to the ability for the system to manage aggregation.</p> <p>Please refer to the following document from GS1 for more information.</p> <p>https://www.gs1.org/docs/healthcare/Publications_position-papers/Aggregation-Paper-Pharma-Supply-Chain.pdf</p>
21	<p>Must be able to identify the geographic location down to at least the country, from the Geolocation information supplied by the verification tool (app). This is so that any alert can be sent to the appropriate contact. This could also be achieved by having a country field within the verification tool which is sent as part of the verification request.</p> <p>Could you provide more detailed information about what is the verification request to be made ?</p>	<p>Please refer to Scenario 1, Appendix B6: Use Cases for GTR within Annex B, for further information on how the verification should operate.</p> <p>For serialised products the verification is expected to be carried out against the GTIN and Serial number + Batch and Expiry information.</p> <p>For non-serialised products the verification is expected to be carried out against either the GTIN or SSCC plus the Batch and Expiry information.</p>
22	<p>GTR must employ an architecture which simplifies upgrades required to support new extension fields</p> <p>Could you specify more details about new extension fields?</p>	<p>With reference to GTR-REQ-095; the EPCIS standard provides for data elements not specified in the standard to be included in EPCIS events as extensions. This is done by including additional XML elements just before the closing tag for an event.</p> <p>Please refer to GS1 published information on the EPCIS standard.</p>
23	<p>GTR must employ an architecture which simplifies upgrades required to support new External messaging output file formats as needed per market regulations</p> <p>What are the types of file format to create output?</p>	<p>See Question Sl.12 above as this has already been answered.</p>

Sl. No	Question	UNICEF Answers
24	GTR must maintain versioning of location master data Will the master data locations be versioned on a country basis?	In reference to GTR-REQ-068. It is not expected that the system will have to use location master data e.g., GLN's for verification purposes. This would only be relevant if the system was tracking products. However, any location could be updated irrespective of where it is, therefore location master data is not versioned on a country basis.
25	May we know what are the 4 selected countries to deploy the solution in the short term?	This is still under discussion and so we cannot confirm these now, however we do expect these to be within Africa.
26	Can we have an estimate of how many nodes there will be in the supply chain of the selected countries?	Given that the GTR will initially be used as a verification system and not a traceability system, we have not yet carried out any supply chain modelling or analysis. Our assumption is that the verification tools covered in GTR-REQ-224 – 227 could be downloaded and used by any number of verification users in country and that there will be no need to deploy to specific supply chain nodes such as a pharmacy or wholesaler, as you would with a traceability system. Therefore, we have not provided any data on supply chain nodes and do not believe they are relevant to this RFPS. If you feel this is incorrect and it is necessary to know the number of nodes as part of your submission, please state the assumptions you have made within your submission.
27	How many points of dispense will there be in the selected countries?	Please see the answer to SI.26

Sl. No	Question	UNICEF Answers
28	Is cold chain monitoring considering an added value?	<p>Cold Chain monitoring does not feature in any of the requirements of this RFPS and therefore the ability to provide this may be of interest but will not influence the scoring of your proposal.</p> <p>Cold Chain monitoring is more likely to be a feature of a traceability system, rather than a verification system, the GTR is not intended to be used as a traceability system initially.</p> <p>Please feel free to include details of other features and capabilities your system provides above and beyond those covered in the RFPS if you wish.</p>
29	About the security of the platform, is SOC 2 Type 2 an acceptable compromise to ISO27001?	<p>Since UNICEF is aligned ISO270001, vendor is expected to map SOC 2 with ISO270001 provide the mapping. If vendor has been with certified minimum compliance with ISO.</p>
30	Do you expect to use the same app and function for all the different types of users?	<p>No, we do not expect to use the same app and function for all the different types of users. Verification users will use the app as described in GTR-REQ-225 – 227.</p> <p>Dashboard users will access the GTR/ Dashboard directly using a Web UI through their user account.</p> <p>Note: verification will not be done through a Web UI as the scanning of the barcodes e.g. 2D DataMatrix or GS1-128, cannot be controlled, therefore there is a potential for the introduction of corrupted scanned data.</p> <p>For further information on the different system users, please refer to Annex B, Appendix B6: Use Cases for GTR, scenario 1 and 4.</p>

Sl. No	Question	UNICEF Answers
31	Referring to TOR p.17, 8.1, a) In the technical “Detailed understanding of UNICEF requirements”, what kind of content is expected? A summary of our proposed solution in line with the requirements?	<p>A detailed understanding of UNICEF requirements can be demonstrated in several ways, including (but not limited to):</p> <ul style="list-style-type: none"> • Clearly demonstrating that your system meets the Requirements Compliance Sheet – Appendix B3. by referencing the relevant section of your proposal against each requirement. • Providing a Project plan which shows how the system will be developed, tested, deployed, and operated. • Through a demonstration of your system which shows how your system meets the scenarios documented in Annex B, Appendix B6: Use Cases for GTR.
32	In reference to the RFPS p. 18, 1.9.3, we understand the proposal can be sent by email in batches of 10 megabytes per email. Is there a limit in the total size or pages for the technical proposal?	No, there is no limit, as long as the size of the email including attachment(s) doesn't exceed 10 MB.
34	Regarding technical requirements “GTR must provide notifications using standard communication protocols including” Does the requirement imply storing all communication for future reference or only ability to send notifications?	GTR-REQ-169 only covers how the notifications must be sent. GTR-REQ-124 covers the requirements regarding storing communications.

35	<p>Regarding technical requirements “In addition to the scanned data from the pack, the application must be able to capture other related data from the phone such as time and location. Where personal data has entered into the app and made available, this must also be made available to the dashboard.” Does this mean PII or just user ID?</p>	<p>UNICEF does not intend to collect personal information on the verification user. The data captured during a verification request should include the mandated elements:</p> <ol style="list-style-type: none"> 1) The data contained in the barcode being scanned. 2) The time and date of the verification request. 3) The geo-location of the verification request. <p>In addition, there will be two more optional data fields which we have classified as persona data, rather than personal data, as it is not intended to identify an individual.:</p> <ol style="list-style-type: none"> 4) A location e.g., City Hospital, Country A 5) A role type e.g., Healthcare professional, Investigator, etc.  <p>The diagram illustrates the data flow and components of the Global Trust Repository system. At the top, a Dashboard (represented by a monitor icon) is connected to the Global Trust Repository (represented by a cloud icon). A label 'User log on account details' points to the dashboard. The Global Trust Repository is the central hub, connected to three main entities: Manufacturer (represented by a factory icon), Pack (represented by a box icon with a barcode), and Persona (represented by a person icon with a stethoscope). The Manufacturer sends data to the repository: 'Serialized batch data or just batch data (if serialization is not available)' and 'Product master data'. The Pack sends data to the repository: 'GTIN/ SSCC', 'Serial Number', 'Batch/ Lot', and 'Expiry Date'. The Persona sends data to the repository: 'Geo-location', 'Time/ Date', and 'Location Role type'. The Global Trust Repository also sends data to the Smart Device (represented by a smartphone icon), which is connected to the Persona.</p>
----	---	---

Sl. No	Question	UNICEF Answers
36	<p>Regarding the technical requirements “There is a check carried out by the app to ensure the expected data is captured prior to sending a verification request to the GTR. This will prevent the GTR returning negative verification requests when the incorrect barcode is scanned, or the data has been encoded incorrectly.” Can you please provide more details?</p>	<p>There may be several barcodes on the secondary packaging and additional barcodes on the other components of the pack (vial label, leaflet, shipping container, etc.).</p> <p>It is possible that the verification user will scan the incorrect barcode e.g. During a verification request a QR code containing a URL is scanned, rather than the 2D DataMatrix containing the GTIN + Serial Number.</p> <p>The verification application should check that the expected data for the service being requested has been scanned.</p> <p>There are some benefits to the GTR being made aware of incorrectly formatted / encoded GS1 DataMatrix barcodes, as this could be an indication of a falsified product.</p> <p>We will leave the proposer to explain how they will meet GTR-REQ-020 and how they may manage other scenarios such as incorrectly formatted and encoded data.</p>
37	<p>Regarding requirements “The Proposer will provide support to the investigation activity following a verification failure or suspect activity.” Can you provide more details on the expectation regarding investigation assistance? Is there any legal implication or liability across countries jurisdictions? Is it only to assist with understanding the data provided by the system?</p>	<p>Regarding GTR-REQ-192, the support to the investigation relates to assistance with understanding and obtaining data within the system and subject matter expertise on the possible root causes of a verification failure from a technical perspective.</p>

Sl. No	Question	UNICEF Answers
38	Are there geography boundaries for the different users of the system? Are users distributed world wide or limited to certain regions or countries such as Europe and Africa for instance?	<p>At this point it is not possible to provide information on the distribution of users geographically, as this will only become evident as the country engagement and deployment planning processes progress.</p> <p>There are primarily two types of users, and it may be useful to consider these differently.</p> <p>1) Verification application users, these will make up the majority of users and will be distributed across the 92 AMC countries in which the verification of COVID-19 vaccines is implemented in. It is important to note that these users do not have any access to the GTR or Dashboard and only need to download an app to have the ability to verify. See the following link for information on the 92 AMC countries:</p> <p>https://www.gavi.org/news/media-room/92-low-middle-income-economies-eligible-access-covid-19-vaccines-gavi-covax-amc</p> <p>Although there are 92 AMC countries, we can expect adoption of verification to focus on around 25-30 initially, however these have not been defined.</p> <p>2) Dashboard users. This is a smaller number of users, estimated at around 200. They will have a user account to be able to access the GTR Dashboard. They will consist of representatives from the countries in which verification is deployed into, likely to be 3-7 people per country. This group will also include several people from each of the manufacturers of the vaccines and several users from the organisations which govern the system.</p>

Sl. No	Question	UNICEF Answers
39	Can we add more than 3 references? We may use the same template and requirements.	You are welcome to add more references, but please be aware we will focus our efforts on contacting the first three, so ensure you prioritise the first three based on this.
40	GTR-REQ-029 Is there a list of the different types of verification implied ?	<p>In simple terms a verification can either be positive or negative, however there may be other responses such as product out of scope of system, or not enough information to complete the verification.</p> <p>The responses may be governed by the functionality and capability of your proposed system, please make this clear within your submission.</p>
41	GTR-REQ-209 What exactly constitutes "suspect activity" (product may be exported therefore scanned in multiple countries) ?	For an understanding of suspect activity please refer to Scenario 3, Appendix B6 of Annex B.
42	GTR-REQ-007 SSCC can be verified but can not be characterised as an indicator of the product legitimacy.	This is correct, however combining the SSCC with batch and expiry may provide some opportunities to detect potential falsified products or monitor for suspect activity.
43	GTR-REQ-026 Are batches expected to be serialized? ?	<p>Serialization will occur at the secondary pack level using a GTIN and Serial Number in accordance with GS1 Standards. The 2D DataMatrix will include four data elements: GTIN, Serial Number, Batch and Expiry.</p> <p>Some manufacturers may not be technically capable of serialising the secondary pack, however if they are able to provide the batch details (GTIN, Batch and Expiry Date) then verification can be carried out at this level, although it is recognised that this is less effective than at a pack level.</p>
44	GTR-REQ-071 & GTR-REQ-072 Could you describe the use case associated with those requirements ?	The use case would involve validating that returned products should be physically accepted. The Unique identifiers would be used to look up other data describing them to assess the suitability of the product to be returned.

Sl. No	Question	UNICEF Answers
45	GTR-REQ-074 which property(ies) of the lot/batch is expected to updated ?	<p>When tracing a product, the serial number can be assigned different status, changing the status of all serial numbers in a batch is one scenario. An example of having to do this could occur if a batch fails a quality check and as a result all the serialised items must be changed to “destroy”.</p> <p>Note: The GTR is not initially going to be used as a traceability system and so this requirement is unlikely to apply in the short term.</p>
46	GTR-REQ-058 what about regulations or requirements coming into effect sooner than 6 months?	If a regulation provides less than 6 months lead time, then we would expect the provider to have the system ready in time to comply with the legislation. It is unusual and not likely that a regulation which has IT traceability system implications would give such a short lead time.
47	GTR-REQ-192 what is the nature of support expected	See question SI.No 37 above.