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1 Document References

1.1 Internal References

Document ID	Version	Title
n/a	n/a	n/a

1.2 External References

Document ID	Version	Title
n/a	n/a	RFPS-NYH-2021-503343 Development of Global Trust Repository
n/a	n/a	UNICEF Security Requirements Appendix D
n/a	n/a	Annex B_Global Trust Repository - ToR
n/a	n/a	Requirements Compliance Sheet Appendix B3 \ Table B
n/a	n/a	Annex A Unicef General Terms

1.3 Attachments




ATT	Title
n/a	n/a





2 Purpose & Scope




This document contains all questions that have arisen from Arvato Systems in the course of working on the documents listed under External References to prepare the proposal to RFPS-NYH-2021-503343. Arvato has compiled the questions with a reference to the respective tender document in the table below and enclosed a detailed description for some of the questions, which may support the answer to the question. The JIRA references listed are internal references used for processing the tender.





Arvato would be very pleased if the "UNICEF Answer" column is used to answer the questions and respond to the questions until June 29th 2021 End of Business New York's local time.




3 List of Questions





#	Tender Document Reference	Question	JIRA Reference	Detailed Description	UNICEF Answer
1	UNICEF Security Requirements Appendix D	The document lists the "UNICEF Identity Management System" - is there a description or an SDK available to get connection to this system?	 GTR-10	It is unclear, how the connection to the UNICEF Identity Management System should work or which technology it use.	UNICEF uses Both Microsoft Azure AD and ADFS and expects vendor to use latest Microsoft Identity Platform Authentication libraries.
2	UNICEF Security Requirements Appendix D		 GTR-18	Wording is unclear. The reference "Systems availability shall be set according to Service Level Agreements, to meet the Confidentiality, Integrity and Availability requirements commensurate with its classification, as noted above" is not clear.	The vendor is expected provide their standard SLAs related availability and uptime.
3	UNICEF Security Requirements Appendix D	Which regulation for the deletion period of personal data shall be used?	 GTR-19	After what period of time, personal data shall be deleted?	The period of inactivity has not been established at this point. Please work on the assumption that accounts for Dashboard Users should be locked after 2 months of inactivity and then the personal data removal process triggered after 6 months.



4	UNICEF Security Requirements Appendix D	assets' inventory related to UNICEF	 GTR-32	It is unclear, in which way the information shall be distributed during the update process.	Assets here are hardware, network, software components making up the system. System elements that comprise the system or solution. The vendor has a list available.
5	UNICEF Security Requirements Appendix D	How shall failed patches be documented? From which level is this requested?	 GTR-47	From our pov it does give an added value, to document each failed build on an internal DEV or QA-environment. Nevertheless it is possible to have a system based documentation in the development tools.	UNICEF would need this information in case there is an incident and the vendor is expected to have that information available. Vendor has measures implemented to track and related documentation.
6	UNICEF Security Requirements Appendix D	How shall an incident communication work - by phone, mail, SMS?	 GTR-57	Way of communication is unclear.	Depending on confidentiality the vendor can communicate using email (if it is confidential by Phone). This will be also decided on per incident basis.
7	Annex B_Global Trust Repository - ToR	Is a documentation available for the UNICEF training platform.	 GTR-77	We are currently not familiar with the UNICEF training platform. To provide a proper plan, it is essential to get some insights about the used tool, to estimate the amount of work to prepare the training material.	UNICEF has Totara based platform that accepts SCORM compliant training and elearning materials" Additional details here




8	Annex B_Global Trust Repository - ToR	To which point in time the integrity certificate shall be delivered.	 GTR-90	Our proposal, we can provide a first draft in the tender documentation and the final confirmation at the end of the development, by handover of the software for customer tests.	The vendor is expected to provide results of assessment of code & vulnerability (security)
9	Annex B_Global Trust Repository - ToR	According to our internal policy, security tests need to be requested in advance, just to inform the system operating.	 GTR-93	The right can be granted to UNICEF, but just with an agreement to request the test 4 weeks in advance.	Yes. We will request with adequate notice.
10	Annex B_Global Trust Repository - ToR	Is the upgrade of the API's in the Maintenance and Support section also related to the "Scale Up" scenario?	 GTR-94	If yes, we need to calculate the operational costs a bit higher, just to cover the additional effort for a new interface.	<p>The purpose of the "Scaled scope" within the Price Schedule is to understand the annual subscription costs should the scope of the system increase.</p> <p>The scaled scope aims to model an increase in the number of SKUs, Dashboard Users, Countries, Serialised packs and Verification events. All other factors should remain the same between the two scenarios. Therefore the number of APIs and Verification Tools does not alter between the Baseline scope and the Scaled scope.</p>



					<p>Both scenarios require the maintenance of three API's:</p> <p>1) National app linked to GTR,</p> <p>2) National traceability system linked to GTR,</p> <p>3) Local system linked to GTR</p>
11	Annex B_Global Trust Repository - ToR	Can the maintenance downtime be added to several months, e.g. if you need a longer downtime in a quarter, but no monthly downtime?	 GTR-111		<p>Ideally the maintenance downtime should not be rolled over as this would prevent products from being verified for a longer in a single period.</p> <p>However, we understand that this may be unavoidable and so this should only happen with prior notice and kept to a minimum.</p>
12	Table B	How is "Alert" defined within GTR-REQ-052?	 GTR-130		GTR-REQ-052 relates to the verification and suspect activity events which are notified to Dashboard Users.
13	Table B	Is GTR-REQ-211 only related to the reporting dashboard, or is this also a requirement for the entire system?	 GTR-133		GTR-REQ-211 relates to Dashboard Users only.
14	Table B	GTR-REQ-237 requests a number of local contacts to inform about a suspect event.	 GTR-135		This will vary by country but is expected to be in the range of 3 - 7 contacts.







		How many contacts should be informed by country?			
15	Table B	GTR-REQ-055 - How many market regulatory systems have to be connected? Is there a related use case available?	 GTR-138		<p>Very few of the 92 AMC countries have traceability systems in place, therefore we do not expect to connect to market regulatory system initially.</p> <p>https://www.gavi.org/news/media-room/92-low-middle-income-economies-eligible-access-covid-19-vaccines-gavi-covax-amc</p> <p>If any market regulatory system is connected then this would be achieved using API described in GTR-REQ-227, however we would not forecast this being any more than one or two countries at most.</p>
16	Table B	GTR-REQ-056 - Is a definition of market regulations available to be planned and implemented?	 GTR-138		We would expect the selected vendor to comply with GTR-REQ-057 and therefore monitor market regulations and be aware of the most up to date requirements.
17	Table B	GTR-REQ-064 - Is a list of all market regulatory required location attributes available?	 GTR-138		The GTR will not initially be used for traceability and therefore we do not expect that there will be any



					location master data regulatory requirements at this point.
18	Table B	GTR-REQ-065 - Can you please describe a use case, where this is relevant - just to get an understanding.	 GTR-146		<p>GTR-REQ-065 requires that a location could be identified using several different identifiers such as a GLN and an MRP reference number.</p> <p>The GTR will not initially be used for traceability and therefore we do not expect there will be a need to identify locations initially.</p>
19	Table B	GTR-REQ-073 - Shall the Recall be done on a Batch - or on Product level?	 GTR-146		Recall should be carried out on a batch level.
20	Table B	GTR-REQ-076 - Does the requirement mean, that different stakeholder shall receive a subset of the data available in the system?	 GTR-157		GTR-REQ-076 requires that in addition to the standard GS1 data sharing standards e.g. EPCIS/ GDSN, that the GTR is able to meet any other message formats as required by regulators. This would typically require the configuration of an output file based on the data stored in the GTR.
21	Table B	GTR-REQ-080 - This requirement is unclear for now. Please specify the related use case, where the data shall be managed.	 GTR-157		An example would be the disaggregation of child items from a parent item, based on traceability event data which indicated that




				<p>some of the child items had been destroyed.</p> <p>Note that the GTR will not be used as a traceability system initially and so the management of aggregation is not required at this point.</p>
22	Table B	GTR-REQ-007 - is a description about the "against specific rules" available?	 GTR-196	<p>There are two elements to GTR-REQ-007.</p> <p>Firstly that the message provided in response to a verification request can be configured against a rule, for example that a different message can be provided to country A vs country B.</p> <p>Secondly that depending on the result of the verification, the response can be configured for example a different message can be sent if the GTIN and Serial Number is known, but the batch does not match versus the expiry date not matching.</p>
23	Table B	GTR-REQ-011 - which information shall be reported within the "compliance report"?	 GTR-208	<p>GTR-REQ-011 refers to the reporting of data to national systems.</p> <p>The requirements for this would most likely be driven by local legislation.</p>




					<p>This could include uploading the product master data for an item, as an example.</p> <p>This is typically the generation of a standardised output file (or report) based on data held in the system.</p> <p>This requirement is not expected to be needed until the GTR is operating as a traceability tool as there is no need to report to national systems currently.</p>
24	Table B	GTR-REQ-004 - Any size information available, GB, TB, PB?	 GTR-226		No specific size information is available, however the system should be able to manage typical serialised batch sizes.
25	Table B	GTR-REQ-218 - How is a "System User" defined, and which applications should be integrated?	 GTR-232		<p>GTR-REQ-218 refers to the Dashboard Users and therefore monitoring how these users utilise the system and which features they make use of.</p> <p>Please note that this is an optional requirement.</p>
26	Table B	<p>GTR-REQ-152 - to which point in time are the master data attributes completed?</p> <p>Target Market(s) as ISO code?</p>	 GTR-238		The product master data should be uploaded by the manufacturer, prior to the uploading of serialised batch data.


					<p>Please note that as the GTR is initially going to be used as a verification system, several of these master data fields are unlikely to be mandated initially. We are also likely to keep the master data set to a minimum to reduce the workload for manufacturers.</p> <p>The Target market field will not be completed initially. COVID-19 vaccines typically use a common GTIN and split batches across countries therefore the target market field is not of any use.</p> <p>If and when the Target Market field is mandated we would use an ISO code.</p>
27	Table B	GTR-REQ-158 - Wording of the requirement is unclear. What exactly is meant by "when created or modified in formats received by the receiving system (e.g. EU EMVS / Hub)" ? Is an example use case available to get a clear picture of the requirement?	 GTR-243		GTR-REQ-158 Agree that the wording is not clear, this simply means that the product master data held in the GTR must be exportable to other systems.
28	Table B	GTR-REQ-216 duplicate to GTR-REQ-162?	 GTR-262		Correct.


29	Table B	GTR-REQ-222 contradicts GTR-REQ-028. If a solution for GTR-REQ-028 is implemented, the GTR-REQ-222 should be obsolete. If not, please specify the differences between the requirements.	 GTR-275  GTR-282		<p>GTR-REQ-028 specifically seeks to ensure we do not provide a verification failure message where the GTIN is not held in the GTR.</p> <p>GTR-REQ-222 may cover a scenario where the Serial Number, Batch and Expiry match a record but the GTIN is not known. We may or may not decide to manage the response differently to a situation where neither the GTIN, Serial Number or Batch is known.</p>
30	Table B	GTR-REQ-102/GTR-REQ-116 - (non) EPCIS Query Interface - which information needs to be queried and by whom?	 GTR-181  GTR-192		<p>Given that the GTR will not be initially used for traceability there are no specified event queries defined currently.</p> <p>Many of the EPCIS/ Traceability requirements have been included in the event that the GTR evolves into a traceability system in future.</p>
31	Table B	GTR-REQ-053-GTR-REQ-056 - specification & prioritization of markets needed	 GTR-136  GTR-139	The markets listed in that requirements have different regulatory aspects which have an impact on the implementation. Is therefore a prioritisation possible?	The GTR will not initially be used for traceability and the majority of the COVAX 92 AMC countries have no traceability systems in place.




				https://www.gavi.org/news/media-room/92-low-middle-income-economies-eligible-access-covid-19-vaccines-gavi-covax-amc
				<p>Therefore GTR-REQ-053 and GTR-REQ-056 are not relevant currently.</p>
32	Table B	GTR-REQ-065-066 - can this be handled as one requirement?	 GTR-146  GTR-147	<p>If you feel your solution is able to handle this as a single requirement then please state this and make reference in the "Requirement Compliance Sheet Appendix B3.</p> <p>However these are slightly different, GTR-REQ-066 is the need for a location to have a parent or child relationship with another location, for example a bay within a warehouse, where the warehouse is the parent and the bay is the child.</p> <p>GTR-REQ-065 simply requests that a location can have more than one identifier, this could be a GLN and proprietary location number, allocated from another system such as an MRP system.</p>

33	Table B	<p>GTR-REQ-069 - Which events are relevant? Commissioning, (Dis-)Aggregation, Shipping etc.</p> <p>Which context does this refer to? Should this comprise all events per pharmaceutical company, per country etc.?</p>	 GTR-150	<p>For a specific GTIN + Serial Number it must be possible to report all events which have occurred in chronological order. This would include commissioning, aggregation, shipping etc.</p> <p>The EPCIS/ Traceability requirements in the "Requirements Compliance Sheet Appendix B3" have been included to cover the situation where the GTR develops from a verification system into a traceability system. However the GTR will initially only be used for verification, therefore we can not be more specific about GTR-REQ-069.</p>
34	Table B	GTR-REQ-071 - Which criteria should identifiers be validated against?	 GTR-152	An example would be that the Unique Identifiers have a status in the system of destroyed.
35	Table B	GTR-REQ-072 - Where should alerts be displayed? Who is the recipient of the alert?	 GTR-153	The EPCIS/ Traceability requirements in the "Requirements Compliance Sheet Appendix B3" have been included to cover the situation where the GTR develops from a verification system into a traceability system. However the GTR will initially only be used for

					verificaiton, therefore we can not be more specific about GTR-REQ-072.
36	Table B	GTR-REQ-075 - What is meant by "execution of business rule"?	 GTR-156		This is similar to point (D) but driven by a business rule rather than a business transaction. An example could be that the business transaction "batch completed" has occurred and the prodcut has been QA released.
37	Table B	GTR-REQ-004 - Do we have any idea which volume is expected?	 GTR-226		No specific size information is available, however the system should be able to manage typical serialised batch sizes.
38	Table B	GTR-REQ-201 - What exactly is meant here? Should the system support partially reported batches & incremental updates or expect to receive all information in one file?	 GTR-226		There must be a method of ensuring that the entire set of serialised batch data has been receieved, so to avoid missing serial numbers for a batch e.g. if the batch has 10,000 serial numbers the system must be able to ensure that all 10,000 have been received.
39	Annex A Unicef General Terms	We understand the RFP section 2.1 as follows: The proposer is allowed (i) to list its amendments to the GTCs in		This is correct in the sense that the vendor proposed amendments would have	Vendors have the option to put a separate sheet with the UNICEF clause and the amendments the

		<p>his Proposal and (2) that - in the event of awarding the contract to Proposer - the contract will include the amendment list.</p> <p>Are we correct in this assumption?</p>		<p>been negotiated between the parties and if agreed, then included in the contract.</p>	<p>vendor is proposing. The eventual contract will reflect the negotiated and agreed wording as applicable.</p>
40	Appendix B1: General Service Level Agreement (SLA)	<p>Annex B1, 11.3 p. 27 defines a "System Availability" with 99,5%.</p> <p>In Annex B2, GTR-REQ-229 defines "99,95 % availability outside of regular housekeeping and planned outages."</p> <p>Do both figures have different scope/ definition or is this an error. Please explain.</p>			<p>This is an error and both should read 99.95%</p>
41	RFPS-NYH-2021-503343 Development of Global Trust Repository	<p>There are two links provided which should be reviewed, but both links lead to a http 404 error (page not found)</p>		<p>http://www.unicef.org/supply/index_procurement_policies.html</p> <p>http://www.unicef.org/supply/index_procurement_policies.html</p>	<p>Both links are identical, here is the functional one:</p> <p>https://www.unicef.org/supply/sources/procurement-policies</p>
42	Appendix B1: General Service Level Agreement (SLA)	<p>What are the requirements regarding a helpdesk?</p>	 GTR-111	<p>Which contact channels should be provided (phone, mail, ticket)?</p> <p>Which service times are required for which time zones?</p>	<p>Contact channels</p> <p>Please state what options are available, we would most likely expect this to be managed by a ticket system.</p> <p>Service times and time zones.</p>

				<p>In which languages should helpdesk services be offered?</p> <p>Which volumes of requests are expected per country and channel?</p> <p>Is there a project plan existing for go live of countries/languages required?</p>	<p>We have made the assumption that verification would occur during normal business hours and therefore we need to cover 9am – 5pm support, locally. The majority of 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> <p>Volumes</p> <p>As this is a new system without any similar previous capability having been operated, there are no volumes to base this on.</p> <p>Project Plan</p> <p>This is being developed in parallel and so there are no details available currently.</p> <p>Languages</p> <p>French and English as a minimum, please state any others that you are able to support.</p>
43	Annex B_Global Trust Repository - ToR / Scalability	How many users are expected to use the verification service by App?	 GTR-66	Based on the Baseline and Scale-Up scenario it is not clear, with how many end user, who are allowed to scan a	We do not have any estimation of the number of verification app users at this point.

				<p>pack, we have to calculate. Please provide us some figures for a first estimation.</p>	<p>The only volume number we can provide is an estimated number of verifications per year of 4-5 million.</p> <p>If you need to make an assumption on this please state this clearly in your proposal.</p>
44	Annex B_Global Trust Repository - ToR / Scalability	How many user need to be registered / onboarded to the system per country?	 GTR-66		<p>It is only the Dashboard Users and System Administration roles that would need to be onboarded to the GTR system. There are a total estimated number of 200 users and around 3-7 per country. The number of 200 also includes manufacturers and representatives for the governance group to onboard as Dashboard Users.</p>
45	Annex B_Global Trust Repository - ToR / Demo	Should the verification request to the scanning station indicate that the scanned pack / item is already flagged with suspicious activities?	 GTR-102	<p>It is currently not apparent in the flowchart of scenarios 1-3 how suspicious activities should flow back into the verification process (scenario 1).</p>	<p>Please indicate in your proposal if your system has this capability. Currently we do not intend to feedback suspicious activities, however this may be something which we review as we finalise the system and tools.</p>
46	Annex B_Global Trust Repository - ToR / Demo	What is the desired result when requested in a verification with an	 GTR-102		<p>The data received from manufacturers will depend on the capabilities they have in place i.e.</p>

		SSCC. What should be returned to the scan point?			<p>A) Serialised batch data, B) Batch data or C) no data at all.</p> <p>Verification can either be undertaken using:</p> <p>1) The serialization batch data (GTIN and Serial Number + Batch and Expiry) – held in a 2D Data-Matrix</p> <p>2) Just the batch data (GTIN, Batch and Expiry) - where the pack is not serialised – held in a 2D DataMatrix</p> <p>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.</p> <p>The verification of SSCC + Batch and Expiry should operate in the same way as GTIN + Batch and Expiry.</p>
47	Table B	GTR-REQ-225 We assume, that the localized Apps differ only in regards of language and some content, not in structure and functionality, right? How many different localized App versions do we have to expect?			<p>Correct – localised apps are intended only to deal with language, branding, etc, and not to provide any additional functionality.</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.
48	Annex B_Global Trust Repository - ToR / Demo	Should the end user app (Tool A - Central App) be compliant with the UNICEF Style Guide? If so, can you provide us with it?	 GTR-283		The branding of Tool A has not been discussed at this point. If required use generic or dummy branding for any demonstrations.