Traceability and Verification

Session 9 UNICEF UNFPA WHO meeting with manufacturers and suppliers December 2024

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The Verification and Traceability Initiative was created to address the impact of falsified and diverted products

\$30.5 Bn

Falsified vaccines and medicines cost LMICs \$30.5 billion per year.

10.5%

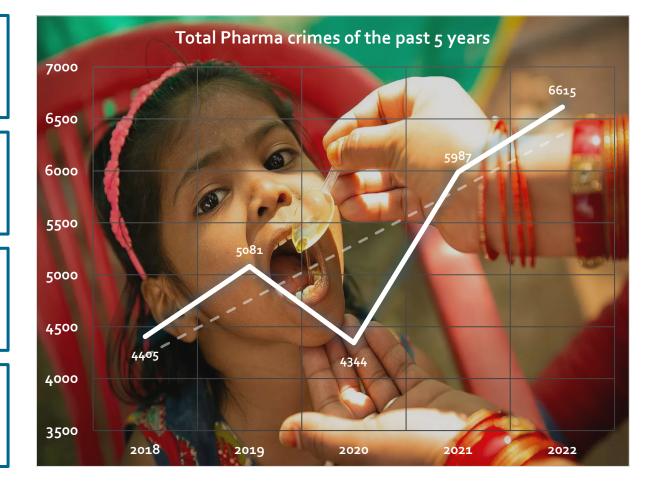
Falsified products accounted for 10.5% of medicines sampled in the supply chain in these countries.

169,000

Estimated 72K –169K deaths caused by substandard and falsified antibiotics in children under 5 suffering from pneumonia*

116,000

Estimated 31K – 116K deaths caused by substandard and falsified antimalarials in sub-Saharan Africa*



Sources

The WHO Member State Mechanism on Substandard and Falsified Medical Products Update 2022

^{*} University of Edinburgh



^{*} Public health and socioeconomic impact study 2017 https://apps.who.int/iris/handle/10665/331690

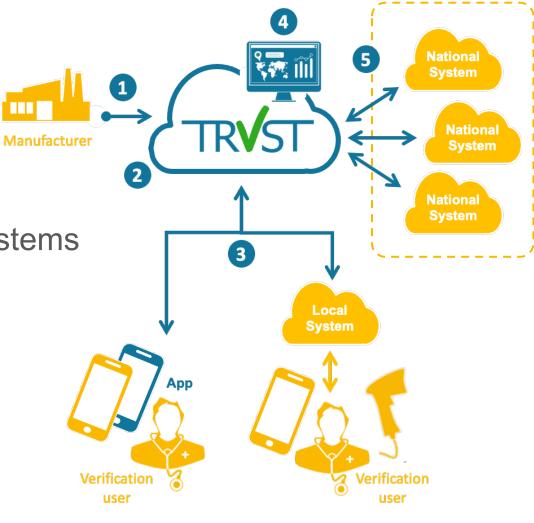
The TRVST system components

- 1) A standard interface to manufacturers
- 2) The TRVST repository

3) Verification API to smart phones and local systems

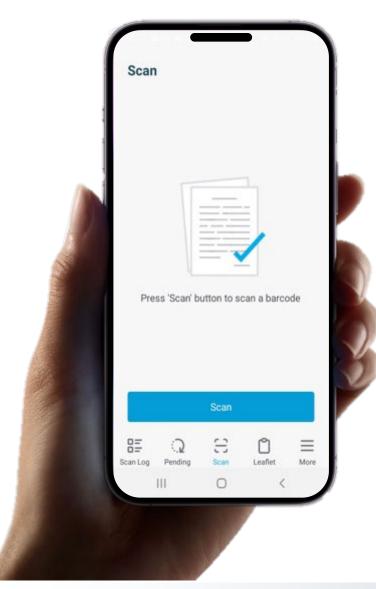
4) The TRVST dashboard

5) TRVST API interface to national systems





The TRVST Application – powerful supply chain surveillance

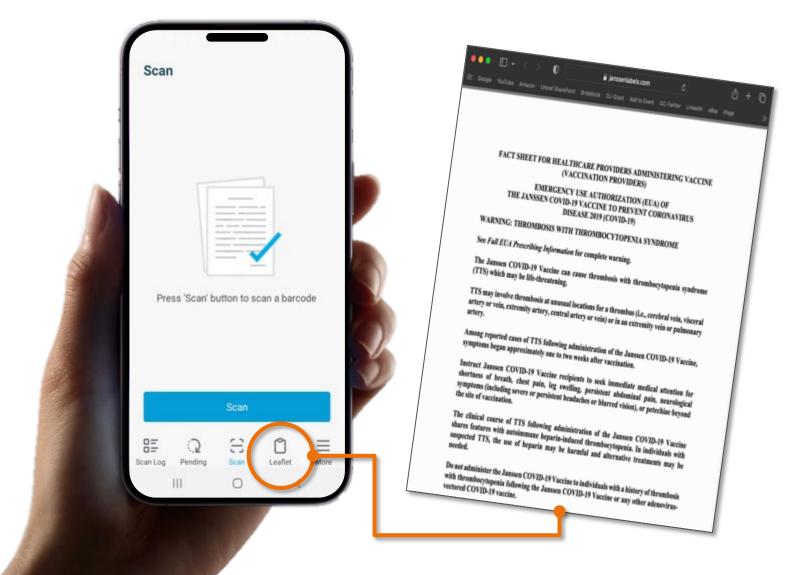


The TRVST application provides access to digital services and content

- Scans and verifies the data in the 2D DataMatrix.
- Can work offline and then upload verification requests once back online.
- The scan also captures the geo-location of the scan with a time and date.
- Available in French and English
- Verification responses can be country specific.
- We can make the app public or put behind passcode access.



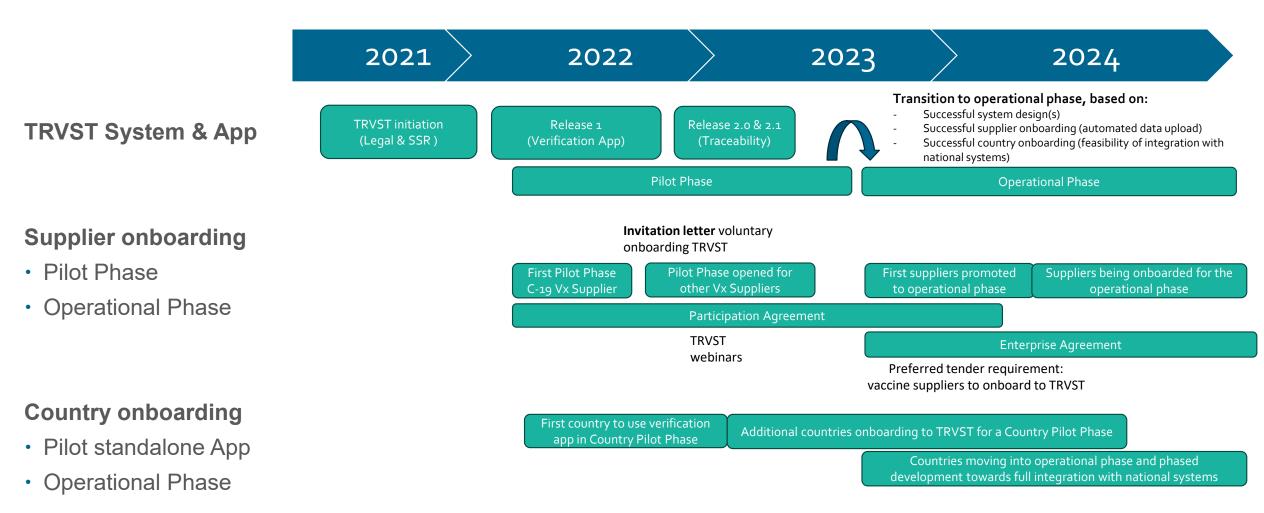
Access to other digital content and services using the TRVST app



- The TRVST also uses GS1 Digital Link Standards to access electronic content using the DataMatrix
- The TRVST leverages the GS1
 Digital Link standards and resolver services to connect to the e-leaflet.
- TRVST can resolve directly to the digital content or redirect to another resolver.
- In addition to verification and e-leaflets other service are provided such as the recall status.



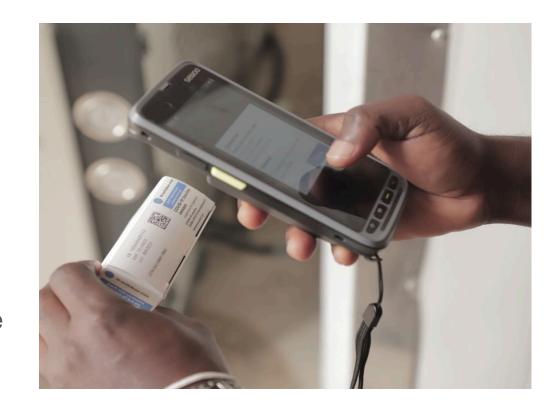
Overview on Verification and Traceability Verification Systems journey till today





There has been significant progress with TRVST

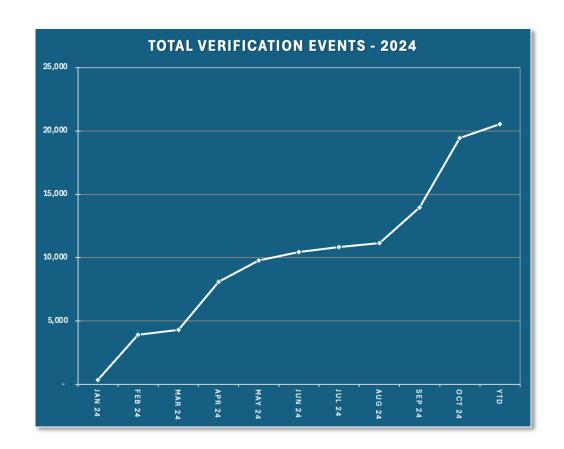
- TRVST has received over **300,000 verifications** in the past 24 months.
 - This represents up to 75M doses of authenticated vaccines.
 - Over 14M serialised packs in the system
- 75% of the vaccines procured by UNICEF are now able to use TRVST, we have commitment from suppliers to drive this up to 86%.

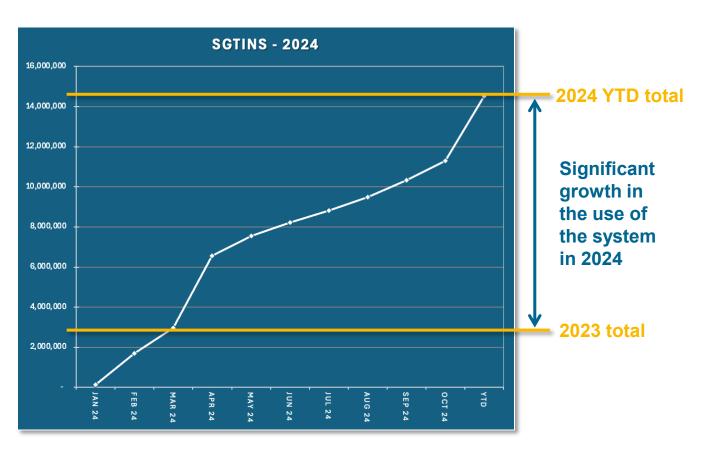


2025 will see further progress as we deploy to more products & countries



Based on 2024 YTD numbers

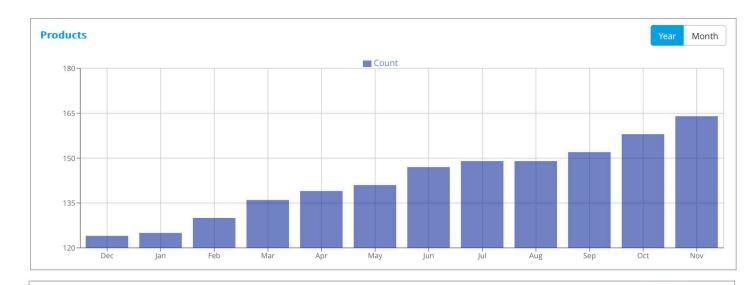




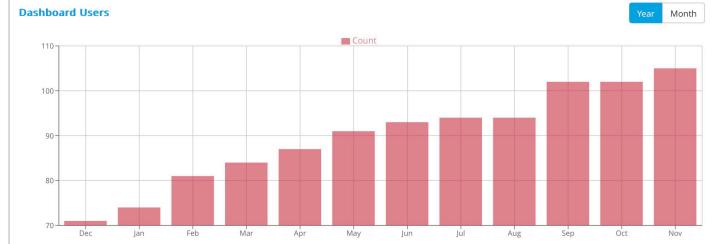
• We achieved a total of **2.7M** last year and we have over **14M** in the system this year a significant increase.



We also see steady growth in system usage



 Manufacturers have uploaded 164 vaccine products.



- System access has been granted to 105 users including manufacturers and country authorities.
- Each organisation can selfadminister their users through their SPOC.



We are live in three countries with Botswana planned in Nov 2024



Nigeria – Modality D

Rwanda – Modality C

Nepal – Modality A

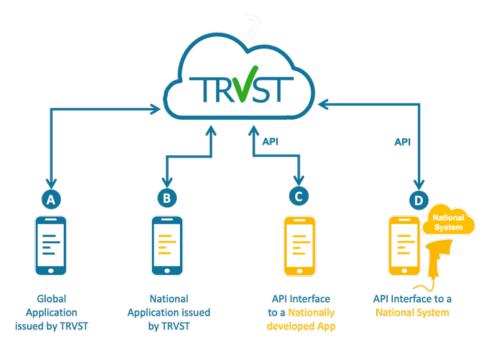
Botswana – Modality A

The reach of TRVST is also growing within the countries

Extensive coverage across the supply chain Nigeria -

Rwanda - Customs and central medical stores. Now moving towards Hospitals and other health facilities

Nepal -Customs, central medical store, provincial stores and district stores (7 provinces and almost 70 districts now live)



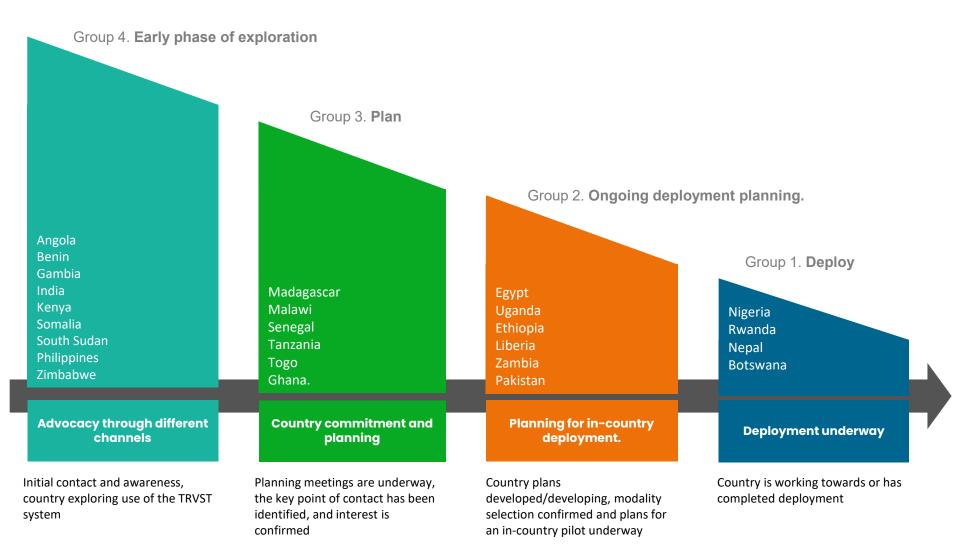




Look ahead to 2025



Increasing onboarding of countries



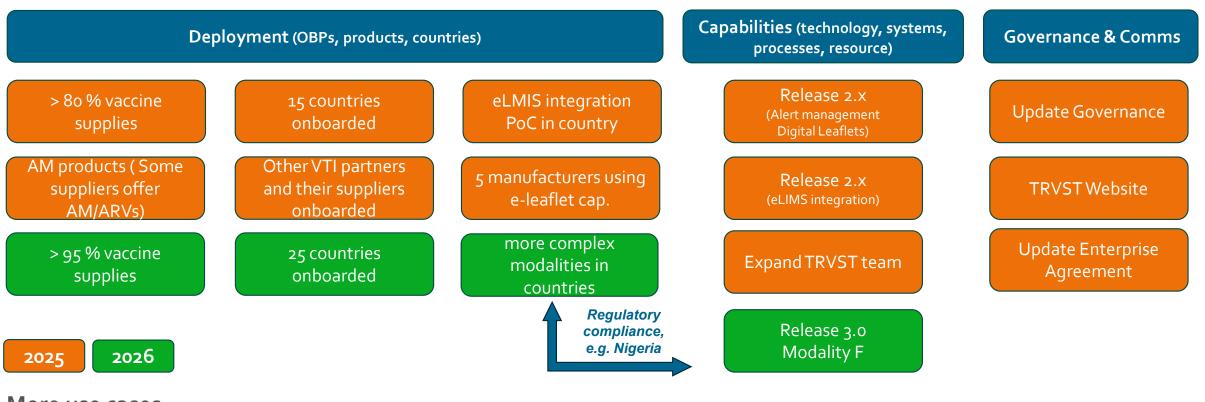
To allow us to accelerate country deployment, next year, we have taken three actions:

- Put in place a dedicated country deployment resource.
- 2. Planning regional workshops for planning and training of countries.
- 3. Country deployment starter set.



Roadmap

• Based on successful pilot phase and shift to operations for vaccines and beyond we have developed a roadmap with following milestones and targets (selection):



More use cases

1st UC: verification

2nd UC: e-leaflets

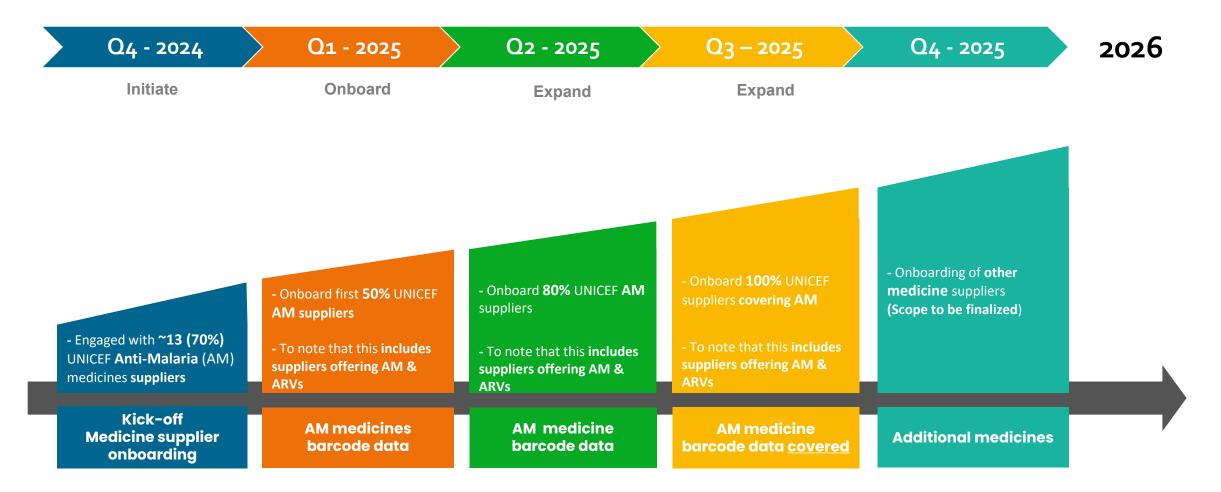
3rd UC: supply chain visibility

2022 - 24



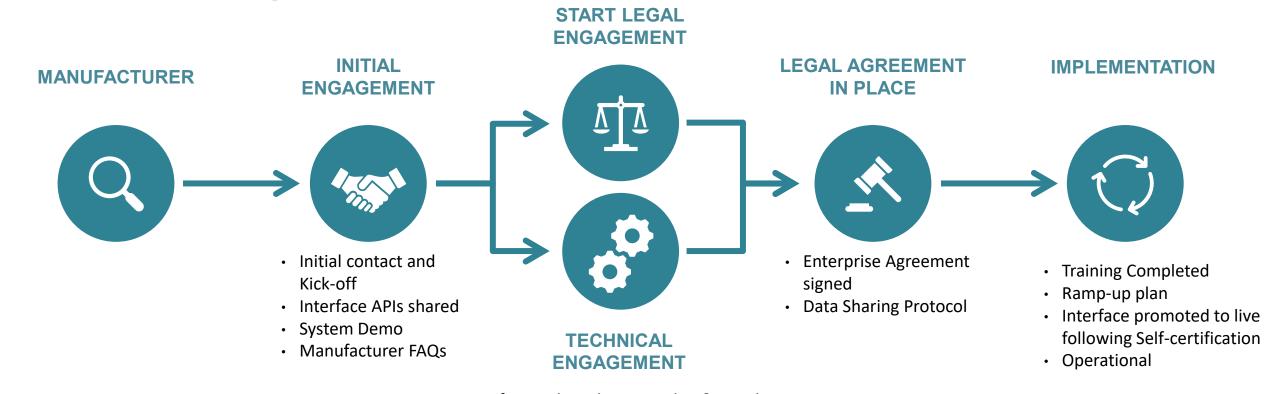
Roadmap – Medicine Supplier Onboarding

Based on successful implementation of TRVST for UNICEF procured vaccines and vaccine supplier onboarding, UNICEF is now working on **fast-track onboarding** of UNICEF **medicines suppliers**:





Onboarding Process





Documentation including interface API, system demo and FAQs can be accessed on:

https://login-ite.trvst4hp.org/Documents

- Define Technical Project Plan & Timeline
- OBP Stakeholder identified, responsibilities discussed & agreed
- Initial product scope agreed
- Interface options presented and agreed
- · Supply chain mapped and upload triggers agreed
- SPOC Identified and setup
- Interface testing (ITE/IQE)

Project plan template									
1	Manufacturer 1	Green		25%	16-Dec-22				
2	Initial contact and kick off complete	Green		100%	16-Dec-22	16-Dec-2			
2	Statement of intent to participate	Green		100%	16-Dec-22	16-Dec-2			
2	OBP Stakeholders identified and responsibilities discussed and agreed.	Green		75%	16-Dec-22	13-Feb-2			
2	Initial product scope agreed	Green		75%	16-Dec-22	13-Feb-2			
2	Interface APIs shared	Green		100%	16-Dec-22	16-Dec-2			
2	Interface options presented and agreed (OBP or OBPE)	Green		100%	16-Dec-22	03-Feb-2			
2	Supply chain mapped and upload triggers agreed	Green		75%	01-Jan-23	24-Feb-2			
2	SPOC Indentified and set up	Green		50%	16-Dec-22	24-Feb-2			
2	Training completed	Green		0%					
2	Interface tested in ITE	Green		0%					
2	Interface tested in IQE	Green		0%					
2	Legal Agreements in place	Amber	Enterprise Agreement Required	0%					
2	Interface promoted to Production	Green		0%					
2	Product ramp up plan in place	Green		0%					
2	Product master data uploaded	Green		0%					
2	First serialisaed batch received	Green		0%					



Supplier Onboarding – TRVST document repository



Documents Repository

	Document Name	Description		Download
	Enterprise Agreement and Governance Documents	Legal agreement to use TRVST and the supporting governance documentation	12/06/2024	8
	OBP-E API Interface	Documentation covering the OBP-E API Interface used to upload data to TRVST	15/12/2023	6
	Frequently Asked Questions	Answers to questions that are frequently asked concerning TRVST	14/03/2023	ß
	Dashboard Terms & Conditions	The Term of Use that TRVST Dashboard users must agree to before using the product	01/06/2022	À
	Mobile App Terms & Conditions	The Term of Use that TRVST verification users must agree to before using the product	01/06/2022	À
	OBP Training Material	Training Curriculum (Master Slide Deck) for On-Boarding Partners	26/02/2024	ß
	OBP Training Material	Training Curriculum for Master Data	26/02/2024	ß
	OBP Training Material	Training Curriculum for Operations Team	26/02/2024	ß
	OBP Training Material	Training Curriculum for Brand Protection/Pharma-Vigilance Groups	26/02/2024	ß
	Country Onboarding	Documentation covering the onboarding of new countries to Modality A&B	31/05/2023	ā
	Country Authority Training Material	Training Curriculum for Country Authorities Modality A&B	25/07/2023	<u> </u>
	Country Authority Training Material	Training Curriculum for Country Authorities Modality C	25/07/2023	ß
	Country Authority Training Material	Training Curriculum for Country Authorities Modality D	25/07/2023	ß



Documentation can be accessed on:

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Enterprise Agreement



OBP API for interface



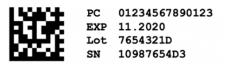
Additional key reference materials for supplier / OBP onboarding

Significant resources to help use TRVST



Next steps

- Onboarding of UNICEF suppliers
 - Initial focus: antimalaria medicines (AM)
 - Move towards firm requirement for onboarding to TRVST (LTAs / RFPs)
 - Other medicines suppliers onboarding (To be communicated)





Anticipated dedicated TRVST webinar with medicine suppliers in 2025

• Beyond UNICEF - Expand onboarding of suppliers from **procuring countries** and other **agencies** in 2025



Thanks for your attention . . . any questions ?









Together we are helping prevent falsification and drive traceability



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THANK YOU