Introduction the the VTI and TRVST

Session 9.1 - Verification, Visibility & Traceability

TRVST

Traceability & Verification System for Health Products

For discussion only – do not distribute

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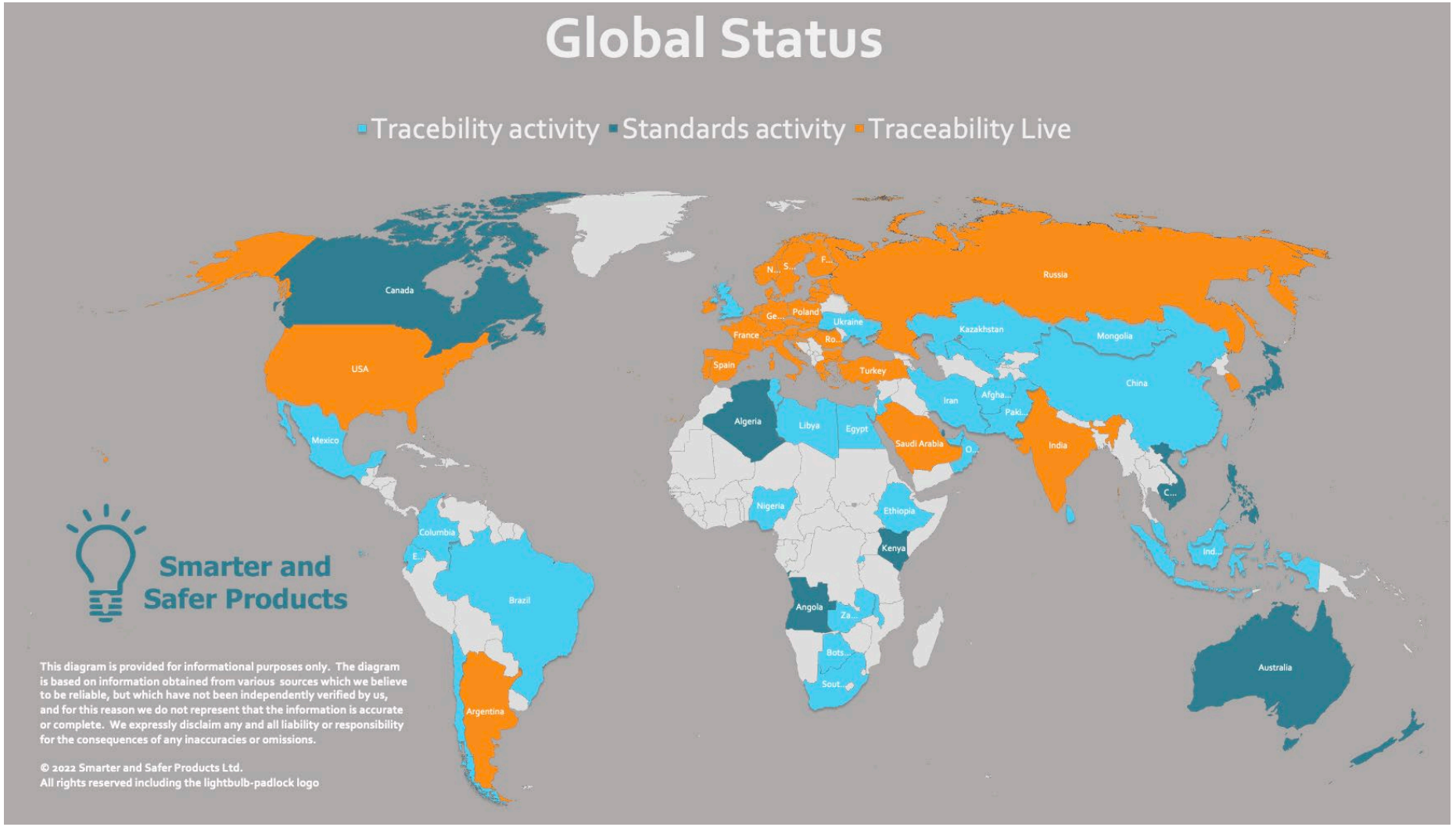
Country implementation & National requirements



- GS1 standards are widely adopted globally in Healthcare.
- Over the past 10 years there has been significant regulatory activity driving the adoption of serialisation and traceability.
- Some multinational pharmaceutical manufacturers serialise up to 70% of all the products they make.

Traceability is becoming an **entry level requirement** to the supply of drugs in Healthcare

TRVST

The impact of substandard and falsified products

- Falsified vaccines and medicines **cost low and middle-income countries (LMIC) $30 billion per year** and over $200 billion globally.
- Before COVID-19, **1 in 10 medical products in LMICs were reported as being substandard or falsified**, potentially causing harm and failing to treat the diseases for which they were intended.
- Counterfeit medicines are estimated to have caused up to **169,000 deaths of children under 5 suffering from pneumonia and 116,000 deaths from falsified medicines to treat malaria**.
- The WHO has received reports from multiple sources of **suspicious offers to sell or supply COVID-19 vaccines to national regulatory authorities or Ministries of Health.**

Reference https://www.unicef.org/supply/stories/first-serialized-vaccine-scan-africa-marks-milestone-tackling-falsified-medical-products

TRVST

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The Verification & Traceability Initiative (VTI)

Goal:

- Enable low and middle-income countries to manage the risk of falsified vaccines and other pharmaceuticals and diversion in their national supply chains, while setting the foundation for the establishment of national traceability systems in the long term

Objectives:

- 1. Support product safety efforts by making available (in the very short term) a verification tool that countries can choose to access and use for managing supply chain risks (i.e., falsification and diversion)
- 2. Establish Traceability and verification system (TRVST) that can host traceability data from manufacturers and can be accessed by in-country verification solutions (e.g., via national system integration with the TRVST or use of a deployable mobile application) on country specific timeline
- 3. Help accelerate the adoption of GS1 enabled traceability systems in low- and middle-income countries

USAID FROM THE AMERICAN PEOPLE · Gavi The Vaccine Alliance · The Global Fund · THE WORLD BANK · Bill & Melinda Gates foundation · unicef · Vital Wave℠

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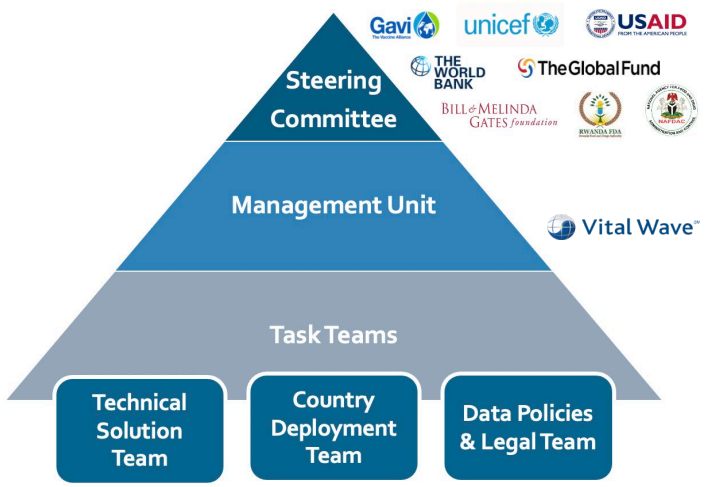
Intro to the VTI and TRVST



Verification and Traceability Initiative (VTI) Rationale:

- COVAX Risk Register: Falsification
- Built TRVST - a foundation for traceability
- VTI is the multi-stakeholder governance
- Digital equity – paramount principle
- Learned from EMVO
- UNICEF is the legal entity behind TRVST.

What is the TRVST?

First global GS1-enabled system for LMICs Regulators to monitor patient safety and enable progress on the “Supply Chain Visibility Journey”

TRVST

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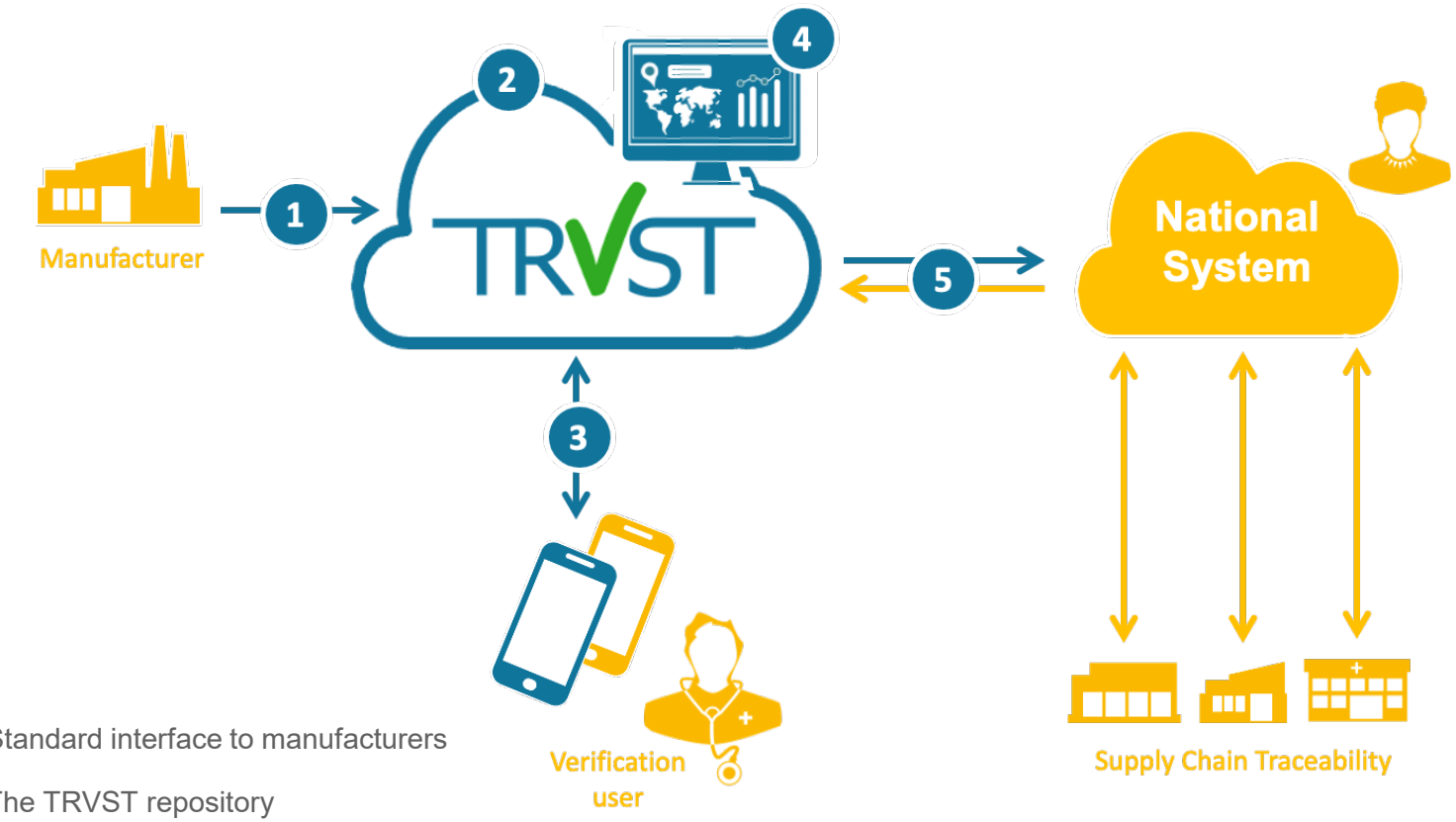
Introduction to TRVST



1. Standard interface to manufacturers
2. The TRVST repository
3. Verification smart phone application and API
4. The TRVST dashboard
5. TRVST API interface to national systems for verification and traceability

- TRVST is both a system to allow verification or traceability using GS1 standards.
- It is not intended to be a national traceability system.
- It acts as a hub for donated products, with the ability to track and trace them in the pre-country supply chain.
- Through an interface, the traceability event data can then be passed to the national systems.
- The national system can return a summary of the national traceability event data to provide supply chain visibility for donated products.
- Product verification will continue to be offered to countries with no national systems.

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TRVST - Key Achievements to date …

- **Technology:** Release 1 scope for the mobile app approved, app tested and validated, and Release 2 in progress.
- **Data sharing and manufacturer engagement:** Participation Agreements signed by several stakeholders including three major manufacturers.
- **TRVST deployment:** Successful training and trial of the mobile app in both Nigeria and Rwanda, with Malawi, Nepal and several other countries confirming their interest in a TRVST deployment.
- **Blueprints developed:** Country deployment and Manufacturer engagement blueprints developed and tested, now in use.
- **Partner alignment:** Major donors aligned in support of TRVST: UNICEF, WHO, GAVI, USAID, The Global Fund, Gates foundation, The World Bank, LMICs.

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Upcoming Priorities

Following the successful live trial in Nigeria and Rwanda (June 22) the VTI has the following next steps.

- Enhance TRVST functionality based on lessons learned and move towards creation of a self-starter package for countries to deploy on their own.
- Onboard additional manufactures and expand into other health products.
- Deploy TRVST in additional countries, starting with Malawi and Nepal.
- Integrate TRVST capabilities into national systems through an API in Rwanda and Nigeria.
- On-going discussions with major medicines and health commodities such USAID and The Global Fund to include data into TRVST beyond vaccines.

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Pipeline of countries for TRVST trial and deployment

Group 4	Group 3	Group 2	Group 1
• Early stages of exploration	• Conversations advanced	• Deployment planning underway	• Trialed mobile application and in process of integrating into national system
Countries			
• Angola • Ethiopia • Gambia • India • Liberia • Madagascar • Pakistan • Philippines • Tanzania • Uganda • Zimbabwe	• Ghana • Zambia	• Malawi • Nepal	• Nigeria • Rwanda

In UNICEF Annual forecasting exercise more then **70%** of the countries indicated a wish to have access to TRVST in the future

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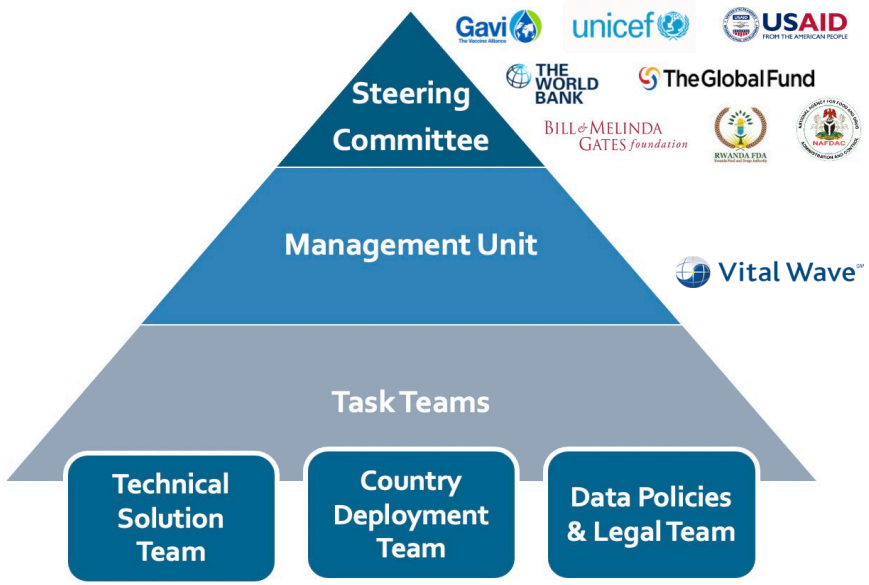
Data Sharing and Governance

- **Core Principle:** Data submitted by a participant belong to that participant.
- **Data sharing:** This is strictly controlled by a Data Sharing matrix, detailing exactly which participants can see each type of data. Serial numbers are considered extremely sensitive.
- **Use Cases:** Initial use case is verification and surveillance, with future plans for pre-country traceability
- **Participation in TRVST:** Participation is by acceptance of a Participation Agreement (for the trial phase) or an Enterprise Agreement (for the operational phase, expected to start in Q1 2023)
- **Governance Structure:** SteerCo, Task Teams, Stakeholders
- **Funding:** Funded by global donor organisations
- **Scope:** Initially focused on **Vaccines and ATM** products in the humanitarian global health supply chain, with potential to expand into other supply chains and product categories



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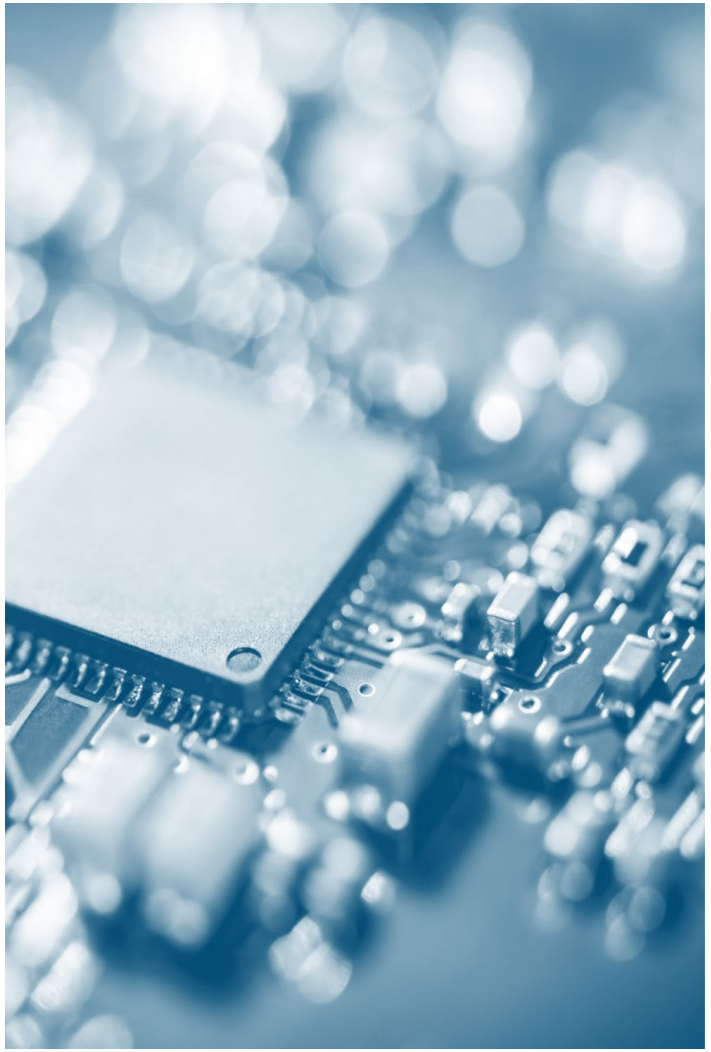
Technology

- **Data Submission:** Onboarding partners submit product master data and product pack data in two ways:
  - OBP API – SOAP API similar to the EMVO system
  - OBP-E API – EPCIS 1.2 compliant REST API (Commissioning, Aggregation and Shipping events)
- **Technical Specifications:** TRVST can supply technical specifications for each API on request
- **L4 Providers:** TRVST is working with a number of L4 providers to develop interfaces which suppliers can leverage
- **Security and Scalability:** TRVST uses the same technology as the European Medicines Verification System, ISO certified and able to handle millions of transactions per day
- **Automation:** Submission of data to TRVST can be triggered on shipment, based on the destination of the shipment, or by the purchaser of the shipment
- **GS1 Adoption:** TRVST works with GS1 barcoded products. Serialization is preferred for maximum benefit, but TRVST can perform batch level verification of non-serialized products
- **Support:** The TRVST solution provider provides a service desk to assist OBPs with onboarding and to give any support necessary



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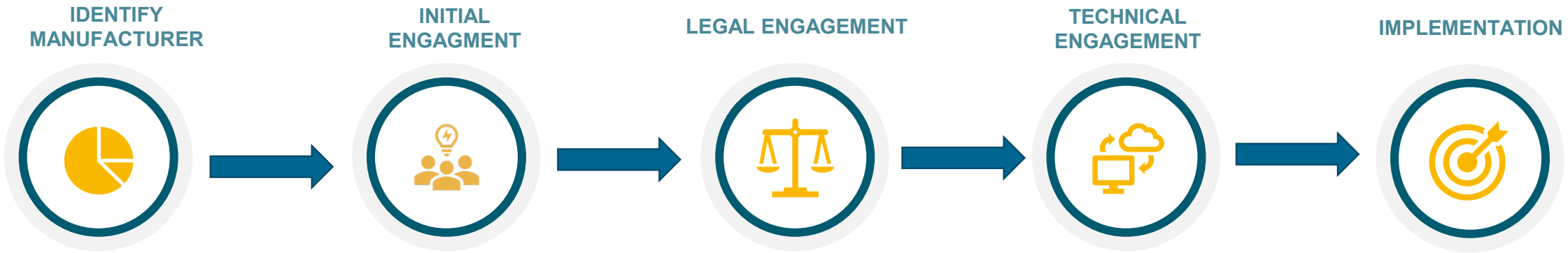
TRVST – onboarding suppliers – Engagement steps



	IDENTIFY MANUFACTURER	INITIAL ENGAGMENT	LEGAL ENGAGEMENT	TECHNICAL ENGAGEMENT	IMPLEMENTATION
STEPS	Identify OBPs willing and able to engage according to metrics	Contact OBP serialization and brand protection teams to set up an introductory call.	Meet with OBP legal counsel to discuss data-sharing and contracting	Meet with technical team, including **L4 providers** where applicable, and provide technical documentation and implementation plan	**Train OBP** on use of dashboard and work with technical team to integrate through testing, quality assurance and production environments
GOAL		• Letter of intent • OBP advocacy	• Signed Agreement	• Defined technical project plan and timeline	• Automated provision of PMD and PPD
RESOURCES	• Prioritization process	• Draft agenda & email • TRVST documents • Estimated LOE meeting schedule	• Data sharing protocol • **Participation Agreement** • Manufacturer FAQs	• OBP Technical Guide • Business rules for data submission	• Service Desk Protocol

OBP = Onboarding Partner, the onboarding supplier

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Barcode - serialisation requirement need (Towards implementing for multiple use cases)

Traceability data … need is underlined by:

- National regulations that evolve and follow GS1 standards *
  - **Entry requirement for national markets** – more and more countries will require serialisation in order to allow import of supply to their country
- WHO Member state driven policy on traceability of medical products **
- International Procurement Agencies – Global Standards Technical Implementation Guideline for Global Health Commodities ***

Required in order to enable:

- Identification of the unique secondary pack for verification
  - Mitigate falsification
- Traceability of the specific secondary pack through the supply chain
  - Mitigate diversion
  - Enable supply efficiencies, increase supply security

Traceability in healthcare and GS1 standard adoption is becoming the norm

*

**

https://www.who.int/publications/i/item/policy-paper-on-traceability-of-medical-products

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https://www.ghsupplychain.org/global-standards-technical-implementation-guideline-global-health-commodities-v21

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Vaccine supplier onboarding to TRVST

TRVST COVID Vaccine supplier onboarding
- Release 1 (verification)
- Release 2 (verification & traceability)

TRVST onboarding
- Additional suppliers
- Release 2 / operational phase

Trials
Participation Agreement
Test update TRVST Verification App
(Release 1)

Operational Phase
TRVST Enterprise Agreement
(Release 2)

Invitation letter
onboarding
TRVST

TRVST
webinar
1 & 2

Onboarding of vaccine suppliers
(voluntarily)

Onboarding L4 providers

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Vaccine supplier onboarding to TRVST – Next steps

TRVST/UNICEF to provide

- Additional reads for suppliers' teams:
  - OBPE API Technical Specification
  - FAQs
    - Highlight: Onboarding may require up to 3 – 6 months depending on:
      - LV4 system, legal engagement and availability of internal capacity
  - National Country Regulations [Nigeria Draft Regulations]

Ask to supplier

- Share potential start data to work with TRVST Data Sharing Task Team to initiate onboarding (allows planning)
- Nominate internal team to work with TRVST (provide names and contact details)
- Share name of L4 system, if used (e.g. SAP, TraceLink, Antares Vision, Movilitas, VisioTT)
- Early adopters encouraged to engage as soon as possible for implementation early 2023

Contact

- Jean-Pierre Amorij, jamorij@unicef.org

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Questions and Discussion

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Barcoding: a mandatory technical requirement in all COVAX and UNICEF tenders

For tenders issued after October 2019, the following language is included in all vaccine tenders as part of mandatory technical requirements:

Bar Codes
With implementation latest 31st December 2021, bar codes are required on all packaging levels used by manufacturers for supply to UNICEF, with the exception of primary packaging. Bar codes shall conform to GS1 standards, allowing through a unique company prefix to identify vaccines available in the global supply chain from each manufacturer. The bar codes shall include Global Trade Item Number (GTIN), lot number and expiry date.

Exceptionally for the Covid-19 tender, the following is included as a preferred characteristic:

In addition to the standard requirements, serialisation is required.

Barcoding Requirements for Vaccines

- GS1-barcodes on <u>secondary packaging and higher level</u>, covering: GTIN, Expiry date and Batch/Lot no.

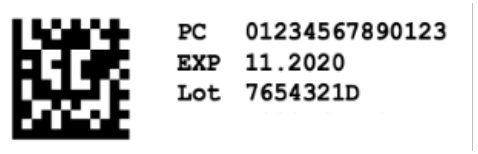
- **Non traded logistic items**
  SSCC within GS1-128

  If, in addition to being a logistic unit, the item is regarded as a trade item by the brand owner, it MAY additionally be identified with a GTIN.

- **Registered item/ Traded item**
  This can be in primary or secondary packaging
  GTIN within 2D DataMatrix

SSCC – GS1-128

2D Data Matrix



(a 2D barcode with human readable information)

- Mandatory
  - tenders <u>issued after 1 October 2019</u>
  - supply of vaccines from **1 January 2022** and onwards

- A guideline on the barcoding specifications has been shared with UNICEF suppliers in 2021 and will be included in UNICEF tenders (part of new tender template)

Falsification Remains a Risk

150 reports of incidents on quality issues with COVID-19 vaccines linked to 41 different countries.

Source: Medical Product Quality Report: COVID-19 vaccines, Issue 5 IDDO

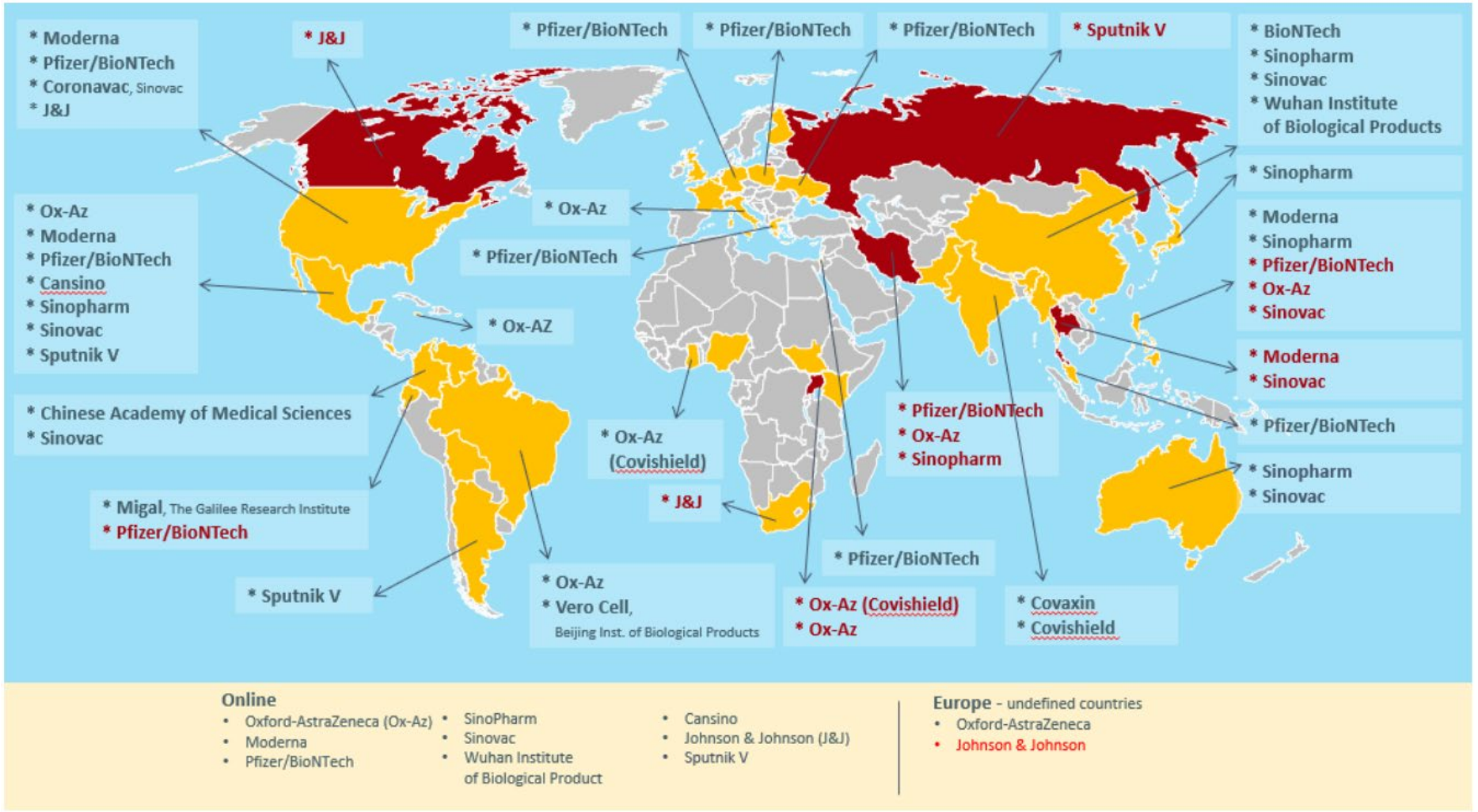


Figure 2. Countries with public reports on COVID-19 vaccine quality issues on the Medicine Quality Monitoring Globe.
Countries linked to incidents are indicated in orange. If a public report mentions a product name or a company, these details are indicated on the map, with in red the information that was added since the last issue. Ox-Az: Oxford-AstraZeneca, and J&J: Johnson & Johnson.

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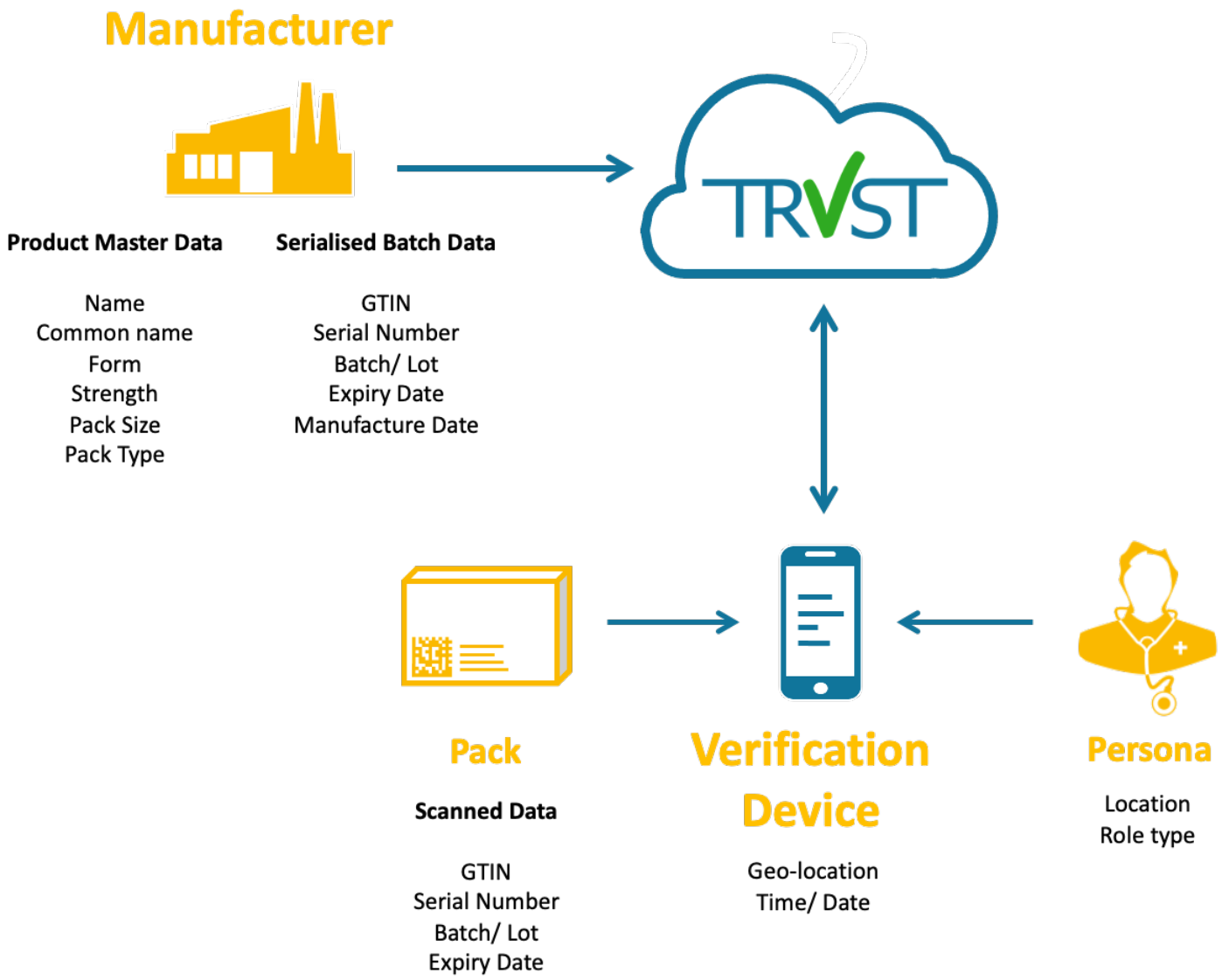
What data is in TRVST

- The diagram shows what data is provided to the TRVST*
- Data is supplied via two main routes:

1. Manufacturer product master data and serialized batch data
2. Verification data as a result of a verification scan



** this data model does not show all the data fields held in TRVST, this is only a high level summary of the main data items.*

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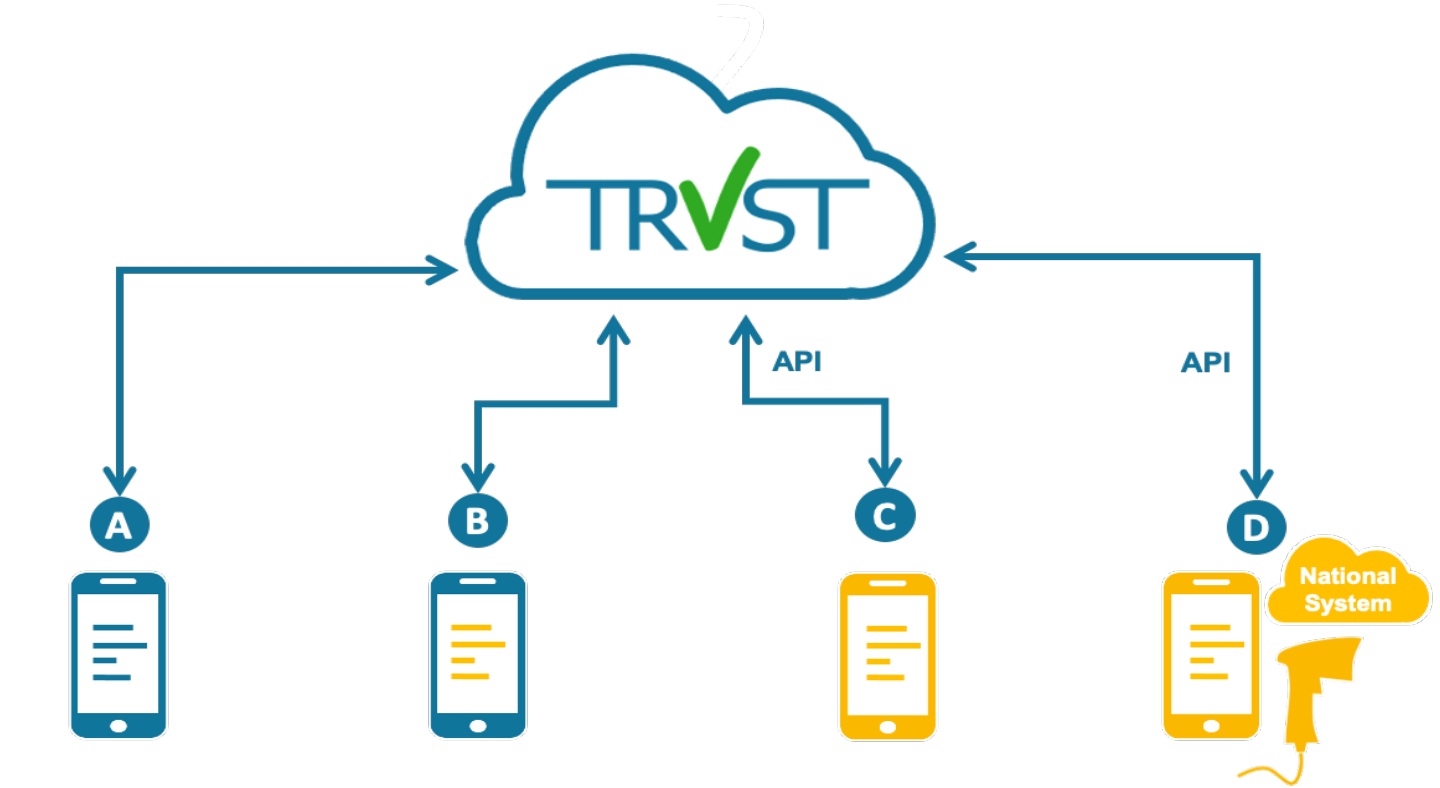
TRVST verification modalities



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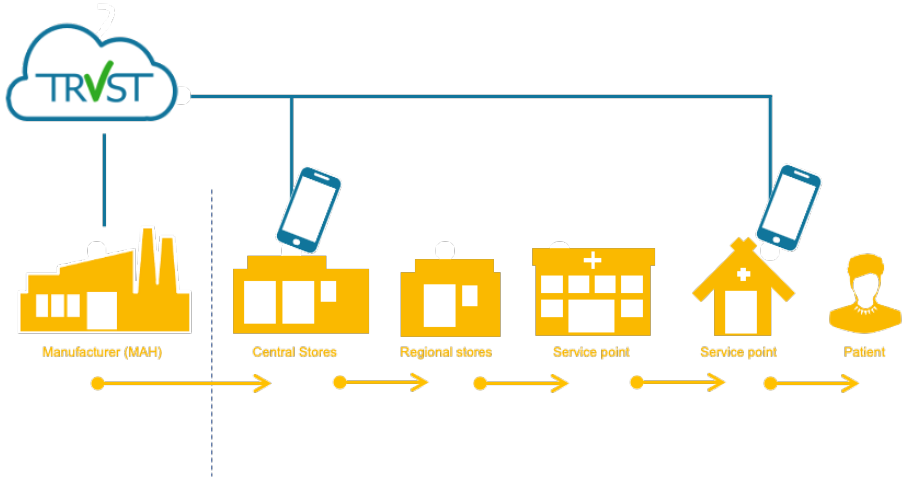
TRVST verification modalities in action

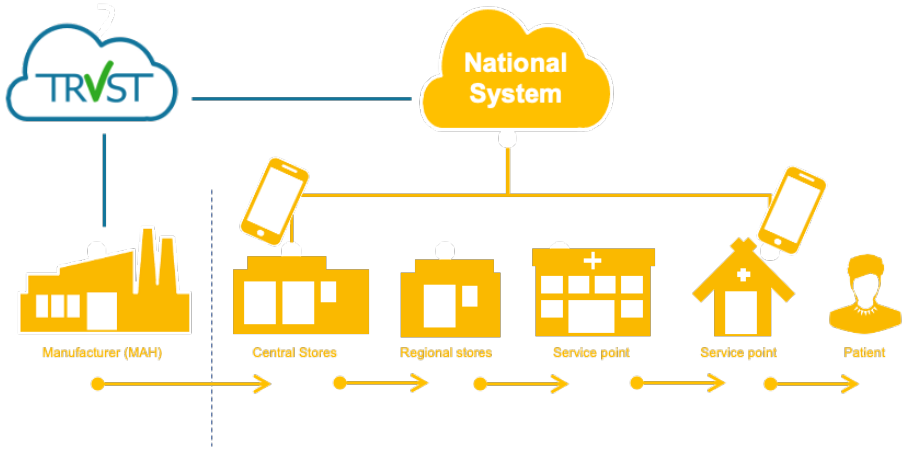
Modality A

- The TRVST verification application can be deployed at any point along the supply chain.
- The European system carries out verification on 100% of prescription drugs which are dispensed and maintains the status of the unique identifier (UI).
- The TRVST model does not maintain the status of the UI and takes more of a “sampling” approach to verification.
- Sampling is an effective method of detecting falsified products.



Modality D

- This modality is similar to A, but instead of an interface directly to a mobile app, the scan is sent to a national system and then forwarded to the TRVST for verification.
- The serialization data is not sent to the national system, only the verification response.



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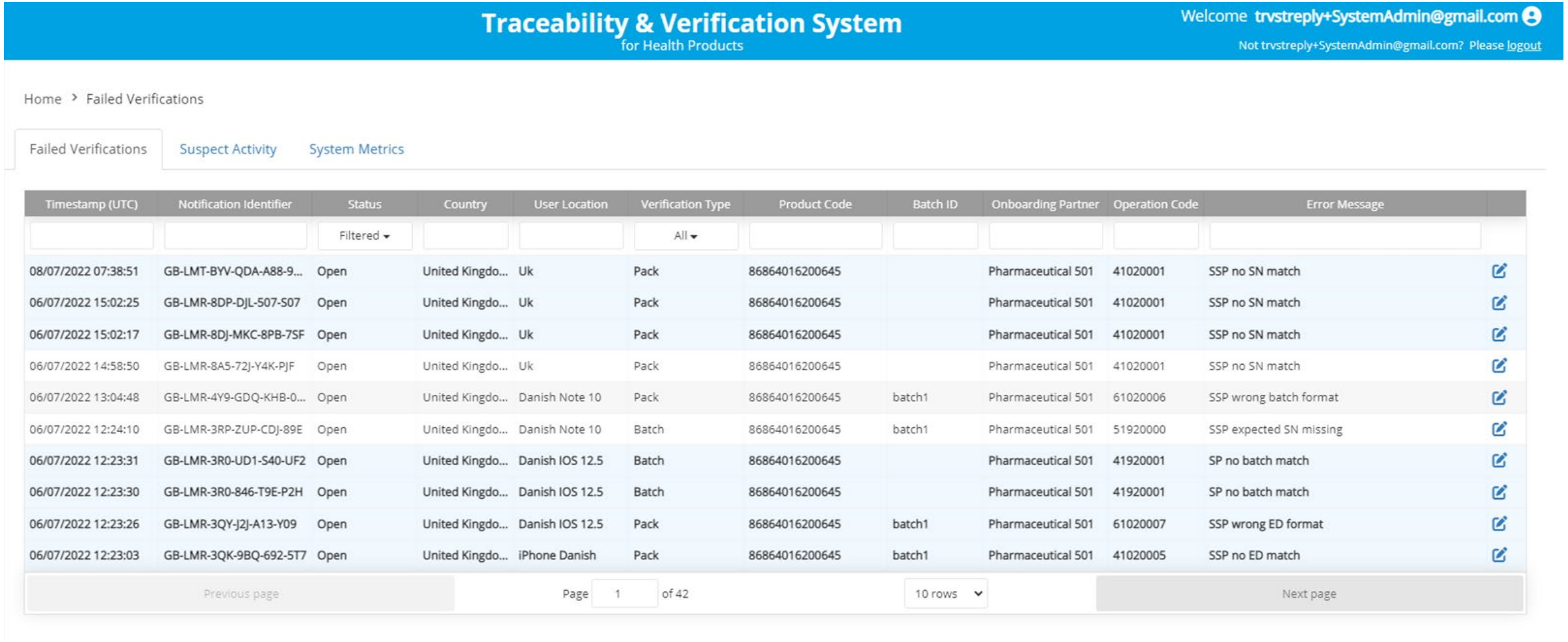
Dashboard – Failed Verifications



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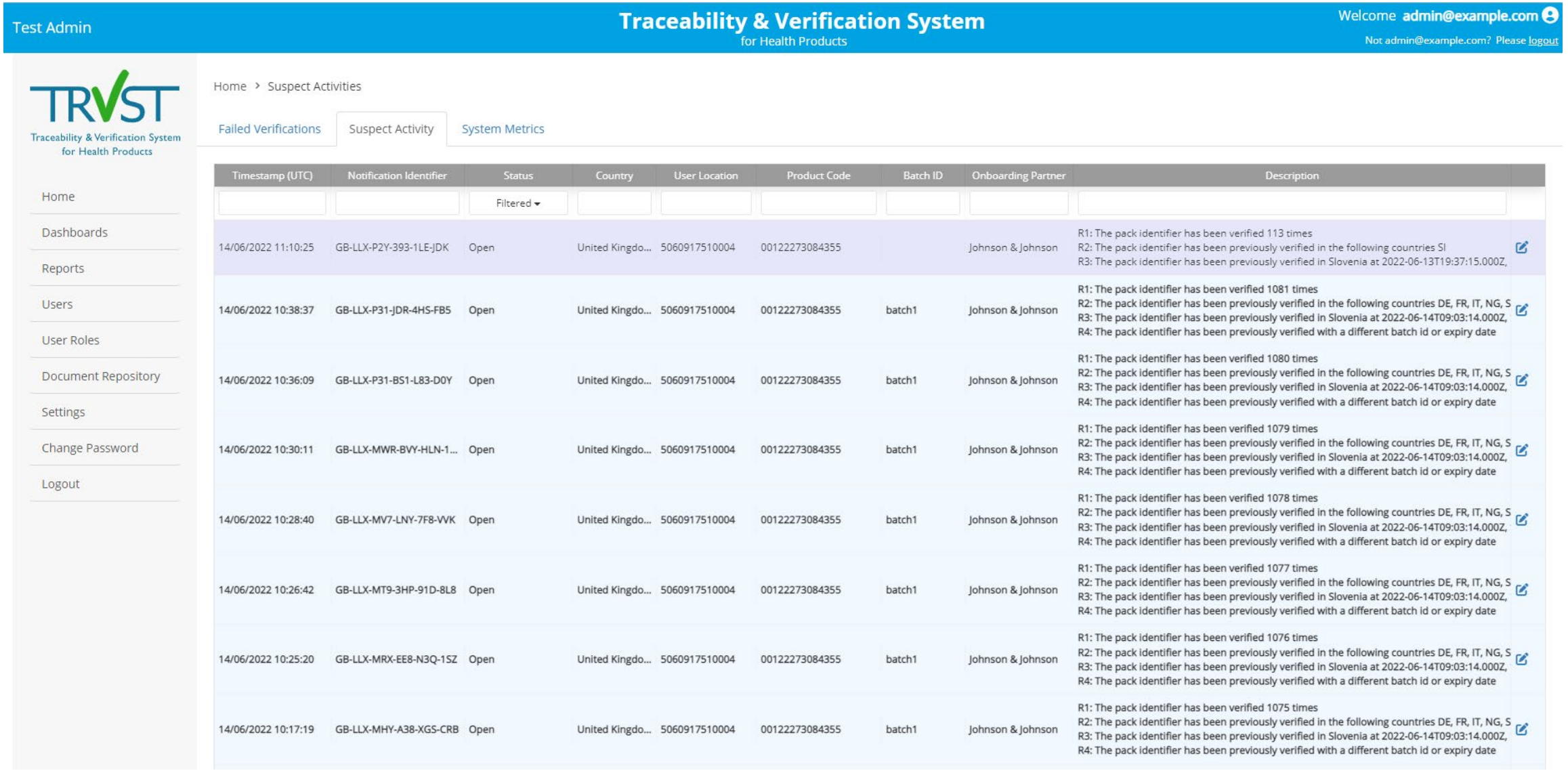
Dashboards - Suspect Activity



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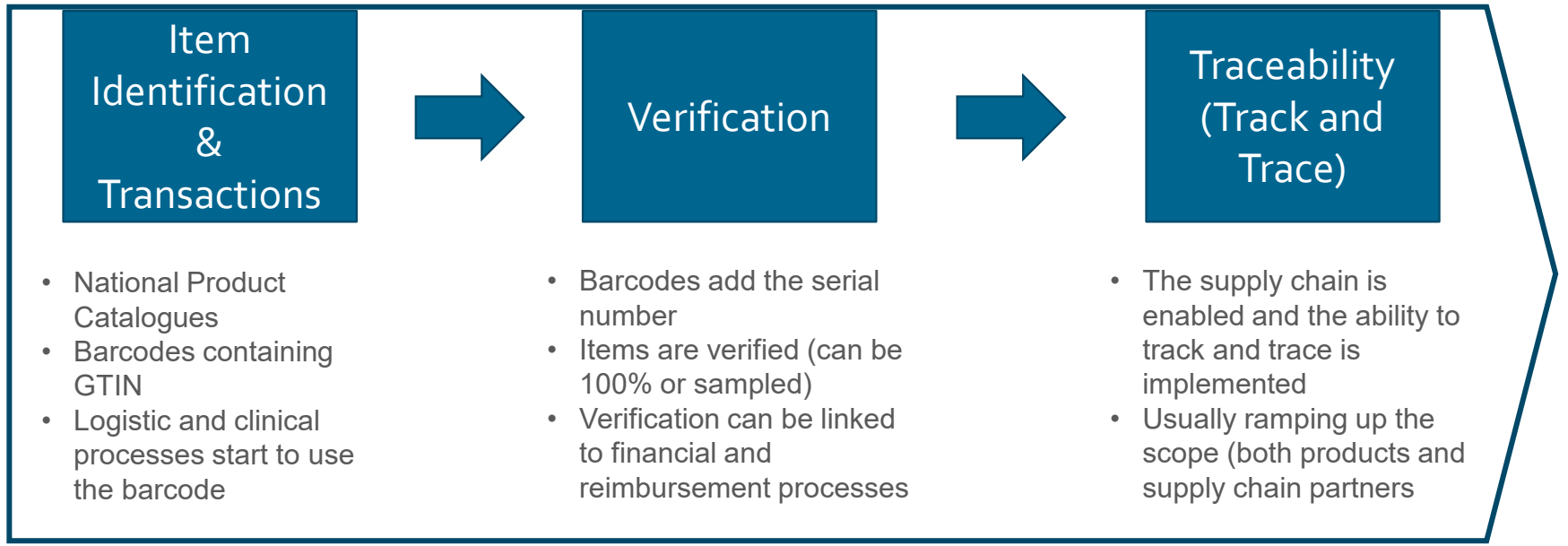
Journey to track and trace

- **Legislation** to drive investment and adoption.
- **Strategic plans** to outline priorities, and a pathway to traceability.
- **Governance** body to lead and collaborate with partners.
- **Significant investment in data, information technology systems and processes**.



- **Supply chain efficiencies**
- **Patient safety benefits**

Staged approach

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