

# **Webinar on Global Supply Chain Integrity Focusing on Track & Trace System for Pharmaceuticals**

APEC Centre of Excellence in Global Supply Chain Integrity

*Taylor's University August 10<sup>th</sup>, 2022*

## **Track & Trace System : Implementation Plan & Updates**

Pharmaceutical Services Programme, Ministry of Health Malaysia

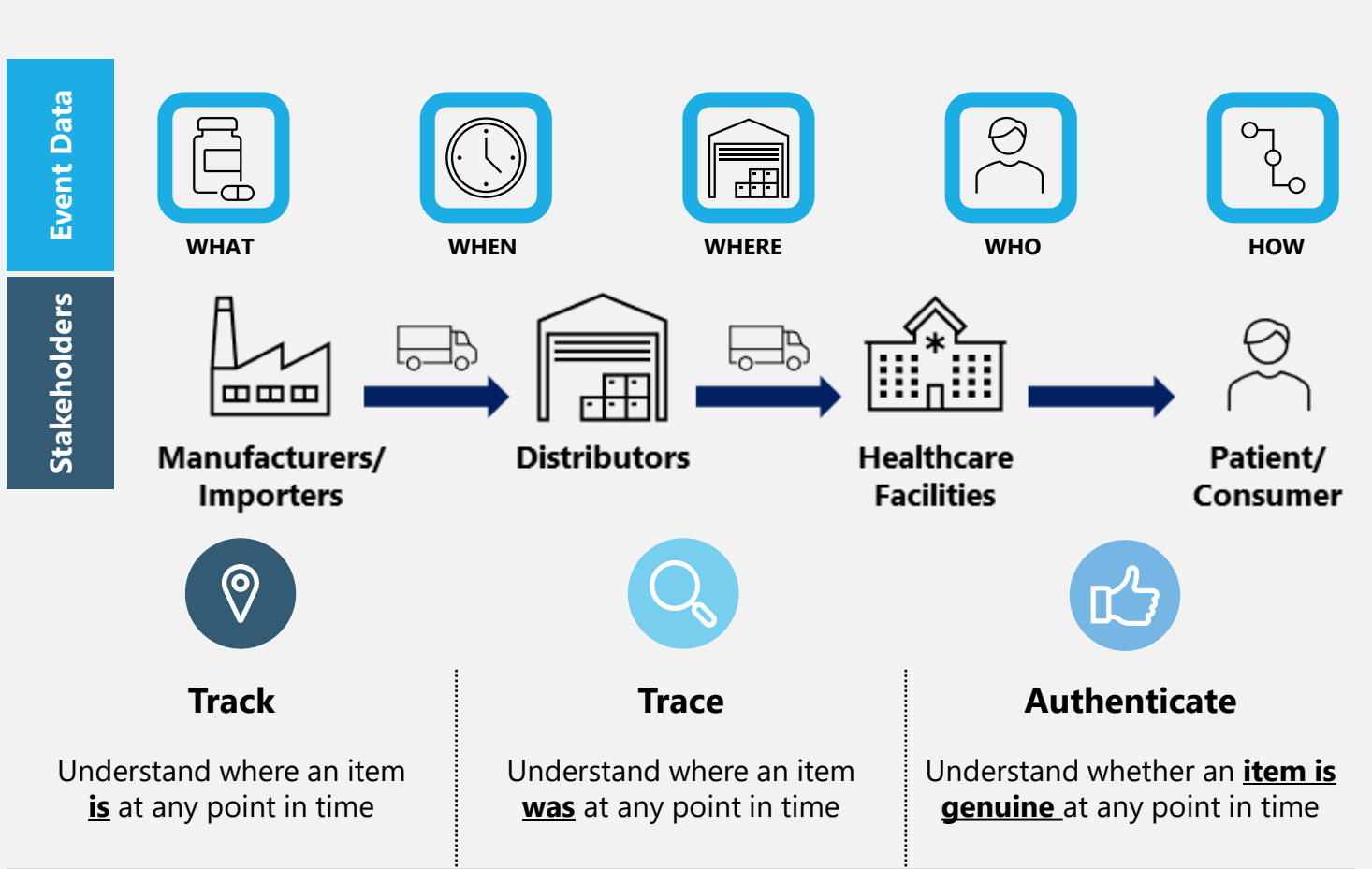
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# Presentation Outline

1. Introduction: What is Traceability or Track & Trace?
2. Control of Pharmaceutical Products in Malaysia, Problem Statement: Challenges in Pharmaceutical Supply Chain
3. Rationale for Track & Trace Implementation
4. Centralized National Track & Trace Approach: Policy, Process & Technology Consideration
5. Track & Trace MOH Malaysia Perspective
6. Implementation Plan & Progress
7. Proof of Concept (POC): Vaccine Management System (VMS)
8. Pharmaceutical Track & Trace System Pilot Project
9. Way Forward

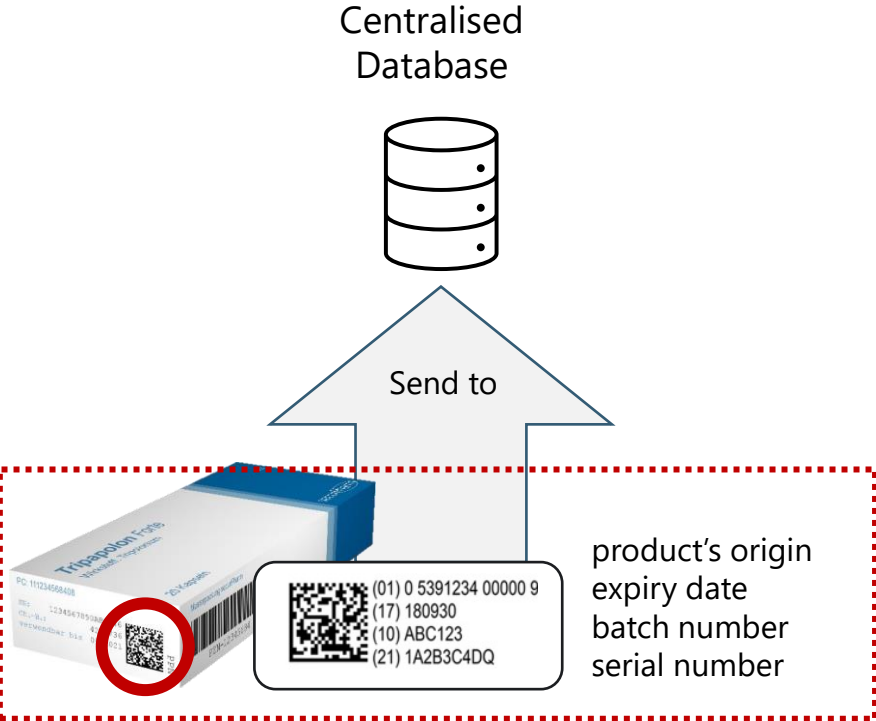
# Introduction: What is Traceability or Track & Trace?

“is the ability to track forward the movement through specified stage(s) of the extended supply chain and trace backward the history, application or location of that which is under consideration” ...generally using documented & recorded “unique” identification. - WHO



Who is allowed to **track**, **trace** or **authenticate** ?

## Pharmaceutical Serialization & Traceability



The units can then be tracked through its entire supply chain — from production to retail distribution to the final dispensation to the patient

# Control of Pharmaceutical Products in Malaysia

## Current Situation

### Acts & Regulations

1. Registration of Pharmacists Act 1951(revised 1989) & Regulations
2. Poisons Act 1952 (revised 1989) & Regulations
3. **Sale of Drugs Act 1952 (revised 1989) & Control of Drugs and Cosmetics Regulations 1984 (revised 2006)**
4. Dangerous Drugs Act 1952 (revised 1980) & Regulations
5. Medicines (Advertisement and Sale) Act 1956 (revised 1983) & Regulations

All pharmaceutical products must be registered with the Drug Control Authority (DCA) before it is marketed and sold to consumers

### Registration Number 1985 - 2005

Control over the sales of pharmaceutical products

Registered pharmaceutical product is given a specific registration number (eg; MAL 20001564A) to be printed on the label or its packaging



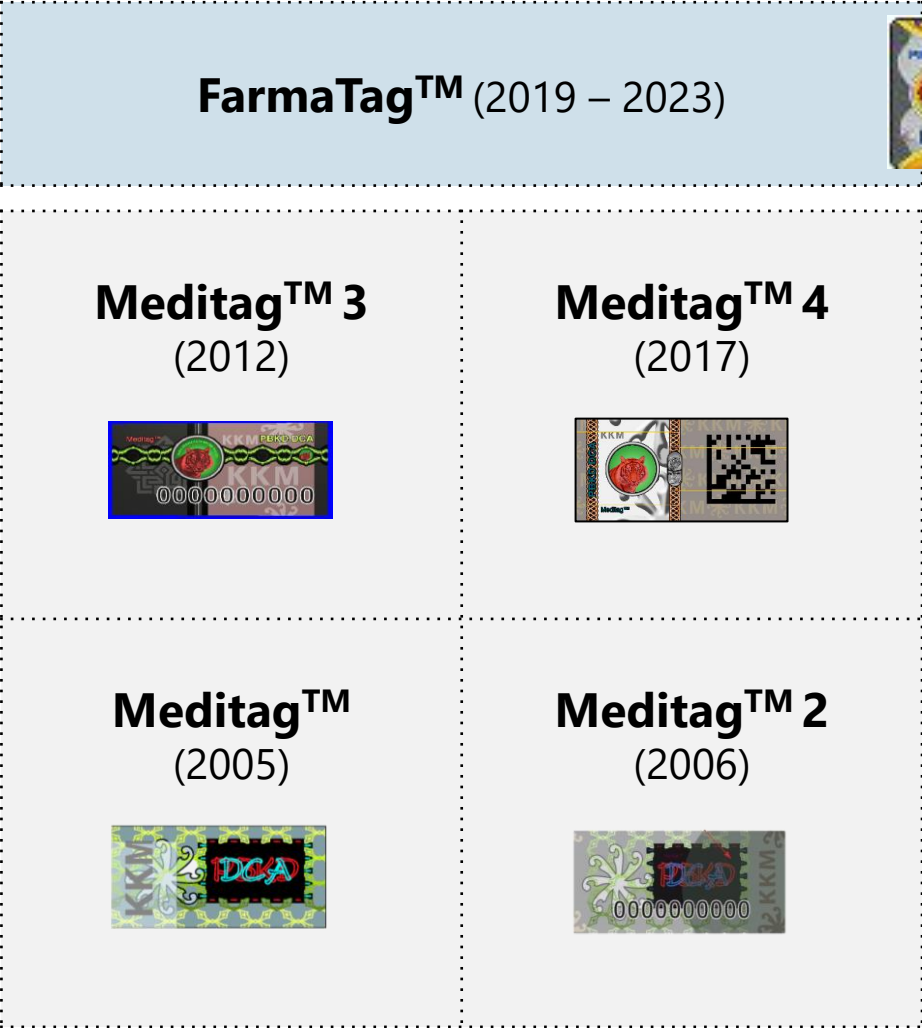
### Security Label (Hologram) 2005 - present

Hologram was introduced in 2005 with an extensive safety features that can be verified by both consumers and pharmacy enforcement officers

**All registered products must display product registration number and hologram security label on its packaging**

# Regulation 29 Control of Drugs and Cosmetics Regulations 1984

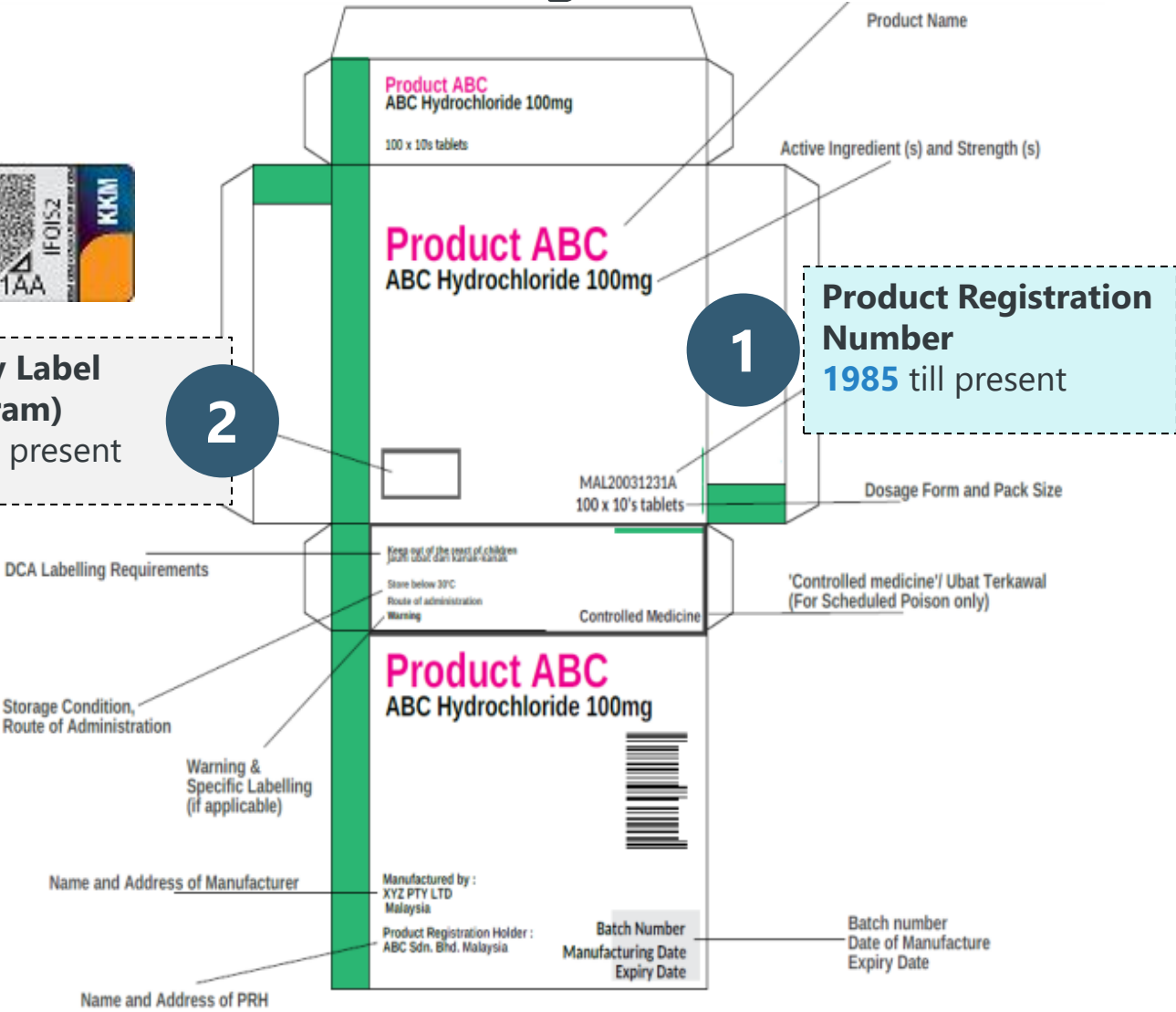
## Current Situation



**Meditag™ (2005 – 2019)**



**Security Label (Hologram)**  
2005 till present



Appendix 19 General Labelling Requirement, Drug Registration Guidance Document (DRGD), January 2022, National Pharmaceutical Regulatory Agency (NPRA)

# Problem Statement: Challenges in Pharmaceutical Supply Chain

## Paracetamol supply shortage in pharmacies, convenience stores

By Bernama - February 18, 2022 @ 4:34pm



### Accessibility & Availability of Medicine

Paracetamol, a drug commonly used to relieve fever and headaches, are reportedly in short supply and relatively difficult to obtain at community pharmacies and convenience stores around the city as well as several other places. - File pic.

## More fake Avastin found in EU, thanks to FMD scanning



Another falsified batch of Roche's cancer drug Avastin has been discovered by a wholesaler in the Netherlands.

Four boxes of the product – in Bulgarian packaging – were found at an as-yet unidentified Dutch pharmaceutical wholesaler, according to an alert issued by the Dutch Health Care Inspectorate IGJ (Inspectie voor Gezondheidszorg).

The falsification came to light when a wholesaler scanned a box in the new system of safety features that has been in force since February 2019. When scanning, the wholesaler was notified of a possible counterfeit and this is one of the first times on public record that the verification system put in place as part of the Falsified Medicines Directive (FMD) in February has protected patients from being exposed to potentially fake drugs.

## WHO says fake cancer drug Iclusig has been "traded globally"



Falsified copies of leukaemia drug Iclusig are being traded around the world and have reached the patient level in Asian markets, says the World Health Organization.

Last month the WHO warned that counterfeit 15mg and 45mg packs of Iclusig had also been found in Asian markets.

the batch number PR0834170. Neither of the batch numbers is genuine, according to Iclusig's manufacturers.

### Substandard & Falsified Medicine

## Health Ministry: Influenza A vaccine supply sufficient, no need to worry

By Davin Chan - January 12, 2020 @ 4:28pm



### Efficient Supply Chain

There is no shortage of the vaccine. Pharamianga has already assured us that there would not be any disruption in terms of the supply of the vaccine.

## Four ways to build supply-chain resilience

Supply-chain resilience requires four elements: end-to-end transparency, routine stress-testing and reassessment, reduced exposure to shocks, and supply-chain resilience on the executive agenda.

### End-to-end transparency

A lack of visibility into the business practices of suppliers and suppliers' suppliers can be a major vulnerability. Major consumer brands have been accused of unfair labor practices. Suppliers have been found to have used child labor.

Companies need to have an end-to-end view of the supply chain and identify vulnerabilities. It's also vital to have a clear understanding of exposures beyond supply, such as geopolitical risks, climate change, and pandemics.

## HSA Stops Supply of Eight Brands of Ranitidine Products in Singapore

Eight brands of ranitidine medicines have been found to contain trace amounts of a nitrosamine impurity, N-nitrosodimethylamine (NDMA), which are above the internationally acceptable level. As a precautionary measure, the Health Sciences Authority (HSA) is stopping the sale and supply of the affected ranitidine medicines at clinics, hospitals and pharmacies [see Table A for full list of medicines].

## Kenyataan Akhbar KPK 29 Mac 2019 - Produk Losartan yang ditarik Balik di Singapura Serta Situasi di Pasaran Malaysia

BY DG OF HEALTH ON MARCH 29, 2019

Kenyataan Akhbar  
Authoriti Kesihatan  
daripada  
nitrosamine  
menyebabkan



### Product Recalls

# Why Track & Trace ?

## Authority

### Industry

### Healthcare Facilities

### Consumer



#### Strengthening Regulatory Activities through Global Standards

Good governance in medicine, Protecting consumer & industries from substandard and falsified product



#### Cost Optimization & Operational Efficiency

Reduce product waste due to obsolescence, Improving product recall efficiency and effectiveness, Improving transaction accuracy, healthcare transformation



#### Enhancing Ecosystem of Pharmaceutical Sector

Bolster the pharmaceutical export growth, Improve efficiency inventory assets & associated costs, Strengthening multiple stakeholders' collaboration



#### Improve Patient Safety

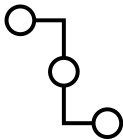
Reducing medication errors; improve patient safety, consumer empowerment



### Visibility



### Product Safety



### Supply Chain Security

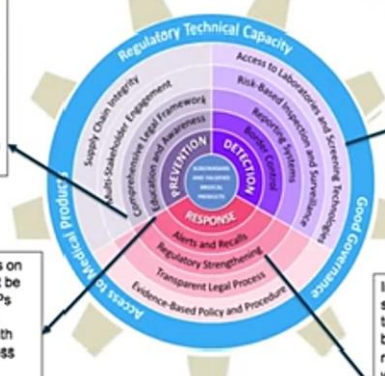
# Rationale of Implementation



**RANCANGAN MALAYSIA KEDUA BELAS**  
2021-2025  
MALAYSIA MAKMUR, INKLUSIF, MAMPAN

## Fight the Fakes: WHO Strategy

*Prevention, Detection, Response*



**SF profits funds other crimes e.g. terrorism, arms trafficking, and further conveys power to corrupt officials & cartels. Legislative reform & extended penalties for SF crime is required for inclusion in the UNOTC**


**Emerging Track & Trace Tech:**

- Blockchain
- Drones
- 2D barcodes
- Mobile Phone Apps
- GPHF-MiniLab
- Nanoscanners

**Improved reporting systems & greater transparency within & between countries is required, together with wide & effective multi stakeholder engagement**

**Education & awareness on the dangers of SF must be improved amongst HCPs and the general public through partnerships with HE and public awareness campaigns**


## Track & trace mandate by NRAs



<p><b>U.S.</b> All over US: <b>Drug Quality and Security Act</b>, signed by Barack Obama in November 2013</p>	<p><b>EU</b> 'Directive 2011/62/EU on falsified medicines' demands a national enforcement of drug serialization activities across EU by 2017</p>	<p><b>TURKEY</b> The Turkish "Pharmaceutical Track and Trace System" (ITS) operated by the health ministry, provides each drug a unique DataMatrix code to track and trace all drugs</p>	<p><b>CHINA</b> China's State Food and Drug Administration has made <b>serialization mandatory for 502 pharmaceutical drugs</b> that fall into the essential drug list</p>
<p><b>BRAZIL</b> National System of Drug Control framework, published by Brazilian Health Surveillance Agency</p>		<p><b>KOREA</b> Ministry of Health and Welfare has issued the law 'Controlling and indicating barcode of pharmaceutical products'</p>	
<p><b>ARGENTINA</b> G1 Standards, implemented by National Food, Drug and Technology Administration</p>		<p><b>INDIA</b> Directorate General of Foreign Trade has made barcode mandatory on packaging for pharmaceuticals exported from India</p>	

## Meningkatkan Kesiapsiagaan untuk Mengendali Krisis Kesehatan

Perkhidmatan penjagaan kesihatan akan diperkukuh dengan penyediaan fasiliti, perkhidmatan farmaseutikal, personel kesihatan dan kelengkapan perubatan yang lebih baik untuk meningkatkan tahap kesiapsiagaan dalam mengendalikan krisis kesihatan. Kapasiti makmal kemahiran klinikal akan ditambah baik bagi meningkatkan kecekapan personel kesihatan dalam menyediakan rawatan berkualiti terbaik. Langkah keselamatan di makmal klinikal juga akan ditambah baik untuk mematuhi sepenuhnya piawaian yang ditetapkan oleh WHO bagi memastikan keselamatan personel. Tambahan pula, personel kesihatan dan kelengkapan perubatan bagi pasukan respons kecemasan awam pelbagai bahaya akan diperkukuh di beberapa pintu masuk terpilih, terutama di Lapangan Terbang Antarabangsa Kuala Lumpur, Sepang. Semua jabatan kecemasan, terutama di hospital negeri akan dilengkapi dengan peralatan yang lebih baik untuk meningkatkan kecekapan penyampaian perkhidmatan. Di samping itu, sistem *track and trace* farmaseutikal akan diperkenalkan untuk memastikan bekalan ubat-ubatan yang mencukupi dan pengedaran yang cekap ke semua fasiliti penjagaan kesihatan. Sistem ini juga akan berfungsi untuk memeriksa ketulenan ubat.



**MALAYSIAN NATIONAL MEDICINES POLICY**  
3<sup>RD</sup> EDITION • 2017-2021



**PELAN STRATEGIK PENDIGITALAN**  
KEMENTERIAN KESIHATAN MALAYSIA  
2021-2025



**PELAN STRATEGIK**  
KEMENTERIAN KESIHATAN MALAYSIA  
2021-2025



# Centralized National Track & Trace Approach

## Policy Consideration

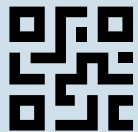
Government issuing **mandates** (laws, regulations, directives etc.) that define, govern, and establish an appropriate incentive structure for the track and trace program. The mandates should address **identification, data capture (barcoding), aggregation, and data exchange** informed by the business need and/or challenge the country wishes to address through track and trace



**PRODUCT SCOPE** – *which products are subject to the regulation*



**DATA CAPTURE** – *how identification data should be encoded in data carriers on specific packaging levels*



**IDENTIFICATION** – *how trade items and logistics units must be uniquely identified that enter the market/ supply chain*



**DATA EXCHANGE** – *what data must be exchanged*

# Centralized National Track & Trace Approach

## Process Consideration

Countries may use the GS1 EPCIS standard for exchanging traceability event data in a way that enables traceability events to be communicated. Countries will have to decide what events need to be recorded for their track and trace system to meet requirements. The table below illustrates key EPCIS events related to track and trace and the party responsible for performing the functions in a chain-of-custody model

	<b>WHAT</b> objects are the subject of this event (GTIN + serial number = sGTIN)	<b>WHERE</b> this occurred and where the objects went after that GLN of physical location	<b>WHEN</b> this event took place	<b>WHY</b> this event took place
<b>Manufacturer</b>	Allocate and retain sGTIN for item	Record GLN where the item/ cases/ pallet was commissioned	Record the date and time of commissioning the item	Commission Aggregation
<b>Wholesalers / Distributors / Warehouses</b>	Assign and record SSCC of pallet, Record package (sGTIN) Transaction Information & Transaction History, and Transaction Statement	Record GLN of ship-to-party Record transferring ownership of the product	Record the date and time of shipment of package / shipment receipt and transfer to next location	Receiving Disaggregation Aggregation Shipping
<b>Healthcare facilities</b>	Record package (sGTIN) Transaction Information & Transaction History, and Transaction Statement Decommission sGTIN	Record GLN of service delivery point Record "ship-from" GLN	Record date and time package was received	Receiving Dispensing Disaggregation Decommission

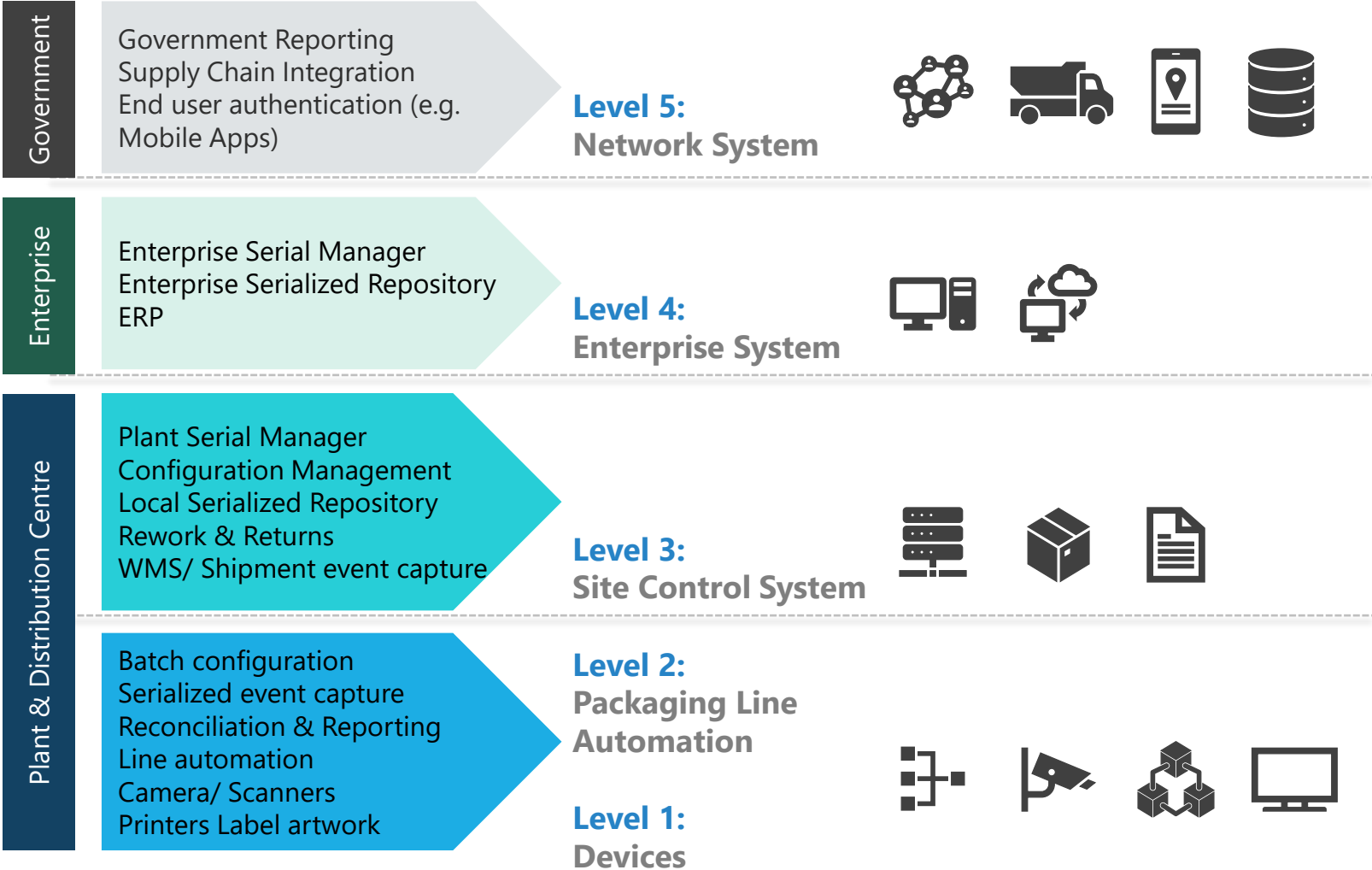
**The illustrative What, Where, When, and Why of traceability events**

# Centralized National Track & Trace Approach

## Technology Consideration

Supply chain stakeholders must be able to capture and exchange product event and transactional data with a central database. To achieve this, each stakeholder must have the following technological capabilities:

- Systems **capable of capturing data scanned from 1D and 2D data carriers** at the trade item secondary and tertiary pack levels
- Supply chain systems able to **send and receive transactional data electronically** to and from supply chain participants, such as vendors, warehouses, and facilities
- Ability to **manage event data exchanged using the GS1 EPCIS standard**
- Technology to capture an event and associate it with a specific item and entity through GTIN and GLN, respectively
- Systems that enable **aggregation and disaggregation of serial numbers** as logistics units are dismantled and/or repackaged through the supply chain



# System Requirement (Hardware & Software) – Industry & Government

## Pharmaceutical Track & Trace System

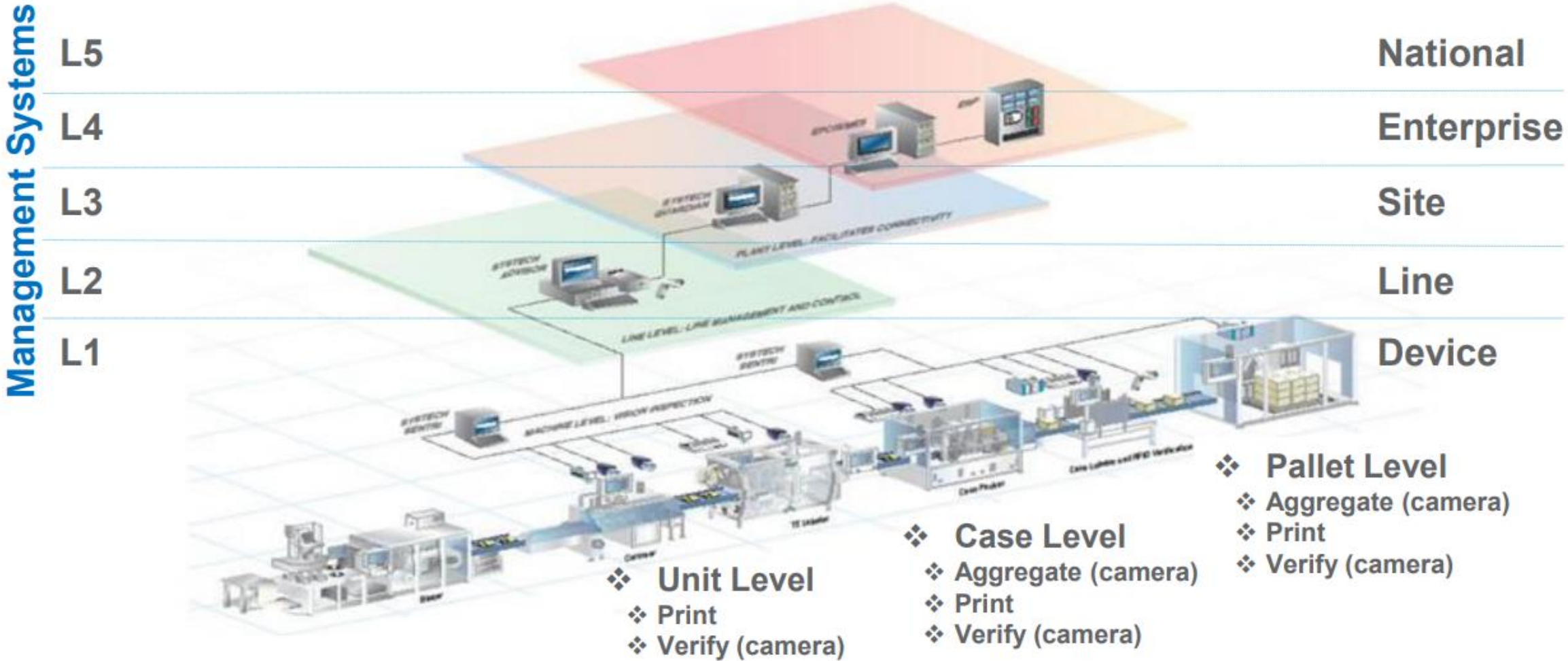
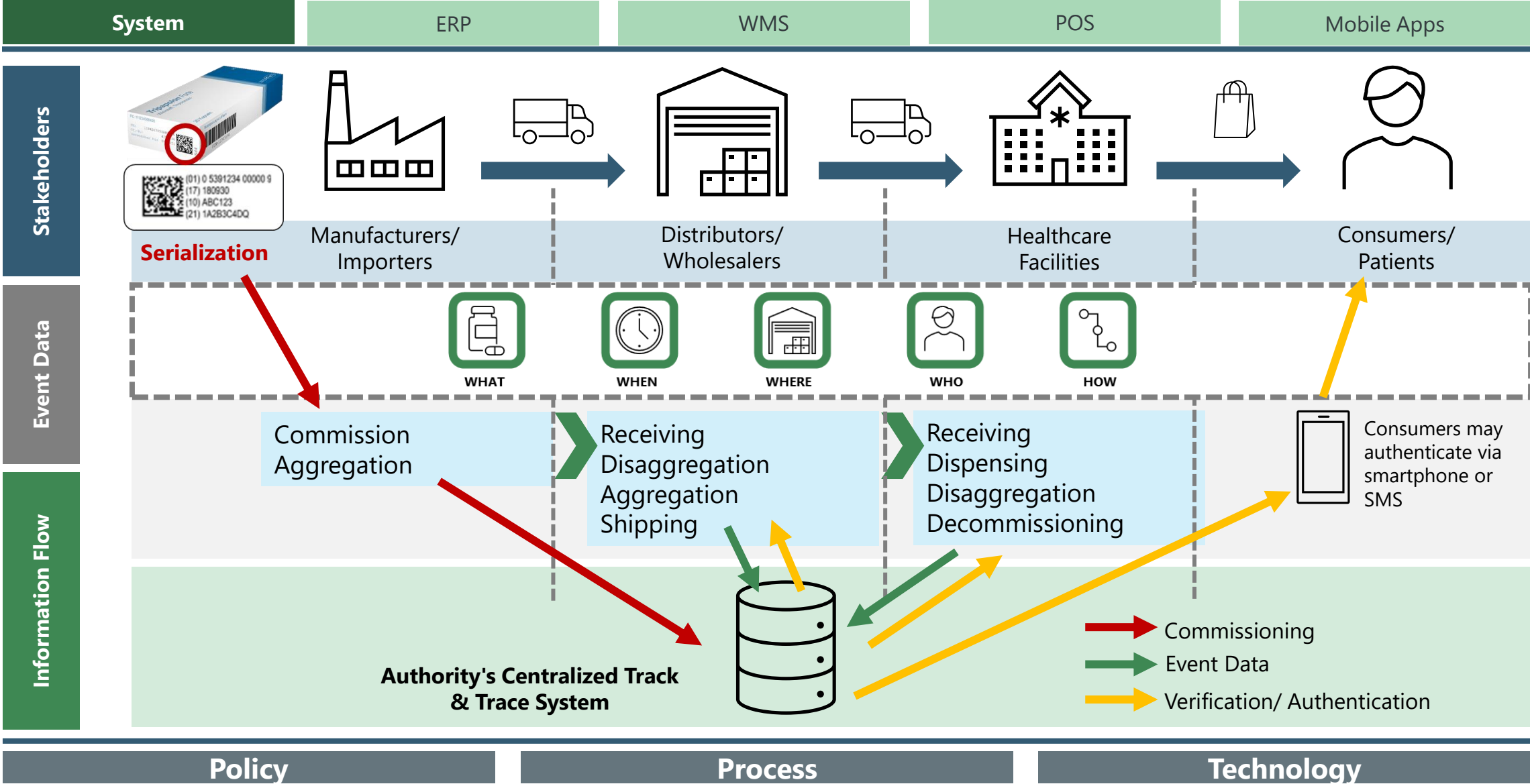


Diagram courtesy of CK Lam, Serialization and traceability as well as challenges and impact on GDP, Pfizer Inc., 2021

# Track & Trace Model

## Centralized National Track & Trace Approach



# Track & Trace MOH Malaysia Perspective

Objective: Traceability & Visibility, Supply Chain Security & Efficiency, Combat Substandard & Falsified Medicine & Unregistered Products and Patient Safety

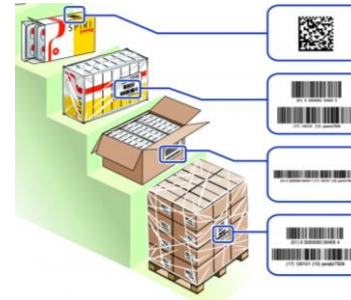
## PRODUCT SCOPE



All registered product  
(A,X,T,N)\*

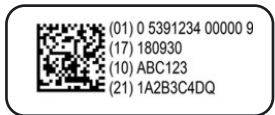
\*Implementation in phases

## PACKAGING LEVELS & AGGREGATIONS



Saleable Unit  
Tertiary Packaging  
Aggregations

## DATA CARRIER & ELEMENTS



GS1 2D DataMatrix

- GTIN
- Expiry date
- Lot/ batch number
- Serial Number

## DATA EXCHANGE & DATABASE



Central Authority's Centralized Track  
& Trace System  
GS1 EPCIS Standard

## FULL TRACEABILITY; END-TO-END MODEL



# Factors Affecting Track & Trace Implementation



## Political

Contextual Factors

### **Government support** and action

The absence of mandate from the government may lead to fragmented implementation

### **Legislation and regulation**

Well-defined legislation and regulation eased the implementation



## Social

Contextual Factors

### **Supply chain actor** support

Costs of implementation, complexity of legislation & incentives

### Awareness, **knowledge** and **skill**

Support by training, preparation & timeline



## Economical

Contextual Factors

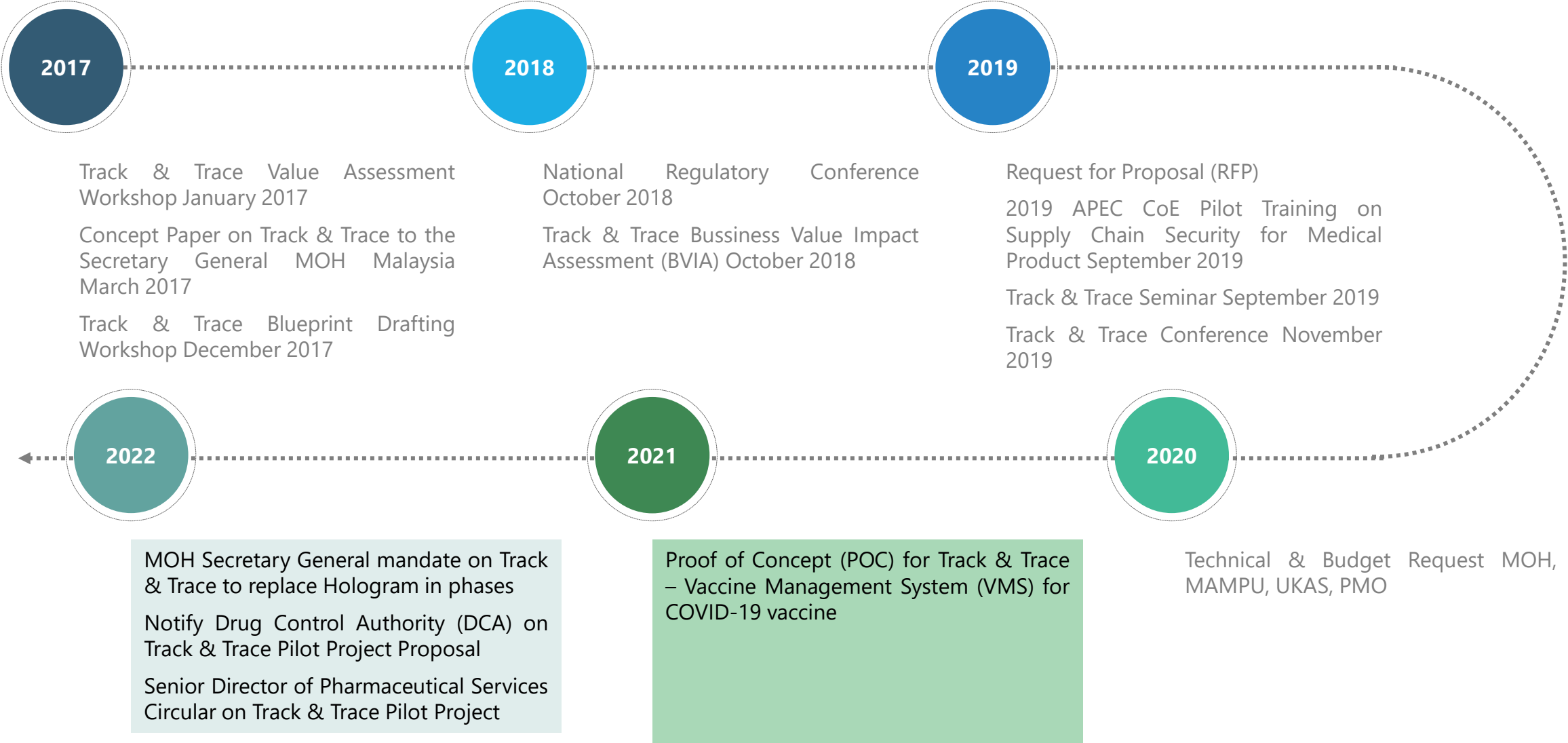
### **Investment**

Money, time & effort – adhere to compliance

### **Technical and digital** capacities

ICT infrastructure, choice of system and technology, system integration, adjustability of system, agile methodology

# Implementation Progress: (2017 - 2022)





# Vaccine Management System (VMS) Track & Trace Proof of Concept (POC)

**Project Scope**



VMS Label



Device & Mobile Apps

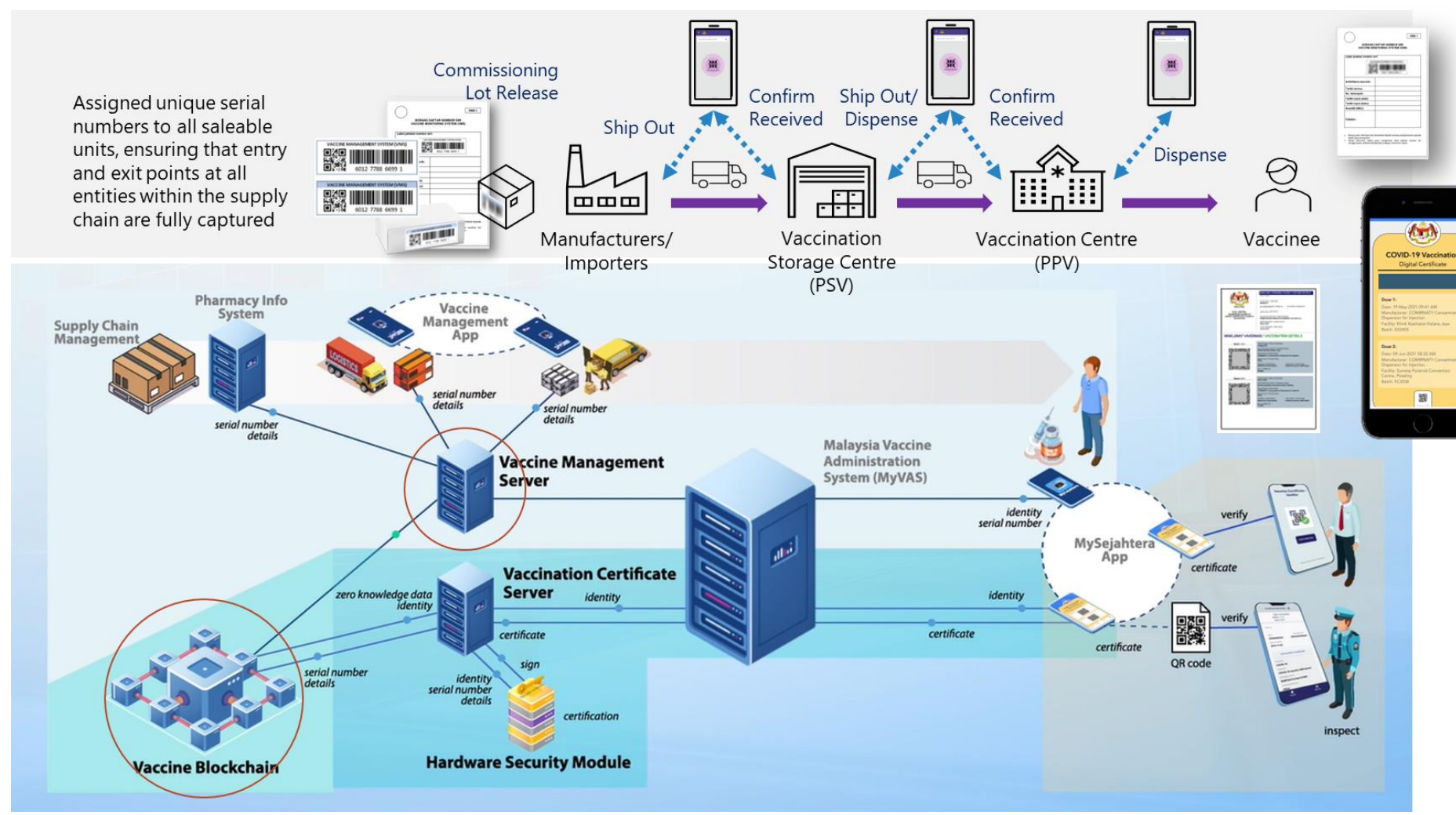


VMS Dashboard



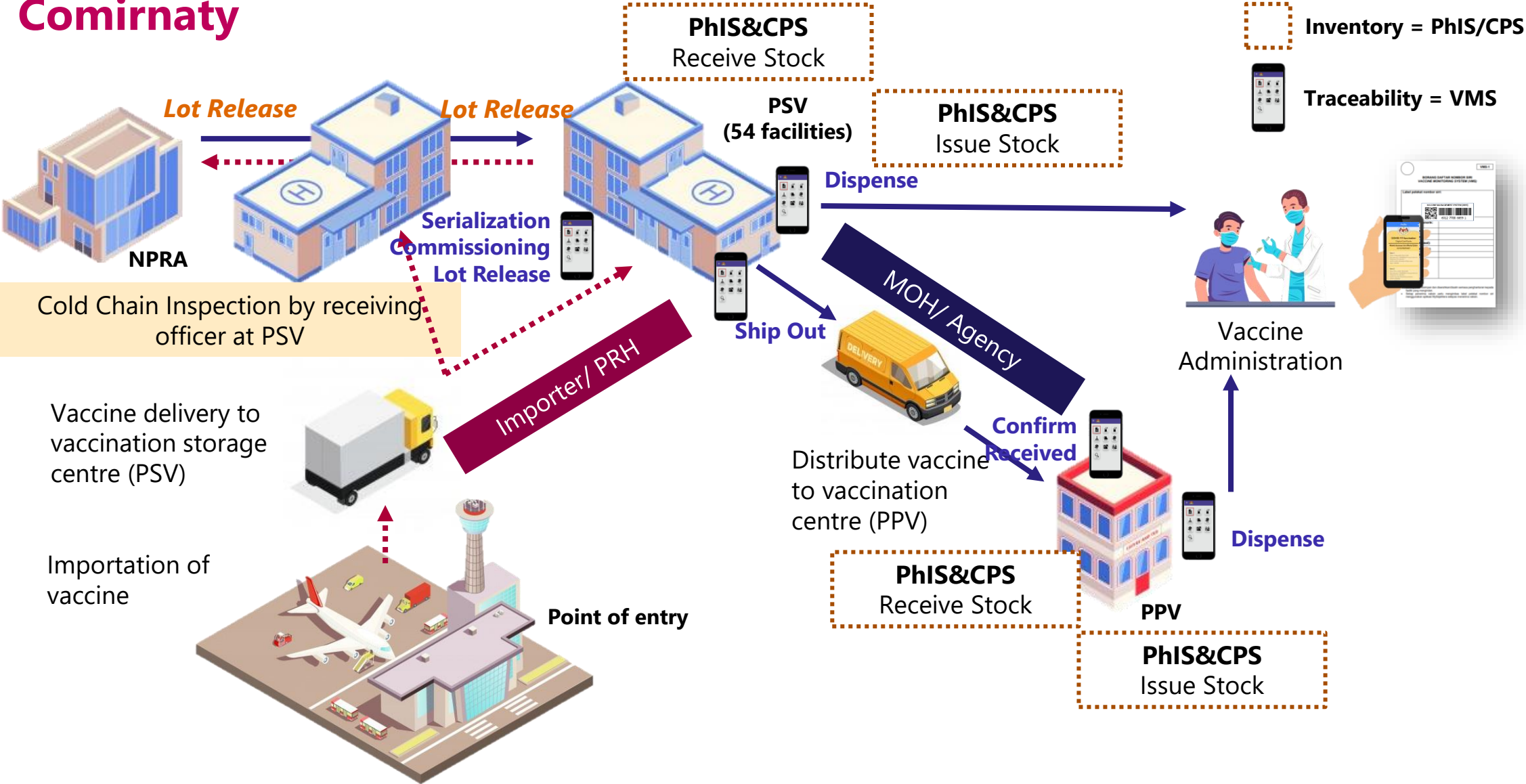
VMS Helpdesk

## High Level Architecture



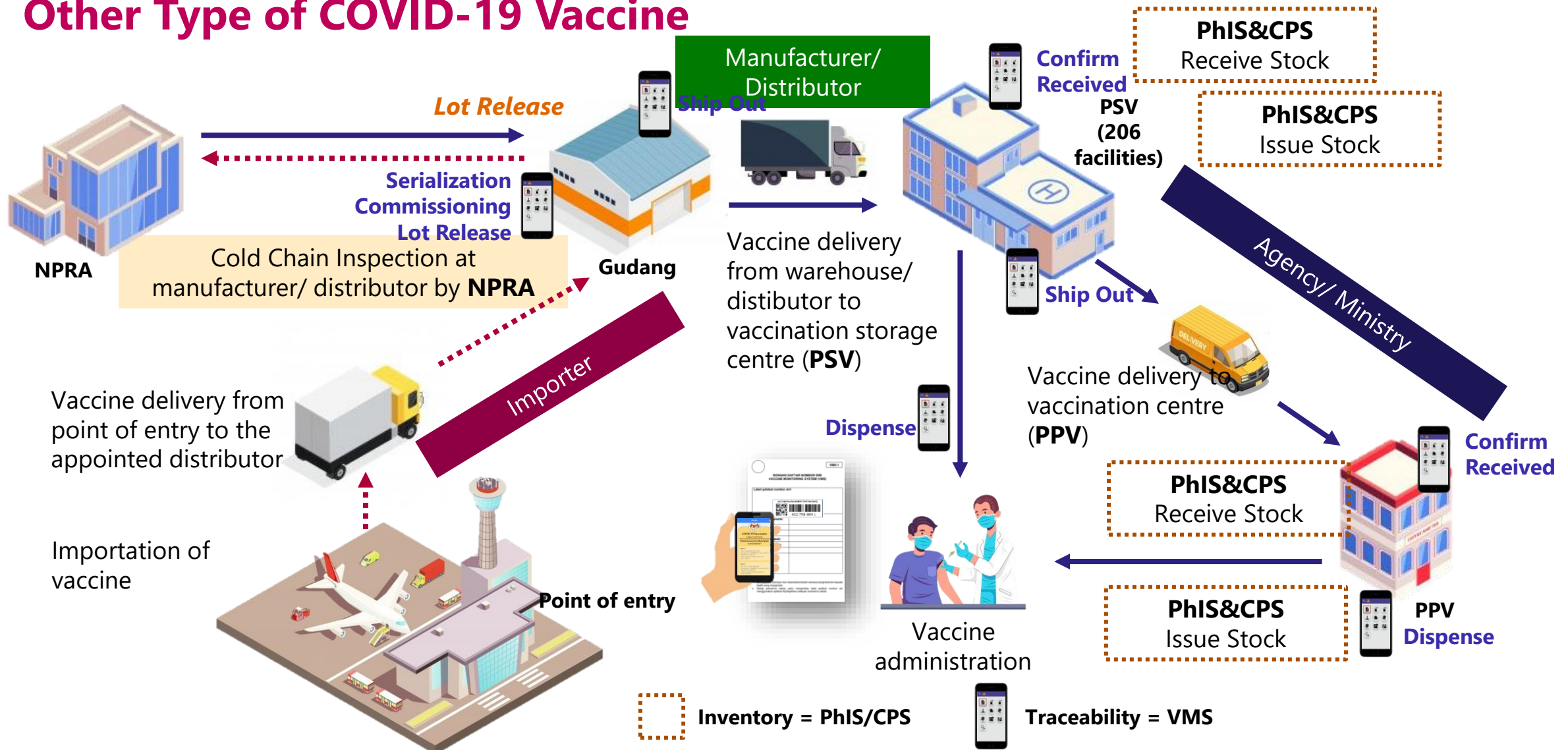
# Vaccine Management System (VMS) Track & Trace Proof of Concept (POC)

**Comirnaty**



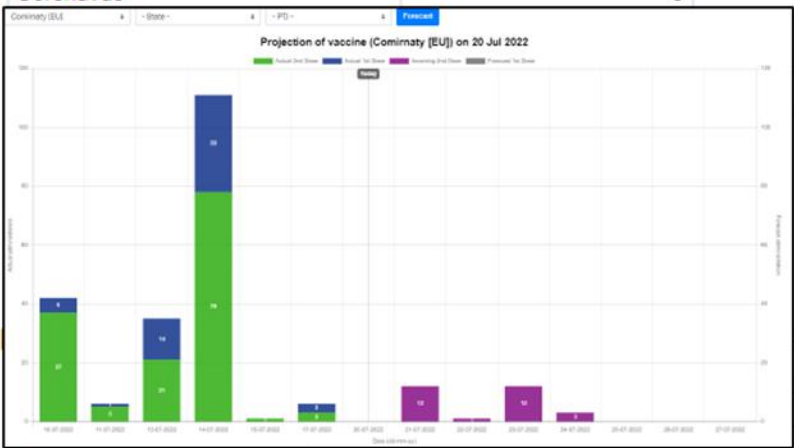
# Vaccine Management System (VMS) Track & Trace Proof of Concept (POC)

## Other Type of COVID-19 Vaccine



# Vaccine Management System (VMS) Track & Trace Proof of Concept (POC)

Vaccine	Commissioned	Rejected	Released
CanSino	0	0	0
Comirnaty [BE]	0	0	0
Comirnaty [EU]	109,785	0	109,785
CoronaVac	0	0	0



Timeline of vaccine events:

- 01 June 2021 04:27:07 PM**  
Activity: CONFIRM RECEIVED  
Quantity: 10  
Facility Code: 11-14010002  
Facility Name: Hospital Kuala Lumpur  
Facility Type: HOSPITAL  
Created by: Pauline Yun Shin Ying
- 31 May 2021 08:48:16 PM**  
Activity: SHIP OUT  
Quantity: 10  
Facility Code: 9555921409995  
Facility Name: Pharmaniaga Logistics Sdn. Bhd.  
Facility Type: MANUFACTURER  
Created by: MOHD HAFIZ BIN AB RAHM
- 26 May 2021 07:33:19 AM**  
Activity: COMMISSIONING  
Quantity: 10  
Facility Code: 9555921409995  
Facility Name: Pharmaniaga Logistics Sdn. Bhd.  
Facility Type: MANUFACTURER
- 26 May 2021 08:31:44 AM**  
Activity: RELEASED  
Quantity: 10  
Facility Code: 9555921409995  
Facility Name: Pharmaniaga Logistics Sdn. Bhd.  
Facility Type: MANUFACTURER

End date  
23/12/2021

Supply & Demand (MyVAS Booking Slots)

Booking Type	Total Open Slots Closed	Total Vaccine Slots Closed	Total Demand
SAPPHIRE/BEA	45,000	0	45,000
SAPPHIRE	4,000	0	4,000
COVID-19	1,000,000	40	725,000
COVID-19 - PHASE	476,770	28,000	48,000
COVID-19 - PHASE	47,000	0	48,000

Vaccine Lifecycle Flow:

- 7925325034038** (Comirnaty [EU] - FG6272) Expired: 31-03-2022 Balance: 5
- 4779742007832** (Comirnaty [EU] - FK9414) Expired: 31-05-2022 Balance: 0
- 4964216653161** (Comirnaty [EU] - FK9414) Expired: 31-05-2022 Balance: 0
- 09-09-2021 22:10:13 **COMMISSIONING** Hospital Keningau (196 Visible)
- 09-09-2021 22:10:40 **RELEASED** (196 Visible)
- 01-12-2021 16:25:26 **DISPENSING** (6 Visible)

Multiple events either SHIP\_OUT or CONFIRM\_RECEIVED recorded.

COVID-19 Vaccination Digital Certificate

# Vaccine Management System (VMS)

## Track & Trace Proof of Concept (POC)

### Gap Analysis

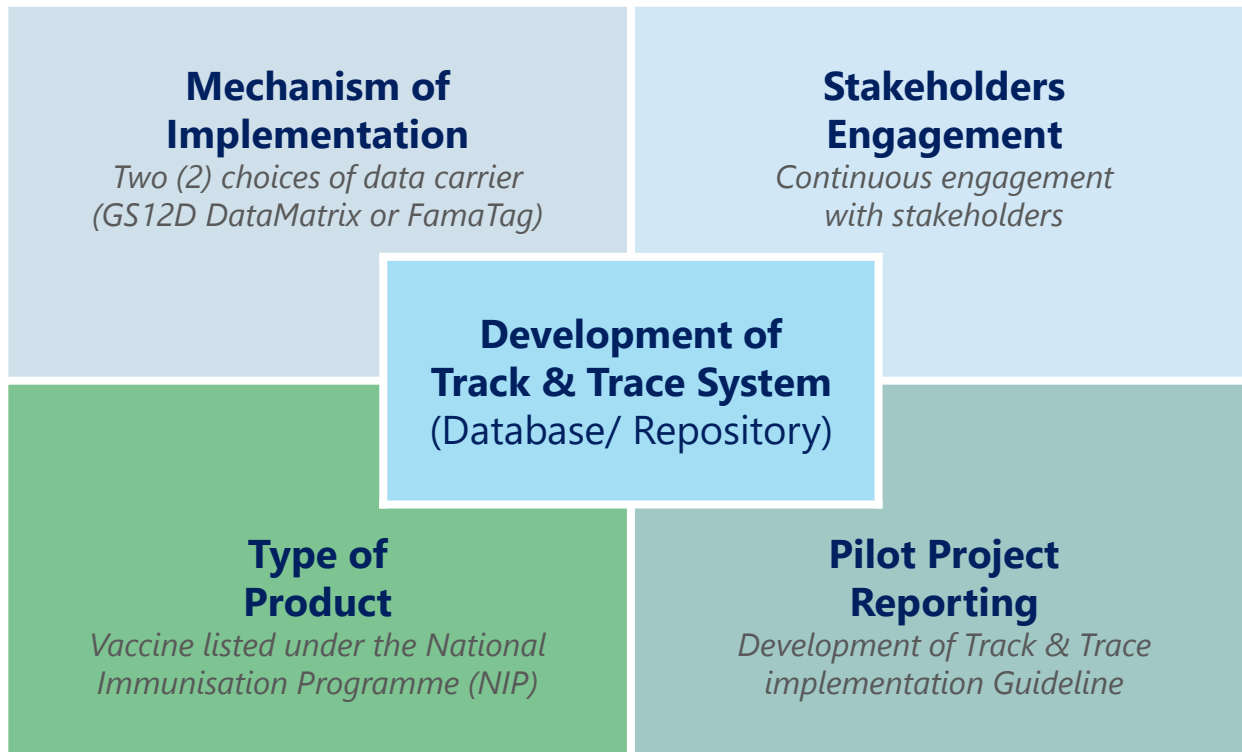
\*NPRA, November 2021

#	Item	VMS	Track & Trace (to be)
1.	<b>Product</b>	COVID-19 vaccine (18 types & variants)	All registered product* (A,XT,N): Scheduled poison (7,317), Non-poison (2,597), Health Supplement (2,307), Traditional (12,900)
2.	<b>Serialization</b>	Serialization number generated by VMS	Serialized GTIN (sGTIN): GTIN, Lot, Expiry & Serialization Number
3.	<b>Packaging levels</b>	PKU/ Unit box/ Secondary packaging	Secondary Packaging/ Saleable unit, aggregation
4.	<b>System integration</b>	PhIS, CPS, MyVAS, MySejahtera	QUEST, ERP, WMS, HIS, PhIS&CPS, POS, other relevant agencies
5.	<b>Activity/ Process</b>	Absence of activity: aggregation, decommission	GS1 EPCIS Standard; Commissioning, Aggregation, Shipping, Receiving, Disaggregation, Dispensing, Decommission, etc.
6.	<b>Database</b>	Government-own	Government-own
7.	<b>Stakeholders</b>	End-to-end (COVID-19 vaccine only)	End-to-end (all registered product)
8.	<b>Patient Data</b>	Vaccinee information	Absence of patient/ consumer information

# Pharmaceutical Track & Trace System Pilot Project

The proposal was presented and notified by the Drug Control Authority (DCA) 374<sup>th</sup> Meeting on July 7<sup>th</sup>, 2022

- i. Improving the existing Security Label (Hologram) System
- ii. Standard data carrier consisting of unique ID (UID) on every product – for identification and verification
- iii. Scanning of UID – capture and record defined activities related to product



Commencement of Pilot Project: **Jan 2023 to June 2023**

 **PEJABAT PENGARAH KANAN PERKHIDMATAN FARMASI**  
**OFFICE OF THE SENIOR DIRECTOR OF PHARMACEUTICAL SERVICES**  
Kementerian Kesihatan Malaysia  
*Ministry of Health Malaysia*  
Lot 36, Jalan Prof Diraja Ungku Aziz, Petaling Jaya 46200 SELANGOR  
MALAYSIA  
Tel: 03-7841 3201  
Faks: 03-7968 2222  
Laman Web: [www.pharmacy.gov.my](http://www.pharmacy.gov.my)  
E-mel: [pejabatpkpf@moh.gov.my](mailto:pejabatpkpf@moh.gov.my)

**POS BERDAFTAR**

Ruj. Kami : NPRA.600-1/9/7 (40)Jid-1  
Tarikh : 18 Julai 2022

**SEMUA PEMEGANG PENDAFTARAN**

**SEMUA PERSATUAN BERKENAAN  
(SEPERTI DI SENARAI EDARAN)**

Tuan / Puan,

**PELAKSANAAN PROJEK RINTIS PHARMACEUTICAL TRACK & TRACE**

Dengan hormatnya saya merujuk kepada perkara tersebut di atas.

2. Pihak Berkuasa Kawalan Dadah (PBKD) melalui mesyuaratnya kali ke-**374** pada **7 Julai 2022** telah mengambil maklum berkenaan perkara berikut :

- 2.1 Kerajaan sedang membangunkan sistem *Pharmaceutical Track & Trace* yang meliputi keseluruhan rantaian bekalan (*end-to-end*) bermula dari Pemegang Pendaftaran Produk (PRH)/ pengilang/ pengimport sehingga ke peringkat pengguna akhir (*end user*).
- 2.2 Projek rintis akan dilaksanakan selama **6 bulan** dan dijangka bermula **Januari 2023 hingga Jun 2023**.
- 2.3 Sesi libat urus bersama semua pemegang taruh yang terlibat dengan projek rintis akan dijalankan sebelum projek dilaksanakan.

# Pharmaceutical Track & Trace System Pilot Project

## Type of Product

Vaccines (imported & locally manufactured) listed under the **National Immunization Programme**: (BCG, Diphtheria&Tetanus, Haemophilus Influenza Type B, Hepatitis B, Measles, MMR, Meningococcal & Typhoid)  
Other products TBC

## Rationale:

- (i) **Cold chain item** – well controlled environment and stakeholders' involvement
- (ii) **Stakeholders** – identify, engagement session, training, system integration & requirement
- (iii) **Align with digitalization of vaccine certificate** by the Public Health Programme MOH Malaysia

## Data Carrier

- (i) **GS1 2D DataMatrix** (direct serialization on packaging)
- (ii) **Hologram FarmaTag™**

## Rationale:

- (i) **Implementation of track & trace by phases** – voluntary & mandatory phases by category of product
- (ii) **During voluntary phases** – both GS1 2D DataMatrix and Hologram will be used; to study the impact, issues & challenges, feedback from stakeholders and feasibility of system & implementation
- (iii) **Stakeholders' readiness** and **sufficient timeline** for mandatory phases

# Mechanism of Implementation

## Pilot Project Pharmaceutical Track & Trace System

Two (2) choices of data carrier :



Serialized GTIN (sGTIN): GTIN, Lot, Expiry & Serialization Number

OR



Product's data submission and commissioning; upload into Authority's Centralized Track & Trace System as follows:

### GS1 2D DataMatrix

### Hologram FarmaTag™

#### Imported Product

- **Direct serialization** from country of origin OR by licensed premises in Malaysia
- **Data submission** and **commissioning** shall be implemented

Import license holder shall:

- Apply Hologram FarmaTag™ on packaging
- Carry out product **data assignment** for every hologram security label applied on packaging

#### Locally Manufactured Product

- **Direct serialization** by the manufacture (in-house process)
- Manufacturing license holder shall carry out **Data submission** and **commissioning**

Manufacturing license holder shall:

- Apply Hologram FarmaTag™ on packaging
- Carry out product **data assignment** for every hologram security label applied on packaging

End-to-end (every stakeholders at all level of supply chain)

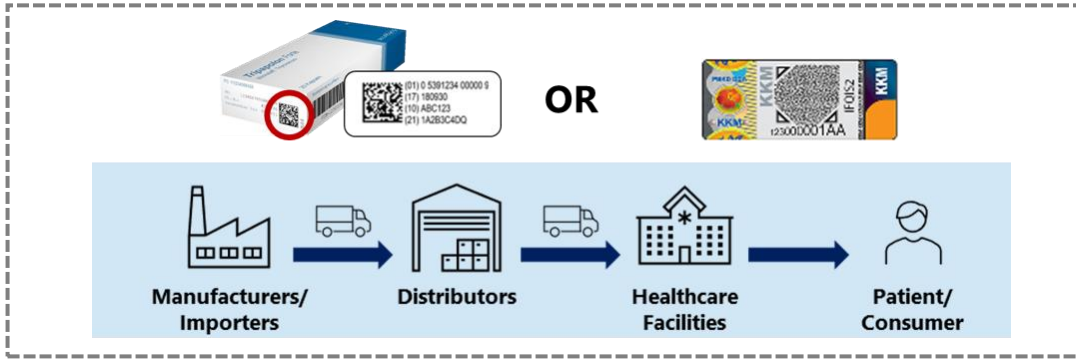


Capture data and record defined activities related to product



# Timeline

## Pilot Project Track & Trace



### Pending:

- (i) Appointment of solution provider to develop Track & Trace
- (ii) Stakeholders' engagement after the appointment of solution provider

2022	Jul	Present & Notify DCA on <b>Pilot Project Proposal</b>		2023	Jan	Implementation of Track & Trace <b>Pilot Project</b>
	Aug	Stakeholders' engagement	Track & Trace <b>module and system development</b>		Feb	
	Sept				Mar	
	Oct				Apr	
	Nov				May	
	Dec				Jun	
					Jul	Pilot Project <b>Report</b> & Implementation <b>Guideline</b>
	Aug	Pilot Project Report in DCA Meeting & <b>DCA Directives on Track &amp; Trace</b> Implementation				
	Sept	Commencement of Track & Trace <b>implementation in phases (scheduled poison)</b>				

## (Potential) Issues & Challenges

# Pilot Project Pharmaceutical Track & Trace System

### Operational Efficiency

Operational efficiency lost is observed while switching to serialized warehouse operations.

Efficiency recovers over time when systems and operations stabilized but maybe not to the original efficiency levels

### Cost

Serialized operations incurs additional cost especially for logistics operations outsourced to 3PL

### Technology

Investment in information system and equipment upgrade is required in supporting integration with sterilization management systems.

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### Good Distribution Practice (GDP)

Instead of managing inventory by quantity, it is necessary to track by individual unit. Scanning and validation of serial numbers in each step is required to ensure data accuracy and capture product movement of individual units for compliance.

Operations are no longer only managing the physical product as GDP. Now operations has to manage the physical product and also the parallel data both as GDP.

**Stakeholders:** Authority, Industry, Healthcare Facilities & Consumer

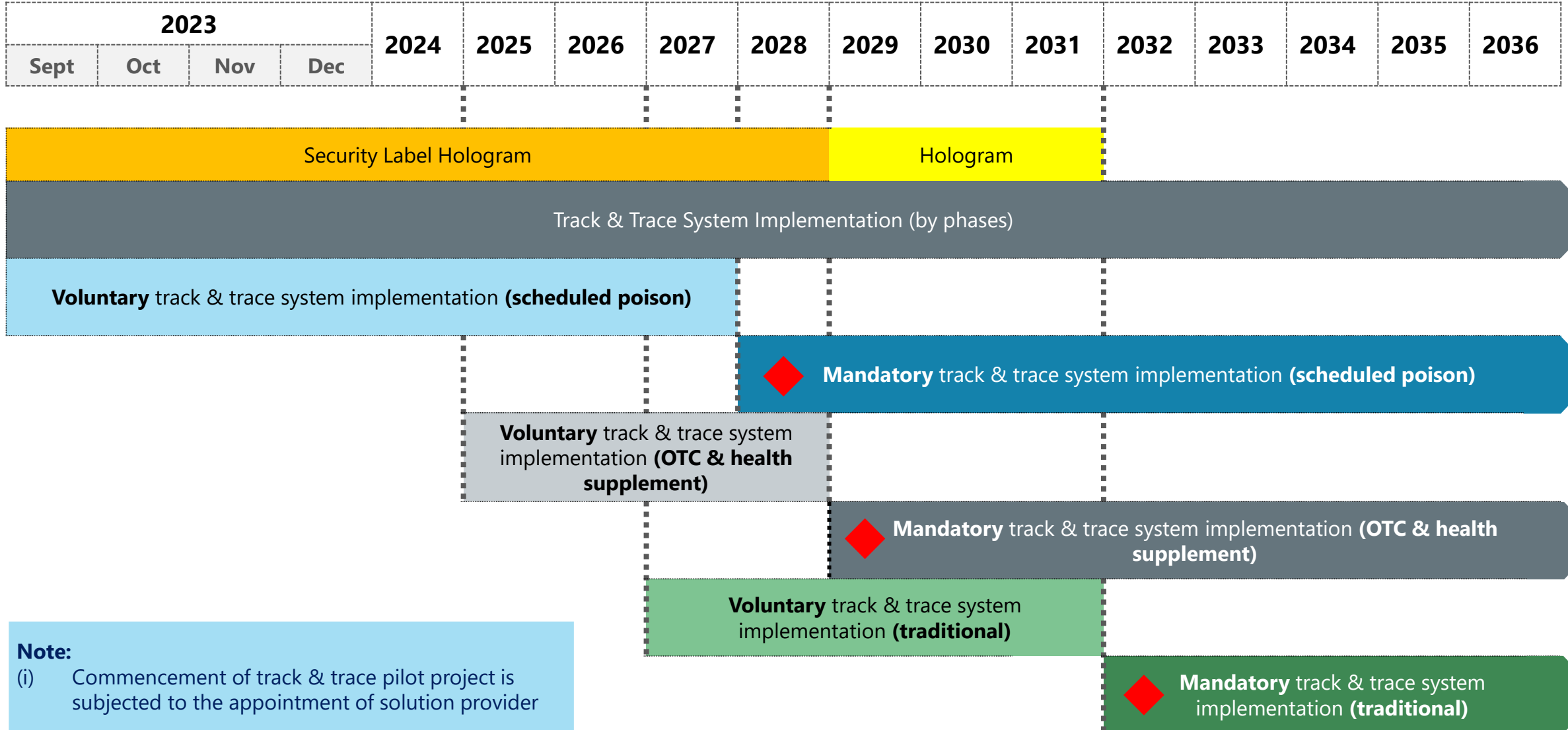
# Moving Forward

## Pharmaceutical Track & Trace System

- Using lessons learned and leveraging from past experiences
- Promoting pilots and tests in case of new regulatory needs or purposes
- Focusing on collaboration and always keeping open dialogue
- Starting simple, gathering learnings and evolving

# (Projected) Timeline

## Full Implementation Pharmaceutical Track & Trace System



# THANK YOU

## Track & Trace : Implementation Plan & Updates

Pharmaceutical Services Programme, Ministry of Health Malaysia

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### References:

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- (iii) Policy paper on traceability of medical products. Geneva: World Health Organization; 2021.
- (iv) Malaysian National Medicines Policy, Ministry of Health Malaysia 3rd Edition (2017-2021).
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- (vi) Pelan Strategik Pendigitalan, Kementerian Kesihatan Malaysia, 2021.
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