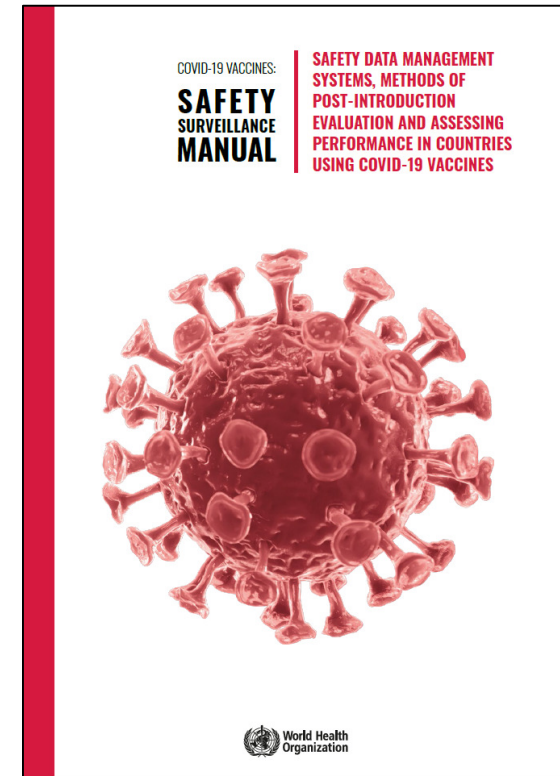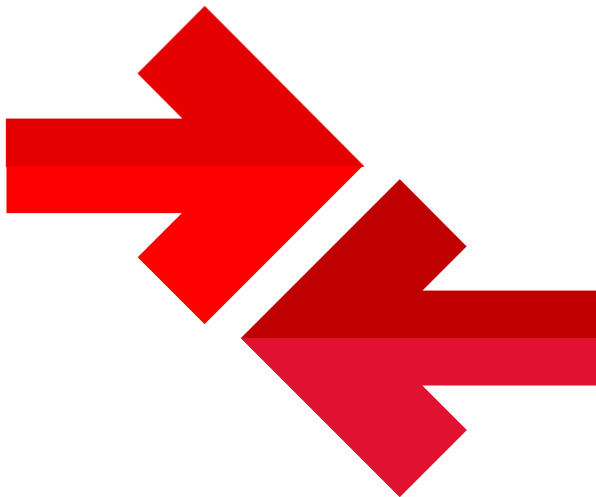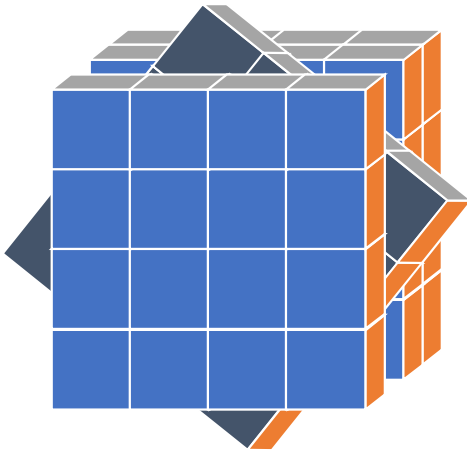Safety data management systems, methods of post-introduction evaluation & assessing performance in countries using COVID-19 vaccines
&
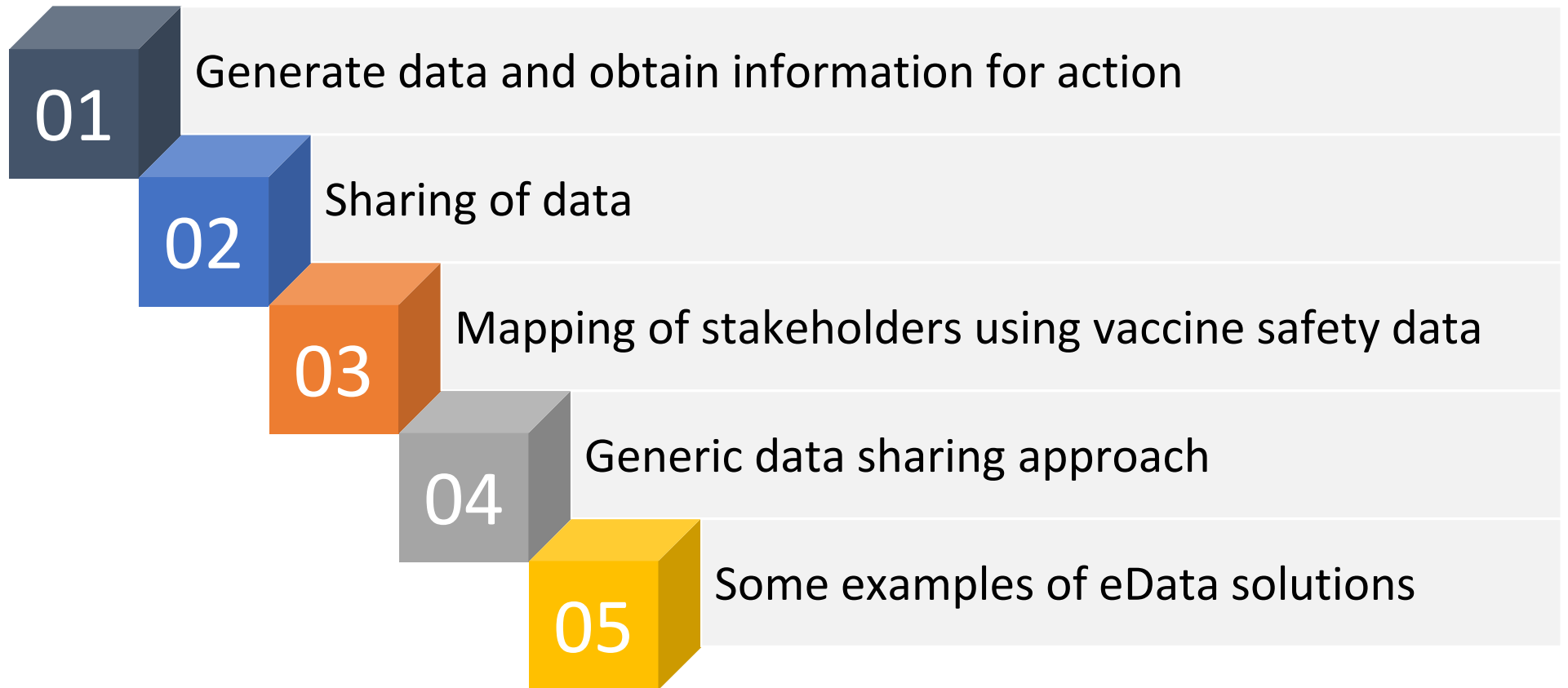Some examples of eData solutions

Learning objectives: The learner should be able to

01 Explain how data generation can provide information for action

02 Demonstrate the impact of sharing of data

03 Map the stakeholders using vaccine safety data

04 Use eData solutions for data management

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Presentation structure

01 Generate data and obtain information for action

02 Sharing of data

03 Mapping of stakeholders using vaccine safety data

04 Generic data sharing approach

05 Some examples of eData solutions

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From data generation to information for action

Source of AEFI data

Interview patient or parent, look at records, logistics etc.

Transcription

Complete reporting form.

Feedback

Use data to explain the logic of the decision to the public and stakeholders

Transmission

Send the completed form to the next level in hierarchy.

Decision

Based on need slice and dice data further

Analysis/interpretation

Look at the graphs, tables and line lists

Processing/data cleaning

Data entry into database

In country software, Complete reporting form.

Review the data entered and check for mistakes and inconsistencies.

Feedback — AEFI Detection — Notification — Reporting — Investigation — Analysis — Causality assessment

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Vaccine Safety Data

Impact of data sharing

National:
- Data in some countries will be reported through multiple channels, with programmes working on data from the same patients and sometimes via the same health care professional, but with different goals and pathways.

Regional and global
- Maximizes resources and capacity to enable efficient responses and decision-making.
- Improves Signal detection capacity and ability to identify rare events
- Data transformation is usually required to facilitate data sharing.

Outcome of data sharing

Data source	Outcome of data sharing
Data from passive and enhanced passive AEFI surveillance systems	Detect signals, monitor immunization programme activities, monitor events that could be related to defective, un-registered or counterfeit COVID-19 vaccines.
Data from active surveillance systems	Verify and confirm the post-licensure safety profiles of COVID-19 vaccines, test hypotheses (epidemiologic associations between AEFIs and COVID-19 vaccines), detect signal with an accelerated time from reporting to detection
Data from COVID-19 vaccine manufacturers	Bi-directional sharing of data with COVID-19 vaccine manufacturers will help ensure that data collection is complete and avoid double counting of events. In addition, the manufacturers may be aware of data from other countries or sources that can help in the evaluation of AEFIs.
Data from other sources such as disease surveillance data, vaccine distribution and utilization data	Generate rapid alerts to trigger common responses from a geographical territory, know the implementation level, know the quality of surveillance at the national level to plan for improvement strategies, understand the distribution of different COVID-19 vaccines and to compare with distribution of the disease for interpreting patterns observed during data analysis.

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Mapping Stakeholders and data

Stakeholder	Current data mapping (variable in different contexts)
District/Subnational level	
Health care institutions	▪ Individual Case AEFI Reports ▪ Case Report Form for ad-hoc studies
Disease surveillance offices	▪ Investigation information to complete Individual Case AEFI report ▪ Data on local epidemiological behaviour of infectious diseases
Immunization programme offices	▪ Data on immunization activities ▪ Individual Case AEFI reports

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Mapping Stakeholders and data

| Stakeholder	Current data mapping (variable in different contexts)
National level	
Disease surveillance Responsible	▪ Data on infectious and non-infectious diseases ▪ Data on AEFI surveillance
National Immunization Programmes / Expanded Programmes for Immunization	▪ Data on immunization activities: Administrative data and distribution activities ▪ Data on AEFI surveillance.
National Regulatory Authorities	▪ Data on AEFI surveillance from primary health care workers and citizens ▪ Data on AEFI surveillance from manufacturers ▪ Data on Adverse Event reports from clinical trials
Health information systems units	▪ Data from all sources in the country
Research institutions/Clinical Research Organization	▪ Individual Case Safety (Adverse Events) Reports from clinical trials ▪ Data on diseases considered as AESI/AEFI
Vaccine manufacturers or marketing authorization holders	▪ Individual Case AEFI report
Clinical Research Sponsors	▪ SUSAR from clinical trials

Mapping Stakeholders and data

Stakeholder	Current data mapping (variable in different contexts)
Regional and Global Level	
WHO regional offices	- WHO-UNICEF JRF - Individual case reports on infectious disease surveillance - Access to WHO UMC Global ICSR/ AEFI database
WHO Headquarters	- WHO-UNICEF JRF - Individual case reports on infectious disease surveillance - Access to WHO UMC Global ICSR/ AEFI database
WHO PIDM/VigiBase (maintained by UMC)	- Individual Case AEFI report - WHO UMC Global ICSR/ AEFI database

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Vaccine safety dataflow for COVID19

Generic data sharing model

Subnational
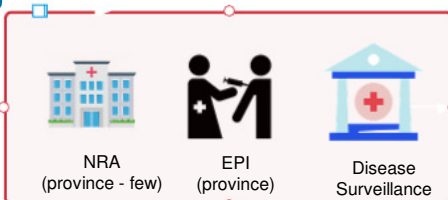
NRA (province - few) EPI (province) Disease Surveillance

❸ eTools eg DHIS2, Vigiflow for vaccines or country developed tools supported by email

❷ eTools eg DHIS2, Vigiflow for vaccines or country developed tools supported by email

District program manager

❷

❶

AEFI reporting form

❶
1. Hard copies directly submitted to districts
2. EDI (electronic data interchange eg DHIS2 & Medsafety APP for AEFI)
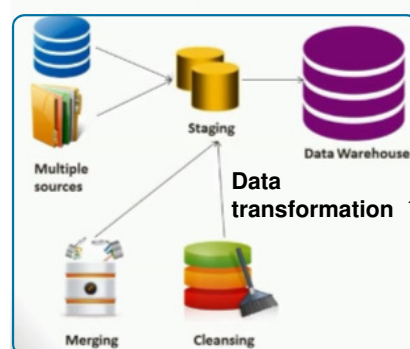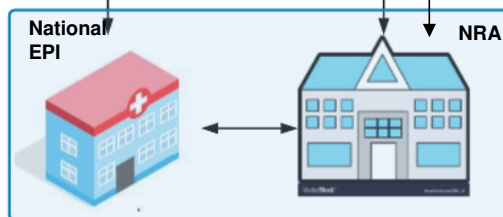
National

❸

National Database

Manufacturers

National EPI NRA

Data transformation

Multiple sources Staging Data Warehouse Merging Cleansing

Global

Relevant Committees

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PV Team PQ Team

Manufacturers

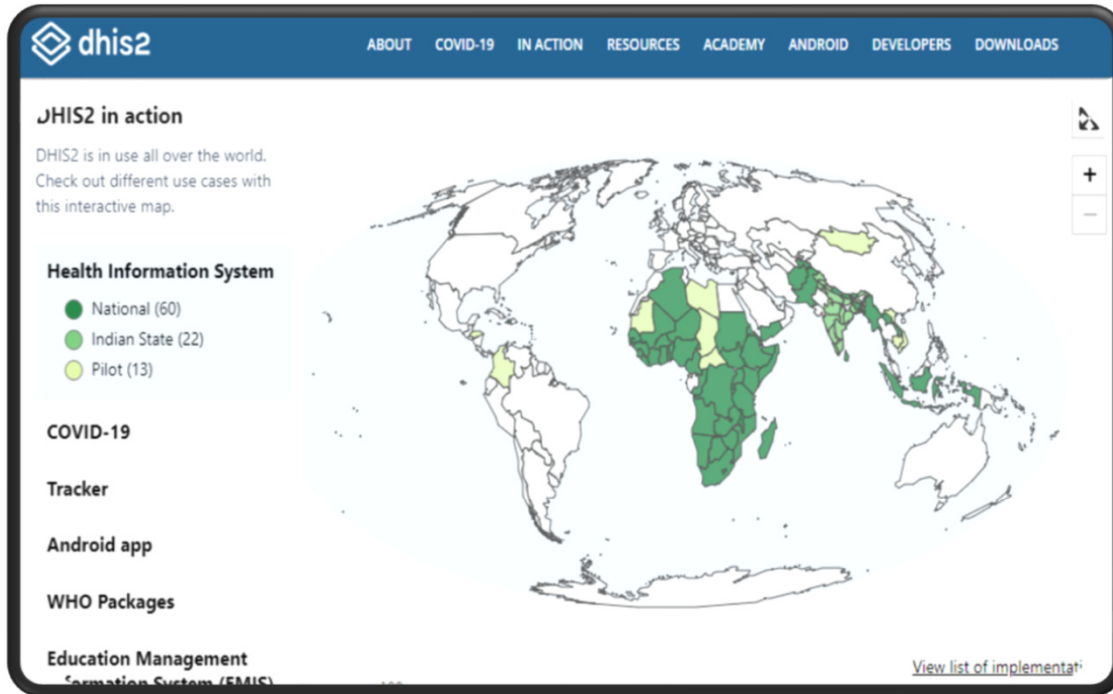**Global Database (WHO PIDM)**

❹

❹
Transformation to E2B (R3) format
• Ready for Vigiflow
• Under development for DHIS2 for AEFI & Medsafety App for AEFI
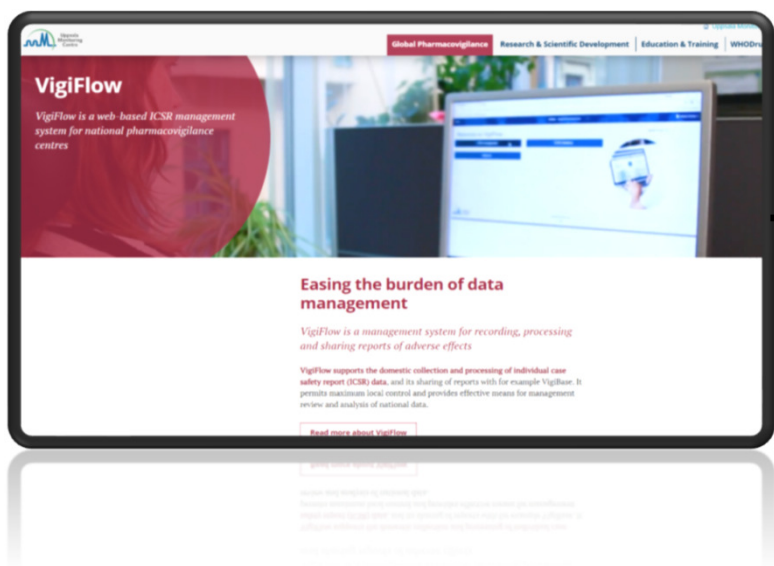
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Some examples of eData solutions

DHIS2

National DHIS2 Database

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Vigiflow

E2B(R3)

National Database

Global Vigibase (Sweden)

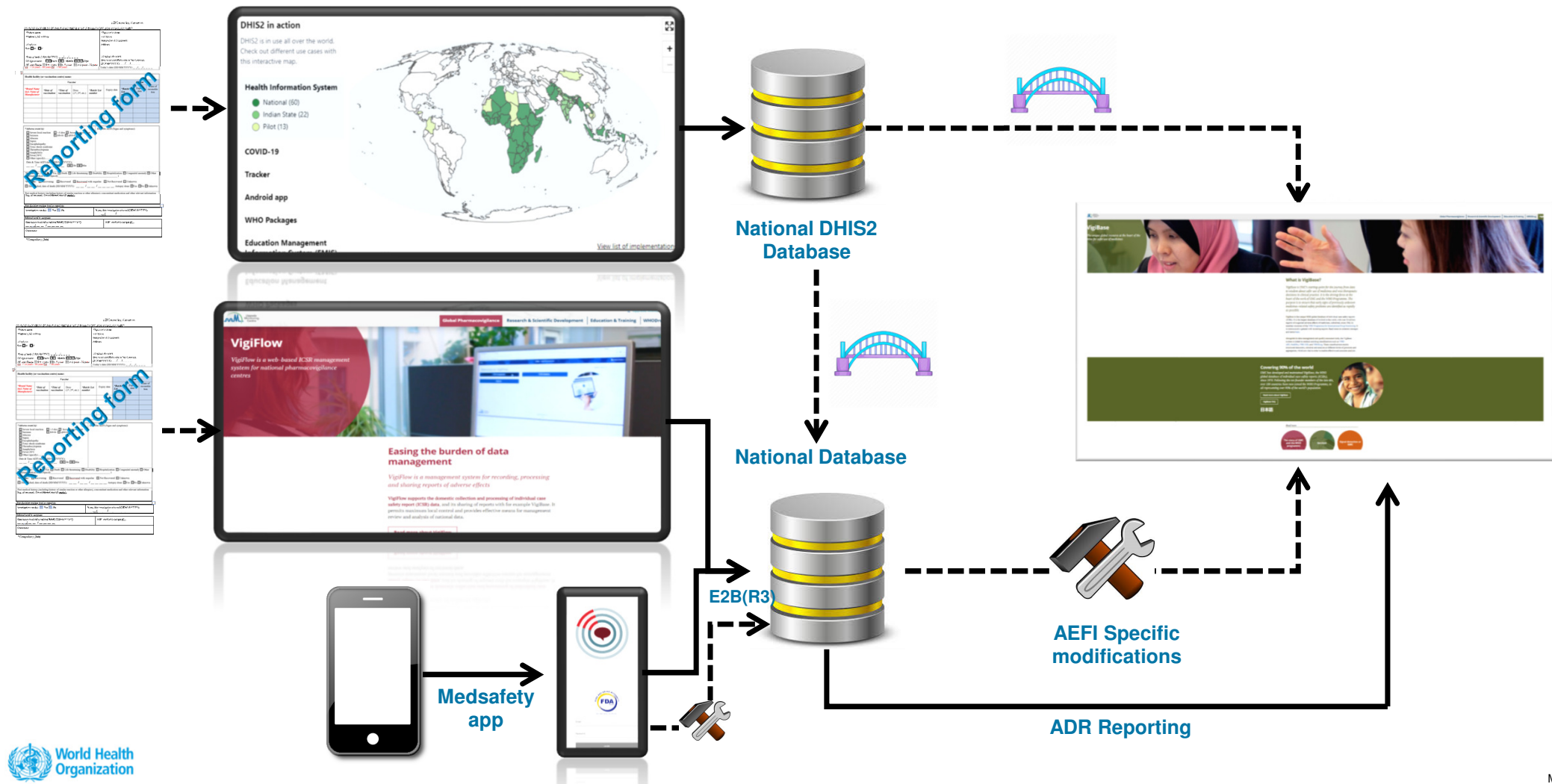MRB

MedSafety App

The Med Safety app is a free smart phone app for reporting suspected adverse effects (or adverse drug reactions) to National Competent Authorities. This simple tool lets you report adverse effects to medicines, keep track of previously reported information and receive official news and alerts about medicines you are taking or interested in.

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COVID19 Solutions under development...

E2B (R3) Bridge

Under development

DHIS2 in action

DHIS2 is in use all over the world. Check out different use cases with this interactive map.

Health Information System
- National (50)
- Indian State (22)
- Pilot (13)

COVID-19

Tracker

Android app

WHO Packages

Education Management

View list of implementation

National DHIS2 Database

National Database

Reporting form

VigiFlow

VigiFlow is a web-based ICSR management system for national pharmacovigilance centres

Easing the burden of data management

VigiFlow is a management system for recording, processing and sharing reports of adverse effects

VigiFlow supports the domestic collection and processing of individual case safety report (ICSR) data, and its sharing of reports with for example VigiBase. It permits maximum local control and provides effective means for management review and analysis of national data.

Reporting form

E2B(R3)

Medsafety app

FDA

AEFI Specific modifications

ADR Reporting

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Key points to remember

- Data is generated to obtain information that leads to action

- Actionable data is obtained only when data is shared, processed and interpreted and decisions taken.

- Data standards and harmonization are mandatory for data sharing particularly when eData solutions are used to handle large volumes of data

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References

- World Health Organization. Global Manual on Surveillance of AEFI: https://www.who.int/vaccine_safety/publications/Global_Manual_on_Surveillance_of_AEFI.pdf

- WHO/UNICEF Joint Reporting Process: https://www.who.int/immunization/monitoring_surveillance/routine/reporting/en/

- VigiBase: https://www.who-umc.org/vigibase/vigibase/

- World Health Organization. The ATC/DDD Methodology: https://www.who.int/medicines/regulation/medicines-safety/toolkit_methodology/en/

- Centers for Disease Control and Prevention. Summary report. Reporting for the adoption strategies for 2D barcode project (page 36) : https://www.cdc.gov/vaccines/programs/iis/2d-vaccine-barcodes/downloads/summaryreport.pdf

- Brighton Collaboration.Safety Platform for Emergency vACcines (SPEAC): https://brightoncollaboration.us/speac/

- Van Holle L, Zeinoun Z, Bauchau V, Verstraeten T. Using time-to-onset for detecting safety signals in spontaneous reports of adverse events following immunization: a proof of concept study. Pharmacoepidemiol Drug Saf. 2012;21(6):603 -10. doi: 10.1002/pds.3226

- Lambert PH, Ambrosino DM, Andersen SR, Baric RS, Black SB, Chen RT, et al. Consensus summary report for CEPI/BC March 12-13, 2020 meeting: Assessment of risk of disease enhancement with COVID-19 vaccines. Vaccine. 2020;38(31):4783-4791. doi: 10.1016/j.vaccine.2020.05.064

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Every country should
have locally
appropriate software
solutions!

Thanks
for listening!