WHO SMART Guidelines Approach

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WHO Digital Health Priorities are shaped by the Global Strategy on Digital Health 2020-25 → Extended to **2027**

To improve health for everyone, everywhere by accelerating the development and adoption of appropriate digital health solutions to achieve the health-related SDGs

Strategic Objectives

- **Promote global collaboration & advance the transfer of knowledge on digital health**
- **Advance the implementation of national digital health strategies**
- **Strengthen governance for digital health at global, regional and national levels**
- **Advocate people-centered health systems that are enabled by digital health**

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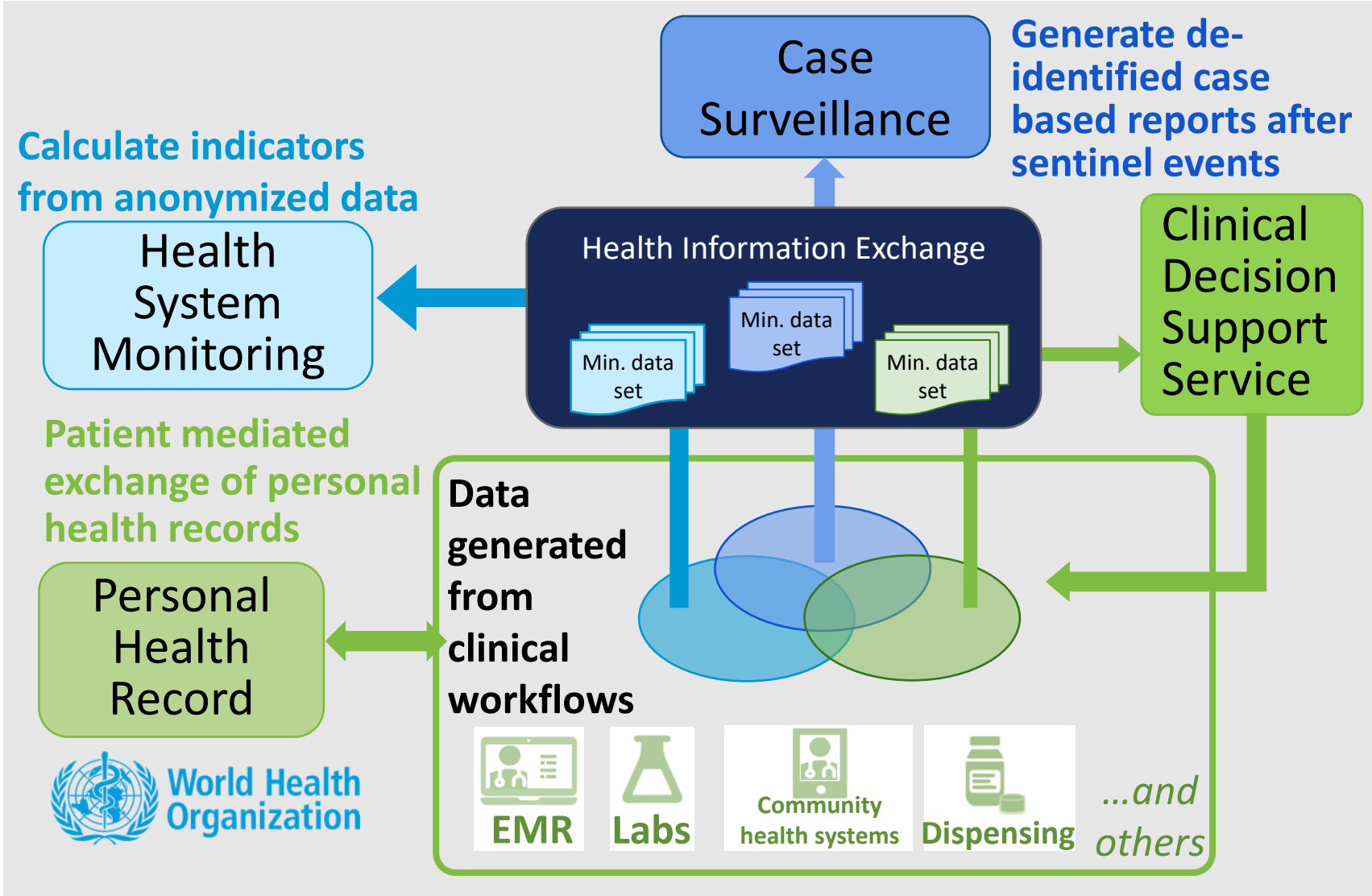
Standardized content enables reuse of data captured in clinical workflows for secondary purposes, reducing burden of data collection ***(Collect once, use many times)***



As countries move forward with digital transformation, there is a need for guidance for technology parties to ensure quality of digital health solutions

WHO develops guidelines using global evidence base.

Ministry of Health ***[Health programme managers]*** adapts global guidance into national policy, procedures, protocols, and data requirements.

Technology partners ***[Digital health teams within Ministry of Health, Digital transformation agency, external vendor]*** translate national policies into digital solutions.

Health workforce delivers health services and conducts reporting according to national policies.

Health service users access person-centered care according to national policies

- **Difficult to scale**
- **Systems are not interoperable**
- "**Black box**" digital systems become **difficult to maintain** and unsustainable
- **Lack of a shared language** for programme needs for digital systems
- Systems not designed in a human-centred way

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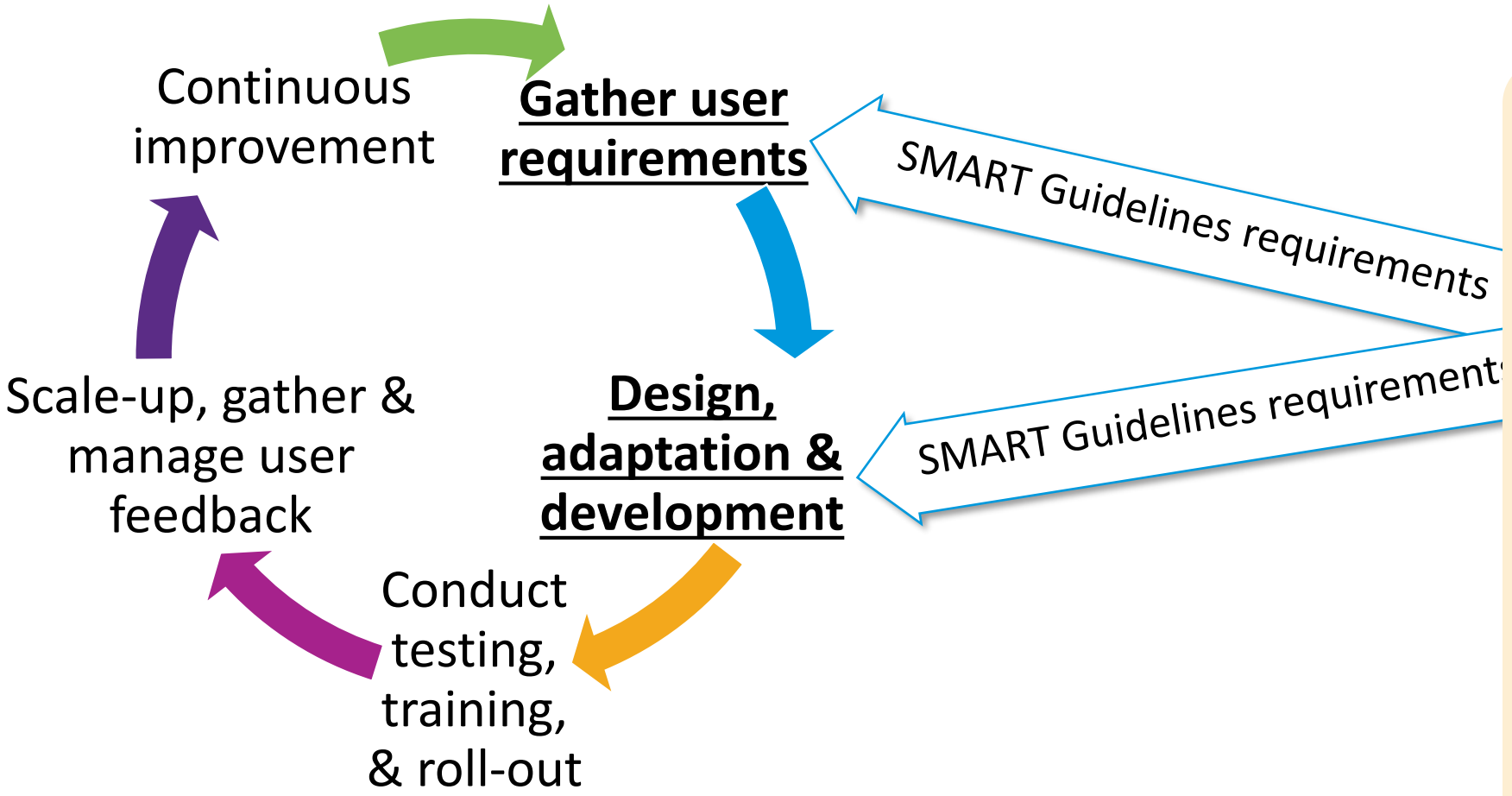
SMART Guidelines intervene at critical steps in the software development lifecycle moving from duplicative development to "building blocks"



Determined by health programmes (e.g. immunization programme)

Health Content

+

Digital health intervention – *discrete functionality of digital technologies*

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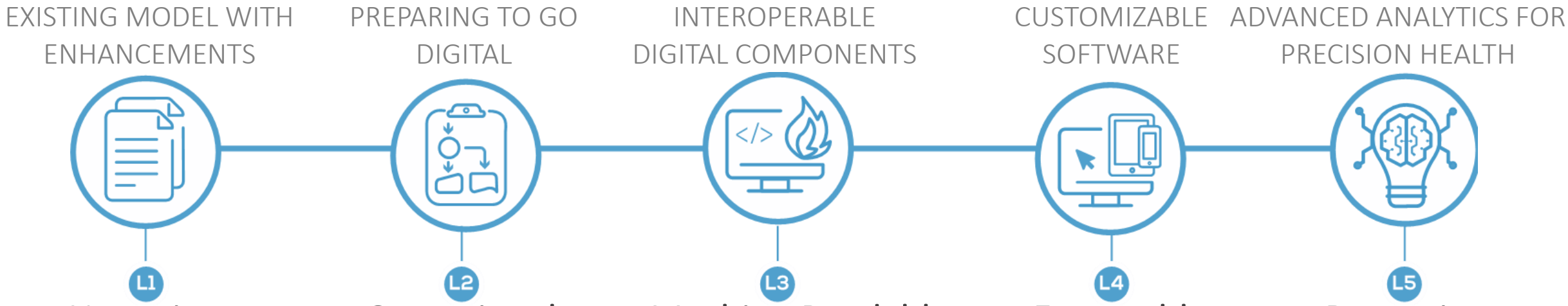
*The software development lifecycle is the same for any and every technology, in any industry

SMART Guidelines are a new approach to representing WHO content as digital health components to preserve fidelity and accelerate uptake

Standards-based, **M**achine Readable, **A**daptive, **R**equirements-based, **T**estable



Narrative

- Operational specificity
- Digital curation of recommendations
- Panels include informatics and standards experts

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Operational

- Consolidation of L1 content
- Digital Adaptation Kit (DAK) – requirements document
- Human-readable components
- Describes how a digital tool should function

Machine Readable

- FHIR Implementation Guide (IG)
- Based on Clinical Practice Guidelines IG
- Software agnostic

Executable

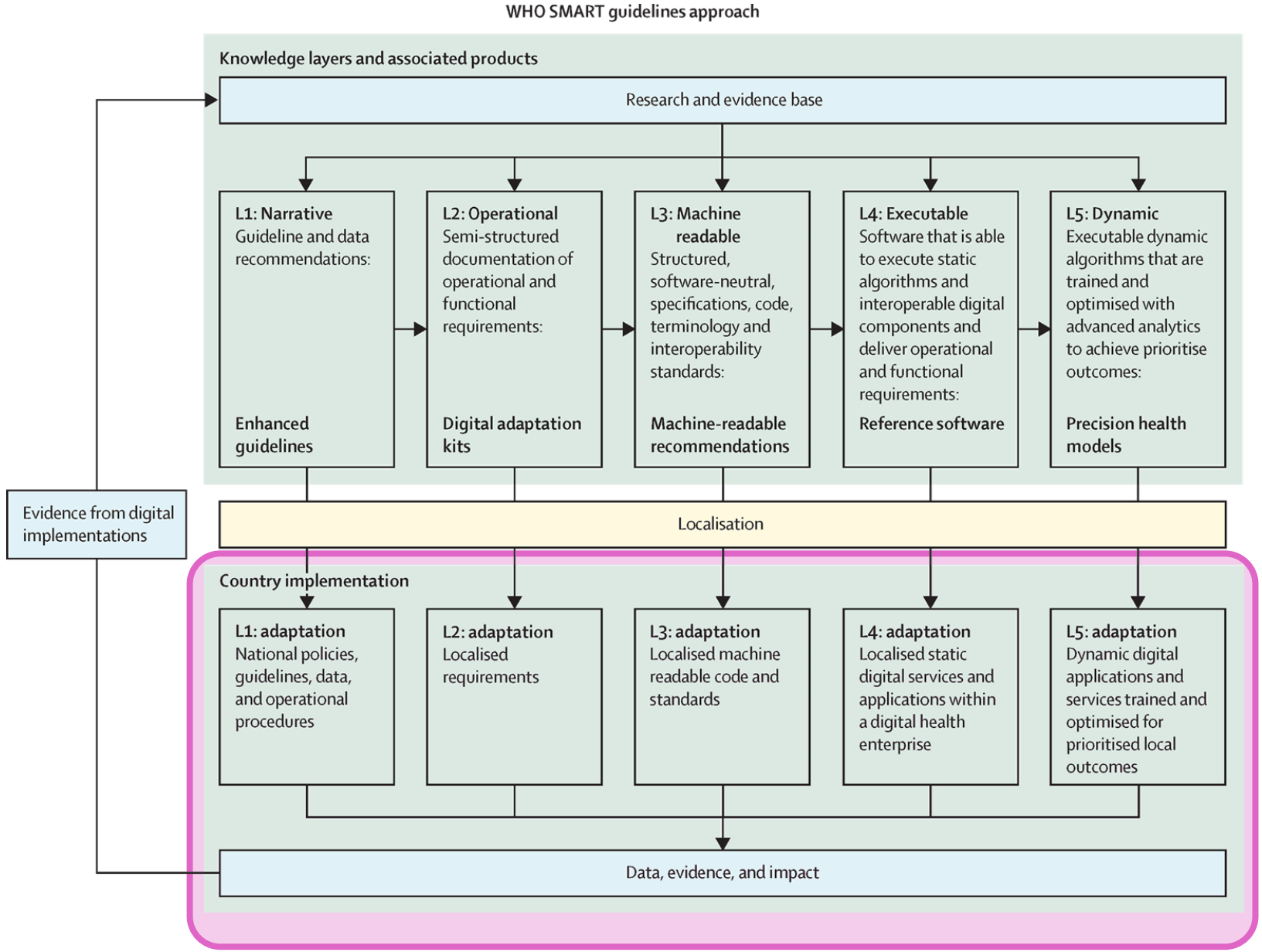
- Fully executable software tools
- Mechanism for real-time updates
- Interoperate with national systems

Dynamic

- Advanced analytics for greater local relevance and precision
- AI-based decision support

Scenarios of use

- Provide a **shared language** among stakeholders
- **Establish benchmark** and standards for systems in countries
- Kick start the requirements gathering process to design the system - **reduce time and resources**
- **Update and align within existing systems** content to WHO standards and guidance, including **interoperability**
- Update content to **improve efficiencies of analog processes** – reducing data collection



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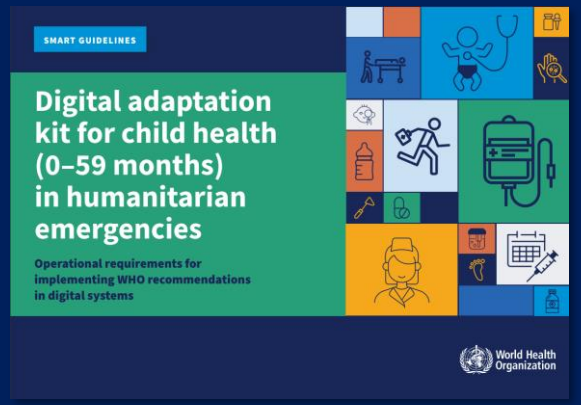
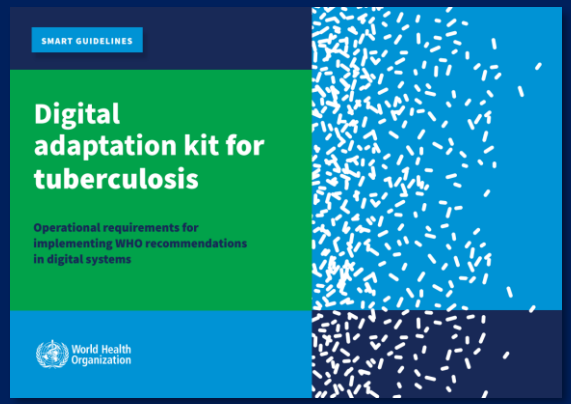
Examples





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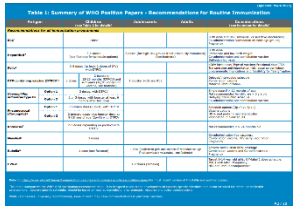
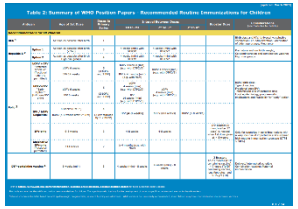
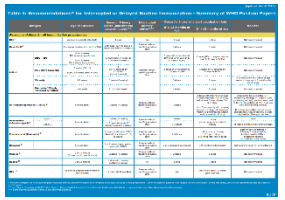
L1: WHO guidelines, recommendations and guidance references



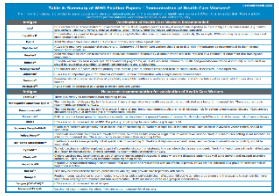
Summarizes recommended routine immunizations for all age groups (updated in 2024) (29)



Detailed information of routine immunizations for children (updated in 2024) (29)

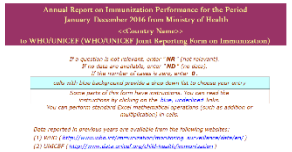


Recommendations for interrupted and delayed vaccination (updated in 2024) (29)

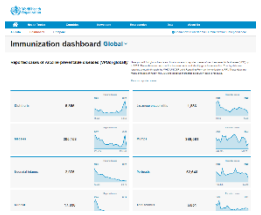


Summarizes WHO recommendations for the vaccination of health workers (updated in 2024) (29)

Analysis and use of health facility data: guidance for immunization programme managers (26)



Sample of the WHO/UNICEF joint report form on immunization (30)

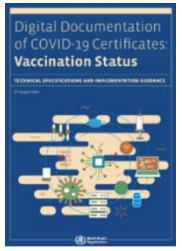


The WHO Immunization Data Portal: providing access to important immunization data and insights (24)

Leave no one behind: guidance for planning and implementing catch-up vaccination (31)

Electronic immunization registry: practical considerations for planning, development, implementation and evaluation (15)

Monitoring metrics related to the global COVID-19 vaccination strategy in a changing world (32)



Digital documentation of COVID-19 certificates: vaccination status: technical specifications and implementation guidance (28)

- **Immunizations guidance in scope of immunizations' DAK**
- **Consolidation of guidance documents & position papers**

Each component of a L2 Digital Adaptation Kit (DAK) is used to inform the design of a digital system (i.e., requirements document)

1 Health Interventions & Recommendations

- Relevant health interventions and recommendations from the WHO guideline and guidance.
- To inform DAK scope.

2 Generic Personas

- Roles, responsibilities, and essential interventions performed by targeted personas.
- Example for human centered design.

3 User Scenarios

- Brief narrative description of how the targeted personas may engage with the digital system.
- Example for human centered design.

4 Business Processes & Workflows

- Generic workflows representing clinical and non-clinical processes.
- To inform when data is collected and used & required features.

5 Core Data Elements

- Data elements, used for clinical decision-making, indicators, and other data needs.
- To inform data collection forms and L3 interoperability requirements.

6 Decision Support Logic

- Decision tables representing counselling and treatment algorithms, and any other logic used to determine workflows paths or clinical actions.

7 Scheduling logic

- Decision tables representing scheduling logic according to care plans.

**Previously combined with decision support logic*

8 Indicators & Monitoring

- Indicators for reporting & monitoring with numerator, denominator of data elements.
- Linking person centered data to aggregate.

9 Functional & Non-functional Requirements

- A non-exhaustive list of key functions and non-functional requirements for a digital tracking and decision support system.
- To inform system features.

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L2: Operational | Preparing to go digital

Key generic and related personas

Table 2. Descriptions of key generic personas

Occupational title	Description	Other Names/examples	ISCO code
Health worker	Health workers facilitate education sessions, administer immunizations, provide counselling when needed, record stock movements and compile/generate reports.	Nurse, registered nurse, practical nurse	3221 (Nursing associate professional)
Community health worker	Community health workers provide health education, referral and follow-up, case management and basic preventive health care and home visiting services to specific communities. They provide support and assistance to clients by reminding them to get their vaccinations, responding to emergencies, and reporting births.	Community health volunteer, village health worker, volunteer assistant, volunteer health worker, treatment	3253 (Worker, community: health)
Expanded Programme on Immunization Manager	Expanded P plans, immu logistics, m EPI activitie		

Table 3. Descriptions of related personas

Name	Description	Other names/examples	ISCO Code
Caregiver	Mother, father, guardian, carer of the child, infant, elderly, or disabled person.	Parent, guardian	N/A
Client	In the context of this document, a client is a person who intends to receive immunization services from the targeted health worker personas. A client who is 15 years of age or younger is considered a child.	Vaccinated person	N/A
Child	A client who is 15 years of age or younger and who intends to receive immunization services from the targeted health worker personas.	Infant, baby, client	N/A
Electronic Immunization Registry staff	An electronic immunization registry (EIR) staff supervises the operation and storage of electronic health records and makes sure the server functions properly to allow clients and staff to communicate with each other, coordinate their actions and take care of essential tasks.	System administrator, IT manager, technical support	2522 (Administrator, IT systems)
Clerical staff	A clerical staff assists in scheduling appointments, answers phone calls, greets clients, keeps/documents medical records and handles medical billing.	Registration clerk	3252 (Clerk, information: health)

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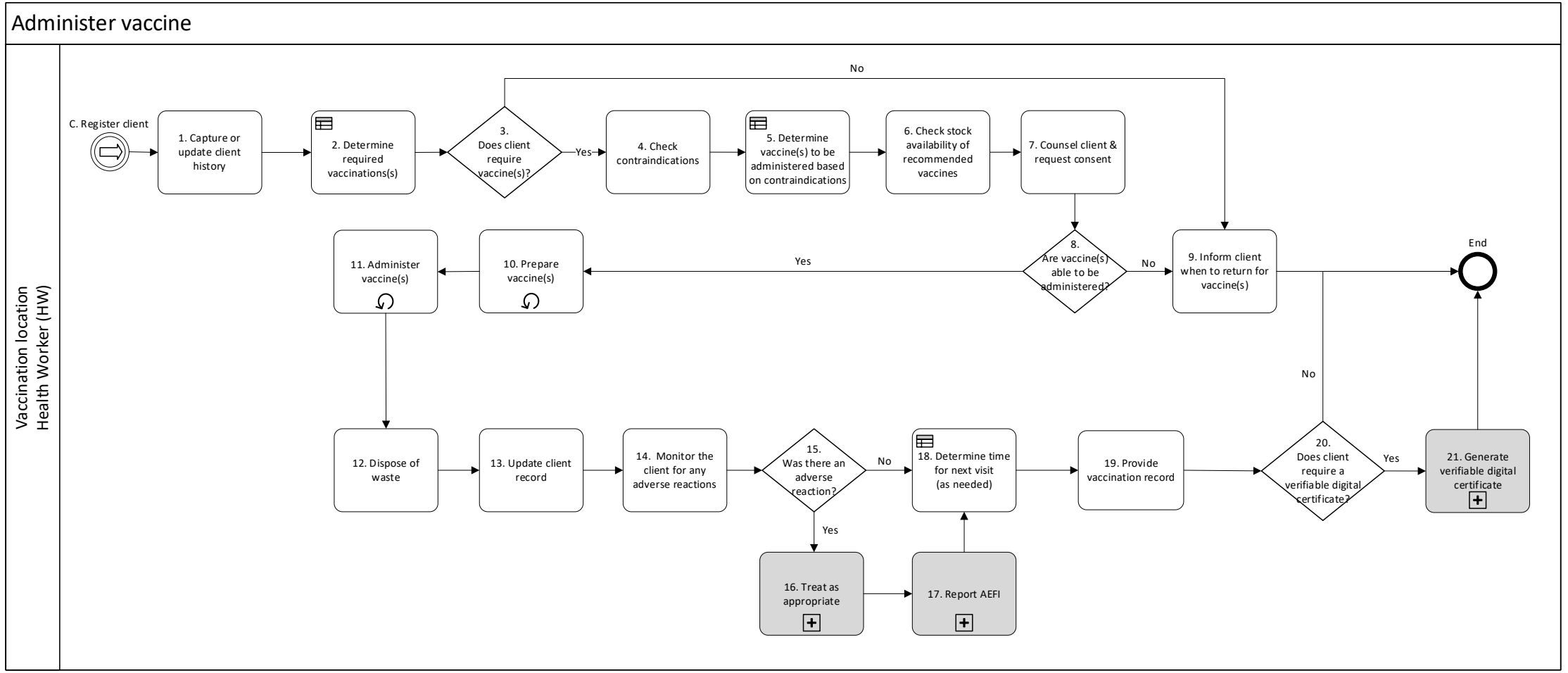
L2: Operational | Preparing to go digital

Administer vaccine workflow



L2: Operational | Preparing to go digital

Core data elements & clinical decision support based on recommended vaccination schedule and potential contraindications

Activity ID	Data Element ID	Data Element Label	Linkages to Aggregate Indicators	Annotations	ICD-11 Code	ICD-11 URI	ICD-11 Comments / Considerations	ICD-11 Relationship	ICD-10 Code	ICD-10 Comments / Considerations	ICD-10 Relationship
IMMZ.D2.Determine required vaccination(s)	IMMZ.D.DE156	Immunization recommendation status		The system can automatically set at value for this data	Not classifiable in ICD-11				Not classifiable in ICD-10		
IMMZ.D2.Determine required vaccination(s)	IMMZ.D.DE.157	Not due			Not classifiable in ICD-11				Not classifiable in ICD-10		
IMMZ.D2.Determine required vaccination(s)	IMMZ.D.DE.158	Due			QC06	http://id.who.int/icd/entity/874796608	Code title: Underimmunization status	Related to	Z28.3	Code title: Underimmunization status	Related to
IMMZ.D2.Determine required vaccination(s)	IMMZ.D.DE.189	Complete									
IMMZ.D2.Determine required vaccination(s)	IMMZ.D.DE.159	Contraindicated									Related to
IMMZ.D2.Determine required vaccination(s)	IMMZ.D.DE.160	Further evaluation needed									
IMMZ.D5.Determine vaccine(s) to be administered based on contraindications	IMMZ.D.DE.161	Potential contraindications									
IMMZ.D5.Determine vaccine(s) to be administered based on contraindications	IMMZ.D.DE.162	Currently pregnant									Equivalent
IMMZ.D5.Determine vaccine(s) to be administered based on contraindications	IMMZ.D.DE.163	Immunocompromised									Source is narrower than targ
IMMZ.D5.Determine vaccine(s) to be administered based on contraindications	IMMZ.D.DE.200	Severely immunocompromised									Source is narrower than targ
IMMZ.D5.Determine vaccine(s) to be administered based on	IMMZ.D.DE.164	Exposed to immunosuppressive treatment									Source is narrower than targ

Decision ID	IMMZ.D2.DT.Yellow fever
Business rule	Determine if the client is due for a yellow fever vaccination according to the national immunization schedule
Trigger	IMMZ.D2 Determine required vaccination(s) in any

Inputs				Output	Guidance displayed to health worker	Annotations	Reference(s)
Number of yellow fever primary series doses administered Count of vaccines administered (where	**Client's age** Today's date - "Date of birth"	**Time passed since a live vaccine was administered** Today's date - latest	-				
No yellow fever primary series doses were administered Count of vaccines administered (where "Vaccine type" = "Yellow fever containing vaccines" and "Type of dose" = "Primary series") = 0	**Client's age is less than 9 months** Today's date - "Date of birth" < 9 months	-	-	**Client is not due for yellow fever vaccination** "Immunization recommendation status" = "Not due"	Should not vaccinate client for yellow fever dose as client's age is less than 9 months. Check for any vaccines due, and inform the caregiver of when to come back for the next	The vaccine is contraindicated in children aged <6 months and is not recommended for those aged 6-8 months, except during epidemics when the risk of infection with the yellow fever virus is very high	WHO recommendations for routine immunization - summary tables (March 2023)
	Client's age is more than or equal to 9 months Today's date - "Date of birth" ≥ 9 months	**Live vaccine was administered in the last 4 weeks** Today's date - latest "Date and time of vaccination" (where "Live vaccine" = TRUE) < 4 weeks	-	**Client is not due for yellow fever vaccination** "Immunization recommendation status" = "Not due"	Should not vaccinate client for yellow fever dose as live vaccine was administered in the last 4 weeks. Check for any vaccines due, and inform the caregiver of when to come back for the first dose.	As a general rule, any live vaccine may be given either simultaneously or at an interval of 4 weeks	
		No live vaccine was administered in the last 4 weeks Today's date - latest "Date and time of vaccination" (where "Live vaccine" = TRUE) ≥ 4 weeks	-	**Client is due for yellow fever vaccination** "Immunization recommendation status" = "Due"	Should vaccinate client for yellow fever dose as no yellow fever dose was administered, client is within appropriate age range and no live vaccine was administered in the last 4 weeks. Check for contraindications.	-In endemic countries, it is recommended that yellow fever vaccine be given to children at age 9-12 months at the same time as the measles vaccine -Preventive mass vaccination campaigns are recommended for inhabitants of areas at risk of YF where there is low vaccination coverage -Vaccination should be provided to everyone aged ≥ 9 months in any area with reported cases -Vaccination should also be offered if the individual is travelling to- and from-at risk areas, if not contraindicated As a general rule, any live vaccine may be given either simultaneously or at an interval of 4 weeks. Oral polio vaccine may be given at any time in relation to yellow fever vaccination.	
One yellow fever primary series dose was administered Count of vaccines administered (where "Vaccine type" = "Yellow fever containing vaccines" and "Type of dose" = "Primary series") = 1	-	-	-	**Yellow fever immunization schedule is complete** "Immunization recommendation status" = "Complete" "Completed the primary vaccination series" = TRUE (where "Vaccine type" = "Yellow fever containing	Yellow fever immunization schedule is complete. One yellow fever primary series dose was administered. Check for any other vaccines due.	-	

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L2: Operational | Preparing to go digital

Collect once, use many times principle

Indicator calculation for % in target population who received one dose of yellow fever vaccine

Indicator ID	Indicator name	Indicator definition	Numerator		Denominator		Disaggregation	References	Annotations
			Description	Computation	Description	Computation			
IMMZ.IND.26	Immunization coverage for Yellow fever containing vaccine	The percentage in the target population who have received one dose of yellow fever vaccine during reporting period	Number of yellow fever doses administered through routine services during reporting period	COUNT of immunization events WHERE "Vaccine type" = "Yellow fever containing vaccines" AND "Date and time of vaccination" is during the reporting period	Number in target group	As defined by the Member States	Administrative area Sex Age in years Age group (depending on schedule)	WHO / UNICEF joint reporting form WHO Immunization data portal WHO Immunization facility analysis guide WHO Handbook on immunization data	The calculation for this indicator is in line with the administrative calculation provided on the WHO immunization data portal.

- Indicators can be **aggregated from individual level data** rather than a separate reporting system
- Each '**variable**' must be **encoded to a standard terminology** (ICD, ICHI, ICF, LOINC)
- Data dictionary, decision support logic, indicator tables, functional and non-functional requirements are in spreadsheet formats

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Functional & Non-functional Requirements

Digital health intervention – *discrete functionality of digital technologies*

L2: Operational | Preparing to go digital

Functional & non-functional requirements

Requirement ID	Activity ID and name	As a...	I want...	So that...
Business process D: Administer vaccine				
IMMZ.FXNREQ.061	IMMZ.D1.Capture or update client history	Health Worker (HW)	The system to provide a history of previous care (including previous vaccination records)	I have access and review client's history
IMMZ.FXNREQ.062	IMMZ.D1.Capture or update client history	Health Worker (HW)	To add client's health history (including previous vaccination records)	I can appropriately determine which vaccinations are required
IMMZ.FXNREQ.063	IMMZ.D2.Determine required vaccination(s)	Health Worker (HW)	The system to display vaccines due according to predefined vaccine protocol	I can assess which vaccines need to be administerd
IMMZ.FXNREQ.064	IMMZ.D2.Determine required vaccination(s)	Health Worker (HW)	The system to determine vaccines due for a given client by considering relevant information, such as the age of the client, vaccine products, vaccines already given and predefined vaccine protocol	it helps me with selecting the appropriate vaccines for the client
IMMZ.FXNREQ.065	IMMZ.D2.Determine required vaccination(s)	Health Worker (HW)	The system to ensure I have the most up to date vaccine protocols	It will recommend the correct schedule
IMMZ.FXNREQ.066	IMMZ.D5.Determine vaccine(s) to be administered based on contraindications	Health Worker (HW)	To be alerted based on age	
IMMZ.FXNREQ.067	IMMZ.D5.Determine vaccine(s) to be administered based on contraindications	Health Worker (HW)	To be able to antigen	
IMMZ.FXNREQ.068	IMMZ.D6.Check stock availability of recommended vaccines	Health Worker (HW)	The system t	
IMMZ.FXNREQ.069	IMMZ.D6.Check stock availability of recommended vaccines	Health Worker (HW)	The system t	
IMMZ.FXNREQ.070	IMMZ.D6.Check stock availability of recommended vaccines	Health Worker (HW)	The system t not administ	
IMMZ.FXNREQ.071	IMMZ.D12.Dispose of waste	Health Worker (HW)	To update st	
IMMZ.FXNREQ.072	IMMZ.D13.Update client record	Health Worker (HW)	To document	
IMMZ.FXNREQ.073	IMMZ.D13.Update client record	Health Worker (HW)	To update cli dose, batch r	

Requirement ID	Category	Non-Functional Requirement
IMMZ.NFXNREQ.001	Performance	Make efficient use of data communication time
IMMZ.NFXNREQ.002	Performance	Make efficient use of capabilities of lower-cost mobile devices.
IMMZ.NFXNREQ.003	Performance	Support data capacity considerations (including those for data transmission, storage, and processing) for all users over the expected lifetime of the system.
IMMZ.NFXNREQ.004	Performance	Use a database that can scale to support projected transaction volume.
IMMZ.NFXNREQ.005	Performance	Provide real-time response to transactions submitted by connected devices up to the configured national volume level.
IMMZ.NFXNREQ.006	Performance	Provide real-time messages such as "report processing" or "in progress" for transactions that affect the system performance
IMMZ.NFXNREQ.007	Compatibility	Use open standards to promote interoperability.
IMMZ.NFXNREQ.008	Compatibility	Exchange actionable data between systems (need to enforce semantic interoperability).
IMMZ.NFXNREQ.009	Compatibility	Provide access from internet-enabled devices.
IMMZ.NFXNREQ.010	Compatibility	Support flexible models for data collection (e.g., including paper forms, web forms, SMS, barcode, etc.).
IMMZ.NFXNREQ.011	Compatibility	Comply with industry standards for data exchange.
IMMZ.NFXNREQ.012	Compatibility	Operate with open-source or third-party reporting tools.
IMMZ.NFXNREQ.013	Compatibility	Comply with industry standards for tracking and tracing of supplies.
IMMZ.NFXNREQ.014	Compatibility	Enable streamlined data collection, organization and dissemination
IMMZ.NFXNREQ.015	Interoperability	Provide access to data through application programming interfaces
IMMZ.NFXNREQ.016	Interoperability	Link with insurance systems to verify eligibility and submit claims
IMMZ.NFXNREQ.017	Interoperability	Allow for data exchange and efficient synchronization across multiple facilities and points of service when the Internet is available, even when it is intermittent and slow

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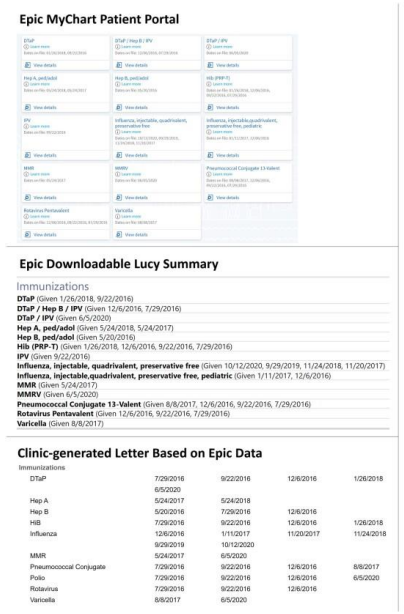
L2: Design still matters and is context-specific to the country

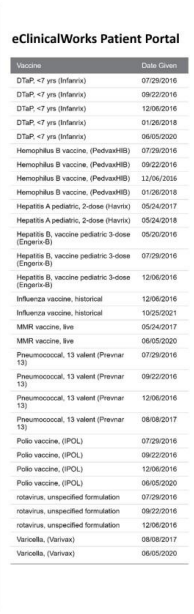
Design of patient–facing immunization visualizations affects task performance: an experimental comparison of 4 electronic visualizations

Jenna Marquard [1 2], Robin Austin [1], Sripriya Rajamani [1 2]

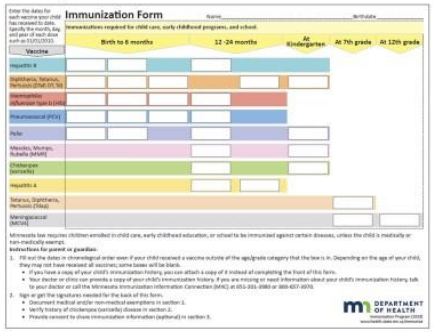
Affiliations + expand

PMID: 38833256 PMCID: PMC11491626 DOI: 10.1093/jamia/ocae125

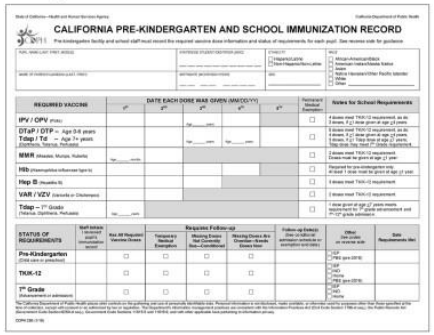




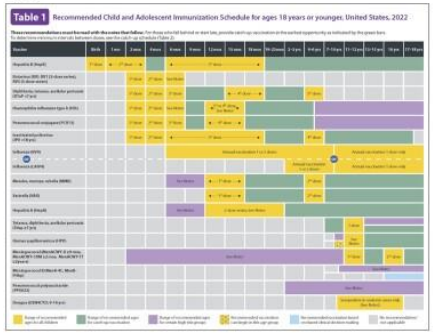
MN Dept of Health



CA Dept of Public Health



CDC



Our Form

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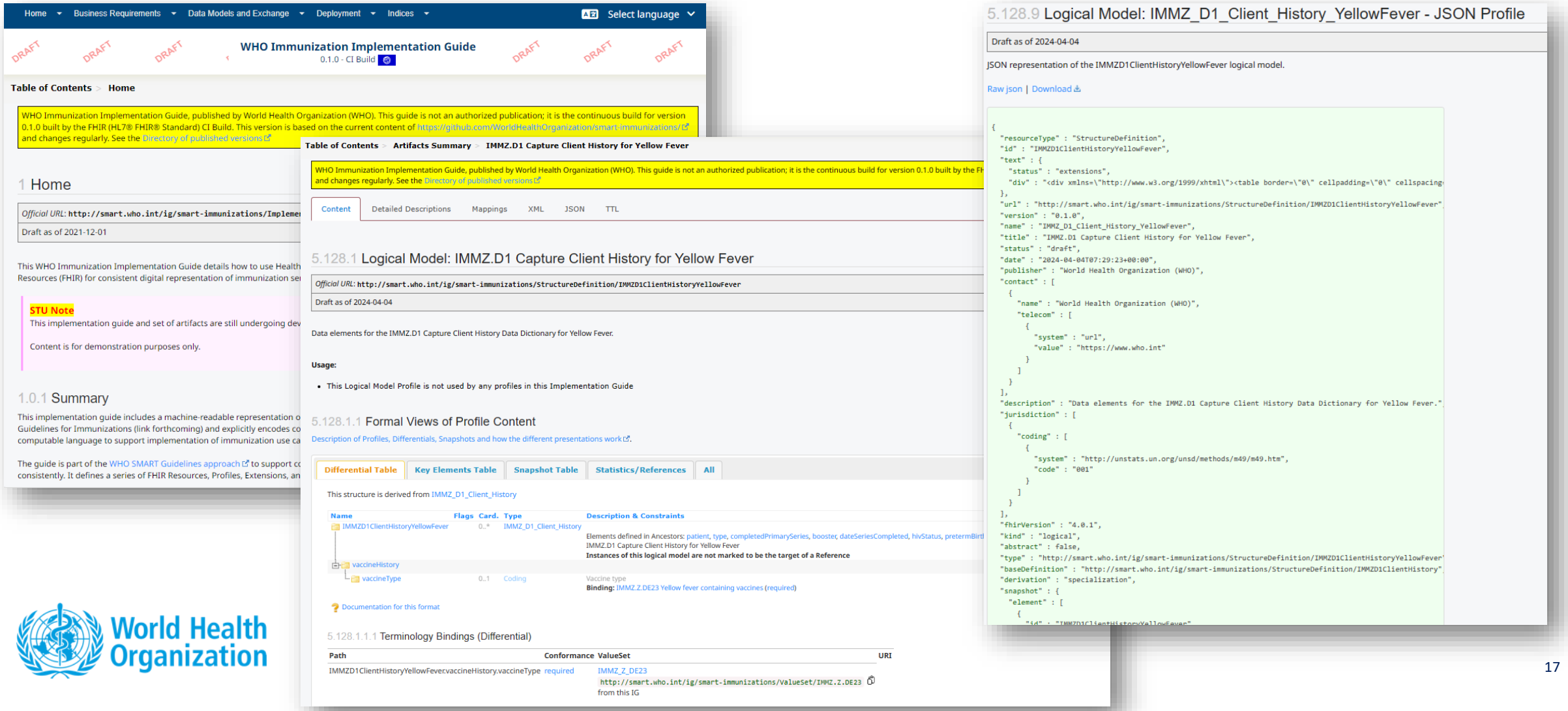
L3: Machine-readable | Interoperable digital components

Same recommendations in standards-based software code format



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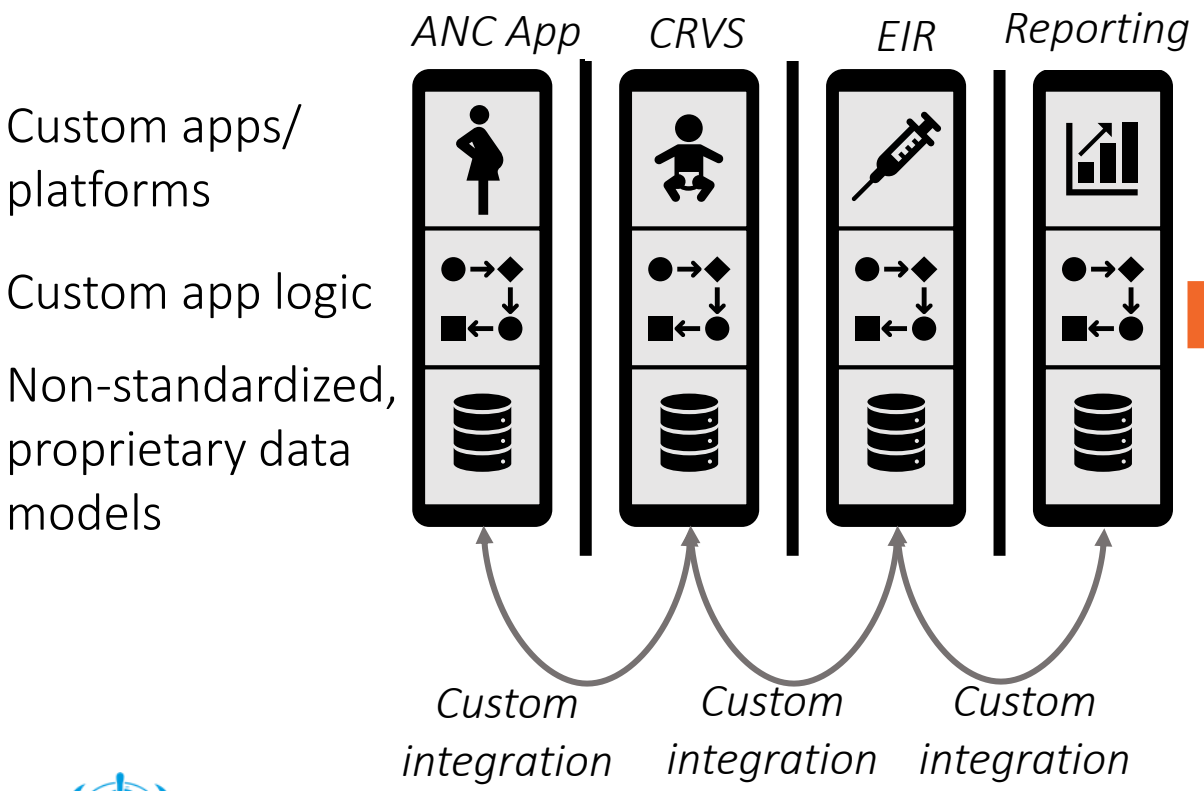
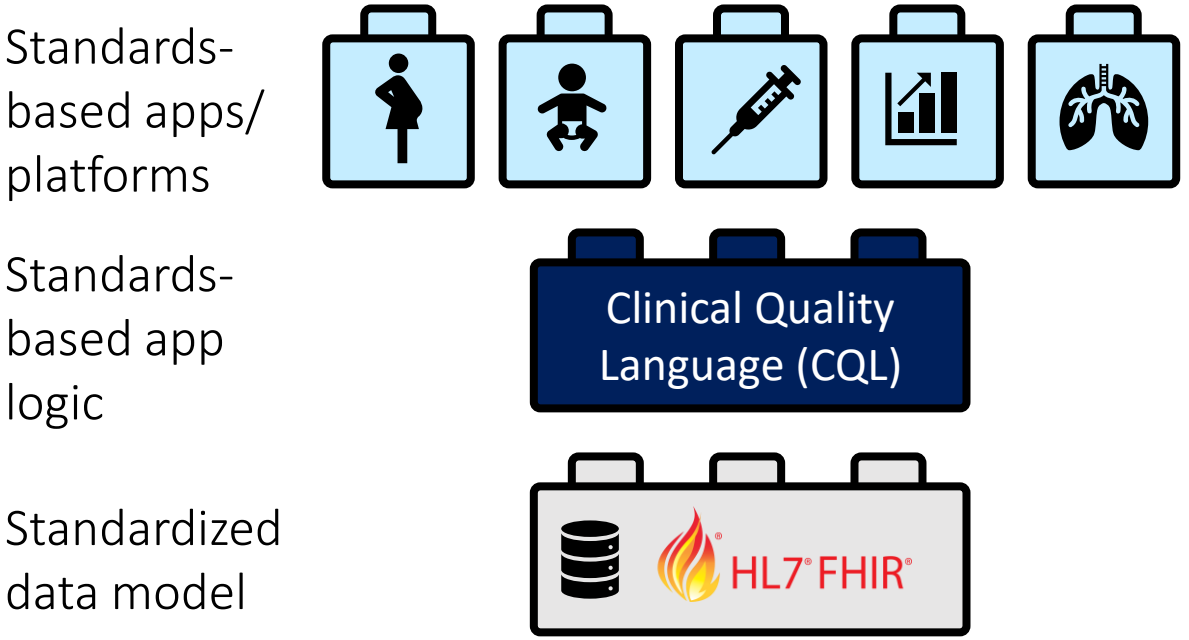
Digital tools need to exist in the context of an ecosystem

Monolithic, siloed, proprietary software requiring integrations



Standards-based architecture, allowing greater flexibility and scale



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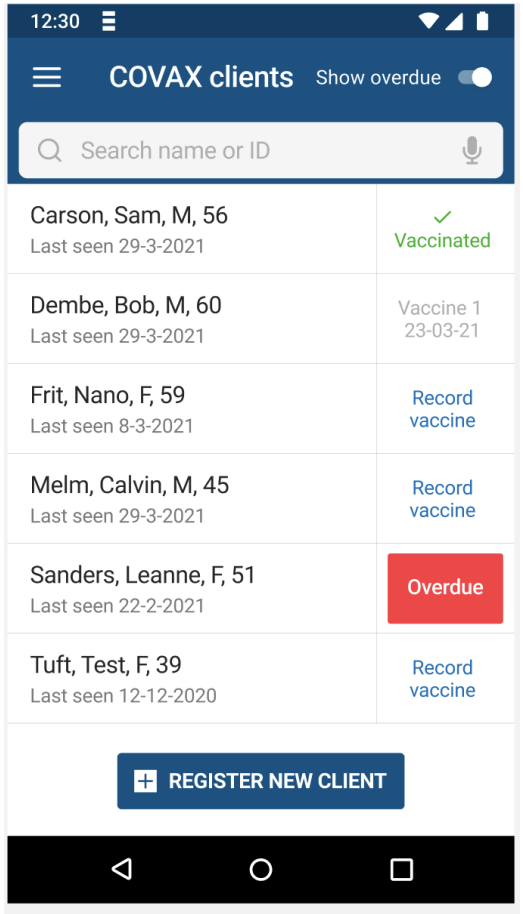
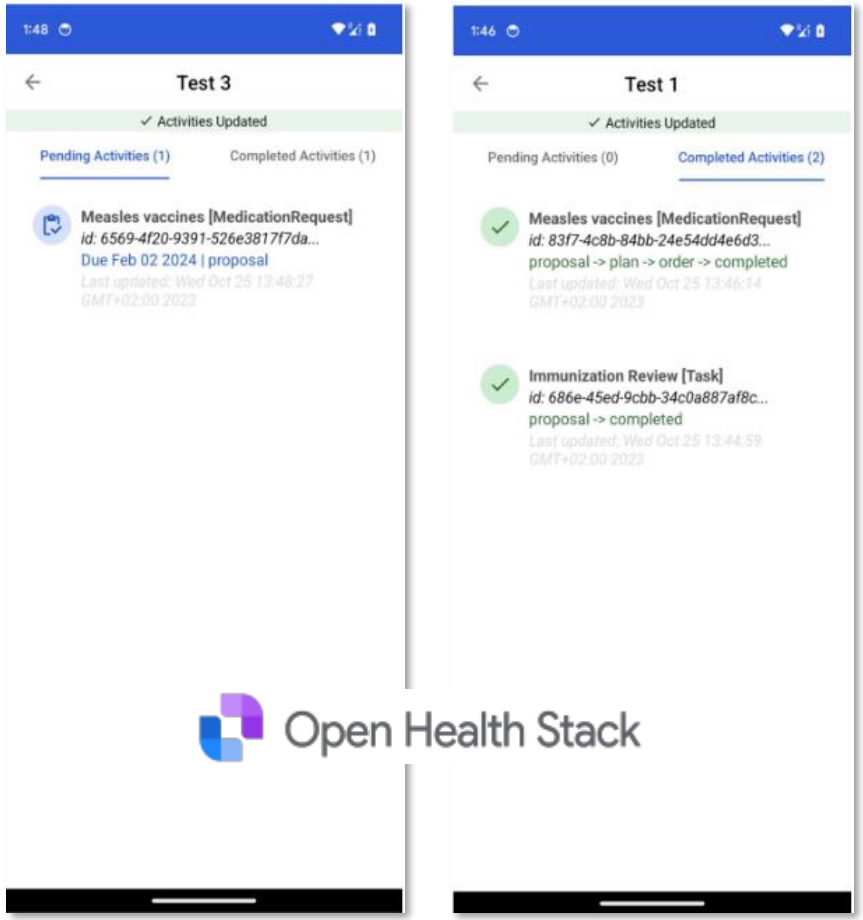
L4: Executable | Customizable software

Same recommendations manifested in reference software applications that can be adapted and deployed in countries





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SMART Guidelines are a new approach to representing WHO content as digital health components to preserve fidelity and accelerate uptake

Standards-based, **M**achine Readable, **A**daptive, **R**equirements-based, **T**estable

EXISTING MODEL WITH ENHANCEMENTS

PREPARING TO GO DIGITAL

INTEROPERABLE DIGITAL COMPONENTS

CUSTOMIZABLE SOFTWARE

ADVANCED ANALYTICS FOR PRECISION HEALTH

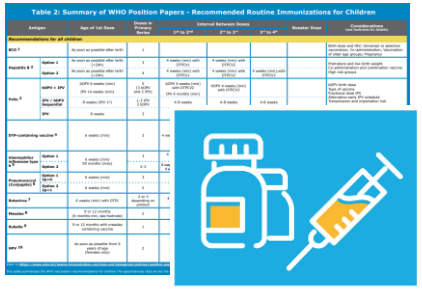
L1 Narrative

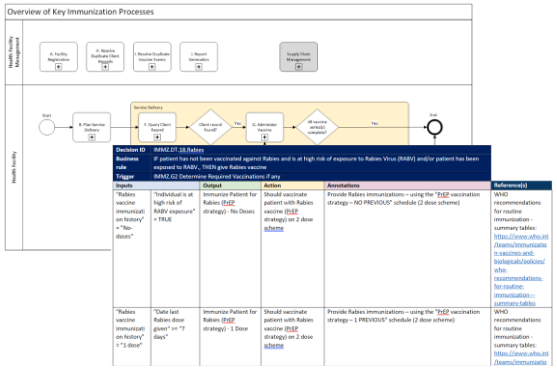
L2 Operational

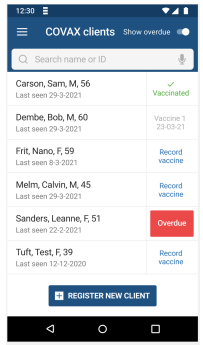
L3 Machine Readable

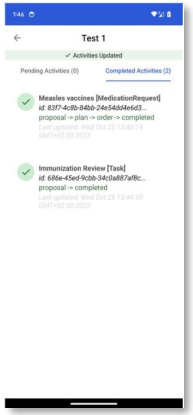
L4 Executable

L5 Dynamic









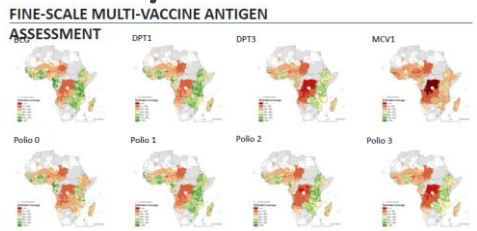
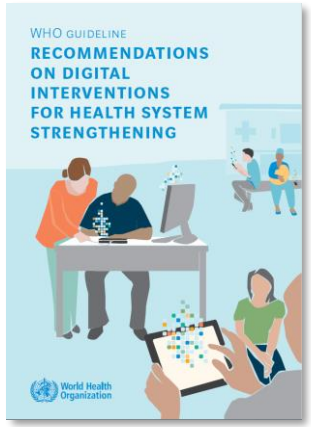


Image sources:
OpenSRP FHIR Core COVID-19 vaccine EIR, Google Open Health Stack
AFRO Precision public health team

SMART Guidelines are only one piece of transformation

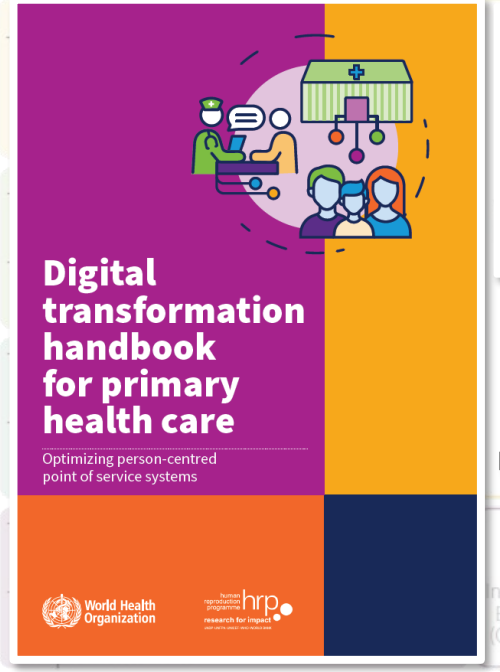


PHASE 01 ASSESSING THE CURRENT STATE AND ENABLING ENVIRONMENT

PHASE 02 ESTABLISHING A SHARED UNDERSTANDING AND STRATEGIC PLANNING

PHASE 03 DEFINING THE FUTURE STATE

PHASE 04 PLANNING THE ENTERPRISE ARCHITECTURE



PHASE 05 DETERMINING HEALTH CONTENT REQUIREMENTS

+ Identify validated health content appropriate for the implementation context
+ Ensure use of content aligned with identified standards for the future state

WHO hand-book for digitalizing primary health care (this document)

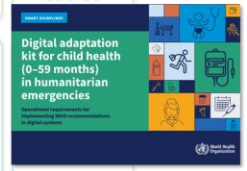
PHASE 06 M&E OF DIGITAL HEALTH IMPLEMENTATIONS AND FOSTERING DATA USE

+ Monitor implementation to ensure digital implementations are functioning as intended and having the desired effect
+ Foster data-driven adaptive change management within the overall health system

PHASE 07 IMPLEMENTING, MAINTAINING AND SCALING

+ Maintain and sustain digital health implementations
+ Identify risks and appropriate mitigations

+



WHO SMART Guidelines

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SMART Guidelines are not…

- ✗ Only about digital
- ✗ Only DAKS
- ✗ Just a clinical solution, or data solution
- ✗ A digital app version of the guidelines
- ✗ Bound to a specific digital solution, product, or platform
- ✗ A way to push ministries into specific software solutions
- ✗ A singular solution to system interoperability and health information exchange

They are…

- ✓ A methodology of documentation for digital interventions
- ✓ Tools used to support governance of digital technologies used for health

They also…

- ✓ Help identify gaps in the science and existing clinical guidelines

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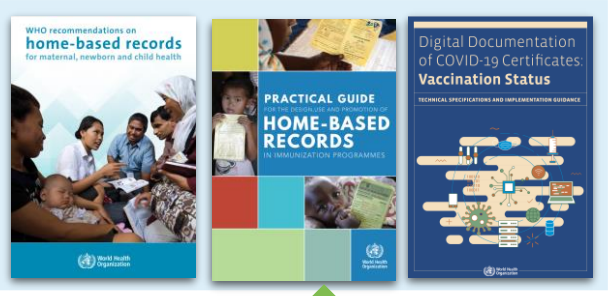
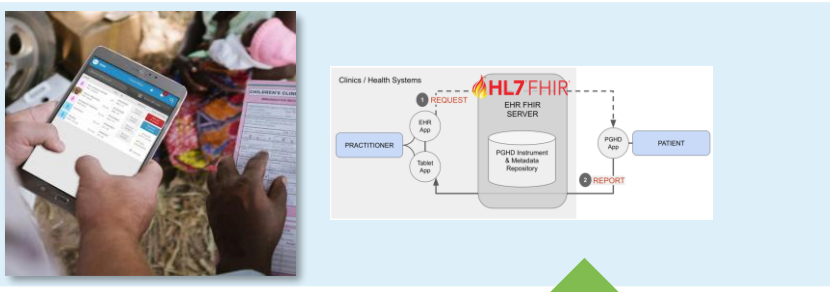
Leveraging the SMART Guidelines to establish technical specifications for a personal health record

Healthcare worker



SMART Guidelines: trusted interoperable health content for service delivery and decision support

Person-centered point of service systems



Health encounter

Patient Mediated Exchange

Individuals

SMART Guidelines: enables individual's agency over personal health records

Personal health wallet

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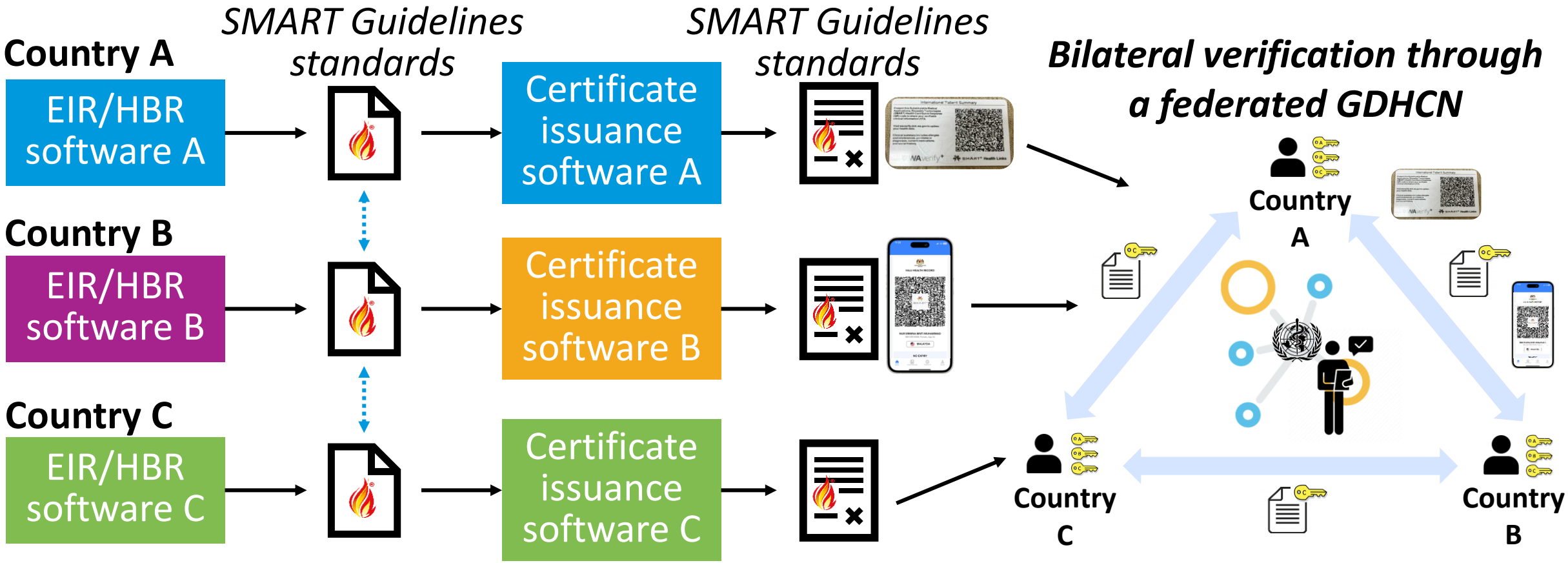
SMART Guidelines combined with the use of the GDHCN allow for the ability for verifiable personal health records nationally or internationally



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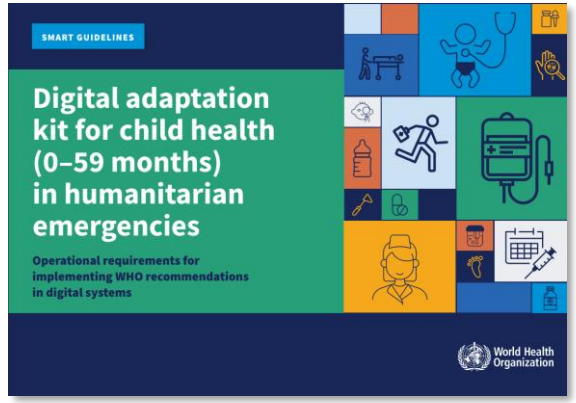
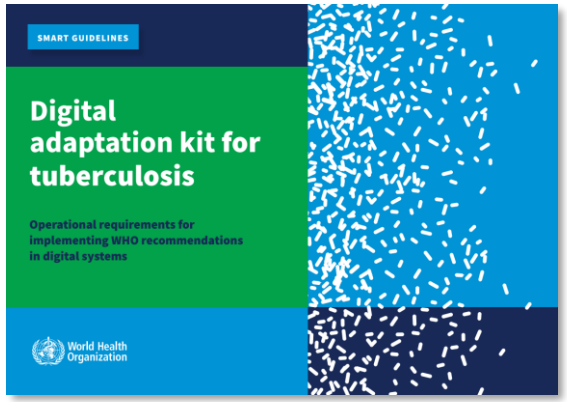
Community of partners

...and many, many more...

Thank you!





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For more information, please contact:
SMART@who.int

DAK for **Community Health**, **Campaign Payments**, and **Surveillance** are in progress

Thank you

This presentation has been designed to be accessible, for a positive and inclusive user experience for all.

For more information, please contact:
SMART@who.int

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