Promoting the Quality of Medicines

Adopting Data Standards and Integrated Regulatory Information Management in LMICs:

Challenges and Opportunities

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U. S. Pharmacopeial Convention (USP)

USP U.S. Pharmacopeial Convention

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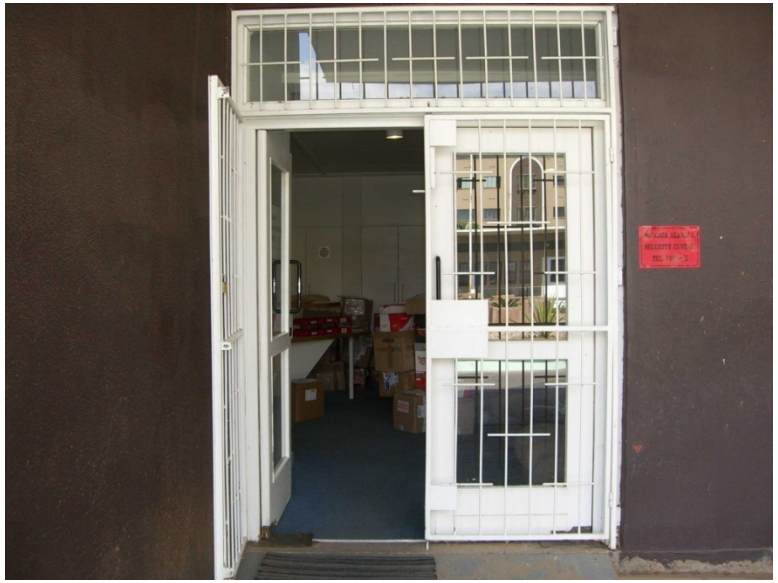
Many LMIC Agencies look like this!



Limited sharing of information

Country	Transparency on drug approval Information	Transparency on drug registration / product	Transparency on compliance
Philippines	X	✓	X
Hong Kong	X	✓	X
China	X	✓*	X
Turkey	X	✓*	X
Thailand	X	✓	X
India	X	✓	X
Indonesia	X	✓*	X
Malaysia	X	✓*	X
Vietnam	X	No data available	X
Singapore	X	✓*	X
Measure	Are assessment reports publicly disclosed	Register available online, contains package leaflets, SmPC, and PILs	Inspection reports are not made publicly available

Challenges of information systems in LMICs

- Fragmented
- Non-structured, heterogeneous data
- Proliferation of disparate databases
- Different terminologies, dictionaries, and scales
- Limited in-country and external exchange and transmission of regulatory information
- Rudimental adoption of ICT.

Challenges – its all about compliance

- Limited capacity to regulate the industry

PIC/S GUIDANCE

GOOD PRACTICES FOR COMPUTERISED SYSTEMS IN REGULATED "GXP" ENVIRONMENTS

- Inability to send, receive, share, and manage information
- Inability to use information from diverse sources for decision making.

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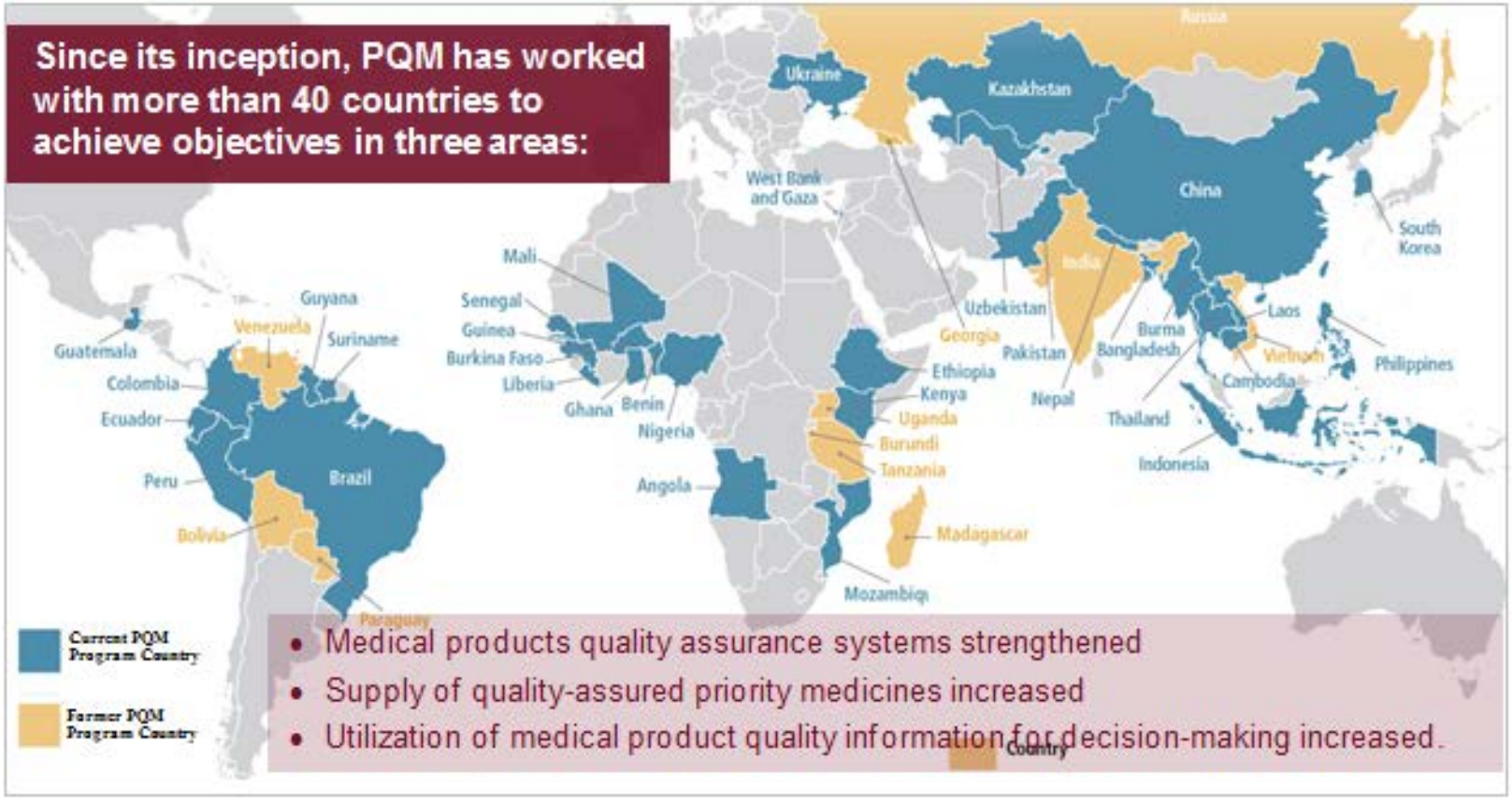
Global footprints



PQM Technical Approach

Building Systems For Quality-Assured Medical Products

Who We Work With

- Medical Products Manufacturers
- Medical Products Regulatory Authorities
- National Quality Control Laboratories
- Public Health Programs
- International Organizations/ Regional Networks

Outcome

Improving Public Health

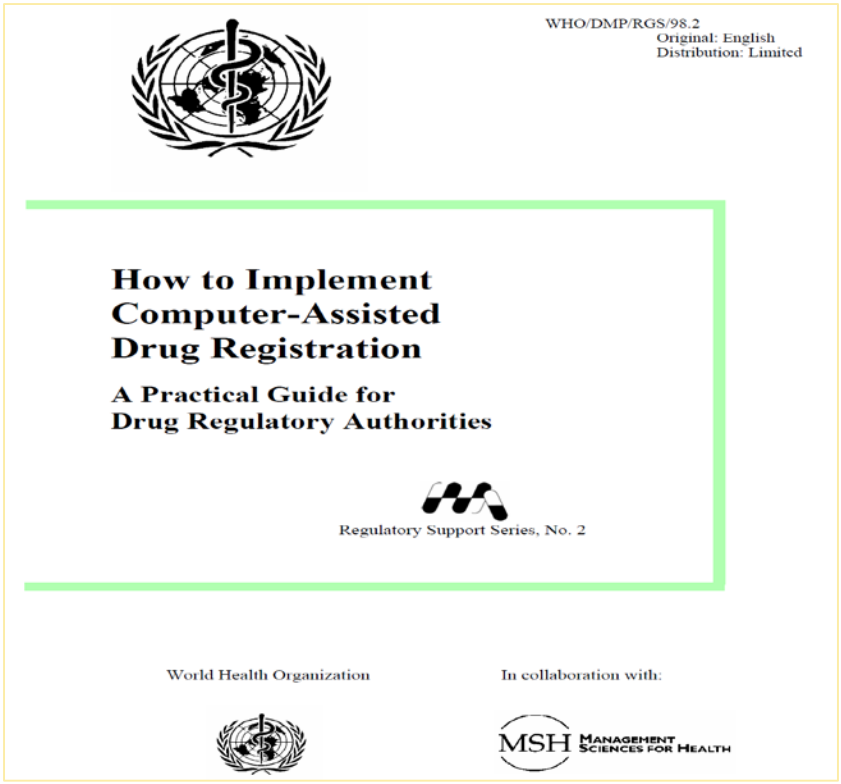
- Supply of safe, effective, quality-assured medical products improved
- Patients protected from substandard and falsified medical products
- Evidence-based decision making increased

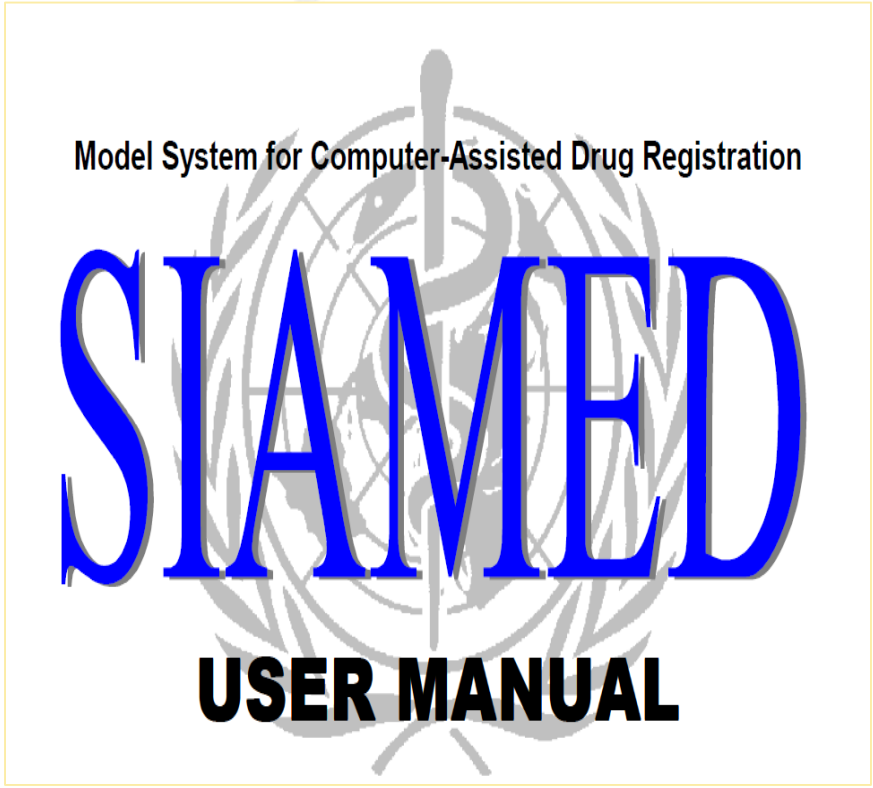
Accountability | Transparency | Sustainability | Information Management

Information Management Systems for Health Products Regulation

- Ideal information management system will enable the establishment of an automated standards-based information technology environment for the exchange, review, and management of data supporting regulatory processes throughout the product life-cycle.

Challenges of early efforts at computer-assisted drug registration





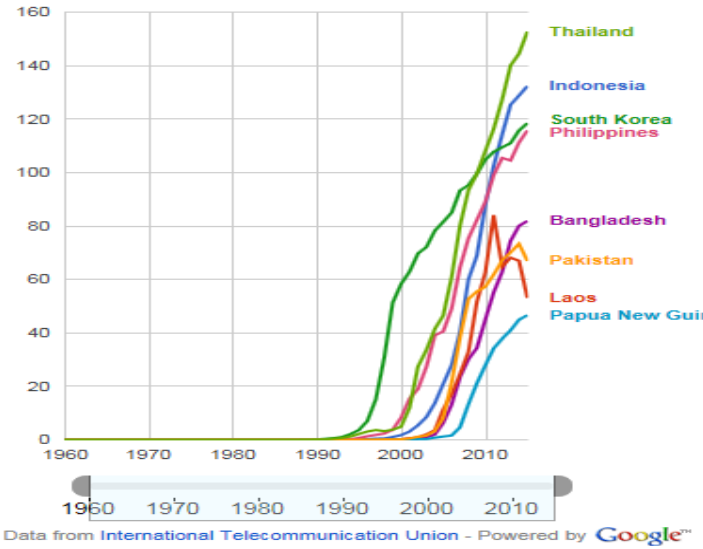
Opportunities

- Learn from mistakes of the past
- Great spate of adoption of ICT
- Open data platforms increasingly available
- National eHealth Policies
- Extensive cellphone diffusion

Atlas of eHealth country profiles

The use of eHealth in support of universal health coverage

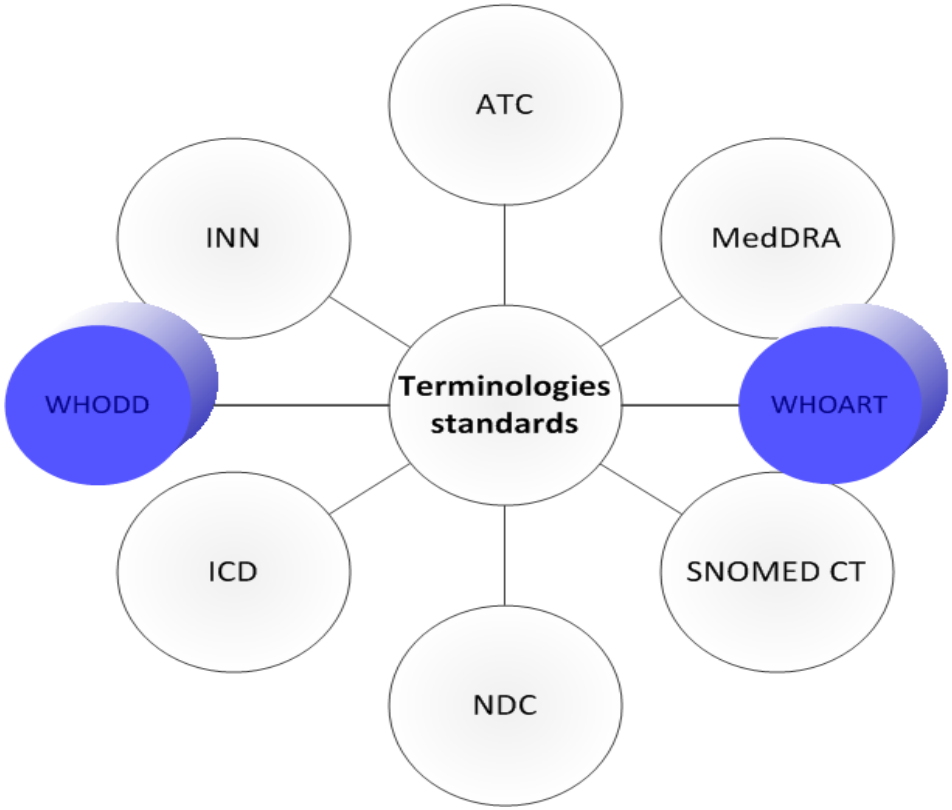
Based on the findings of the third global survey on eHealth 2015

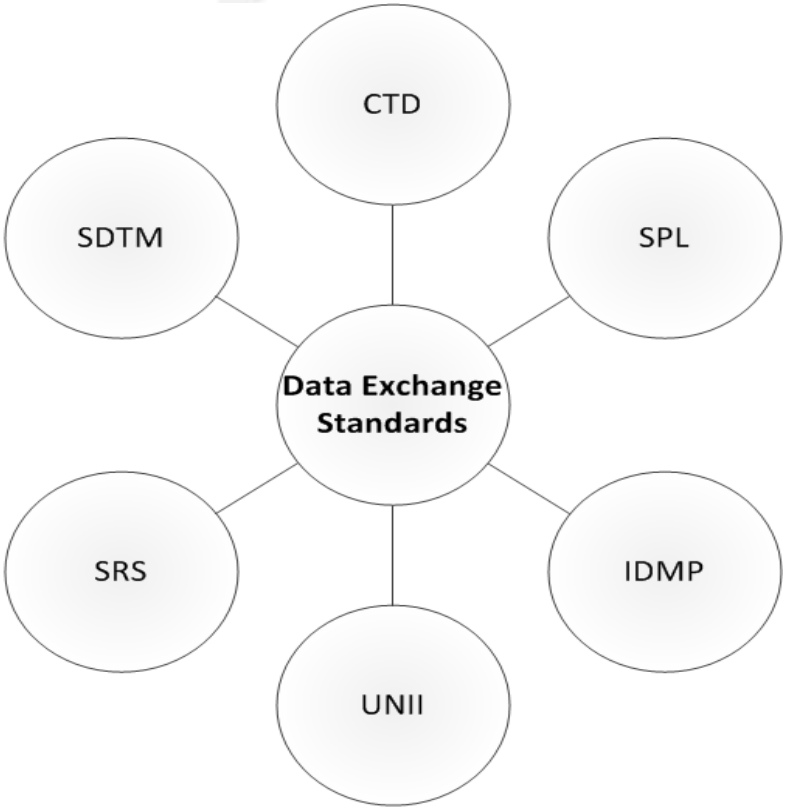


Ideal features of the Integrated Regulatory Information System

1. **Standards-based** - complies with international and national standards
2. **Interoperable** with PMIS and EMR
3. **Integrated and comprehensive** - across all the regulatory functional areas
4. **Facilitates electronic submissions** and application reviews
5. **Life cycle** – maintains holistic information throughout product's life cycle, meets patients need
6. **Facilitates FAIR** Findable, Accessible, Interoperable, Reusable
7. **Federated** – be a knowledge repository.

Standards-based



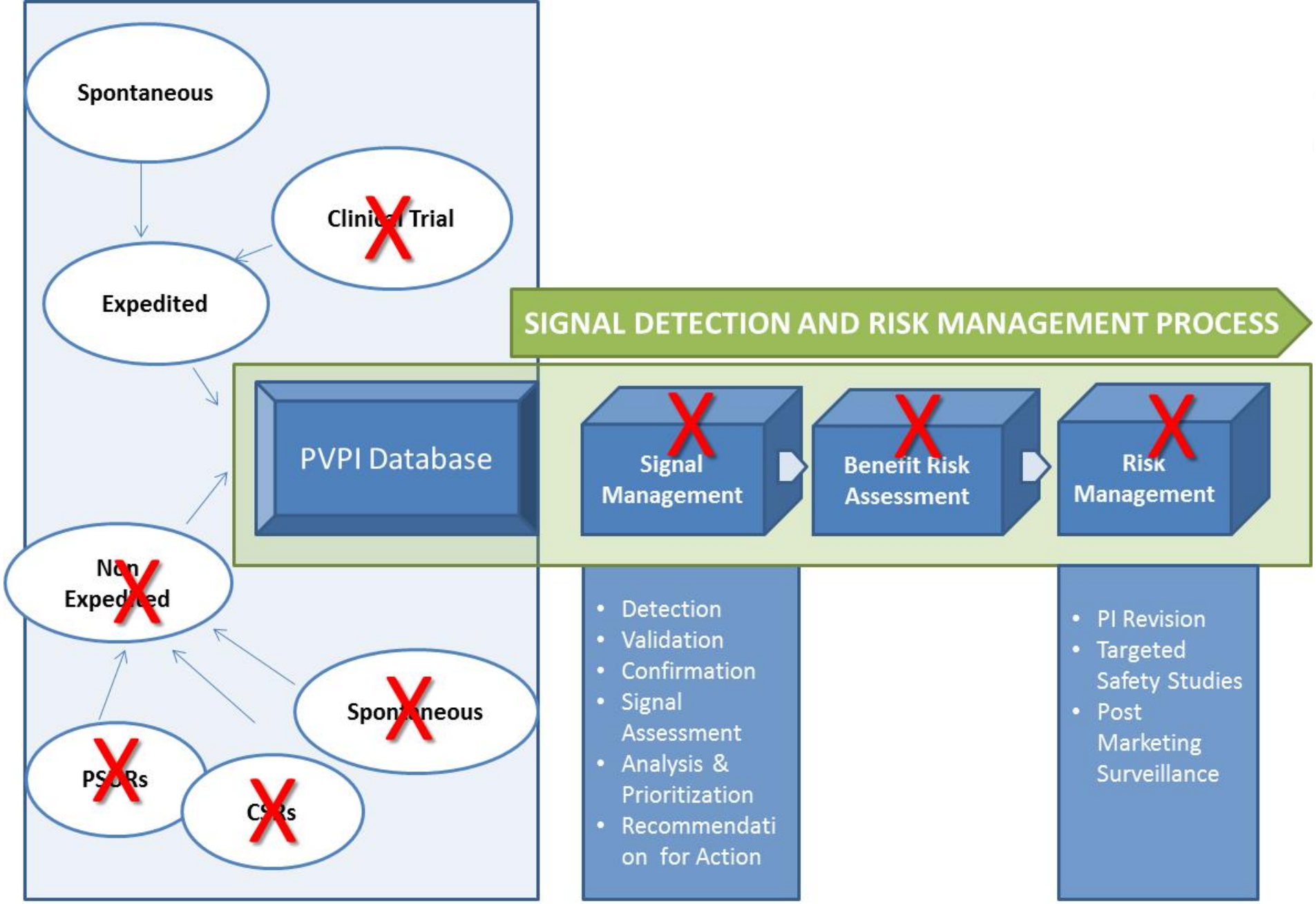


INN/ATC

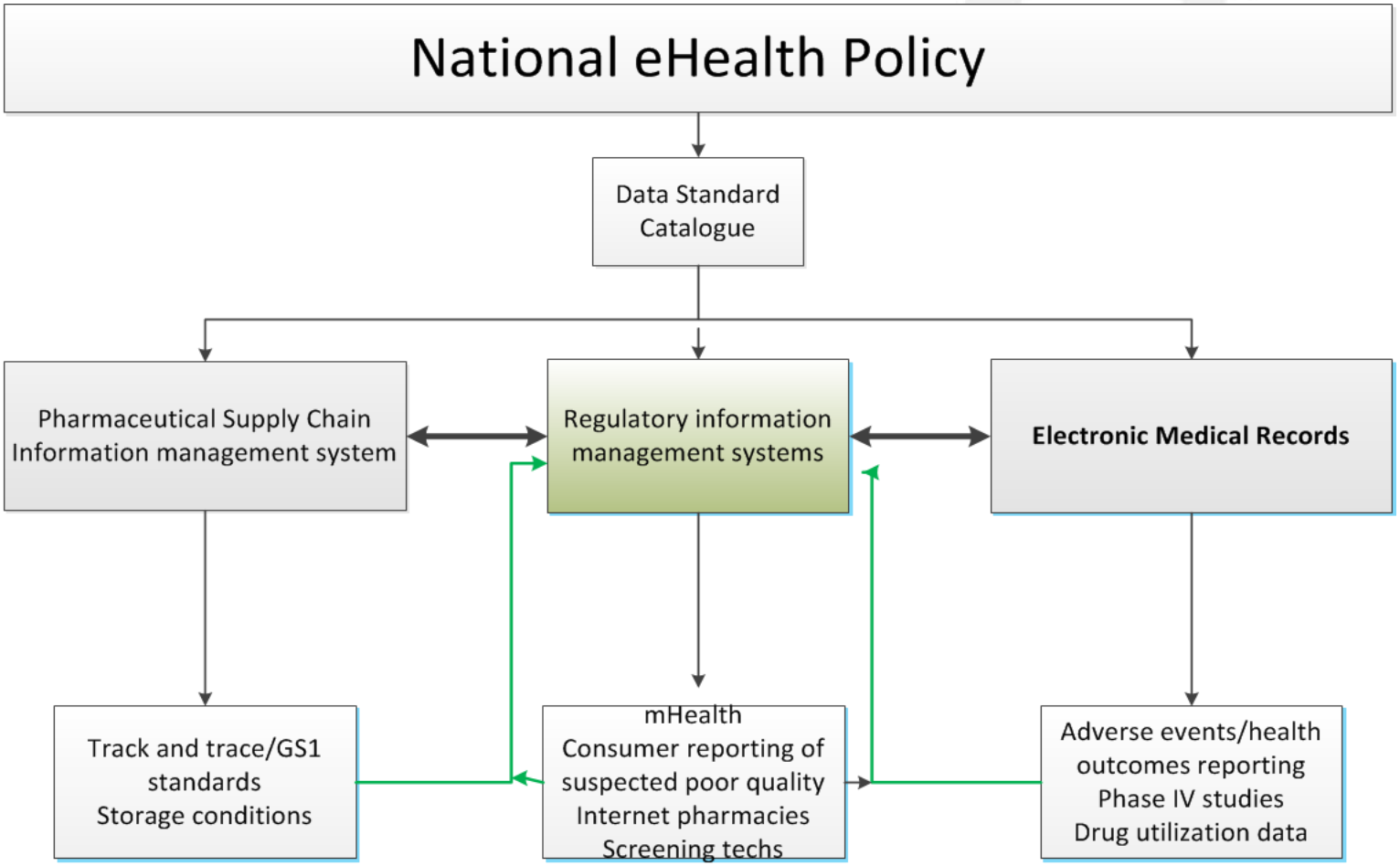
- Facilitates medical products regulation
- Facilitates Drug utilization studies
  - INN
  - ATC-DDD Classification
  - Drug strength (e.g. mg, ml)
  - Form (tablet, syrup, capsule)
  - NDC

Example for Pharmacovigilance

- Decide what to adopt and load into the Application
  - ICD10
  - MedDRA
  - INN
  - ATC Classification
  - WHODD
  - SNOMED CT
  - WHO toxicity grading scale
  - Scale for Causality assessment
  - Metrics for signal detection; PRR, ROR


Spontaneous
Clinical Trial
Expedited
SIGNAL DETECTION AND RISK MANAGEMENT PROCESS
PVPI Database
Signal Management
Benefit Risk Assessment
Risk Management
Non Expedited
Spontaneous
PSURs
CSRs
• Detection
• Validation
• Confirmation
• Signal Assessment
• Analysis & Prioritization
• Recommendation for Action
• PI Revision
• Targeted Safety Studies
• Post Marketing Surveillance

Interoperable - comprehensive information on medical products



↔ Denotes interoperability

mHealth possibilities - average cell phone ownership in 8 Asian LMICs very high, use for health reporting very limited.

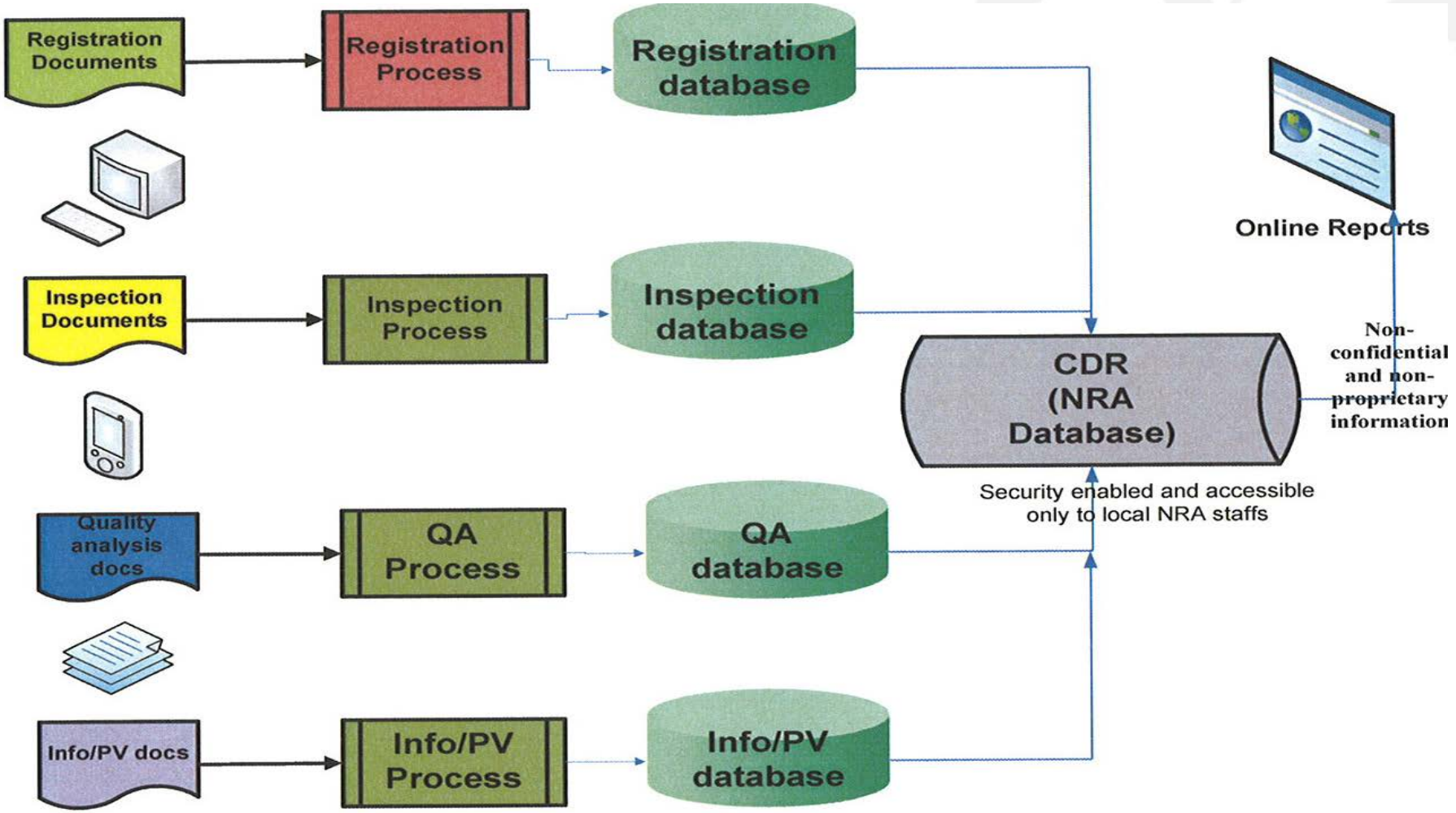
Announcement of Intention to Implement Global Standards for Product Identification, Labeling, and Data Exchange

MAY 15, 2017

TRACEABILITY

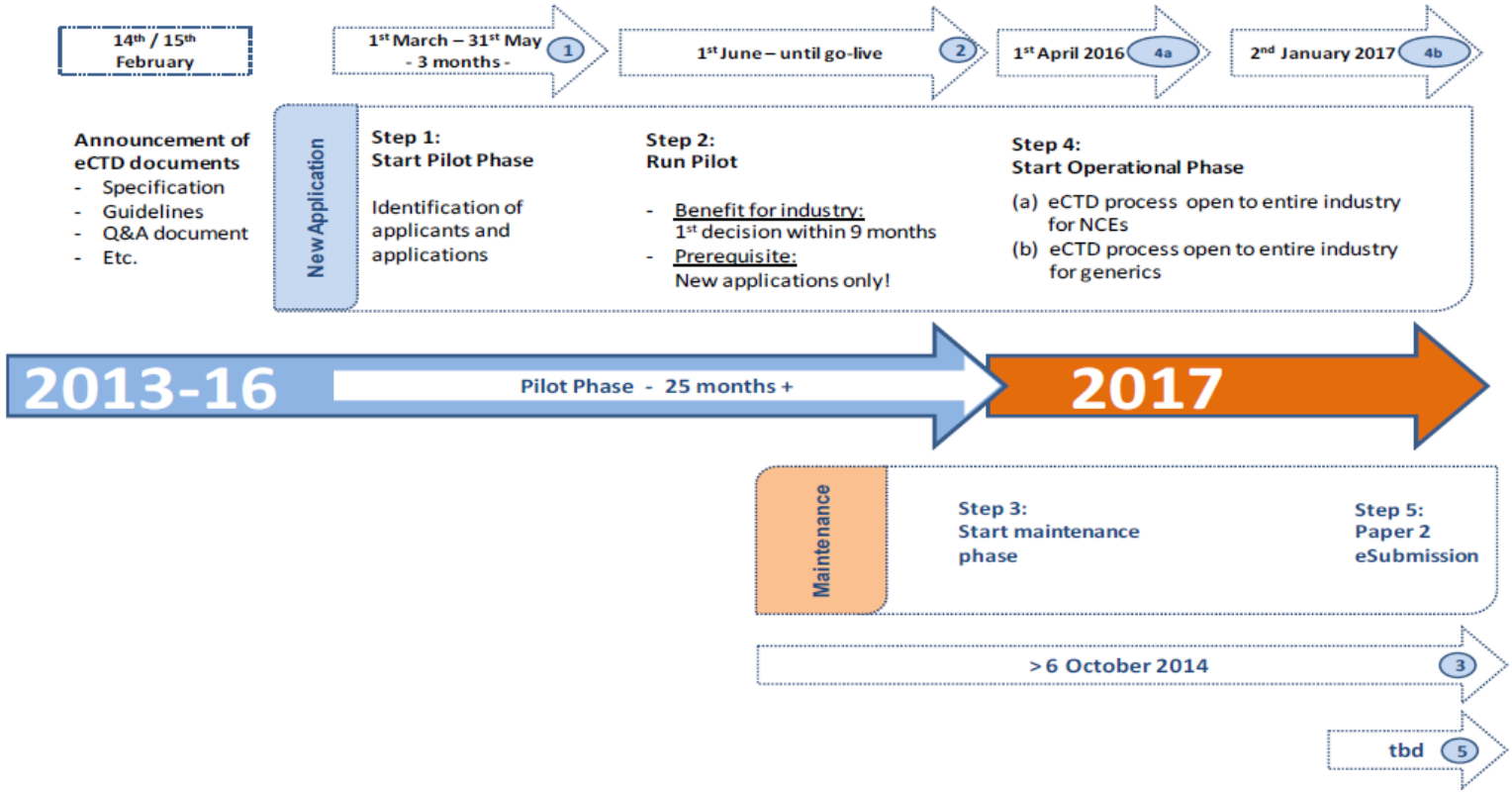
- Track
- Trace
- Authentication
- Chain of Custody / Ownership
- Returns
- Recalls

Integrated and comprehensive



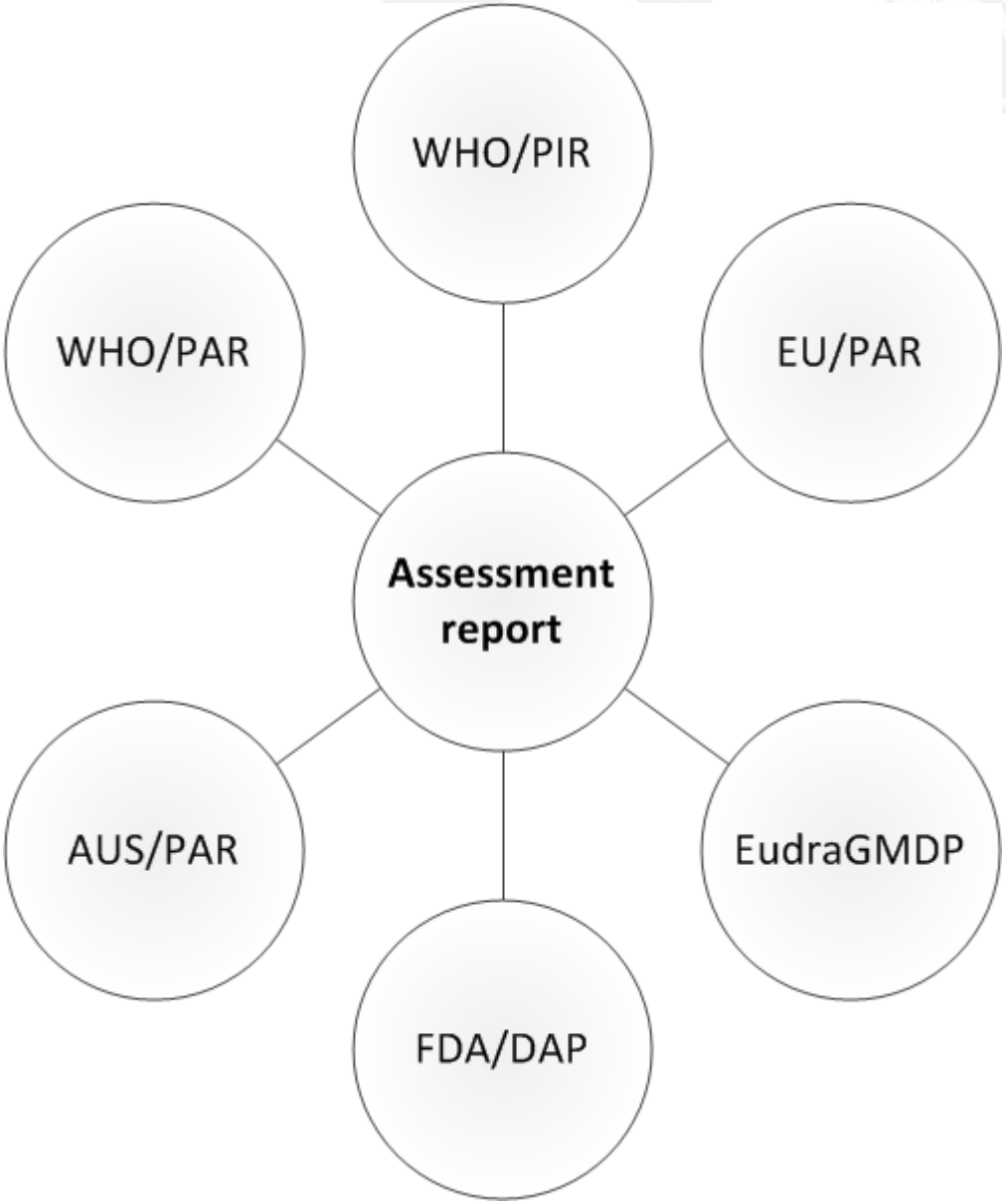
South Africa example

Project Plan eCTD implementation at MCC



Federated – reliance through data interchange

- Use big data analytics to advance reliance, improve efficiency
- Information as a public good
- Analyze globally available information sources for local decision making



Drug Approval Package https://www.accessdata.fda.gov/drugsatfda_docs/nda/2000/50-670S015_Zithromax.cfm

How to implement – start with Biz Goals

Survey current state – Agency, Industry

1. Do you have electronic records and signature regulations, e.g. 21 CFR 11
2. Do you have electronic submission gateway
3. Which are the adopted data standards and file formats
4. Do you have an IT dept, describe your IT infrastructure
5. Do you have electronic databases, are they integrated
6. Have you conducted a User Requirement Specification survey
7. Do you accept eCTD
8. Does industry softwares meet standards – SDTM, E2B (R3), etc.
9. Do you have online dossier review
10. Do you have manual on GRevP
11. Do you have electronic access to Federated sources - PARs, Pharmacopeia (USP, BP, IP)
12. Do you have eForms?

Possible steps for the adoption of IRIMS

- Conduct survey
- Benchmark data standards
- Develop roadmap
- Define specifications for ICT
- Develop or revise existing tools to meet data standards and user specifications.

Key messages

1. Data standards, dictionaries, and harmonized terminologies are critical for exchange of regulatory information,

2. Integrated Regulatory Information Management System is important for optimal pharmaceutical regulation,

3. Information technology provides the greatest opportunity for the transformation of product safety in LMICs.

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Questions

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