Prequalification of IVDs and the Collaborative Registration Procedure

World Health Organization

In vitro Diagnostics assessment Team

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Presentation Outline

Prequalification (PQ) of IVDs

- WHO PQ for IVDs
- PQ Assessment
  - Dossier review
  - Performance Evaluation
  - Site Inspection
- Collaborative Registration procedure

PQDx: aim, scope and impact

Prequalification of IVDs began in 2010

The aim of PQDx is to promote and facilitate access to safe, appropriate and affordable IVDs of good quality

Focus is placed on IVDs for priority diseases and their suitability for use in resource-limited settings

More IVDs will be added to PQ over time:

NEXT → TB tests

HIV

Malaria

Hepatitis C

Hepatitis B

HPV

G6PD

Cholera

Syphilis

Haemoglobin POC*

Glucose meters & test strips*

PQ assessment components

PQDx undertakes a comprehensive assessment of individual IVDs through a standardized procedure aimed at determining if the product meets WHO prequalification requirements

The prequalification assessment process includes three components:

- Review of a product dossier
- Performance evaluation
- Manufacturing site inspection

Labelling review

Review of the product dossier

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Assessment of manufacturer's data

Analyzing the relevance of the data in the dossier

- Quality data that supports the manufacturers claims of quality, safety and performance
- Appropriate & well-designed validation studies

Review evidence of completeness, accuracy and consistency of data over IVD life-cycle

- From initial product design, through validation, manufacture, quality control and release onto the market

➢ Are the technical specifications met?

➢ Has the manufacturer considered the use of the product in resource-limited settings?

Performance evaluation

Analytical, clinical and operational performance

Independent **verification** of the performance of IVDs submitted for prequalification assessment

- Assays are challenged with a focus on their use in resource-limited settings and in the context of WHO guidelines
- A standard PQ protocol is followed for the evaluation
- The dataset obtained complements the verification and validation data submitted by the manufacturer in the product dossier and findings in the site inspection
- Currently takes place in a WHO Collaborating Centre (CC) and/or a site otherwise designated by WHO

Manufacturing site inspection

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All sites relevant to the IVD are considered

Evidence of a fully implemented quality management system based on International Standards

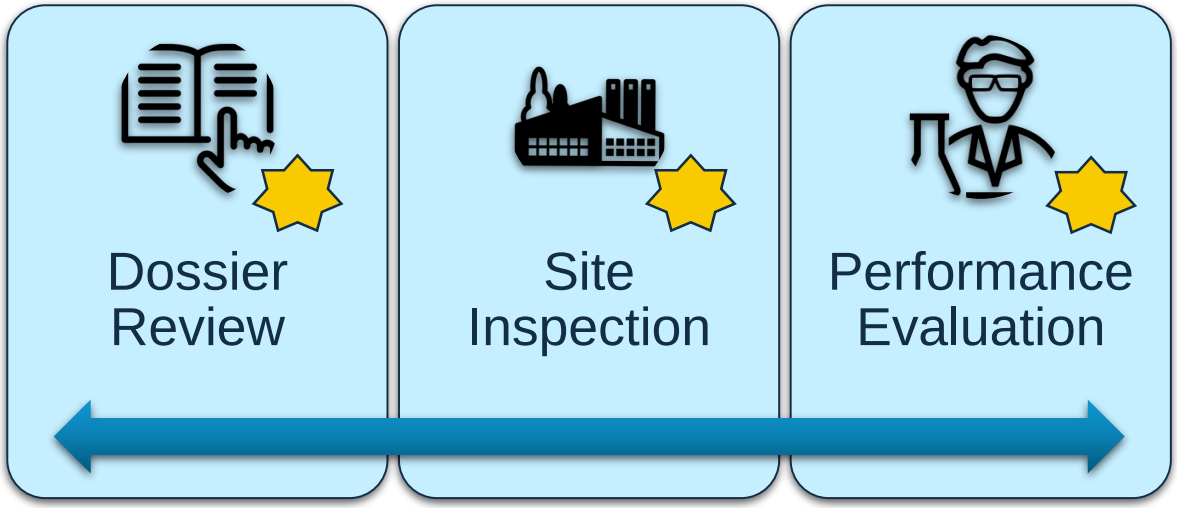
- IVD design & manufacture meets ISO 13485
- Risk management meets ISO 14971

Consideration of the robustness of the product for WHO intended settings and users

- The products undergoing prequalification have to be in routine manufacturing
- Evidence of sufficient capacity to ensure reliable delivery

Prequalification decision

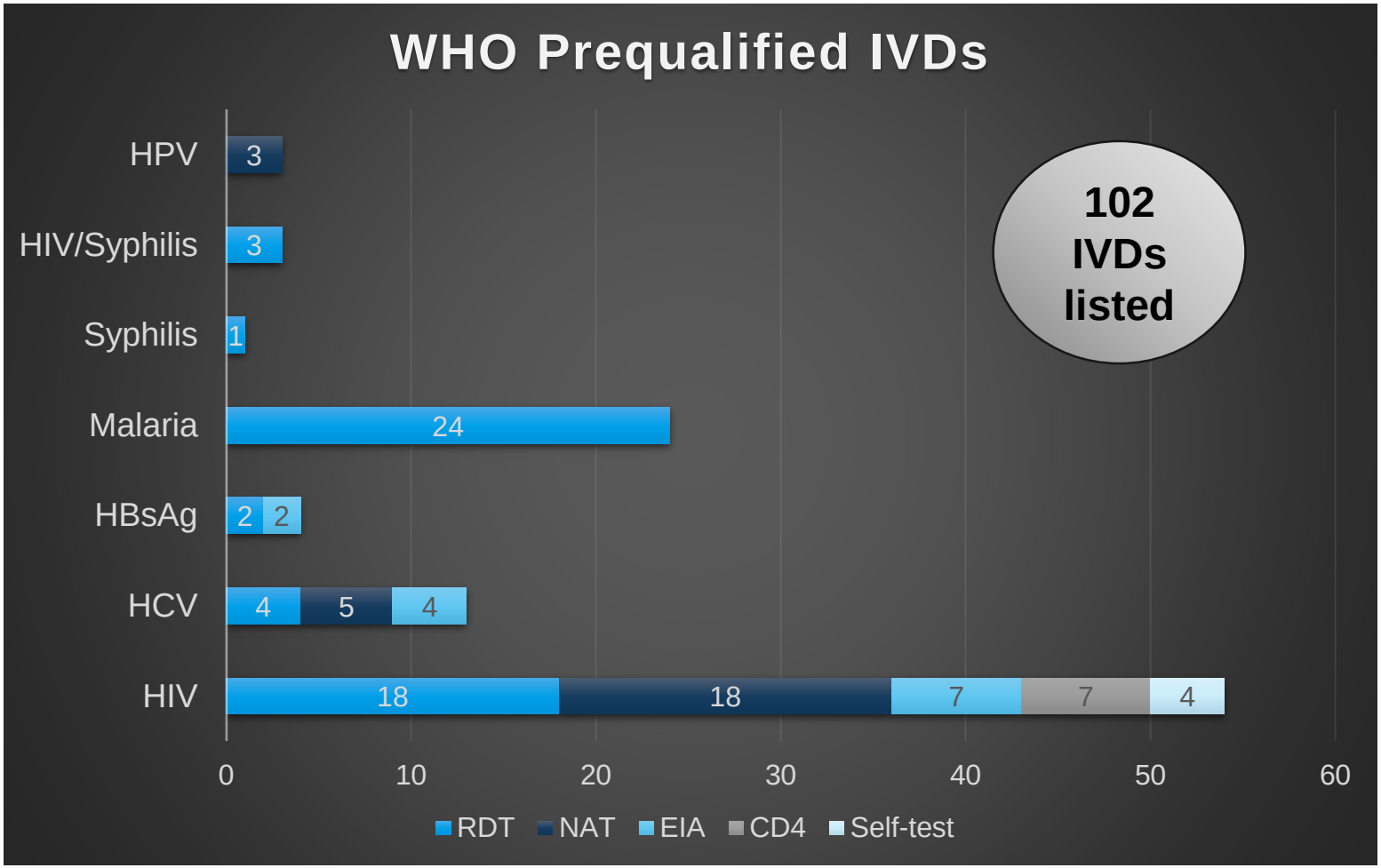
Final prequalification outcome depends on:



- A final labelling review is performed and the public report prepared
- WHO PQDx Public Report is posted on WHO website and product is added to the list of WHO prequalified products
- Product is then eligible for WHO and UN procurement

Prequalified IVDs

PQ List available at: https://extranet.who.int/pqweb/vitro-diagnostics/vitro-diagnostics-lists



Accelerating access to IVDs

With a regulatory approach based on reliance

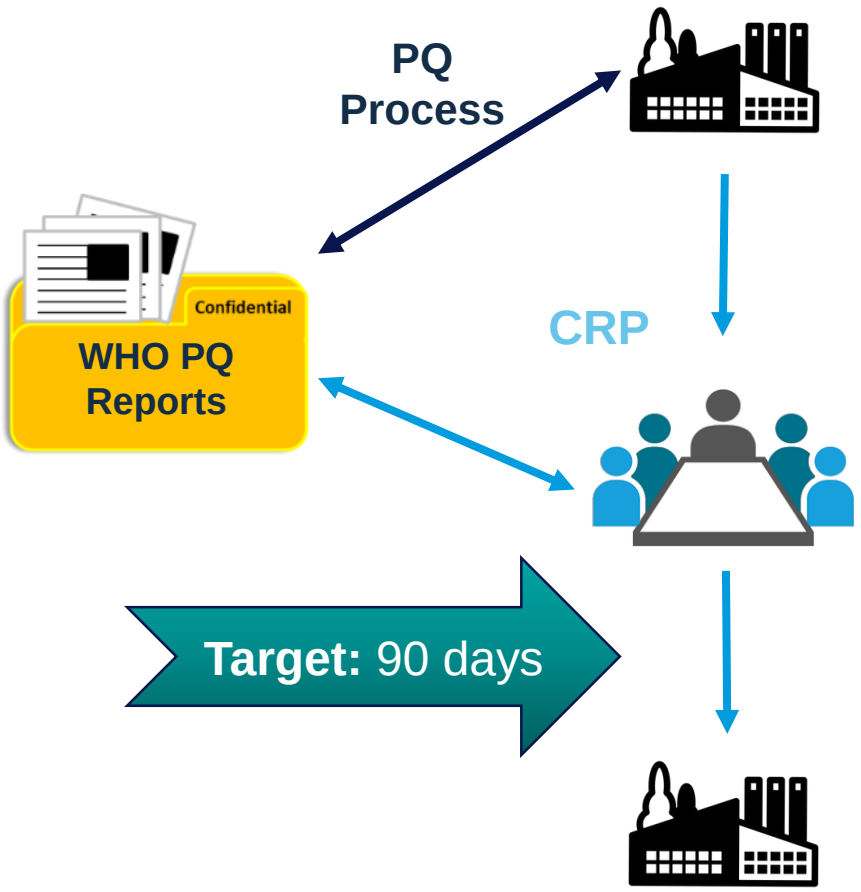
Aims to accelerate country registration of prequalified IVDs through information sharing between WHO PQ and National Regulatory Authorities

PRINCIPLES

- Voluntary for Mx of prequalified IVDs
- Product sameness must be guaranteed
- Confidentiality of data shared
- Target timeline for NRA decision

WHO PQ REPORTS SHARED

- Product dossier review
- Site Inspection
- Performance Evaluation



Collaborative Registration Procedure for IVDs

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Collaborative agreement between stakeholders

NRA

Participation agreement and undertaking for focal point

Manufacturer

Consent for WHO to confidentially share PQ reports

WHO

Shares full outcome pf PQ assessment with NRA

WHO PQ Reports

Reports shared using confidential online platform

Dossier Review Report

Assessment of manufacturer's:

- Product information
- Design and manufacturing
- Product performance specifications
  - Validation and clinical studies
- Labels
- Commercial history
- Regulatory history
- Quality management system

Site inspection Report

On-site inspection findings:

- Scope of inspection
  - Objectives
  - Limitations
- Information about the manufacturer
- Inspection findings
  - Audit trails and sources of evidence
  - Evaluation and conclusions
  - List of non-conformities and observations
  - Grading of NCs

Performance evaluation Report

Details provided:

- Product provided for evaluation
- Specimen panels tested
- Reference results
- Data Analysis
- Results
- Appraisal by laboratory technician
- Appendices containing data generated during the evaluation

Implementation of CRP for IVDs

CRP Guidelines for IVDs published in 2021

Keys for success

- Clear regulatory pathway for IVDs
- Good communication between stakeholders

Assistance available

- Information sessions to introduce CRP
- Workshop on WHO-PQ reports

Participation

- 13 NRAs have signed CRP agreement
- Reports have been shared for 7 IVDs

Using CRP to accelerate access to IVDs

NRA and Manufacturer of IVD sign agreements to permit confidential data sharing

RELIANCE MECHANISM

- Avoid duplication of effort
- NRA experts can review WHO findings
- Accelerate decision on registration

GOALS

- Shorter pathway to national registration for quality assured IVDs
- Optimization of resources for participating countries

Guidelines published on WHO Website
https://www.who.int/publications/m/item/collaborative-procedure-between-the-who-and-nra-s-in-the-assessment-and-accelerated-national-registration-of-who-prequalified-ivd-s-annex4

Thank you

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