

Workshop with Neglected Tropical Diseases (NTD) Diagnostics manufacturers

UN city, Copenhagen

WHO Collaborative Registration Procedure for In vitro diagnostics (CRP for IVDs)

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Agnes Sitta Kijo
Technical Officer,
Facilitated Product Introduction
Regulation and Safety Unit
Regulation and Prequalification Department
World Health Organization

Accelerating access to in vitro diagnostics

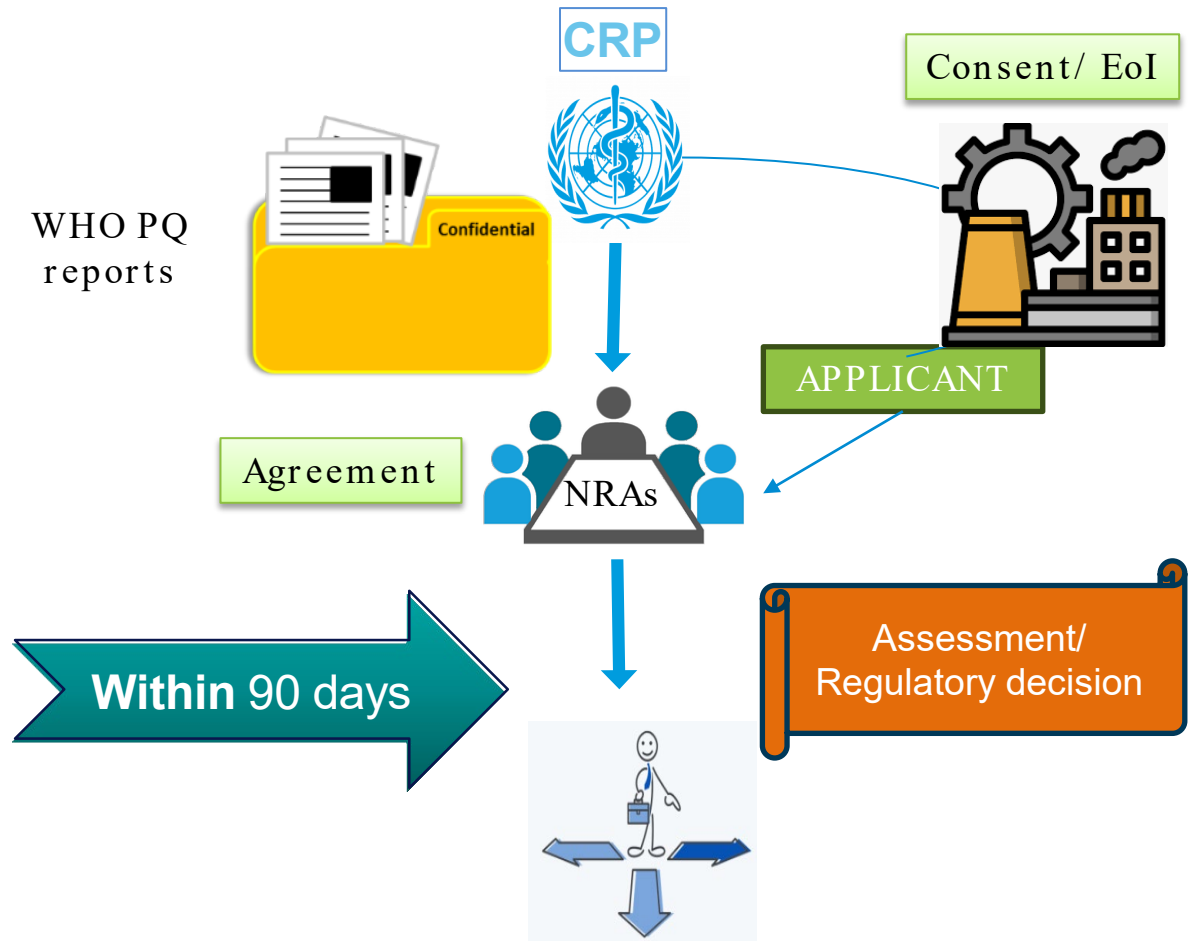
Aims to accelerate country registration of prequalified IVDs through information sharing between WHO PQ and National Regulatory Authorities

Principles:

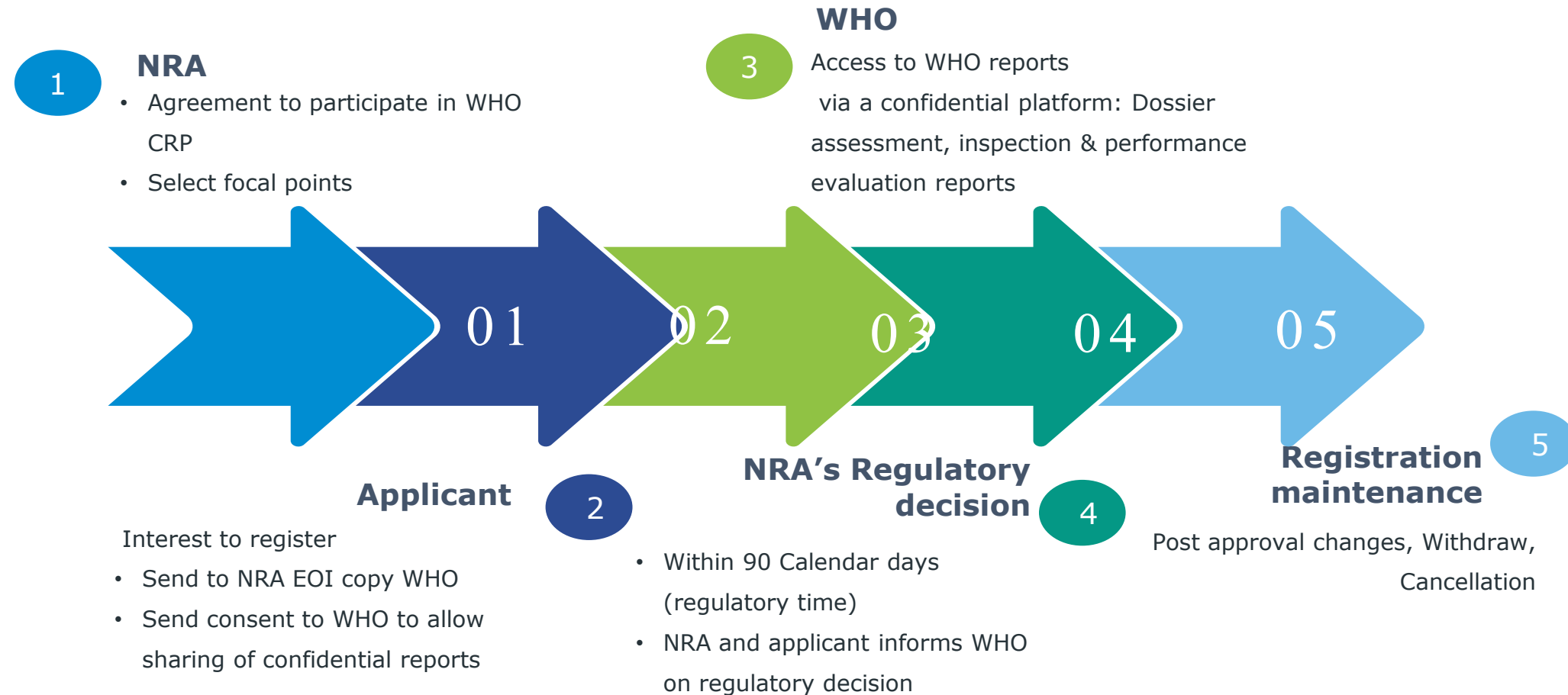
- Voluntary for MA of prequalified IVDs
- Product sameness must be guaranteed
- Confidentiality of information shared
- Target timeline for NRA decision

WHO PQ reports shared:

- Product dossier review
- Site inspection
- Performance Evaluation



Key Steps of CRP IVDs Implementation





Using CRP to accelerate access to IVDs

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

Reliance mechanism

- Shorter pathway to national registration for quality assured IVDs
- Avoid duplication of effort
- NRA experts can review WHO findings
- Accelerate decision on registration
- Optimization of resources for participating countries registration-of-who-prequalified IVDs

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-ified-ivd-s-annex4>

WHO CRP for IVDs: product scope



CRP IVDs: Product scope

- ✓ Focus on IVDs that address major public health concern and needed in member states
- ✓ IVD products eligible for CRP: WHO prequalified IVDs
 - This list is regularly updated as new IVDs are added to the prequalification scope.
- ✓ Product scope:
 - HIV
 - Hepatitis B virus
 - Hepatitis C virus
 - Malaria parasites
 - HPV
 - Glucose-6-phosphate dehydrogenase (G6PD) enzyme
 - Toxigenic *Vibrio cholerae*
 - Syphilis
 - MTBC and resistance to first and/or second line anti-tuberculosis drugs
 - SARS-CoV-2
 - Blood Glucose
 - HbA1c

WHO CRP- IVDs: 35 participating NRAs

As of 25 November 2024

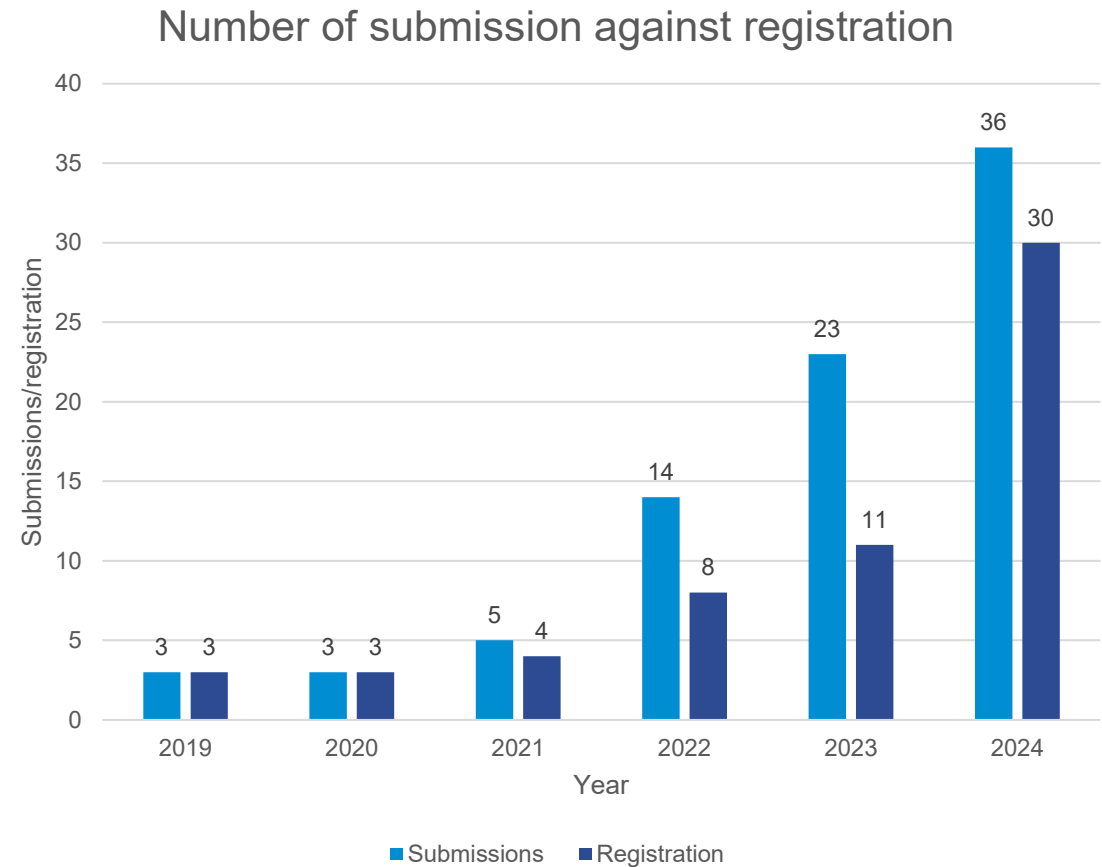
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- Angola
 - Bangladesh
 - Benin
 - Bhutan
 - Botswana
 - Burkina Faso
 - Burundi
 - Cabo Verde
 - Chad
 - Comores
 - Côte d'Ivoire
 - Democratic Republic of the Congo(DRC)
 - Eritrea
 - Ethiopia
 - Gabon
 - Gambia
 - Ghana
 - Kenya
 - Malawi
 - Mauritania
 - Mozambique
 - Namibia
 - Nigeria
 - Republic of Congo
 - Rwanda
 - Senegal
 - South Africa
 - Tanzania (Mainland)
 - Tanzania (Zanzibar)
 - Thailand
 - Togo
 - Uganda
 - Yemen (Sana'a)
 - Zambia
 - Zimbabwe

[Collaborative Procedure for Accelerated Registration | WHO - Prequalification of Medical Products \(IVDs, Medicines, Vaccines and Immunization Devices, Vector Control\)](#)



WHO CRP IVDs experience: submissions and registrations per year

- ✓ More than 90% of submissions resulting in successful registrations since 2019.
- ✓ Almost 50% of submission in 2023 resulted in registration.
- ✓ There is significant increase in number of submission and registrations in 2024 indicating CRP efficiency as a result of increased CRP advocacy: NRAs and applicants' willingness to apply the Procedure.



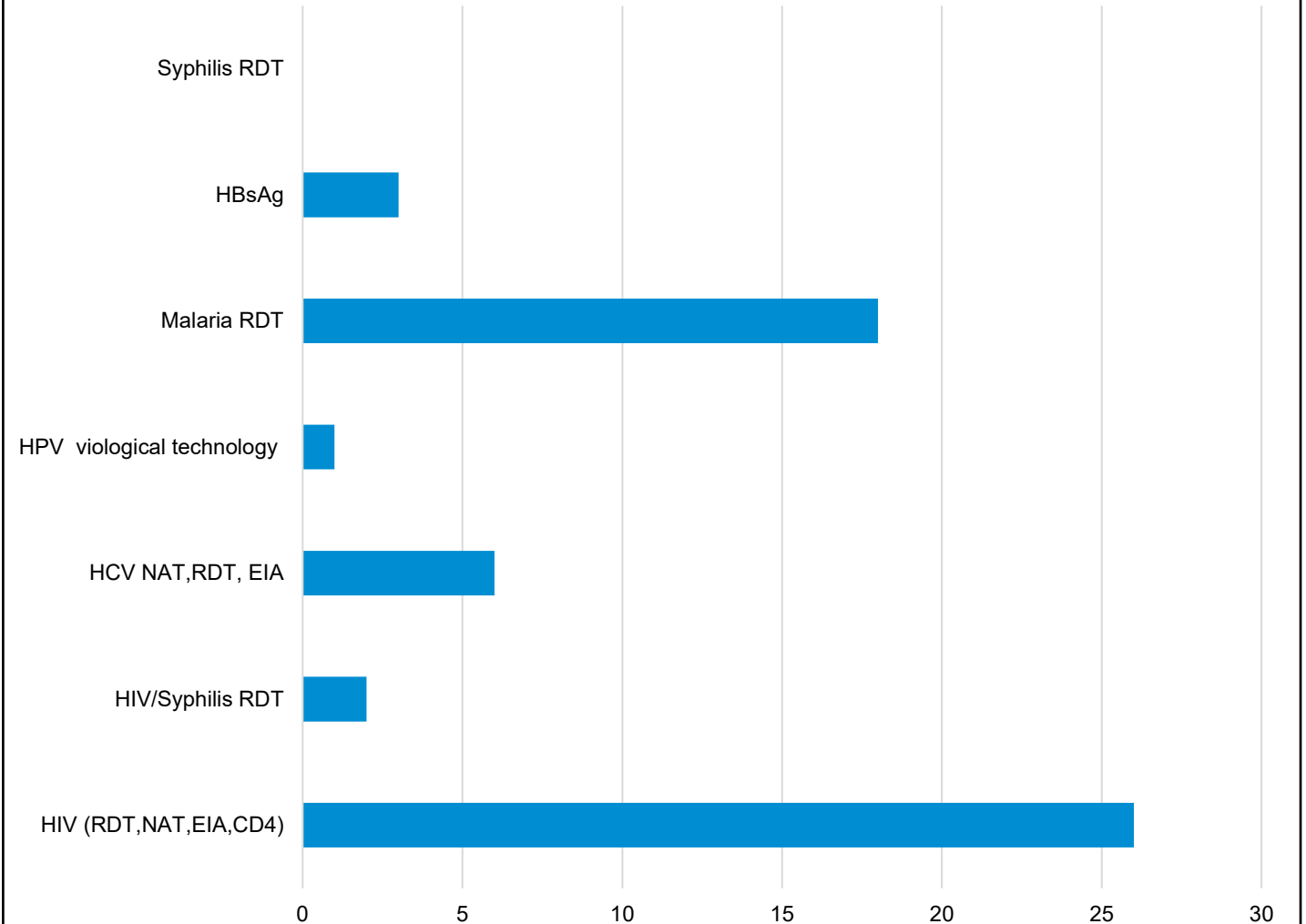
WHO CRP IVDs experience:

Registered assay types

- ✓ Assays registered under CRP based on the listed WHO prequalified products.
- ✓ Most registered IVD products: HIV technologies including NAT, EIA, RDT, self tests kits followed by Malaria test kits.
- ✓ Syphilis RDTs, HBsAg and HPV assays very few or no registrations.....opportunity??

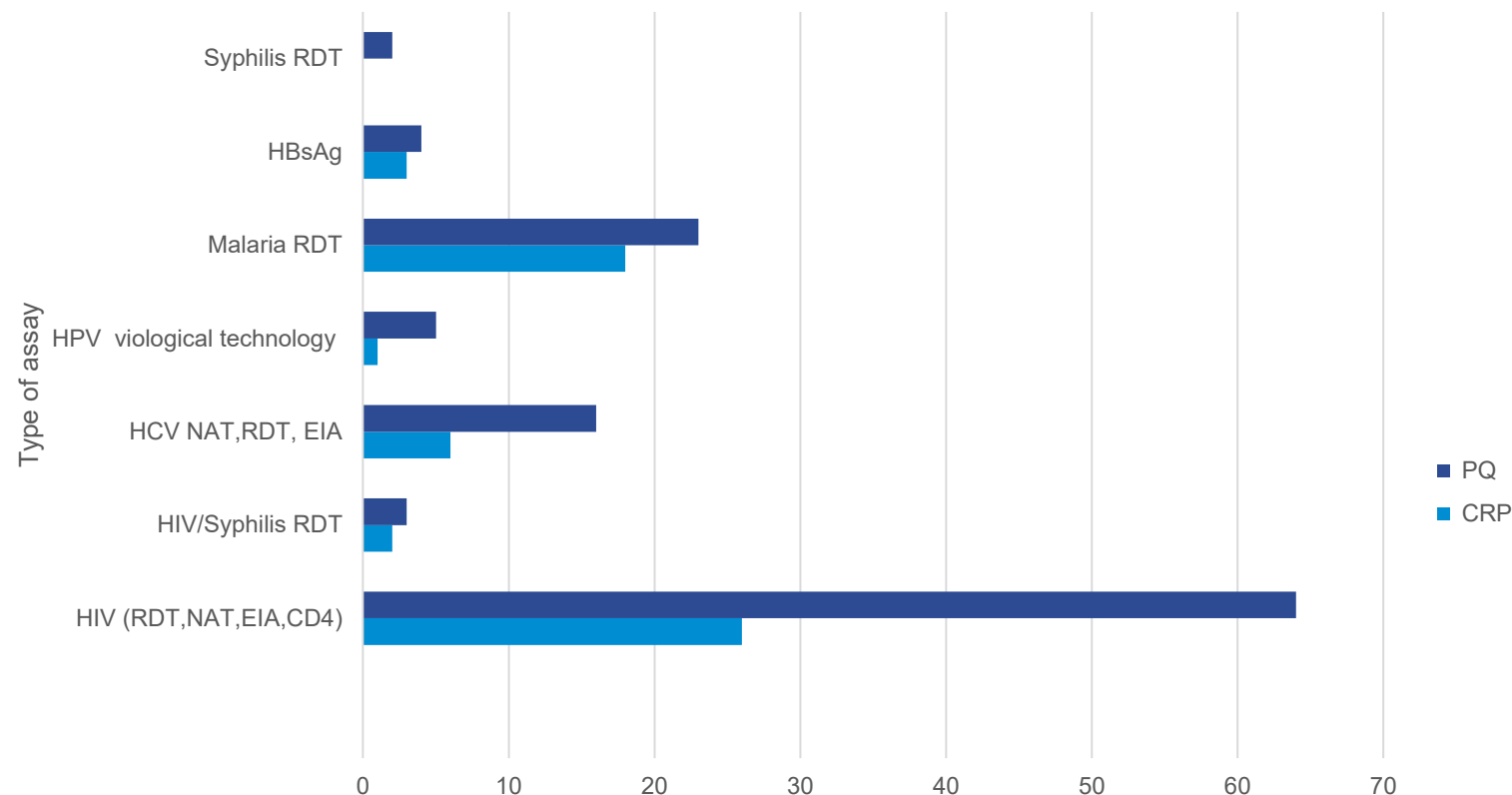


Type of Assays Registered under CRP



Registered assays under CRP vs WHO - Listed assays

Assays registered under CRP against WHO prequalified



- ✓ Only 26% of the total number of WHO –listed assays are registered under CRP.
- ✓ HIV assays have high percentage among WHO listed – assays.
- ✓ There is improvement in the types of assays registered including HBsAg HCV and HPV.
- ✓ No application for Syphilis RDT.

	HIV (RDT,NAT,EIA, CD4)	HIV/Syphilis RDT	HCV NAT,RDT, EIA	HPV viological technology	Malaria RDT	HBsAg	Syphilis RDT
■ PQ	64	3	16	5	23	4	2
■ CRP	26	2	6	1	18	3	

Resources to support implementation of CRP for IVDs

WHO Expert Committee on Specifications for Pharmaceutical Preparations

Annex 6

Good practices of national regulatory authorities in implementing the collaborative registration procedures for medical products

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ePQS - Electronic Prequalification System

The ePQS, developed by WHO, is a comprehensive platform for processing pre-qualification information across various healthcare products. Set to open its portal to manufacturers and external users in 2024, ePQS aim to streamline the application process, enhance transparency, and boost efficiency. It integrates vital aspects of WHO's Pre-Qualification Unit, providing a centralized database, a Document Management System (DMS), a repository for product dossiers, and a community portal.

ePQS simplifies application submission and management, enhances reporting capabilities, and enables real-time monitoring of application statuses. Moreover, it facilitates the submission of electronic Common Technical Document (eCTD) dossiers, improving document organization and review efficiency.

For more information on ePQS, please use the link below

[ePQS Portal | WHO - Prequalification of Medical Products \(IVDs, Medicines, Vaccines and Immunization Devices, Vector Control\)](#)



ePQS Portal

- Provides a resource for manufacturers/applicants and participating NRAs to implement facilitated national registration of WHO PQ IVDs
- Covers the national registration and management of post-approval changes
- WHO Good Practices of NRAs in implementing CRP for medical products
- WHO CRP IVDs ProcedureAnnex 4 published in the WHO TRS No. 1030
- Electronic Prequalification System (ePQS)
- Other principles elaborated in the WHO guidelines



Annex 4

Collaborative procedure between the World Health Organization and national regulatory authorities in the assessment and accelerated national registration of WHO-prequalified in vitro diagnostics

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[FPI website](#)

WHO CRP IVDs experience: Challenges & intervention



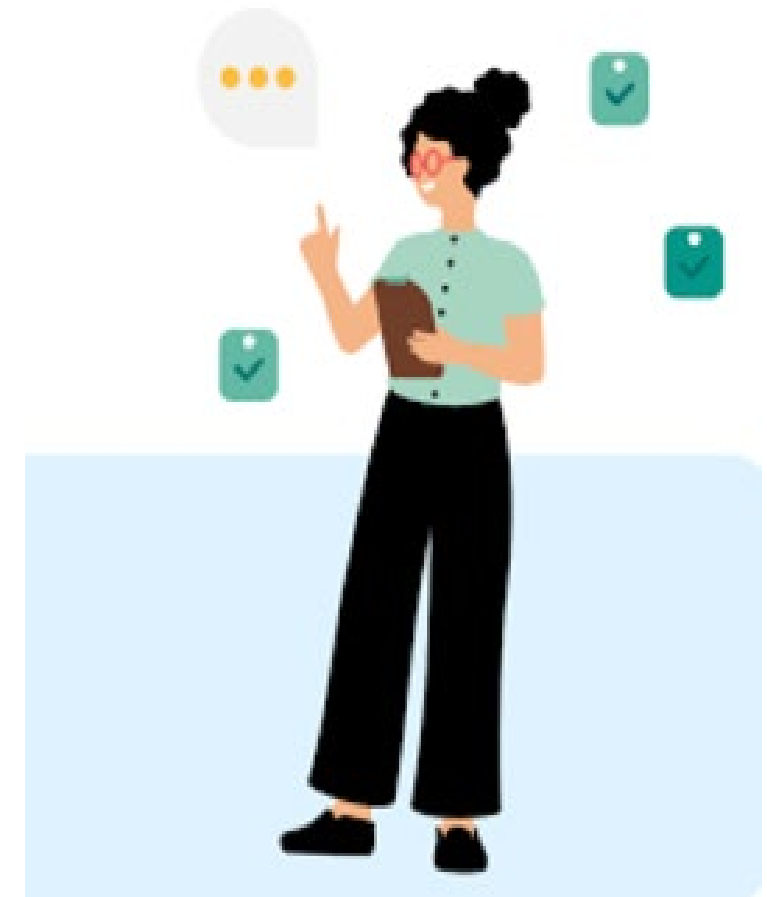
- ✓ Low expression of interest from the manufacturers
- ✓ Lack/varying regulatory systems for medical devices and IVDs
- ✓ Lack/low responsiveness from NRAs
- ✓ National regulatory requirements
- ✓ Information sharing and exchange



- ✓ Manufacturers workshop, CRP Annual meetings, 1 to 1 meetings on regulatory pathways and specific NRA requirements
- ✓ Regional workshops, individual NRA trainings on reliance practices, assistance on NRA guidelines and procedures
- ✓ Assist in review of national requirements (guidelines and procedures) to enhance more reliance and minimize specific national requirements, communications with manufacturers, training and capacity building
- ✓ Centralized information sharing and exchange under dedicated platform (ePQS). Pilot for NRA and manufactures initiated

Take away messages

- CRP works effectively in accelerating registration for IVDs: stakeholders to utilize this validated reliance mechanism
- Short timelines vs standard national process : access to patients, quick product introduction
- Can facilitate reliance in PAC management: reduce manufacturers regulatory burden
- Expansion of CRP for IVDs to WLA CRP
- Full migration and utilization of ePQS
- Sensitization for other regions to a sign CRP participation agreements
- Facilitate communication between the manufacturer and the NRA





Thank you

For more information contact:

prequalreg@who.int / kijoa@who.int