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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Accelerating access to in vitro diagnostics

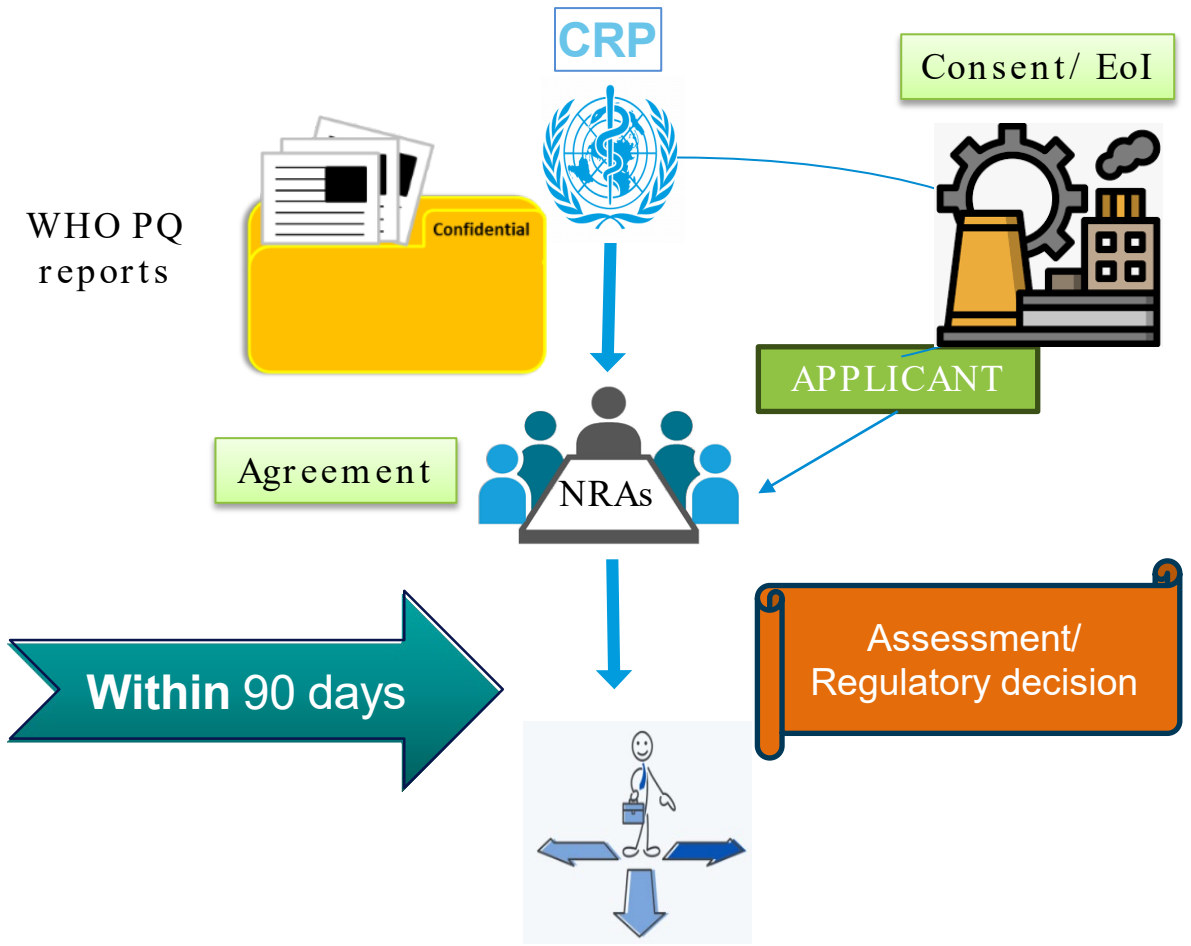
Aims to accelerate country registration of prequalified IVDs through information sharing between WHO PQ and National Regulatory Authorities

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

1

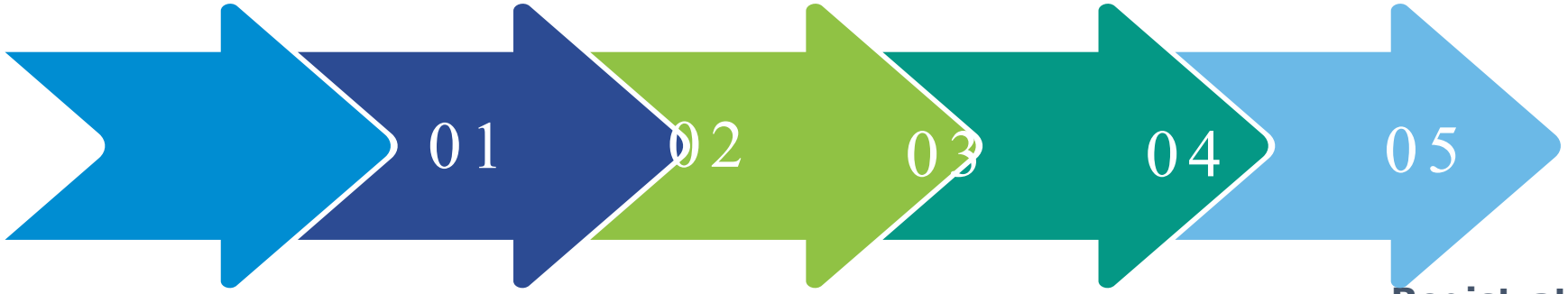
NRA

- Agreement to participate in WHO CRP
- Select focal points

3

WHO

Access to WHO reports via a confidential platform: Dossier assessment, inspection & performance evaluation reports



Applicant

2

Interest to register

- Send to NRA EOI copy WHO
- Send consent to WHO to allow sharing of confidential reports

NRA's Regulatory decision

4

- Within 90 Calendar days (regulatory time)
- NRA and applicant informs WHO on regulatory decision

Registration maintenance

5

Post approval changes, Withdraw, Cancellation

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

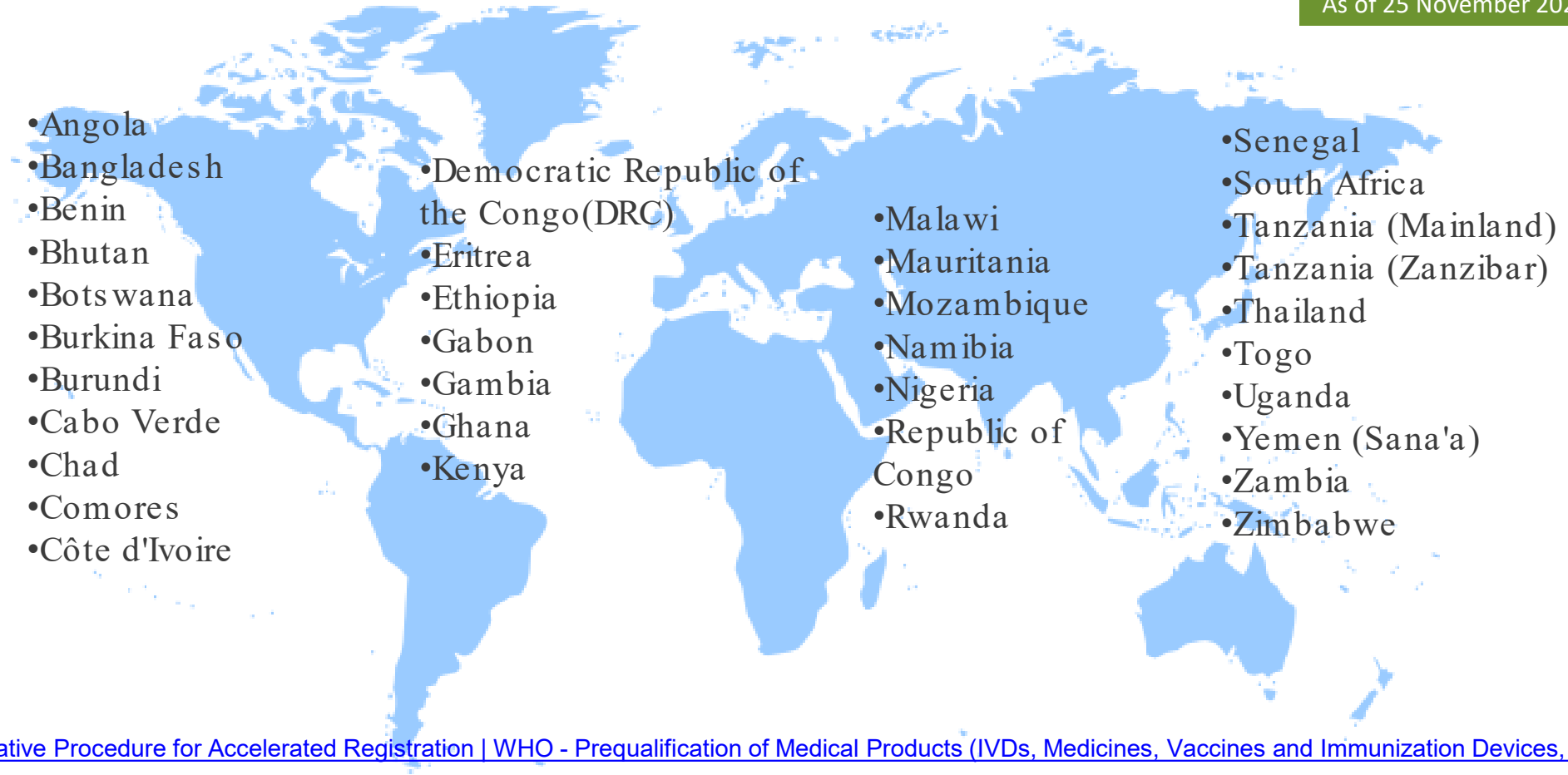
CRP IVDs: Product scope

- ✓ 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

List of Prequalified In Vitro Diagnostics | WHO - Prequalification of Medical Products (IVDs, Medicines, Vaccines and Immunization Devices, Vector Control)

WHO CRP- IVDs: 35 participating NRAs

As of 25 November 2024

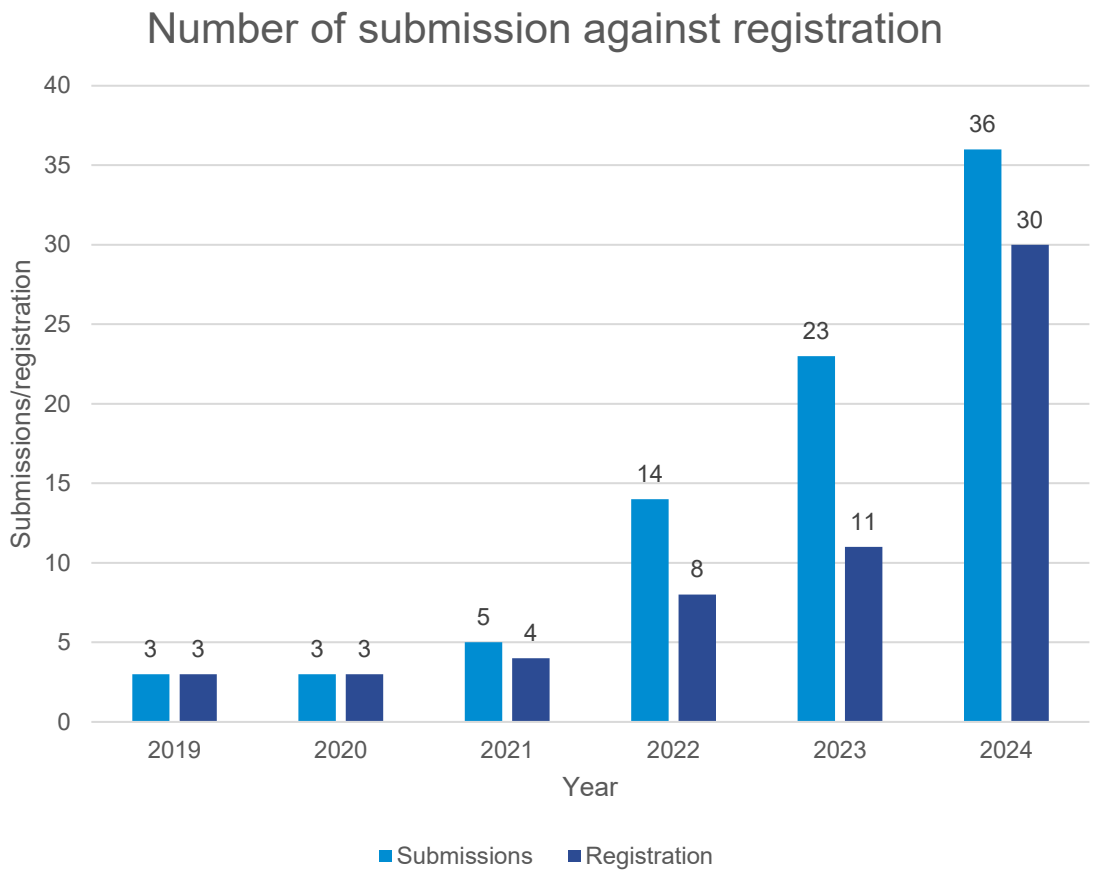


Collaborative Procedure for Accelerated Registration | WHO - Prequalification of Medical Products (IVDs, Medicines, Vaccines and Immunization Devices, Vector Control)




WHO CRP IVDs experience: submissions and registrations per year

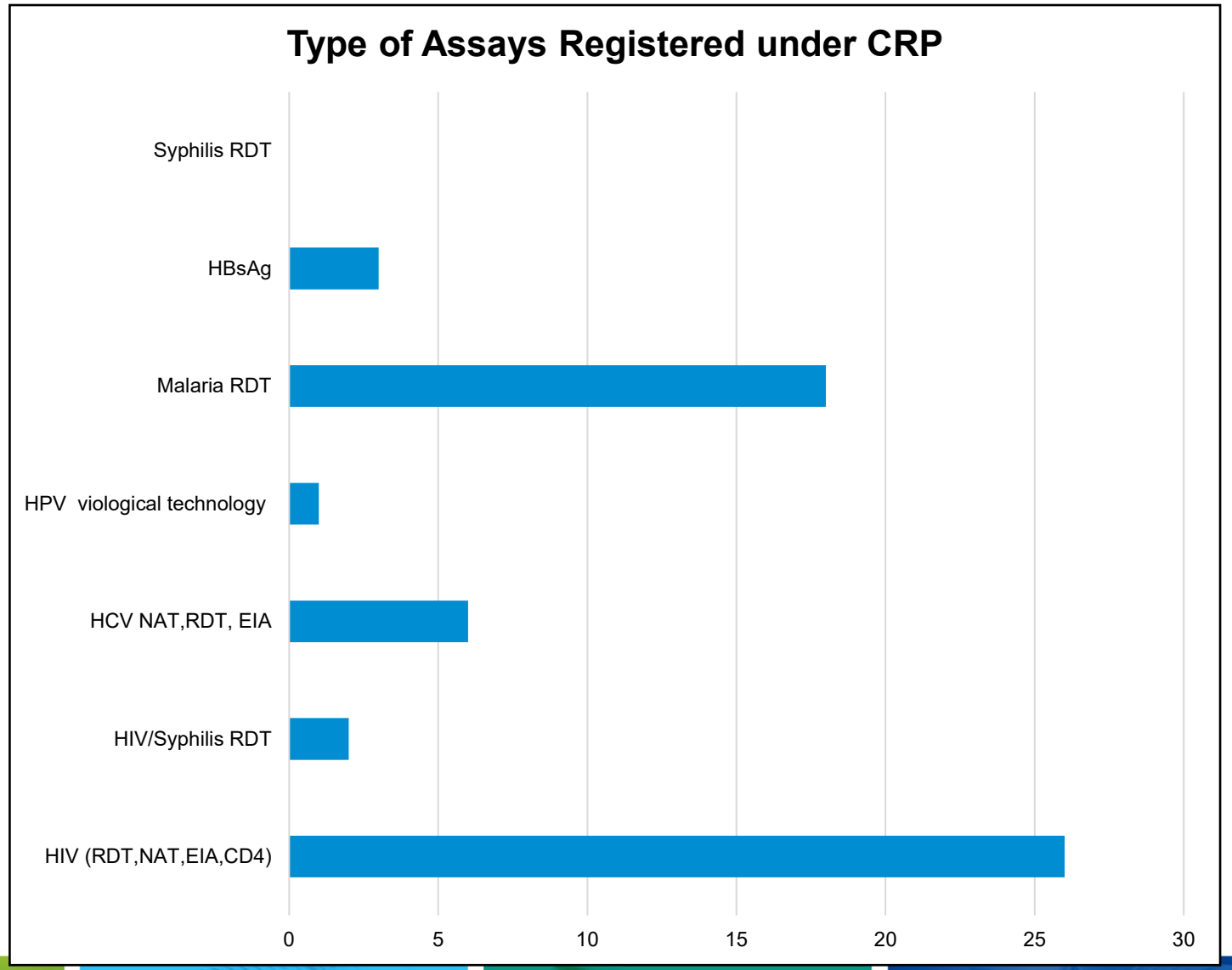
- ✓ More than 90% of submissions resulting in successful registrations since 2019.
- ✓ Almost 50% of submission in 2023 resulted in registration.
- ✓ There is significant increase in number of submission and registrations in 2024 indicating CRP efficiency as a result of increased CRP advocacy: NRAs and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



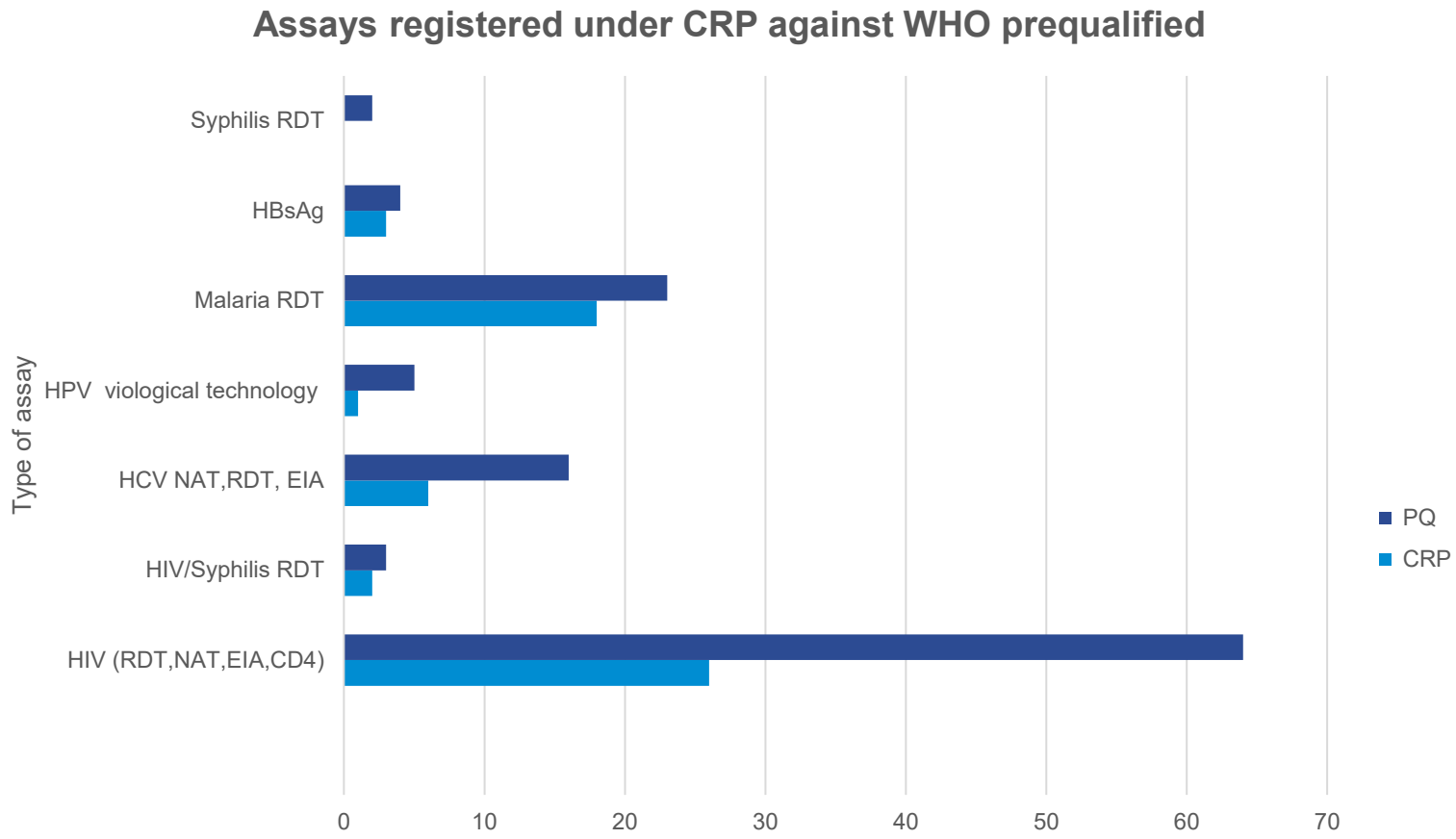



WHO CRP IVDs experience: Registered assay types

- ✓ 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??



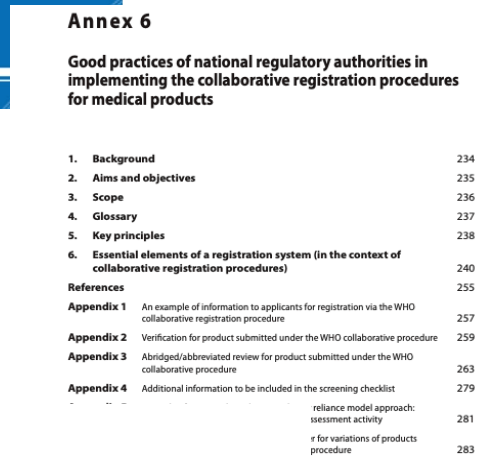
Registered assays under CRP vs WHO - Listed assays



		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	

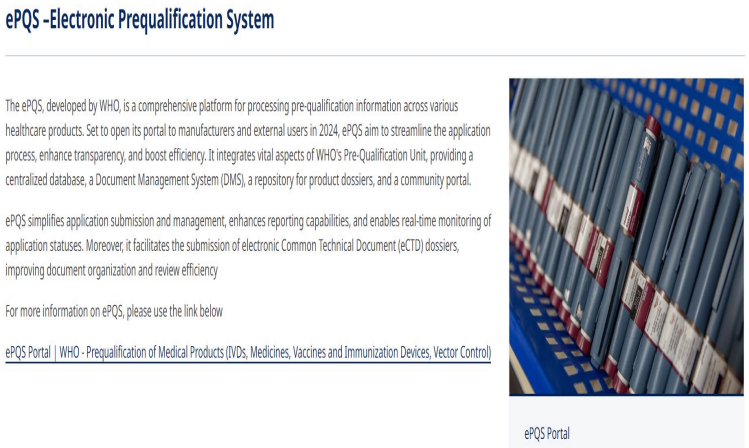
- ✓ Only 26% of the total number of WHO –listed assays are registered under CRP.
- ✓ HIV assays have high percentage among WHO listed – assays.
- ✓ There is improvement in the types of assays registered including HBsAg HCV and HPV.
- ✓ No application for Syphilis RDT.

Resources to support implementation of CRP for IVDs

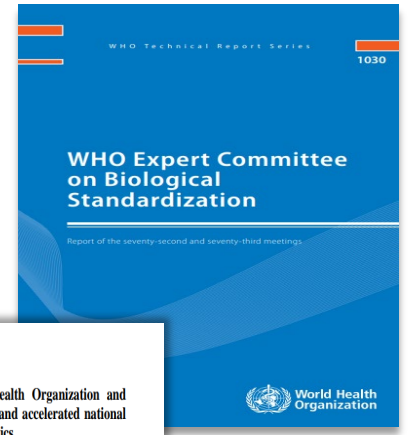


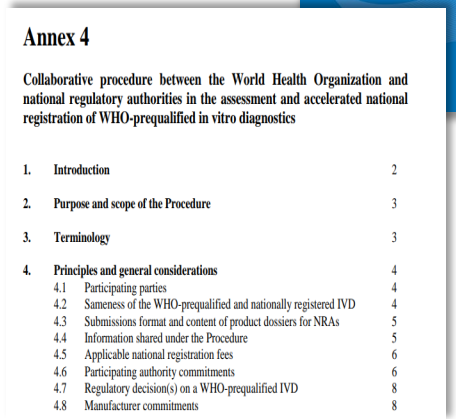
Annex 6

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



- 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

FPI website

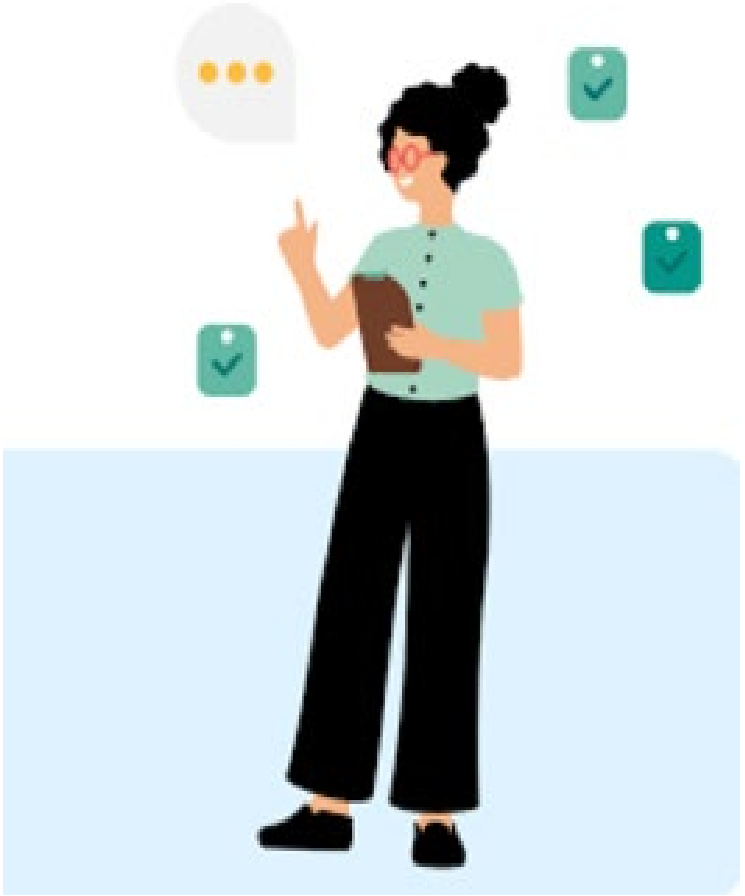
WHO CRP IVDs experience: Challenges & intervention

- ✓ 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

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