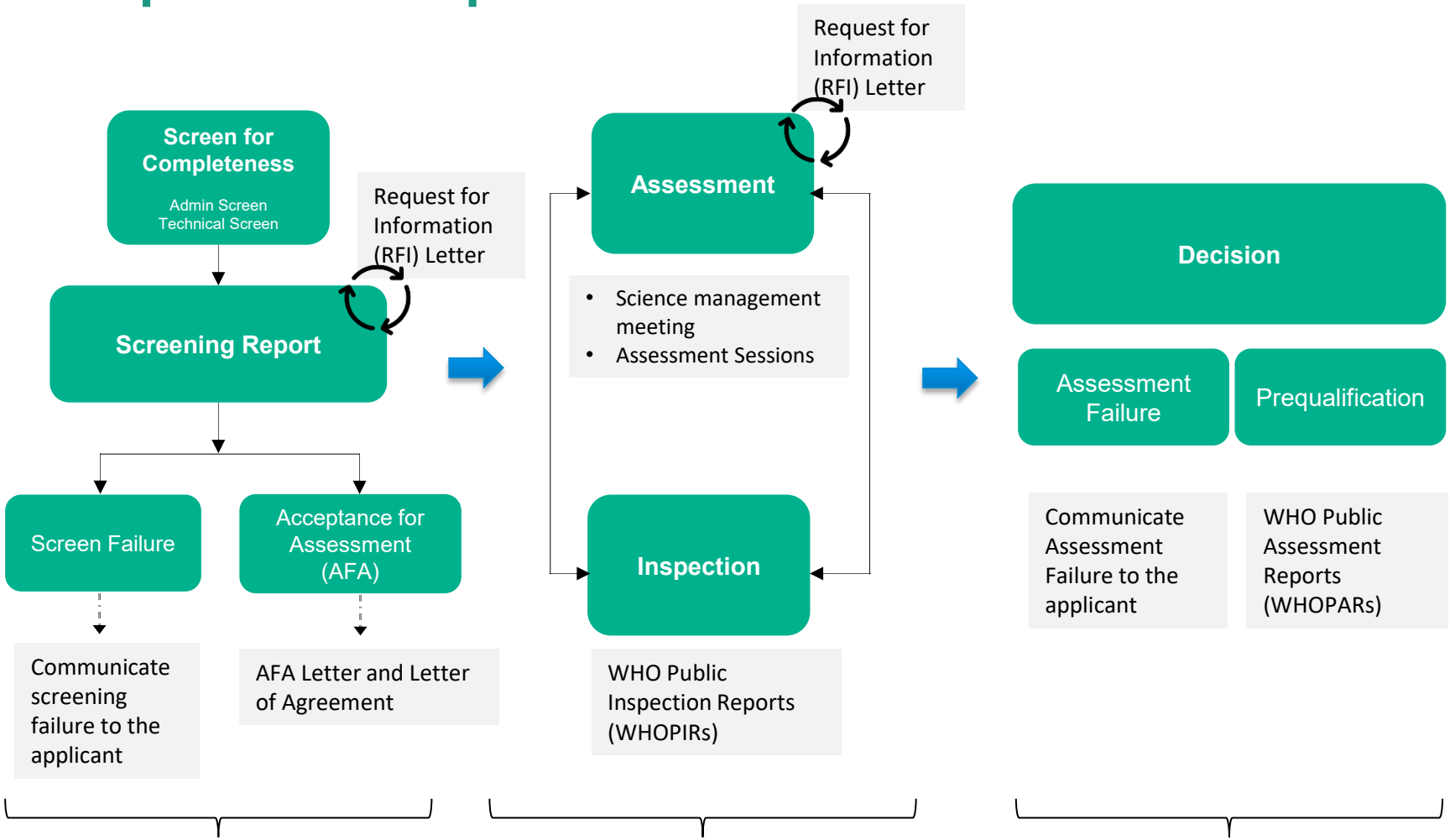
Overview of the activities of the WHO PQT/VCP team and New ITN guidelines and implications for improved ITN quality

D. Schuler and G. Foster
WHO prequalification vector control products team
RBM VCWG webinar: Addressing non-biological threats to the impact of ITNs

Prequalification process



2023-2024 Review

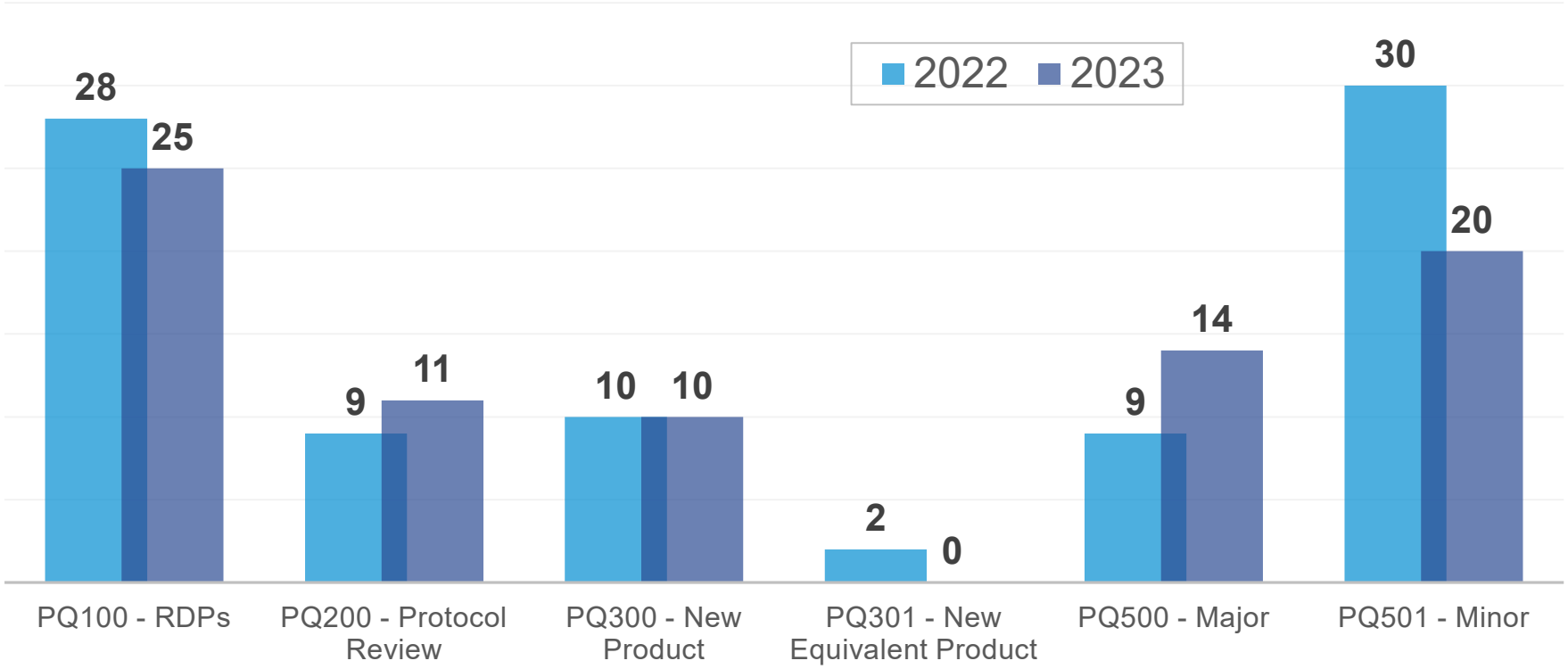
2023 – 2024 Activities

Team, assessments, and communication

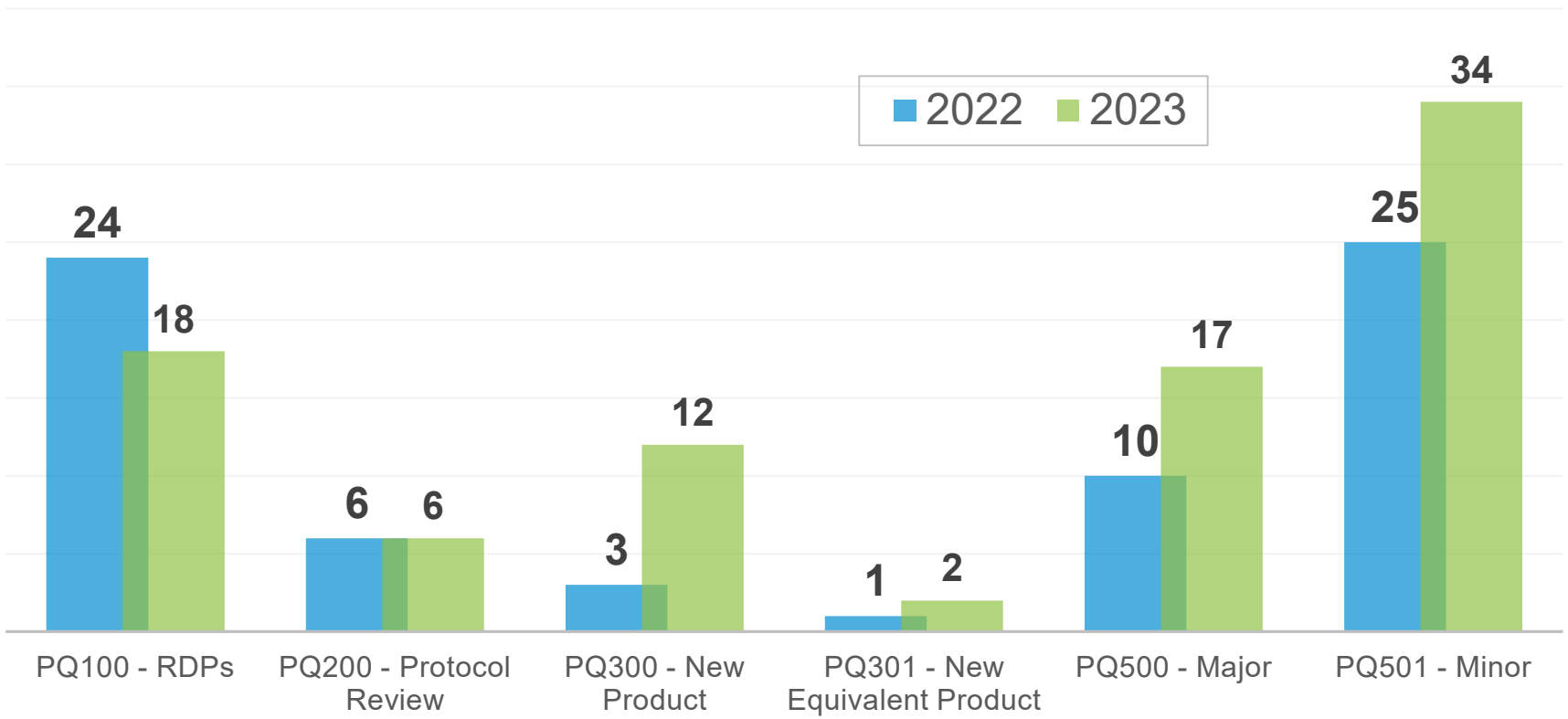
- ✓ Staffing – filled entomologist and chemist positions
- ✓ Two vector control products assessors (ASVCP) meetings in 2023, one in 2024, second 2024 meeting planned for November 2024
- ✓ Increased ASVCP roster
- ✓ Continued to engage the best experts in the field
- ✓ Managed submission workload and timely advancement of assessments
- ✓ Enhanced public assessment reports - WHOPARs
- ✓ Continuation of communication tools and approaches

PQ Applications received 2022/2023

- 195 applications were received 2022-23
- Over 200 pre-submission meetings were held



Applications closed in 2023



2023 – 2024 Activities

Guideline and guidance

- ✓ WHO Guideline for prequalification assessment of ITNs and corresponding implementation guidance – published December 2023
- ✓ Expansion of Advice to Manufacturer Series (AMS)

Collaborations with countries and partners

- ✓ Collaborative Registration Procedures (CRP) pilot launch

Advice to Manufacturers Series

Communication and Submission of Applications

- Preparing an application for electronic submission
- Use of third-party agents for communication and interaction with WHO PQT/VCP

Dossier and Data Requirements

- Fulfilling dossier and data requirements

Generating Data to Support Quality Assessments

- Number of batches required for testing of physical/chemical properties

Generating Data to support Safety Assessments

- Considerations for fulfilling the acute 6-pack requirement for ITNs

Assessment Process

- Entomology assessment process
- Preparation of entomology study reports

Development of Specifications

- WHO specification for source material - New applications and extensions

Collaborative registration procedures (CRP)

- CRP is a process whereby the registration of products in individual countries is facilitated by partial or full reliance by the countries in question on the assessments conducted by WHO PQT/VCP.
- There has been no CRP in place for vector control products until now, but in January 2024 a pilot scheme involving six countries (Rwanda, Tanzania, Nigeria, Ghana, Kenya, DRC) was launched in collaboration with WHO department of facilitated product introduction (FPI) and i2i.
- The first product under CRP, Yorkool G3 was registered in Ghana in September 2024

First WHO Prequalified Vector Control Product Registered through the Collaborative Registration Procedure

FAO/WHO Specifications vs manufacturing release specifications – ITN

ITNs are no longer reviewed through the JMPS process

- Considering the variety of formulations, manufacturing processes, and phys/chem characteristics, each ITN is unique. Therefore, each product must be supported by its own published manufacturing release specifications.

- The current WHO specifications published as an outcome of the JMPS process will be replaced by manufacturing release specifications for each ITN as part of the implementation of the new guideline.

2024 – 2026 priorities

2024 - 2026 Priorities (1)

- **Submissions**
- **Guidelines and guidance (2024-2026)**
    - WHO Guideline for Prequalification Assessment of IRS
    - WHO Guideline for Prequalification Assessment of Larvicides
    - WHO Guideline for Prequalification Assessment of Aircraft Disinsectants
    - Implementation Guidance

Spatial repellents

Modified mosquitoes

– joint mission with NTD May 2024

– development of modified mosquito assessment product assessment framework

WHO Public Assessment Reports

Structure and publication

WHOPAR - Structure

- New structure for the WHO public assessment reports
  - Part 1 - Letter of Prequalification
  - Part 2 - Executive summary
  - Part 3 - Quality Assessment (Module 3)
  - Part 4 - Safety Assessment (Module 4)
  - Part 5 - Efficacy Assessment (Module 5)

- All WHOPARS for all modules published simultaneously with prequalification decision

- Website walk through

Processes and guidance

Complaints submission

Submission of Complaints and Process

- Complaints should be submitted to WHO by email via **rapidalert@who.int**.

- The manufacturer of the product will be contacted and requested to submit an investigation report:
  - Root cause analysis (how/why did this happen);
  - Analysis regarding related areas (is this same issue impacting/occurring elsewhere);
  - Correction (fix now) with completion dates;
  - Corrective action, if application (to prevent recurrence) with planned completion dates.

- https://extranet.who.int/prequal/vector-control-products/submission-complaints