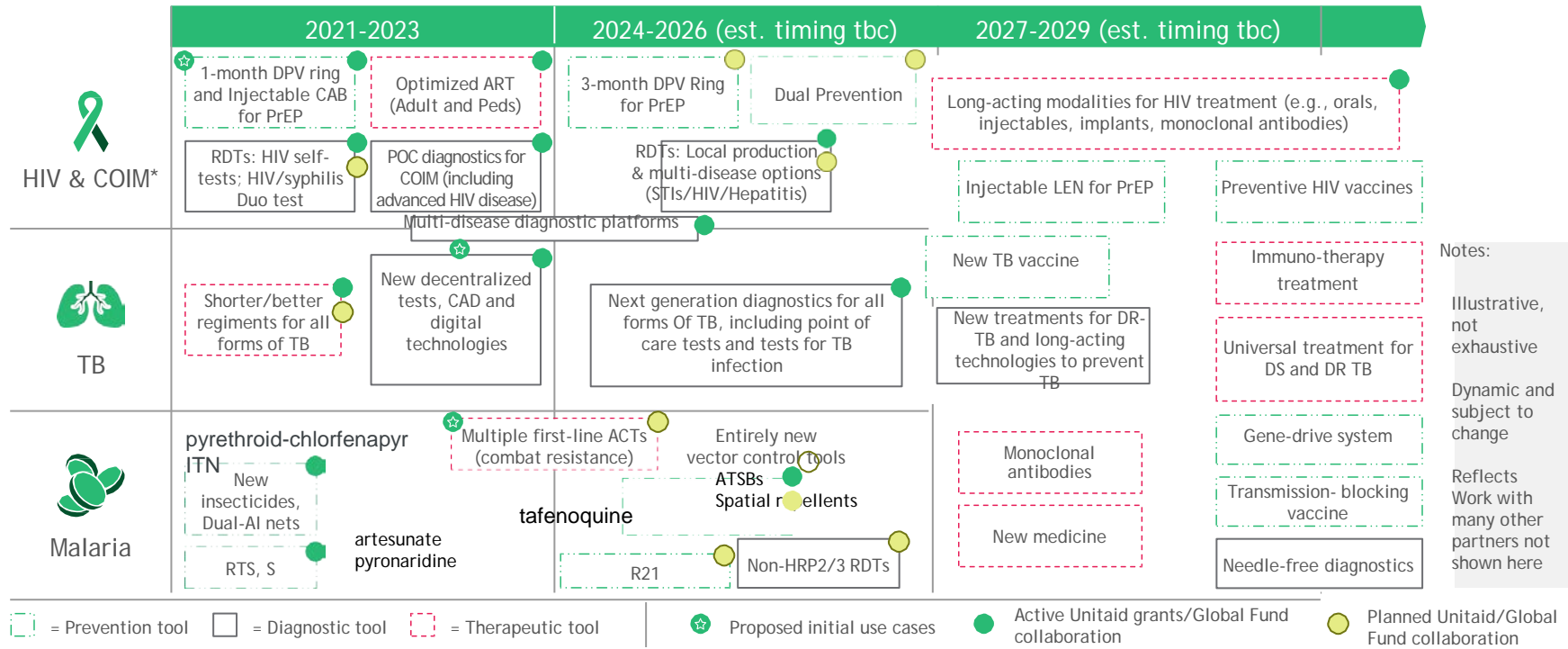


Mapping and prioritizing new product development across HIV, TB and malaria

Professor Jérôme Salomon
WHO Assistant Director General
Universal Health Coverage, communicable and
noncommunicable diseases, mental health
Division

Opportunity (and challenge) to address a large pipeline for HIV, TB, malaria in upcoming years

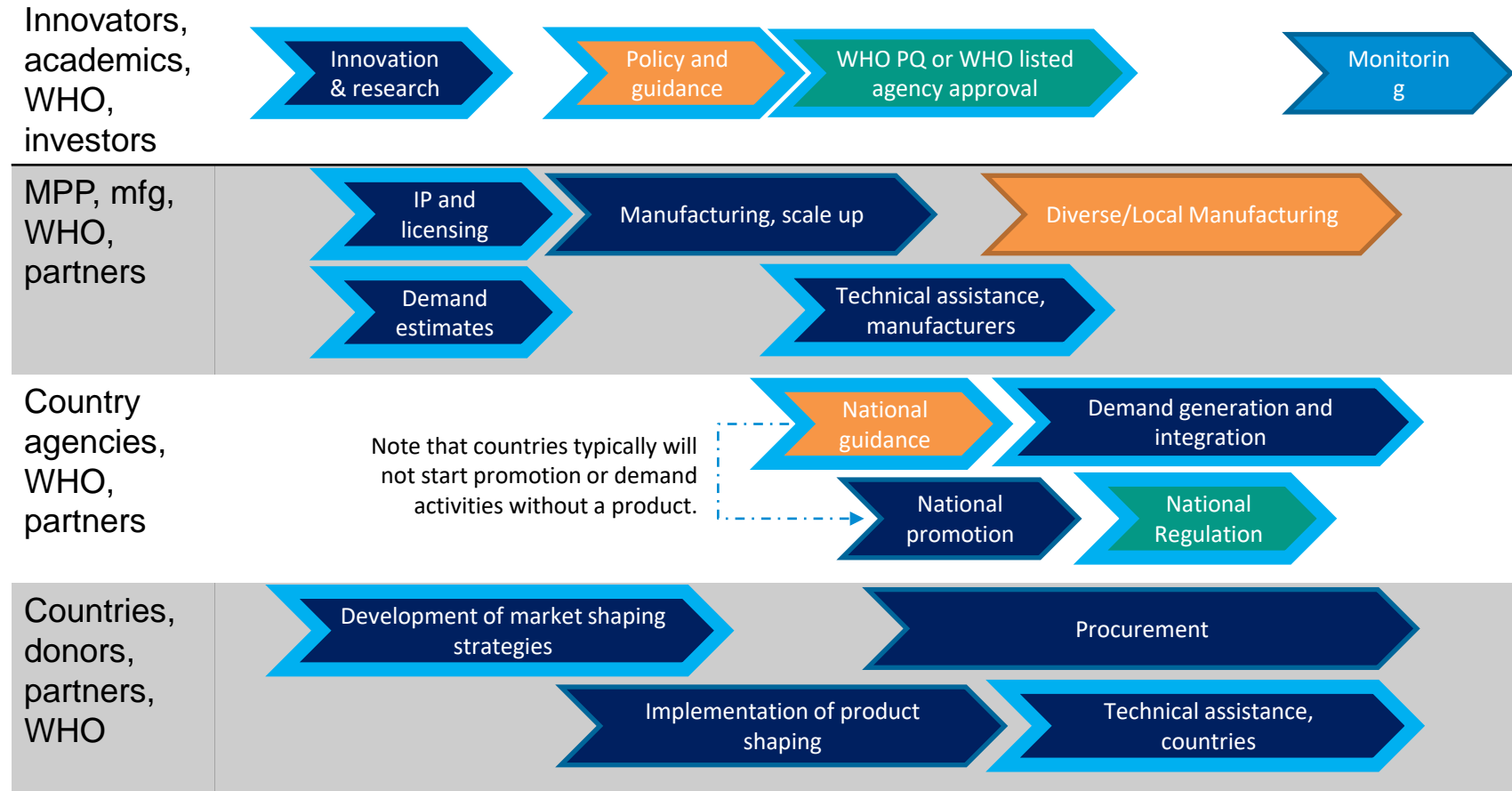


Notes:

- Illustrative, not exhaustive
- Dynamic and subject to change
- Reflects work with many other partners not shown here

Source: Adapted from a presentation made by BCG to WHO/UCN

WHO value add / entry points to the product cycle



Timelines for malaria guidelines, norms and standards

New Guidelines/norms/standards	Date expected	Anticipated new product recommendations*
The use of tafenoquine, G6PD point-of care diagnostic devices, primaquine	July 2024 (depending on prequalification of G6PD)	
Guidelines updated to reflect new evidence from the WHO review of the R21/Matrix-M malaria vaccine and ancillary RTS,S studies (for eg. Vaccine + SMC).	TBD. Awaiting the outcome of the joint session of SAGE and the Malaria Policy Advisory Group (MPAG) review of evidence on the R21/Matrix-M malaria vaccine (27 th September 2023)	Recommendation for use of R21/Matrix-M in children to prevent P. falciparum burden and disease in endemic areas?
Update on spatial repellents	March 2025 (currently working with PQ on alignment)	
Update on Attractive Toxic Sugar Baits (ATSBs)	March 2025	

In March 2023, WHO issued guidelines for the deployment of pyrethroid-chlorfenapyr ITNs to prevent malaria in areas where mosquitoes have become resistant to pyrethroids. Unitaid and Global Fund supported market interventions to improve affordability.

Timelines TB guidelines, norms and standards

New Guidelines/norms/standards	Date expected	Anticipated new product recommendations*
Catalogue of mutations in M.tb	October 2023	New set of mutations conferring resistance to Mtb PQ not needed. No new product/s
Target regimens profiles for TB treatment, target product profiles for TB biomarkers, target product profiles for TB diagnosis	October and December 2023	New set of standards for the development of new TB treatment regimens, diagnostics and biomarkers PQ not needed. No new product/s
Guidelines on the use of targeted Next Generation Sequencing (tNGS) for the diagnosis of DR-TB (guidelines and operational handbook)	December 2023	New tNGS products to detect resistance to anti-TB drugs New products: Deeplex® Myc-TB (GenoScreen): NanoTB® (Oxford Nanopore Technologies): TBseq® (ShengTing Biotech)
Guidelines on TB preventive treatment (guidelines and operational handbook)	June 2024	New regimen to treat TB infection in DR-TB contacts (no new products) PQ not needed. No new product/s

In December 2022, WHO issued new guidelines on the treatment of drug-resistant TB, which include a new recommendation on a novel 6-month all-oral regimen. The regimen (BPaLM) is composed of 4 drugs, bedaquiline (B), linezolid (L), moxifloxacin (M) and pretomanid (Pa), a new compound. Thanks to the close coordination between EML secretariat and GTB colleagues, pretomanid has been already included in the latest EML

Timelines for HIV guidelines, norms and standards

New Guidelines/norms/standards	Date	Anticipated new product recommendations*
Providing care to people with advanced HIV disease who are seriously ill	March 2023	Recommendation on SD Lipo Amp for Cryptp, Recs on fungal dz, rec POC CD4
The role of HIV viral suppression in improving individual health and reducing transmission	July 2023	Supporting U=U messages for HIV VL
Primary health care and HIV: convergent actions: policy considerations for decision-makers	July 2023	In support of Service integration
The diagnostics landscape for sexually transmitted infections	July 2023	Pipeline of innovative POC or near POC STI test (LFA & NAAT)
Point-of-care tests for sexually transmitted infections: target product profiles	July 2023	TPP for POCT for STI (GC,CT, TV & Syphilis)
Laboratory and point-of-care diagnostic testing for STIs, including HIV	July 2023	Guidance on laboratory testing for specific STI - focus on POCT for GC, CT, TV, syphilis and other STIs, need for low cost POCT
Addressing trust through digitally enabled community engagement approaches in HIV/AIDS	July 2023	Digital innovations to support Comm Led Delivery
Target product profile for HIV drug resistance tests in low- and middle-income countries: Africa	Sept 2023	Targeting DTG/INSTI for HIVDR tests
Monoclonal Ab for HIV Prevention and Post-Natal Prophylaxis	Oct 2023	Guidance developed post scoping meeting. BNabs to infants for PNP
Updated Hepatitis B guidelines for prevention, testing and treatment of Hepatitis B	Nov 2023	Delta testing, New permissive rec on HBV treatment
Consolidated HIV testing services guidelines	Dec 2023	Updates HIV ST, Network testing and other self-care recommendations
Consolidated STI Guidelines	Dec 2023	Syphilis trep/non-trep RDTs (active syphilis) & syphilis self-testing ; point of care test for gonorrhoea, chlamydial infection; treatment for STIs
Triple elimination of MTCT of HIV, Syphilis and Hepatitis B – Operational tool and guidance	Dec 2023	Brings together ANC interventions to eliminate vertical transmission
Recommendations on LEN, LA Buprenorphine, LA TAF PrEP	2024	Guidelines to be reviewed in Q1-2 2024 to assess data for Long Acting AVS, OAT, PrEP
Recommendations on LA ART	2025/26	Guidelines to review evidence on LA LEN and other pipeline LA ART

HIV – from guidelines/norms/standards to prequalification

New Guidelines/norms/standards	Guideline date est.	PQ EOI Open date	First PQ'd product	Key risks
Providing care to people with advanced HIV disease who are seriously ill	March 2023	Pending	Pending	No PQ Crypto Ag
The role of HIV viral suppression in improving individual health and reducing transmission	July 2023	NA	Many HIV VL PQ	NA
The diagnostics landscape for sexually transmitted infections	July 2023	NA	STANDARD Q Syphilis AB Test (SD Biosensor) & One Step Syphilis Blood/Serum/Plasma test (Guangzhou Wondfo Biotech).	Need for Prioritization of STI triple (HIV, HepB and Syphilis, Trep/NT & NAAT)
Point-of-care tests for sexually transmitted infections: target product profiles	July 2023	NA	Pending	As above
Addressing trust through digitally enabled community engagement approaches in HIV/AIDS	July 2023	NA	NA	
Monoclonal Ab for HIV Prevention and Post-Natal Prophylaxis	Oct 2023	NA	Pending	
Updated Hepatitis B guidelines for prevention, testing and treatment of Hepatitis B (contains recommendation on Hepatitis Delta testing)	Nov 2023	Request to PQ for dossier for Hep RDTs/delta	Pending	Prioritization of Hep RDTs and new tests (Delta RDT)
Consolidated HIV testing services guidelines	Dec 2023	ERDP for African Manu	Expected Q1-2 024	Manufacturer readiness
Triple elimination of MTCT of HIV, Syphilis and Hepatitis B – Operational tool and guidance	Dec 2023	Requests	NA	Need for prioritization
Recommendations on LEN, LA ART, LA Buprenorphine	2024	Pending	pending	

WHO recommended CAB-LA for prevention in July 2022, after supporting PQ and EMA article 58; it has had rapid uptake with start of implementation studies (Unitaid Brazil and SEARCH, Kenya). In 2024, CIFF & GF supported countries will start, as will 5 CATALYST countries (Lesotho, Kenya, South Africa, Zimbabwe and Uganda) + Unitaid SA project among young women.