WHO – PDPs Forum:

Aligning R&D efforts and promoting local production

12–13 February 2025

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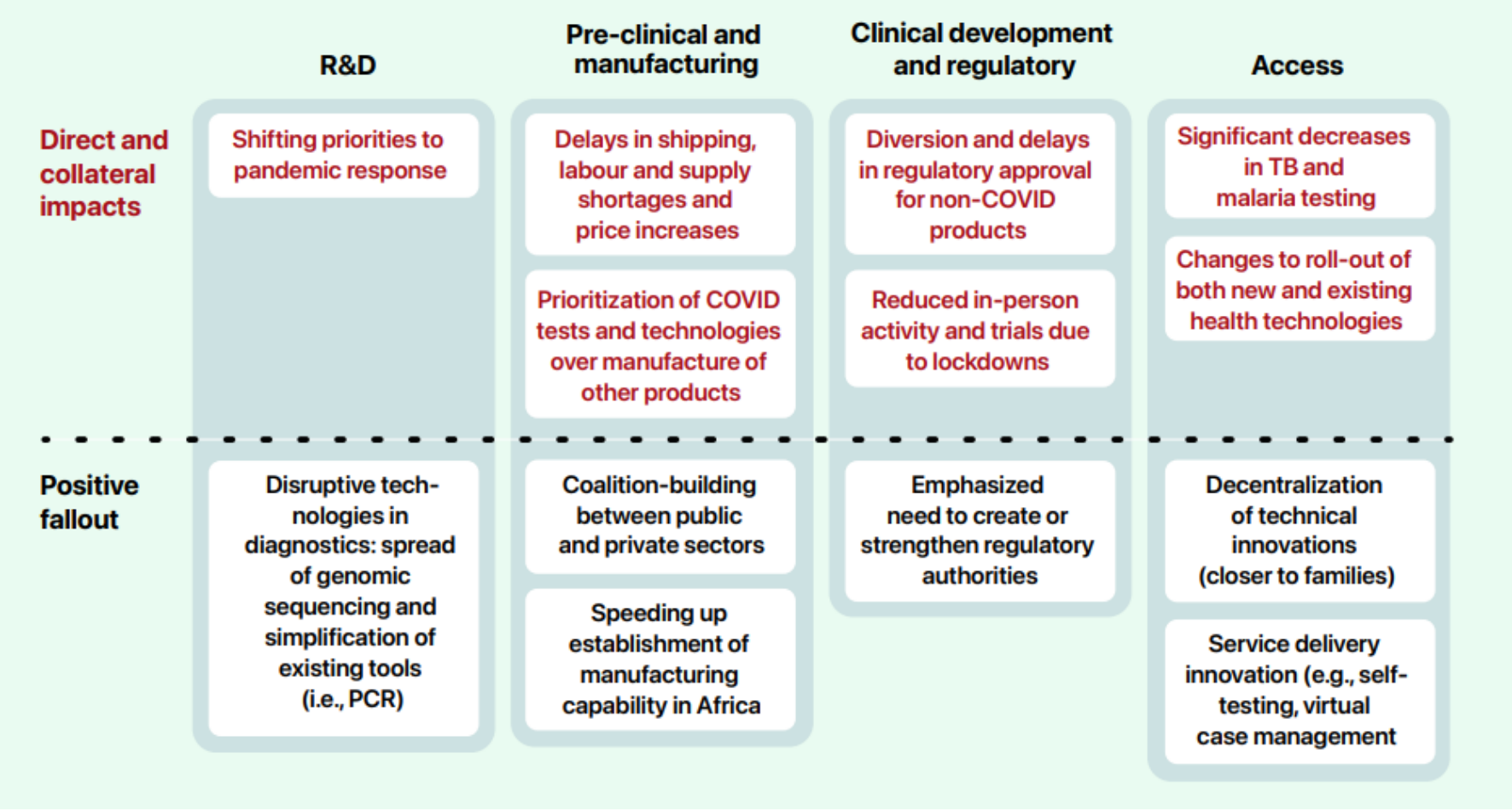
2022 Forum: **Collaboration and perspectives during the COVID-19 pandemic**



Source: WHO–Product Development Partnerships Forum: Collaboration and perspectives during the COVID-19 pandemic, meeting report, 1–2 June 2022)

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2023 Forum: **Health technologies gaps and strengthening R&D systems**

Main findings:

- While promising technological advances are underway to develop new health products to fight poverty-related diseases, considerable gaps exist.
- More funding and collaboration needed to advance health technology development and access, particularly for marginalized groups.
- 2 topics emerged for more in-depth discussion:
  - Research prioritization, especially in times of decreasing funding
  - Implications of shift towards local and regional R&D as well as manufacturing

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2025 Forum: **Aligning R&D efforts and promoting local production**

Day 1:

- **Session 1: Research Prioritization: Towards More Targeted Collaborative Action**
- **Session 2: Research Prioritization: Towards More Targeted Collaborative Action (continued)**
- Lunch Break (WHO Cafeteria)
- **Session 3: Strengthening the Clinical Trials Ecosystem**
- **Session 4: Opportunities and Challenges of Local Production**

Day 2:

- **Session 5: Opportunities and Challenges of Local Production (continued)**
- **Session 6: Leadership Discussion: Recent Trends in Global Health: Resilience and Collaboration**
- Lunch Break (WHO Cafeteria)
- **Session 7: Next Steps**

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Introduction

- Submissions by 13 PDPs: CEPI; Concept Foundation; DNDi; EVI/TBVI; GARDP; IAVI; IVCC; IVI; MDGH; MMV; PATH; TB Alliance
- Submission by one funder: GHIT
- Objectives of sessions on R&D alignment and local production:
  - Information exchange
  - Update on WHO efforts
  - Deciding on next steps

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Session 1&2:

Research prioritization:
Towards More Targeted Collaborative Action

Research prioritization: Current approaches

Diversity of approaches:

i. **Aligment with WHO priorities**, such as WHO TPPs, WHO R&D blueprint or WHO Bacterial Priority Pathogen List

ii. **Some alignment with WHO priorities** plus own stakeholder consultations

iii. **Independent priority setting,** coordinating with experts, investors and Board

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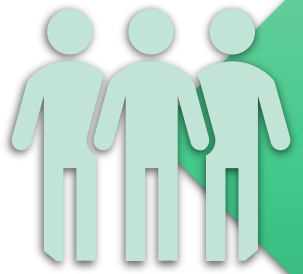
Research prioritization: Current approaches (cont.)

Public health in LMICs

- Burden of disease /public health needs in LMICs
- Level of neglectedness /underserved populations
- Potential health impact
- Access considerations
- Possible co-deployment with other interventions



Other stakeholders

- Specific mission of PDP
- Stakeholders' preferences
- Funders' interests
- Governments and research partners in LMICs

Internal considerations

- Internal capabilities / possible synergies
- Technical feasibility
- Financial feasibility
- Agility to emerging threats

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Shaping research and development for global health: WHO's role

Prioritising research can lead to better health, faster

- The basic premise of prioritization of research is to have the biggest impact on health with the finite resources available – time, money and skill
- Prioritisation works if priorities are
  - Developed equitably and rigorously
  - Resourced appropriately
- If priorities are developed poorly, or the time and money is not directed towards them, then we are missing out on having the most impact for the limited resources.

It's like trying to cook five different dishes with only enough ingredients for two meals. You'll end up with five half-cooked, unsatisfying dishes rather than two well-prepared, complete meals.

The same applies to research - better to fully resource your priority projects than partially fund everything.

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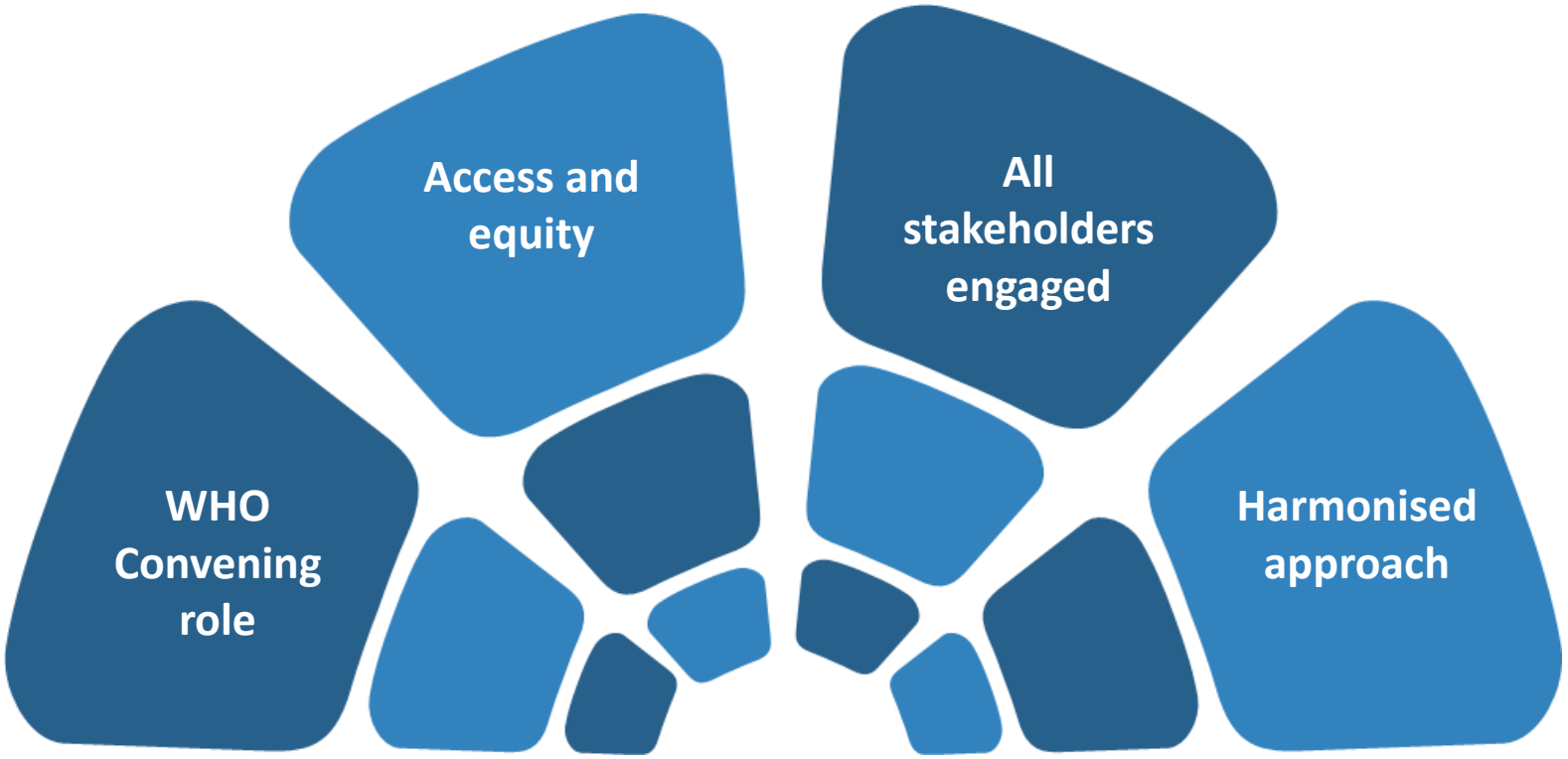
WHO's vantage point – a rigorous process to identify the priorities which will impact health



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Priorities at different stages of development – all rigorous approaches

Priorities

- Pipeline analyses and gap identification
- Research agendas and roadmaps
- Target Product Profiles
- Guidance on Evidence Generation
- CSA
- Research needs in Guidelines
- Prequalification guidance eg TSS

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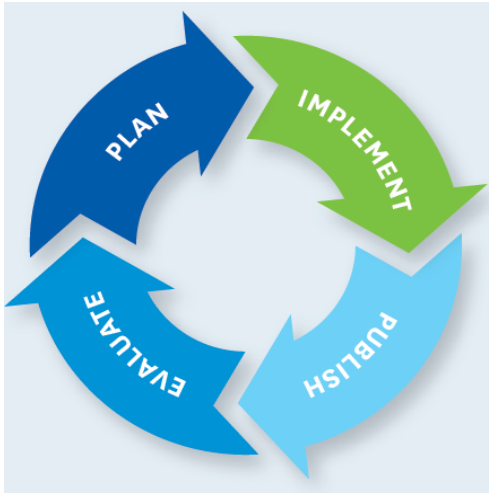
Research Agendas: process and examples

Research Prioritization development group – Very broad ensuring expertise and end-user needs and perspectives. Scientists, experts, public health officials, regulators, end-users such as MoH, patient representative and civil society. **Does NOT include funders or PDPs,** but they can contribute as observers and provide input when requested.

- No one size fits all
- Public health need or gaps
- Rigorous, transparent, consultative and inclusive process
- Many different methodologies dependent on the context/scope/topic eg CHNRI, CAM, James Lind, Delphi
- Explicit criteria against which the research questions are assessed eg public health benefit, feasibility, cost
- Can be topic specific or regional or national focus



Dissemination – Funders and PDP specifically sought to interact with the Research agenda – if it isn't funded and used the effort is wasted

Figure 1 from A systematic approach for undertaking a research priority-setting exercise. Guidance for WHO staff. Geneva: World Health Organization; 2020.

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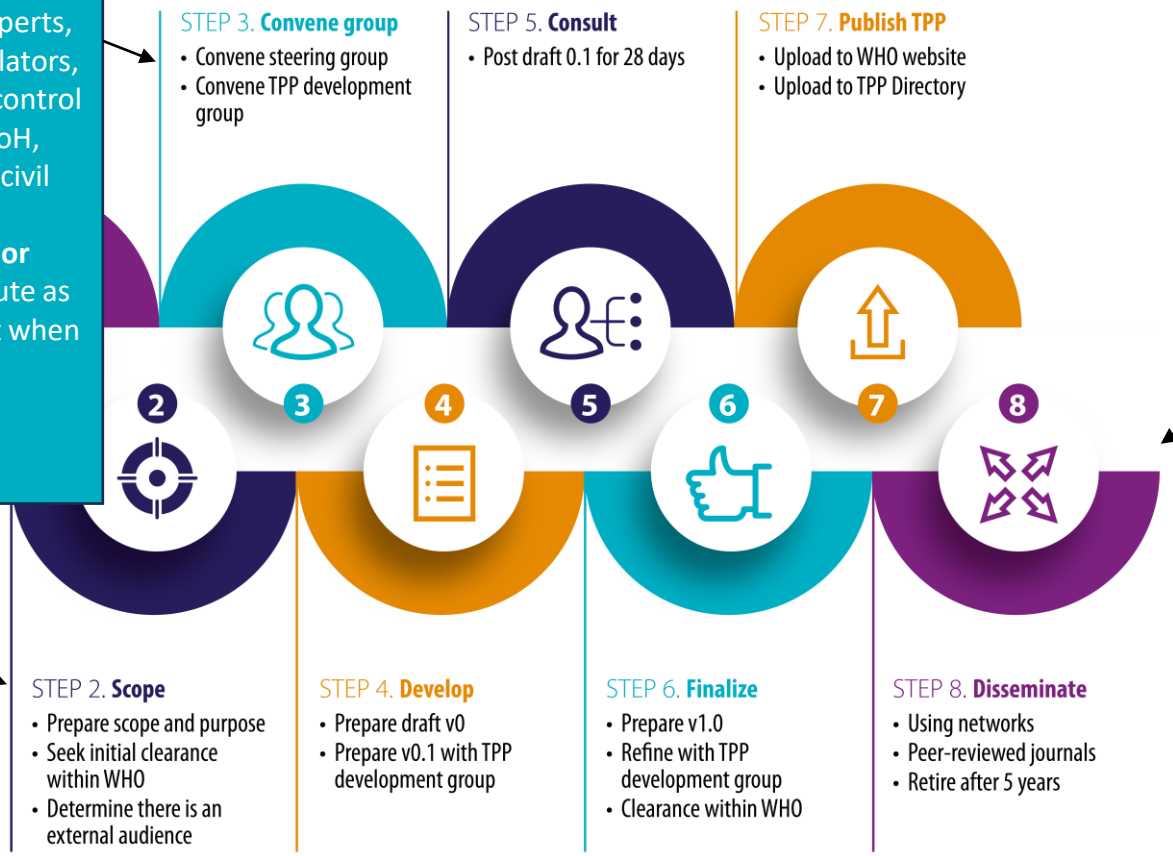
TPPs: process and exar

Decision – public health that is a priority for WH through World Health ass resolution or other docur WHO priority setting pr including review of literat existing TPP, gaps ident during guideline develop external consultative pr

TPP development group – Very broad ensuring expertise and end-user needs and perspectives. Scientists, experts, public health officials, regulators, end-users such as disease control programme officers and MoH, patient representative and civil society.
Does NOT include funders or PDPs, but they can contribute as obsevers and provide input when requested.

Public consultation – 28 days open call for comments. **PDP expertise specifically sought here!** Along with industry, funders and any other interested party



Dissemination – PDP specifically sought to interact with the TPP. TPP should be reassessed after 5 years to determine if the technology has moved on etc.

Need for External audience – eg via external requests to WHO for position on product characteristics

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Coordinated Scientific Advice: process

Manufacturer or product developer applies

Eligibility:
Public health potential
Innovative
New indications
Within scope of PQ

How does CSA work?
The CSA procedure consists of 4 steps and is estimated to take approximately 10 weeks.

1. **Eligibility determination:** Product developer submits a request and WHO evaluates eligibility
2. **Formal application:** Product developer submits a full Submission Package to WHO for in-depth review by the technical unit(s) and the Prequalification Team.
3. **Meeting:** Product developer meets with relevant WHO focal points to discuss joint advice
4. **Advice report:** WHO provides product developer with a detailed written report

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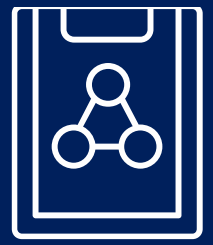
Recent priorities WHO developed and published



Research agendas

- Sexually transmitted infections
- Hypertension care delivery
- Violence against children and women
- Pandemic and epidemic intelligence

TPPs and similar

- TPP: drugs for pre-eclampsia
- TPP: diagnostics for Trypanosoma
- PPC: diagnostic for risk of *P. vivax* relapse
- Guidance on evidence generation for TB treatment regimens

Global analyses of pipelines

- Malaria vaccines
- Anti-fungal vaccines
- Anti-bacterial agents for priority pathogens in clinical and pre-clinical development
- Paediatric clinical trials

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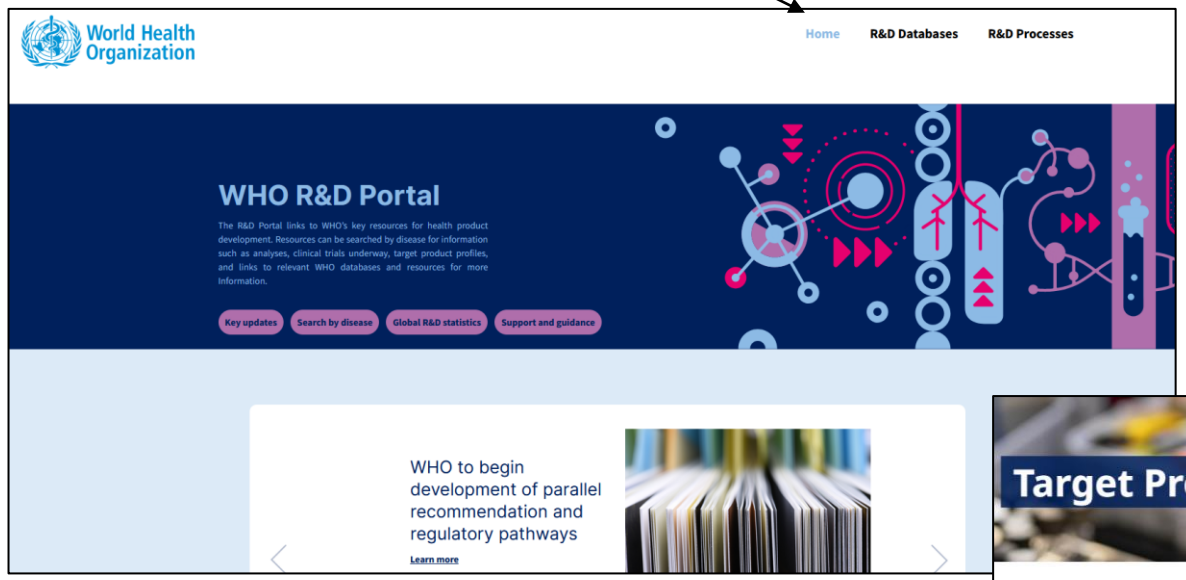
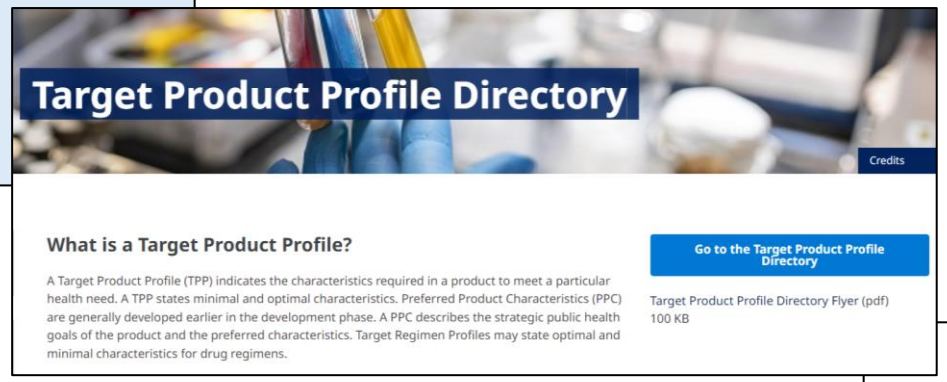
Priorities can be found using the R&D portal and the TPP Directory

Find research priority documents and others here



https://rnd.who.int/r-d-databases

Find global health TPPs and contribute your TPPs here

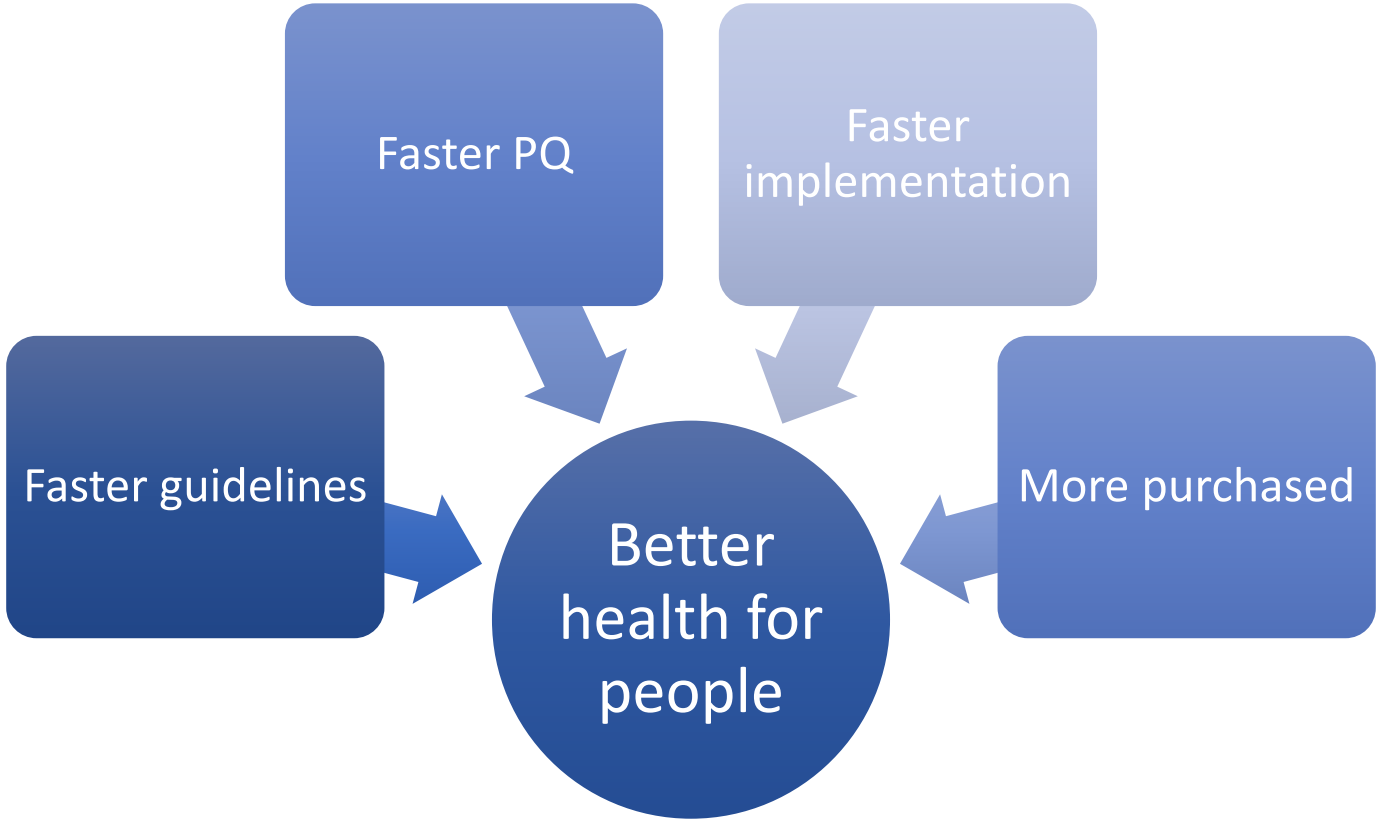


https://www.who.int/our-work/science-division/research-for-health/target-product-profile-directory

Central contact for WHO R&D here

researchsupport@who.int

Benefits of working towards prioritized research and products



Aligning efforts can lead to better health outcomes faster

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When we align, we can move together faster….for example…

Medicines Development for Global Health

GARDP
Global Antibiotic Research & Development Partnership

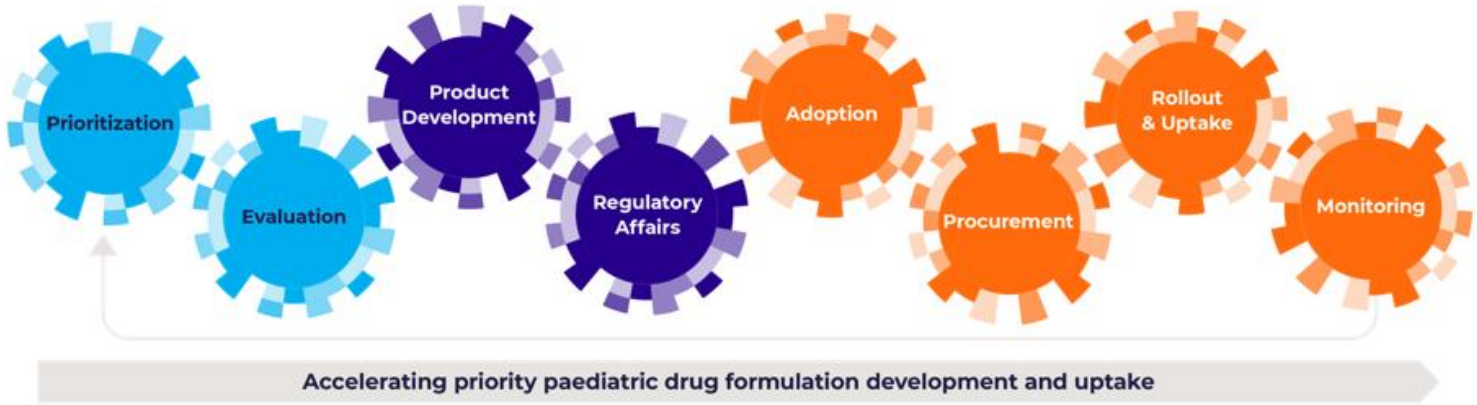
DNDi
Drugs for Neglected Diseases *initiative*

Approved products

- Inclusion in EOI
- Communication to manufacturers
- Market shaping

Pipeline products

- Clear and shared TPP
- Regulatory efficiencies
- Evidence generation package



Research prioritization: Main themes

Alignment of R&D among PDPs

Combination vaccines

S&T innovation

Demand forecast

Diversity vs unity

Coordination of R&D efforts

Engagement with partners

WHO updated guidance

Funding considerations

Collaboration between communities

Country participation in R&D setting

Better R&D for underserved pop.

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Research prioritization: Topics of discussion

- Alignment of research priorities
- Research funding
- Research collaboration
- Engagement with partners

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Research prioritization: Next steps

	PDPs	WHO	PDP Funders
R&D PRIORITIZATION	- Collaboration between PDPs on common resources - Map expertise and current resources within PDP community - Exchange and joint learning on new technologies, e.g. AI - Increased collaboration across interventions - Stronger engagement with target countries	- Facilitate convening among PDPs and WHO across interventions and new technologies - Enhanced communication with PDPs, in particular about updates of research guidance - Brokerage between PDPs and WHO's technical departments and clarification about WHO partners - Encourage use of CSA procedure - Stronger engagement with target countries	- Collaborate closely with WHO, PDPs, and co-funders to ensure coherence and optimal communication across disease programs - Promote and foster core and flexible funding models - Recognize changing landscape of funding and partnering of PDPs and support evolving model

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Session 4&5:

Opportunities and Challenges of Local Production

Local production: Current approaches

Recurrent pattern:

- No or little manufacturing in Africa due to lack of manufacturing capacity and insufficient regulatory expertise
- Considerable amount of manufacturing done in LMICs outside Africa
- Procurement driven mainly by price

Mechanisms to enable local manufacturing:

- Acquisition of commercial and manufacturing rights for LMICs
- Granting of non-exclusive, non-royalty bearing licenses
- Providing technical assistance to support local manufacturers:
  - to optimize the manufacturing process
  - to support readiness for WHO PQ
  - for product readiness assessments

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Local production: Current approaches (cont.)

Mechanisms to enable local manufacturing (continued):

- Building a network of long-term industrial partnerships
- Evaluating of manufacturing partners in different geographies, including to ensure supply security
- Supporting HTAP to expand regional manufacturing capacity via tech transfers
- Influencing market shaping efforts

Upcoming activities:

- Establishing a vaccine manufacturing facility network to provide surge capacity
- Assessing regional manufacturing capacity
- Blueprint for small-scale mobile manufacturing developed

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Local production: Economic viability and financing

- **Cost-effectiveness:** Is local manufacturing cost-effective? Who will pay the mark-up price for locally manufactured products? Trade-off between increased costs and public health impact: How can we ensure economic viability?
- **Funding models:** What funding models are on the table to enable local manufacturing? How can PDPs encourage funders to increase CAPEX investments through grants or loans?
- **Linking R&D and manufacturing:** What roles can PDP funders play in supporting an end-to-end regional manufacturing ecosystem, by fostering and incentivizing linkages between PDPs and regional manufacturers?
- **More alignment:** How to better align financing mechanisms that aim to enhance African R&D and manufacturing capactiy?

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Local production: Coordination, supply chains and procurement

- **Coordination:**
  - Who coordinates national and regional activities to optimize local manufacturing and support regional and global supply and demand?
  - How should PDPs align to maximize support to local manufacturers?
- **Supply chain challenges:**
  - Will local manufacturing help solve supply-chain problems experienced during COVID-19?
- **Procurement:**
  - How to strengthen forecasting and create a procurement process incentivising local manufacturing (IVCC/PATH), especially for diseases outside the scope of GF or GAVI?

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Local production: Product differences and tech transfer

- **Product differences:**
  - How to develop and sustain manufacturing of mRNA vaccines locally?
  - Are the manufacturing imperatives for vaccines and small molecules the same? How the market dynamics differ across diagnostics, therapeutics and vaccines and what are the implications?
- **Tech transfer/quality:**
  - How can tech transfer be facilitated and funded?
  - Can funders (and PDPs) work together and share information so that tech transfer can be done «in a package» to effectively bring down the price together?
  - What strategies are most effective to ensure quality, especially to comply with WHO PQ standards of producers in Africa?

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Local production: Next steps

	PDPs	WHO	PDP Funders
Local Production	- Collaboration among PDPs when engaging with LMIC governments and regional entities as well as support to SMEs - Engage with NCD community - Collaboration to identify balanced portfolio - Explore investment opportunities with DFIs, option of volume guarantees - Collaborate with RVMC - Establish common goal for local production and shift centre of gravity for the end-to-end product development to target countries	- Sharing experience among LMICs to best build up pharmaceutical sector (in collaboration with other UN agencies) - Continue support PDPs in their effort to promote local production - Advocacy increase in health budget spending - Facilitate synchronization of workforce training initiatives, including WHO Academy	- Jointly develop with PDPs common principles for local production and shift centre of gravity for the end-to-end product development to target countries

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