100 Days Mission

Implementation Report – 2023
Reducing the impact of future pandemics by making diagnostics, therapeutic, and vaccines available within 100 days

An independent report from the International Pandemic Preparedness Secretariat
100 Days Mission
Implementation Report
24 January 2024
I am writing this foreword in my last month as chair of the 100 Days Mission (100DM) Steering Group. In 2021, a group of G7 Scientific Advisors and experts came together to set out the recommendations that would form the basis of the 100DM. Since then, the world has changed. We are no longer in the throes of a global pandemic; world leaders are dealing with multiple competing crises and the global health landscape appears increasingly complex as organisations grapple with how to optimally prioritise limited funds, and contend with multiple needs and threats. But we know that future epidemics and pandemics are not just likely, they are inevitable.

Set against this background it is important to start this report with a reminder of the original vision of the 100DM. It is a vision for an optimal state of readiness for the production of diagnostics, therapeutics and vaccines (DTVs) that enables the most efficient and equitable response possible to emerging pandemic threats. Of course, there are many other key components to preparing for epidemics and pandemics including surveillance, strengthening of healthcare systems, capacity building, equitable funding and others. The 100DM is deliberately focused specifically on the question of how to get the key tools of diagnostic, therapeutics and vaccines in place fast, knowing that every day counts when managing outbreaks.

It is a vision of a world in which we have filled the R&D gaps to create well stocked prototype libraries for DTVs, which give us the essential building blocks to tackle a known pathogen, or enough knowledge to rapidly pivot in a Disease X scenario.

It is a vision of a world in which we have pre-agreed pandemic response protocols that set out how the products in those libraries are thoroughly and efficiently tested for safety and efficacy, and manufactured, procured and made accessible where they are needed most.

And finally, it is a vision of a world in which we have sought to make the exceptional routine by embedding best practice in inter-pandemic periods, learning from experience to strengthen surveillance systems, clinical trial networks, regulatory processes, public health functions and community healthcare; so that we are collectively ready to respond to emerging outbreaks as efficiently as possible, while still handling everyday health needs.

2023 saw some structural progress in the implementation of the 100DM, with the creation of the 100 Days Mission Science and Technology Expert Group (STEG). The 100DM also received continued endorsement from the G7 and G20, thanks to Japanese and Indian leadership, and the nascent beginnings of a more coordinated approach to pandemic therapeutics, through the development of the 100DM Therapeutics roadmap, co-created with the collaboration of multiple partners. The establishment of the International Pandemic Preparedness Secretariat, hosted by Wellcome, has put the mission more squarely on a global footing. In the course of 2023, informative discussions were facilitated with regional partners through a series of listening exercises, aimed at better understanding regional capacities and challenges in implementing a 100DM preparedness framework. A key takeaway from these discussions is that global solutions have to be translated into regionally appropriate strategies if we are to truly make an impact at a national or community level.

This year, for the first time, we are pleased to launch the 100DM scorecard within this report, developed together with Policy Cures Research, which gives a more quantifiable sense of our state of readiness. Over time, the intention is that this scorecard will have indicators to show the health of every part of the value chain, from R&D to manufacturing across the major countermeasure technologies. For this year, we have started where we have the most data, focusing on funding and the R&D pipeline. It shows some stark gaps in our preparedness.

Last year, we set out six high-level priorities for 2023, and while we have seen progress in some areas, there is still much more to do. This year, we want to be even more specific about the steps that we as the International Pandemic Preparedness Secretariat and its leadership identify as essential priorities for 2024.

Some of these areas already have a lead organisation and involve partnerships across public and private sectors, others are at an earlier stage. We hope that by the end of 2024 each of the four areas will have a clear overall lead, a credible plan, and the funding necessary to make progress.

Throughout this report we present the work done with implementation partners to set an overarching goal for each element of the 100DM; and the most urgent next steps to be taken towards that goal in 2024. This will need collective action from scientists, policymakers and funders, across all sectors to help us reach these goals. New technologies will continue to help reduce the time between idea and product. But we must not lose sight of why we are ultimately doing this; to minimise the impact of pandemics and epidemics and save lives.

As 2023 draws to a close, I will be passing the chair of the 100DM Steering Group to Dr Mona Nemer. Dr Nemer has been Canada’s Chief Scientific Advisor since 2017 and was a key part of the group of G7 Scientific Advisors in 2021 who helped shape the original 100DM recommendations. An internationally renowned scientist and a distinguished academic leader, she has made seminal contributions to several fields, ranging from gene regulation to molecular cardiology, as well as playing a crucial role in Canada’s domestic and international response to COVID-19. She will be an outstanding leader for this global mission.

Let me finish by thanking all the contributors to the 100DM and to this report, who share the vision for a change in basic assumptions in preparedness and who are daily taking us closer to that goal. Partnership is the lifeblood of this collective endeavour, and we couldn’t do it without each and every one of you.

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The 100 Days Mission (100DM) remains a crucial ambition in the wake of COVID-19’s profound global impact. With 16 million lives lost before the first vaccine’s availability, and a staggering US$2.5 trillion economic loss forecasted by 2024, the urgency for faster diagnostic, therapeutic, vaccine (DTVs) development is undeniable. As shown by the data in our 100DM scorecard, despite the lessons of COVID-19 we simply do not have approved, widely accessible DTVs to respond to a pandemic from any other pathogen.

### 2023 PROGRESS AGAINST 100DM OBJECTIVES

In 2023, the International Pandemic Preparedness Secretariat (IPPS) tracked progress through research, interviews, and partner feedback, focusing on key determinants of progress such as funding, political support, and leadership. Despite a challenging backdrop of competition for funding and so-called ‘pandemic fatigue’ setting in, there have still been areas of progress toward a 100DM ready world in several areas:

- **Continued political support** from Japan’s G7 presidency and India’s G20 presidency, in the alignment of this year’s G7 and G20 agendas. Facilitated discussions on surge financing, access to medical countermeasures, MCMs, and a potential future medical countermeasures network to replace the Access to COVID-19 Tools Accelerator (ACT-A), as well as commitments to the aims of the 100DM.

- **Structural progress** in the implementation of the 100DM, with the creation of the 100DM Science and Technology Expert Group (STEG), which has been driving research through five subgroups, a published opinion piece in The Lancet and catalysing scientific exchange on some of the most challenging aspects of the mission, including via an event on the margins of the UN General Assembly 2023.

- **The independent nature** of the IPPS has also enabled the mission to be put on a shared global and regional footing. In the course of 2023, informative discussions were facilitated with regional partners through a series of listening exercises, aimed at better understanding regional capacities and challenges in implementing a 100DM preparedness framework. A key takeaway from these discussions is that any global solutions have to be translated into regionally appropriate strategies if we are to truly make an impact at a national or community level. Simultaneously, regional, national and community strategies work to inform global solutions.

- **Vaccines research** has seen promising progress with the US Food and Drug Administration (FDA) approval of a Chikungunya vaccine and Phase 1 trials beginning for Crimean-Congo Haemorrhagic fever, supplemented by multiple new Coalition for Epidemic Preparedness Innovations (CEPI) partnerships around the globe working towards optimising vaccine production covering everything from simplified administration routes to sustainable regional manufacturing strategies.

- **Nascent beginnings of a more coordinated approach to pandemic therapeutics**, through the development of the 100DM Therapeutics Roadmap and the collaboration of multiple partners around this effort. Industry groups, international organisations and publicly-funded research groups have come together to map a route to achieving the goal of having at least two ‘Phase 2 ready’ therapeutic candidates for each of the priority pathogen families.

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**Key messages:**

- Funding is heavily weighted towards COVID-19 and Ebola, and overly reliant on US Government funding, creating vulnerabilities.

- Only COVID-19 and Ebola (Zaire) have a full complement of approved DTVs, and these are not available to patients in all countries who need them.

- Diagnostics and therapeutics funding is lagging behind vaccines.

- Action is needed to agree on non-human models for testing products to accelerate licensure, for example, regulator approved animal models to enable use of the Animal Rule for product approvals, agreed correlates of protection and updated Target Product Profiles (TPPs) to drive suitable product development.
EXECUTIVE SUMMARY | 100 DAYS MISSION

PRIORITY 100DM ACTION AREAS FOR 2024

While significant progress has been made, analysis from implementation partner feedback and the 100DM scorecard data highlights key areas needing urgent attention in 2024. These are not meant to be an exhaustive list of actions, but rather focus on the issues which have received least attention to date, and where there are concrete steps forward that could be taken in 2024.

THERAPEUTICS PIPELINE ENHANCEMENT

Except for COVID-19 and Zaire Ebolavirus, the therapeutics pipeline is critically underdeveloped, lacking in both funding and coordination. However, a coalition is growing around the 100DM Therapeutics Roadmap, which sets out an end-to-end plan and investment case of what is needed to reach the updated goal of at least two ‘Phase 2 ready’ therapeutic candidates for the top 10 priority pathogens (as identified by WHO). In 2024, early-stage research needs greater investment and coordination from all sectors.

DIAGNOSTICS FRAMEWORK FUNDING

The 100DM Diagnostics Framework, addressing gaps in R&D and regulatory pathways, requires urgent financing. With only four WHO priority pathogens having approved diagnostics and funding waning post-COVID-19, 2024 must see a concerted effort to fund this framework. This framework needs to be supported by a coalition of stakeholders, working with FIND, and others including industry, governments and regulators, and to be integrated into national, regional and global surveillance systems to ensure sustainable markets.

REGULATORY ALIGNMENT AND PREPARATORY REGULATORY APPROACHES

To achieve the 100DM, the world should not wait until a pandemic is declared to start collecting data on the safety and efficacy of prototype pandemic countermeasures. Harmonised regulatory pathways and joint global assessment for emergency use authorisation (EUA) will strengthen response. In 2024, we advocate for advanced agreement with regulators, under the International Coalition of Medicines Regulatory Authorities (ICMRA) leadership, on appropriate alternative methods of data generation, including the use of the animal-rule and acceptable correlates of protection (for vaccines) that allow products to progress through development in the absence of an outbreak. This should be coupled with agreement on shared risk-benefit frameworks for pandemic products and a method of storing this data through platform or pathogen master files, so it can be rapidly drawn on when expedited approvals are needed.

SUSTAIN AND STRENGTHEN REGIONAL AND GLOBAL CLINICAL TRIAL INFRASTRUCTURE

The ability to test products rapidly in humans during an outbreak relies on the continued existence of high-quality, regionally dispersed, inclusive global clinical trial networks that are kept active in inter-pandemic periods. These trials need to be appropriately powered, generating the right data to enable approval decisions. In 2024, under WHO leadership, practical discussions on pre-agreeing master trial protocols for emergency use should take place alongside support for regional authorities to maintain sustainable clinical trial capacity with joint ethics reviews, in line with implementation of World Health Assembly resolution 75.8.

THE ROLE OF MULTILATERAL FORA IN DELIVERING THE 100DM PRIORITIES

While the G7 and G20 alone cannot deliver all the capabilities needed to have approved pandemic products ready for mass production in 100 days, they do have a crucial role to play in catalysing coordinated international action. As set out in the priorities above, there are several key implementing organisations who will play a central role in driving progress in 2024. However, the G7 and G20, working with other member states, have the potential to make this progress infinitely more achievable with the right financial and political support.

The G7 and G20 health agendas are not short of challenges to address. Historically, attaining Universal Health Coverage (UHC), tackling antimicrobial resistance (AMR), and improving pandemic preparedness have been seen as competing issues. However, they share common challenges and solutions, which, if sufficiently resourced, will lead to an overall strengthened global health architecture fit to tackle all future health challenges.

It is suggested that there is a particular subset of commitments that the G7 and G20 could make to work towards the 100DM and in the process, strengthen an equitable, sustainable and responsive product development ecosystem capable of responding to all future health threats.

Areas of potential impact for G7 and G20

- **Coordinated and equitable product development funding** to make maximum impact from limited resources. Specifically, by committing to developing virtual global prototype libraries of DTVs for WHO’s updated priority pathogen list (once released), and directing R&D funding agencies to coordinate accordingly.

- **Investing in diagnostics** to strengthen surveillance and response systems. Specifically, by providing the US$80-100 million needed by FIND for their 100DM diagnostics framework, as well as committing to integrate digitally-connected multiplex diagnostics into routine use in national health systems.

- **Taking a preparatory regulatory approach and making clinical trial infrastructure sustainable.** Specifically by tasking regulators with working together under the leadership of ICMRA, towards a proportionate, simplified and flexible preparatory system with a goal of mutual recognition where possible and pre-agreed plans for emergency approvals.

However, as outlined above, the 100DM is a global endeavour that requires the commitment of all countries and regional bodies, not just the G7 or G20, and the expertise of all sectors to have any chance of success. As the IPPS and its governance boards, our commitment to the 100DM is unwavering. The path ahead in 2024 is clear: we must unite in our efforts to fortify global health security, ensuring readiness and resilience against future pandemics.
Background to the 100 Days Mission

In June 2021, the G7 leaders endorsed the ambitious 100 Days Mission (100DM), aiming to revolutionise pandemic preparedness. This initiative focuses on delivering three key medical countermeasures (MCMs) within 100 days of a pandemic threat being declared by the WHO as a Public Health Emergency of International Concern (PHEIC).

The essence of the 100DM is to significantly reduce the time to develop diagnostics, therapeutics, and vaccines (DTVs), maximising the health impact and saving lives. Achieving this goal could prevent the escalation of an outbreak into a full-scale pandemic.

\[\text{International Pandemic Preparedness Secretariat. 100 DAYS MISSION to Respond to Future Pandemic Threats, June 2021, dfnnpnmd5zvwd. cloudf ront.net/prod/uploads/2023/01/100\_Days\_Mission\_to\_respond\_to\_future\_pandemic\_threats\_3_.pdf}\]
For the purposes of this report, ‘programmable platform technologies’ refers to technologies which can be redirected to multiple different pathogen targets, such as mRNA Vaccine technology.

For the purposes of the 100DM, Day Zero is defined as the WHO’s declaration of a PHEIC. While it is acknowledged that in many ways this is likely to be too late and response activities should start sooner, a PHEIC is currently the clearest global trigger unless a tiered health emergency traffic light system is brought in with the updates to the International Health Regulations. Some regions are also in the process of discussing the merits of having triggers to announce public health emergencies of regional concern. The most important element is that any triggers are connected to clear pre-agreed actions for financing and accelerating product development and distribution.

The 100DM offers a framework for implementers at all levels to take forward and apply, whether at the global, regional or national level. Despite fundamentally being a global mission that unites key actors, it will only be effective when implemented in all countries and in local communities around the world, and particularly in those that have historically been left behind in access to MCMs.

How to use this report: keeping our eyes on the prize

This year’s report maintains a rigorous focus on the overarching end goals of the 100DM and the impact the world can expect to see from the collective actions of partners. This is best depicted in the 100DM Theory of Change.

Within each section, we have reiterated the overarching goals, critical bottlenecks to achieving these goals and the proposed inputs needed in 2024 to maintain satisfactory progress. The chapters provide high-level analysis, and a summary of 2024 milestones those already planned by implementation partners, and more aspirational goals set by the IPPS. Assessment of progress against the original recommendations is summarised at Annex A based on input from over 30 implementation partners from governments, industry, academia, Civil Society Organisations (CSOs) and international organisations (see Annex C for full list of contributors), in the form of survey responses, interviews and desk research.

Written input was requested from implementation partners through standardised pro-formas covering progress in 2023, alignment of 100DM with ongoing priorities and approach to implementation, barriers, risks, and enablers to achieving 100DM goals and future progress indicators and what constitutes a successful outcome. The draft report was reviewed by key implementation partners who provided input and was finalised with input from the IPPS Steering Group and Science and Technology Expert Group (STEG).
100DM theory of change

**VISION:**
within 100 days of a recognised international trigger (e.g. WHO PHEIC), diagnostics, therapeutics and vaccines are approved* and ready to be produced at scale for global deployment

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### SPHERE OF CONTROL

**IPPS activities**

- Facilitating and convening multisectoral collaborations
  - Providing technical expertise (STEG, implementation reports)
  - Influencing global political agendas

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### SPHERE OF INFLUENCE

#### 100DM 2024 outputs

**DIAGNOSTICS R&D**
- US$80-100m invested in 100DM diagnostics framework
- Pathogen-agnostic platforms and multiplex diagnostics developed

**THERAPEUTICS R&D**
- Therapeutics roadmap launched and operationalised
- Coordinator(s) support a coalition to take de-risked candidates through clinical development

**VACCINES R&D**
- Global prototype vaccine library defined and launched

**SURVEILLANCE**
- Collaboration enhanced through international networks
- National capacities for data collection strengthened
- Digitally connected diagnostics feed into the surveillance system

**CLINICAL TRIALS AND REGULATORY PROCESSES**
- Regulators coordinate to adopt preparatory regulatory approaches
- Countries supported to have mature regulatory authorities
- Global clinical trial guidance finalised and adopted, utilising regional networks

**SUSTAINABLE MANUFACTURING**
- Regional authorities supported to implement sustainable manufacturing capacities
- Continued strengthening of public-private partnerships within regional manufacturing strategies
- Preparatory voluntary licensing systems expanded

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#### 100DM long term outcomes

**100DM theory of change**

#### SPHERE OF INTEREST

**Impact**

- DTVs are rapidly developed, and equitably distributed based on greatest impact and need, in the event of a pandemic threat

- Pathogens are identified with genomic sequencing and surveillance data shared to prevent an outbreak from becoming a pandemic

- Products authorised for use in humans (e.g. EUL) within 100 days due to pre-emptive data generation and high-quality clinical trials mobilised rapidly utilising existing infrastructure

- Each region produces technologies, pivoting its manufacturing sites in the event of a threat

- Countries have access to and mobilise funding to reduce pandemic threat escalation

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* Approved, available under Emergency Use Licensing (EUL) or pre-authorisation
Introducing the 100DM Science and Technology Expert Group

This year’s report has also benefitted from the input and advice of the 100DM Science and Technology Expert Group (STEG) for the first time. Reporting to the Steering Group, the STEG delivers an assurance function for the annual report against the 100DM recommendations and galvanises support from the scientific community on pandemic preparedness through meetings, working groups, and assessments.

The 100DM STEG is co-chaired by Dr Victor Dzau (President of the US National Academy of Medicines) and Shingai Machingaidze (Ag. Chief Science Officer at Africa Centres for Disease Prevention and Control, Africa CDC). Membership was drawn from an open global nominations process and includes members from a wide range of regions and sectors (a full list of members can be found at Annex B).

Five subgroups, composed of STEG members and experts drawn in from international organisations, civil society, industry, regional and national partners, were formed in 2023 to address the different challenges highlighted in last year’s report:

2023 STEG subgroups

- **R&D Coordination** developed the 100DM Scorecard
- **Therapeutics** developed the 100DM Therapeutics Roadmap
- **Diagnostics** developed the 100DM Diagnostics Report, launched at the International Conference for Public Health in Africa (CPHIA) and focusing on embedding diagnostic best practice between pandemics
- **Clinical Trials and Regulatory Processes** advised on the content of the report chapter and led discussions on how to garner support for preparatory regulatory approaches
- **Sustainable Manufacturing** developed a case study of the components that enabled the rapid manufacturing of the ChAdOx vaccine for the Ugandan Ebola Sudan outbreak

Each subgroup helped to review input received from implementation partners to assess progress and necessary next steps across all areas of this report. The IPPS team would like to express their thanks to all STEG members for their generous input of advice and expertise.

One Year of the International Pandemic Preparedness Secretariat (IPPS)

This report also marks the anniversary of the establishment of the IPPS. The Secretariat’s focus for this first year has been:

1. Establishing strong governance, in the form of the Steering Group and the STEG
2. Working to understand what further support is needed for all regions to be equipped to deliver pandemic countermeasures within 100 days
3. Building coalitions in areas where the need for greater cohesion was identified, such as in the area of Therapeutics R&D
4. Developing a more quantifiable approach to assessing 100DM readiness through the 100DM scorecard
5. Advocating for continuity of commitment to pandemic preparedness in multilateral fora, including the G20 and G7, World Health Assembly and UN General Assembly. The 100DM has enjoyed the support of the Japanese and Indian presidencies, and it is hoped that this can be built on by Italy and Brazil in 2024

The IPPS has three years left of its mandate, which runs until the end of 2026, and intends to use the coming years to continue to support and elevate implementation partners, to build sustainable coalitions around previously neglected areas and to ultimately put the delivery of the 100DM on a sustainable trajectory. The IPPS will continue to use the twin levers of catalysing scientific exchange on the biggest challenges through the 100DM STEG and advocating for the systemic commitments needed through the C7 and G20.
The IPPS has been working with Policy Cures Research, the organisation behind the G-FINDER project, to develop a 100DM scorecard which aims to quantify and visualise the world’s readiness to develop and approve pandemic countermeasures within 100 days.

For this first version of the scorecard, the focus has been on where most data is available – mainly in product development – including where candidate DTVs are in the R&D pipeline, what funding is available and identifying gaps. For each WHO R&D Blueprint priority pathogen, this year’s indicators describe:

- R&D funding landscape: funding that has been invested in DTV R&D for each disease in the last 4 years, and the top funders
- Approved products: the complement of approved products for DTVs and whether they approved in low- and middle-income countries (LMIC)
- Candidates in clinical development: number of candidates that are in clinical development for all three DTVs
- R&D enablers: The facilitators of R&D that are available or being used for each diseases, for example, the animal rule to facilitate licensure, widely accepted correlates of protection and WHO Target Product Profiles (TPPs)
- Disease X: A breakdown of funding for DTV platform technologies and their top funders

Full descriptions of all indicators can be found in Annex E.

**100 Days Mission Scorecard Findings**

**INDICATORS**

**Findings**

MCMs are not available to address most WHO R&D Blueprint priority pathogens. COVID-19 and Ebola Zaire are the only two pathogens with a full complement of products that are authorised either by a Stringent regulatory Authority (SRA), a National Regulatory Authority (NRA) at maturity level 3 or above or pre-qualified by WHO. However, these products are not always accessible to all, nor do they always match the TTPPs that can best enable equitable access. Diagnostics are only approved for Crimean-Congo Haemorrhagic Fever (CCHF), Rift Valley Fever (RVF), Lassa and Zika, none of which have been approved in endemic countries. Other priority pathogens have no approved MCMs at all.

When it comes to clinical candidates under development, the reactive nature of R&D means that pathogens which have had recent outbreaks and so are perceived as a greater threat benefit from a more mature pipeline of candidates (COVID-19, Ebola and Zika). It is also worth noting that all vaccines and therapeutic candidates (other than COVID-19) are in phase 1. Diseases in the same viral family have benefitted from repurposed candidates and vaccine platform technologies (e.g. viral vector based filovirus vaccines), however, there has not yet been progress in developing platform technologies for therapeutics, and some pathogens have almost no platform technologies being used to develop clinical candidates.

Finally, the animal rule has only been used to enable product approval for Ebola. There is a need to consider regulator approved non-human models for testing products outside of an outbreak setting, such as the animal rule, to prepare sufficiently to achieve the 100DM. Whilst the animal rule has been used to enable product approval for Ebola (Zaire), its use is not yet routine; having a harmonised regulatory approach to accepting animal model data would guide developers and de-risk this approach, potentially enabling more rapid emergency use authorisations during outbreaks.

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1. The animal rule permits approval based on well-controlled animal studies when the results determine that the DTV is reasonably likely to produce clinical benefit in humans.
FUTURE INDICATORS

It is recognised that further indicators will be needed in future years to fully capture the breadth of the R&D ecosystem and the pre-requisites needed to enable a 100DM response. Future indicators could leverage data from additional sources, including Policy Cures Research’s “Evidence for Impact” indicator framework and Global Research Collaboration for Infectious Disease Preparedness (GLOPID-R) Pandemic PACT database, with discussions underway to ensure data is shareable and interoperable.

The data here shows a snapshot of product development aspects within the R&D ecosystem. However, even when a product has been approved, it is not a sufficient indicator of the health of the full pandemic R&D ecosystem, and more data is needed on equitable access, manufacturing, and procurement.

In the future, we plan to include indicators drawing on further data sources covering the following topics. Currently, Policy Cures Research has leveraged its “Evidence for Impact” Indicator Framework as an initial menu to choose relevant indicators to meet different needs. However, it should be noted that data is not currently in the public domain for all of this indicators so in parallel we will be advocating for all partners to be collecting additional data and making this publicly available.

For more detailed analysis of the data in this year’s 100DM scorecard, a short explainer document is published alongside this report, exploring the indicators, the implications for the health of the vaccines, therapeutics and diagnostics ecosystems and what future iterations of the scorecard must take into account.

Future indicators for inclusion in the 100DM scorecard

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<th>RESEARCH CAPACITY</th>
<th>ACCESS ENABLERS</th>
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<tr>
<td>Such as the number and location of operational clinical trial sites; number of medium to large scale clinical trials in LMICs.</td>
<td>Such as the number of pipeline candidates with LMIC market access plan in place before starting trials.</td>
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<tr>
<th>GROWTH INDICATORS</th>
<th>TIME TAKEN</th>
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<td>Such as expansion in regional manufacturing capacity across DTVs and other countermeasures; number of product developers engaging in voluntary licensing agreements and similar mechanisms.</td>
<td>Including time between trial phase completion and initial of next clinical phase; and time between first stringent regulatory approval and product introduction in an LMIC.</td>
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Investing to fill gaps in R&D

Cross cutting R&D Insights from the 100 Days Mission Scorecard

The 100DM scorecard reveals a critical shortfall in the development of DTVs for pathogens with pandemic potential. Currently, comprehensive DTV solutions exist only for SARS-CoV-2 and Ebola (Zaire). Even for these, accessibility issues persist, with some products falling short of WHO TPPs, particularly in terms of suitability for low-resource settings. For the remaining eight priority pathogens on the WHO’s R&D Blueprint priority pathogen list, the gap is more pronounced: there are no approved vaccines or therapeutics and limited diagnostics.

In early 2024, the WHO’s updated prioritisation of viral families will refocus R&D efforts. This shift towards understanding entire viral families, rather than individual pathogens, aims to foster the development of broad-spectrum countermeasures crucial for responding to unforeseen threats like a ‘Disease X’. This new focus presents a pivotal opportunity to guide R&D across all three tools, leveraging both traditional methods and innovative technologies like artificial intelligence (AI) and machine learning (ML) for advancements in disease tracking and drug discovery.

However, the R&D ecosystem requires further fortification. This involves enhancing coordination across the entire product development spectrum encompassing industry, biotechnology, academia, public sectors, and philanthropic organisations. To catalyse innovation and expedite the delivery of DTVs, it is essential to establish clear commercial incentives, financial risk mitigation, and robust collaborative frameworks.

While specific challenges for DTVs are detailed in subsequent sections, this section underscores several overarching lessons and data gaps identified in this year’s 100DM scorecard analysis.

Enhancing R&D Through Coordination and Diverse Funding

The current level of funding for DTVs and platform technologies for priority pathogens is inadequate. The COVID-19 response demonstrated that with ample resources, rapid development of novel DTVs is possible. However, the funding for COVID-19 R&D from 2022-23, which was nearly ten times higher than DTV R&D funding for all other WHO Blueprint priority pathogens from 2019-2022, often lacked coordination and efficiency.

A proactive, rather than reactive, funding approach is essential to prepare for and prevent future outbreaks. Committing to the development of prototype libraries for DTVs could streamline R&D funding, with public and philanthropic funders playing a key role in bridging knowledge gaps. Diversifying funding sources is also crucial, as current reliance on public funding, predominantly from US Government agencies, leaves investment vulnerable to political shifts. Better coordination, and partnership with regions where diseases are endemic, could facilitate risk-sharing among funders for specific products and viral families.
Platform technologies that are adaptable for various pathogens have shown success in vaccine development, such as mRNA technologies. However, tools for diagnostics, such as the GeneXpert MTB/RIF platform, exist but are limited, and equivalent platform technologies for therapeutics are still at a very early stage of discovery. The development of a diverse range of technologies is crucial for rapid adaptation to Disease X or rapidly mutating pathogens. The significant upfront cost and time required for scientific breakthroughs highlight the urgency of starting now. Innovative technologies like AI and ML hold promise for accelerating R&D, from protein sequencing to target identification. These technologies could expedite the collation of vital information on each viral family, forming the foundation for prototype DTV libraries.

**Advancing Preparatory Regulatory Approaches and Correlates of Protection**

Reducing regulatory approval timelines without compromising safety is a critical prerequisite of the 100DM. Generating extensive data in advance will allow regulators to gain familiarity with major platform technologies, and the risk-benefit profiles of new DTVs. Preparatory regulatory approaches, including pre-agreed correlates of protection for vaccines (and other surrogate outcomes for therapeutics and diagnostics) secure data sharing systems, platform master files, standardised protocols and assays, and shared risk-benefit frameworks, will streamline the approval process during outbreaks.

Aligning SRAs on these approaches will enhance global collaboration in DTV development and deployment. Additionally, the broader adoption of the animal rule (which is currently underutilised) requires the establishment of regulator-qualified animal models for WHO R&D Blueprint pathogens to expedite R&D and facilitate approvals outside of outbreak scenarios.

**Figure 3: Research and development for pandemic DTVs will involve a significant effort in non-pandemic times, a pivot during the first 100 days of a pandemic and continued scale up and innovation beyond the ‘100 Days Mission’ target. Distinct efforts are required for diagnostics, therapeutics, and vaccines R&D, but cross-DTV collaboration is key, especially to develop a joint understanding of values of pandemic potential and the right DTVs to test them. The 100 Days Mission Timeline focuses on DTV R&D and does not represent a full view of broader health system preparation and response.**

**Therapeutics R&D**

**CONTEXT AND AIMS**

Given the multiple unknowns about the next pandemic, investment is needed in treatments that can be deployed in various settings. Effective therapeutics are vital to reducing the burden of morbidity and mortality from pandemic diseases. They are essential for treating people who fall ill, particularly while a vaccine is being developed, tested and rolled out, or for diseases for which vaccine development is difficult. Crucially, for some groups a protective vaccine response is unlikely due to underlying co-morbidities, these may also be the people at highest risk of worse outcomes from infectious disease, making the availability of effective treatment even more important. Therapeutics can also be deployed as pre- and post-exposure prophylaxis, especially for health workers and those in vulnerable groups, and reduce the burden on health systems by slowing symptom progression.

It is worth clarifying that there are multiple routes to reaching the goal of ‘an initial regimen of therapeutics’ within a 100 days of a pandemic being declared. It is highly likely that in the first days and weeks focus will be on repurposing existing drugs, anti-inflammatories etc. This relies on the rapid establishment of well design clinical trials (ideally based on existing infrastructure) and careful selection of existing medicines to trial. This is distinct from the need to also have set up all the work for identification of new and specific antivirals. Given the latter can take years of discovery it is crucial that this work starts now, that we might have a better stocked pipeline of novel therapeutics for priority pathogens. Setting out practical steps for how this might be achieve is the focus of the newly launched 100DM Therapeutics roadmap (Box 1).

A key learning from the COVID-19 pandemic is the need for funding across all three tools. The Therapeutics Pillar of the Access to COVID-19 Tools (ACT) Accelerator received less than 10% of donor funding, compared to nearly 70% allocated to the vaccines pillar, COVAX. The lack of funding for therapeutics hampered efforts to develop and facilitate access to COVID-19 treatments, at all stages of the value chain, it took almost two years longer for an effective oral antiviral treatment for COVID-19 to be become available, compared to multiple approved vaccines. Today, although several affordable versions of oral COVID-19 antivirals have received regulatory approvals, the products are not widely available in LMICs and governments have a low appetite for procuring therapeutics due to reduced perception of COVID-19 burden in the community (from scaled back diagnostics and surveillance programmes).

In the 2022 100DM implementation report, it was highlighted that unlike vaccines and diagnostics – which have international R&D convenors in the form of CEPI and FIND – the therapeutics ecosystem lacked the same coordination and structure, and faced barriers that were distinct from other tools.

![A sustainable R&D ecosystem and improved international coordination and funding for therapeutics R&D for infectious disease pandemic threats](image)

![25 Phase-2 ready therapeutics developed against priority virus families](image)

The 2022 report elaborated milestones related to increased funding for therapeutics in 2023; enhanced coordination via a new body or coalition; progress on making mAbs more affordable and easier to administer; and for industry to remain engaged and invest in early-stage R&D to advance candidates.
A major area of progress in 2023 has been the development of the 100DM Therapeutics Roadmap, facilitated by the IPPs and the result of the collective contributions of more than 20 global partners from all sectors, including international organisations, industry, academia and civil society (See Box 1 on 100DM Therapeutics Roadmap). The roadmap aims to provide a framework for actioning updated versions of the 100DM Therapeutics objectives, encompassing key strategic milestones, as well as potential partners to implement the recommendations. It also sets out the major challenges facing the realisation of the 100DM for therapeutics and suggested solutions for all sectors.

Overall, the therapeutics pipeline and ecosystem are not seeing the same level of investment as vaccines at all stages of the value chain, resulting in a concerning dearth of candidates. As exemplified by our 100DM scoreboard, the early-stage therapeutics R&D pipeline for pathogens of pandemic potential is very limited. The 100DM original target of 25 Phase-2 ready candidates by 2026 will not be reached; indeed, it seems unlikely that even a quarter of that number of products will be ready for Phase 2 trials by 2026, based on the current trajectory.

Industry has continued to engage in the development of promising technologies, especially via the INTREPID Alliance. In 2023, the INTREPID Board reaffirmed its focus on the creation and stewardship of a centralised listing of antiviral compounds with potential utility against the eight pandemic viral families prioritised by the US National Institutes of Health (NIH)6. The group also published a landscape of antiviral global R&D efforts in Q46. However, pull incentives for industry and diversification remains a major barrier to both the availability and affordability of many small molecule antivirals.

The UK Biomedical Advanced Research and Development Authority (BARDA) and National Institute of Allergy and Infectious Diseases (NIAID) NextGen programme made investments of almost US$400m in 2023 in developing next-generation monoclonal antibodies for prophylaxis and treatment, incorporating work to make them less susceptible to reduced efficacy in the face of viral mutation17. Unitaid, International AIDS Vaccine Initiative (IAVI), MPP and Wellcome collaborated in 2023 to explore novel business models to enable equitable access to mAbs in LMIC countries, recognising that manufacturing capacity and diversification remains a major barrier to both the affordability and availability of mAbs.

Platform technologies received a boost in investment in 2023, with Germany’s Federal Agency for Disruptive Innovation (SPRiND) and the Cumming Centre supporting the development of antiviral platforms via awards to the developers of promising technologies60,61. The Pandemic Antiviral Discovery (PAD) initiative (funded by BMGF, the Novo Nordisk Foundation and Open Philanthropy), announced grants totaling more than US$265m for 14 research projects aimed at facilitating early-stage development of drugs to treat henipavirus infection and disease10. In late 2023, a group of early-stage antiviral researchers formed a loose alliance to work together to avoid duplication and ensure a good spread of research activities across viral families.

Unidades continued to support late-stage R&D efforts for COVID-19 treatments, including the Drugs for Neglected Diseases Initiative (DNDi)-led ANTICOV platform trial to enable research institutions in 13 African countries10,11. Nirmatrelvir/ritonavir from two additional manufacturers licensed by Medicines Patent Pool (MPP) became available for sale in 2023 after approval in December 202211. Generic sub-licenses were also announced for emtricitab, an oral antiviral developed by Shionogi and approved in Japan, that was also sublicensed to MPP. MPP also started to consult with relevant stakeholders to explore mechanisms for building on lessons learnt on the licensing of COVID-19 therapeutics for pandemic preparedness.

The BIOMED Advanced Research and Development Authority (BARDA) and National Institute of Allergy and Infectious Diseases (NIAID) NextGen programme made investments of almost US$400m in 2023 in developing next-generation monoclonal antibodies for prophylaxis and treatment, incorporating work to make them less susceptible to reduced efficacy in the face of viral mutation17. Unitaid, International AIDS Vaccine Initiative (IAVI), MPP and Wellcome collaborated in 2023 to explore novel business models to enable equitable access to mAbs in LMIC countries, recognising that manufacturing capacity and diversification remains a major barrier to both the affordability and availability of mAbs.

| The ultimate objective for the 100DM for therapeutics is to work towards prototype therapeutics libraries, supported by pre-agreed procedures in place for their adaption, approval, manufacture, procurement and equitable access in the event of a pandemic. |

**SUMMARY PLANS FOR 2024**

The ultimate objective for the 100DM for therapeutics is to work towards prototype therapeutics libraries, supported by pre-agreed procedures in place for their adaption, approval, manufacture, procurement and equitable access in the event of a pandemic.

2024 will be an important year for the Therapeutics 100DM Partners will come together in a series of workshops convened by IPPs to discuss and commit to the operationalisation of the 100DM Therapeutics Roadmap. WHO is expected to publish its priority pathogen list in Q1 2024, which will particularly help to focus antiviral discovery efforts; a TPP exercise based on that publication will help develop more concrete use cases for novel therapeutics. Many of the drug development programmes awarded funding in 2023 will publish initial results in 2024, while the WHO-led and G20-endorsed i-MCM-Net process will develop further, and the INTREPID Alliance will publish its first compounds.

Given the challenges in furthering the early-stage R&D pipeline and the constrained funding landscape, advocating for the importance of investment in pandemic therapeutics will be essential in 2024. The publication of the 100DM Therapeutics Roadmap provides a springboard for such advocacy efforts, engaging funders, member states and industry.

Given the lack of products currently in the pipeline and the need to ensure variety across viral families, the 100DM objective related to the specific number of therapeutics targeted has been adjusted. Instead of aiming for 25 Phase-2 ready products by 2026, the new target aims to have at least two Phase-2 ready products for the top 10 WHO priority pathogens families, ideally with different mechanisms of action. Work around the roadmap’s operationalisation in 2024, including detailed attrition rate analysis, will lead to concrete timelines being attached to this objective in next year’s report.

The need for enhanced coordination and coherence is still of utmost importance in the fragmented Therapeutics landscape. The convenings of groups such as the INTREPID Alliance and the 100DM Therapeutics subgroup provide the basis for further collaboration. Early-stage antiviral researchers who are already being funded for their work will form a coalition in 2024 to collaborate, avoid duplication, and ensure discovery efforts are spread across different research groups, with clear milestones and timelines being planned for Q1 2024. International organisations, academics and industry should look towards combining efforts in 2024, ideally into a formal therapeutics coalition, with one organisation leading and hosting the work. The scope of this coalition should take in monoclonal antibodies, host-directed therapies and repurposed treatments, as well as small-molecule antivirals, which arguably have the greatest potential utility from an access perspective, along with new promising platform technologies. The coalition should consider the current lack of pull incentives for product development, and the potential breakthrough role of AI in advancing drug discovery, along with critical equitable access enablers such as voluntary licensing and technology transfer.
The 100DM Therapeutics Roadmap has been produced by a 100 Days Mission STEG subgroup, comprised of STEG members, industry partners, early-stage researchers, international organisations, regional organisations and CSOs. A full list of members is available at Annex B.

AIMS

The roadmap aims to provide a vision for an ideal state of preparedness for pandemic therapeutics, and a delivery plan for this vision for stakeholders to coalesce around. The headline goal is the development of at least two ‘Phase 2 ready’ therapeutic candidates for the top 10 WHO priority pathogen families, but also for there to be pre-agreed routes for trials, regulatory approval, manufacture and procurement. The roadmap has four high level objectives:

- To raise awareness of the need for increased investment in the therapeutics pipeline and an end-to-end approach to development, with access embedded by design
- To highlight ongoing scientific drug discovery and development activities being carried out by stakeholders aligned to 100DM therapeutics goals
- To identify gaps in the current therapeutic discovery and development pipeline and setting objectives accordingly
- To provide a framework for action, based on concrete objectives, as well as suggesting potential partners to implement the recommendations

The objectives in the roadmap are based on the three original overarching goals for the 100DM for Therapeutics, namely:

**Sustainable R&D funding**
Ensure sustainable R&D funding throughout development lifecycle ideally coordinated via a formal Therapeutics coalition, with the capacity to bring together the existing and newly created stakeholders in pandemic therapeutics.

**‘Phase 2 ready’ therapeutic candidates**
As part of pre-pandemic preparedness, develop ‘Phase 2 ready’ therapeutic candidates against the identified pathogen families of greatest pandemic potential (ideally minimum 2 differentiated candidates per family; antiviral small molecules, mAbs or other suitable modalities), based on inclusive TPPIs, which address the needs of all patients and markets, and are conducive to rapid, equitable access.

**Programmable platforms or technologies**
Develop scientifically rigorous and validated programmable platforms or technologies capable of speeding the delivery of new, or enhancing existing therapeutics in case of a pandemic, and to be rapidly re-purposed to ‘Disease X’.

In the absence of a single end-to-end coordinator for therapeutics development, it is hoped that this roadmap will offer a step towards a more formalised Therapeutics coalition, and in time, the emergence of an appropriate coordinator.

Throughout 2024, the IPPS and subgroup partners will convene a series of workshops to identify concrete next steps for the implementation of the roadmap. These workshops will cover early-stage R&D coordination; clinical trials and regulatory pathways; and access and market shaping. The IPPS would like to give special thanks to Untaid, MPP, DNDi, the INTREPID Alliance and READDI Inc for their contributions as part of the core working group and looks forward to working with a growing number of partners to see the roadmap implemented.

CHAPTER 2 – INVESTING TO FILL GAPS IN R&D

**Diagnostics R&D**

**CONTEXT AND AIMS**

Accurate and swift diagnostics are crucial for the early detection and containment of infectious diseases. COVID-19 underscored the critical role of diagnostics in managing pandemic threats as well as in supporting various challenges health systems face, from pandemics to antimicrobial resistance.

FIND, the Diagnostics Alliance, serves as a global convener in diagnostics R&D and have developed a comprehensive framework to define what is needed to achieve the 100DM’s diagnostic goals. FIND estimates that an initial investment of US$80-100 million over five years, if leveraged effectively, could substantially advance the development of a prototype library for pandemic diagnostics. However, a significant challenge remains: post-COVID-19, funding for diagnostics R&D has markedly declined, undermining the capacity of agencies, research institutions, and the private sector to develop essential diagnostics. This funding shortfall poses a serious risk to health systems in the face of potential epidemic or pandemic pathogens. Bridging this funding gap is imperative to maintain this vital pillar of pandemic prevention and response. Despite commendable coordination and technical efforts from FIND and others including but not limited to PATH and Clinton Health Access Initiative (CHAI), the objectives of the 100DM for diagnostics, are not on track.

**Strengthened International Coordination**

There is a need for enhanced global collaboration among governments, industry, and international organisations to create a sustainable diagnostics R&D ecosystem.

**Development of Diagnostic Libraries**

The goal of creating comprehensive diagnostic libraries offering broad coverage for priority pathogen families remains unfulfilled—purposed to ‘Disease X’.

Addressing these challenges requires renewed focus and investment to ensure that diagnostics R&D can help address future health emergencies effectively.
In the recent report, “Making the Exceptional Routine: Embedding Diagnostic Best Practice to Improve Pandemic Preparedness,” the IPPS and FIND highlight three key strategies for integrating advanced diagnostic practices into healthcare systems, crucial for both routine healthcare and during major infectious disease outbreaks:

**KEY STRATEGIES**

1. **Multiplex Diagnostics for Enhanced Efficiency**
   These innovative diagnostics can detect multiple biomarkers in a single test, revolutionising disease surveillance. Their ability to facilitate early detection, guide patient care, and offer cost-effectiveness, particularly in resource-limited settings, is transformative. Multiplex diagnostics are instrumental in simultaneously tracking various pathogens, thereby significantly improving outbreak surveillance.

2. **Digitally Connected Diagnostics**
   The integration of digital technology in diagnostics is a game-changer. It enhances the accuracy and efficiency of test data, shortens the time to treatment, bolsters disease surveillance, and provides real-time insights into diagnostics and disease patterns.

3. **Programmable platforms or technologies**
   Establishing a direct link between diagnostics and subsequent care and treatment is crucial. Evidence shows that this integration boosts testing uptake and facilitates early intervention. Successful initiatives like the ‘test-and-treat’ pilots by the ACT-A and the US government exemplify its effectiveness and potential. Overcoming the existing challenges in this area requires collaborative efforts from research funders, policymakers, and regulatory bodies.

The report offers targeted recommendations for national and global policymakers, regulators, and researchers to embed diagnostic practices more effectively into healthcare and surveillance systems. This approach serves a dual purpose: to strengthen routine healthcare delivery but also significantly enhances capabilities for outbreak detection and response.

**PROGRESS IN 2023**

Despite funding challenges, significant strides were made in diagnostics R&D in 2023, contributing to the goals of the 100DM. The 76th World Health Assembly in May 2023 marked a pivotal moment with the adoption of the Diagnostics Resolution. This resolution addresses key issues of access, affordability, and quality of diagnostic tests, placing diagnostics at the forefront of member states’ agendas. Efforts are underway to form an international diagnostics alliance, contingent on securing adequate funding.

FIND and its Pandemic Threats Team has been instrumental in advancing the diagnostic objectives of the 100DM, focusing on developing diagnostics for pathogens like Lassa fever and Ebola virus. Efforts are also being made to broaden the scope to include Nipah virus and Disease X diagnostics. FIND and other organisations including PATH have continued to support initiatives for distributed diagnostics manufacturing in several countries, aiming to enhance global access and preparedness with new partnership agreements signed with PAHO and South Korea in 2023.

BARDA Dive in the US made progress on introducing diagnostics for sepsis and infection severity, which is critical step to better identify patients who are likely to be severely ill from an infection rather than simply infected. This was a huge gap in the covid response in the US and around the world. BARDA funded the California-based company Cytovalle for their 10 minute emergency department sepsis test and funded Ad Astra Diagnostics for their 2 minute point-of-care haematology analyser that has a similar capability. BARDA is also working with the European Commission’s Health Emergency Preparedness and Response Authority (HERA) on advancing metagenomic sequencing as a point-of-care clinical diagnostic agnostic to any particular pathogen which could transform surveillance.

Furthermore, global partnerships and initiatives have been begun. For example, in India, the National Diagnostics Catapult (C-CAMP) in its 2.0 was launched, aiming to enhance pandemic preparedness and scale up diagnostics for infectious diseases. Senega’s diaTROPIX platform, a collaboration between the Institut Pasteur of Dakar and Global Access Diagnostics (GADx), continues to make progress in infectious disease diagnostics. The UK Health Security Agency (UKHSA) is developing a diagnostics accelerator to support novel test development for emerging pathogens.

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24 FIND, 2023. “FIND and its Pandemic Threats Team has been instrumental in advancing the diagnostic objectives of the 100DM,” https://www.who.int/news-room/columns/76th-world-health-assembly/.


**SUMMARY PLANS FOR 2024**

The two overarching end goals of the 100DM for diagnostics are a **coordinated and sustainable diagnostics R&D ecosystem** and the development of diagnostics libraries to provide broad coverage for priority virus families.

**Looking ahead to 2024, the focus will be on achieving these primary goals:**

- **Strengthening the diagnostics R&D ecosystem** by securing adequate funding to initiate work on prototype diagnostic libraries. Efforts should be made to leverage additional financial support from G7 and G20 members for FIND’s 100DM diagnostics framework, as well as building a broader multisectoral diagnostics coalition to support implementation.

- **Advancing scientific and regulatory progress** through collaborations between industry, government, and international organisations is essential to support the 100DM diagnostics framework. Priority should be given to research into pathogen-agnostic platforms capable of detecting Disease X.

- **Embedding best practices during inter-pandemic times** with policymakers and health ministries prioritising the procurement and integration of multiplex diagnostics with data connectivity and link diagnostic testing to treatment pathways.

**CONTEXT AND AIMS**

Of all three tools, vaccines for pandemic pathogens are unique in having CEPI as a single, internationally recognised convenor with comparatively strong funding support, who have embedded the 100DM for vaccines in their 2.0 Strategy. Their advocacy and leadership, along with political support for the value of vaccines and CEPI’s mission, has put vaccines R&D on a strong trajectory. That being said, 2024 will be a transition year, with multiple initiatives seeking to codify the learnings from COVID-19 into new ways of working, such as through the Pandemic Accord negotiations and discussions on the i-MCM-Net, as well as the need to re-establish routine vaccination programmes globally post-COVID.

Despite the contextual and political shifts, the overarching end goals of the 100DM for vaccines remain the same as when set out in the original 100DM report.

**End goals of the 100DM for vaccines:**

- A global prototype vaccine library developed for 10 high-priority viral families
- Readily programmable vaccine platform technology available, which can be rapidly repurposed to an emerging ‘Disease X’ threat
- Vaccine platforms optimised for large-scale production and simplified routes of administration and storage (i.e., to comply with the WHO TPPs)

NB: this section is focused specifically on vaccine R&D – vaccine manufacturing capacity is covered in Chapter 3.
PROGRESS IN 2023

Overall, good progress was made in 2023 against the original recommendations and towards the overarching end goals of the 100DM. A notable update being in November 2023, the US FDA approved the first vaccine for Chikungunya Virus developed by Valneva.

A key goal set out in the first implementation report is the development of a prototype vaccine library for the top 10 priority viral families by 2026. This year CEPI has started a conversation with global partners on what supporting infrastructure is needed to realise the vision of a global prototype vaccine library. There is much to be done in understanding the necessary data requirements, IT infrastructure and access requirements, it is critical that these conversations take place.

To facilitate a clear focus for future R&D efforts, the WHO Prioritisation Advisory Committee is developing its updated list of priority pathogens of pandemic potential. This progress is coupled with complementary work led by CEPI and the University of California, Davis, who are developing their ranking of the potential of ‘Disease X’ emergence from viral key families.

In 2023, CEPI has worked towards developing clinical proof of concept (PoC) for four virus families and pre-clinical PoC for an additional six virus families for the vaccine library. CEPI also signed a partnership agreement with Elanco/Chiron & Institute for Drug Discovery at Leipzig University to advance its pilot to create prototype vaccines for paramyxoviridae and arenaviridae.

Additionally, CEPI has funded several partnerships to develop Disease X vaccine library platforms, such as with University of Oxford using a Junin vaccine as an exemplar for use of their viral vector vaccine platform for arenaviruses, as well as mRNA based platform technologies for exemplary candidates such as Lassa, Japanese Encephalitis Virus and Mumps. CEPI has also expanded its animal model network to consider risk factors associated with spillover risk of domestic animal viruses, gathering expert knowledge in interviews and workshops.

International collaboration and coordination will be critical to develop prototype vaccine libraries in the coming years. In support of this, CEPI has launched its Centralized Laboratory Network to five new members from Africa and India, bringing the network to over 15 partner facilities in 13 countries. The Strategic Center of Biomedical Advanced Vaccine Research and Development for Preparedness and Response (SCARDA), Japan Agency for Medical Research and Development (AMED) and CEPI have also signed a Memorandum of Cooperation to strengthen collaboration between the organisations. In June 2023, the Department of Pharmaceuticals, Government of India, PATH, and CEPI, held a co-branded event ‘Global Vaccine Research Collaborative’ aimed at building consensus among stakeholders engaged in vaccine research, development, and manufacturing. Eight countries and 65 organisations participated, including vaccine research institutes, academia, international organisations, and industry. This conversation has informed subsequent discussions on the formation of a prototype global vaccine library.

Significant progress has also been made with investment towards modernising vaccine technology. In 2023, BARDA and NIAID’s NextGen programme funded just over US$1 million to advance vaccine R&D through providing broader more durable protection and better transmission blocking capabilities.

Additionally, the Bill and Melinda Gates Foundation (BMGF) invested US$40 million towards mRNA vaccine innovation and production in LMICs to enable low-cost and high-quality vaccines to be produced at large scale. NIH are also continuing their support in universal influenza vaccines, with US$260 million in funding from Vaccine and Infectious Diseases Division this year.

In July 2023, the European Commission and the European Investment Bank announced the creation of HEIRA Invest, a flagship initiative of the HERA+ which will provide €100 million to the InvestEU programme to support R&D.

SCARDA launched a strategic funding programme supporting vaccine development through inter-pandemic and pandemic periods and established R&D centres (comprising a flagship centre, synergetic centre, and support institutions) which aim to strengthen and promote vaccine-related research.

In April 2023, the Engineering and Physical Sciences Research Council (EPSRC), part of UK Research and Innovation (UKRI), announced £34.5 million investment to fund for the development of prototype vaccines with epidemic potential in LMICs up to 2030, led by the University of Oxford and University College London. UKHSA has also unveiled its world-leading Vaccine Development and Evaluation Centre (VDEC), and this year CEPI extended their collaboration with VDEC to include application of assays for Mpxo vaccine assessment and to conduct further research.

The UK Department for Health and Social Care’s (DHSC) UK Vaccine Network announced a second phase in 2023 with a commitment of up to £103.5 million in Official Development Assistance (ODA) funding over five years. This funding includes £33 million for collaborative manufacturing innovation research hubs managed by EPSRC and working with LMIC organisations, to address challenges relating to vaccine delivery and manufacturing. Finally, the UK government also announced a 10-year strategic partnership with Moderna to invest in mRNA research and development.

In 2023, CEPI supported technology innovations to apply to potential next-generation vaccine platforms through partnership agreements with innovators, including Tiba Biotech, Celestial Therapeutics, and GenovaVax, 20Med, Jurata Thin Film and Vaxiphen.

Sanofi has also supported innovations in vaccine technology with R&D programmes for pan-coronavirus, and paranyravirus programmes and is progressing preclinical projects through clinical trials. Furthermore, Sanofi are collaborating with the US Walter Reed Army Institute of Research, the Vaccine Research Center from NIH, and Sheba Medical to design and clinically validate a new protective responses against all known (and future) variants of SARS-CoV-2 and to provide a strong basis for future pandemic response to Sarbecovirus outbreaks.
**BOX 3 CRITICAL COMPONENTS OF A PROTOTYPE VACCINE LIBRARY**

To note, this is an IPPS perspective only, owners would need to be agreed for each component, and a strong coalition built to maintain political and financial buy-in. Such a library could lay foundations for future Therapeutic and Diagnostic Libraries.

**COMPONENTS**

- **Scientific Library contents**
  - Knowledge, working material and analytical methods for each viral family:
    - Natural history of the viral family and human responses
    - Genetic sequences of pandemic priority viral families
    - Prototype products per viral family - at least Phase 2 ready pre-outbreak
    - Collation of safety, and toxicity data for prototype products
    - Applicability of animal rule and any correlates of protection data

- **Repository of pre-agreed pandemic protocols**
  - Ideal Phase 3 clinical trial protocols for pandemic use
  - Pre-agreed regulatory pathways
  - Possible mapping of regionally available manufacturing capacity per platform
  - Guidance on preparing high quality voluntary licences

**SUPPORTED BY**

- **Robust Virtual Operating System**
  - Knowledge management, secure overarching infrastructure that enables differentiated access permissions and dashboard monitor priorities, gaps, and needs

- **Clear Terms of Reference for Library Contributors and Users**
  - Including clarity on access clauses, Intellectual Property (IP) management and any changes to use protocols in a PHEIC scenario

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**SUMMARY PLANS FOR 2024**

The three overarching end goals of the 100DM for vaccines are a strengthened international system that enables a sustainable and coordinated vaccine R&D ecosystem; prototype libraries to be developed for the ten highest priority pathogen families; and vaccine platform technologies that can be rapidly repurposed and deployed globally at scale to an emerging Disease X threat.

- To achieve the development of a prototype vaccine library for the top 10 viral families, research and development needs to continue at pace, alongside development of the governance and digital infrastructure to support a library approach. Therefore, in 2024, a global prototype vaccine library should be defined in alignment with the 100DM goals, with a coalition of supporting partners formalised to include WHO, CEPI, national R&D funders, companies and regulators.

- On the R&D front, CEPI – working with funding and delivery partners – will complete preclinical tests for the development of initial prototype exemplar vaccines for Lassa virus, Junin virus, Nipah virus, Mpox, Japanese Encephalitis and enter further candidates into the pre-clinical phase.

- The development of platform technologies that are robust, stable and easily to deliver globally will be critical to respond rapidly to future unknown threats; the next step in 2024 towards achieving this goal will require funded innovations that have met proof of concept criteria to be applied to vaccine product development programs.

- Gathering a clear understanding of LMIC capacity for vaccine R&D (and manufacturing) is essential for informed funding, prioritisation, and partnership decisions to be made across industry, academia, and the public and private sector. Multiple partners are developing mapping exercises, such as WHO’s i-MCM-Net, GloPID-R’s Pandemic PACT mapping exercises and WHO’s mRNA Hub. However, there is a risk that multiple bilateral or even multilateral initiatives in one country can breed confusion without clear communication and alignment with priorities set by national governments. Maintaining and accelerating progress will require coordinated action by industry, governments, regulators, and multilateral organisations, with the right incentives to support the pipeline of vaccines that will be needed to respond to future pandemics. If science is to respond even faster than it did against COVID, we must make innovation central to pandemic preparedness plans, with investment in surveillance, rapid access to pathogen data for scientists, and robust intellectual property protection and enforcement underpinning the voluntary collaborations necessary for rapid scale up of production and supply. The IPPS will seek to support and highlight all efforts to align behind national and regional strategies, such as those set by Africa CDC.
Participants highlighted examples of previous success in fighting pandemics and epidemics in their region, the current challenges and barriers to effectively implementing the 100DM, strategies to ensure equity at each stage of countermeasure development and delivery, and how local and national systems can best interact with regional and global systems.

Case study: Regional listening exercises

The IPPS held a series of four regional ‘listening exercises’ over the summer to better understand different regional contexts and approaches to delivering the 100DM. Working with regional partners, the events provided valuable insights into the strengths and challenges within different regions, featuring in-depth discussions with a diverse set of experts, focusing on South and Southeast Asia, West Africa, East Africa and Latin America and the Caribbean respectively.

Case study: Regional listening exercises

The criticality of regional governance institutions to connect the national to the global, and to increase solidarity and distribution of support in economically diverse regions.

The need for regulatory capacity-building and the value of regional regulatory harmonisation to boost local product development.

A strong desire from national representatives to work collaboratively with other partners in their region and make a virtue of their differing strengths, to develop a regional end-to-end product development system.

A desire for more infrastructure and frameworks to support the technical cooperation that had worked well during COVID-19, but could now be formalised through digital platforms or shared projects, such as the development of regional product libraries.

Support for the strengthening of regional manufacturing is growing in all four regions, albeit at different rates; this contrasts with early-stage R&D investments, where funding and infrastructure are more uneven.

The need for effective, equitable and sustainable financing systems.

The centrality of strengthening community health systems for surveillance, response, effective clinical trials and building trust in MCMs.

The importance of strong regional representation in global decision-making processes on MCMs, especially International Negotiating Body (INB), G7 and G20 discussions.

The full summaries from each region, translated into French, Spanish and Portuguese where relevant, downloaded from the IPPS website.
The 100 Days Mission aims to prepare as much as possible, to try within the first 100 days of a pandemic threat. Being light, safe, effective, and affordable diagnostic tests, therapeutics, and vaccines are ready to produce at scale.

Four listening exercises brought together diverse experts from across different regions to share successes and challenges in the global delivery of the 100 Days Mission.

**Good Practices**
- **West Africa**: Supply chains 1
- **East Africa**: Support for vulnerable access
- **LATAM and the Caribbean**: Improving local manufacturing capacity
- **South and Southeast Asia**: R&D funding

**Challenges**
- **West Africa**: Local regulation enforcement
- **East Africa**: Political instability
- **LATAM and the Caribbean**: Global coordination
- **South and Southeast Asia**: Economic instability

**Achieving the 100 Days Mission for Pandemic Preparedness**

**Regional Listening Exercise Outcomes**

**Good Practices**
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**IPPS**

**Professor**

**Dr. Taw Chorl** Shin

**CASE STUDY**

**Dr. Adourahmane Sow**

**Director of Public Health, Instituto Pasteur de Dakar**

**Dr. Toffu Lulyama**

**Deputy Director, World Health Organization (WHO)**

**UC: Tomás Pippo**

**Vice-Minister,WHO Regional Office for the Americas, OAS**

**Dr. Memories Sharp**

**Director, Institute of Social Philanthropic Projects (IPS)**

**CASE STUDY**

**45**
The Economic Community of West African States (ECOWAS) and West African Health Organization (WAHO), in collaboration with United Nations Industrial Development Organization (UNIDO), established the West Africa Medicines Regulatory Harmonization initiative (WA-MRH) in 2017.

To improve access to medicines and vaccines in the region, WA-MRH embraced digital solutions (e.g., an electronic submission system) to accelerate the product application and joint assessment procedure (JAP). Once a product is approved on the regional platform, it is automatically recommended for market authorization issuance for use in the 15 member states. To date, the initiative has approved 11 products from 25 applications.

ECOWAS is now seeking to establish similar alignment in regional pooled procurement to facilitate access to approved products. Their proposal has received strong support from governments and partners, and will include:

- a mechanism to facilitate the pooled procurement and supply chain of medicines;
- a revolving fund, providing a repayable funding mechanism enabling products to be purchased through the ECOWAS pooled procurement mechanism rapidly; and
- a quality-assurance policy framework that will support procurers in any setting.

In January 2020, accurate serology was required to differentiate between SARS-CoV-1 and SARS-CoV-2 infections. A beta test was rapidly developed, a patent was applied for, and regulatory approval was received—all enabling delivery within 70 days. Pre-existing industry connections made such speed possible, as they had resources to develop it and trusted it was the right thing to do, despite economic profit not being guaranteed. Discussions with regulatory bodies and other partners began before the product was finalized, so there was sufficient data and familiarity with the product to enable rapid approval.

Fundamentally, developing cross-sectoral networks during inter-pandemic periods was essential, so that they could be drawn on when accelerated approaches are needed. Although this product was developed, approved and delivered in 70 days for one country, it took three years to get approval for use in other countries in the region showing the importance of regional regulatory harmonization.
The success of the 100DM has potential benefits for national, regional and global players, and relies on all working in concert.

**POTENTIAL 100DM BENEFIT**
- Faster more equitable access to pandemic tools
- Global insurance policy for future pandemics
- Strengthened health system in inter-pandemic periods through embedded best practice
- Economic benefits from connectivity into end-to-end medical countermeasure development ecosystems
- Prototype libraries
- Pre-agreed roadmaps for product development, testing and delivery
- Regionally harmonised regulatory pathways for accelerating product approvals and access
- Critical coordinating function
- Framework for end-to-end MCMs development to inform PPR strategies

**POTENTIAL ROLE**
- Surveillance
- Strengthened health systems to roll out MCMs and reduce transmission
- R&D investment in pathogens most prevalent in region
- Global norm setting
- Financial coordination
- Advocating for smaller nations needs on global stage
- Translating global policy to regional context
- Collective decision making at a regional level is complementary to global efforts

**POTENTIAL ROLE**
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**Think globally, organise regionally, and act nationally.**

"Ambassador John Nkengasong"
In 2023, efforts have been made to ensure surveillance can be established in countries in a more globally connected way, with WHO leading on coordination. At the 76th WHA in May 2023, WHO launched its collaborative surveillance concept, defined as “the systematic strengthening of capacity and collaboration among diverse stakeholders, both within and beyond the health sector, with the ultimate goal of enhancing public health intelligence and improving evidence for decision-making.” Efforts are now being made to disseminate and align surveillance efforts using this approach at the regional level, working across the World Health Emergencies programme at WHO.

To facilitate the implementation of collaborative surveillance, the WHO Hub for Pandemic and Epidemic Intelligence (WHO Pandemic Hub) exists to connect, innovate and strengthen capacities for surveillance. It has established institutional partnerships with the Robert Koch Institute (RKI), Fiocruz, among others, and has undertaken the following activities in 2023:

- **Building networks** In 2023, the Hub launched the International Pathogen Surveillance Network (IPSN), a global network of pathogen genomic actors to accelerate progress on the deployment of pathogen genomics sequencing (PGS) and improve public health decision-making. The IPSN consists of Communities of Practice to solve common challenges, a Country Scale-Up Accelerator to align efforts and enable South-South exchange, grant funding, a Global Partners Forum for genomic surveillance and high-level advocacy to keep PGS on the agenda. It has now reached 50 partners and is set to award funds through a Catalytic Small Grants Fund in 2024.

- **Establishing communities** The Hub continued deployment of the Epidemic Intelligence from Open Sources (EIOS) initiative for early detection of public health threats. This year, EIOS has increased its user communities to 113 globally, encompassing member states, UN agencies, and other organisations. Furthermore, 67 EIOS training workshops were conducted across all WHO regions in 2023, across 45 member states and organisations, resulting in over 1,100 new users trained to enhance capabilities globally.

- **Facilitating regional collaborations** July 2023 saw the launch of the Health Security Partnership (HSP) in collaboration with Africa CDC, RKI, and WHO, supported by the Canadian government. It aims to strengthen capacities in biosecurity, integrated disease surveillance, event-based surveillance, genomic surveillance, and epidemic intelligence in six pilot countries (Tunisia, Malia, Gambia, Morocco, Namibia and South Africa).

Furthermore, the WHO BioHub has furthered its pilot phase with a total of 23 Standard Material Transfer Agreements signed with countries; eight countries have shared Biological Materials with Epidemic or Pandemic Potential (BMESP) and 15 requested BMESP through the system. This is enabling faster and more equitable access to biological materials, as well as greater knowledge and data sharing. Standardised documentation has also improved operational transparency, security and efficiency, increasing trust in the multilateral system.

At the national level, the Pandemic Fund is financing surveillance projects with the first round of funding allocations awarded in July 2023, while Resolve to Save Lives’ 7-1-7 framework is now being used to assess capabilities in 15 countries. Epiverse, a data.org programme, has built local open-source software tools for the epidemiological community through projects with the London School of Hygiene and Tropical Medicine, the Medical Research Council (MRC) Unit in the Gambia, Universidad de Los Andes, and Pontificia Universidad Javeriana (both in Colombia). These digital public goods are essential for surveillance and have been downloaded over 10,000 times since release.

However, despite international organisations working together and discussions about Access and Benefit Sharing featuring as a key part of the INI negotiations, there has been a lack of government backing to ensure progress and prioritisation of data sharing. For example, the Global Pandemic Data Alliance (GPDA) established in 2021 under the UK’s G7 presidency has seen a drop off in engagement from government and non-government partners as political attention has moved on from the pandemic to other pressing priorities. Members of the alliance still see the value in having a forum to coordinate and so are now working towards uniting efforts between the WHO Pandemic Hub, UKHSA and data.org.
SUMMARY PLANS FOR 2024

To **enhance surveillance that supports the 100DM**, implementing partners will continue to work to implement collaborative surveillance, particularly to achieve data and pathogen sharing goals that would enable DTV R&D.

- The WHO Pandemic Hub will further establish networks and active collaborations through partnerships with National Public Health Agencies around the world. It also plans to pool efforts in the area of wastewater surveillance and is continuing work on a pandemic decision simulator after having developed a blueprint in 2023 – a data-driven decision support platform for the impact of various interventions before and during health emergencies.

- In-country capacities will also be strengthened through the IPSN’s Catalytic Small Grants Fund for pathogen genomic sequencing, which is set to be implemented in 2024, along with the Pandemic Fund’s second round of surveillance funding, and locally-led software tool development through programmes like Epiverse.

- In addition, governments should work to tie diagnostic development to surveillance systems to better detect diseases in clinical and non-clinical settings. This includes creating market incentives by normalising the use of multiplex diagnostics in primary care. Globally, the WHO-led International Health Regulations (IHR) review should identify surveillance-based pre-PHEIC triggers, and the INB will set out a framework for Access and Benefit Sharing.

- Sharing pathogen samples and genomic sequence data at speed is critical for the rapid development and deployment of DTVs, as well as enabling cross-border surveillance.

- Political, economic and scientific challenges exist around the sharing of materials and data, with tensions arising between public, non-governmental and private sector organisations over wanting access to data and samples, while ensuring the fair and equitable benefit sharing in line with the Nagoya Protocol. LMICs want to ensure their right to control their own data and pathogen samples is protected, and that they get benefits in return for sharing it. On the other hand, industry partners have called for the “immediate and unhindered” sharing of data in the Berlin Declaration, in return for committing pharmaceutical companies to early access during pandemics. Companies have said they are willing to reserve an allocation of real-time production of vaccines, treatments and diagnostics for priority populations in lower-income countries and take measures to make them available and affordable.

- Pathogen sharing is important for the 100DM as the ability to rapidly develop and deploy novel DTVs is dependent on a timely and systematic approach to data, information and biological sample sharing between industry, academia, international organisations, civil society and governments.

**PRE-REQUISITES**

- A pre-agreed framework for the rapid sharing of samples
  When a PHEIC is declared, the pre-negotiated pandemic rules of the road can take effect to facilitate sharing of samples and materials, including having the mechanisms in place for biological sample collection and sharing.

- Data access agreements
  That set the terms of use for data sharing that ensure data is available, accessible and ready for future health emergencies (e.g., building off work by the GISAID), agreed in advance.

- Data sharing platforms and systems based on a system of trust
  Whereby communities that share data benefit from the outputs (particularly in accessing medical countermeasures that have been subsequently developed using shared data). It should follow the WHO guiding principles on genomic data sharing, aiming for pathogens to be sequenced and shared globally through integrated data and sample sharing mechanisms, in advance of a PHEIC being declared.
CONTEXT AND AIMS

During the COVID-19 response, clinical trials and regulatory processes underwent a transformation. Innovations in platform trials such as the UK’s RECOVERY and the WHO’s Solidarity trials, whilst not perfect, presented a model for large-scale clinical trials, showcasing their relevance beyond the pandemic context. Regulators demonstrated agility in identifying accelerated pathways and engaging with innovators for swift guidance and data review. Emergency use authorisation was standardised across the regulators and became an instrument for fast-tracking approvals without compromising safety and quality of vaccines.

Despite these successes, challenges persist in advancing clinical trials and streamlining regulatory processes during inter-pandemic periods to ensure readiness for future pandemics. Addressing these challenges requires a commitment to the establishment of a sustainably funded, regionally dispersed inclusive, network of clinical trial sites that can pivot for emergency response. Such a network needs to be complemented by systems for joint ethics reviews, pre-agreed trial protocols within prototype libraries for DTVs, and reinforced regulatory capacity globally with regional regulatory harmonisation to ease the burden on innovators.

Moreover, further and continuous capacity building will be necessary in several areas for strong high-impact clinical trials, globally. Improvements needed include greater capacity for joint ethics reviews, more Phase I trials to take place closer to end-user communities (i.e. to bolster R&D ecosystems in LMICs), and greater genetic diversity to make trial results more representative. Growth in these areas will allow for more significant and sufficiently funded trials that yield results with relevance for informing public health policy.

In 2023, there were several political declarations on strengthening regulatory processes to support pandemic preparedness and response (PPR). The G7 and G20 health ministers reiterated the importance of fostering innovation and catalysing R&D through global cooperation, emphasising adherence to international frameworks to enhance global harmonisation such as guidance from the International Coalition of Medicines Regulatory Authorities (ICMRA) and the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH). However, these multilateral declarations have not universally translated into greater regulatory alignment or adoption of more preparatory regulatory approaches that would speed up pandemic response.

There is increasing appetite to bring regulators together to align approaches. The European Medicines Agency (EMA), for example, hosted a workshop on the lessons learned from Mpx and COVID-19 identifying that more transparent processes are needed to assess products in emergencies as well as funding to sustain clinical trial networks during inter-pandemic periods that can pivot when required64.

In Africa, the African Vaccine Regulatory Forum (AVERAGE) continues to deploy its Joint Review Process to enable regulatory alignment across members in Africa65, and NISH, the Network for Immunization Technical Advisory Groups (NITAGs) Support Hub, continues to actively support the work of NITAGs in Africa (supported by Wellcome)66.

In clinical trials, WHO conducted a consultation on its guidance for best practices for clinical trials (which incorporates principles from the Good Clinical Trials Collaborative, GCTC), and in November 2023 convened a new Global Clinical Trials Forum to discuss how to ensure robust clinical trials are operationalised sustainably67.

With guidance developed, organisations are now moving to support their regional implementation. The GCTC formed the Good Trials Prism, a strategic collaboration funded by Wellcome bringing together four clinical trial networks in LMICs: Advancing Clinical Evidence in Infectious Diseases (ADVANCE-ID), Africa Health Research Institute (AHRRI), Oxford University Clinical Research Unit (OUCRU), and The Global Health Network (TGHN)68.

In Africa, the Science for Africa Foundation and partners launched the Clinical Trials Community Africa Network this year to map clinical trial sites and lab networks in the continent69. This initiative will build up on the gains from the Clinical Trials Community initiative that profiles clinical trial sites and their clinical trial capacity, clinical trialists conducting the trials, DTVs being assessed, as well as making individual country regulatory and ethics information more transparent and accessible70.

R&D funders are also increasingly aligned to better coordinate and capacitate clinical trial networks through the GloPID-R. GloPID-R have brought 37 member organisations into a Clinical Trial Networks & Funders Working Group to define standards and actions that can prepare clinical trial infrastructure regionally during outbreaks, publishing a Living Roadmap on Clinical Trial Coordination to guide funders71. They also launched a ‘Regional Hub Strategy’ with Hubs so far in Asia-Pacific region and South Africa Hub72.

As outlined in the original 100 Days report, a clinical trial and regulatory system that enables a 100-day response would be built on these components:

Sufficient clinical trial capacity and capability, especially in areas where outbreaks are most prevalent  
Coordinated clinical pipelines for this global network of trials  
Best practices on trial design embedded across global efforts  
Flexible regulatory procedures, including pre-agreed emergency regulatory procedures during a PHEIC  
Added this year:

Strengthened regulatory capacity in all regions to expedite national approvals  
Adoption of preparatory regulatory approaches such as pathogen master files, cloud-based data platforms, platform approach and shared risk-benefit frameworks

PROGRESS IN 2023

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SUMMARY PLANS FOR 2024

For clinical trials, in 2024 100DM implementation partners should come together under the leadership of WHO’s programme to implement WHA resolution 75.8 to support the twin objectives:

- Strengthening regionally dispersed clinical trial networks for use in interpandemic periods
- Pre-agreeing trial protocols for emergency response against known priority pathogens

In 2024, a number of activities are already planned to work towards these overarching goals. The WHO clinical trials guidance will be finalised and adopted, supported by partners such as CCTI, who will co-develop resources with TransCelerate, TGHN and Clinical Trials Transformation Initiative (CTTI) to help regions implement guidelines. The Africa CDC has recently agreed to launch a new clinical trials coordination mechanism which will foster collaboration across all parties in the clinical trials ecosystem. Its function will include evaluation of the pipeline of clinical trials in line with African public health and research priorities. In 2024, Africa CDC and African Union Development Agency (AUDA-NEPAD) will continue to engage with the African clinical research ecosystem and African member states to shape and refine this coordination role, including through the evolution of a ten-year execution roadmap. CloPID-IL’s Clinical Trials Working Group will help enable best practices, and develop a monitoring, evaluation and learning framework for its Living Roadmap on Clinical Trial Coordination. It will also publish an update of its scoping review (PEARLES) on the barriers affecting the implementation of clinical research of viruses with pandemic potential. As part of this, there should be regionally coordinated discussions on sustainable clinical trial networks that can remain in use in inter-pandemic periods.

On the regulatory side, ICMRA will support further practical steps to bring regulators together and discuss practical steps on moving to a more preparatory regulatory approach, for example, through cloud-based data platforms, platform master files, shared risk/benefit frameworks, and exploring correlates of protection. The C7 and C20 should support more formalised ‘winning’ initiatives to build capacity in LMIC regulators, helping more countries to reach maturity level 3 (ML3), while FIND will work with regulators to better define criteria and standards for effectiveness, quality and use cases for diagnostics, as part of 100DM diagnostics framework. Discussions between partners, governments and research institutions will need to take place around the practicality, development and implementation of pre-agreed, master protocols for clinical trials; working closely with the World Health Organization, with a view to having these protocols approved across jurisdictions.

ProgrEss towards the african medicines agency (AMA)

Strengthening Africa’s regulatory framework for medicines is crucial to achieving the goal of 60% local vaccine production by 2040. Currently, over 90% of national medicines regulatory agencies in Africa lack capacity. Despite progress, only 7% have moderately developed capacity. As of October 2023, only five out of 54 states’ national regulatory authorities (NRAs) have an assessed ML3 or above according to the WHO global benchmarking tool. Initiatives like the African Medicines Regulatory Harmonisation (AMRH) which is a precursor for the African Medicines Agency (AMA) aim to harmonise regulations across the continent. However, the implementation and widespread ratification of the Treaty for the establishment of the AMA is needed for substantial change. Currently, 27 out of 55 countries have ratified the treaty.
Preparatory regulatory approaches are needed to ensure that as much work as possible is done before an outbreak that is a pandemic threat occurs. In practice, this means:

**Cloud-based approaches**
To enable real-time exchange of information between developers and regulators, as the data becomes available during the drug development lifecycle. Such approaches would play a critical role in preparedness, enabling real-time and rolling regulatory review by multiple agencies; increased transparency with regulators able to see others’ questions and company responses; and reduced workload.

**Risk-benefit methodologies**
That enable informed decisions to be made on whether DTVs have a favorable risk-benefit profile (i.e. the benefits of the technology outweigh any potential risks of its use). This includes having a package of tools (e.g. standardised templates for gathering information) to plan, conduct and evaluate DTVs and enable increased transparency around the development, licensure and deployment of DTVs. This is particularly important for using correlates of protection, where agreement is needed over the biomarkers and associated evidence that are likely to predict clinical benefit.

**Platform master files**
That capture all the information and data available on innovative platform technologies in a standardised way, to ensure information is only submitted once to regulators and can then be re-used and re-reviewed by agencies when common components and manufacturing process steps have been used.
Voluntary licensing enables innovators to support the manufacturing of effective new treatments for supply in licenced countries, such as LMICs, that might otherwise face delays in accessing needed, new, pandemic products. Voluntary licensing fosters collaboration by allowing partners to contribute to global health initiatives on a voluntary basis on mutually agreed terms. For populations, it facilitates improved access to essential medicines, addressing critical healthcare needs and contributing to public health outcomes.

Licensing has contributed to facilitating access to essential medicines in various disease areas, including HIV, hepatitis C and was widely used to rapidly scale up production of new, small molecule antivirals in over 100 LMICs. Across all disease areas, the MPP has secured licence agreements with 20 patent holders, established partnerships with 58 manufacturing companies across 16 countries, including a network of generic manufacturers built during the COVID-19 pandemic. Its manufacturing partners have delivered 35 billion doses of generic versions of patented-protected medicines in over 140 LMICs, with significant health and economic impact. The voluntary nature of these partnerships makes this approach attractive to industry, including generics manufacturers, and policymakers. G20 health ministers have recognised the need to leverage existing networks of generic manufacturers built during the COVID-19 pandemic for equitable access to future pandemic countermeasures.

Indeed, the G7 health minister’s communiqué agreed in Nagasaki in May 2023 noted that:

The G7 would welcome the MPP to work with relevant stakeholders on strengthening the voluntary licensing processes for vaccines and other medical products as an important tool to improve equitable access.

Manufacturers have been supported through regulatory approvals by 100DM implementation partners. PATH’s Center for Vaccine Innovation and Access has supported manufacturers working toward national licensure and WHO prequalification of vaccines, including advancing multiple vaccines to the global marketplace through either PQ or Emergency Use Listing with two vaccine suppliers receiving PQ status in 2023.

Much of the progress in manufacturing capacity in 2023 has focused on Africa, with recent strategies and agreements in place as of this year. Gavi developed a comprehensive, four-pillar regional manufacturing strategy to support sustainable vaccine manufacturing through an African Vaccine Market Accelerator (AVMA), aimed at leveraging its market shaping and innovative financing capabilities to support. They also partnered with the Africa CDC to ensure regional ownership and coordination of manufacturing, signing an MOU with the African Union Commission in May 2023 to enhance access to vaccines across member states (focused on immunisation, technical assistance and health system strengthening). In addition, the Africa CDC and Gavi hosted the First Manufacturers Marketplace for Vaccine Manufacturing African Union member states in October 2023, where discussions around sustainability of vaccine manufacturing projects in Africa and preferential procurement of African-manufactured vaccines were held.

In December 2023, Gavi’s Board approved the establishment of AVMA, that will make up to US$ 1 billion available to support sustainable vaccine manufacturing in Africa. CEPI has also signed agreements with three organisations including Aspen and the Institut Pasteur Dakar (IPD) in Senegal, Africa’s first GMP vaccine manufacturing facility, BioFrama in Indonesia with additional facilities to be announced in other Global South regions. Alongside this progress, there are significant developments in other regions, with the Pasteur Network’s leading regional manufacturing efforts via Fiocruz and IPD with several other partners.

The mRNA Technology Transfer program, co-led by the WHO and MPP was established to develop sustainable mRNA manufacturing capabilities in LMICs and includes manufacturing partners across 15 LMICs.

Technology transfer initiatives have advanced to enable the transfer of knowledge and production processes. The mRNA Technology Transfer program, co-led by the WHO and MPP was established to develop sustainable mRNA manufacturing capabilities in LMICs and includes manufacturing partners across 15 LMICs.

Furthermore, Unitaid is supporting the late-stage development and catalytic introduction of multiplex diagnostic and next-generation sequencing platforms. They are collaborating with governments, organisations, and regional manufacturers to improve the profitability and competitiveness of diagnostic products and achieve WHO prequalification.

To support this objective, CEPI has released a call for proposals to receive for proposals to enhance the competitiveness of vaccine manufacturers, implement multiplex diagnostic and next-generation sequencing platforms, and support capacity development in LMICs. CEPI has also announced a call for proposals to support the scale-up of mRNA vaccine manufacturing in Africa.

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The program initially focused on COVID-19 vaccines, but it also aims to empower LMICs to develop mRNA vaccines against various diseases relevant to the regions and for long-term pandemic readiness. South African biologics firm Afrigen, which serves as the hub for the programme’s technology development and transfer, has successfully completed the development of its vaccine candidate (AfriVac 2121) which demonstrated comparable immunogenicity, safety and efficacy to the control in pre-clinical animal models. The program is also undertaking mRNA platform technology development. Technology transfer agreements have been signed with 13 out of 15 program partners across LMICs. mRNA technology packages have been delivered and Afrigen has conducted introductory training on laboratory scale mRNA production for the partners. Manufacturing sites gap assessments were initiated in 2023 and would be concluded in 2024. Furthermore, in October 2023 the BMFC announced new investments to advance access to mRNA research and vaccine manufacturing technology that will support LMICs capacity to develop high-quality, lifesaving vaccines at scale.

New public-private partnerships have been established in high-income countries. In May 2023, the UK government announced an investment of £650 million in the ‘Life Sciences for Growth package’ to include funding for manufacturing, skills and infrastructure. Moderna is collaborating with the UK government to establish a research and development center capable of producing up to 250 million doses of mRNA vaccines annually by 2025. Moreover, the Canada-UK Biomanufacturing of Biologics and Advanced Therapies Fund was launched to invest up to £3.5 million in developing and implementing innovative technologies for biomanufacturing.

Finally, strides have been made in advancing the regionalisation of manufacturing through the eight pillar framework being developed by the World Economic Forum’s Regionalised Vaccine Manufacturing Collaborative (RVMC). A joint study conducted by the Africa CDC, CHAI and PATH between December 2022 – March 2023 engaged 19 African manufacturers. The study found that a high level of collaboration between technology and manufacturing through the eight pillar framework being developed is key. In 2024, the RVMC are moving towards measures. In 2024, the RVMC are moving towards a new model in an operational phase. The RVMC has proposed developing a network of generic manufacturers for future pandemic response that will continue to support engagement with South Africa CDC, CHAI and PATH between December 2022 – March 2023 engaged 19 African manufacturers. The study found that a high level of collaboration between technology and manufacturing is needed across the centres that exist in all African regions to ensure that Africa’s vaccine needs avoid surplus supply.

As learnings from the COVID-19 pandemic are embedded globally, greater adoption of access-oriented voluntary licensing frameworks is needed to enable timely and equitable access to products wherever they are most needed. During COVID-19, several companies used voluntary licences to enable COVID-19 products to be manufactured around the world but experience and learnings from the various approaches will need to be considered for pandemic preparedness for the future. Outside of an emergency response, more detailed discussions are needed between technology IP and licences holders, manufacturers and recipient organisations on the most important components of usable voluntary licences.

It is welcomed that the Brazil G20 presidency plans to prioritise local manufacturing in 2024. Early licensing (while the innovator product is still under development), prior identification of qualified manufacturers, sharing of technical know-how and streamlined mechanisms for sharing of reference product, mechanisms to de-risk manufacturers (where appropriate) and accelerated regulatory pathways for quality assurance and in-country regulatory approval are some of the critical enablers for delivering rapid access to new therapeutics during a pandemic. The G20 has proposed developing a network of generic manufacturers for future pandemic response that could build on the network developed by MPP in the context of COVID-19.

The RVMC – launched at Davos in 2022 – is taking strides by sharing multi-year implementation roadmaps that not only facilitate manufacturing efforts, but also emphasise sustainability measures. In 2024, the RVMC are moving towards a new model in an operational phase. The RVMC will continue to support engagement with South East Asia, Latin America, and Middle East regions in 2024, working to promote sustainable practices in manufacturing globally.

Central to the success of building biomanufacturing capacity in previously low manufacturing regions is the transfer of appropriate technologies and the upskilling of labour that is technology agnostic and thus, transferable. An upskilled workforce allows for adaptation and customization of technologies to suit local needs, fostering a culture of continuous improvement. The resulting competitiveness attracts investments, expanding markets and sustaining economic growth. This reduction in dependence on imported pharmaceuticals and biopharmaceuticals is a significant benefit to sustaining economic growth. This reduction in dependence on imported pharmaceuticals and biopharmaceuticals is a significant benefit to sustaining economic growth. This reduction in dependence on imported pharmaceuticals and biopharmaceuticals is a significant benefit to sustaining economic growth. This reduction in dependence on imported pharmaceuticals and biopharmaceuticals is a significant benefit to sustaining economic growth. This reduction in dependence on imported pharmaceuticals and biopharmaceuticals is a significant benefit to sustaining economic growth. This reduction in dependence on imported pharmaceuticals and biopharmaceuticals is a significant benefit to sustaining economic growth. This reduction in dependence on imported pharmaceuticals and biopharmaceuticals is a significant benefit to sustaining economic growth.

Diversified manufacturing networks focused solely on fill, finish and formulation processes without further capacity are necessary but remain reliant on imported drug substance for upstream and downstream processes. Strategically expanding global capacity for other stages of the bioproduction processes in the long-term benefits global health security efforts though it is recognised that this will take time.
Case study: Sustainable manufacturing in the Sudan Ebolavirus outbreak

Within the first 100 days of an outbreak, it is essential to have rapid production of doses for clinical trials. In September 2022, an outbreak of Sudan Ebolavirus (SUDV) was declared in Uganda. WHO, international organisations and governments worked collaboratively with vaccine developers and researchers to expedite manufacturing of investigational vaccine doses for a clinical trial led by Uganda’s Makerere University and co-sponsored by the Ugandan Ministry of Health and WHO, resulting in the first doses arriving on the ground in a record time of 79 days. The quick, coordinated response demonstrates that the 100DM is achievable in the event of another emerging infectious disease outbreak. While the effective deployment of public health measures to curb the epidemic meant that it was too late for vaccines to support the outbreak response and the planned trial did not need to go ahead, both availability of investigational doses and clinical trial infrastructure could be expedited in the future, building on these lessons learnt.

Three vaccine candidates were included in the Tokomeza ring vaccination trial namely: (i) ChAd3 (Chimpanzee adenovirus 3)-vected candidate vaccine, (ii) ChAdOx1 (Chimpanzee adenovirus Oxford, strain 1)-vected candidate vaccine and (iii) VSV-vected candidate vaccine, all of which are configured as single-dose vaccines. Two of the candidate vaccines developed used the ChAdOx and ChAd3 vector platform, a technology that uses chimpanzee adenovirus modified to reduce its pathogenicity. When injected, it triggers antigens to be produced, stimulating a strong immune response. The VSV-vected candidate vaccine used a vesicular stomatitis viral vector (single-stranded, negative-sense RNA genome of VSV encoding five structural proteins).

This case study primarily focusses on the lessons learnt from the experiences of those working on the ChAdOx1 vaccine and the partnership with the Serum Institute of India. Many of the lessons learnt are likely to be cross cutting with the other candidate vaccines, though further research is ongoing by the STEG to expand on this case study.

Several key factors contributed to the rapid development of investigational doses:

1. Vaccine candidate development & manufacturing

Preparedness efforts gave the world a head start on the manufacturing of vaccines for SUDV, particularly as filoviruses are a well-known viral family. Platform technologies were established for SUDV and kept “warm” by being used for other clinical candidates in the inter-outbreak periods, such as Ebola Zaire, Marburg and other filoviruses.

Given the Serum Institute of India’s (SII) experience in the ChAdOx adenoviral vector platform, they could quickly adapt to produce SUDV vaccine developed by the University of Oxford based on this technology in a timely manner. They leveraged established manufacturing, testing and release methods and other vaccine candidates from Sabin Institute and IAVI, who had intermediates (‘bulk drug substance’) already available to be formulated and filled by contract manufacturing organisations. Manufacturers quickly assessed bottlenecks in the supply chain to ensure there was a supply of the necessary raw materials, and reached out to organisations such as CEPI if they were not. Some pre-assessment in cold storage infrastructure was also valuable in so that the doses could be shipped and held at the trial sites.

2. Partnerships and communication

There was constant communication between the manufacturers and regulatory authorities in Uganda, India and the UK, as well as the Ugandan Ministry of Health at a senior level, supported by WHO, UNICEF, Gavi and CEPI to ensure challenges could be overcome. Such challenges included concerns over at-risk shipping of biological materials to manufacturers; the unclear export and import procedures of virus-containing clinical doses; the acceptance of rapid sterility testing methods for batch release, so that doses could be shipped before all data was available. These partnerships were not new, which meant that technology and material transfer agreements were in place, and there was shared knowledge. This enabled the baton to be passed more smoothly from the developers involved in the SUDV response to manufacturers, where scaling of vaccine production could take place.

Finally, developing and maintaining a skilled workforce is critical for biomanufacturing. The manufacturers and their outsourced testing laboratories already had a technical workforce with experience of the base production platform. For SII, this was via agreements were in place, and there was shared knowledge. This enabled the baton to be passed more smoothly from the developers involved in the SUDV response to manufacturers, where scaling of vaccine production could take place.

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3. Funding, clinical trials and regulation during uncertainty

The uncertainty at the start of an infectious disease outbreak can become a hurdle for funding, regulation and establishing clinical trials. In the Sudan Ebolavirus example, there was a lack of certainty around how many doses would be needed, so doses were manufactured at-risk, based on early estimates that 100,000 doses would be needed for a WHO ring vaccination protocol – supported by the quick release of funding from the UKHSA, BARDA and manufacturing partners.

The involvement of regulators and health authorities was crucial throughout the process; it was also important that processes were started simultaneously to save time. Manufacturers adhered to the Good Manufacturing Practices (GMP) guidelines set by regulatory authorities, while in parallel gaining permission to import the Starting Materials required to manufacture the vaccine, release and export from India. Furthermore, the Investigational Medicinal Product Dossier (IMPD, a central document containing data on the quality, production and control of a product being researched) was written alongside development, which allowed the manufacturers to deliver the IMPD on the same day as clinical doses left the manufacturing site. Furthermore, WHO rapidly established pre-agreed components to enable clinical trials to start rapidly. This included a prioritised set of candidate vaccines, immediately accessible funding agreements, trial insurance which provided appropriate liability and compensation framework, and adapted trial protocols.

What improvements are now needed?

The response to the SUDV outbreak was rapid, but arguably not rapid enough, even with a significant head start given by the availability of Phase 1-tested candidate materials. This case study demonstrates the need for a whole-ecosystem approach, and many of these improvements need to be made before another major outbreak.

The essential improvements that are now needed are:

- Strategic investments in platform technologies with a focus on priority pathogen families and better coordination of R&D between outbreaks
- Harmonised, accelerated regulation and pre-agreed clinical trial designs
- Access to investigational doses based on agreements established between outbreaks
- Regional manufacturing funding and capabilities
- Improvements to manufacturing processes, products and documentation
- Incentivised development of prioritised candidate vaccines through licence for stockpiling/procurement
- Timely support for deployment of experimental doses at country level and in-country vaccination as part of clinical trials

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93 WHO R&D Blueprint meeting 12th January 2023: Sudan Ebolavirus Candidate Vaccines: What additional research should be conducted to accelerate the evaluation of these candidate vaccines? https://www.who.int/publications/m/item/sudan-ebolavirus-candidate-vaccines-what-additional-research-should-be-conducted-to-advance-the-evaluation-of-these-candidate-vaccines

NB it should be noted that the starting point for day 1 in each of the first scenarios differed greatly, and there is of course great uncertainty about the level of preparedness that will be attained before any future attempts at a ‘100 day response’.
Pre-agreed pandemic protocols

Pandemic financing, equitable procurement and rigorous global health governance are essential components of pandemic preparedness and response. Whilst their impact on the 100DM cannot be underestimated, it is beyond the scope of the IPPS to influence discussions and negotiations underway as these are driven by member states. As such, we did not collect extra evidence on these areas from implementation partners but have highlighted the core areas relevant to the 100DM below.

Moreover, pre-agreed arrangements should be in place to fund both R&D and DTV procurement. This section details efforts to strengthen financing and procurement mechanisms to enable pandemic readiness and emergency response but does not cover general funding provision for R&D, which is expanded on in the relevant DTV sections in Chapter 1.

Sustainable Pandemic Financing and Procurement for Equitable Access

CONTEXT AND AIMS

There is a strong economic and health imperative for investing in pandemic preparedness to ensure mechanisms are in place to unlock surge financing as well as investing in systems to build capabilities in inter-pandemic times. Surge financing refers to “rapidly deployable technical and financial support that allows regional and national bodies to respond to global health threats at a local level.” Adequate surge financing mechanisms would allow LMICs and upper-middle-income countries (UMICs) to purchase sufficient volumes of DTVs quickly and at risk when a threat materialises, and it should be complemented by preparatory funding, such as that provided through the Pandemic Fund, that help build capacities to identify outbreaks and mobilise resources quickly.

Establish mechanisms that enable immediate access to pandemic response funding to promote equitable access to DTVs. (The automatic release of funding should be tied to globally agreed trigger points, whether that be a PHEIC or clear pre-PHEIC milestones)

Support LMICs in purchasing and distributing DTVs through equitable allocation and procurement of supplies, including eliminating trade barriers where applicable.

There are two core actions required to achieve this goal as set out in the original 100DM report:
In 2023, global dialogues have been underway to make progress towards equitable financing, access and distribution of DTVs. As part of the G20 Joint Finance and Health Task Force (JFHTF) workplan, WHO and the World Bank have been helping existing pandemic response financing mechanisms and gaps to inform the development of future financing approaches96. They identified that less than 40% of G20 countries have dedicated pre-existing contingency financing mechanisms for health crisis response (i.e., during COVID from Multilateral Development Banks), but this did not necessarily mean the funds could be deployed as rapidly as was needed.

Whilst the G20 JFHTF will be reviewing its priorities in 2024, these need to be implemented by member states, and in practice should be tied to globally agreed triggers that enable the release of funding. Currently, when a PHEIC is triggered by WHO, states have a legal duty to respond to the threat, however this timing is too late for many preparatory R&D processes. For example, in COVID-19, major clinical trials for therapeutics had begun well in advance of a PHEIC, but mainly in High Income Countries (HICs) that had funding and resources to mobilise R&D quickly. Other organisations such as CEPI and Gavi are considering alternative earlier triggers that could be used as Day 0 for the 100DM for DTVs, and in absence of pre-PHEIC triggers regions are also using their own mechanisms for unlocking resources based on data surveillance.

At the G7 Hiroshima Summit in May 2023, the G7 announced the “the G7 Hiroshima Vision for Equitable Access to Medical Countermeasures (MCs)” and reconfirmed the importance of ensuring equitable access to MCMs, including therapeutics and vaccines throughout the world97. In addition, as one of its concrete initiatives, “the MCM Delivery Partnership for Equitable Access (MCDP)” was launched. The kick-off meeting of the MCDP working group was held in July with the G7, India as the G20 presidency and other related countries, and international organisations such as WHO and UNICEF98. Additionally, G7 Development Finance Institutions have committed to contributing to the financing gap and released a new G7 Development Finance Institutions Collaboration Framework for Health Emergencies, which featured several instruments pioneered by Gavi as possible models for the future.

In response and complement to these discussions, Gavi has developed the Day Zero Pandemic Financing Facility for Vaccines (DZF), a suite of financing tools that will enable the Alliance to deliver a rapid and more equitable end-to-end vaccine response in the next pandemic99,100.

It consists of two elements that complement each other: (1) the creation of a new First Response Fund that will enable funds to be deployed faster than any other mechanism in Gavi’s PPR toolkit, and (2) the expansion of the use and effectiveness of Gavi’s existing surge financing mechanisms so that they can be used beyond COVID-19. This includes an adapted European Bank for Reconstruction and Development Facility, the US International Development Finance Corporation Rapid Financing Facility, and the International Finance Facility for immunisation (IF-FIm) Contingent Financing Mechanism. In 2024 Gavi will continue to seek the DZF for Vaccines’ alignment with discussions and outputs from G20 and G7 discussions on pandemic financing.

Alongside surge financing mechanisms, the Pandemic Fund was established to strengthen prevention, preparedness and response. In July 2023, the Fund awarded its first round of grants in after a call for proposals which received 179 applications from 133 countries (demonstrating exceptionally high demand from LMICs to invest in pandemic prevention)100. The World Bank awarded grants totalling US$38 million to 17 projects benefitting 37 countries, focused on disease surveillance, laboratory systems and strengthening workforce capacity within countries100. These projects are expected to mobilise over US$2 billion in additional resources. However, whilst progress has been made, sustainably financing the Fund remains a challenge as it has only received US$2 billion in pledges, far below the US$10.5 billion annual estimated need.

**SUMMARY PLANS FOR 2024**

Going forward, globally agreed pre-PHEIC triggers would be critical to automatically enable the release of financing to support countries to respond to outbreaks.

1. The G20 JFHTF will provide recommendations on surge financing for governments, which Gavi will also seek to align the DZF with.

2. The Pandemic Fund should also attract increased contributions for preparedness, should ensure regional bodies are involved in setting priorities and funding decisions. Should the fund be sufficiently recapitalised it should be reconsidered whether grants may also be awarded to strengthen pandemic R&D. Experienced procurement agencies should also consider having advanced purchase frameworks with no-fault compensation systems, indemnification and liability in place to allow the development and fast deployment of pandemic countermeasures.

3. Overall, the global system should work towards ensuring greater coordination between funders and those countries and entities receiving funding, to facilitate greater coherence, particularly in the therapeutics space. Procurement agreements that ensure equitable access to DTVs are needed between manufacturers and procurers such as Gavi, UNICEF and The Global Fund, and need to be implemented before an outbreak occurs.
This year, the main global health governance developments related to the 100DM were:

**Interim-Medical Countermeasures Network (i-MCM-Net):** Throughout 2023, WHO convened its member states and stakeholders to develop the concept for an i-MCM-Net. The objective of i-MCM-Net is to strengthen the global MCM ecosystem’s resilience, preparedness and responsiveness to pandemic threats by creating a measure of convergence and enhance communication, collaboration and coordination between existing key MCM networks, actors and constituencies at global and regional levels. The 100DM STEG outlined what a genuine multisectoral partnership should ensure in a Lancet opinion piece in September 2023:

1. New DTVs are inherently accessible in a timely manner
2. R&D is coordinated internationally, particularly when there is limited funding
3. A global clinical trials network is developed and maintained
4. Preparatory regulatory approaches based on aligned requirements

The stakeholders convened in the i-MCM-Net are collaboratively drafting a report on the MCM ecosystem for publication in 2024. The report will provide a landscape of current activities stakeholders operating in the MCM ecosystem, and critical gaps that need attention with a specific focus on Pandemic Influenza, Novel Coronavirus, and Disease X preparedness. It will cover R&D, manufacturing, supply & demand, allocation, and last mile delivery.

**Global Preparedness Monitoring Board (GPMB) Monitoring framework:** GPMB, the independent body responsible for assessing the state of the world’s preparedness for pandemics, completed analysis for its Monitoring Framework for Preparedness in 2023, highlighting that there are significant weaknesses in several areas of preparedness. No area that was assessed was deemed as doing well. Moving forward, the GPMB outlined four key priorities, much of which is complementary to the 100DM:

1. Strengthen independent and multisectoral monitoring and accountability
2. Reform the global financing system for pandemic preparedness, prevention and response
3. Achieve more equitable and robust R&D and supply chains
4. Enhance multisectoral, multistakeholder engagement

**INB discussions:** In December 2021, the World Health Assembly established an INB to draft and negotiate a convention, agreement or other international instrument under the Constitution of the World Health Organization to strengthen pandemic prevention, preparedness and response. INB negotiations and consultations have been progressing throughout 2023, with the process expected to conclude in 2024. It is hoped that whatever is agreed in the final Pandemic Accord will have a positive impact on the world’s ability to deliver the 100DM. Targeted amendments to IHR in October 2023 also hold promise for financing public health emergencies and implementation in several relevant areas.

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The year ahead

THE URGENCY OF NOW

Four years post-COVID-19, the world has grappled with economic, conflict and climate crises, inadvertently shifting focus away from pandemic preparedness. Yet, the cost of unpreparedness for the next pandemic could magnify these challenges and spawn new ones. The need for sustained political and financial commitment to pandemic preparedness is more critical than ever.

The 100DM offers a robust, globally endorsed framework for pandemic response. It transcends the usual cycle of panic and neglect in infectious disease R&D. In 2024, we stand at a pivotal moment to transform this plan into action. This mission calls for a united front from international partners, industry, academia, and leaders at all levels.

OPPORTUNITIES IN 2024

The upcoming year is pivotal to put pandemic preparedness on a sustainable footing. There are major milestones such as the conclusion of the Pandemic Accord negotiations at the World Health Assembly in May, advancement of the i-MCM-net concept and release of updated International Health Regulations. These efforts will enhance our ability to respond swiftly and effectively to future pandemics.

As the pandemic fades into the rearview mirror for some political leaders, the health community must find smarter ways to call for multi-benefit investments that will enable UHC, tackle AMR, and lay the groundwork for a 100DM response to any future major outbreaks. The agendas of the Italian and Brazilian presidencies show great potential to acknowledge the common challenges and potential common solutions to these threats. By aligning resources and strategies, we can fortify a global health architecture capable of confronting all future health challenges.

THE ROLE OF THE INTERNATIONAL PANDEMIC PREPAREDNESS SECRETARIAT

The IPPS and its leadership will continue its multisectoral approach, collaborating with global partners to keep pandemic preparedness at the forefront of the political agenda. By facilitating scientific exchange and monitoring progress, the Secretariat aims to drive policy and ensure the realisation of the 100DM.

As we look ahead, the call to action is clear and urgent. It is incumbent upon all stakeholders to engage, invest, and collaborate. Together, we can turn the 100DM from aspiration to reality, ensuring a world better prepared for the challenges of tomorrow.
## Annex A:
### Summary of Recommendations

**NOTE B:**
- Progress summarised is not exhaustive but seeks to highlight updates of international relevance
- Recommendations have been grouped by theme rather than original numerical order
- Information in this table has been collated from pro formas and interviews with the named implementation partners.

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<td>Strengthening Global Surveillance</td>
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| 07. Governments should normalise the use of accurate diagnostics for coronavirus and influenza in point-of-care and nonclinical settings | - Governments, such as UK and Japan, have made progress towards normalising the use of accurate diagnostics in point-of-care and nonclinical settings. The UK launched the next phase of the Winter COVID-19 Infection Study, providing data on the effects of epidemiological changes in COVID-19, and Japan made antigen qualitative test kits for simultaneous testing of COVID-19 and influenza available as over the counter products that can be purchased online
| 08. WHO should support an enhanced role for diagnostics in the surveillance of pandemic threats | - WHO has accelerated deployment of the Epidemic Intelligence from Open Sources (EIOS) system for early detection, which now includes 72 members and 113 user communities globally
| 21. Explore the scope for a system that enables biological samples to be collected and shared immediately and unhindered in a pandemic | - WHO launched the International Pathogen Surveillance Network (IPSN), bringing together pathogen genomics actors to accelerate progress and improve public health decision-making
| 22. Support the recommendations of the Science Academies of the G7 and endorse the development of a roadmap towards a more systematic approach to data capture, standards, sharing and analysis for health emergencies | - WHO's Pandemic Hub launched the International Pathogen Surveillance Network (IPSN), bringing together pathogen genomics actors to accelerate progress and improve public health decision-making

**Overarching end goals**
- An international network of local surveillance systems, able to identify and characterise local outbreaks for rapid responses
- A global ecosystem of interoperable data analytics platforms to enable data sharing that can identify emerging patterns and trends
- Mechanisms for rapid exchange of pathogen samples to enable global R&D efforts for diagnostics, therapeutics, and vaccines (including reciprocity with sample providers)
- Routine use of diagnostics, especially in high-income settings where it has a key role in underpinning global affordability and promoting innovation
- Trusted data sharing mechanisms and platforms

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110. PATH, 2023 PATH Diagnostic Image Repository” https://www.path.org/programs/diagnostics/diagnostic-image-repository#:

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110. PATH, 2023 PATH Diagnostic Image Repository” https://www.path.org/programs/diagnostics/diagnostic-image-repository#:
## Strengthening Global Surveillance

- United Nations General Assembly High-level Meeting on Pandemic Prevention, Preparedness and Response (UNHLM PPR) political declaration committed to encouraging fair, equitable and timely sharing of benefits of pathogens with pandemic potential, including genomic sequences through a multilateral system.
- BMGF has been strengthening disease surveillance in Africa by focusing on a small set of high-impact levers which provide value across both high-burden diseases and epidemic threats. These levers include foundational health metrics on population and mortality; multi-pathogen surveillance platforms; and investments in data integration, modelling and use that make them actionable for public health decisions.
- Resolve to Save Lives progressed their 7-1-7 framework for monitoring outbreak response and have been providing technical assistance, to help countries to implement surveillance systems for health emergencies through their 7-1-7 Alliance.
- Epiverse, a data.org programme, has built local open-source software tools for the epidemiological community through projects with the London School of Hygiene and Tropical Medicine, the MRC Unit in the Gambia, Universidad de los Andes, and Pontificia Universidad Javeriana (both in Colombia).
- Data.org is working with WHO and UHSA to consolidate and collaborate on data sharing for surveillance.

## Diagnostics R&D

**Q2. Build prototype vaccines and diagnostic libraries applicable to representative pathogens of pandemic potential**

- BARDA has supported multiplex diagnostic test for COVID-19, and Flu and RSV received FDA clearance.
- BARDA has supported the development of the BD Respiratory Viral Panel, which is a single consumable and ready-to-use assay that runs on the automated sample-to-result BD MAX system used by hospitals and labs nationwide.
- FIND has entered discussions with the European Commission, Health Emergency Preparedness and Response Authority (HERA) regarding diagnostics for pandemic preparedness and submitted a proposal for significant EU funding to advance the 100DM diagnostics agenda.
- WHO member states endorsed a resolution on diagnostics to address the challenges related to access, affordability, and quality of diagnostic tests, which was passed at the 76th World Health Assembly in May 2023.
- FIND, CHAI, and Africa CDC, among others, have taken initial steps to promote a vision for an international diagnostics alliance.
- FIND and other organisations including PATH have continued to support initiatives for distributed diagnostics manufacturing in several countries, aiming to enhance global access and preparedness with new partnership agreements signed with PAHO and South Korea in 2023.

**Q6. Strengthen the role of the international system in R&D capability and coordination for [therapeutics and] diagnostics**

Note that progress against this recommendation has been broadened to diagnostics R&D coordination more broadly, beyond a potential CSP role.

**PROPOSED 2024 ACTIONS AND OVERARCHING GOALS**

- Funders and fundraising bodies should prioritise funding and investment in Diagnostics R&D to achieve appropriate diagnostics infrastructure.
- Funders, in coordination with FIND, should explore mechanisms to ensure adequate funding to initiate work on prototype diagnostic libraries, including garnering investment against FIND’s US$80-100 million proposed plan.
- FIND to hold quarterly meetings to progress partnerships between governments, industry and international organisations towards the 100DM Dx framework.
- Research to continue into effective pathogen-agnostic platforms with the potential to detect Disease X, in line with WHO’s“Pathogens X”.
- Policymakers, research funders and health ministries should prioritise multiplex diagnostics and data connectivity for existing and novel diagnostic tools.
- Health ministries and healthcare governing bodies should prioritise linking diagnostic testing to treatment.

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119 Data.org interview
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<td><strong>Diagnostics R&amp;D</strong></td>
<td>- FIND has initiated discussions in China aimed at supporting technology transfer from China to low-resource countries and their present and future manufacturers.</td>
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<td>- Overarching end goals</td>
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<td>- FIND and its Pandemic Threats Team have been advancing 100DM diagnostics objectives in 2023, focusing on developing diagnostics for pathogens like Lassa fever and Ebola virus.</td>
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<td>- Strengthened international coordination between governments, industry and international organisations on a sustainable diagnostics R&amp;D ecosystem.</td>
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<td>- The National Diagnostics Catapult (C-CAMP [Indx 2.0]) was launched, aiming to enhance pandemic preparedness and scale up diagnostics for infectious diseases.</td>
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<td>- Diagnostics library developed providing broad coverage for priority virus families.</td>
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<td>- Senegal’s staTIOPIX platform, a collaboration between the Institut Pasteur of Dakar and GADx, continues to make progress in infectious disease diagnostics.</td>
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<td>- Africa CDC in partnership with key partners have launched the Africa Collaborative Initiative to Advance Diagnostics (ACFAD).</td>
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<td>- UOHSA are developing a diagnostic accelerator capability with the aim of supporting academic, NGO, and commercial partners to rapidly develop and evaluate new diagnostics.</td>
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<td>- BARDA’s Division of Research, Innovation, and Ventures (ORIv) demonstrated clinical mNGS capability for respiratory RNA viruses through its NGS-based agnostic diagnostics program.</td>
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| **Therapeutics R&D** | - READDI launched broad spectrum antiviral discovery efforts for multiple priority virus families, with >50 active projects (up from ~30 in 2022) spanning the discovery and development continuum. | - The Cumming Centre launched the first of two rounds of grant funding under its Foundation Grants (~US$1million). | - Advocating for the importance of investment in pandemic therapeutics will be essential in 2024. The publication of the 100DM Therapeutics Roadmap provides a springboard for such advocacy efforts, engaging funders, member states and industry. |
| | - The Pandemic Antiviral Discovery (PAD) initiative announced grants totaling more than US$36 million for 14 research projects aimed at facilitating early-stage development of drugs to treat henipavirus infection and disease released a Request for Proposals (RfP) focused on Antivirals for Pandemic influenza in late-2022. | | - IPPS will convene partners in a series of workshops to discuss and commit to the operationalisation of the 100DM Therapeutics Roadmap. |
| | - BARDA’s Division of Research, Innovation, and Ventures (ORIv) demonstrated clinical mNGS capability for respiratory RNA viruses through its NGS-based agnostic diagnostics program. | | - WHO is expected to publish its priority pathogen list in Q1 2024, which will particularly help to focus antiviral discovery efforts; a TRP exercise based on that publication will help develop more concrete use cases for novel therapeutics. |
| - Invest in simplified cheaper routes for producing monoclonal antibodies and other new therapeutic modalities | - The Pandemic Antiviral Discovery (PAD) initiative announced grants totaling more than US$36 million for 14 research projects aimed at facilitating early-stage development of drugs to treat henipavirus infection and disease released a Request for Proposals (RfP) focused on Antivirals for Pandemic influenza in late-2022. | - Many of the drug development programmes awarded funding in 2023 will publish initial results in 2024, while the WHO-led and G20-endorsed i-MCM-Net process will develop further, and the INTREPID Alliance will publish its first compounds list. |

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<td>Therapeutics R&amp;D</td>
<td>Increase the role of the international system on R&amp;D and coordination for therapeutics and diagnostics</td>
<td>In March 2023, IAVI, Unitaid, the MPP and Wellcome convened a consultation to explore novel business models to enable equitable access to mAb in LMICs. The two-day meeting concluded that an action plan was needed to advance key recommendations to ensure a pathway to access could be developed, and a coordinating mechanism which could help galvanise stakeholder interest and investment activities.</td>
<td>Early-stage antiviral researchers who are already being funded for their work will form a coalition in 2024 to collaborate, avoid duplication, and ensure discovery efforts are spread across different pathogen families, with an initial meeting planned for Q1 2024. International organisations, academics and industry should look towards combining efforts in 2024, ideally into a formal therapeutics coalition, with one organisation leading and hosting the work. The scope of this coalition should take in monoclonal antibodies, host-directed therapies and repurposed treatments, as well as small molecule antivirals, along with new promising platform technologies. The therapeutics coalition should consider the current lack of pull incentives for product development, and the potential breakthrough role of AI in advancing drug discovery, along with critical equitable access enablers such as voluntary licensing.</td>
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<td>Note that progress against this recommendation has been broadened to therapeutics R&amp;D coordination more broadly, beyond a potential CEPI role</td>
<td>Generic sub-licensees were announced for ensitrelvir, an oral antiviral developed by Shionogi and approved in Japan, that was licenced to MPP. The inaugural INTREPID Alliance Antiviral Summit, “Averting the Next Pandemic: Nox,” took place in Washington, D.C. in March 2023 and involved almost 100 international participants from the pharmaceutical and biotech industries, academia, government, regulatory bodies, foundations and NGOs. The INTREPID Board reaffirmed its focus on the creation and stewardship of a centralised listing of antiviral compounds with potential utility against the eight pandemic viral families prioritised by the NIH. INTREPID Alliance published a landscape of antiviral global R&amp;D efforts in Q3 2023. 100DM Therapeutics subgroup convened, comprising around 15 partners – including 100DM STEG members – to focus on therapeutics [and diagnostics] 100-days mission.</td>
<td>Planned partner commitments - SPRID will continue pre-clinical demonstration of broad-spectrum activity of candidates from at least 5 platform technologies in 2024 - INTREPID will publish a centralised listing of promising antiviral compounds by January 2024, advise academia on prioritising compounds for development, and will develop industry policy perspectives on enablers of R&amp;D pipelines. They will facilitate further collaborations with NIAID, AViDD centres and government agencies. MPP will continue to develop capacities and learnings from voluntary licensing in COVID-19 - The Cumming Centre will distribute US$19m to accelerate Tx target discovery and platform technology development. They will also establish a Future Fellow Fund to develop a global community and network - REACD will continue preclinical development of existing leads and develop new leads from our existing hits, with target validation and hit discovery efforts proceeding in parallel. Given PAXLOVID’s pan-coronavirus potential, Pfizer would plan to evaluate its activity against a new, similar pathogens should one emerge in the future.</td>
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<td>The Cumming Centre will distribute US$19m to accelerate Tx target discovery and platform technology development. They will also establish a Future Fellow Fund to develop a global community and network. - The Cumming Centre will distribute US$19m to accelerate Tx target discovery and platform technology development. They will also establish a Future Fellow Fund to develop a global community and network.</td>
<td>Overarching end goals: - Therapeutics library developed providing broad coverage for priority virus families (antivirals and host directed therapies) - Pre-agreed procedures in place for adaption, approval, manufacture, procurement and equitable distribution of therapeutics in the event of a pandemic.</td>
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**Notes:**

# Therapeutics R&D

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<td>01.</td>
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<td>02.</td>
<td>Invest in modernising vaccine manufacturing processes and make technology transfer and scalable manufacturing easier in a pandemic by investing in R&amp;D</td>
<td>- Simplified cheaper routes of mAb production and administration in widespread use ready for rapid roll out in the event of a pandemic</td>
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<td>10.</td>
<td>CEPI and the University of California Davis are developing their ranking of the potential of ‘Disease X’ emergence from key viral families</td>
<td>- A global prototype vaccine library should be defined in alignment with the 100 Days Mission goals, with a coalition of supporting partners formalised to include, WHO, CEPI, national R&amp;D funders, companies and regulators</td>
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<td>11.</td>
<td>CEPI partnered with Oxford to develop Disease X Vaccine Library platforms and prototype vaccine for Junin virus platforms</td>
<td>- CEPI working with funding and delivery partners, will complete preclinical tests for the development of initial prototype vaccines for Lassa virus, Junin virus, Riftia virus, Mopox, Japanese encephalitis and enter further candidates into the pre-clinical phase</td>
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<td>12.</td>
<td>CEPI has expanded its Centralized Laboratory Network (CLN) to five new members from Africa and India, bringing the CLN to 15 partner facilities in 13 countries</td>
<td>- Innovations made in vaccine platforms should be demonstrated in immunogenicity studies produced by CEPI and partners</td>
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<td>13.</td>
<td>CEPI and Houston Methodist are advancing the development of a prototype junin virus vaccine platform</td>
<td>- IPS will look to support and highlight all efforts to align behind national and regional strategies such as those set by Africa CDC</td>
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**Notes:**
- CEPI, 2023. “CEPI and Houston Methodist Announce Partnership to Leverage AI to Combat Next Global Pandemic” https://www.houstonmethodist.org/147

# Vaccines R&D

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**Notes:**
## TOPIC

### Vaccines R&D

- SCARDA, AMED, and CEPI have signed a Memorandum of Cooperation (MoC) to strengthen collaboration between the organisations.
- SCARDA launched a strategic funding programme supporting vaccine development throughout inter-pandemic and pandemic periods and established R&D centres.
- The Department of Pharmaceuticals, Government of India, PATH, and CEPI, held a co-branded event ‘Global Vaccine Research Collaborative’ (CVRC) in June 2023.
- The European Commission and the European Investment Bank announced the creation of HERA Invest which will provide €300 million to the InvestEU programme to support R&D.
- The UK Health Security Agency (UKHSA) unveiled its world-leading Vaccine Development and Evaluation Centre (VDEC), helping to develop life-saving new vaccines for the UK and worldwide.
- CEPI extended their collaboration with VDEC to include application of assays for Mpox vaccine assessment and to conduct further coronavirus research.
- UK also announced a 10-year strategic partnership with Moderna for mRNA R&D.
- The UK’s Department for Health and Social Care (DHSC) UK Vaccine Network (UKVN) announced a second phase in 2023 with a commitment of up to £253.6 million in Official Development Assistance (ODA) funding over five years.
- Pfizer Vaccine R&D has reached across the globe with approvals for REVENAR 2019 pediatric, ABRYSVO™ for older adult, ABRYSVO™ first and only RSV vaccine through maternal immunisation, and COMIRNATY® 2023-2024 formulation and a potential approval on the horizon for Maringococcal Pertavacket.
- Sanofi R&D vaccine programs for pan-coronavirus, pararnervovirus and flavivirus reached pre-clinical stages of development, while Vero cell-based yellow fever (vYF) vaccine has completed the Phase 2 trial stage positively.
- Sanofi are collaborating with the US Walter Reed Army Institute of Research, the Vaccine Research Center from NIH, and Sheba Medical to design and clinically validate a vaccine able to induce broad protective responses against all known (and future) variants of SAR-CoV and to provide a basis for future pandemic response to Sarbecovirus outbreaks.

## 2023 SUMMARY PROGRESS UPDATE

### OVERARCHING END GOALS
- Strengthened international coordination between governments, industry and international organisations enables a sustainable vaccine R&D ecosystem without over reliance on any one partner.
- Prototype vaccine libraries developed for the ten highest priority virus families, with preclinical and clinical trials conducted for as many products as possible pre-pandemic.
- Pre-agreed procedures in place for adaption, approval, manufacture, procurement and equitable distribution of vaccines in the event of a pandemic.
- Programmable vaccine platform technology (including mRNA vaccine technologies) able to be rapidly re-purposed and deployed globally at scale to an emerging ‘Disease X’ threat, and accessible for use by all populations in all regions.
- Industry, academia, and public-private partnerships working to achieve the goal to optimise vaccine platforms for large scale production and simplified routes of administration and storage. (i.e., to comply with the WHO TPPs).

### PROPOSED 2024 ACTIONS AND OVERARCHING GOALS

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**TOPIC**
- The COVID-19 Technology Access Pool (C-TAP) hosted by WHO, and MRG have announced that three new licence agreements have been concluded with the Spanish National Research Council (CSIC), Medigen Vaccine Biologics Corp, and the University of Chile on three COVID-19 products. The agreements will enable multiple vaccine producers to increase global access to vaccines made at large scale. "Launch of a New Tool for Funders: Living Roadmap Will Support Stronger Coordination of Clinical Trial Responses to Epidemics and Pandemics." www.glopid-r.org/

**RECOMMENDATION**
- GloPID-R has brought 48 member organisations into a Clinical Trial Networks & Funders Working Group to define standards and actions that can prepare clinical trial infrastructure regionally during outbreaks, publishing a Living Roadmap on Clinical Trial Coordination to guide funders. The FDA approved Ixchiq, the first vaccine for Chikungunya Virus.
- PATH’s Centre for Vaccine Innovation and Access has partnered with vaccine manufacturers globally to advance multiple vaccines to the global marketplace. PATH has also worked with partners to assess the current state of vaccine manufacturing in Africa and make recommendations for how to advance a sustainable manufacturing ecosystem.

**PROPOSED 2024 ACTIONS AND OVERARCHING GOALS**
- T00D implementation partners will implement clinical trials guidance in regional settings.
- In 2024, the WHO clinical trials guidance will be finalised and adopted, supported by partners such as GCTC, who will co-develop resources with TransGebra. TCHN and CTTI to help regions implement guidelines.
- GloPID-R’s Clinical Trials Working Group will help enable best practices, and develop a monitoring, evaluation and learning framework for its Living Roadmap on Clinical Trial Coordination.
- GloPID-R’s Clinical Trials Working Group will publish an update of its scoping review (PEARLES) on the deployment of Joint Review Processes to enable regulatory alignment across members in Africa.

### Improvements to Clinical Trials Capability and Regulation Processes

**TOPIC**
- The NISH, the National Immunization Technical Advisory Group, has secured funding from several funding organisations to deploy its Joint Review Process to enable regulatory alignment across members in Africa. The COVID-19 Technology Access Pool (C-TAP) hosted by WHO, and MRG have announced that three new licence agreements have been concluded with the Spanish National Research Council (CSIC), Medigen Vaccine Biologics Corp, and the University of Chile on three COVID-19 products.

**RECOMMENDATION**
- The G7 and G20 should support more formalised ‘twinning’ initiatives to build capacity in LMIC regulators, moving to a more preparatory regulatory approach.
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- The G7 and G20 should support more formalised ‘twinning’ initiatives to build capacity in LMIC regulators, helping more countries to reach NLM while FIND will work with regulators to better define criteria and standards for effectiveness, quality and use cases for diagnostics, as part of T00D diagnostics framework.

## TOPIC RECOMMENDATION 2023 SUMMARY PROGRESS UPDATE

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16. Stringent Regulatory Authorities and the WHO should form an international alliance in a pandemic to support timely exchange of knowledge and information relating to standards and guidelines for DTVs.

18. The Science for Africa Foundation launched the Clinical Trials Community (CTC) platform.

20. Stringent Regulatory Authorities and the WHO exchange experience and best-practice on regulatory evaluation of other types of studies (e.g., human challenge trials, immunogenicity studies) during pandemics to support the development of appropriate protocols and guidelines.

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| Improvements to Clinical Trials Capability and Regulation Processes | The Science for Africa Foundation launched the Clinical Trials Community (CTC) platform. | The Science for Africa Foundation and partners launched the Clinical Trials Community Africa Network (CTCAN) to map clinical trials sites and lab networks in the continent. | Planned partner commitments:
- CTC will continue to support WHO and ICH in implementation of new guidelines, and will co-develop resources with TransCelerate, TGH, CTTI to help regions implement guidelines.
- GloPID-R’s clinical trials working group will enable best practices, and develop a monitoring, evaluation and learning framework for its Living Roadmap on Clinical Trial Coordination. They will also publish an update of their scoping review (PEARLES) on the barriers affecting the implementation of clinical research of viruses with pandemic potential.
- Africa CDC to launch a new clinical trials coordination mechanism which will foster collaboration across all parties in the clinical trials ecosystem. Its function will include evaluation of the pipeline of clinical trials in line with African public health and research priorities. In 2024, Africa CDC and AUDA-NEPAD will continue to engage with the African clinical research ecosystem and African member states to shape and refine this coordination role, including through the evolution of a ten-year execution roadmap.

Overarching End Goals | WHO convened a new Global Clinical Trials Forum to discuss how to ensure robust clinical trials are operationalised sustainably. | Global Regulatory Authorities and the WHO should exchange knowledge and information relating to standards and guidelines for DTVs. | - Sustainably funded, regionally dispersed and regularly used network of clinical trial sites ready to respond in an emergency.
- Pre-agreed clinical trial protocols and regulatory pathways for vaccines, therapeutics and diagnostics from within prototype libraries under emergency protocol.
- Strengthened regulatory capacity in all regions with regional regulatory harmonisation agreements in place where possible to reduce burden on innovators.

190. GCTC pro forma
191. GCTC pro forma.

ANNEX A | 100 DAYS MISSION
### TOPIC | RECOMMENDATION | 2023 SUMMARY PROGRESS UPDATE | PROPOSED 2024 ACTIONS AND OVERARCHING GOALS

#### Improvements to Clinical Trials Capability and Regulation Processes

**Regionalised manufacturing of DTVs**

16. Governments and industry should share risk to maintain vaccine manufacturing capacity

**Note:** Recommendation 16 extended to cover manufacturing capacity across DTVs

- The African Union Commission (AUC) and Gavi signed a memorandum of understanding (MoU) to increase access and accelerate the uptake of life-saving vaccines across African Union member states. Gavi sought industry input into the AVMA design through collaboration with the Developing Countries Vaccine Manufacturers Network (DCVMN). In addition, the Africa CDC and Gavi hosted the Africa Vaccine Manufacturing Marketplace for Vaccine Manufacturing African member states in October 2023, where discussions around sustainability of vaccine manufacturing projects in Africa and preferential procurement of African-manufactured vaccines were held.

- The Gavi Board approved the establishment of AVMA, that will make up to US$1 billion available to support sustainable vaccine manufacturing in Africa.

- UN General Assembly High Level Meeting in September 2023 on Pandemic Preparedness and Response Declaration recognised the need to support developing countries in building expertise and in developing local and regional manufacturing capacities for tools, including by building on efforts under the COVID-19 Vaccine Global Access (COVAX) Facility.

- CEPI has signed agreements with three organisations including Aspen and the Institut Pasteur Dakar (IPD), Africa’s first GMP vaccine manufacturing facility, with an additional facility to be announced.

- CEPI provided technical consultation for supply chain systems modelling by KU Leuven, in conjunction with industrial partners such as BioNTech and ICF.

- CEPI established new standards in partnership with the UK NIBSC and is also working on investigational stockpiles to assess the suitability of materials for interim stockpiles in collaboration with UNICEF, Gavi, and WHO.

Outside of an emergency response, more detailed discussions are needed between patent holders, manufacturers and recipient countries on the most important components of usable voluntary licences.

- The Medicines Patent Pool’s pandemic strategy should be supported by the G7, G20 and a broader coalition of companies to standardise the approach to voluntary licence usage in a pandemic.

- The RVXMC will continue to support engagement with ASEAN, LatAm and GCC regions in 2024, working to promote sustainable practices in manufacturing globally.

- Regional Vaccine Manufacturing diversification is part of the “vaccines ready” PPRR approach. Following the review of the Gavi strategy including the 4th pillar on the African Vaccine Manufacturing Accelerator (AVMA) and approval by the Board in December 2023, Gavi will design the full governance, legal and operational details of AVMA, during the first half of 2024 allowing for potential launch in June 2024 while continue collaboration with other pandemic recovery and PPRR initiatives (TBIC). CEPI is strategically establishing partnerships to prioritise rapid-response technology platforms funding, with a specific focus on sustainable manufacturing capacity building in LatAm and SE Asia.

- Pfizer is contributing to sustainable manufacturing by continuing its regional ‘Higher Height’ training programmes, in partnership with Ministries of Health, strengthening responsible and ethical production practices.

- An unsupplied workforce allows for adaptation and customisation of technologies to suit local needs, fostering a culture of continuous improvement.

Global manufacturers should work towards tertiarising their manufacturing processes in the long term.

**Planned partner commitments**

- RVXMC will share its multi-year implementation roadmaps to facilitate manufacturing efforts. It will continue to support engagement with ASEAN, LatAm and GCC regions.

- CEPI will establish strategic partnerships to prioritise rapid-response technology platforms funding at further sites in LatAm and SE Asia.

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<td>• Unlaid, in collaboration with the Global Fund, is supporting the development and piloting of pathways through the Expert Review Panel for Diagnostics (ERP-D) to facilitate an expedited regulatory review process for regionally manufactured diagnostics.</td>
<td>• WHO have developed a new prequalification system (ePQS) portal to enable manufacturers, National Regulatory Agencies and other stakeholders to lodge applications for products.</td>
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| Regionalised manufacturing of DTVs | - CERF provided technical and financial support to strengthen and develop manufacturing capabilities in LMICs, with agreements signed with 3 organisations over 2 regions, including a 10-year partnership with Bio Farma to boost rapid manufacturing of outbreak vaccines at Indonesia's leading vaccine manufacturer.207  
  - CERF launched funding calls for Mfg (CMC) innovations to enable equitable access via transitional products, and speed of manufacture. Approximately US$8 million has been awarded so far to fund proof-of-concept studies for novel microarray patches, solid dose and polymer nanoparticles, all applicable to mRNA or protein vaccine platforms205  
  - MPP has made significant progress on the mRNA Technology Transfer Programme, with the mRNA Technology Hub facility at Afrigen, South Africa completed and inaugurated. Afrigen has started knowledge transfer on laboratory scale production of AfriVac ZI2S as part of a fast track first step in an extensive technology transfer to capacitate 5 partners in LMICs206  
  - Pfizer received approval for its regulatory filing to the South Africa Health Products Regulatory Authority (SAPHRA) for COMIRNATY and received full approval as a supply node in 2022204  
  - The Canada-UK Biomanufacturing of Biologics and Advanced Therapies Fund was launched to invest up to £35m in developing and implementing innovative technologies for biomanufacturing207  
  - In April 2023, the Engineering and Physical Sciences Research Council (EPSRC), part of UK Research and Innovation (UKRI), announced a £12 million investment to fund the Future Vaccines Manufacturing Hub for the next seven years, up to 2030208  
  - GHIT Fund and MPP agreed a M4d to strengthen their collaboration to improve access to medicines. The partnership between the two organisations is designed to help improve global access to products, especially in LMICs210  
  - PATH’s Center for Vaccine Innovation and Access has supported manufacturers working toward national licensure and World Health Organization prequalification (PQ), including advancing multiple vaccines to the global marketplace through either PQ or Emergency Use Listing with two vaccines receiving PQ in 2023209  
  - Unitaid are collaborating with governments, organisations, and regional manufacturers to improve the profitability and competitiveness of diagnostic products and achieve WHO prequalification211  
  - The UK government announced an investment of £650 million in the ‘Life Sciences for Growth package’ to include funding for manufacturing, skills and infrastructure212  
  - CEPI provided technical and financial support to strengthen and develop manufacturing capabilities in LMICs, with agreements signed with 3 organisations over 2 regions, including a 10-year partnership with Bio Farma to boost rapid manufacturing of outbreak vaccines at Indonesia’s leading vaccine manufacturer.205  
  - CEPI launched funding calls for Mfg (CMC) innovations to enable equitable access via transitional products, and speed of manufacture. Approximately US$8 million has been awarded so far to fund proof-of-concept studies for novel microarray patches, solid dose and polymer nanoparticles, all applicable to mRNA or protein vaccine platforms205  
  - MPP has made significant progress on the mRNA Technology Transfer Programme, with the mRNA Technology Hub facility at Afrigen, South Africa completed and inaugurated. Afrigen has started knowledge transfer on laboratory scale production of AfriVac ZI2S as part of a fast track first step in an extensive technology transfer to capacitate 5 partners in LMICs206  
  - Pfizer received approval for its regulatory filing to the South Africa Health Products Regulatory Authority (SAPHRA) for COMIRNATY and received full approval as a supply node in 2022204  
  - The Canada-UK Biomanufacturing of Biologics and Advanced Therapies Fund was launched to invest up to £35m in developing and implementing innovative technologies for biomanufacturing207  
  - In April 2023, the Engineering and Physical Sciences Research Council (EPSRC), part of UK Research and Innovation (UKRI), announced a £12 million investment to fund the Future Vaccines Manufacturing Hub for the next seven years, up to 2030208  
  - GHIT Fund and MPP agreed a M4d to strengthen their collaboration to improve access to medicines. The partnership between the two organisations is designed to help improve global access to products, especially in LMICs210  
  - PATH’s Center for Vaccine Innovation and Access has supported manufacturers working toward national licensure and World Health Organization prequalification (PQ), including advancing multiple vaccines to the global marketplace through either PQ or Emergency Use Listing with two vaccines receiving PQ in 2023209  
  - Unitaid are collaborating with governments, organisations, and regional manufacturers to improve the profitability and competitiveness of diagnostic products and achieve WHO prequalification211  
  - The UK government announced an investment of £650 million in the ‘Life Sciences for Growth package’ to include funding for manufacturing, skills and infrastructure212  | Overarching end goals  
  - Governments, global health funders, and industry, should have collaborated to build expanded capacity for DTV manufacturing available to contribute to meeting regional demand in the event of an outbreak, and contributing to sustainable production in inter pandemic periods, adhering to international standards  
  - Manufacturing technology developed to enable flexibility of production to produce both routine and pandemic products  |
### TOPIC  |  RECOMMENDATION  |  2023 SUMMARY PROGRESS UPDATE  |  PROPOSED 2024 ACTIONS AND OVERARCHING GOALS
--- | --- | --- | ---
Regionalised manufacturing of DTVs | The IMF to explore expanding their Article IV consultation with member countries to include a pandemic preparedness assessment, and draw on the analysis and expertise of others. Concurrently, multilateral development banks continue to support investment to strengthen and prepare health systems and part of their core day-to-day business. | - Strides have been made in advancing the regionalisation of manufacturing through the eight pillar framework being developed by the World Economic Forum’s Regionalised Vaccine Manufacturing Collaborative (RVMC)212.  
- A joint study conducted by the Africa CDC, CHAI and PATH between December 2022 - March 2023 engaged 19 African manufacturers213.  
- Africa CDC hosted the Partnerships for African Vaccine Manufacturing (PAVM) Forum in which AU Member States technical experts met with African vaccine manufacturers and partners to garner consensus to establish a Platform for Harmonized African Health (Product) Manufacturing214.  
- PAVM established a Ministerial Working Group to support expanding the local manufacturing efforts beyond vaccines215.  
- PAVM champions the first manufacturer marketplace in Morocco resulting in AU Communiqué to prioritize procuring vaccines from African producers (and partners to procure 30% for global consumption), and acceleration mechanisms for WHO PQ216.
- G20 Joint Finance and Health Task Force (JFHTF) will set their priorities for governments to agree and implement in 2024, completing its work on surge financing  
- Pandemic Fund should attract increased contributions, involve regional authorities in granting decisions and where funds allow also welcome funding requests for medical countermeasure R&D  
- Gavi will launch a Day Zero Pandemic Financing Facility for Vaccines and agree IFJim contingent financing mechanisms by pre-positioning donor commitments to the IFJim  
- Funders and recipients are better coordinated to lead to greater coherence of effort, particularly in the therapeutics space  
- Engage in and contribute to relevant G7 and G20 discussions on solutions to pandemic response financing  
- Progress and finalize the IFJim Contingent Financing Mechanism, currently under development, including seeking necessary approvals  
- Operationalise the First Response Fund, including its Financing, treasury mgmt, etc and bring relevant considerations back before the Gavi Board.

Sustainable Pandemic Financing & Procurement for Equitable Access | Governments should build in conditions into DTV funding contracts for LMIC access to access DTVs at not for profit and scale, which is to be enacted if a PHEIC is declared. | The IMF reports progress in channeling special drawing rights (SDRs) to the Resilience and Sustainability Trust, a promising instrument for financing pandemic preparedness217.  
- The G20 Joint Finance and Health Ministerial Taskforce (JFHTF) continues to serve as a platform for enhanced collaboration between the Finance and Health sectors, to mitigate economic vulnerabilities and pandemic-related risks while improving preparedness for large-scale pandemic responses218. The 18th summit of the G20 leaders was held in New Delhi, India in September 2023219.  
- CEPI has commissioned the development of an integrated vaccine development costing and macro-economic benefits model to understand the optimal combination and interconnection of preparedness and surge investments in a crisis220.  
- At the G7 Hiroshima Summit, the G7 announced the “the G7 Hiroshima Vision for Equitable Access to Medical Countermeasures (MCMs)” and reconfirmed the “the G7 Hiroshima Vision for Equitable Access to Medical Countermeasures (MCMs)” and reconfirmed the importance of ensuring equitable access to MCMs including therapeutics and vaccines throughout the world221.
- Engage in and contribute to relevant G7 and G20 discussions on solutions to pandemic response financing  
- Progress and finalize the IFJim Contingent Financing Mechanism, currently under development, including seeking necessary approvals  
- Operationalise the First Response Fund, including its Financing, treasury mgmt, etc and bring relevant considerations back before the Gavi Board.

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221. CEPI pro forma.
### PROPOSED 2024 ACTIONS AND OVERARCHING GOALS

**Sustainable Pandemic Financing & Procurement for Equitable Access**

24. As part of countries’ bilateral DTV procurement, any advance purchase agreements with manufacturers should include a requirement for products provided to LMICs to be provided at not for profit. This must also be done within a similar timeframe to when HICs are supplied.

25. Multilateral development bank loans should be made available so LMICs can purchase DTVs above the 30% provided through the DTV financing facility in line with recommendation.

- Gavi has developed the Day Zero Financing Facility (DZF), a suite of financing tools that will enable the Alliance to deliver a rapid and more equitable end-to-end vaccine response in the next pandemic. It consists of two elements that complement each other: (1) a new First Response Fund that will enable funds to be deployed faster than any other mechanism in Gavi’s ERRT toolkit, and (2) the expansion of the use and effectiveness of Gavi’s existing surge financing mechanisms so that they can be used beyond COVID-19 (including an adapted EIB Frontloading Facility and DFC Rapid Financing Facility), and the under-development IFFIm Contingent Financing Mechanism.

- The Pandemic Fund awarded its first round of grants in after a call for proposals which received 179 applications from 133 countries.

- In its Dec. 23 meeting the Gavi Board approved the amendments to the DFC and EIB facilities that allow them to be used beyond COVID-19. The Board additionally approved the financing of a First Response Fund of up to US$ 500 million, under Gavi’s Day Zero Financing Facility, contingent on the available funding from the COVAX AMC Pandemic Vaccine Pool (PVP).

- Global funds for medical countermeasures should be available so LMICs can purchase DTVs above the 30% provided through the DTV financing facility in line with recommendation.

- Multilateral development bank loans should be made available so LMICs can purchase DTVs above the 30% provided through the DTV financing facility in line with recommendation.

**OVERARCHING END GOALS**

- Globally agreed pre-PHEIC triggers automatically enable the release of financing to support countries to respond to outbreaks.

- Procurement agreements that foreclose equitable access to DTVs are established between manufacturers and procurers such as Gavi and Unitaid and are implemented before an outbreak occurs.

- Innovative financing tools are in place to channel funds and meet the immediate needs for vaccines within the first 100 days of a pandemic.

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Annex B: Secretariat Governance detail

STEERING GROUP

The Secretariat is led by a small Steering Group which provides oversight, accountability and strategic direction. The Steering Group meets on a quarterly basis and comprises representatives from the following organisations:

- World Health Organization (WHO)
- Wellcome Trust
- Bill and Melinda Gates Foundation (BMGF)
- International Federation of Pharmaceutical Manufacturers & Associations (IFPMA)

Science and Technology Expert Group (STEG) Co-Chairs

- Patrick Vallance, Former UK Chief Scientific Adviser (Independent Chair)
- Professor John-Arne Røttingen, Ambassador for Global Health at the Ministry of Foreign Affairs Norway

SCIENCE AND TECHNOLOGY EXPERT GROUP

The Science and Technology Expert Group (STEG) provides technical input to the Secretariat. Reporting to the Steering Group, it delivers an assurance function for the annual report against the 100D recommendations and galvanises support from the scientific community on pandemic preparedness through meetings, working groups, and assessments. It has subgroups focusing on specific issues, including diagnostics, therapeutics, manufacturing, clinical trials and regulatory matters, and R&D coordination.

Membership was drawn from an open global nominations process and includes members from a wide range of regions and sectors. Its members include:

- Dr Victor Dzau, President of the National Academy of Medicine USA (Co-chair)
- Shingalai Machigaidze, Ag Chief Science Officer, Africa CDC Zimbabwe (Co-chair)
- Dr Rick Bright, Bright Health, Former Director of BARDA USA
- Dr José Castillo, CTO at Universiti & CEO at Quantum Biosciences Spain
- Professor Tan Chorh Chuan, Chief Health Scientist, Ministry of Health, Singapore Executive Director, NMH Office for Healthcare Transformation Singapore
- Dr Ruxandra Draghia-Akli, Global Head at Johnson & Johnson Global Public Health R&D USA
- Dr Rennes Eardley Patel, Ag Chief of Staff, CERI Manufacturing & Supply Chain division UK
- Dr Jorge Luis Castillo, Dean of the School of Medicine and Biotechnology, University of Chinese Academy of Sciences China
- Professor Ken Ishii, Director of the International Research and Development Center for Mucosal Vaccines, University of Tokyo Japan
- Dr Yenew Kebede, Head, Division of Laboratory Systems & Networks at Africa CDC Ethiopia
- Dr Lalith Kishore, Head of Research and Development at Sanofi Vaccines France
- Dr José Castillo, CTO at Universiti & CEO at Quantum Biosciences Spain
- Dr Umesh Shaligram, Former Secretary of the Department of Biotechnology, Ministry of Science & Technology, Government of India
- Dr Niteen S Wairagkar, Founder and CEO, Vaccines for All, Consultant for Africa CDC Partnership for Africa Vaccine Manufacturing, Consultant in Vaccine Development at CERI India
- Dr Mariângela Simão, Former WHO Assistant Director-General for Drug Access Vaccines and Health R&D USA
- Dr Daniel Bausch, Head of Research and Development at Sanofi Vaccines France
- Dr Emmanuel Agojo, CTO at Univercells & CEO at Quantoom Biosciences Spain
- Dr Ruxandra Draghia-Akli, Dean of the School of Medicine and Biotechnology, University of Chinese Academy of Sciences China
- Dr Amadou Sall, CEO of Institut Pasteur de Dakar Senegal
- Professor Teresa Lambe OBE, Professor of Vaccinology and Immunology at the University of Oxford UK
- Dr Umesh Shaligram, Former Secretary of the Department of Biotechnology, Ministry of Science & Technology, Government of India

STEG COORDINATION SUBGROUP

- Dr Rennen Eardley Patel, Former Secretary of the Department of Biotechnology, Ministry of Science & Technology, Government of India

THERAPEUTICS SUBGROUP

- Dr Ranna Eardley Patel, Head, Division of Laboratory Systems & Networks at Africa CDC, Ethiopia
- Dr Charles Howes, MPhD
- Dr Sujat Chheda, MPhD
- Dr Peter Szucs, MPhD

DIAGNOSTICS SUBGROUP

- Dr Rick Bright, CEO, Bright Global Health, Former Director of BARDA USA
- Professor George Gas, Dean of the School of Public Health and Sheikh Hamad Bin Khalifa University Professor, University of Qatar Qatar
- Dr Daniel Bausch, Head of Research and Development at Sanofi Vaccines France
- Dr Emmanuel Agojo, CTO at Univercells & CEO at Quantoom Biosciences Spain
- Dr Mariângela Simão, Former WHO Assistant Director-General for Drug Access Vaccines and Health R&D USA
- Dr Yenew Kebede, Head, Division of Laboratory Systems & Networks at Africa CDC Ethiopia
- Dr Ranna Eardley Patel, Head, Division of Laboratory Systems & Networks at Africa CDC, Ethiopia

SUSTAINABLE MANUFACTURING SUBGROUP

- Dr José Castillo, CTO at Universiti & CEO at Quantum Biosciences Spain
- Dr Umesh Shaligram, Executive Director, Serum Institute of India Private Limited India
- Dr Ranna Eardley Patel, CEO of Institut Pasteur de Dakar Senegal
- Dr Ruxandra Draghia-Akli, Head, Division of Laboratory Systems & Networks at Africa CDC, Ethiopia
- Dr Professor Mayumi Shikano, Professor at Tokyo University of Science Japan
- Dr Professor John-Arne Røttingen, Ambassador for Global Health at the Ministry of Foreign Affairs Norway
- Dr Professor Victor Dzau, President of the National Academy of Medicine USA (Co-chair)
- Shingalai Machigaidze, Ag Chief Science Officer, Africa CDC Zimbabwe (Co-chair)
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- Professor Tan Chorh Chuan, Chief Health Scientist, Ministry of Health, Singapore Executive Director, NMH Office for Healthcare Transformation Singapore
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- Dr Jorge Luis Castillo, Dean of the School of Medicine and Biotechnology, University of Chinese Academy of Sciences China
- Dr Umesh Shaligram, Former Secretary of the Department of Biotechnology, Ministry of Science & Technology, Government of India

SCIENCE AND TECHNOLOGY EXPERT GROUP SUBGROUPS

To address the challenges highlighted in last year’s report five subgroups were formed, composed of STEG members and experts drawn from international organisations, civil society, industry, regional and national partners.

Its members are as follows:

UK
- Dr Ranna Eardley Patel, Head of Research and Development at Sanofi Vaccines France
- Dr Ruxandra Draghia-Akli, Dean of the School of Medicine and Biotechnology, University of Chinese Academy of Sciences China
- Dr Shingai Machingaidze, Ag Chief Science Officer, Africa CDC

India
- Dr Umesh Shaligram, Former Secretary of the Department of Biotechnology, Ministry of Science & Technology, Government of India

USA
- Dr Ranna Eardley Patel, Head, Division of Laboratory Systems & Networks at Africa CDC, Ethiopia
- Dr Charles Howes, MPhD
- Dr Sujat Chheda, MPhD
- Dr Peter Szucs, MPhD

France
- Dr Amadou Sall, CEO of Institut Pasteur de Dakar Senegal

China
- Dr Professor Mayumi Shikano, Professor at Tokyo University of Science Japan
- Dr Professor John-Arne Røttingen, Ambassador for Global Health at the Ministry of Foreign Affairs Norway

UK
- Dr Ranna Eardley Patel, Head, Division of Laboratory Systems & Networks at Africa CDC, Ethiopia
- Dr Charles Howes, MPhD
- Dr Sujat Chheda, MPhD
- Dr Peter Szucs, MPhD

Brazil
- Dr Ranna Eardley Patel, Head, Division of Laboratory Systems & Networks at Africa CDC, Ethiopia
- Dr Charles Howes, MPhD
- Dr Sujat Chheda, MPhD
- Dr Peter Szucs, MPhD

Spain
- Dr Ranna Eardley Patel, Head, Division of Laboratory Systems & Networks at Africa CDC, Ethiopia
- Dr Charles Howes, MPhD
- Dr Sujat Chheda, MPhD
- Dr Peter Szucs, MPhD

China
- Dr Ranna Eardley Patel, Head, Division of Laboratory Systems & Networks at Africa CDC, Ethiopia
- Dr Charles Howes, MPhD
- Dr Sujat Chheda, MPhD
- Dr Peter Szucs, MPhD

India
- Dr Ranna Eardley Patel, Head, Division of Laboratory Systems & Networks at Africa CDC, Ethiopia
- Dr Charles Howes, MPhD
- Dr Sujat Chheda, MPhD
- Dr Peter Szucs, MPhD

Sustainable Manufacturing Subgroup

- Dr Jose Castillo, CTO at Universiti & CEO at Quantum Biosciences Spain
- Dr Umesh Shaligram, Executive Director, Serum Institute of India Private Limited India
- Dr Ranna Eardley Patel, CEO of Institut Pasteur de Dakar Senegal
- Dr Ruxandra Draghia-Akli, Head of Research and Development at Sanofi Vaccines France
- Dr Niteen S Wairagkar, Founder and CEO, Vaccines for All, Consultant for Africa CDC Partnership for Africa Vaccine Manufacturing, Consultant in Vaccine Development at CERI India

Clinical Trials and Regulatory Processes Subgroup

- Dr Professor Mayumi Shikano, Professor at Tokyo University of Science, Japan
- Dr Shingalai Machigaidze, Ag Chief Science Officer, Africa CDC
- Professor John-Arne Røttingen, Ambassador for Global Health at the Ministry of Foreign Affairs, Norway
- Dr Adam Hacker, Director and Head of Global Regulatory Affairs at CERI
- Professor Sir Dany Landing, GCTE
- Dr Vsase Hasmury, WHO
Annex C:

Additional Contributors

The Secretariat would like to extend their thanks to representatives of all organisations listed below who have contributed to the 2023 100DM implementation report and ongoing efforts to prepare medical countermeasures for pandemic response.

ADDITIONAL CONTRIBUTORS

1 Day Sooner
Africa CDC
African Medicine Agency (AAMA)
African Union Development Agency-NEPAD (AUDA-NEPAD)
AfriGen Biologics
Arfinity Ltd
Bill & Melinda Gates Foundation (BMGF)
BioNTech
Cumming Global Centre for Pandemic Therapeutics (GGCPT)
Data.org
Development Alternatives Incorporated (DAI) Fleming Fund Indonesia
Drugs for Neglected Diseases Initiative (DNDi)
Duke-NUS Medical School, Singapore
European Commission
European Investment Bank
European Medicine Agency (EMA)
Foundation for Innovative New Diagnostics (FIND)
Gavi
Global Health Innovative Technology (GHIT) Fund
Global Health Technologies Coalition (GHTC)
Global Research Collaboration for Infectious Disease Preparedness (GloPID-R)
Good Clinical Trials Collaborative (GCTC)
Government of India
Government of Japan
Health Poverty Action
Institut Pasteur de Dakar (IDP)
International AIDS Vaccine Initiative (IAVI)
International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH)
International Federation of Pharmaceutical Manufacturers and Associations (IFPMA)
INTREPID Alliance
Japan Agency for Medical Research and Development (AMED)
Johnson & Johnson Global Public Health R&D
Leipzig University
Medicines Sans Frontières (MSF)
Medicines Patent Pool (MPP)
Regeneron
Regionalised Vaccine Manufacturing Collaborative (RVHC)
RESULTS UK
Sanofi
Science for Africa Foundation
Serum Institute of India Private Limited
Singapore Government
SPRING
Strategic Center of Biomedical Advanced Vaccine Research and Development for Preparedness and Response (SCARDA)
The Centre for Cellular and Molecular Platforms Indigenisation of Diagnostics (CCAMP-InDx) Program
The Coalition for Epidemic Preparedness Innovations (CEPI)
The Oswaldo Cruz Foundation (Fiocruz)
UK Government
UNICEF
University College London
University of Oxford
US Government
Vaccines for All
Wellcome
World Health Organization (WHO)

Annex D:

Methodology

This report provides detailed coverage of progress against the 100DM and each of the 25 recommendations (from January to December 2023), based on three data sources, collected in Q4 of 2022:

Desk research for relevant documents and datasets
Structured interviews with key global health and PPR stakeholders
30+ Pro-forma surveys from key stakeholders (listed in contributors)

DESK RESEARCH FOR RELEVANT DOCUMENTS AND DATASETS

Sources for desk research includes (but is not limited to):

- Implementation and strategy reports of key initiatives related to PPR
- Updated guidelines, protocols, and frameworks from regulatory authorities
- Press releases and publications from international organisations
- Resolutions and agreements from international governance forums
- Annual reports and press releases from relevant private sector organisations
- Peer reviewed research literature from academic institutions
- External evaluations of international progress towards PPR

COLLECTION OF PRO-FORMA SURVEYS FROM KEY STAKEHOLDERS

Written input was requested from implementation partners through standardised pro-formas across the following topics:

- Progress in 2023
- Plans to take forward 100DM and proposed milestones
- Alignment of 100DM with ongoing priorities and approach to implementation
- Organisations identified as collaborators and engagement framework
- Barriers, risks, and enablers to achieving 100DM by 2026
- Future path, progress indicators and what constitutes a successful outcome

The draft report was reviewed by key implementation partners who provided input and was finalised with input from the Secretariat Steering Group and STEG.
## Annex E:
### Definition of 100DM Scorecard Indicators

<table>
<thead>
<tr>
<th>INDICATORS</th>
<th>CATEGORY</th>
<th>DEFINITION</th>
<th>SOURCE</th>
</tr>
</thead>
<tbody>
<tr>
<td>R&amp;D funding for diagnostics, vaccines and therapeutics (DTV)</td>
<td>Now</td>
<td>This indicator shows the total R&amp;D funding invested by disease between 2019 and 2022 broken down by donor.</td>
<td>G-FINDER R&amp;D funding data1</td>
</tr>
<tr>
<td>Approved products (as of 2022)</td>
<td>Now</td>
<td>This indicator shows where vaccines, diagnostics and therapeutics have been approved for use for each disease. Approved products were defined as inhaled pharmaceutical products, drugs, vaccines, biologics, or diagnostics that had been granted a marketing authorisation by a medicines regulatory authority or had obtained WHO prequalification. A preliminary list of approved products was identified through a normative literature review of treatment guidelines, WHO position papers, and essential medicines and diagnostic list databases. This preliminary list was then cross-referenced against regulatory authority databases. The outer section of the visualisation also shows where products have been approved for use in LMICs. LMIC approval was defined as a product being approved by a National Regulatory Authorities (NRAs) of vaccine producing countries of maturity level 3 or above (as defined by WHO Listed Authorities framework) or has WHO prequalification.</td>
<td></td>
</tr>
<tr>
<td>Clinical candidates tested in humans (as of 2022)</td>
<td>Future</td>
<td>This indicator shows the number of candidates for each disease that are being tested in humans. These are broken down by R&amp;D stage and include Phase I,II,III for vaccines and therapeutics and late-stage development for diagnostics. Candidates were defined as potential drugs, vaccines, vector control products, diagnostics, or platform technologies, currently under investigation that had yet to be approved by a medicines regulatory authority.</td>
<td></td>
</tr>
<tr>
<td>Platform technologies</td>
<td>Future</td>
<td>This indicator shows if platform technologies are being used to develop clinical candidates. The outer section shows where multiple technologies [i.e., &gt;3] are being applied to the pipeline. The platform technology category includes vaccine, drug, and biologics platforms; adjuvants and immunomodulators; and general diagnostic platforms.</td>
<td>Policy Cures Research’s updated infectious disease R&amp;D tracker data, and additional data sources for COVID-19</td>
</tr>
<tr>
<td>Use of animal rule to support licensure (as of 2022)</td>
<td>R&amp;D enablers</td>
<td>This indicator shows where the animal rule, has been used to support product licensure. The animal rule is a principle for an alternative licensure pathway to allow for the approval of drugs and biological products when human efficacy studies are not feasible and is instead based on well-controlled animal studies, when the results of those studies establish that the drug or biologic product is reasonably likely to produce clinical benefit in humans.</td>
<td>US FDA8 and EMA9</td>
</tr>
<tr>
<td>Generally accepted correlates of protection</td>
<td>R&amp;D enablers</td>
<td>This indicator shows where there are generally accepted correlates of protection as defined by CEPI.</td>
<td>CEPI10</td>
</tr>
<tr>
<td>WHO Target Product Profiles (TPPs)</td>
<td>R&amp;D enablers</td>
<td>This indicator shows which diseases have active WHO Target Product Profiles for vaccines, diagnostics and therapeutics.</td>
<td>Policy Cures Research’s updated infectious disease R&amp;D tracker data and WHO TPP directory11</td>
</tr>
<tr>
<td>R&amp;D funding for platform technologies</td>
<td>Disease X</td>
<td>This indicator shows total R&amp;D funding invested into platform technologies between 2019 and 2022 broken down by donor. WHO recognises ‘Disease X’ as an unknown pathogen that could cause a serious international epidemic. In G-FINDER this is captured as non-disease-specific R&amp;D, for this indicator it includes the following categories: Therapeutic platforms include drug and biologic delivery platforms; Vaccines include vaccine platform and adjuvants and immunomodulators.</td>
<td>G-FINDER R&amp;D funding data1</td>
</tr>
</tbody>
</table>

1. https://gfinderdata.policycuresresearch.org/
2. https://www.who.int/publications/i/item/9789240019102
7. Castillo-León et al. (2021), “Commercially available rapid diagnostic tests for the detection of high priority pathogens: status and challenges” | DOI:10.1039/D0AN02286A
Glossary of Terms

100DM – 100 Days Mission, A global public-private effort to harness scientific and clinical capabilities to have safe and effective diagnostics, therapeutics, and vaccines (DTVs) ready to be deployed within the first 100 days of a future pandemic threat being identified and be ready to do so equitably by 2026.

ACT-A – Access to COVID-19 Tools Accelerator, A global collaboration launched in April 2020 to accelerate the development, production, and equitable access to COVID-19 tests, treatments, and vaccines.

ADVANCE-Id – Advancing Clinical Evidence in Infectious Diseases, A global network for infectious disease clinical studies that aims to conduct rapid, cost-effective randomised controlled trials to deliver relevant and high-quality evidence to guide clinical practice.

AFCAD – Africa Collaborative Initiative to Advance Diagnostics, A strategic partnership between the Africa Centres for Disease Control and Prevention; African Society for Laboratory Medicine; Institut de Recherche, de Surveillance Épidémiologique et de Formation; WHO-AFR; Clinton Health Access Initiative; African Field Epidemiology Network; UNITAID, and other partners to increase access to quality diagnostics towards the achievement of universal health coverage in Africa.

Africa CDC – The Africa Centres for Disease Control and Prevention, A continental autonomous health agency of the African Union established to support public health initiatives of member states and strengthen the capacity of their public health institutions to detect, prevent, control and respond quickly and effectively to disease threats.

AHRI – Africa Health Research Institute, An independent, transdisciplinary science platform based across two campuses in the province of KwaZulu-Natal (KZN) in South Africa.

AI – Artificial Intelligence, Intelligence demonstrated by machines.

AMISD – African Medicines Regulatory Harmonisation, A programme started in 2009 as a response to addressing challenges faced by National Medicines Regulatory Authorities (HMAs) in Africa.

AMA – African Medicines Agency, A Specialized Agency of the African Union (AU) dedicated to improving access to quality, safe and efficacious medical products in Africa.

AMED – Japan Agency for Medical Research and Development, An independent Japanese medical research and development organization.

Antiviral therapeutics – Therapeutics to treat or prevent viral infections.

Avvisa – The Brazilian Health Regulatory Agency.

AUC – The African Union Commission, The African Union’s secretariat which undertakes the day to day activities of the Union.


AVAREF – The African Vaccine Regulatory Forum, A network of African national regulatory authorities and ethics committees that uses harmonisation and reliance as pillars for capacity building.

AVOID – Antiviral Drug Discovery Centers for Pathogens of Pandemic Concern, A set of research centres funded by the U.S. National Institutes of Health as part of the Antiviral Program for Pandemics.

BARDA – Biomedical Advanced Research and Development Authority, An authority within the U.S. Department of Health and Human Services, uses the development of medical countermeasures for public health medical emergencies.

BMGF – Bill and Melinda Gates Foundation, A global foundation focused on helping all people lead healthy, productive lives.

C-CAMP Index 2.0 – The Centre for Cellular and Molecular Platforms Indigenisation of Diagnostics Program, A program launched in August 2020 to boost India’s preparedness for current & future pandemics, scale-up diagnostics for infectious diseases for COVID & beyond.

CEPI – Coalition for Epidemic Preparedness Innovations, A global partnership between public, private, philanthropic, and civil organisations launched to accelerate the development of vaccines and other biological countermeasures against epidemic and pandemic threats so they can be accessible to all people in need.

CHAI – Clinton Health Access Initiative, A global health organisation committed to saving lives and reducing the burden of disease in low- and middle-income countries.

Clinical trial – A prospective research study on human participants designed to answer specific questions about biomedical or behavioural interventions, including DTVs. Clinical trials generate data on dosage, safety and efficacy.

CLN – Centralized Laboratory Network.

CMC – Chemistry, manufacturing, and control.

COVAX – COVID-19 Vaccines Global Access, The vaccine pillar of ACT-A, co-led by Gavi and CEPI. It houses the COVAX Facility, a COVID-19 vaccine procurement pool led by Gavi and CEPI.

COVID-19 – The disease caused by the virus SARS-CoV-2.

CPHIA – International Conference on Public Health in Africa, The annual International Conference on Public Health in Africa (CPHIA) provides a unique African-led platform for leaders across the continent to reflect on lessons learned in health and science, and align on a way forward for creating more robust health systems.

CSA – Chief Scientific Adviser (or Chief Scientific Adviser equivalent) of a government.

C-TAP – COVID-19 Technology Access Pool, A single global platform for the developers of COVID-19 therapeutics, diagnostics, vaccines and other health products to share their intellectual property, knowledge, and data with quality-assured manufacturers, and provides support for technology transfer agreements.

CTC – Clinical Trials Community Platform, A platform that enable the identification of African clinical trials sites by providing access to African clinical trials, site feasibility data and regulatory and ethics information.

CTCAN – Clinical Trials Community Africa Network, A project that seeks to enable increased sustainable, and coordinated clinical trials on the African continent.

DAI – Development Alternatives Incorporated Fleming Fund Indonesia, A collaboration with the Indonesian government to strengthen systems using a “One Health” approach.

DCVMN – Developing Countries Vaccine Manufacturer Network, An international public health driven industry association of vaccine manufacturers from developing countries.


DHSC – UK’s Department for Health and Social Care, A department in UK Government responsible for government policy on health and adult social care.

Diagonstics – Products which diagnose diseases, commonly known as tests.

Disease – A deviation from normal healthy functioning, in this report typically refers to infectious diseases that affect humans.

Disease X – Term that represents the knowledge that a serious international epidemic could be caused by a pathogen currently unknown to cause human disease.

DNDS – Drugs for Neglected Diseases initiative, A not-for-profit research organisation developing new treatments for neglected patients.

DRIVe – Division of Research, Innovation, and Ventures, A programme set up by BARDA to form unique public private partnerships and funds early stage companies for life saving innovation.

DTVs – Diagnostics, Therapeutics and Vaccines.

DZF – Day Zero Pandemic Financing Facility for Vaccines, A facility set up by Gavi that aims to ensure that funds for response will be available from the outset in future pandemics.


ECRAID – European Clinical Trial Network for Infectious Diseases, A legal framework providing access to a pan-European clinical trial network.

ECDTP – The European & Developing Countries Clinical Trials Partnership, A public-private partnership between countries in Europe and sub-Saharan Africa, supported by the European Union.

EIOS – Epidemiological Intelligence from Open Sources, A collaboration between various international public health stakeholders. It uses publicly available information to bring together new and existing initiatives, networks and systems to strengthen public health intelligence (PHI) by creating a unified all-hazards, One Health approach to early detection, verification, assessment and communication of public health threats.

Epidemic disease – A disease that affects a large number of people within a region, population or community.

ePaaS – An IT solution that brings all core areas of work of WHO’s Prequalification Unit into one centralised platform including WHO’s collaborative procedures and complaints testing.

EPSCRC – Engineering and Physical Sciences Research Council, The main UK government agency for funding research and training in engineering and the physical sciences.

Equitable access – The notion that with equal needs have equal access. In this report usually referring to DTVs such that DTVs are readily available to people affected by a public health emergency.

EUL – Emergency Use Licensing, A WHO procedure for assessing and listing vaccines with the aim of making them more readily available to people affected by a public health emergency.

FDA – Food and Drug Administration, A federal agency of the US Department of Health and Human Services responsible for protecting and promoting public health.

FINO – Foundation for Innovative New Diagnostics, An organisation aiming to ensure equitable access to reliable diagnostics around the world.

G20 – The Group of 20, A forum for international economic cooperation between 19 countries and the European Union.

G7 – The Group of 7 nations, A intergovernmental organisation consisting of Canada, France, Germany, Italy, the United Kingdom, the United States, Japan and the European Union.

Gavi – The Vaccine Alliance, An organisation aiming to increase access to immunisation in developing countries. Formerly the Global Alliance for Vaccines and Immunisation.

GCP – Good Clinical Practice, A set of internationally recognised ethical and quality requirements that must be followed when designing, conducting, recording and reporting clinical trials that involve people.

GTCT – Good Clinical Trials Collaborative, A partnership launched in June 2020 to develop guidance to enable and promote innovative, ethical and efficient randomised controlled trials.

Genomic sequencing – A scientific methodology to identify the genetic material found in an organism or virus.

Genomic surveillance – The collection of statistically significant genomic sequence data to represent populations. Genomic sequence data is then compared to help track the spread of a virus, detect new variants, and monitor trends in circulating variants.

GET – Global EISOs Trainers Team, An international team of expert trainers set up by the EISOs, to enhance the capacity to use EISOs tools effectively around the globe.

GHT – Global Health Innovative Technology Fund, An international public-private partnership between the Government of Japan, 16 pharmaceutical and diagnostics companies, the Bill & Melinda Gates Foundation, the Wellcome Trust and United Nations Development Programme.

Global Fund – An international financing and partnership organisation fighting AIDS, Tuberculosis and Malaria epidemics.

GloPID-R – Global Research Collaboration for Infectious...
Disease Preparedness, A global coalition of research funders, aiming to increase preparedness and speed up the research response to outbreaks with pandemic potential

CoPDA – Global Pandemic Data Alliance, An alliance formed in September 2021 to drive forward implementation of the CoPDA recommendations to improve safe data access and use for health emergencies

CVRC – Clinical Vaccine Research Collaborative, An event held in June 2023 and co-ordinated by the Department of Pharmaceuticals, Government of India, PATH, and CERHR

HDT – Host-directed therapy

HERA – Health Emergency Preparedness and Response Authority, An EU department launched in 2020 to improve Europe’s capacity and readiness to respond to health emergencies

HHS – US Department of Health & Human Services, A cabinet-level executive branch department of the US federal government created to protect the health of the US people and providing essential human services

HICs – High-Income Countries

IAVI – International AIDS Vaccine Initiative, A non-profit scientific research organisation that develops vaccines and antibodies for HIV, tuberculosis, emerging infectious diseases (including COVID-19), and neglected diseases

ICH – International Council for Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use, An initiative bringing together regulatory authorities and the pharmaceutical industry to increase harmonisation through development of technical guidelines and requirements across the pharmaceutical product lifecycle

ICMR – National Centre for Disease Control and Prevention, A public health organisation responsible for the prevention and control of communicable diseases

IFPMA – International Federation of Pharmaceutical Manufacturers & Associations, An international industry association representing research-based pharmaceutical companies and associations

IHR – International Health Regulations, A binding instrument of international law last revised in 2005 to prevent, protect against, and control a public health response to the international spread of disease

I-MED-Net – Medical Countermeasures Network, An end-to-end medical countermeasures platform for the rapid development of, and equitable access to, pandemic tools

IMIF – International Monetary Fund, An international financial agency formed by the promoters of global growth through financial stability and monetary cooperation

Infectious diseases – Diseases caused by pathogens that can be spread from person to person

INTREPID Alliance – A research-based pharmaceutical industry initiative to discover and develop antivirals for future pandemics

IPD – Institut Pasteur Dakar, A non-profit foundation of public utility, dedicated to promoting public health and well-being in West Africa

IPSN – International Partnership for Drug Discovery, A global network of pathogen and genomic actors, brought together by the WHO Hub for Pandemic and Epidemic Intelligence, to accelerate progress in pandemic prevention, preparedness, and response, thus ensuring that the international community is better prepared in the eventual case of future health threat outbreaks

LMICs – Low- and Middle-Income Countries

MABS – Monoclonal antibodies

MCPD – Monoclonal Delivery Platform, A public partnership on the G7 Hiroshima Vision for Equitable Access to mAbs, that aims to coordinate and mobilise financing for production, procurement, and delivery of mAbs

MDM – Multilateral Development Bank, An international financial institution chartered by two or more countries, with a purpose to encourage economic development in developing countries


MR – Multi-stakeholder Roundtable, A collaborative group of stakeholders to determine and prioritise pandemic preparedness and response strategies

MRA – Ministry of Research, Innovation and the Digital Economy, An Australian government department responsible for driving innovation and growth in the economy

MoC – Memorandum of Cooperation, The consultation on matters of common interest to coordinate their activities and to avoid duplication of efforts, as appropriate

MoE – Memorandum of Understanding, A cooperative agreement between two parties that can include general terms and goals and is not intended to be legally binding

MPP – Medicines Patent Pool, A United Nations-backed public health organisation working to increase access to and facilitate the development of life-saving medicines for LMICs

mRNA – Messenger ribonucleic acid in vaccines it stimulates/teaches cells to make a specific protein which generates an immune response

NIAd – US National Institute of Allergy and Infectious Diseases, One of the 27 institutes and centres that make up the US National Institutes of Health, focused on conducting and supporting research to better understand, treat, and ultimately prevent infectious, immunologic, and allergic diseases

NIH – US National Institutes of Health, A medical research centre in the US Department of Health

NVP – New Variant Assessment Platform, A platform set up by the UK government (UKHSA) that deploys the UK’s sequencing and viral assessment capabilities to help other countries to build their genomic surveillance capacity and capability to effectively identify, assess and track new COVID-19 variants and is now expanding to cover other pathogens of pandemic potential

ODA – Official Development Assistance, Funding provided by official agencies around the world to promote the economic development and welfare of developing countries

One Health Approach – A collaborative, multi-stakeholder, and transdisciplinary approach, working at the local, regional, national, and global levels, with the goal of achieving optimal health outcomes recognising the interconnection between people, animals, plants, and their shared environment

OUCRU – Oxford University Clinical Research Unit, A locally driven research programme on infectious diseases in Southeast Asia with local, regional, and global impact on health

PAHO – Pan-American Health Organisation, The specialised international health agency for the Americas

PAND – Pandemic Antiviral Discovery, A research funding initiative created by BMGF, the Novo Nordisk Foundation, and Open Philanthropy

PAHO – Pan-American Health Organisation, The specialised international health agency for the Americas

PANP – Pandemic Preparedness Platform, A platform to prevent and treat infectious disease through supporting research, teaching and public health initiatives through partnerships with international scientific authorities

PATH – An international, non-profit global health organisation that aims to accelerate health equity

Pathogen – An organism causing disease to its host

PAVM – Partnership for African Vaccine Manufacturing, A partnership owned to strengthen the African vaccine manufacturing ecosystem and set Africa on the path to locally manufacture 60 percent of the continent’s routine immunisation needs by 2040

PDDF – Pathogen Disease Development File

PHEIC – Public Health Emergency of International Concern, A formal declaration by the WHO of an outbreak of a disease that is a public health risk that can spread between many countries and require an international response

Platform trials – A clinical trial with a single master protocol in which multiple treatments are evaluated simultaneously, with mechanisms to add and remove new treatments throughout the trial

PPI – Pandemic Preparedness and Response

Priority pathogens – A list of diseases and pathogens prioritised for R&D in public health emergency contexts by the WHO R&D Blueprint team, due to be updated in early 2023

Programmable technologies – Denotes the transformative impact of new technology platforms and approaches, like mRNA, which allow scientists to rapidly amend medical tools to respond to a specific pathogen

Prototype diagnostic/therapeutic/vaccine – Broad-spectrum or generic DTVs developed in response to a class of pathogen e.g., coronavirus, that could be rapidly adapted to respond to a specific type of pathogen e.g., COVID-19

Prototype pathogen – Pathogen groups or families with similar characteristics, against which it is possible to produce prototype DTVs

PTMF – Platform Technology Master File

PVF – Pandemic Vaccine Pool

R&D – Research and Development

RCT – Randomised Controlled Trial, A trial in which subjects are randomly assigned to one of two groups (the experimental group) receiving the intervention that is being tested, and the other (the comparison group or control) receiving an alternative conventional treatment

RTD – Rapid Diagnostic Test, A medical diagnostic test that is easy to use and provides quick results, typically in 20 minutes or less

READDI – Rapidly Emerging Antiviral Drug Development Initiative, A global non-profit initiative aiming to develop new broad-spectrum antiviral drug solutions against viral diseases of pandemic potential

RECOVERY – Trial Randomised Evaluation of COVID-19 Therapy, A randomised evaluation of COVID-19 therapy, large-scale clinical trials of possible treatments for severe COVID-19 infection

RP – Request for proposals

Rules of the road – Denotes expected protocols of behaviour and collaboration for use in a pandemic context. These protocols should form part of a wider suite of guidance WHO sets out for (for instance, covering travel and PPE) which must be agreed in advance and demonstrate a step-change from business as usual when a PHEIC is declared

RVNC – Regionalised Vaccine Manufacturing Collaborative, A WHO-supported Coalition launched in 2022 to close the Global Vaccine Equity Gap by promoting a new model of Regionalized Vaccine Manufacturing
Glossary of Terms

SAHPRA - South African Health Products Regulatory Authority, An entity of NDOH created by the SA government to ensure that health and well-being of humans and animals health are at its core

SCARDA – Strategic Center of Biomedical Advanced Vaccine Research and Development for Preparedness and Response, A vaccine-research initiative funded by the Japanese government

SDR – Special Drawing Rights, Supplementary foreign exchange reserve assets defined and maintained by the IMF

Small molecule antivirals – Chemical compounds typically comprising only 20-100 atoms. These drugs can enter cells easily due to low molecular weight

Solidarity Trial – A global RCT set up by the WHO to provide robust results on life-saving treatments for those hospitalized with severe or critical COVID-19

SPRING – Federal Agency for Disruptive Innovation, An agency that provides financial support for individual and corporate research and development projects based on novel approaches to solutions on behalf of the German government that have the potential to fundamentally develop existing products, technologies or business models and thereby create new markets

SRA – Stringent Regulatory Authorities, National drug regulatory authorities which are members or observers or associates of the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use, as defined by WHO

STECC – Science and Technology Expert Group, Advisory group to the International Pandemic Preparedness Secretariat

SUDV – Sudan Ebolavirus

Surge financing – Rapidly deployable technical and financial support that allows regional and national bodies to respond to global health threats at a local level

T&T – Test and Treat Technology transfer – The process of transferring the knowledge, physical objects, skills and technology management required to manufacture DTVs with a particular emphasis on the challenges and complexity of vaccine manufacturing technology transfer


Technology transfer – The process of transferring the knowledge, physical objects, skills and technology management required to manufacture DTVs with a particular emphasis on the challenges and complexity of vaccine manufacturing technology transfer

Therapeutics – The branch of medicine concerned with the treatment of disease and the action of remedial agents. Commonly referred to as medicines or treatments

TPP – WHO Target Product Profile, The desired R&D outcome of a product that is aimed at addressing a particular disease or diseases

UKHSA – UK Health Security Agency, An executive agency sponsored by the UK’s DHSC, that provides national and local leadership towards security against infectious diseases, chemical, biological, radiological and nuclear incidents and other health threats

UKVN – UK Vaccine Network, A ODA-funded project which makes targeted investments to support the development of new vaccines and vaccine technologies for emergent infectious disease threats in low and middle-income countries

UMICs – Upper-Middle-Income Countries

UNHLM PPPR – United Nations High-Level Meeting on Pandemic Prevention, Preparedness and Response, A meeting convened by the President of the United Nations General Assembly on 20 September 2023. The overall theme of the HLM was “Making the world safer: Creating and maintaining political momentum and solidarity for Pandemic Prevention, Preparedness and Response”, and consisted of an opening segment, a plenary segment for general discussion, two multi-stakeholder panels, and a brief closing segment

Unitaid – An international financing and partnership organisation hosted by the WHO funding initiatives to address diseases such as AIDS, Tuberculosis and Malaria

Vaccine – A product that stimulates a person’s immune system to produce immunity to a specific disease, protecting the person from that disease

VDECC – Vaccine Development and Evaluation Centre, A unique facility in the UK, delivering multiple critical early pre and post clinical research and evaluation studies

Virus – A submicroscopic infectious agent that replicates only inside the living cells of an organism

Virus families – Classification of viruses according to characteristics (e.g., single or double stranded); viruses in the same family have similar characteristics

WEF – World Economic Forum, An international organisation that brings together its membership of political and business leaders on a yearly basis to discuss major issues concerning the world political economy

Wellcome – A global charitable foundation supporting science to solve urgent health issues

WHA – World Health Assembly, The decision-making body of the World Health Organization

WHO Biotech – A system that aims to offer a reliable, safe, and transparent mechanism for WHO member states to voluntarily share novel biological materials

WHO Pandemic Hub – WHO Hub for Pandemic & Epidemic Intelligence

WHO – World Health Organization, An agency of the United Nations that sets standards for disease control, healthcare, and medicines; conducts education and research programs; and publishes scientific papers and reports

WIPO – World Intellectual Property Organisation, Global database that provides free of charge access to legal information on intellectual property

WTO – World Trade Organisation, An intergovernmental organisation that deals with the global rules of trade between nations to facilitate and regulate international trade