ADDENDUM
ACT-A Transition Plan (01 October 2022 to 31 March 2023)

Key learnings and perspectives from ACT-A Pillars and Partners to inform ongoing processes and discussions focused on strengthening the global health architecture for pandemic preparedness and response

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ABOUT THIS DOCUMENT

It is widely recognized that the ACT-Accelerator was a ground-breaking initiative that was instrumental in advancing access to vaccines, tests, treatments (including oxygen) and personal protective equipment during the COVID-19 pandemic. This document was prepared as an addendum to the ACT-Accelerator Transition Plan (01 October 2022 to 31 March 2023) in recognition of the fact that many conversations are ongoing about changes that need to be implemented to improve the global health architecture for pandemic preparedness and response (PPR) based on the world’s experience with COVID-19. This addendum contains perspectives from ACT-A Pillars, the ACT-A CSO Platform and ACT-A industry partners on key learnings from ACT-A experience that may be helpful for informing these PPR discussions.
VACCINES (COVAX)

During its two years in existence, COVAX has delivered many landmark achievements across its value chain, from spurring R&D activities through innovative procurement mechanisms to supporting in-country delivery efforts.

In September, Vaccine Pillar partners published COVAX: Key learnings for future pandemic preparedness and response which provided a detailed review of the lessons taken from COVAX so far, as well as indications of how these might inform future PPR work.

To fulfil its mission, COVAX developed more than 50 workstreams and innovations as illustrated in Appendix B of the key learnings document. These activities were either non-existent at the onset of the pandemic or were smaller scale initiatives that were intensified through heightened collaboration or fast-tracked within existing organizations.

The document also highlights three key learnings, including challenges and recommendations for the future. Below is a short summary, additional detail is provided in the full document which can be accessed using the hyperlink provided above.

Key learnings and recommendations

1. Equitable access requires an end-to-end solution that centres on public health, and the needs of the most vulnerable, at every step. Capabilities should be strengthened during non-pandemic periods to ensure a resilient ecosystem is in place when an emergency strikes.

2. Hoarding, export restrictions and nationalism should be expected. To mitigate this, institute models – in advance – that ensure volumes supplied to high-income countries are accompanied in parallel by proportionate doses for lower-income countries.

3. A successful global pandemic response involves taking risks. Given this, ensure that response mechanisms are flexible and agile; outline a clear shared understanding of risk thresholds and risk sharing; make available, in advance, contingent at-risk funding for global health agencies’ and sustain and leverage existing financing mechanisms.

DIAGNOSTICS

The ACT-A Diagnostics Pillar, co-convened by FIND and the Global Fund, with WHO support, brings together 50 partners to develop, deploy, and scale up equitable access to COVID-19 diagnostics. Reflecting on progress to date, through the support of the ACT-A Diagnostics Pillar and its partners in-country and globally, significant strides have been made towards this goal. Moreover, the global community now has the necessary tools and resources available at affordable prices to effectively respond to COVID-19. Although gains have been achieved, there are many challenges and hurdles that continue to hamper progress. Looking forward, to achieve scale, sustainability, and continued preparedness, the global community, with support from the ACT-A Diagnostics Pillar, needs to continue partnering to deliver on key diagnostics priorities.

The following summarizes key insights and learnings that have been, and will continue to be, instrumental in ongoing COVID-19 response efforts.

- It is critical to convene partnerships across the care cascade and value chain that are representative of global, regional, and country views to effectively deliver public health priorities. Although nearly every global health program, agency, and country has an implicit diagnostics agenda, prior to ACT-A, there was no central diagnostic mechanism to coordinate across the diagnostics value chain on a global scale. The scope and impact of the COVID-19 pandemic made clear that pre-pandemic mechanisms are not alone adequate, and that global partnerships under a common agenda must continue not only for COVID-19 but across diagnostic priorities.

- Working closely with countries to strengthen primary healthcare systems is necessary for the effective rollout of medical and non-medical countermeasures. National and local ownership and co-investment, alongside strong regional and global level support, are essential to have scaled and sustained impact. It is therefore vital to ensure country countermeasures are shaped, identified, led and owned by countries in partnership with regional and global partners.

- Investing in pandemic preparedness is necessary. A key lesson from COVID-19 is that the world has significantly underinvested in pandemic preparedness. Health systems are
critical to making the world battle-ready for the next pandemic and therefore investments in strengthening laboratory systems dedicated to pandemic response are critical.

- In an epidemiological context that is changing rapidly, it is important to remain agile, while also communicating with key stakeholders to identify and address challenges in real time.

- Global diversity in research, development, local manufacturing, technology transfer and digital tools is essential to ensure equitable access to diagnostics especially in LIC and LMIC settings. The COVID-19 pandemic exposed fundamental gaps around diagnostics in the care cascade and made clear how profoundly a lack of diagnostics can affect patients, providers, communities, and economies. As a result of years of underinvestment in diagnostics research, test kit manufacturing, global laboratory systems, and global surveillance, both high- and low-income countries initially found themselves without the diagnostic tools necessary to contain the spread of SARS-CoV-2.

  » Targeted and coordinated research and development are vital to developing tools to effectively respond to global health crises. Specific activities include the investment in late-stage product development, performance evaluations, technology transfers, regulatory support, boosting production capacity, strengthening local capacity, decreasing prices and securing volumes despite demand volatility. These activities accelerate the development, manufacturing and launch of tests improving equitable and timely access. Moreover, the rapid development and rollout of tests and surveillance systems enable countries to understand transmission dynamics and implement timely countermeasures to safeguard their communities.

  » Maintaining a healthy market and ensuring the availability of diagnostics are important aspects that significantly impact the equitable distribution of tools especially to LIC and LMIC settings. Specifically, there is a need for diagnostic local/regional manufacturing capacity to be significantly expanded and supported by global funders. The lack of diagnostics manufacturing capacity in Latin America, Africa, and in much of Asia greatly hinder the ability to monitor and detect pathogens of concern. Routine use of locally produced diagnostic tests will be essential to surveillance and will drive vaccination and therapeutic strategies for pandemic threats moving forward.

  » Regulatory bodies must be adequately resourced to respond under the rigid timeline requirements of a pandemic. Sufficient resource are needed to address regulatory challenges and bottlenecks, including funding for strengthening regulatory harmonization, oversight, specifications, and providing adequate human resources.

  » New diagnostic technologies, like digital tools and multi-pathogen tests, together with existing diagnostic systems should be leveraged to strengthen pandemic preparedness.

- To introduce and successfully scale the use of diagnostics in countries, it is crucial to closely work alongside and partner with countries to address their needs to ensure:

  » Meaningful engagement with communities and country stakeholders. In outlining the pandemic response, it is critical to co-create and co-develop initiatives with country representatives (civil society organizations, country programs, and communities). Ensuring countries and civil society have equal footing from the beginning is needed for sustainable, impactful, and equitable access to COVID-19 diagnostic tools.

  » Diagnosis and care are moved closer to communities through the strengthening of lab systems and supply chains, especially at the primary healthcare level, with a clear link to public health interventions along the care cascade. Supporting community systems is vital to reaching rural and vulnerable populations. It is, therefore, critical to prioritize the role of community health workers who are poised to play a pivotal role in fighting pandemics, especially in LIC and LMIC settings with vulnerable health systems. The ability to train and deploy community health workers rapidly, the trust that communities place in them, and their presence in areas with few resources make them an essential part of systems for health and pandemic preparedness and response in LIC and LMICs.

  » Public health laboratories need to be prioritized. To address the main drivers that inhibit availability and equitable access to the
supply of diagnostic tests (i.e., competition from HIC, preferred tests by HIC that are priced too high for non-HICs, regulatory delays, lack of well performing tests), more investments need to be made for diagnostics. However, funding alone is not the solution. In hand with financial investments, the complexities of diagnostics access require political will, prioritization of laboratory systems, healthcare worker capacity and community engagement.

Everyone, everywhere have the right to access available tools. The importance of diagnostics and the need for sufficient funding for diagnostic agendas is important to highlight and advocate for at the country, regional, and global levels. A key lesson from the COVID-19 experience is the importance of working towards a comprehensive approach to care which encompasses support for diagnostics, therapeutics and vaccines. Only a comprehensive response will defeat the virus. However, the donor response heavily weighted its resources towards vaccines in the start of the pandemic which limited the funds available for tests, treatments, and strengthening of health systems. Insufficient and inequitable access to health products including diagnostics contributes to the spread of the virus and the emergence of new variants, reducing the efficacy of current tools and threaten to undo progress.

- **Diagnostics and therapeutics, and associated test-to-treat strategies, are fundamental components of the pandemic response, both for COVID-19 and for future health threats.** Addressing the test-to-treat approach is as much a structural problem as a technical one as diagnostics and therapeutics are often considered different markets with independent stakeholders. Effective clinical management to reduce morbidity and mortality requires integration of diagnostics and therapeutics including test-to-treat strategies in primary health care systems, along with vaccines and public health measures. Going forward, the Diagnostics Pillar will continue to collaborate closely with the Therapeutics Pillar to promote test-to-treat strategies in countries.

- **Building Next-Generation Sequencing (NGS) capacity in all countries is critical to ensure an effective global public health response.** NGS enables rapid identification of unknown pathogens, discovery of novel genetic variations, and improved understanding of disease-causing pathogens, to inform the development and utility of tests, treatments, and vaccines. Without a robust sequencing program and data sharing by countries, the world will be blind to the emergence of new pathogens, putting global health security at risk. Including this as a component of a strong national laboratory programme is critical and investments should be continued.

**THERAPEUTICS**

Through its work, the ACT-A Therapeutics Pillar gained valuable insights into the strategic identification and implementation of interventions to establish access pathways for a prompt and equitable roll-out of fit-for-purpose therapeutics for low and middle-income countries in a pandemic context. Additional lessons learned to inform our collective thinking on addressing global health emergencies going forward are also included in the ACT-Accelerator Facilitation Council Working Group Report on Diagnostics and Therapeutics, published 22 September 2022, and in the Addendum to the External Evaluation of the ACT-A Accelerator published 18 October 2022.

In the context of pandemic prevention, preparedness and response, the following elements are key:

1. **Maintaining a flexible strategy and active communication with stakeholders in a rapidly changing epidemiological and medical countermeasures landscape.**
   - Continuous analysis of evolving information and evidence is required to rapidly adjust the strategy, whether related to investments in R&D, market preparedness, or country support.
   - As significant investments need to be made with limited evidence and a high degree of uncertainty, it is important to establish robust decision-making processes and risk management policies.
   - Given the uncertainty on needs projections and forecasts, adopting a scenario planning approach to prepare for several possible futures is key to ensuring markets and countries can respond in a timely manner.
   - Meaningful engagement with country partners and decision-making bodies at the country level – including governments, communities, and civil society – should happen at each stage of the process, from R&D to planning for procurement and delivery.
2. Ensuring early and adequate availability of funding to build, and maintain, the capacity to develop, produce and deliver treatments.

- As disease trajectory is highly unpredictable, we should identify and support “no-regret” moves to incentivize R&D, manufacturing, and countries’ preparedness for the adoption of therapeutics in line with anticipated need, even at the risk of the pandemic course eventually negating initial assumptions.

3. Having a cohesive strategy across the different medical countermeasures (e.g., vaccines, diagnostics, and therapeutics).

- A strong and coordinated response across medical countermeasures is crucial to enable countries to develop successful, comprehensive responses to health threats. More strategic, predictable, and integrated financing across medical countermeasures is required in this regard.

4. Creating a continuum between pandemic preparedness and response to avoid delays in countries’ uptake of critical tools.

- Coordinating for targeted and efficient R&D that responds to the specific needs of low and middle-income countries and includes them in research platforms.

- Prioritizing equitable access terms for potentially game-changing treatments early in the industry response, to include low and middle-income countries and enable prompt availability and affordability of supplies.

- Expanding and maintaining a sustainable and affordable supply of oxygen in low and middle-income countries, in view of broad public health needs and potential future respiratory pandemic-prone pathogens.

- Supporting early investments in country readiness to be equipped to cope with different epidemiological scenarios.

HEALTH SYSTEMS & RESPONSE CONNECTOR (HSRC)

- Investments need to be made upfront to rapidly scale up delivery of countermeasures (including surge capacity and workforce). Public Health Care systems must be adapted to emergencies to be able to rapidly scale up the delivery of countermeasures; but strengthening UHC is not going to help with emergencies.

- In a response, upstream countermeasures need to be hard-wired to the downstream delivery systems. Those links must be jointly developed from the beginning following a “one team, one plan, one budget” logic - because we collectively took a verticalized approach and operated with an overall disconnect between ACT-A pillars and SPRP pillars, we will struggle to integrate COVID management into routine health systems.

- Coordination only works if there is a clear purpose and funding transparency is critical down to the implementation level (to whom / for what) to facilitate coordination. However, although global coordination platforms need to be informed by and responsive to local needs, we must not divert regional and country levels from being nearer to the front line and we need to be mindful of their bandwidth.

- Ahead of the next pandemic, we need to identify the few things that can be strengthened during a response. We cannot solve all chronic health systems issues in the middle of a pandemic; therefore, we need to have clarity on the things that can still be strengthened (e.g., waste management, RCCE, and more generally, non-biomedical interventions, which cannot be underestimated during a pandemic).
Key enablers which supported the Platform’s effective engagement with ACT-A include:

• Funding for the functioning of the Platform mobilised by the co-leads and dedicated funding for community representatives (provided by FIND and Unitaid) enabled smooth and coordinated functioning of the Platform; as well as liaison with civil society and communities beyond ACT-A to feed into the Platform’s engagement with ACT-A.

• Continuing good relationship with the ACT-A hub and CSO focal points from each of the lead agencies, pillar focal points and lead agencies.

• Governance structures of some lead organisations with clear mechanisms for civil society and community participation as well as further mechanisms to ensure civil society and community participation in their work in ACT-A.

The challenges in the work of the Platform include:

• The Civil Society Platform was built on the structure of ACT-A; which in itself had no clear decision making or accountability structures. This made it hard for the Platform to advance its goals and advocacy asks as the main power holder and decision makers were not clear.

• Civil Society was brought onto the Resource Mobilization and Financing working group after the launch of the financing framework. The absence of a single resource mobilisation strategy and approach, meant that each agency was responsible for raising their own resources, often competing with the same donors. Except for the Global Fund, CS were not engaged in individual lead agency financing asks. This was a missed opportunity.

• Insufficient focus on addressing inequalities and community-led responses via ACT-A brokering innovative solutions, for example lack of support to the civil society and communities input on the importance of prioritising community based testing.

• Low activity of the working groups with key strategic importance, such as the Vaccine Strategy working group and several streams of work in HRSC pillar. The current crisis in vaccines delivery could have been prevented and there would not have been a need for the Vaccines Delivery Partnership initiative if effective civil society engagement and functioning, including in relation to the course correction, would have been ensured in these key groups.

• Lack of up-to-date detailed ACT-A mapping (including a clear and transparent overview of working groups in each pillar and timely information sharing about the changes) as well changing governance structures and key contacts within pillars has made it difficult to build relationships, maintain connections and ensure our full and meaningful participation in decision-making processes

Key learnings from the work of the Platform:

• The need to acknowledge and address intellectual property barriers in order to increase and diversify supply, to lower prices, and to enable more certain equitable access. There has been a peculiar reluctance of ACT-A to acknowledge intellectual access barriers to adequate supply, affordable prices, and equitable distribution of covid countermeasures.

• Low and middle-income country governments must be co-creators, including strategy development and decision-making.

• Sustained civil society and communities engagement in the current and future COVID-19 responses require focussed funding. Continued representation and functioning of the Platform post September, 2022, requires additional resources. We welcome lead agencies’ proposals to fund the Platform, including to ensure effective transitioning across ACT-A. We will continue to work with the lead agencies and other partners to sustain core functioning of the Platform as well as secure funding for representatives.

• Strong civil society and community engagement leads to effective decision-making and implementation led by evidence from the ground, effective course correction and cross-pillar responses. While key contacts at lead agencies acknowledge and recognize the importance of civil society and community participation, civil society and communities must be co-creators and with participation institutionalised in decision-making processes (i.e. allocating specific seats within
core governance structures for civil society and communities, and purposefully facilitating their full participation).

Diagnostics

- A process of prioritization that evaluates priorities and presents these priorities in a framework of their funding needs, their ideal sequence, their time horizons, and feasibility. Equity of access to diagnostics must be measured and prioritised.
- Vertical (local to national to global level) and horizontal integration (across the clinical, laboratory, and public health officials) of processes must be improved.
- Stronger / clearer principles on human rights and community rights (including the right to health) must be introduced for developing guidelines on testing and diagnostics.

Therapeutics

- Capable mechanisms of coordination on the development, clinical trials, clinical guidance, regulatory approval, and adequate and equitable supply of therapeutics to respond to this and future pandemics are desperately needed.
- The commercial and profit maximizing goals of the biopharmaceutical industry need to be overturned by treating pandemic medical countermeasures as global public goods with mandatory sharing of technology, information, and other fruits of scientific progress with all global citizens no matter where they live.

Therapeutics and Diagnostics

- It is essential to accelerate WHO guidance development, use cases, and prequalification and emergency use authorization processes and then via more rapidly in country uptake and implementation. Civil society has raised these concerns consistently.
- Prioritization of and earlier planning for and promotion of test-to-treat strategies will be appropriate for all future pandemics. We are 2 3/4 years into the COVID-19 pandemic and we are in the preliminary stages of articulating the need for test-to-treat, working with countries, and addressing supply, affordability, and demand barriers. Much of this work could have and should have been done a year earlier even admitting that Unitaid and FIND in particular have taken up the cause for test-to-treat in a more serious way. But WHO has insisted on waiting for evidence while simultaneously ignoring the evidence of test-and-treat programming that has significantly impacted past infectious disease responses from HIV to malaria to HCV and others.

Vaccines (COVAX)

- Timely and predictable supply and fully funded delivery of the medical products, such as vaccines, via community-focussed and led systems is of essence when addressing the pandemics. It is of the key importance to strategically address the bottlenecks holding the availability and delivery of the medical supplies: such as technology transfer and eco-system delivery in low and middle income countries.
- Addressing root causes of the problems, such as lack of the manufacturing capacity in low- and middle-income countries; complex market dynamics focussed on profit and need for finding innovative solutions to address these challenges; developing strategic solutions around community-driven delivery and demand creation, particularly among the most vulnerable groups is needed.
- Prioritizing, cross-pillar/cross issues work, such as further development of resilient health and community systems, is the critical priority.

Health Systems & Response Connector

- Health systems must be the foundation for equitable access to HEPR countermeasures. A key lesson from the ACT-Accelerator is the need to invest in health systems, particularly key aspects required for response (e.g., health workforce, essential health services, community systems) that can deliver commodities when available.
- There should be a standing HSRC country coordination team (based on ACT-A HSRC model) in all governments, country-owned and country-led, that are multi stakeholder and multi sector and involve diverse representation of international organizations and CSOs.
- There should be clear communication and coordination channels for all stakeholders at the country level from the beginning stages of design to implementation.
• Partners must also commit to sustaining the progress made by the ACT-Accelerator, regardless of the form or structure of future PPR mechanisms. Within the HSRC’s scope, this includes continuing to scale-up and support the uptake of the data platforms as well as beginning (or re-starting) workstreams, such as the one focused on the health workforce.

• Financial support for civil society participation and community health systems strengthening is essential.

More information on key lessons from civil society and community representatives in ACT-A can be found [here](#).
International Federation of Pharmaceutical Manufacturers & Associations (IFMPA):

COVAX has operated very differently from the other ACT-A pillars and lessons must be learned on why some workstreams were more successful than others. For example, the Therapeutics Pillar is underutilizing the use of advance market commitments (AMCs) for procurement of COVID-19 therapeutics, which has rendered the mechanism non-competitive with other national bilateral mechanisms. Sole reliance on publication of recommendations in the WHO Living Guidelines for COVID-19 and Therapeutics prior to any commitment for purchase or early investment has been one of the factors that has hindered the ability of The Pillar to initiate AMCs and secure much needed supply agreements: reliance on stringent regulatory authority emergency use approval could accelerate this process. Notably, even where supply agreements have been secured with The Pillar, treatments do not appear to have been procured and shipped to countries in a timely manner.

Outside of the ACT-A pillar, certain LMICs have moved forward of their own accord to procure millions of courses of antiviral treatment in the past several months. This undermines equity between those LMICs with the financial ability to procure bilaterally and those which rely on the ACT-A system to support procurement. There are indications that demand remains sustained in private markets supplied by generic manufacturers outside our members’ voluntary licensing networks. This poses unknown quality-assurance risks, which could create even greater inequality in LMICs where the public sector has not yet provided access.

The presumption that IP is a barrier to access by the ACT A Therapeutics Pillar has been a distraction to the real bottlenecks. Throughout the market access discussions there was a call for joining mechanisms such as C-TAP or for compulsory licenses, whilst the creation of certain sub workstreams relating to licensing and IP specifically excluded the private sector. Our companies have actively responded to all IP concerns throughout (i.e. through voluntary licenses, MPP partnerships etc) and the experiences outlined above simply illustrate that access issues have had nothing to do with IP.

International Generics and Biosimilar Medicines Association (IGBA):

On the therapeutics front, looking at the future global health architecture for PPR and within ACT-A, IGBA believes that, not only is it vital to fund research and development of new therapeutics but also to fund research into repurposing authorized medicines. Repurposing has emerged as an important strategy to address unmet medical need. We are all familiar with the tremendous impact of dexamethasone. A pilot project by the EMA and the Heads of Agencies is open in Europe for academia and non-profit organization. An overview of repurposing initiatives is needed as well as a framework for funding this type of research.

Not sure if there has ever been an industry coordination platform for therapeutics. This would be an approach to consider given the phase we are in today and for future health crises. This platform should be built upon the lessons learned from the vaccine platform. IGBA was ready to assist in mapping manufacturers, especially when mAbs were high up on the agenda during the pandemic. We did it proactively, but in general we were not directly invited to help mapping manufacturers for therapeutics, and learned about the mapping outcome via ACT-A. Further clarification on how best to engage more directly with industry trade associations for the future is needed.

As we all know, the generic and biosimilar medicines industry has played and continue to play a crucial forefront role by providing access to quality-assured and affordable essential medicines to people across
the world, but also for other communicable and non-communicable diseases. Many of the therapeutics that have proven effective in lessening the suffering of COVID patients, whether by directly addressing COVID-19 or supporting ICU patient needs, are already generic or have had voluntary licenses granted by the originator companies, directly or via the Medicines Patent Pool. An important aspect for the transition is to identify the hurdles for generic development of the more recent antivirals to ensure this is no gap between the medicines delivered by the originators and the time the generic versions can be made available.

Developing Countries Vaccine Manufacturing Network (DCVMN):

The Vaccine industry was a part of principals group of ACT-A and did make a significant contribution in innovating, developing, manufacturing and supplying over 12 billion vaccine doses in an unprecedented short time period which was sufficient to vaccinate the whole planet. In fact, around 60% of this capacity came from Developing Countries Vaccine manufacturers. However, DCVMs felt ignored on many occasions when critical decisions were being made without involving representation from Industry and most of these were just being informed. A case in point is in obtaining advance purchase commitments from GAVI COVAX and also product development funding from CEPI which was mostly focused on new technologies from new companies with no prior track record in LICS and MICs ignoring many DCVMs who had a long history of vaccine manufacturing, supplies and distribution in LICS and MICs.

Now when the pandemic is waning down, though not over, it is time to review and take appropriate measures to taper down the activities of such a great initiative in such a way that it can be reactivated at will without having to waste precious time which will be of essence during an onset of another pandemic.

DCVMN, therefore, strongly recommends that post March’ 23:

1. ACT-A should not be dismantled rather kept in hibernation, warm but not active. For this a small strategic core group (SCG) can be kept as a watch dog within WHO to monitor and alert any signals of a Pandemic.

2. All the stakeholders including Industry should be involved immediately as & when there’s an alert signal received by the SCG.

3. Funding became a critical issue in timely deployment of the tools leading to vaccine hesitancy in certain parts of the World, therefore, it would be of utmost importance to create innovative financial mechanisms and organise funds in advance to avoid any such reoccurrence.

4. Industry, which is actually providing the final output, needs to be put on equal platform as a reliable partner.

5. Manufacturing capacity of vaccines has been ramped up several fold, however, regional imbalances still need to be addressed on priority and an end-to-end value chain has to be reviewed to ensure consistent and uninterrupted supplies of raw and packaging materials as well as testing reagents.

6. A global political agreement needs to be reached to avoid recurrence of export bans in such emergencies of international scale.