GHTC's G7 Priorities

The Japanese government has shown great leadership in advancing innovations to mitigate emerging and enduring health threats. Their agenda for this year's G7 presidency, which focuses on building and delivering on the United Kingdom's 100 Days Mission proposal, universal health coverage (UHC), and the future of the global health architecture, has rightfully highlighted the importance of research and development (R&D) to tackling all three themes.

The world remains dangerously unprepared to prevent and respond to emerging diseases and global health threats—a risky political choice. G7 leaders must take action and seize opportunities to ensure every country and community has the tools they need to address poverty-related and neglected diseases (PRNDs) as part of UHC and create a pandemic-proof future. This means investing in both new and existing mechanisms that facilitate and enable the development of new health technologies and strengthening the R&D ecosystem globally to create a more fit-for-purpose global health architecture with equity and human rights at its core.

The Global Health Technologies Coalition (GHTC) would like to elevate the following priorities under the three health themes being advanced by the G7 this year:

Theme 1: 100 Days Mission and Access & Delivery (100 Days Mission PLUS)

Advance the 100 Days Plus Mission by funding the Coalition for Epidemic Preparedness Innovations (CEPI) 2.0, FIND, and public health institutes.

- Invest in CEPI to achieve the US$3.5 billion target to accelerate R&D of new vaccines and support and invest in equitable access to diagnostics through FIND for emerging epidemic and pandemic threats. Prioritize R&D into diagnostics, therapeutics, and vaccines against the World Health Organization's (WHO's) list of priority pathogens, with the aim to have prototype biomedical countermeasures against the virus families of the greatest pandemic threats.
- Scope and develop an international clinical trials network to enable a coordinated and efficient approach to testing new diagnostics, therapeutics, and vaccines, as well as existing therapeutics. The network should bring together national clinical trials infrastructure, interlinked regionally in a way that it can be rapidly commandeered as a global resource during a pandemic. The network should enable immediate and transparent knowledge and information sharing, with appropriate confidentiality protections and clear data disaggregation standards for impact by gender and race at all stages of analysis. This clinical trials network should always be active, should be leveraged for other diseases, and should be able to rapidly refocus in a pandemic or epidemic, supported by a mechanism to prioritize which drugs, vaccines, and therapeutic products to trial.
- Invest and promote local R&D, manufacturing, and distribution capacity and engage local communities in this process. The regional mRNA hubs supported by WHO and other stakeholders should be further capacitated, and these hubs should also serve to

support other critical disease areas, such as tuberculosis, malaria, HIV/AIDS, and neglected tropical diseases. Leaders should also seek to optimize manufacturing processes for rapid initial production and subsequent scaling and maintain a network of 'warm base' manufacturing facilities and reserved capacity for multiple different platforms that could be activated within days.

- Support the capacities of national and regional public health institutes in lower- and middle-income countries, including in the fields of epidemiology, disease detection, and laboratory diagnosis.
- Enhance collaboration between regulatory agencies to align on preclinical and clinical standards, approaches, protocols, and data structures to facilitate multicountry approvals. Coordinate among relevant agencies to encourage innovative regulatory approaches, including novel study designs, utilization of platform data, and digitization of review and submission processes.
- Establish a multi-stakeholder international Diagnostics Alliance, as outlined in the Lancet Commission on Diagnostics, to have a key role in advocacy, setting specific, country-driven targets, monitoring progress, and convening an international forum for stakeholders to share best practices and expertise.

Fully fund the Pandemic Fund for year one and commit to a sustainable capitalization plan for the ensuing years.

To date, the Pandemic Fund has secured only $1.6 billion in pledges against the $10.5 billion agreed annual target for additional international financing to close critical global preparedness gaps. The Fund should include opportunities to support countries and regions in strengthening laboratory, clinical research, and regulatory capacity in support of the development of and access to biomedical countermeasures including diagnostics, therapeutics, and vaccines.

Leaders must ensure the activities of the Pandemic Fund are complementary to those of other organizations and initiatives to create a strengthened, more cohesive global health architecture.

Theme 2: Resilient, Equitable, and Sustainable UHC

Increase investment in R&D for PRNDs

Global progress continues to be threatened as resources to address ongoing PRNDs have been reallocated or have stagnated during the COVID-19 response. It is vital to advance funding for R&D to address diseases like tuberculosis, malaria, HIV/AIDS, and neglected tropical diseases, as well as platform technologies, to ensure a robust pipeline of new tools, including vaccines, diagnostics, therapeutics, vector control products, and other health technologies.

- Support product development partnerships, which have been a key instrument in the fight against PRNDs, and make further investments in this essential component of the global health architecture. This is particularly critical to ensure that products are developed and distributed with an equity lens, with the end user in mind, and with

characteristics, including affordability, acceptability, and ease of administration that facilitate their uptake and delivery.
- Create incentives for the timely licensure of new innovations and commit resources toward subsidizing novel approaches and helping new access-focused developers overcome R&D bottlenecks and high start-up costs.

Ensure that the specific R&D needs of women, children, and other vulnerable populations are addressed.

The COVID-19 pandemic has exacerbated gender-related structural inequalities and barriers in women's health care access—a phenomenon similarly observed in past economic and health crises. The same can be said of pediatrics and other vulnerable or neglected populations. Yet long-term, intersectoral, and structural reforms are given low priority.

- The G7 created a Gender Equality Advisory Council last year, and such mechanisms should be strengthened and expanded, including with financial capacities, to execute their mandate to advance gender-specific issues.
- We encourage governments to call on health researchers to routinely embed sex- and gender-based perspectives into R&D so that unmet needs in women's health are addressed and innovations are advanced. This includes:
    - Ensuring governments have policies in place to enable collection and analysis of sex- and gender-disaggregated data.
    - Work with WHO on the development of specific target product profiles for health technologies that address the needs of vulnerable populations, as WHO can play a major role in guiding product developers and providing technical support to countries to facilitate equitable distribution and uptake of new tools.
    - Leaders must support R&D to fill technology gaps for children, pregnant people, and other at-risk populations and advocate for changes in product development that promote the safe inclusion of pregnant women in clinical studies to generate data to support earlier access to innovative medicines for this population.
    - Work with respective regulatory agencies to draft and implement guidance to ensure adequate representation of women and other underrepresented populations in clinical trials, including during pregnancy and lactation.

Reprioritizing AMR and a One Health approach as part of G7 global health strategies.

Leader must invest in new tools and technologies to fight the rising threat of the silent pandemic and develop and operationalize national action plans.

- Invest in R&D to develop quality-assured, new, and improved antimicrobials, novel compounds, diagnostics, vaccines, and other health technologies to address drug-resistant bacterial, viral, parasitic, and fungal microorganisms. There are few new antimicrobials in clinical development and waning private investment, and we must take urgent action to support the fragile antimicrobial pipeline.
- Support the development of rapid point-of-care testing devices that bring the full spectrum of essential diagnostics closer to where people live and work. Improved

access to affordable point-of-care tests will ensure data on priority diseases, antimicrobial resistance (AMR), and their spread are generated in all countries and regions of the world.
- Ensure a sustainable market for antibiotics by developing research incentives to develop new antimicrobial drugs, accelerating access to new antimicrobials against drug-resistant infections, increasing vaccine access to reduce the risk of infections, and promoting the availability of a diversified drug portfolio in countries to reduce pressure on existing drugs and reduce the risk of the development of AMR.
- Provide ongoing support to the Global AMR R&D Hub in its work providing countries and investors with the latest AMR R&D landscape analysis, which helps address gaps in the market. The hub should also pave the way for the efficient deployment of tailor-made incentives for R&D and facilitate global discussion on priorities and opportunities for increasing R&D investments.

Theme 3: Global Health Architecture Development

Integrate R&D into pandemic prevention, preparedness, and response mechanisms and governance structures.

While COVID-19 has pushed pandemic R&D into the spotlight, a global framework or process to assess country or global R&D readiness for pandemic threats is not included among the tools we currently have to govern and coordinate global health security. R&D must be a central pillar in the new global health architecture that is being developed.

- Push for a more holistic approach to governance of R&D of medical countermeasures as part of the pandemic accord. The current zero draft published by the Intergovernmental Negotiating Body bureau still largely emphasizes downstream response measures such as manufacturing and registration. While these are critical elements to a country's global health security, they are not sufficient to ensure the end-to-end approach—from early-stage discovery to clinical development to access and delivery of health tools post-registration—that is needed.
- Leverage existing external assessments, such as the Global Health Security Index, WHO's Joint External Evaluation, and other platforms like the Global Health Security Agenda, to assist in decision-making by helping to identify gaps and health security threats.
- The Working Group on Strengthening WHO Preparedness and Response to Health Emergencies is reviewing the International Health Regulations, and countries should push for targeted amendments, which could include adding specific guidance language on R&D coordination and genetic sequence sharing, as well as using WHO as a convener for global research experts to share knowledge via the R&D Blueprint. R&D indicators should also be formally incorporated into the International Health Regulations and WHO's Joint External Evaluation.