



**International  
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# **Catalyzing Global Collaboration to Strengthen Clinical Trials Systems**

**World Health Assembly 79 side event**

International Vaccine Institute

Pasteur Network

Co-sponsored by the governments of Brazil, Ghana, Rwanda, Sweden, and Viet Nam

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# Executive Summary

The side event “Catalyzing Global Collaboration to Strengthen Clinical Trial Systems”, held during the 79th World Health Assembly (WHA79) on 19 May 2026 in Geneva, convened policymakers, researchers, regulators, funders, and implementing partners to discuss practical strategies for strengthening clinical trial ecosystems globally. Organized by the International Vaccine Institute (IVI) and the Pasteur Network (PN), in collaboration with the World Health Organization (WHO) and co-sponsored by Brazil, Ghana, Rwanda, Sweden, and Viet Nam, the event focused on addressing persistent inequities in global clinical research and identifying pathways toward stronger and more inclusive systems.

A central message throughout the discussions was that strengthening clinical trial systems is essential for global health equity, preparedness, and innovation. Despite carrying a high proportion of the global disease burden, low- and middle-income countries (LMICs) continue to host only a small share of clinical trials, limiting the availability of locally relevant evidence and reducing equitable access to health innovations. Participants emphasized that clinical trial systems must better reflect the populations most affected by disease to ensure more effective and contextually relevant interventions.

Country experiences from Brazil, Ghana, Sweden, Tanzania, and Viet Nam demonstrated that progress is possible through national leadership, regulatory reform, data digitalization, stronger coordination, and sustained investment in institutional capacity. Several countries highlighted efforts to improve ethics and regulatory systems, standardize trial sites, strengthen research infrastructure, and link clinical research to broader vaccine manufacturing and health priorities.

WHO highlighted the importance of country-led and context-specific approaches, supported by frameworks such as the WHO Guidance for Best Practices for Clinical Trials (2024) and the Global Action Plan for Clinical Trial Ecosystem Strengthening (GAP-CTS, 2025). These initiatives promote stronger governance, ethics oversight, workforce development, and sustainable systems capable of responding to both routine health priorities and emergencies.

Across discussions, participants stressed that strengthening clinical trial systems requires investment in ecosystems rather than isolated projects. Key priorities included interoperable data systems, clinical trial networks, harmonized study protocols and standard operating procedures, workforce development, sustainable financing, and equitable partnerships. Organizations including WHO, IVI, CEPI, EDCTP3, PATH, Wellcome Trust, the Pasteur Network, and Team Europe’s MAV+ initiative highlighted ongoing efforts to strengthen clinical trial readiness and research capacity in LMICs.

The event concluded with a call for coordinated global action, emphasizing that while tools and partnerships already exist, sustained progress will depend on country ownership, long-term investment, and stronger collaboration to build resilient and equitable clinical trial ecosystems worldwide.



Speakers and moderators from the event. *Photo credit: Christine Demstader, IVI.*

## Introduction

Strengthening clinical trial systems has become an increasingly urgent global health priority, driven by the recognition that equitable, high-quality, and efficient research is essential to addressing current and future health challenges. Clinical trials are fundamental to the development of vaccines, therapeutics, diagnostics, and other health technologies, yet substantial inequities remain in where and how research is conducted. Despite carrying a significant proportion of the global disease burden, low- and middle-income countries (LMICs)—particularly in Africa—continue to be underrepresented in clinical research, limiting the generation of locally relevant evidence and constraining equitable access to innovation.

The importance of addressing these disparities has been reinforced through several recent global commitments. The adoption of World Health Assembly Resolution WHA75.8 (2022) called for strengthening the global clinical trials ecosystem to improve the quality, coordination, ethics, and inclusivity of research, particularly in settings that have historically been underserved. This mandate has subsequently been operationalized through the WHO Guidance for Best Practices for Clinical Trials (2024) and the WHO Global Action Plan for Clinical Trial Ecosystem Strengthening (GAP-CTS, 2025), both of which emphasize the need for coordinated national systems, stronger regulatory and ethics frameworks, workforce development, sustainable financing, and research systems capable of responding to both routine health priorities and public health emergencies.

At the same time, regional and international initiatives have increasingly recognized that strengthening clinical trial systems is inseparable from broader ambitions around health sovereignty, local manufacturing, and pandemic preparedness. Initiatives such as the Team Europe Initiative on Manufacturing and Access to Vaccines, Medicines and Health Technologies (MAV+), the WHO mRNA Technology Transfer Programme, and investments led by organizations including CEPI, EDCTP3, PATH, Wellcome Trust, IVI, and the Pasteur Network

reflect growing momentum toward strengthening research and manufacturing ecosystems in LMICs. These efforts seek not only to expand clinical trial activity but also to ensure that countries can generate evidence relevant to their own populations, strengthen institutional capacity, and respond more rapidly to future outbreaks.

Against this backdrop, the side event “Catalyzing Global Collaboration to Strengthen Clinical Trial Systems” was convened during the 79th World Health Assembly (WHA79) on 19 May 2026 in Geneva, Switzerland. Organized by the International Vaccine Institute (IVI) and the Pasteur Network (PN), in collaboration with the World Health Organization (WHO) and co-sponsored by the governments of Brazil, Ghana, Rwanda, Sweden, and Viet Nam, the event brought together policymakers, researchers, regulators, funders, international organizations, and implementing partners to explore practical pathways for strengthening clinical trial ecosystems globally.

The discussions reflected a growing consensus that strengthening clinical trial systems is not solely a technical challenge, but a strategic and political imperative requiring sustained national leadership, coordinated governance, long-term partnerships, and investment in enabling ecosystems. Participants highlighted experiences from countries and institutions that are already implementing reforms and innovative approaches to improve clinical trial readiness, efficiency, and inclusivity.

This report summarizes the key discussions, country experiences, institutional perspectives, and emerging priorities identified during the event. It highlights lessons learned on strengthening regulatory systems, ethics oversight, digitalization, workforce development, clinical trial networks, financing mechanisms, and outbreak preparedness, while emphasizing the importance of country ownership, equitable partnerships, and sustainable ecosystem strengthening. Ultimately, the report aims to inform future dialogue and action toward building clinical trial systems that are more coordinated, resilient, and responsive to the health needs of all populations.

# Welcome and Opening Remarks

Dr. Anh Wartel, Deputy Director General, Head of Europe Regional Office, International Vaccine Institute (IVI) and Dr. Rebecca Grais, Executive Director, Pasteur Network opened the side event.

Dr. Anh Wartel welcomed participants and emphasized the importance of convening diverse stakeholders at the 79th World Health Assembly to address persistent inequities in the global clinical research landscape. Dr. Wartel underscored that the event was taking place at a critical moment for global health. Despite carrying a disproportionately high burden of infectious diseases, low- and middle-income countries (LMICs) continue to host only a small fraction of global clinical trials. She highlighted the example of Africa, which accounts for approximately 25% of the global disease burden and 35% of neglected tropical diseases, yet hosts only 3% of global clinical trials. She stressed that this disparity is not only a matter of health equity but also one of clinical effectiveness, as evidence generated outside LMIC settings may not adequately reflect the realities, health conditions, and needs of the populations most affected by disease. As a result, health interventions are not always sufficiently adapted or effective for those who need them most. Dr. Wartel emphasized that the event provided an important opportunity to bring together policymakers, researchers, funders, implementers, and global health partners to share experiences, identify practical solutions, and strengthen partnerships. She concluded by highlighting a shared objective for the event: to move from dialogue to action in support of stronger, more inclusive, and more resilient clinical trial ecosystems worldwide.

Dr. Rebecca Grais welcomed participants and reinforced the importance of addressing inequities in the global distribution of clinical trials. She emphasized that only a small proportion of clinical research is conducted in LMIC, despite the urgent need to ensure that vaccines, therapeutics, diagnostics, and other health tools are appropriately tested, adapted, and implemented in populations with the highest disease burden. Dr. Grais stressed the need to build a strong and coordinated global community capable of supporting clinical trials in settings where they can have the greatest impact. She highlighted that many of the world's most pressing health challenges—particularly those affecting vulnerable and underserved populations—often receive insufficient attention and visibility. In this context, she emphasized the importance of the side event as a platform to elevate attention to neglected priorities, strengthen partnerships, and promote more equitable approaches to clinical research. Dr. Grais underscored that building stronger clinical trial ecosystems is essential not only for preparedness and innovation, but also for ensuring that scientific advances benefit all populations equitably.

# High-Level Remarks from Co-Sponsoring Countries

## Viet Nam



Dr. Vu Manh Ha, Deputy Minister of Health, Viet Nam, emphasized that strengthening clinical trial ecosystems has become a global priority and reaffirmed Viet Nam’s commitment to advancing research, regulatory systems, and vaccine development capacity. He noted that many LMICs continue to face significant barriers related to infrastructure, financing, and regulatory capacity, which limit their ability to participate fully in global clinical research. Viet Nam has made substantial progress in recent years, including achieving WHO Maturity Level 3 (ML3) status in 2021, reflecting strengthened national regulatory systems. The country has also expanded its participation in international clinical trial initiatives and next-generation vaccine development efforts through partnerships supporting research capacity, technology transfer, local manufacturing, and equitable rollout strategies. Dr. Ha stressed that continued progress will depend on stronger collaboration, knowledge

sharing, workforce development, and sustained political commitment. He emphasized the importance of building efficient, inclusive, and sustainable research systems that contribute to both national priorities and the broader global clinical trial ecosystem.

## Brazil



Dr. Igor Bueno, Director of the Health Economic-Industrial Complex Department, Ministry of Health, highlighted Brazil’s broader commitment to health sovereignty and to strengthening clinical research as part of a coordinated national innovation strategy. Brazil has launched a National Clinical Research Program with an initial investment of approximately USD 24 million to strengthen clinical research capacity and position the country as a strategic partner in global clinical development. The initiative focuses on five key pillars: digital transformation and transparency, social participation, patient-centered approaches, regulatory strengthening aligned with Good Clinical Practice (GCP), and

integration with innovation and industrial policies. Dr. Bueno emphasized the importance of coordination between academia, industry, and regulatory agencies to expand participation in international research and improve access to innovative health technologies. Brazil has also introduced stronger legal and regulatory frameworks for research involving human participants and has institutionalized clinical research as part of its long-term health strategy. Additional investments in genomics, precision medicine, and biobanks representative of Brazil’s population are helping strengthen scientific capacity and improve the diversity of global scientific datasets, while also expanding opportunities for international collaboration.

## Ghana



Dr. Sodzi Sodzi-Tettey, CEO of the Ghana National Vaccine Institute, highlighted Ghana's efforts to strengthen clinical trial ecosystems as part of Africa's broader ambition to achieve 60% local vaccine manufacturing by 2040. To support this vision, Ghana established the National Vaccine Institute (NVI) three years ago to coordinate vaccine-related research, development, and manufacturing activities. Ghana's efforts are supported by a strong regulatory foundation, including the country's WHO Maturity Level 3 (ML3) Food and Drugs Authority and recognition as a Regional Centre of Regulatory Excellence. Dr. Sodzi-Tettey described a recent clinical trial ecosystem assessment workshop, conducted in collaboration with WHO and supported by the European Union, which reviewed Ghana's readiness to support expanded manufacturing and clinical research activities. While the assessment identified strengths such as experienced research institutions and a

robust regulatory framework, it also highlighted challenges including fragmented trial activity, limited early-stage clinical trial capacity, and dependence on externally driven research agendas. To address these gaps, Ghana has begun mapping clinical trial sites nationwide and plans to apply the WHO benchmarking tool to conduct systematic national assessments. The country's long-term objective is to move beyond a "fill-and-finish" approach toward end-to-end vaccine manufacturing capacity, supported by stronger clinical trial systems and strategic partnerships.

## Strengthening the Global Clinical Trials Ecosystem

Dr. Vasee Moorthy, Senior Advisor, Science and Strategy, WHO Science for Health Department, emphasized that resilient and coordinated clinical trial ecosystems are essential for effective outbreak preparedness and equitable research. Drawing on lessons from the COVID-19 pandemic, he noted that countries require systems capable of rapidly generating high-quality, inclusive, and contextually relevant evidence during both routine and emergency situations. He highlighted WHO's efforts to strengthen national clinical trial systems through a suite of country-driven guidance and tools, including the Global Clinical Trials Forum (GCTF) Guidance (2024) and the WHO Global Action Plan for Clinical Trial Ecosystem Strengthening (GAP-CTS, 2025). These frameworks emphasize governance, ethics oversight, workforce development, regulatory strengthening, coordination, sustainable financing, and integration with health systems.

Dr. Moorthy also highlighted the growing importance of equity, patient involvement, and inclusion of underrepresented populations in clinical research. WHO has developed practical implementation tools, including regulatory benchmarking frameworks, ethics oversight assessment tools, and a new clinical trials training course that attracted approximately 2,000 participants on its first day. Importantly, he stressed that WHO's approach is intended to be country-led and context-specific, supporting countries in developing systems aligned with national priorities and capacities rather than imposing external models. He concluded by emphasizing that global clinical trial structures must ultimately be responsive to the populations they are intended to serve to ensure equitable and meaningful outcomes.

# Global Partnerships in Action: Strengthening Clinical Trial Capacity through the International Vaccine Institute projects

Dr. Jessica Cowden, Deputy Director General, IVI CARE Unit, highlighted the role of the International Vaccine Institute (IVI) in strengthening clinical trial capacity through strategic partnerships and implementation-focused initiatives across Africa. She emphasized that IVI's work spans the entire end-to-end vaccine development pathway, from discovery and product development to clinical evaluation, implementation, and policy, with a strong focus on building sustainable systems for global health. Central to this effort is IVI's Clinical Assessment, Research, and Evaluation (CARE) Unit, which supports Phase I–III clinical trials and works closely with both IVI programs and external partners to strengthen clinical trial capabilities, infrastructure, and operational readiness. Dr. Cowden presented three flagship initiatives that illustrate IVI's partnership-based approach to strengthening clinical trial ecosystems:

## **ARC-WA: Advancing Research Capacity in West Africa**

The ARC-WA initiative, funded by CEPI, focuses on strengthening capacity for Lassa fever vaccine clinical trials while establishing a broader, pathogen-agnostic network of Good Clinical Practice (GCP)-compliant trial sites across West Africa. IVI serves as the technical coordinating partner, working alongside institutions including MRC Gambia and national research partners in Nigeria, Ghana, Liberia, and Sierra Leone. The initiative seeks to ensure that participating sites are not only prepared for Lassa fever research but also capable of responding rapidly to future outbreaks and health emergencies. Dr. Cowden noted that Track A of the project has been completed, with participating sites achieving GCP compliance and readiness.

## **Clinical Trial Centers of Excellence MAV+: Rwanda**

Under the MAV+ Cluster Project, IVI is partnering with the Rwanda Biomedical Centre (RBC) to strengthen the capacity of five nationally identified clinical trial sites. A comprehensive site assessment has been completed, using an approach aligned with the WHO benchmarking tool to ensure standardization and consistency in evaluating clinical trial readiness. Through support from Sida and Expertise France, the project aims to strengthen infrastructure, systems, and operational preparedness while aiding Rwanda's broader ambitions to expand national clinical research capacity.

## **ACT-CHIK: Accelerating Clinical Trials for Chikungunya Vaccines in Africa**

ACT-CHIK, a newly launched project funded by EDCTP3 to accelerate clinical trials for chikungunya vaccines in Africa, includes a Phase I/III clinical trial across Rwanda, Senegal, Kenya, and Nigeria, as well as the technology transfer of a measles-vectored chikungunya vaccine candidate from the Institut Pasteur in Paris to an African manufacturing partner, Institut Pasteur de Dakar. Importantly, ACT-CHIK includes a strong capacity-building component, designed to strengthen clinical trial sites and local expertise to support not only the current study, but also future vaccine research and development activities, including pandemic preparedness.

Dr. Cowden concluded by emphasizing that IVI's model focuses on working side-by-side with local partners through implementation, ensuring that investments in clinical trials also contribute to long-term institutional capacity, workforce development, and sustainable research ecosystems.

## Strengthening National Clinical Trial Systems: Country Experiences and Practical Strategies

This panel, moderated by Dr. Ibrahima Socé Fall, Director General, Institut Pasteur de Dakar, explored how countries are strengthening national clinical trial systems through regulatory reform, improved coordination, digitalization, and long-term investment in research ecosystems. Discussions focused on practical strategies to improve efficiency, reduce approval timelines, and strengthen national capacity to conduct high-quality and locally relevant clinical research. A consistent theme was the importance of strong governance, coordinated systems, workforce development, and sustainable partnerships to support both communicable and non-communicable disease research.



Panel session on national-led clinical trial initiatives. *Photo credit: Christine Demstader, IVI.*

Dr. Karin Tegmark Wisell, Ambassador for Global Health, Sweden, emphasized Sweden's longstanding commitment to global health and research equity, highlighting the importance of international collaboration in clinical research. She reflected on lessons learned from Sweden's experience with vaccine safety, underscoring the importance of population diversity in clinical trials. She highlighted the establishment of Clinical Studies Sweden in 2015 as a major reform aimed at strengthening coordination among universities, hospitals, regulators, industry, and patient groups. Sweden also continues to support clinical research capacity globally through initiatives such as MAV+ and EDCTP3, prioritizing long-term institutional partnerships in LMICs.

Dr. André Bastos Daher, Coordinator of the Fiocruz Clinical Research Platform in Brazil highlighted the importance of governance, operational coordination, and regulatory efficiency in strengthening clinical trial systems. Brazil has introduced reforms to streamline ethics and regulatory approvals, reducing delays and supporting earlier-stage clinical trials. He emphasized that successful clinical research requires more than physical infrastructure, noting the importance of operational capacities such as data management, protocol development, pharmacovigilance, and trial coordination. Brazil's approach aims to strengthen connections between researchers, government institutions, and the national health system to ensure research aligns with national priorities and supports broader South-South collaboration.

Dr. Nguyen Trong Toan, Pasteur Institute of Ho Chi Minh City, Viet Nam, described Viet Nam's progress in strengthening clinical trial capacity through regulatory reform and institutional standardization. Since conducting its first vaccine clinical trial in 1997, Viet Nam has developed national guidance aligned with Good Clinical Practice (GCP) standards and established standardized requirements for clinical research centers. Dr. Toan emphasized the importance of clear regulatory frameworks and institutional compliance, which have strengthened Viet Nam's participation in international research and supported national vaccine manufacturing ambitions.

Dr. Nyanda Elias Ntinginya, Director of Research Coordination and Promotion, NIMR, Tanzania, highlighted three major reforms that have strengthened Tanzania's clinical trial ecosystem: standardization of clinical trial frameworks, digitalization of submission systems, and improved coordination between ethics and regulatory authorities. The move to online submissions has reduced bottlenecks and increased transparency, while closer alignment between ethics and regulatory reviews has shortened approval timelines. Dr. Ntinginya emphasized that these reforms are helping transform Tanzania's clinical trial system into a more efficient and responsive ecosystem linked to broader manufacturing and research ambitions.

Dr. Vasee Moorthy, Senior Advisor, Science and Strategy, WHO, highlighted the WHO Global Action Plan for Clinical Trial Ecosystem Strengthening (GAP-CTS) as a practical framework for strengthening national systems. He stressed the need for national leadership, coordinated governance, and stronger integration between ethics and regulatory systems. WHO has developed benchmarking tools and assessment frameworks to support countries in strengthening regulatory systems, research ethics oversight, and workforce development. Dr. Moorthy also emphasized the importance of using clinical trial systems developed for infectious diseases to support non-communicable disease (NCD) research, ensuring broader and more sustainable health system benefits.

## Key Takeaways

The discussion underscored that strengthening clinical trial systems requires national leadership, coordinated governance, harmonized ethics and regulatory systems, digitalization, and workforce investment. Panelists emphasized that clinical trial ecosystems must support both routine health priorities and outbreak preparedness, while generating evidence relevant to local populations.

Continued collaboration through initiatives such as WHO, EDCTP3, MAV+, and national partnerships will be essential to sustain momentum and strengthen equitable clinical research capacity globally

# Strengthening clinical trial systems through Global Network Partnerships: The Pasteur Network approach

Dr. Rebecca Grais, Executive Director, Pasteur Network, presented the Pasteur Network (PN) approach to strengthening clinical trial systems through global collaboration, highlighting the Network's role in building sustainable research, manufacturing, and preparedness ecosystems. The Pasteur Network is a global alliance of 32 member institutes across 25 countries and five continents, bringing together expertise in public health, epidemiology, research, and outbreak response to advance equitable access to health innovations. Dr. Grais outlined the Network's four strategic priorities: epidemic preparedness and intelligence, research and innovation, knowledge sharing, and good governance and equity, all of which support stronger and more inclusive health systems.

A major focus of PN's work is the Vaccine Manufacturing Initiative (VMI), launched in 2024 to strengthen coordination among vaccine manufacturers across the Network. The initiative connects 12 vaccine manufacturers and vaccine development research institutes, collectively producing approximately 500 million vaccine doses annually, with the goal of accelerating vaccine development through technical exchange, collaboration, and shared expertise.

Dr. Grais emphasized the importance of partnerships and ecosystem development, noting that PN works closely with global initiatives such as the WHO mRNA Technology Transfer Hub, CEPI's Global Manufacturing Network, Gavi, and UNICEF supply systems, while also partnering with the International Vaccine Institute (IVI) to strengthen vaccine and manufacturing capacity in the Global South.

A key pillar of the initiative is capacity building, including workforce development, mobility, and training. Several Pasteur Network members now serve as WHO regional training hubs for biomanufacturing, supporting technical expertise and regional skills development in areas including West Africa, North Africa, and Latin America.

Dr. Grais also highlighted the need to invest in the broader ecosystem surrounding vaccine development and manufacturing, emphasizing that sustainable progress depends not only on individual products but also on strong regulatory systems, workforce capacity, infrastructure, and research networks. In this context, PN is increasingly focused on sustainable vaccine production, including preparation for future WHO guidelines on the carbon impact of vaccine manufacturing.

In parallel with manufacturing efforts, the Pasteur Network is strengthening clinical trial readiness and capacity across member institutions by establishing a clinical trial network. These efforts aim to improve preparedness for health emergencies while strengthening the long-term research and development ecosystem.

Dr. Grais concluded by underscoring a central message of the discussion: sustainable vaccine innovation depends on strong systems and partnerships, not only products, and requires long-term investment in

institutions, infrastructure, training, and collaboration to ensure equitable access to health innovation globally.

## Panel Discussion 2: Practical Approaches to Strengthening Capacity, Efficiency, and Global Collaboration

This panel, moderated by Dr. Jessica Cowden, Deputy Director General, IVI CARE Unit, explored practical tools, innovative trial models, digital systems, and strategic partnerships to strengthen clinical trial capacity in low- and middle-income countries (LMICs). Discussions focused on approaches to improving efficiency, preparedness, sustainability, and outbreak responsiveness, while emphasizing that strengthening clinical trial systems requires connected ecosystems rather than isolated investments. Panelists highlighted the importance of interoperable data systems, harmonized protocols, sustainable financing, workforce development, and long-term partnerships.



Panel session on tools to strengthen clinical trial capacity and efficiency. *Photo credit: Christine Demstedeier, IVI.*

Dr. Melanie Saville, Chief Scientific Officer, PATH, emphasized the importance of data systems and interoperability as essential enablers of effective clinical trials, particularly during outbreaks. Drawing on PATH's experience supporting vaccines such as MenAfriVac and RTSS malaria vaccines, she highlighted that while many countries have data systems in place, a major challenge remains the lack of interoperability across institutions and countries. Fragmented systems can delay data sharing and decision-making, particularly in multi-country trials. Dr. Saville stressed the need for strong governance, trust, and interoperable platforms to enable real-time collaboration and rapid evidence generation during health emergencies.

Aurelia Nguyen, Deputy CEO, CEPI, highlighted clinical trial networks as a cornerstone of outbreak preparedness and sustainable capacity building. She emphasized that effective trial systems depend on linkages between trial sites, regulators, research institutions, and global partners, supported by harmonized standard operating procedures (SOPs), governance mechanisms, and data systems. Outbreak-ready sites, she noted, must remain active through routine research to maintain readiness. Ms. Nguyen highlighted ARC-WA (Advancing Research Capacity in West Africa) as an example of CEPI's work to establish Good Clinical Practice (GCP)-ready sites, while also referencing the Bundibugyo Ebola outbreak as a real-world test of CEPI's 100 Days Mission, which aims to accelerate vaccine development and emergency response timelines.

Dr. Michael Makanga, Executive Director, Global Health EDCTP3 Joint Undertaking, emphasized equitable partnerships and ecosystem strengthening as central to the work of Global Health EDCTP3, which has supported more than 600 clinical trials across Africa. He highlighted investments in workforce development, research infrastructure, ethics and regulatory systems, and regional research networks, noting that stronger systems are critical for outbreak preparedness. EDCTP3-supported investments in genomic surveillance and laboratory capacity have already contributed to recent outbreak detection and response, including in the current Ebola Bundibugyo outbreak. Dr. Makanga also emphasized the growing role of digital technologies and artificial intelligence (AI) in improving clinical trial implementation, particularly in underserved settings, while maintaining scientific and ethical rigor.

Dr. Florian von Groote-Bidlingmaier, Head of Clinical Research, Wellcome Trust, identified platform trials and artificial intelligence as key innovations for improving the efficiency and cost-effectiveness of clinical research. He emphasized the value of platform trial designs, which allow multiple interventions to be evaluated within a shared framework, enabling faster and more flexible evidence generation. Lessons from COVID-19 platform trials demonstrated how adaptive models can accelerate results while reducing costs. He also cited ADVANCE-ID, a Wellcome-supported network in Southeast Asia, as an example of how locally led platform trials can address regional health priorities. Wellcome continues to support the expansion of platform trial infrastructure in LMICs to strengthen long-term research responsiveness.

Cecile Billaux discussed the role of the European Commission's DG-INTPA and the Team Europe Initiative MAV+ in strengthening pharmaceutical and clinical trial ecosystems in Africa. With more than €2 billion invested, MAV+ supports African local manufacturing ambitions through investments in supply, demand, and ecosystem strengthening. Ms. Billaux stressed that clinical trial capacity is fundamental to sustainable manufacturing, as product development and regulatory approval depend on strong research systems. She emphasized the importance of country-led partnerships, long-term collaboration, and innovative financing approaches, including blended finance and risk-sharing mechanisms, to ensure sustainability beyond grant funding.

## Key Takeaways

The panel reinforced that strengthening clinical trial systems in LMICs requires integrated ecosystem development rather than stand-alone projects. Priorities identified included:

- Interoperable data systems and stronger governance frameworks to improve coordination and data sharing;

- Clinical trial networks and harmonized protocols to strengthen preparedness and rapid outbreak response;
- Equitable partnerships and local scientific leadership to build sustainable institutional capacity;
- Platform trials and digital innovations, including AI, to improve efficiency and reduce costs;
- Long-term, country-owned investments linked to broader manufacturing ambitions and national priorities.

Participants also emphasized the importance of ensuring clinical trial systems support not only vaccines and therapeutics, but also diagnostics, recognizing their essential role in outbreak preparedness and response.

## Conclusion

The discussions throughout this side event underscored a clear and urgent message: strengthening clinical trial ecosystems is essential for global health equity, preparedness, and innovation. Clinical trials are not merely a technical component of research and development—they are foundational to ensuring that vaccines, therapeutics, diagnostics, and other health interventions are safe, effective, and relevant to the populations they are intended to serve.

Across country experiences and institutional perspectives, participants highlighted both substantial progress and persistent challenges. Countries including Brazil, Ghana, Tanzania, Viet Nam, and Sweden demonstrated that meaningful improvements are possible through national leadership, coordinated governance, and sustained investment in systems. Regulatory reform, ethics coordination, digitalization, standardization of clinical trial sites, and stronger linkages between research institutions and health systems were repeatedly identified as key enablers of success. Experiences shared during the event reinforced that strong clinical trial systems must be embedded within broader health, research, and manufacturing ecosystems, rather than developed in isolation.

A major theme emerging from the discussions was the importance of building sustainable ecosystems rather than supporting individual projects alone. Strengthening clinical trial capacity requires investment not only in infrastructure, but also in workforce development, operational expertise, interoperable data systems, ethical and regulatory frameworks, and long-term institutional partnerships. Participants emphasized the need for clinical trial systems that are capable of supporting both routine health priorities and rapid outbreak response, including through platform trial models, harmonized protocols, and outbreak-ready research networks.

The event also highlighted the critical role of global partnerships and collaborative networks. Organizations including WHO, CEPI, EDCTP3, PATH, IVI, the Pasteur Network, Wellcome, and Team Europe initiatives such as MAV+ are already supporting countries through technical assistance, financing, research coordination, and capacity-building efforts. However, participants consistently emphasized that successful partnerships must be country-owned, aligned with national priorities, and focused on long-term sustainability, rather than fragmented or donor-driven approaches.

Importantly, discussions reinforced the need to ensure that strengthened clinical trial systems serve all populations equitably, particularly those in low- and middle-income countries that continue to face barriers related to infrastructure, financing, and access. Investments in clinical trials must also extend beyond infectious diseases to address growing burdens of non-communicable diseases while ensuring diagnostics, therapeutics, and vaccines are developed with diverse populations in mind.

Ultimately, the event demonstrated that the tools, expertise, and partnerships needed to strengthen global clinical trial ecosystems already exist. The challenge now is to sustain momentum, deepen collaboration, and translate commitments into coordinated action that strengthens national capacity and ensures more equitable access to health innovation worldwide.

## References

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