



IFPMA

The road to strengthening clinical trials

A discussion convened by IFPMA at WHA76

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Introduction

One year following the adoption of the World Health Assembly (WHA) Resolution on “Strengthening clinical trials to provide high-quality evidence on health interventions and to improve research quality and coordination” ([WHA75.8](#)), IFPMA convened [a discussion](#) to assess progress made with the Resolution’s implementation and next steps. The discussion took place on 24 May 2023, on the margins of the 76th World Health Assembly (WHA76), in Geneva.



Speakers

- **Dr Vasee Moorthy**, Senior Advisor, R&D, World Health Organization
- **Dr Mary De Silva**, Deputy Chief Scientific Adviser, UK Department of Health and Social Care
- **Dr M. Khair ElZarrad**, Director, Office of Medical Policy, Center for Drug Evaluation and Research. US Food and Drug Administration
- **Dr Nathalie Strub-Wourgaft**, COVID Preparedness and Response Director, DNDi, PANTHER Delegate General
- **Dr Wiweka Kaszubska**, Vice President, Head of Product Development, Medicines for Malaria Venture
- **Dr Jennifer Harris**, Director of Research Policy, ABPI

What does the Resolution entail?

- The Resolution was put forward by Argentina, Peru, the United Kingdom, and Northern Ireland and was co-sponsored by Norway, Switzerland, and Singapore at the 75th session of the World Health Assembly in 2022.
- It is the first Resolution focused on randomized controlled trials (RCTs) since the 2005 Resolution ([WHA58.22](#)) establishing the World Health Organization (WHO)'s [International Clinical Trials Registry Platform](#), and enabling global standards for clinical trials registries.
- It recognizes the importance of well-designed and well-implemented clinical trials for assessing globally the safety and efficacy of health interventions; their role in the development of safe and efficacious new health interventions; the potential benefits of collaboration, coordination, and the exchange of information between public and non-public funders of clinical trials; and acknowledges the importance of promoting equity in clinical trial capability with a focus on Low-and-Middle Income Countries (LMICs).
- It outlines actions for Member States, national authorities (research funders, ethics, regulatory), non-state actors (private and public sector) and the WHO to enable well-designed and implemented trials globally.
- The Resolution aims to:
 - Streamline features needed for reliably informative evidence;
 - Remove excessive bureaucracy and add new models for coordinated approvals;
 - Ensure better international coordination, prioritization, and links with policy; and
 - Support capacity development initiatives.

The Resolution:

- Calls for governments to acknowledge the central role of RCTs in the health sector, in generating knowledge for decision-making.
- Calls for national authorities and non-state actors (NSAs) to focus RCTs on the key aspects needed to generate needs-based, high-quality evidence.
- Calls for the WHO to develop guidance on design quality, ecosystem strengthening and filling gaps in evidence in under-served groups.

Event summary

Panelists and speakers attending the event shared their expert insights and highlighted where they see the greatest potential for impact of the Resolution, both in pandemic and inter-pandemic settings. They explored potential challenges, identified opportunities, and facilitated dialogue on the actions necessary to ensure successful implementation of the Resolution's various elements.

Key messages that emerged from the discussion include:

- There is the urgency to strengthen the ecosystem for clinical trials globally, a process that will need strong collaboration from a variety of stakeholders, including the pharmaceutical industry, the funding community, Product Development Partnerships (PDPs), Non-Governmental Organizations (NGOs), public sector, and political will from national governments.
- There are already many useful initiatives ongoing - such as the [ICH](#)-Good Clinical Practice (E6), the Global Research Collaboration for Infectious Diseases ([GloPID-R](#)), and International Coalition of Medicines Regulatory Authorities ([ICMRA](#)) -, eliminating the need to create new ones, and rather calling for a more structured and streamlined coordination to use them at their best.
- Funders have a critical role to play in achieving a stronger, healthier clinical trials ecosystem. Funds need to be directed towards building sustainable clinical trial capability, infrastructure, and networks, ensuring good quality overall.

In the next pages, we provide a high-level summary of the role this Resolution plays in advancing and modernizing clinical trials and achieving a stronger global clinical trials ecosystem.

The WHO defines as a clinical trial any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes.¹

Setting the scene, speakers initiated the discussion by summarizing how the Resolution came to be and expanding on its potential. The discussion continued with exchanges on where we stand today in terms of implementation and future activities.

¹ <https://www.who.int/news-room/questions-and-answers/item/clinical-trials#:~:text=For%20the%20purposes%20of%20registration,the%20effects%20on%20health%20outcomes>

A stronger clinical trials ecosystem

Building on and coming off the lessons learned from the COVID-19 pandemic, which highlighted the urgent need to strengthen the clinical trials ecosystem, the Resolution was labelled by all as a great opportunity to “*actually change the world*”. To do this, strong collaborations, and involvement by a variety of stakeholders, including the pharmaceutical industry, funders, PDPs, NGOs, public sector, and governments, will be needed.

Quality as the cornerstone

In the context of the lessons learned, speakers highlighted that during the pandemic many trials did not produce generalizable results, therefore failing to deliver. Most of the time this was because they were too small and sometimes single arm, overall indicating a lack of robust design, a quality that cannot be underestimated for a clinical trial to be successful. This is one of the topics on which the Resolution urges for more attention and implementation.

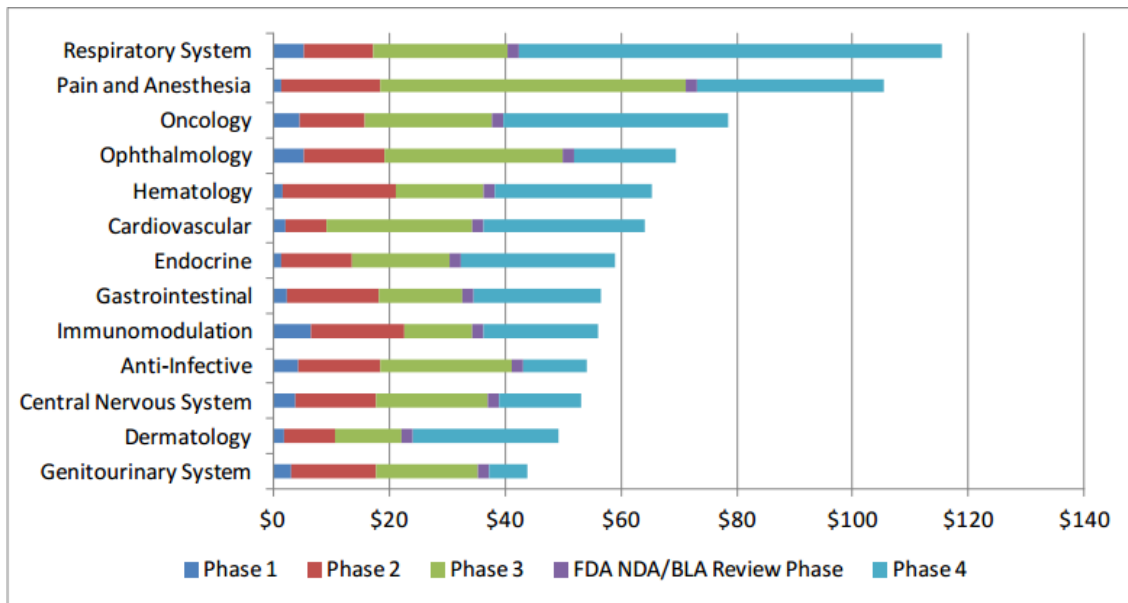
The Resolution further highlights the need to strengthen clinical research capabilities and to address the needs of underserved populations. But its real aim is to strengthen the ecosystem for clinical trials globally. To do this, according to the speakers, stakeholders will need to work across four different pillars that are articulated in the Resolution, namely:

- Enhancing clinical trial capability, particularly in LMICs;
- Strengthening coordination and international collaboration so that infrastructure and capabilities are used to the best effect;
- Improving standards for clinical trials; and
- Streamlining regulatory and ethical processes, so to ensure that trials start quickly, and that the products resulting from them can be used in a timely manner.

This collaborative process will enable a more efficient and diverse global clinical trials ecosystem, with quality as a cornerstone. It will also help deliver effective health interventions for diverse populations.

A known need

The urgency to modernize and advance clinical trials is not new. In fact, as one of the speakers mentioned, clinical trials today are still costly. A lot of them are protracted, complex, burdensome and have significant failure rates that need to be addressed across the board. Some are also not responsive to patient or community needs or lag in incorporating innovations. To address this, and advance clinical trials, speakers voiced the need for multiple efforts including the introduction of responsive guidelines, harmonizing implementation, effective training, and capacity building.



Clinical Trial Costs (in \$ Millions) by Phase and Therapeutic Area²

Pivoting during a pandemic

The diverse global clinical trials ecosystem the Resolution is aiming to achieve will need to be flexible enough to be applicable not just during pandemic times, but also for ongoing health challenges. To achieve this, speakers voiced the need to work in many areas, particularly to understand the infrastructure required to effectively pivot during a pandemic:

- Understanding and developing the required pre-existing infrastructure globally to enable effective and coordinated clinical trial responses to pandemic threats, such as clinical trial networks and standing trial platforms.
- Understanding the mechanisms required to pivot routine clinical trial capacity across the global ecosystem to trigger effective pandemic response.
- Understanding the roles of all actors in coordination and facilitating high quality research more readily through trials.

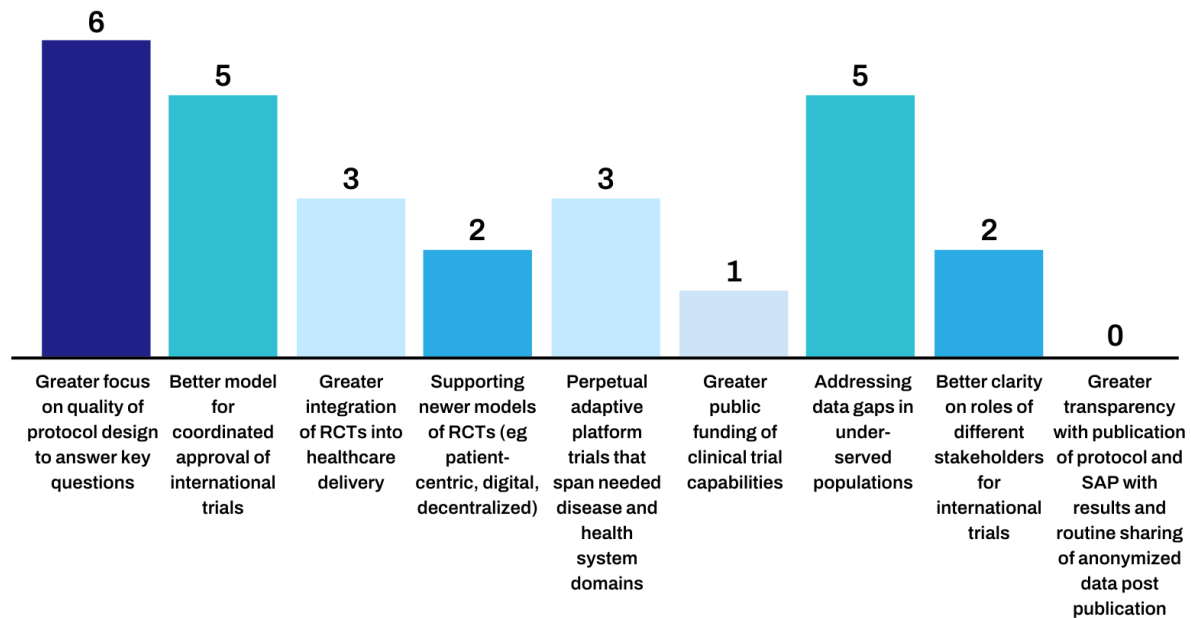
To support this, collaboration among different actors will be crucial.

The case for robust global collaboration

A common theme brought up by the speakers was the need for better coordination among stakeholders globally. There are in fact already several initiatives ongoing - such as the [ICH-Good Clinical Practice \(E6\)](#), the [Global Research Collaboration for Infectious Diseases](#)

² <https://aspe.hhs.gov/reports/examination-clinical-trial-costs-barriers-drug-development-0>

(GloPID-R), and International Coalition of Medicines Regulatory Authorities (ICMRA) -, bypassing the need to create new ones, with discussants rather urging to make them more than the sum of their parts so to deliver better outcomes. In this regard, the WHO has been identified as one of the key players able to understand current capacity and the roles each actor has in strengthening it.



Results from Mentimeter poll conducted with audience: *Which of the following do you see as the priority area of focus for advancing the role of RCTs in health decision-making?*

Strengthening international coordination

Taking as an example the ICH-Good Clinical Practice (E6) - the only agreed upon guideline that is harmonized among the global regulatory community for clinical trial conduct – speakers stressed the need to avoid confusion in applicability and utility of guidelines. These are in fact useful, but alone are not adequate in addressing all scenarios and evolving innovations. What is needed is:

- Collaboration on implementation and capacity building, critical with increasingly global clinical trials;
- Development of responsive and accessible training with the global community in mind; and
- Avoiding an all-or-nothing approach to innovative designs and technologies, taking under consideration that hybrid designs utilizing fit-for-purpose tools and technologies may be most efficient.

Discussing the current ecosystem, the panelists further acknowledged the fact that funding is key to ensure this works properly and clinical trials run correctly, providing the ability to change policies and practices in the long run. For funding to better address the needs of the ecosystem, speakers considered it will be crucial to ensure that clinical trials capability and infrastructure are sustainable; that they are of good quality; and the funding of clinical trials networks.

When it comes to inclusion and equity in clinical trials, panelists underlined that it is important that initiatives include a fair representation including from LMICs. There was also agreement on the urgency to fill the data gap that currently exists when it comes to vulnerable and underserved population, such as pregnant women and women of unknown pregnancy status and women of childbearing age (or potential) who may be pregnant. In this regard, the Resolution has the potential to improve these aspects, protecting these populations not from clinical research but through it.



Results from Mentimeter poll conducted with audience: *Where do you see potential challenges in the implementation of the WHA Resolution?*

Looking towards a successful implementation

The event brought to light how the clinical trials Resolution cannot exist in isolation. In order for it to have a real impact, several parts need to be addressed and implemented. Speakers agreed that its success relies on the ability to ensure quality of design, appropriate fundings, stakeholders' coordination (including by funders), as well as on Member States' action and change at the domestic level. Both the audience and the speakers agreed that the greatest challenges in the implementation of the Resolution will be capacity and funding. But if addressed, these will help with trial design, quality, and pivoting from endemic to emergency setting faster when needed.

It was also made clear how the Resolution plays a key role when it comes to capacity and capability building, in highlighting the importance of data sharing, and in promoting diversity and access to underserved communities. It can in fact also help ensuring research is embedded in healthcare systems therefore ensuring a pro innovation ecosystem.

For the resolution to be fully and effectively implemented, collaboration at the international level will be key.

Resolution timeline and next steps

- Efforts to have different kinds of consultations, with different stakeholders from all over the world are being undertaken. The WHO maintains a [webpage dedicated](#) to the implementation of the Resolution.

About IFPMA

The International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) represents over 90 innovative pharmaceutical companies and associations around the world. Our industry's almost three million employees discover, develop, and deliver medicines and vaccines that advance global health. Based in Geneva, IFPMA has official relations with the United Nations and contributes industry expertise to help the global health community improve the lives of people everywhere.

For more information, visit ifpma.org