



Ensuring global equity and population diversity in clinical trials and drug approval

STUDY GUIDE



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LETTER FROM YOUR CHAIR

Welcome, delegates!

My name is Marco Marciano, I'm a tenth-grader and I'm very excited to be your chair this year for WHO at SPMUN alongside your co-chair Emma Ottone. I started to be a part of SPMUN in seventh grade (ironically, also in WHO), and have had the opportunity of being a delegate for the past three years both in school and outside. I'll be very transparent with all of you. At first, I was very (VERY) scared of participating in activities like this, however, once I stood up to try it, I surprised myself by finding out that I ended up enjoying almost every part of it. Delegates, I recommend you all to see the MUNs as an opportunity to test yourselves. Not only in your use of English, but in speaking out loud, doing research, defending a position, getting to know new people, and most importantly, getting to know more about yourselves.

It doesn't matter if this is your first or last MUN, what matters most is that you enjoy every moment, and try to do as best as you can as a delegate. I assure you both Emma and I will do our best at moderating the debate, to ensure that all of you have an entertaining and memorable experience while being part of WHO 2026. As you all know by now, we have chosen "Global equity and population diversity in clinical trials and drug approval" as our topic this year. I won't go in depth about the implications or importance of these discussions in this letter, let's leave that for the research and the debate itself, however, I'm very excited to see all the information you'll come up with to get the debate rolling. This is a very extensive topic that can be seen from many perspectives of the WHO, so don't limit yourself while investigating, the more you know, the more present you'll be in the debate, and more confident you'll be in your own arguments.

If any of you has the same struggle I had regarding speaking publicly, I highly recommend that to overcome it, you participate actively in the debate. Once you know where the discussion is going towards, and you know you're prepared for it, confidence comes by itself. Don't be afraid of bringing up your ideas to the table, be afraid of ending this MUN without having said everything you wanted to, and knowing you could've done more. I can guarantee you that inside every committee, there's way more than one person that struggles with this, so take into consideration that if you're scared to participate, you're not alone. I'll share this with all of you. I can confidently say, through my personal experience, that the feeling of having done everything you could, regardless of the result, is way more satisfying than staying with thoughts like "I could've done better" or "I could've tried harder". I humbly suggest applying this in your life, not just in these activities.

Delegates, remember that both Emma and I are here to guide and help you in anything you need, so know you can contact us at any time if any of you has doubts regarding the MUN. We hope that you're as excited as we are for this edition of the MUN, and as your chair, I wish you all the best of luck.

LETTER FROM YOUR CHAIR

Dear delegates,

I hope this letter finds you well and excited for this year's SPMUN. My name is Emma Ottone, I am a tenth-grade student, and I am very excited to welcome you to the World Health Organization, WHO, as your Co-Chair alongside your Chair, Marco Marcano.

Last year was my first MUN experience, and I was very nervous at the beginning. I did not know what to expect, but seeing the conference unfold and watching everyone debate made me want to step out of my comfort zone. With the support of my chairs, I became more confident in participating and defending my position. I soon realized that MUN was about much more than debating; it was about listening to different perspectives, challenging ideas, and working with others to find solutions. That experience is one of the reasons why I am so excited to be part of the team leading WHO this year.

This year, we will be discussing "Ensuring Global Equity and Population Diversity in Clinical Trials and Drug Approval". This topic raises important questions about representation in medical research, drug approval, and healthcare equity. I encourage you to look beyond the study guide, research your country's position, and come prepared to question different perspectives and think critically about possible solutions. There is rarely one perfect answer, and some of the best debates come from finding a balance between different priorities.

Whether this is your first MUN or you are already experienced, I encourage you to challenge yourself. Do not let nerves keep you from raising your placard, sharing your ideas, or participating in debate. A good delegate is not simply the one who argues the most, but the one who contributes, listens, proposes solutions, and works with others to move the discussion forward.

Marco and I are here to guide you and make sure you have a great experience in WHO. I am looking forward to meeting all of you, hearing your ideas, and seeing how this committee develops throughout the conference.

Come prepared, participate actively, challenge yourself, and most importantly, enjoy the process. I cannot wait to see you in WHO!

Your Co-Chair,
Emma Ottone

COMMITTEE INTRODUCTION

The World Health Organization, WHO, is a specialized organization of the United Nations that was established in 1948 with the primary objective of promoting health and well-being worldwide. Its work focuses on coordinating international health efforts, establishing global health standards and recommendations, supporting countries in strengthening their healthcare systems, and responding to public health emergencies.

Throughout its history, WHO has performed a fundamental role in the prevention/control of diseases, promoting vaccination, improving the access to medicines, and addressing health inequalities. In addition, WHO also serves as a platform for cooperation between member states, allowing them to discuss global health challenges and develop international strategies and policies.

In this committee delegates will address one of the current challenges in global health, *“Ensuring Global Equity and Population Diversity in Clinical Trials and Drug Approval”*. Through debate and negotiation, delegates will examine inequalities in clinical research and work for solutions that promote more inclusive and equitable approaches to the development and approval of medical treatments.

INTRODUCTION TO THE TOPIC

Clinical trials are an essential part of developing and approving medicines because they provide the evidence needed to determine whether treatments are safe and also effective. However, people from different regions, ethnic backgrounds, ages, health conditions, etc, are not always equally represented in the clinical research. This lack of diversity can make it more difficult to determine if a treatment will work equally well for different populations.



At the same time countries around the world face inequalities in access to medical research, technology, funding, new treatments, etc. Drug approval therefore requires countries to balance the scientific evidence, the safety, the efficiency, and the specific needs of their populations. International cooperation can help greet these challenges by promoting greater diversity in clinical trials, strengthening regulatory systems, and encouraging fairer access to the medical advances.

Ultimately this topic raises an important question for the global community, how can countries ensure that medical progress is safe, inclusive, and accessible to people around the world, regardless of where they live or the population they belong to?



KEY TERMS

Tech transfer— the formal, structured process of sharing product knowledge, manufacturing methods, analytical procedures, and quality standards.

Bridging studies— a supplemental clinical or analytical test conducted to prove that existing drug data from one population, region, or formulation can be safely applied elsewhere.

Clinical trial — controlled research study that evaluates the safety, efficacy, and side effects of a drug or medical treatment before it can gain regulatory approval.

Adverse event — unfavorable and unintended medical occurrence in a patient who receives a pharmaceutical product, regardless of whether it has a causal relationship with the treatment.

Bureaucratic process— highly structured, formalized, and strictly regulated workflows designed to ensure the safety, efficacy, and quality of medical products.

Manufactured — the industrial-scale process of transforming raw materials and active ingredients into safe, effective, and standardized finished medication.

Globalization — the integration of drug research, manufacturing, supply chains, and markets across international border.

Drug lag — time delay between when a new pharmaceutical is first approved or made available in a leading global market

Regulatory authority — a government or public agency that ensures medicines and medical devices are safe, effective, and of high quality.

Outbreak — a sudden, unexpected increase in microbial contamination, product defects, or adverse events linked to a specific manufactured drug, medical device, or manufacturing facility.

HISTORICAL BACKGROUND

The history of modern pharmaceutical regulation was profoundly influenced by the Thalidomide tragedy in the early 60s. “Thalidomide” was a drug developed in West Germany, to help pregnant women in relieving sickness, nausea, and vomiting; produced by the pharmaceutical company Chemie Grünenthal, and started being used because of its low toxicity rates and little dependance risk. Time passed, and the drug had already been distributed to 46 countries, under different names, and as its use increased, the discoverage of adverse effects in fetuses was made.

This tragedy caused severe birth defects on over ten thousand children world wide, and displayed the importance of sufficient drug testing to find adverse effects of a medicine in the population. While the tragedy was ongoing, the regulatory systems of the countries globaly stated their positions regarding this drug, such as the United States of America, that never approved the drug for legal marketing in their country to begin with due to a lack of safety evidence.

The USA’s position towards this problem helped the other countries be mindful of the importance of independent regulatory review and adequate scientific evidence before a medicine reaches the patients. Years later, in 1962, the United States strenghtened their drug regulation system with the Kefauver-Harris Amendments, that emphasised on the requirement of manufacturers to prove with solid evidence the safety and effectiveness of a drug before being released to the market. However, not all healthcare systems around the world denied the commercialization of the Thalidomide as quick as the United States did, and had their populations affected by this problem because of the impossibility of a fast



HISTORICAL BACKGROUND

response to the issue. In Germany, the Thalidomide tragedy led to the withdrawal of the Contergan brand (brand name under which Thalidomide was sold), and eventually proliferated into major pharmaceutical regulation response, including stricter requirements to prove a medicine's safety, quality and efficacy. Since then, pharmaceutical companies have evolved and become more international, and with this, a new problem has appeared, the bureaucracy in the implementation of a pharmaco in different countries. Each country has their own regulations for accepting a pharmaco in their territory, taking into consideration different variables that can change the effectiveness of a medicine amongst different populations.

To ensure cases like the Thalidomide tragedy don't occur again, during the 90s, the International Council for Harmonisation (ICH) was created, an international regulatory authority that's in charge of making the technical requirements between countries be more similar regarding the implementation and use of a medicine in the country's healthcare system. It created a permanent framework for regulators and pharmaceutical companies to develop common scientific and technical standards for the quality, safety, and efficacy of medicines.

The ICH's guidelines are implemented by individual countries and regions through their own regulatory systems. During 1998, the ICH introduced the "Ethnic Factors in the Acceptability of Foreign Clinical Data" (E5), a new framework that acknowledges that the differences in environment, metabolism, ethnicity, genetics and physiology can be factors that contribute to the appearance of adverse effects when using a pharmaco in different populations. This means that the result from a clinical trial in one population can't always be assumed to work in another.



HISTORICAL BACKGROUND

The ICH created a permanent framework for regulators and pharmaceutical experts to develop common scientific and technical standards for the quality, safety, and efficacy of medicines. These guidelines were designed to reduce unnecessary duplication in pharmaceutical development and regulatory review while maintaining high standards for patient safety. Importantly, the ICH does not directly approve medicines or replace national regulatory authorities; its guidelines are implemented by individual countries and regions through their own regulatory systems.

The importance of this harmonization can be seen in the Common Technical Document (CTD), which established a common format for presenting information on a medicine's quality, safety, and efficacy to regulators. This helped reduce the need for pharmaceutical companies to reorganize the same scientific information into completely different formats for different regulatory authorities and contributed to more harmonized regulatory review processes.

Even though these new regulations have been made, the Thalidomide tragedy in the 60s hasn't been the only healthcare problem drug regulation and clinical trials have been a part of. In the past century, we've had problems such as the Troglitazone and Vioxx drugs in the US, the underrepresentation of pregnant women in various clinical trials, Diethylene glycol poisoning in Nigeria, contaminated medical glycerin in India, the Nimesulide in Europe, etc.



CURRENT SITUATION

In current times, medicine as a whole has become more globalized. A single drug can be researched in one country, tested elsewhere, manufactured somewhere else, and eventually, following this process, sold to the entirety of the world. Drug approval is still decided by each country's regulatory healthcare system; for example, a medicine approved in the United States is not necessarily approved for use in an Asian country or the rest of the world. Regulatory requirements are not intended to cause drug lag, their main purpose is protecting public health by ensuring a medicine's quality and the veracity of the scientific studies behind it. However, the differences between regulatory systems can cause additional procedures, costs, and delays.

One of the challenges of this topic is that reducing regulatory requirements too aggressively could also be counterproductive, because of the inadequate evaluation of a medicine's characteristics. Another challenge the international community is currently facing regarding these issues is the concern about how safe it is to use foreign clinical data gathered from one specific population, because this links with the population's diversity and representation in clinical trials. Clinical research has historically been more concentrated on North America and Europe, because of their high investment on pharmaceuticals, infrastructure and regulatory capacity, but this has created uncertainty about whether the generated evidence from predominantly represented populations can be applied to populations different from them in genetics, environment, location, or healthcare characteristics.

The COVID-19 pandemic demonstrated how important the acknowledgment of these inequalities between countries was regarding the rapid development and authorization of vaccines, research

CURRENT SITUATION

infrastructure, manufacturing capacity, access to technology, and availability of clinical evidence. During this global healthcare crisis, countries tried to accelerate international cooperation in clinical research, rolling assessments, and emergency or conditional authorization pathways to make vaccines and treatments available more quickly.

These disparities, showed that global equity can not solely depend on the ability of a country to purchase or approve medicines developed elsewhere, but also requires countries to be capable of participating in research and contribute to pharmaceutical development; because of this, international efforts have focused on the improval of regulatory cooperation, clinical-trial coordination, research capacity, and equitable participation.

In 2022, the World Health Assembly adopted Resolution WHA75.8, which called for stronger international collaboration, greater inclusion of underrepresented populations, and increased clinical-trial capacity in low-to-middle income countries. Responding to this resolution, in 2024, the World Health Organization published the Guidance for Best Practices for Clinical Trials, which promoted representative participation, ethical oversight, risk-proportionate regulation, reduced bureaucracy, and sustainable financing.

Following this publication, in 2025, the WHO further established a Global Action Plan for Clinical Trial Ecosystem Strengthening, highlighting nine priority areas for implementing these reforms and creating more efficient, inclusive and sustainable clinical-trial systems.

Despite these efforts, there hasn't been a single approach that has completely resolved the issues on its own. The international community faces the need to build upon these previous efforts to hopefully reach global equity.

PAST SOLUTIONS

The global community has previously implemented some initiatives so clinical trial systems can improve and address inequalities in medical research. These include:

1. **WHA Resolution 75.8:** In 2022 this program encouraged countries to strengthen clinical trial systems, improve their coordination and build research capacity.
2. **International Clinical Trials Registry Platform (ICTRP):** In 2006, the World Health Organization promoted transparency by making the information about the clinical trials accessible for everyone, this with the purpose to encourage the registration and the sharing of data.
3. **African Medicines Regulatory Harmonization Initiative (AMRHI):** In 2009 this program was established to strengthen regulatory authorities in Africa, with the purpose of harmonizing technical requirements, making information sharing easier and improving the efficiency of medicine registration across the participating countries.
4. **WHO Guidances for best practices for Clinical Trials:** This program was created in 2024 establishing recommendations to make the clinical trials more ethical and efficient as well as transparent and inclusive,

POSSIBLE SOLUTIONS

The following are the possible approaches that should be considered when developing the solutions to the topic. Delegates are encouraged to research these areas a little further and propose/develop realistic and actionable proposals.

1. Increasing diversity and representation in clinical trials

Encourage the inclusion of populations from different geographical areas, ethnic groups, age, sex, and health backgrounds.

2. Strengthening research capacity in underrepresented countries

Through funding, training, improved equipment and infrastructure, technology, etc.

3. Promoting equitable access to medicines and treatments

Through mechanisms like regional cooperations, pooled procurement, technology transfer, and many other measures that can help improve affordability and availability, particularly in lower income countries.

4. Improving cooperation in drug approval and regulation

By strengthening collaboration between the national regulatory authorities and promoting compatible international standards.

5. Promoting international cooperation and data sharing

Between countries and research institutions, via international organizations to facilitate the exchange of scientific knowledge, expertise and clinical trial data.

BLOC POSITIONS

United States of America: To avoid unnecessary repetition of trials, the United States of America encourages the use of high-quality international clinical data, fomenting strong standards for medicines world-wide, and trying to make the process of drug approval as efficient as possible.

Japan: The National Medical Products Administration (NMPA) focuses on whether the clinical trial data shared by foreign nations applies to its own population. It recognizes that different factors can influence how patients respond to medicines, such as genetic, physiological, environmental, etc. The NMPA encourages the creation of bridging studies that can ensure the safety of the drug before implementing it to their health care industry.

Brazil: As a supporter of international cooperation and user of foreign clinical evidence, Brazil's health care system focuses more on the equitable representation of developing countries in clinical researches. Brazil promotes the technology transfer between nations, to ensure that no underdeveloped country remains as permanently dependent on foreign pharmaceutical systems.

China: China promotes multiregional clinical trials, and harmonization for drug development standards. Its healthcare system combines international cooperation and domestic development of pharmaceuticals.

Germany: As a supporter of international regulatory harmonization, Germany encourages high standards for medicines, ethically, scientifically and safety wise, while acknowledging that multinational trials can contain valuable data.

BLOC POSITIONS

Pfizer: International biopharmaceutical company in favor of global access to medicines and the reduction of unnecessary regulatory delays. Supports greater acceptance of high-quality foreign clinical data and international regulatory cooperation. Believes that repeating similar studies in every country can increase costs and delay patients' access to medicines. However, they argue that this should be achieved without compromising safety or efficacy standards.

QUESTIONS A RESOLUTION PAPER MUST ANSWER

The following questions should guide the committee's Resolution Papers. The proposed solutions should address the main challenges presented by the topic and provide realistic and actionable measures for the international community.

- How can countries ensure greater diversity and representation in clinical trials?
- How can underrepresented populations and regions gain greater access to clinical research?
- How can countries with limited research and regulatory capacity be supported?
- How can countries cooperate and share clinical research, data, technology, and expertise?
- How can drug approval processes be made more efficient without compromising safety?
- How can the international community promote fair and equitable access to new medicines and treatments?

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