

Opening Remarks

Opening Remarks and instructions

Chieko Kurihara

Specially-appointed Professor, Kanagawa Dental University,
Kanagawa, Japan



Welcome Address

Chiaki Kagawa

Professor Emeritus, Yamanashi University
Representative Director, Japan Association for Bioethics (JAB),
Japan



Remarks from Drug Information Association

Courtney A. Granville

Director, Scientific Affairs, Drug Information Association,
Washington DC, USA



Opening Remarks and instructions

Chieko Kurihara

Thank you very much for your participation. This symposium on Clinical Trials in Ukraine and Bioethics is organized as a part of the 34th Annual Meeting of the Japan Association for Bioethics with the support of members of the Ethics Working Group of the International Federation of Association for Pharmaceutical Physicians and Pharmaceutical and Medicine (IFAPP). There is no financial support to this meeting, and all the speakers and participants are voluntarily and willingly participating.

I am Chieko Kurihara, moderator of this symposium as a member of Japan Association for Bioethics and Ethics Working Group of IFAPP.

The primary objective of this symposium is described here (Table 1). The Japanese constitution has a paragraph of eternal renunciation of war and many of the Japanese bioethicists recognize “peace” and “do no harm”, including “against war” to be among the core principles of bioethics. We wish to strengthen the structure to support Ukrainian clinical research as this represents an integral part of the scientific and healthcare system of the country, as well as being integral to the continued development of the society. This is a right of sovereign state, and we as a community of bioethicists and researchers have an obligation to strengthen solidarity to provide ongoing support to Ukrainian researchers and patients and the public. Today, we are grateful

Table 1 The primary objectives of the symposium

- The Japanese Constitution has a paragraph of **eternal renunciation of war** and many of the Japanese bioethicists recognize peace and "do no harm" (against war) to be among the core principles of bioethics.
- This symposium wishes to strengthen the structure to support Ukrainian Clinical Research as this represents an integral part of the scientific and healthcare systems of the country as well as being integral to the continued development of the Ukrainian society.
- This is a **right of a sovereign state** and we as a national and international community of bioethicists and researchers have an obligation to strengthen solidarity to provide ongoing support to the importance of clinical research and the expansion of awareness regarding the situation of research, medicines, and health in Ukraine.
- To day we are grateful to have the Ukrainian speakers to convey the real status of current situation.
- We wish to learn how we can support Ukrainian researchers and patients/public, while also considering development of international guidelines for research in war/conflict and other disruptive situations, based on reflection in depth of bioethical implications.

Table 2 The secondary objectives

- The Japanese participants will take this symposium as a precious opportunity for reflection on a more in-depth analysis of the bioethical implications of the current situation, framing it in their own historical experience of both of aggression in other countries as well as being attacked by weapons of mass destruction during World War II.
- The international participants will expand our ongoing considerations for publication of scientific papers considering international guideline development and outputs based on this symposium and other for addressing research and ethics in conflict and other disruptive situations.

to have the Ukrainian speakers to convey the real status of their situations.

This is the secondary objectives (Table 2). The Japanese bioethicists will take this precious opportunity for reflection on the bioethical implications of the current situation considering our own historical experience of both of aggression in other countries, as well as being attacked by weapons of mass destruction during World War II. The international participants will expand our ongoing discussions for publication of scientific papers considering international guideline development, addressing research and ethics in conflict, and other disruptive situations.

This is the profile of participants (Table 3). There are participants from these countries, and many are medical professionals and researchers, but most of them are bioethicists and others are bioethicists of non-medical professionals.

For the opening, Chiaki Kagawa, Professor Emeritus, Yamanashi University and Representative Director of the Japan Association for Bioethics will have Welcome Address. After one commentator from Drug Information Association (DIA), Courtney Granville will provide a message bridging the previous webinar organized by DIA to this one, three Ukrainian speakers will give presentations, and then four commentators will make comments. We hope that all the participants could learn from this precious opportunity.

Table 3 Profile of participants

Country	Detailed profile	
Japan	Bioethicists: 2 Medical professional: 2	4 (Later shared among bioethicists (members of JAB) in Japan.)
Ukraine	Medical professional/research specialists (speakers): 3 Medical professional/research specialists (participants): 4	7
Europe	Bioethicist, Belgium: 1 Medical professional/research specialists, Hungary, Switzerland, France, Poland: 4	5
USA	Medical professional/research specialists: 3 Bioethicists: 2 Regulator (bioethicist): 1	6
Australia	Medical professional/research specialists: 1	1
Liberia	Bioethicist: 1	1
India	Bioethicist: 1	1
Total	Medical professional/research specialists: 17 Bioethicists: 7 Regulator (bioethicist): 1	25

* This categorization is not based of the agreement of each participant.
Most/many of medical/research specialists seem to be bioethicist.

Welcome Address

Chiaki Kagawa

As the Representative Director of the Japan Association for Bioethics (JAB), I am pleased that JAB will host this important international workshop under the title ‘A Symposium on Clinical Trials in Ukraine and Bioethics.’

The Russian attack on Ukraine has not only shocked people around the world, but it continues to have a dismal effect on many aspects of people’s lives. Around the world, people have been shocked and dismayed by this war. Scientists, public health officials, ethicists, and people generally are becoming increasingly aware of issues in clinical research that have become more challenging and urgent than previously thought.

Ukraine and Russia still hold large positions internationally as places where clinical researches are conducted. Big pharmaceutical companies with global activities are conducting large number of clinical studies in both countries as are too smaller and equally important investigator-driven studies. The international community as well as the national and local communities have benefited from the valuable work in clinical trials conducted in Ukraine and Russia. However, the recent military conflict has made it extremely difficult to continue clinical studies in both countries. The current changes will have a direct impact not only on Ukraine, but also on the international community. First and foremost, we need to understand the situational challenges of research in this disruptive situation. This includes the ethical challenges, as well as the challenges arising in trial conduct and logistics.

In this symposium, we will explore the current situation of clinical research in Ukraine from the perspective of ethics. We will ask what this new situation of conflict means for the ethics of clinical research internationally and what we need to learn from it. Furthermore, we need to think about how clinical research should be conducted scientifically and ethically in the limited situation of war, based on an appreciation of the current situation. It is not just the special issues related to extreme situations such as war that needs to be considered. Considering the universal conditions required for clinical research itself, regardless of the situation, it should be indispensable even when we are in the extreme situation of war.

In an exceptionally fluid situation fraught with many new problems, it is difficult to find the direction that the international community should take in response to the clinical research situation in Ukraine today. However, in order to grasp such a difficult perspective, we should be able to provide solid clues based on both the recognition of the current state of clinical research in Ukraine and a broader consideration of the role the clinical research enterprise plays in our societies today.

It is our hope that this symposium on ‘Clinical Research in Ukraine’ will help us to have a better understanding of the role of ethics in research during conflict situations as well as the responsibility of the international science and ethics communities in providing adequate responses.

On behalf of my colleagues at the JAB, I look forward to welcoming you to this symposium.

Remarks from Drug Information Association

Courtney A. Granville

I am here from Drug Information Association (DIA), a neutral, multidisciplinary membership organization. We use our neutral platform to educate and convene stakeholders to solve problems and ensure the integration of innovation into our clinical trials and clinical research continuum.

Back in March of 2022, I was at our Europe annual meeting where our stakeholders talked to us about bringing forward the conversation around the impact of the war in Ukraine. So beginning in May, we started to organize a webinar series, recognizing that the war brought with it an unprecedented crisis in clinical trials and research. We saw that we could use our platform to share experiences and up-to-date information and also to unite the international clinical research community around what they needed to do to develop local, regional, and global responses, and going beyond that, also about preparedness for disruptive events and to create a lasting output and impact that could guide response in the future.

Starting those webinars back in May enabled a connection to the Ukraine Clinical Research Support Initiative (UCRSI). Working with this group, which is led by Francis Crawley, Viktoriia Dobrova, Mark Turner, and Beata Aurich, names that are not unfamiliar to this group, we were able to bring this important discussion forward through another six webinars with many, many expert speakers, and about 600 different registrants and participants in the webinars. We covered the regulatory response to the war, the needs that exist for streamlining future guidance and good clinical practice guidelines to apply in conflict situations, ethical considerations to prioritize support and protect study participants who have been impacted, and spe-

cifically also the impact of the war on cancer clinical trials and on patients living with what is rare disease. So we covered quite a breadth.

The webinars highlighted not just the resilience of the clinical research enterprise in the region, but also highlighted the need to think differently about clinical trials and research in our current ecosystem, so we can preserve its ability to innovate and bring solutions forward to patients even in times of crisis. In fact, the conflict has highlighted the critical societal importance of research and its role in maintaining both health and economic prosperity.

We are now working as a team with IFAPP and the UCRSI and many, many experts to publish the findings and recommendations that emerged from our conversations in publications including our magazine called the Global Forum (Fig. 1), which anyone can access, and we will be continuing to have follow-up conversations and discussions. Thank you again, for having me in this symposium. I look forward to a robust morning of discussion.

Fig. 1 DIA Global Forum

Special section in March 2023 Global Forum

<https://globalforum.diaglobal.org/issue/march-2023/>

● **SPECIAL SECTION: CLINICAL RESEARCH IN UKRAINE**

Special Section Introduction: Protecting Clinical Research, Researchers, and Research Participants in Ukraine

Cancer Trial Continuity in Ukraine Is a Shared Responsibility and a Global Imperative Responding to the Wartime Needs of Ukraine's Patients with Rare Diseases

Ethical Considerations: Clinical Research in Wartime Ukraine and Beyond

Giving Voice to the Unheard

Part 1: Ethical Considerations for Research with War-Affected Populations

Part 2: Ethical Consideration for Children in Wartime

Ethical Considerations on Clinical Trial Participation and Management in Wartime

Conditions: Perspective from the IFAPP Ethics Working Group

From COVID-19 Pandemic to War: Clinical Trial Industry Powers On Under Extreme Conditions



Special section in April 2023 Global Forum

<https://globalforum.diaglobal.org/issue/april-2023/>

- **SPECIAL SECTION: CLINICAL RESEARCH IN UKRAINE – PART 2**
- The Lessons of War Inform Good Clinical Practice Guidelines
- Three Perspectives: Maintaining Good Clinical Practice (GCP) During War
- GCP in the Context of Global Regulatory Reliance and the Situation in Ukraine
- Clinical Trials Continuity: Ukraine State Expert Center Perspective and Recommendations
- Maintaining Safety While Relocating Ukrainian Clinical Trial Participants