www.jcimcr.org

JCIMCR OPEN ACCESS Journal of Clinical Images and Medical Case Reports

ISSN 2766-7820

Short Commentary

Open Access, Volume 6

Global continuity of care in clinical trials during the invasion in Ukraine in 2022

Anna Titkova[1]; Aditi Hazar[2]*

[1]Pratia Ukraine LLC; Kharkov National Medical University, Kharkiv, Ukraine.

[2]Division of Preventive Medicine, Brigham and Women's Hospital, Harvard Medical School, Boston, MA, USA.

***Corresponding Author: Aditi Hazar**

Division of Preventive Medicine, Brigham and Women's Hospital, Harvard Medical School, Boston, MA, USA.

Email: ahazra@bwh.harvard.edu

Received: Jul 04, 2025

Accepted: Jul 31, 2025

Published: Aug 07, 2025

Archived: www.jcimcr.org

DOI: www.doi.org/10.52768/2766-7820/3727

Abstract

On February 24, 2022, with the start of a full-scale invasion, clinical trials inside Ukraine stopped. The implementation of evidence-based digital health solutions and patient-centric policy frameworks enabled accessible and sustainable care continuity for 451 clinical trial participants in times of conflict. The digital health solutions bear relevance to climate emergencies, pandemics, and times of peace. Continuity of clinical trials facilitated Sustainable Development (SDG) goal 3 on good health and well-being, goal 10 on reducing inequalities, goal 16 on peace, justice, strong institutions, and goal 17 on partnerships for the goals.

Keywords: Continuity of care; Decentralized clinical trial; Digital health; Global health equity; Non-communicable diseases; Participant transfer; Patient; Refugees; Ukraine.

Introduction

In conflict zones, chronic Non-Communicable Diseases (NCDs), including cancer, accompany the displaced. 110,000 million people have been forced to flee their homeland, including 6,906,500 refugees from Ukraine. The repercussions of war, including the destruction of healthcare infrastructure, gender-based violence as a weapon of war, workforce shortage, lack of access to essential medicines, environmental disasters, and interruption of NCD treatment, culminate in delayed and worse outcomes [1-3]. Although public health programs for refugees are outlined in the Alma Ata Declaration [4], 67% of UNHCR-recognized refugees are in protracted settings and face disparities in access to NCD care [5]. Continuity of cancer care is falling through the humanitarian cracks [1]. In February 2022, 794 clinical trials had been approved by the Ministry of Health (MoH) Ukraine, of which 584 were active. On February 24, 2022, with the start of a full-scale invasion, life inside Ukraine stopped, and with it, clinical trials also stopped. The State Expert Center of the MoH of Ukraine, the regulator of clinical research, received 108 letters for the premature termination of clinical trials in Ukraine due to the war. We summarize patient-centric policy frameworks, digital health solutions, and cross-sectional NCD clinical trial data on participant transfers within Ukraine and to neighboring countries in 2022.

The State Expert Center of the MoH issued recommendations for Local Ethics Committees, Sponsors, clinical research organizations (CROs), and patients regarding clinical trials performance during the martial law to enable telephone calls, home visits, delivery of IMP to the patient, and switching to local labs to help patients continue clinical trials participation. The following policy measures facilitated the continuity of clinical trials for NCDs:

1. Expedited approval timeline of clinical trials materials from 47 to 30 days.
2. Digitalization of processes.

3. 24/7 communication in Ukraine.

4. Simplified transportation rules for medical products.

a. Enabled public transport, postal, and luggage shipments.

b. Maintain protocol temperature\storage conditions.

5. Simplified requirements for import and use of medicines and medical devices.

6. Simplified packaging and shelf-life requirements for the import and distribution of medical devices.

7. Exceptions for medical device storage.

In solidarity, Member States of the European Union Clinical Trials Coordination Group (CTCG) adopted a common strategy aligned with ICH E9 (R1) to enable the continuation of treatment and the continuation of CT during the war. The European Union activated the Temporary Protection Directive, providing access to residence permits and social support services [6].

Study population

The State Expert Center of the MoH in Ukraine received 223 letters from Sponsors/CROs for the transfer of 451 CT patients on February 24, 2022. Consent and IRB approval for these de-identified analyses were obtained by the ongoing clinical trials in Ukraine.

Statistical analysis

Aggregate data from clinical trial sites was analyzed using descriptive statistics. The frequencies are presented by therapeutic area.

Results

From 24 February to 31 December 2022, a total of 451 adult clinical trials participants were transferred from conflict sites (Table 1). 172 trial participants were transferred to other sites in Ukraine, and 279 trial participants were transferred internationally to 25 countries (including 107 to Poland, 54 to Germany; Table 1).

Table 1: Distribution of 451 clinical trial participants transferred to alternate sites in 2022.

Therapeutic area	Participant Transfers in Ukraine N (%)	Participant Transfers Internationally N (%)
Total transfers, n=451	172 (38.1%)	279 (61.9%)
Oncology	122 (70.9%)	99 (35.5%)
Neurology	22 (12.8%)	6 (24.0%)
Rheumatology	15 (8.7%)	32 (11.5%)
Gastroenterology	4 (2.3%)	35 (12.5%)
Cardiology	1 (0.6%)	20 (7.2%)
Endocrinology	2 (1.2%)	5 (1.8%)
Dermatology	3 (1.7%)	2 (0.7%)
Hematology	0	7 (2.5%)
Gynecology	0	4 (1.4%)
Other	-	-

The most common therapeutic area for patient transfer was oncology. Specifically, 122 participants were safely transferred to alternate oncology clinical trials sites in Ukraine, and 99 participants were transferred to oncology trial sites in neighboring countries (Table 1). For neurology, 22 participants were safely transferred to alternate clinical trials sites in Ukraine, and 67 participants were transferred to neurology trial sites in other countries.

Conclusion

Globally, displaced populations face barriers to NCD care, exacerbated by health insurance gaps and financial insecurity. Our data highlight the critical provision of clinical trial treatment to 451 displaced Ukrainian patients across diverse therapeutic areas, including oncology (n=221), neurology (n=89), rheumatology (n=47), and gastroenterology (n=39). Multilateral policy change and collaborative efforts among sponsors, CROs, and Decentralized Clinical Trials (DCT) sites in Ukraine, Poland, Germany, Moldova, and neighboring countries identified safe and effective solutions for expedited approval, patient transport, and DCT treatment in protracted conflict. Decentralized and digital health solutions, including phone calls, video calls, home visits, use of local labs, and safe IP shipment routes, were implemented to continue treatment, retain, and transfer patients. Our data within Ukraine and internationally across 25 countries is a strength of this study [6-9]. The EMA policy measures for clinical trials implemented in Ukraine and in the EU are benchmarks for inclusion. There are costs to implementing patient transfers for NCDs in conflict or climate crisis, but the cost of inaction is steeper [9-11]. Furthermore, the Global Summit on War and Cancer emphasized the importance of cancer research in conflict zones and refugee populations. The future application of Artificial Intelligence (AI) tools may help personalize clinical trial navigation for refugees [13,14].

In summary, our data underscore that policy and evidenced-based digital solutions (including Starlin internet terminals) can safely facilitate accessible and sustainable clinical trial care in times of conflict, bearing relevance to climate emergencies, pandemics, and times of peace [15].

Declarations

Competing interests: Anna Titkova is the Country Head of Pratia Ukraine and CEO of Pratia Clinic Ukraine. Dr. Titkova has no other conflicts of interest related to the content of the manuscript.

Aditi Hazra does not have a conflict-of-interest relationship/activity/interest related to the content of the manuscript.

Funding: There are no sources of funding for this study based on data from Research4Life eligible countries.

Author contributions: AT analyzed and interpreted the participant data regarding transfers. AH interpreted the data and was a major contributor in writing the manuscript. All authors read and approved the final manuscript.

References

1. UNHCR. 2024. https://data.unhcr.org/en/situations/ukraine.

2. Vulpe H, Minzatean A, Tocino I, Baltaga R, Kacso G, et al. Design and implementation of a humanitarian cancer care programme

for Ukrainian refugees in Moldova and Romania. The Lancet Oncology. 2024. PubMed PMID: 38307101.

3. Klek S, Chrobak-Kasprzyk K, Machnicka K, Kret K, Litewka A, et al. Cancer Care to Ukrainian War Refugees in Poland. JAMA network open. 2023; 6(7): 2321967.

4. Mired D, Johnson S, Tamamyan G. Cancer disparities in war-torn and post-war regions. Nature reviews Cancer. 2020; 20(7): 359-60.

5. Declaration of ALMA-ATA. American journal of public health. 2015; 105(6): 1094-5.

6. Impact of the war in Ukraine on methodological aspects of ongoing clinical trials - Scientific guideline. European Medicines Agency (EMA). 2024. https://www.ema.europa.eu/en/impact-war-ukraine-methodological-aspects-ongoing-clinical-trials-scientific-guideline.

7. Hazra A, Bondarenko I. Clinical trials can adapt for refugees. Science. 2023; 380(6645): 592.

8. Bloswick A, Mustra D, Harasymiv O, Dubov A. Facilitating Ukrainian Refugees' Continued Participation in Clinical Trials. The Hastings Center report. 2022; 52(3): 6-8.

9. Charalambous A, Price R, Jha P. Accelerating progress on EU cancer control. The Lancet Oncology. 2024; 25(2): 158-60. le in cancer clinical trials. Nature. 2023; 621(7977): 2-5.

10. Kalinski P, Kokolus KM, Azrak R, Berezin MY, Brentjens R, et al. Meeting Highlights: The Third Marie Sklodowska-Curie Symposium on Cancer Research and Care at Roswell Park Comprehensive Cancer Center, Buffalo, Ny, September 20-22, 2023. Wiadomosci lekarskie. 2023; 76(12): 2543-55.

11. Joseph A. War zone or not, Ukraine seeks to reclaim its role as a hub for clinical trials. 2024. https://www.statnews.com/2024/02/22/ukraine-clinical-trials-hub/.

12. Arakelyan J, Margaryan T, Hovsepyan S, Babak M, Baloyan, et al. First Global Summit on War and Cancer: The Hidden Impact of War on Cancer—Urging Global Action for Change. JCO Glob. 2024; 10: 2400018. DOI:10.1200/GO.24.00018.

13. Hazra A, Ullrich A, Nimri O. Disparities in breast cancer characteristics among Syrian migrants and Jordanian women in the Jordan Cancer Registry from 2010-2016. 2023; 6(7): 2325197. doi:10.1001/jamanetworkopen.2023.25197.

14. Gujinovic D, Vidak T, Melnikova M et al. Changes in registration parameters for ongoing clinical trials in Ukraine after 2022 Russian invasion. JAMA Netw Open. 2023; 6(6): 2320202. doi:10.1001/jamanetworkopen.2023.20202.