

## **CONDUCT OF CLINICAL TRIALS IN UKRAINE DURING THE PERIOD OF MARITAL STATUS**

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The relevance of the topic of clinical research in Ukraine during the full-scale war is that these studies are an important tool for ensuring access to quality medical care for Ukrainian patients. Clinical trials allow for the development of new and improved treatment methods, which can lead to improved public health.

The war in Ukraine has led to significant challenges for the conduct of clinical trials. These challenges include physical danger for trial participants and staff, difficulties in the supply of materials and equipment, and disruptions in communication and coordination. [1].

Despite these challenges, some clinical trials in Ukraine are continuing. These studies are focused on topics such as military trauma and its treatment, common conditions such as cancer and cardiovascular disease, and new treatment methods that could be beneficial for Ukrainian patients.

The continuation of clinical trials in Ukraine is important to ensure access to quality medical care for Ukrainian patients even in wartime. These studies can help in the development of new treatments for military trauma, common diseases, and other health problems that are relevant to Ukraine.

Here are some specific examples of the relevance of the topic of clinical research in Ukraine during the full-scale war:

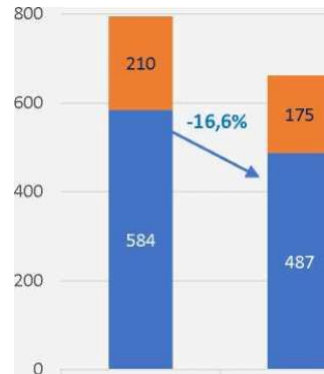
- Clinical trials focused on the development of new treatments for military trauma can help save lives and improve the quality of life for soldiers who have been injured in the war.
- Clinical trials focused on common diseases such as cancer and cardiovascular disease can help in the development of new treatments for these diseases, which are a serious public health problem for the population of Ukraine.
- Clinical trials focused on new treatment methods that could be beneficial for Ukrainian patients can help in the development of new treatments that can be affordable and effective for Ukrainian patients.

Overall, the topic of clinical research in Ukraine during the full-scale war is relevant because these studies are an important tool for ensuring access to quality medical care for Ukrainian patients even in wartime. [2].

Based on the data of the State Enterprise “State Expert Centre of the Ministry of Health of Ukraine” (SEC and MoH, respectively) for 20221 and Q1 20232, the state with the CTs in Ukraine is outlined in the following major figures:

PHARMACEUTICS  
DISTANCE EDUCATION AS THE MAIN PROBLEM OF YOUNG PEOPLE

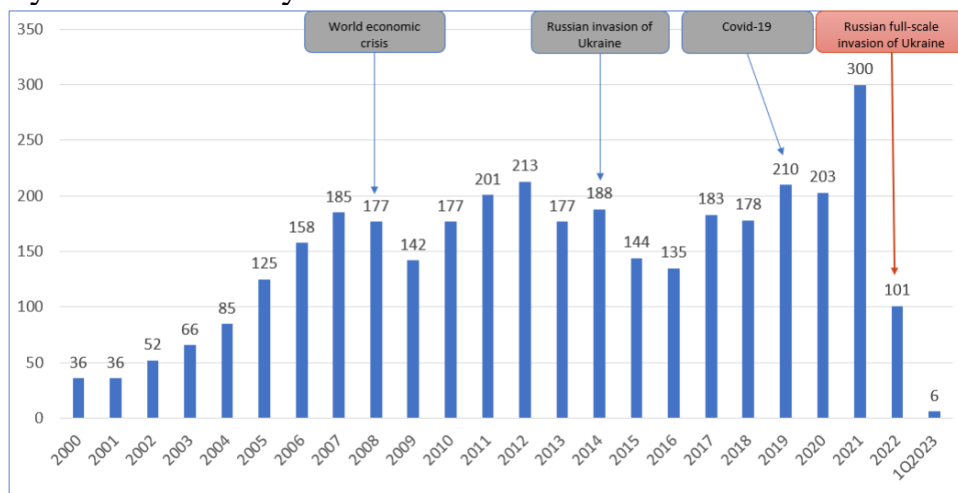
- in 2023, the total number of started CTs reduced by 16.6% as compared to 2022;



- 18.5% of current started CTs were early terminated in 2022 due to the full-scale war;
- it was announced that 472 subjects would be transferred to other approved clinical trial sites in Ukraine and abroad, for the period of 2022-2023;
- in the first year of the full-scale war, the recruitment of new patients and/or screening and/or randomization was suspended in 36.6% of started CTs, and the start was suspended in 21.4% of CTs approved by MoH.

It should be noted that due to the influence of external negative factors, during the last 10 years, some fluctuations in the number of CTs in Ukraine were observed, but the industry managed to recover its position quickly and proceeded to develop, in particular, due to the presence of significant unrealized potential. In detail, the state of fluctuations in the number of international multicentre CTs in Ukraine, depending on external factors, is shown in the diagram below.

The history of CTs recovery in Ukraine



Approvals of international multicentre CTs in Ukraine in 2000-2023

Currently, there are certain signs of CTs recovery in Ukraine after the start of a full-scale war:

- 31 CTs were submitted for Regulatory Authority (RA) evaluation o the MoH/SEC;
- 42 CTs submitted after the start of a full-scale war were approved for conduct;
- 43 CTs were started;

- 71 new CT sites in active CTs were approved with substantial amendments, thereby the total number of approved CT sites for active CTs increased by 23% and as on March 31, 2023, numbered 379 CT sites;
- 11 CTs were resumed;
- In 20 active CTs, the patients' recruitment was resumed;
- in 2023, there were no notifications on any suspended patients' recruitment in CTs;
- 32 patients returned from abroad to the CT sites in Ukraine;
- 1,550 substantial amendments (SA) were approved.

In this context, it should steadily evaluating and approving period of 2022 and Q1 2023 conduct of CTs/SAs.

The relevance of clinical research in Ukraine is clear. These studies are essential for the development of new and improved treatment methods that can help improve the health of the Ukrainian population. Despite the challenges posed by the war, some clinical trials are continuing in Ukraine. These studies are important for ensuring that Ukrainian patients have access to quality medical care, even in difficult times. [3].

#### **References:**

1. link <https://www.dec.gov.ua/news/klinichni-doslidzhennya-v-ukrayini-provodyatsya-vidpovidno-do-mizhnarodnyh-etychnyh-pryncypiv/>
2. link <https://umj.com.ua/articles/klinichni-doslidzhennya-v-ukrayini-v-umovah-viyni/>
3. link <https://www.dec.gov.ua/materials/aktualna-informacziya/?role=applicant>