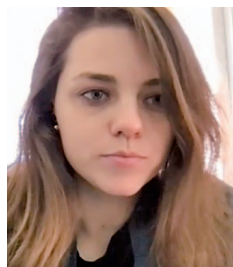


# Clinical trials under the Air Raid Alert accompaniment<sup>\*1</sup>



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## 1. Introduction

My name is Veronika Patsko, who is a clinical oncologist at the National Cancer Institute. The National Cancer Institute is the largest governmental oncological center in Ukraine. We consulted more than 100,000 patients annually. There are 20 surgical rooms where thousands of surgeries are performed.

## 2. Before 24th of February

Before 24th of February, Ukraine had many clinical trials in different spheres, mainly oncology, rheumatology, therapy, and so on (Fig. 1). On the moment of 24th of February, Ukraine, there were 120 ongoing oncological studies, and over 80 of them were ongoing at the National Cancer Institute in different departments.

On 24th of February, terrible events began. People moved west, and some moved abroad. Many people are afraid.

## 3. New phase of clinical trials

Therefore, that day, we had to start a new “phase” of clinical trial during the war. This came together with the medical care. In addition, clinical trials are part of treatment, so especially in oncology, many patients require new types of treatment, so we need to start something new. There were issues that I tried to combine

<sup>\*1</sup> This presentation was provided on October 10, 2022, when our world saw terrible Russian attacks on the city center of Kyiv, with an increasing number of civil victims even during this talk. According to the lecturer, at the time of publication in July 2023: bombing, their capabilities of conducting clinical trials become much better, keeping the level in peaceful time, with substantial global support; Ukrainian oncological patients desperately need clinical trials for them to be able to receive effective new treatments for severe diseases, and Ukrainian infrastructure of clinical trials have been kept responding to the people who most in need.

**Fig. 1 Before 24th of February**



Source: World Health Organization. Number of clinical trial registrations by location, disease, phase of development, age, and sex of trial participants (1999-2021). <https://www.who.int/observatories/global-observatory-on-health-research-and-development/monitoring/number-of-trial-registrations-by-year-location-disease-and-phase-of-development>

into groups that was very important in the decision. First is information. Therefore, we need to assess the capacity of our staff. They needed to save their families and children, so some of the staff moved. There was a need for supplies, the need to save data, because it is very important in clinical trials, and everything was about safety: safety of personnel, safety of patients, and safety of data.

#### 4. Information

Information: I called it a period of letters and calls. It was very important for doctors to know where patients were, whether they were safe, whether they could get to the clinic, whether they could receive medical care, and to inform them what to do next. Therefore, if they are safe, they can visit the clinic where we informed them whether we can continue their treatments. The second was to inform all team members. We needed to know where all were, to whom we can rely in this period, who were staying in Ukraine, who were moving abroad or moving to the western part, because for a few months, half of our team moved to the western part of Ukraine, so we could only have calls from them, but they could continue care of patients who also moved to the western part. As part of our patients, they moved and our doctors moved there, they could continue, and also inform sponsors that we are continually working. We can provide them with information and we can provide them supplies. So, it was a period when we had this bombing, and in the corridor, I was working with a laptop writing many letters. We need to do many jobs like this.

#### 5. Capacities

During the entire period starting from 24th of February, the National Cancer Institute did not stop its work (Fig. 2).

**Fig. 2 Capacities**



National Cancer Institute  
didn't stop its work

We worked everyday 24/7, and in these photos, you can see the basement. It was supplied by water. The beds were moved on the basement of National Cancer Institute. On the first days, we continued treatment under- ground for patient to be safe, and also one bone marrow transplant was performed underground because patient was already planned for this procedure. This procedure was planned for 24th, so we could not post- pone it. Moreover, there was a problem in that a lot of clinics in Kyiv District were closed due to occupation of that area, due to problems with roads, and a lot of patients who were treated there before the work required oncological help in this period, and they were looking for an oncology clinic who can continue this work. Starting from the beginning of the March, we just moved from the basement to our floors, in rooms without windows. So we continued our work at the beginning, not as normal, but we tried to come back to normal.

## 6. Staff

This was a big problem because many medical staff, especially nurses, lived in the Kyiv region, and they could not work because of bombing, tanks, and troops on the roads. Thus, Kyiv was mostly isolated, with only one road left to leave Kyiv or to come to there in the first month. Other areas were very dangerous to go inside. You can see the doctors who were giving drugs to continue the treatment of patients. As a doctor, I needed to examine the patients, take blood tests, make the drug for them, and then control the infusion. Thus, a lot of work has been done. Most doctors performed the entire treatment cycle.

## 7. Supplies

Talking about supplies, I would like to remind me that I am not talking only about the general work of the National Cancer Institute as an oncological clinic, but also about clinical trials. So, everything like that was done. All clinical trials were performed because we needed to collect biological samples and to work with them, and we needed to provide patients with drugs from clinical trials. We had a pharmacist, me, and other

doctors from other departments who continued this clinical trial. We continued to perform this procedure according to the protocol and avoid protocol deviations. Our local laboratory performed all the required tests, as well as an MRI machine and CT, and we could continue it according to the schedule.

As for supplies, we are lucky enough to be the biggest center, so there were a lot of supplies in our local depots that we had enough to share with patients from other sites. Therefore, some sponsors decided that patients, for example, from Kharkiv, which was and is continually and severely bombed, were moved to Kyiv, and they just told us which medication we can give them in this clinical trial, because clinical trials are ongoing in 5, 6, or 10 cities of Ukraine, so we have different sites, and we can move patients from site to site in one clinical trial. From some parts of Kyiv, the patients, for example, were moved to the western part of Ukraine, and some from the eastern part of Ukraine were moved to Kyiv, and we could continue their treatment because we had enough supplies. This was a big problem for the first month because there was a problem with couriers. Nobody can bring this to us. Fortunately, we had sufficient drugs, so we only covered this period. Then, when courier companies started to work again and when central depots started to work again, we could obtain new deliveries of drugs.

In addition, on 24th of February, all civil flights stopped, and there was a problem with delivery because it took more time. Essentially, it was difficult in Kyiv, as there was only one road left that could be used for civil transportation for the first period. It was difficult for sponsors to deliver the drug and also to deliver back biological samples from sites to the central laboratories. In addition, many men went into the army, so there were not enough workers, but now we are working almost as it was before the war.

## **8. Data**

It was very important for us to have access to the Internet, source, documentation, and safety of source documentation on sites, because some sites in Ukraine were bombed. However, at the National Cancer Institute, there was no problem with electricity, there was no problem with access to source documentation, and there were enough doctors to put this information into the eCRFs. Talking about the National Cancer Institute is safe. The building was not directly bombed.

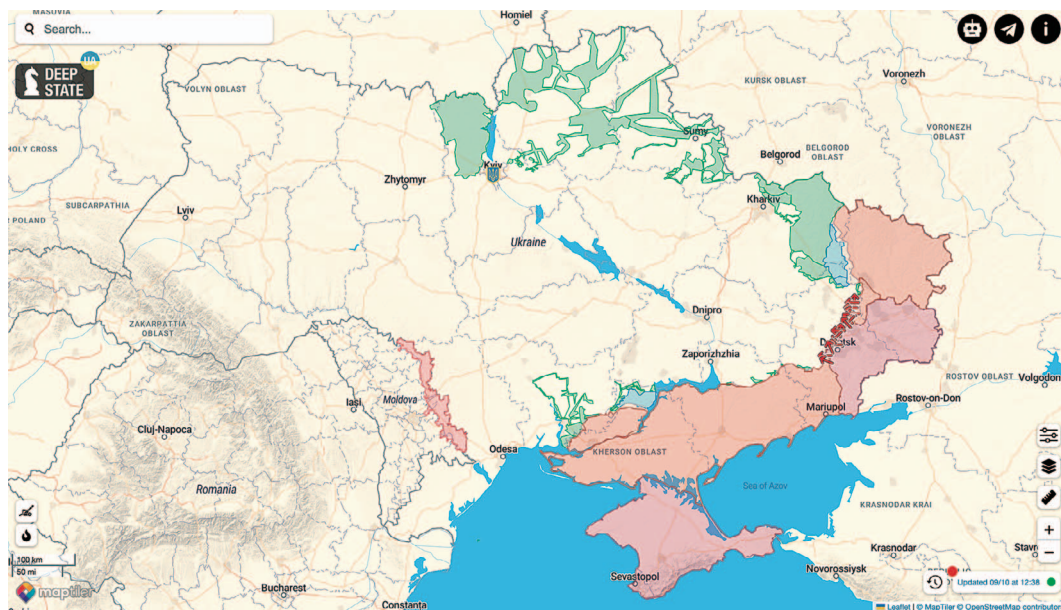
As for the biological samples, we were lucky enough to have uninterrupted power supplies all the time. Therefore, there were no problems with electricity. All samples survived this period until courier companies worked again, so everything was safe. There were no protocol deviations even during the hardest period, but there was a problem with kit supply for the first few months, but now it is also absolutely fine, almost as it was before the war.

## **9. New reality of clinical trials in Ukraine**

This is a map of the attacks on Ukraine (Fig. 3). Data is till yesterday. Ukraine is quite a large country, and there is a large distance between the battlefield and other cities in which many clinics have participated in clinical trials, including oncological trials. Therefore, the distance is quite large, and we can continue to perform clinical trials almost as before the war.

We are in great demand from the patients who require this help (Table 1). I can provide you with a simple

Fig. 3 Clinical trials in Ukraine – new reality: map of attacks (as of October 9, 2022)



This map was copied from the data provided in “DeepStateMap. Live” on October 9, 2022. The situation is changing every day, and you can find the latest map on the website of “DeepStateMap. Live.” Its update is not secured; thus, it is cautioned not to use it for actual needs, for example, evacuation.

example from Oncology. For example, for people with melanoma, we have immunotherapy, but in the case they progressed, we had no treatment for them, and only conducted clinical trials. There are many patients who require new treatment, which has not yet been registered, because they used all their probabilities of treatment that we have in this study. Some of them cannot move abroad because they have children, they probably have old parents, and they cannot move abroad for treatment, but they need it here. Often, patients ask me about this. They called our center and asked me whether we had clinical trials. Therefore, statistically from the Cancer Institute, 10% of our patients in clinical trials were moved abroad to other sites with the same protocol and continued treatment in the clinical trial. Now, we have high requests from patients because patients from territories that were occupied come to the west, so Kyiv, Lviv, or in cities where it is more peaceful currently, they are asking about treatment, so we need to treat even more patients, and so there is high demand.

As it was during the COVID period, now also there is a big gap in diagnostics and treatment and many patients who could be treated at earlier stages. In addition, for advanced diseases, according to

Table 1 Clinical trials in Ukraine – new reality: demand from patients

|  |
|--|
| Nearly 10% of patients were moved on sites abroad and continuing their treatment there |
| Now the quantity of patients 30% higher than on 23rd of February                       |
| More advanced diseases due to gap in accessibility of medical care                     |
| High demand on clinical trials among Ukrainians  |
| But recruitment that was stopped on 24th of February still not opened                  |

Fig. 4 UPD: morning of 10th of October, 2022



international guidelines, we need to include these patients in clinical trials to have more opportunities to live longer.

Our workforces are almost the same as before the war. We are working in our general routine, and it is relatively safe for both patients and staff to continue working as we used to. In addition, patients are moving, and they require this help, so there is a high demand, and there is a possibility from our side to continue treatment like this. We can also continue to provide shipment of biological samples, and sponsors can deliver drugs with temperature control, so it is absolutely possible as it was before.

## 10. Present situation in Kyiv

Here is a phrase like a military joke, “Being a Ukrainian is to be ready for the end of the world but also have plans for the future.” However, today, I would like to make some updates regarding the situation in Kyiv and just to remind us that the war is still ongoing. Today, these are photos taken a few hours ago (Fig. 4). It is similar to the city center of Kyiv. Eighty rockets were fired in many cities in Ukraine, and they bombed the entire country. I would also like to show you several videos. You can see a kindergarten ground in the city center. The consequences of the bombing are evident. It was our morning today.

So please stay with Ukraine and support Ukraine. Thank you for your attention.

## Discussion

**Q** I am thinking about where the rest of the world today? They watched these presentations. This war was not simply a military action. These are not simply armies or weapons. However, it is also people fighting for their lives, and you people here are on the front lines. You are fighting for your country and your lives because the soldiers are there. The final video was terrible. If I refer correctly, that is, to the bridge to the

peace monuments between Russia and Ukraine. It is an absurdity. It is very important what you are doing, and the work you do is heroic. Thank you for coming here today sharing this information with us.

**Patsko** Thank you for your support and attention. You are correct about this monument, but there is no further friendship between our people. They are just terrorizing civil cities. Today, there were 10 bomb attacks, which came into the city, 10 dead people, and while we were talking, it is already 11, so one person died in the hospital during our talk, and there were kids among them. Thus, it was just civilian people who were going to work in the city center with no military objects at all. The Central Ukrainian University has museums in this region. We only had a hole on the road and 10 dead bodies. We continue to live and discuss our main topic in this talk. My colleagues, who have presented before, agree with this. Today, until five in the morning, the situation is slightly different. Therefore, it is almost calm in the city. There was a problem in the eastern Ukraine. We have our soldiers dying there for our freedom, for our democracy, but we continue to develop science, we continue to develop. During the war, for example, at the National Cancer Institute, we put a new linear accelerator and opened a new neurosurgical department, so we continue to develop and live here. We cannot simply freeze or stop doing things.