Participation of patients from Ukraine in the clinical trials conducted in Poland

Good practice of the clinical trials industry

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In the opinion of sectoral organisations, that is: POLCRO (Polish Association for Employers of Contract Research Organizations), GCPpl (Polish Association for Good Clinical Practice) and INFARMA (Employers' Union of Innovative Pharmaceutical Companies), it is necessary to take joint efforts to enable patients who are participants of clinical trials and who migrate from Ukraine to take advantage of an innovative therapy as part of clinical trials conducted in Poland.

The issue of foreigners' participation in the clinical trials conducted in Poland has not been regulated in a specific manner, separately from general rules governing the inclusion of participants in the clinical trials. The law does not prohibit foreigners from taking part in the clinical trials conducted in Poland, and foreigners may be admitted to a study upon fulfilment of certain conditions.

With the war in Ukraine and the current dramatic situation, we need to take swift and extraordinary measures. Humanitarian aid for people coming from Ukraine, as well as the protection and safety of clinical trial participants, have become the utmost and absolute priority.

Based on the experience to date, it is possible to transfer a patient who has participated in a clinical trial in Ukraine to a research centre in Poland so that they can continue their treatment. Guidance on this topic was issued by the President of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products in a communication dated 31 March 2022 on the impact of the situation in Ukraine on the conduct of clinical trials, which are also included in these recommendations.

The sponsor of a clinical trial in consultation with the investigators, on the basis of a detailed risk-benefit analysis, shall decide on the transfer of a patient in a clinical trial that has been authorised in Poland.

It should be emphasized that the participation of patients from Ukraine does not affect the availability of such an option for patients from Poland, and that processes for relocating patients between countries should be agreed between the sponsor and the investigators.

Recommendations for primary care physicians, specialist clinics and hospitals

Status of patients from Ukraine in the health care system

A citizen of Ukraine who arrived in Poland in connection with the military aggression of Russia on the territory of Ukraine and who reports with a health problem to a family doctor, a specialist clinic or a hospital should be provided with adequate medical assistance, in accordance with the Act of 12 March 2022 on assistance to citizens of Ukraine in connection with armed conflict on the territory of that state as amended on 8 April 2022 (Special Act). The Special Act grants, as of 24 February 2022, the right to medical benefits to citizens of Ukraine who came to Poland in connection with the Russian aggression on the same terms as medical services provided to persons subject to medical insurance, that is:

- the right to medical services pursuant to the Healthcare Services Funded from Public Funds Act of 27 August 2004 (including guaranteed services relating to the reimbursed products on the "pharmacy list", medicine programmes and chemotherapy), except for health resort treatment or health resort rehabilitation, and the administration of medicinal products issued to service recipients as part of healthcare policy programmes pursued by the minister for health,

- administration of medicinal products issued to service recipients as part of healthcare policy programmes pursued by the Minister for Health.

Consequently, the financing of benefits also includes reimbursement of medicines, foodstuffs for particular nutritional uses and medicinal devices according to the same rules as those applicable to persons subject to mandatory or voluntary medical insurance. Healthcare benefits are to be provided by the service providers pursuant to agreements on the provision of healthcare benefits and by pharmacies pursuant to agreements on the prescription fulfilment with the National Health Fund. Medicinal products administered as part of the healthcare policy programmes pursued by the Minister of Health are to be administered by entities executing those programmes. The costs of said benefits will be settled with the service providers and pharmacies by the National Health Fund, and they will be funded from a specific subsidy from the state budget which is provided from the portion managed by the Ministry of Health. The detailed procedure for and the manner of the benefits financing are to be agreed as part of a contract between the Minister of Health and the President of the National Health Fund.

Information for all Polish patients and patients from Ukraine is available at **800 190 590** / TIP, or the Patient Phone Information Service. It is a free nationwide helpline number that can be called by anyone who wants to receive quick, comprehensive and transparent information on patient rights and on the health care system in Poland. It is a shared phone number of the Commissioner for Patients' Rights and Provincial Branches of the National Health Fund.
This helpline is also available for the Ukrainian medical staff who want to get information on employment opportunities in Poland. The helpline is free of charge, available 24 hours a day, 7 days a week, and offered in Ukrainian and Polish. Patients can also get in touch with the National Health Fund helpline by electronic mail (tip@nfz.gov.pl), chat or a video call with a sign language interpreter.

First Contact Teleplatform (TPK) **800 137 200** is accessible outside the working hours of the Primary Healthcare, that is:

- Monday to Friday, from 6:00pm to 8:00am on the following day
- Saturdays and Sundays and other statutory holidays, from 8:00am to 8:00am on the following day

In urgent cases, patients may use free medical care which is offered to all persons coming from Ukraine at the LuxMed medical centres
You can get psychological help in Ukrainian or Russian here:

- Polish Migration Forum – phone: 669 981 038 (Mondays from 4pm to 8pm, Wednesdays from 10am to 2pm, and Fridays from 2pm to 6pm),
- Damian Medical Centre – 22 566 22 27 (7 days a week, from 8am to 8pm),
- Helpline for Children as part of the Ombudsman for Children Office – Phone 800 12 12 12

You can find more information on the rights of patients from Ukraine on these websites:

Centrala NFZ - Aktualności / Aktualności / Narodowy Fundusz Zdrowia (NFZ) – finansujemy zdrowie Polaków [National Health Fund Head Office – News / News / National Health Fund – we finance Poles' health]
Teleplatforma Pierwszego Kontaktu – Ministerstwo Zdrowia – Portal Gov.pl (www.gov.pl) [First Contact Teleplatform – Ministry of Health – Gov.pl Portal]

Dealing with a patient from Ukraine who is a participant of a clinical trial

There are currently around 600 clinical trials (including more than 400 with active recruitment) conducted in Ukraine in various therapeutic areas (including clinical trials for oncology patients, hematology patients, neurology patients, gastroenterology patients, patients with rare diseases and others). As a result of military actions, many participants of the clinical trials look for opportunities to continue their therapy with an innovative product which is studied in research centres in Poland. Such a solution is permitted under current regulations; however, it is extremely important to enable Ukrainian patients to get in touch with the sponsor/CRO of the clinical trial or with the research centre that conducts a parallel clinical study in Poland.
Primary health care doctors have an extremely important role to play in terms of identifying such participants of clinical trials and helping them to get in touch with a clinical trial sponsor.

The minimum information required for a patient to continue his/her participation in a clinical trial in Poland:
- name of the sponsor and the clinical trial number / protocol number / disease classification
- patient number in the clinical trial
- patient's full name, date of birth, PESEL Number
- medical records presenting the entire or partial medical history, including the forms of informed consent to participate in the clinical trial signed in Ukraine or patient card form / other materials / patient's diaries or other data carriers containing medical records

Where the above details are missing, the following information will be of help:

- the place where the patient took part in the clinical trial (such as the name and location of the research centre, the name of the study doctor/name of the principal investigator)
- the date on which the patient commenced his/her participation in the clinical trial
- the name of the medicine or the designation of the study drug, the medicine administration route
- Where the patient does not have any documents and does not have any contact with the investigator in Ukraine, or should there be any difficulties identifying the patients, we recommend calling the helpline **TIP**, or the Patient Phone Information Service at 800 190 590, or the selected sponsor helpline (the list is available at the end of the recommendations).

The role of the sponsor and the investigator / research centre in the process of admitting patients from Ukraine

The sponsor and the investigator have the duty to consider all circumstances, analyse the risks and apply adequate measures to ensure safety of the clinical trial participants. Where a patient from Ukraine declares willingness to continue participation in a clinical trial, the sponsor should create favourable conditions to take over the care of the patient in a research centre in Poland. The best solution, if possible, is to conduct the relocation in consultation

with the Ukrainian centres. The sponsor conducting the clinical trial in Poland and Ukraine may be able to facilitate cooperation between centres in both countries, allowing for the exchange of necessary information.
In such a case, the investigator and the sponsor should consider all the possible therapeutic options (including continued application of the study drug or the implementation of a standard treatment existing on the market), following a full analysis of risks and benefits so that the best interest and safety of the patient who is a participant of a clinical trial is the absolute priority.

It requires detailed communication between the sponsor and the investigators conducting the clinical trial in Poland in order to confirm that a research centre in Poland is ready to admit a patient from Ukraine and has the capacity to do so, taking into account the enrolment capacity of the sites and the availability of the study drug.
Sponsors or designated persons from the CRO must get in touch with investigators / research centres in Poland well in advance to learn about the current situation and the ability for patients from Ukraine to continue their therapy with the study drug.
The sponsor should consider multiple aspects concerning the standards and procedures for clinical trials, including in particular the ones described below.

Process of obtaining informed consent to participation in a clinical trial

The process of obtaining informed consent of any patient who is not a Polish national must be in strict compliance with the applicable Polish laws and the highest ethical standards.
It would be optimal for Ukrainian patients to have Ukrainian-speaking staff in the research centres to assist in communicating with the investigator and the research team.
Once s/he has been transferred to a Polish research centre, a patient from Ukraine should sign the current version of the relevant document; the document should be signed in the relevant language version to express the patient's consent for further participation in the clinical trial in Poland. The sponsor/CRO should provide the research centre in Poland that expressed its willingness to admit patients from Ukraine with a Ukrainian or Russian version of the patient information and consent form for the patients, depending on the language they use. No additional approval is required when the Ukrainian/Russian patient information and consent form is fully compliant with the currently applicable version of the document in Polish which received positive opinion of the Ethics Committee and permission of the Office for Registration of Medicinal Products (URPL). The submission of a new (ICF) document in Ukrainian/Russian to the Ethics Committee and the Office for Registration of Medicinal Products (as a non-significant change) is sufficient. The same (notification) process applies to the patient's diaries, ePRO, manual, patient card/identity card and other materials addressed to the participants of the clinical trial conducted in Poland (provided the materials obtained positive opinion of the Ethics Committee and permission of the Office for Registration of Medicinal Products).

Under extraordinary circumstances where it is necessary to implement an expedited process of continued treatment with a study drug as part of a clinical trial with a patient transferred from a research centre in Ukraine, you can apply the rule of Urgent Safety Measures in keeping with Article 37y of the Pharmaceutical Law Act of 6 September 2001 (Journal of Laws of 2001, No. 126, item 1381) ("Pharmaceutical Law"). The sponsor immediately informs the President of the Office and the Ethics Committee, which gave its opinion on the clinical trial, about the situation and the safety measures applied.

Together with the investigator, the sponsor decides on a solution that will be safe and beneficial for the patient who is a participant of the clinical trial.

The sponsor and the investigator should be ready for the two options of including a patient from Ukraine in a clinical trial:

Option 1. A scheduled inclusion of patients from Ukraine to a clinical trial conducted in the research centres in Poland

The sponsor analyses and evaluates the recruitment strategy and adjusts it to the requirements of the clinical trial. Depending on the indications, the phase of the study, the provisions of the protocol, the size of the patient population, and project milestones, the sponsor may decide to include patients from Ukraine who have come to Poland since 24 February 2022.
If there are active Ukrainian research centres in the study and patients have been included, and if we expect them in the Polish research centres, we suggest that you prepare a translation of the consent form in advance:
- from Polish to Ukrainian or from Polish to Russian

The sponsor of the clinical trial or the investigator may propose including patients who are not Polish citizens. The patient information and informed consent form (ICF) in Ukrainian (or Russian) should be a translation of the current consent form in Polish approved in Poland. The process of verifying linguistic correctness (validation) takes place according to the procedures applied by a given sponsor/CRO.

It is proposed that you prepare bilingual signature pages (e.g. the page with informed consent to the participation in the clinical trial, the consent for personal data processing under GDPR, the pages concerning additional studies, e.g. pharmacokinetics, genetic tests, etc.): in Polish and Ukrainian or in Polish and Russian, depending on the needs and the decision of the sponsor and the investigator.
It is recommended that the patient and the investigator sign the form in both languages as part of the informed consent process to facilitate the monitoring process. The process should be documented in the medical history and in the sponsor's systems.

OPTION 2. Sudden arrival of the patient who is a participant of a clinical trial from Ukraine/patient's transfer to a research centre in Poland

Such a situation typically requires fast decisions and immediate actions as we do not have sufficient time to follow Option 1. Please keep in mind that we assume that the patient is an existing participant of a clinical trial and that he or she gave an informed consent in his/her native language in his/her research centre. As part of continuing the trial in Poland, the patient must sign the consent form that is valid in Poland.
If we do not have a form translated into Ukrainian (or Russian) in extraordinary and urgent cases, we recommend the following **two options:**

1. An interpreter (a person fluent in Ukrainian/Russian) interprets the consent form simultaneously from Polish for the patient during the visit at the research centre. The patient and the investigator sign the

consent form in Polish. Other witnesses are not required. The interpreter should sign the consent form at a blank space to confirm his/her participation in the process or sign a statement to that effect:

STATEMENT

I, the undersigned <<first name, last name>>, declare that on <<date>> I attended <<via remote channels/in person>> the process of informed consent being given by a Patient who is a Ukrainian national, as a person interpreting from Polish to <<Ukrainian/Russian>>.

FULL NAME	
LEGIBLE SIGNATURE	
DATE	

2. We are working on a breakdown/ a summary of differences between the English versions of the consent form in Poland and in Ukraine. The investigator, in the presence of an interpreter (in person or via remote channels), outlines the differences in Polish, and the patient signs the Ukrainian and Polish versions of the consent form on that basis. The interpreter signs the signed consent form at a blank space to confirm his/her participation in the process or signs a statement to that effect.

A carefully described process of obtaining informed consent should be documented in the medical records, described and explained in detail in the relevant procedures of the sponsor.
In accordance with Section 9(2) of the Regulation of the Minister of Health of 2 May 2021 on Good Clinical Practice (Journal of Laws, item 489), the sponsor shall also inform about any changes to the document that confirms informed consent or other documents containing information intended for clinical trial participants.
Any deviations from the standard process should be reported according to the arrangements with and procedures of the sponsor. The mode of reporting deviations from the protocol affecting the safety of clinical trial participants is not subject to change. Deviations from the protocol, which do not meet the criteria for reporting as provided for in Article 37y of the Pharmaceutical Law (or Article 51 of the Medical Devices Act), may be presented to the President of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products and the Ethics Committee reviewing the trial in a separate communication after the end of the pandemic or as part of the report on the conduct of the trial referred to in Article 37aa(5) of the Pharmaceutical Law.

Access to the medical history of patients from Ukraine

It is unlikely that you will get access to the medical history or medical records of the patients and the source, and it is uncertain whether it will be possible to access source data after the war in Ukraine ends. The sponsor must be aware of the risk that the data (or a part thereof) obtained from a patient from Ukraine will not be included in the final statistical processing of the clinical trial results and that it will not be possible to use them for the product

registration or for a change in the registration. To ensure the robustness and integrity of the data, the sponsor may consider different solutions. If possible, a copy of the source data may be transferred from the facility in Ukraine to the facility in Poland, and the transfer of patient data should comply with data protection regulations and applicable laws.
In the new medical history of the patient, the investigator should document whether or not the patient's medical records, source data, other data from the systems were accessed and whether or not the investigator reviewed the previously available data. Furthermore, all medical records obtained from a patient from Ukraine should be translated into Polish so as to ensure proper medical records in the research centre and to enable the monitoring of the clinical trial.

Access to the data of patients from Ukraine in the CRF database

The research teams in the research centres in Poland should not have problems with completing them for patients transferred from the research centre in Ukraine. Information from CRF should also clearly state in which stage of the clinical trial the patient from Ukraine currently is.

Should online systems gathering the data of the clinical trial participants be used, the sponsor together with the Data Management and Quality Assurance Teams should implement procedures to transfer the patient from one centre to another. You need to consider whether or not it would be possible for the investigator from Ukraine to sign the pages in the CRF system as a confirmation of their responsibility before the patient's transfer to another centre. Where the investigator from Ukraine is not available or s/he does not have access to the CRF system, the sponsor should document such a case as an explanation for an auditor or inspector. The sponsor should check whether or not the patient's data have been properly mapped in the different systems and document the entire process for the purpose of future audits and inspections.

Any deviations from the standard process should be reported according to the arrangements with and procedures of the sponsor. The mode of reporting deviations from the protocol affecting the safety of clinical trial participants is not subject to change. Deviations from the protocol, which do not meet the criteria for reporting as provided for in Article 37y of the Pharmaceutical Law (or Article 51 of the Medical Devices Act), may be presented to the President of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products and the Ethics Committee reviewing the trial in a separate communication or as part of the report on the conduct of the trial referred to in Article 37aa(5) of the Pharmaceutical Law.

Civil liability insurance of the sponsor and of the investigator.

The civil liability insurance covers the civil liability of the sponsor and of the clinical investigator for damages caused by an action or omission of the insured which took place during the term of the insurance coverage in relation to the clinical trial.

Since the patient as such is not covered by insurance, his/her nationality is irrelevant. It is important to take a look at the policy and check it in terms of the number of patients declared for the insurance policy purposes - the insurance premium depends on the number of patients. New patients will "increase" the pool.

In accordance with the Communication of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products dated 31.03.2022, the sponsor managing the process of relocation of participants from Ukraine should inform the President of the Office about the increase in the number of patients and any updates to the insurance document (if applicable), unless the increase is significant in terms of the total number of participants. It is recommended to include a detailed account of the solutions applied in connection with the relocation and the number of patients in the annual progress reports for the trial. *The minimum sum insured under a civil liability insurance in regard to one insurance event and all insurance events the consequences of which are covered by the insurance depends on the number of participants of the clinical trial who use the study drug or who are in the control group, and is the PLN equivalent of: a) EUR 500,000 if there are up to 10 participants in the clinical trial, b) EUR 1,000,000 if there are from 11 to 25 participants in the clinical trial, c) EUR 2,000,000 if there are from 26 to 50 participants in the clinical trial, d) EUR 4,000,000 if there are from 51 to 100 persons participating in the trial, e) EUR 5,000,000 if there are more than 100 participants in the clinical trial. The minimum sum insured, as referred to hereinabove, is defined jointly in regard to the sponsor and the investigators taking part in the clinical trial.*

The changes in law have a retroactive effect, as of 24 February 2022 (legal basis: Act of 12 March 2022 on the aid to Ukrainian citizens in relation to the military conflict in that state; the Act came into force upon announcement, that is on 12 March 2022, effective as of 24 February 2022).

In keeping with Article 37 of the said Act [The right of Ukrainian citizens to healthcare services]:

"A citizen of Ukraine whose stay in the Republic of Poland is deemed legal pursuant to Article 2.1 (has the right to medical care provided in the Republic of Poland including healthcare services provided according to the rules and within the extent to which persons covered by the mandatory or voluntary medical insurance are entitled to healthcare services pursuant to the Healthcare Services Funded from Public Funds Act of 27 August 2004 (Journal of Laws of 2021, item 1285, as amended), except for health resort treatment or health resort rehabilitation, and the administration of medicinal products issued to service recipients as part of healthcare policy programmes pursued by the minister for health."*

*Note: *The exclusion does not apply to medicine programmes; it only applies to healthcare policy programmes (concerning prevention).*

Ukrainian citizens whose stay has been made legal under a special act of law are entitled to medical care and benefits provided in the Republic of Poland which includes medical services provided according to the rules and within the same scope as persons subject to mandatory or voluntary medical insurance have:

- the right to medical services pursuant to the Healthcare Services Funded from Public Funds Act of 27 August 2004 (including guaranteed services relating to the reimbursed products on the "pharmacy list", medicine programmes and chemotherapy), except for health resort treatment and health resort rehabilitation, and the administration of medicinal products issued to service recipients as part of healthcare policy programmes pursued by the minister for health,

- administration of medicinal products issued to service recipients as part of healthcare policy programmes pursued by the Minister for Health. Consequently, the financing of benefits will also include reimbursement of medicines, foodstuffs for particular nutritional uses and medicinal devices according to the same rules as those applicable to persons subject to mandatory or voluntary medical insurance.

In accordance with Article 2 of the Act: "*Where a citizen of Ukraine arrived in the Republic of Poland lawfully during the period from 24 February 2022 until the date set out in regulations (to be specified in separate regulations), and declares his or her intention to stay in the Republic of Poland, his or her stay in the Republic of Poland is deemed legal during the period of 18 months, counting from 24 February 2022. The stay of a child born in the Republic of Poland by a mother who is the person defined in the first sentence is also deemed legal during the period concerning the mother."*

NOTE: Information on the Act of 23 March 2022 on amending the Act on assistance to citizens of Ukraine in connection with armed conflict on the territory of this state and the Act - Law on Higher Education and Science.

The purpose of the Act of 23 March 2022 on amending the Act on assistance to citizens of Ukraine in connection with the armed conflict on the territory of this state and the Act - Law on Higher Education and Science **is to extend the provisions of the Act** of 12 March 2022 on assistance to citizens of Ukraine in connection with the armed conflict on the territory of this state (Journal of Laws, item 583) **to citizens of Ukraine who arrived on the territory of the Republic of Poland from the territory of Ukraine, in connection with military operations conducted on the territory of Ukraine, not directly, but crossed the border of Ukraine with another state and then arrived in Poland. A similar change (consisting in the deletion of the word 'directly')** concerns also specific solutions provided for in the Act on assistance to citizens of Ukraine in connection with armed conflict on the territory of this state as well as the Act - Law on Higher Education and Science, addressed to Polish citizens who came to the territory of the Republic of Poland from the territory of Ukraine in connection with military operations conducted on the territory of Ukraine.

The Act entered into force on the day of its publication, with effect from 24 February 2022.

Pursuant to Article 11 of the Act [Entitlement to stay in the territory of the Republic of Poland for citizens of Ukraine vs. entitlements under other legislation]:

1. The entitlement referred to in Article 2(1) shall be independent of other entitlements to enter and stay in the territory of the Republic of Poland arising from legal provisions.

2. **Departure of a citizen of Ukraine from the territory of the Republic of Poland for a period exceeding 1 month shall result in deprivation of the entitlement referred to in Article 2(1).**

A helpline of the National Health Fund is operated 24 hours a day at 800 190 590 and provides information on healthcare services provided to refugees from Ukraine. The helpline is also available in Ukrainian

Access to and continuation of study drug administration to the patient

Stock of study drug must be secured and delivered for participants of clinical trials migrating from Ukraine who have been classified for a transfer to a selected research centre(s) in Poland. Due to the military action, it is currently impossible to send a study drug from the research centre in Ukraine. It is the responsibility of the sponsor or CRO company to secure the deliveries of the study drug and ancillary treatment (where applicable) to the research centres in Poland.

Access to materials and devices for the patient / PRO/ePRO/ patient's diaries

All materials, life quality questionnaires, self-evaluation scales, PRO/ePRO (Patient Reported Outcomes) available to participants of the clinical trial transferring from Ukraine should be available in the research centre in an approved local language version (Ukrainian or another one, for example, Russian if necessary). The sponsor or CRO are responsible for the preparation and distribution of such materials in the research centres.

The sponsor or CRO are responsible for ensuring the delivery of the equipment and additional materials required to carry out the clinical trial. The equality rule should be applied to all patients who are participants of the clinical trials, regardless of their nationality.
You also need to agree on technical issues (for example, how the new ePRO will be downloaded to the tablet in the research centre; will a new tablet be sent together with the questionnaire forms in Ukrainian/Russian?). The research centre should keep in mind resynchronisation of the device upon receiving a confirmation from the sponsor/CRO representative that the Ukrainian forms have been added.
If necessary and possible, patients may receive a paper version – you need to agree with the sponsor which data are to be transferred to the system.

Communication between the sponsor and the Ethics Committee and the Office for Registration of Medicinal Products (URPL)

The sponsor should promptly determine which active research centres in Poland can take over the care over patients coming from Ukraine and document the procedures for the transfer of patients from one research centre to another.
The sponsor is required to file new language versions of the information and informed consent to participation in a clinical trial, as well as all documents addressed to patients from Ukraine. It is important to confirm that the text of the materials translated for patients from Ukraine is the same as the current text in Polish approved by the Ethics Committee and the Office for Registration of Medicinal Products.

The sponsor/CRO also must prepare the relevant notice to the Ethics Committee and the Office for the Registration of Medicinal Products as part of the process for registering a non-material change In accordance with Section 9(2) of the Regulation of the Minister of Health of 2 May 2021 on Good Clinical Practice (Journal of Laws, item 489).

The sponsor should complete the procedure for filing the application to the Ethics Committee and the Office for Registration of Medicinal Products (URPL) if the number of patients covered by the insurance policy changes.
Due to the sudden need to transfer a patient from a research centre in Ukraine to a research centre in Poland, the urgent safety measures (USM) rule may be applied, and the sponsor should promptly report such a case to the relevant ethics committee and the Office for Registration of Medicinal Products (URPL). The information on urgent safety measures should include a detailed assessment of the risks arising from the changes.

In accordance with the Communication of the President of the Office for Registration of Medicinal Products of 31 March 2022, the intention to transfer a patient from one clinical trial centre to another does not have to be approved by the ethics committee or by the Office for Registration of Medicinal Products (URPL). The sponsor will notify the institutions of that in the annual report from the clinical trial.

Additional logistic costs relating to the transfer of patients from Ukraine

Any issues relating to the costs and logistics relating to the patient transfer should be agreed in detail between the centre/investigator and the sponsor of the clinical trial or CRO conducting the clinical trial in Poland.

Recommendations for investigators and centres

Identification of a patient who is a clinical trial participant

The investigator should explicitly confirm that a given patient is a participant of a specific clinical trial.
There are various circumstances which may lead to a participant of a clinical trial in Ukraine to a research centre in Poland:
- he or she will be referred directly by an investigator / research centre from Ukraine
- he or she will be referred directly by the sponsor of the clinical trial / CRO
- he or she will be referred by the employees of the helpline of the Commissioner for Patient's Rights Office
- he or she will be referred by a Patient Organisation in Poland (an association, a foundation, etc.)
- he or she will be referred by the UACR (Ukrainian Association of Clinical Trials)
- he or she will come directly to a visit at a research centre in Poland

Ideally, the confirmation should be between the investigator from Ukraine and the investigator from Poland. The sponsor/CRO does not have to, and if possible should not, be included in the exchange of medical information/patient data between the research centre in Ukraine and in Poland.

The minimum information required for a patient to continue his/her participation in a clinical trial in Poland:
- clinical trial number
- patient number in the clinical trial
- patient's full name, date of birth
- medical records presenting the entire or partial medical history, including the forms of informed consent to participate in the clinical trial signed in Ukraine or patient card form / other materials / patient's diaries or other data carriers containing medical records

Where the above details are missing, the following information will be of help:

- The place where the patient took part in the clinical trial (such as the name of the research centre, the name of the study doctor/name of the principal investigator)
- the date on which the patient commenced his/her participation in the clinical trial
- where the patient does not have any documents or contact with the investigator in Ukraine, it will be necessary to obtain the data from the clinical trial sponsor (from the sponsor's systems (IxRS, Lab, eCRF) and get the missing information during the interview (the address of the research centre, the approximate date of inclusion in the clinical trial, date or year of birth, objective diagnosis symptoms)
- Should there be any difficulties with identifying a clinical trial, it is recommended that you use the following sources of information on clinical trials conducted in Poland, including: the portal Home - ClinicalTrials.gov or TIP Patient Phone Information Service (**800 190 590**) or the selected helpline of the sponsor (the list of sources at the end of the recommendation)

Including a patient from Ukraine by a research centre in Poland

Upon reviewing the available information, medical records, the patient's data and upon analysing the risks and benefits, the investigator declares the willingness to include the patient and cover him with care in the research centre in Poland. However, the sponsor's decision concerning the transfer of a patient from Ukraine and continued application of the study product is equally important. Therefore, the decision on the patient inclusion is a shared responsibility of the investigator and of the sponsor, and it requires clear and swift communication to ensure the safety of each patient who is a participant of the clinical trial.

Conducting a visit with the assistance of an interpreter of Ukrainian/Russian

It is necessary to agree with the Investigator / research centre whether or not an external interpreter will need to be present during a patient's visit and on the extent to which the research centre requires support from the sponsor/CRO.

Some research centres have staff who speak Ukrainian or Russian and who may act as interpreters for/companions of the patients in such cases.

Due to the ongoing COVID-19 pandemic, it may happen that an external interpreter will not be able to stay in the research centre. Under such circumstances, you may consider obtaining support in the form of a remote session with an interpreter or a person from Ukraine who speaks Polish.

Linguistic support may be needed during all visits and outside visits – in urgencies, that is why the process should be clearly defined by the investigator and accepted by the trial sponsor.

Delegating responsibilities to new team members

Where the research centre hires new members of the research team (doctors, nurses, coordinators), the investigator should make sure that they have been trained on the conduct of the clinical trial in accordance with the sponsor requirements and the applicable regulations. The qualifications and the role of the new person on the research team must be confirmed by the investigator and documented on the "Delegation Log" form specific for the clinical trial.

The foregoing provision does not apply to the interpreter attending the process of consent giving, unless it is a permanent member of the research team (e.g. the coordinator or co-investigator) who only acts as an interpreter. More information on the rules of employing staff from Ukraine in the research centre can be found here: https://www.gov.pl/web/zdrowie/komunikat-w-sprawie-zasad-zatrudnienia-personelu-medycznego-z-ukrainy-w-polsce

Communication with the investigator from Ukraine

Whenever possible, you need to ensure communication between the research centres involved in the transfer of patients from Ukraine to Poland. Upon completing the process of transferring a patient to a research centre in Poland, it would be worth considering whether to communicate the same to the investigator in Ukraine. The communication form and method are to be agreed between the investigator and the sponsor or CRO.

Communication / Helpline for patients and doctors

In view of the situation, the sponsors of the clinical trials and the CRO companies are making efforts to set up special helplines and contact points for participants of clinical trials, Ukrainian patients, investigators and doctors.

The Office of the Commissioner for Patient Rights expressed the willingness to use a permanent helpline for patients to ensure adequate support and information for all participants of clinical trials from Ukraine who are staying in Poland and who need that.

When using the portal **Przyjacielska Pomoc Medyczna**, it will be also possible to connect a potential patient who is a participant of clinical trials in Ukraine with a selected research centre in Poland.
The portal will list all clinical trials at the open recruitment stage in centres that stated that they were ready in operational terms to include patients from Ukraine as part of the clinical trials they conduct.
The patient will be able to search for current clinical trials all over Poland as part of two options:

1. Depending on the indications or therapeutic area;
2. Upon entering the data allowing for the identification of the clinical trial in which the patient took part.

When a patient reports, the relevant information will be sent both to the centre and to the coordinator designated by the sponsor of a given trial to coordinate the patient's inclusion in the trial.

When a patient who is a participant of a clinical trial reports to you, you need to collect as much information identifying the patient as possible.
The overarching goal is to reduce the risk concerning the personal information of the patient and to respect the GDPR rules; however, it is important to confirm the clinical trial in which the patient participates.

The following information should be collected from a patient who contacts directly with the doctor, research centre, the company via the helpline or TIP**:**

1. Disease classification unit to which the clinical trial refers;
2. Number/acronym or any other designation of the clinical trial and the patient number in the clinical trial (protocol number);
3. Details regarding the product examined (number, name, acronym);
4. Details of the research centre in Ukraine (research centre name and location, investigator's name);
5. Place in which the person is staying or to which s/he is heading.

In addition, the following details should be determined:

6. If s/he has the patient card – the information contained therein; the centre in which s/he participated in the clinical trial; the contact details of the investigator; the date of the last administration of the medicine; the name of the medicine and the planned date of the next medicine administration;
7. Does s/he have any documents concerning his/her medical history and participation at the hospital (a signed consent form), any medical records, prescriptions, recommendations, discharge summaries from the hospital, etc.;
8. What language does s/he proficiently communicate in; if s/he does not speak English, does s/he have anyone who can accompany him/her during a hospital visit;
9. Contact details: full, PESEL (if s/he has one), e-mail address, contact phone number, the place of current residence or ultimate place of residence, date of birth;
10. When talking to patients, you need to remind them that they need to have a certificate issued by the Polish Border Guard or a stamp of the Polish Border Guard in their travel document to confirm that their stay in the Republic of Poland is legal after they crossed the border on or after 24 February 2022. It is important in terms of insurance as part of the National Health Fund.

Sources of information on clinical trials and contact details of the sponsors

Currently some clinical trial sponsors and CROs are setting up designated helplines/points of contact for Ukrainian patients of clinical trials, investigators and doctors.

Numerous patient organizations actively joined in the process of conveying information, seeking possible solutions for Ukrainian patients and relocating participants of clinical trials in between research centers.

The information about clinical trials being currently conducted in Poland is posted on the following websites:
https://clinicaltrials.gov

http://www.badaniaklinicznewpolsce.pl/baza-badan-klinicznych/
https://przyjacielskapomocmedyczna.pl / https://medychnadopomoha.com
Helpline 800 190 590 / TIP, or the **Patient Phone Information Service** is a shared phone number of the **Commissioner for Patients' Rights** and **Provincial Branches of the National Health Fund**. A free nationwide helpline number that can be called by anyone who wants to receive quick, comprehensive and transparent information on patient rights and on the health care system in Poland.

Pharmaceutical companies are setting up helplines intended for clinical trial participants, e.g.:

- a free helpline of **ROCHE** +36 146 182 58 for participants of clinical trials conducted by Roche.

Information about newly opened helplines and websites created with the aim of improving effective communication with Ukrainian patients can be found in the amendments to this document (Good practice of the clinical trials industry).

Information on clinical trials in Ukrainian

As arranged previously, the Medical Research Agency set up a special tab dedicated to clinical patients from Ukraine as part of the "Pacjent w badaniach klinicznych" (*Patient in clinical trials*) portal (https://pacjentwbadaniach.abm.gov.pl/).
The tab contains information in Ukrainian on clinical trials that are posted there and updated on a regular basis if needed.

The information currently available includes:

- Contact details of the Commissioner for Patients' Rights
- General information on a clinical trial and the types of clinical trials
- Recommendations on "Participation of Ukrainian patients in the clinical trials conducted in Poland" in Ukrainian
- Databases of clinical trials
- Information on patient qualification for a trial and the course of a clinical trial
- Rights of a clinical trial participant
- Frequently Asked Questions.

The portal is used as an element of an informational and educational campaign for potential patients from Ukraine.

Sources and publications:

- Komunikat Prezesa Urzędu z dnia 31.03.2022 r. w sprawie wpływu sytuacji na Ukrainie na prowadzenie badań klinicznych | Urząd Rejestracji Produktów Leczniczych, Wyrobów Medycznych i Produktów Biobójczych (urpl.gov.pl)
- Ustawa z dnia 12 marca 2022 r. o pomocy obywatelom Ukrainy w związku z konfliktem zbrojnym na terytorium tego państwa (sejm.gov.pl)
- Ustawa z dnia 8 kwietnia 2022 r. o zmianie ustawy o pomocy obywatelom Ukrainy w związku z konfliktem zbrojnym na terytorium tego państwa oraz niektórych innych ustaw (sejm.gov.pl)
- ochrona zdrowia ◈ охорона здоров'я ◈ healthcare | LinkedIn
- Impact of the war in Ukraine on methodological aspects of ongoing clinical trials | European Medicines Agency (europa.eu)
- Advice to sponsors on managing the impact of the war in Ukraine on clinical trials | European Medicines Agency (europa.eu)Heads of Medicines Agencies: Recently Published (hma.eu)
- Heads of Medicines Agencies: Recently Published (hma.eu)
- AGES Standardvorlage englisch (hma.eu)
- SÚKL´s opinion on the inclusion of Ukrainian patients in clinical trials in the Czech Republic, State Institute for Drug Control (sukl.eu)
- Guidance from the State Institute for Drug Control on the reassignment of Ukrainian clinical trial participants from centres in Ukraine to centres in the Slovak Republic | ŠÚKL (sukl.sk)
- Országos Gyógyszerészeti és Élelmezés-egészségügyi Intézet (gov.hu) https://zdravlje.gov.hr/o-ministarstvu/djelokrug-1297/lijekovi-i-medicinski-proizvodi/1349
- https://www.basg.gv.at/en/healthcare-professionals/clinical-trials/war-in-ukraine
- Clinical trials and the war in Ukraine - BASG
- Information for Patients With Cancer & Physicians in Ukraine & the Neighboring Countries | ASCO
- EURORDIS - The Voice of Rare Disease Patients in Europe