Patient in Clinical Trials

INFORMATION FOLDER

Updated version 3.0

Coordination:

MEDICAL RESEARCH AGENCY

Partners:

Children's Memorial Health Institute

Office for Registration of Medicinal Products, Medical Devices and Biocidal Products

Urszula Jaworska Foundation

Polish Pharmaceutical Chamber

POLCRO

GCPpl Polish Association for Good Clinical Practice

INFARMA

MEDICINES FOR POLAND

Co-organiser:

Ministry of Health Republic of Poland

Patrons:

Ministry of Economic Development and Technology Republic of Poland

The Ombudsman for Patients

ABOUT THE SERVICE

Patient in Clinical Trials (PiCTs) is an information service that was created to provide patients and their families with knowledge about clinical trials. Clinical trials offer a chance for alternative therapeutic options. It is important that patients have the ability to make an informed choice about their treatment path, so it becomes crucial to provide knowledge about clinical trials.

Patient in Clinical Trials

On the portal, patients, physicians and non-governmental health care organisations will find the most important information on the standards, procedures and requirements of the clinical trial process, detailed information on participating in a clinical trial, stories of clinical trial participants, as well as answers to frequently asked questions presented in an accessible manner. The service was created so that patients can receive reliable information on clinical trials, based on which they will be able to make decisions related to participation in the clinical trial. Reliable and complete information about clinical trials is extremely important in the treatment process. Patients should be able to receive it at the beginning of diagnosis so that they can make informed decisions about how their treatment path should proceed. Currently, clinical trials are often treated as a treatment of last resort, which can make it difficult for patients to assess the risks and benefits of clinical trials.

DEFINITION OF A CLINICAL TRIAL

Patients often wonder about the effectiveness and safety of medications prescribed by a physician, how often and in what dosage they should be taken, and where the information about side effects on the medicine's package insert was obtained. Clinical trials provide answers to questions about the efficacy and safety of the investigational product.

What is a clinical trial?

A clinical trial of a medicinal product is any study involving the participation of human subjects for the purpose of:

- the discovery or confirmation of the clinical, pharmacological, including pharmaco-dynamic, effects of one or more investigational medicinal products, or
- identifying adverse reactions to one or more investigational medicinal products, or
- tracking the absorption, distribution, metabolism and excretion of one or more investigational medicinal products, with a view to their safety and efficacy*.

Each medicine has to undergo a clinical trial in order to be registered and made available to patients. Its goal is to test whether a substance that will be in a medicine is effective and safe when used by patients with a particular disease, and whether it is better than already implemented treatments, for example by comparing its performance with other treatments and medicines already available to patients.

Why are clinical trials needed?

Clinical trials contribute to improving the efficacy and safety of diagnostic and therapeutic regimens used by physicians in daily medical practice, while contributing to the advancement of knowledge, science and medical practice. Conducting clinical trials enhances physicians' medical knowledge and ensures more effective clinical practice. Their results are also taken into account in making decisions on medicine reimbursement from the state budget.

* Article 2 of the Pharmaceutical Law

CLINICAL TRIAL REQUIREMENTS

The clinical trial must be, among other things:

- justified by the results of preclinical trials/data from previous clinical trials,
- scientifically justified and described in the clinical trial protocol,
- based on ethical principles,
- conducted by persons with appropriately high professional qualifications,
- conducted at the research centre.

Types of clinical trials

Commercial

- Conducted to obtain a marketing authorization for a medicinal product or medical device, as well as to amend an existing authorization
- Pharmaceutical and biotechnology companies are sponsors of commercial clinical trials.

Non-commercial

- Conducted to advance clinical practice and search for new treatments, they mainly focus on analysing the efficacy and safety of medicines already on the market.
- Mainly, universities, research institutes, associations and foundations are sponsors of non-commercial clinical trials.

Both commercial and non-commercial clinical trials are conducted after obtaining a positive opinion from the Bioethics Committee and approval from the President of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products.

HOW IS THE MEDICINE MADE?

*URPLWMiPB – Office for Registration of Medicinal Products, Medical Devices and Biocidal Products
**KB – Bioethics Committee

CLINICAL TRIAL PHASES

PHASE I

It defines the potential toxicity of the medicine, the minimum and maximum dose, and any pharmacological characteristics.

PHASE II

It confirms the medicine's effectiveness in a specific disease. It is conducted on a small group of patients (several dozen people).

PHASE III

It confirms the effect of a medicine in a given disease on a large population of patients (several hundred or several thousand people). It verifies the safety of the treatment, and its effectiveness compared to already available medicines.

PHASE IV

It is most often implemented after registration of the medicine. It determines whether the medicine is safe for all indications recommended by the manufacturer and for all patient groups.

The medicine is available to the patient in the pharmacy only after the competent authority has issued a decision on its marketing authorization. Before issuing a decision, the competent authority confirms whether the medicinal product is of adequate quality, whether it is safe. The evaluation is based on the documentation submitted by the responsible entity.

- In Poland, the competent authority is the President of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products.
- Once a registration decision is issued, the medicine can be marketed.
- The decision on whether a new medicine will be reimbursed for a particular indication is made in Poland by the Minister of Health.

CLINICAL TRIALS

Medicinal products

Clinical trials of medicinal products are conducted on every new medicine to be marketed. They are also organised when it is necessary to test the safety of medicines already registered, or to check their efficacy if used for new medical indications. The main purpose of clinical trials is to determine the safety and efficacy of a medicine. Conducting this type of clinical trials is a prerequisite for registering a new medicine and marketing it.

Medical devices

Clinical trials of medical devices are aimed at verifying whether the properties and performance of the device comply with the essential requirements, i.e. verifying that the performance of the medical device meets the objectives assumed in its design, as well as that it does not cause risks related to the safety of use of the device; determining any adverse effects; and assessing whether the risks generated are acceptable, taking into account the expected benefits that the use of the device may bring to patients affected by the condition.

Note that clinical trials do not apply to dietary supplements. Indeed, dietary supplements are defined as foodstuffs. Placing them on the market for the first time in Poland requires only the submission of a notification to the Chief Sanitary Inspector.

My attending physicians and nurses are very empathetic, and I remember them very warmly

BENEFITS TO THE PATIENT ARISING FROM PARTICIPATION IN A CLINICAL TRIAL

An access to modern and innovative treatments.

The possibility of free specialized examinations.

A chance to improve the quality of life.

Free medical care, provided by high-level specialists.

Contributing to the advancement of medicine and the development of the health care system.

Participation in a clinical trial gave me hope and a chance to live

INFORMED CONSENT TO PARTICIPATE IN THE CLINICAL TRIAL

Giving informed consent is the process during which a potential participant in a clinical trial obtains all the necessary information about the clinical trial and then voluntarily decides to participate in it (or opt out).

Persons confirming their participation

They must be informed of all aspects of the clinical trial that are important in deciding whether to participate. Both before deciding to participate in the clinical trial and during the clinical trial, the patient has the right to ask questions and receive comprehensive answers and explanations from their physician. Most importantly – **they have the right to withdraw from participation at any stage of the clinical trial without suffering any consequences**.

When discussing the clinical trial with the attending physician, the patient is given the relevant documents: the clinical trial information, describing in detail the purpose and conduct of the clinical trial, and the informed consent form. For consent to be given correctly, **the informed consent form should be signed in person and dated prior to the actual commencement of participation in the clinical trial** by the person to participate in the trial or their legal representative and by the physician conducting the interview on consent to participate in the trial. If informed consent cannot be given in writing, consent given orally in the presence of at least two witnesses is considered equivalent.

In the case of a minor, the legal requirements describing how to obtain informed consent are governed by separate regulations – Article 25 of the Act of 5 December 1996 on the profession of a physician and dentist – according to which the written consent of the child's legal representative is necessary.

I would recommend participation in the trial to any patient who is considering whether to undergo this treatment

CLINICAL TRIALS INVOLVING CHILDREN

Clinical trials play a key role in determining the safety and efficacy of new treatments in the youngest patients.

Rapid growth and maturing of the child

They can significantly alter the pharmacokinetics, pharmacodynamics and safety profile of the medicine, compared to the body of an adult. Therefore, there is a need for clinical trials in the pediatric population.

Currently, almost half of the medicines used in children are not registered as a medicinal product with an indication for the pediatric group and are used off label. Lack of knowledge about proper dosage, side effects, mode of absorption, excretion, half-life in different age groups of children is associated with the risk of side effects. On the other hand, not using these medicines would result in preventing the treatment of many diseases and conditions and would be unethical.

Reliably conducted pediatric studies are a guarantee of safety and matching the therapeutic dose in the youngest patients.

HOW THE PATIENT'S QUALIFICATION AND CLINICAL TRIAL IS CARRIED OUT

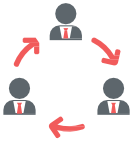
Initial **verification of eligibility to participate in a clinical trial** by the investigator based on criteria strictly defined in the clinical trial protocol.

Interview between the patient and the investigator in charge of the trial in question, **a detailed medical history and determination of the patient's health status, the patient reads the clinical trial information**.

The patient's informed consent to participate in the trial.

Performing tests and other procedures to verify **that the patient meets the inclusion criteria and does not meet the exclusion criteria**, which are specified in the clinical trial protocol.

Making a final decision by the investigator on the patient's eligibility for the clinical trial.



Randomization procedure – eligible participants are randomly assigned to an investigational therapeutic entity group or a control group.

The patient, according to the schedule, makes scheduled appointments and **undergoes treatment based on the clinical trial protocol**.

The clinical trial participant completes participation in the trial.

Qualification visit

After an initial positive verification by the attending physician (meeting inclusion criteria and not meeting exclusion criteria), a detailed interview and possible investigator-led tests are required. After the patient gives informed consent, during the qualification visit, the investigator reads the patient's medical records and orders the necessary tests for the clinical trial, e.g. blood pressure measurement, ECG, medical examination – general, blood and urine collection, etc. Only after analysing all the results does the investigator decide on the patient's qualification for the clinical trial.

Randomization

Most often (it depends on the specific clinical trial), during the trial, eligible participants are divided into two groups. One group will receive the investigational therapeutic entity, while the other will be assigned to the control group. Patients in the control group will receive either standard treatment for the disease or a placebo. This division is done randomly and is called **randomization**. To ensure objectivity, **the trial can be blinded – participants and the investigator do not know whether the person is receiving the investigational therapeutic entity or standard treatment or a placebo**.

Course of clinical trials and follow-up appointments

After qualifying for the trial, the patient proceeds to the next stage of the clinical trial. It can take the form of an outpatient program (the participant attends consecutive scheduled follow-up appointments, without having to stay permanently at the research centre) or an inpatient program (the participant stays permanently for a designated period of time at the research centre).

The examining physician informs the patient about when to attend appointments, how a particular appointment will go and how to prepare for it. During follow-up appointments, the patient also provides the examining physician with any information about their health from between appointments at the centre. During the follow-up appointment at the research centre, the patient may receive recommendations to continue taking the medicine, along with instructions on how to take the medicine and how to store it.

The frequency, course, and any procedures performed are specified in the clinical trial protocol and described in the clinical trial information, which is provided to the patient before consent is given.

THE MOST IMPORTANT RIGHTS AND OBLIGATIONS OF A CLINICAL TRIAL PARTICIPANT

- Participation in a clinical trial is **completely voluntary**.
- The patient has **the right to refuse to participate in a clinical trial at any moment without suffering any consequences**.
- **The decision to participate in a clinical trial must be fully informed**. If the patient's information is incomprehensible to them, they have the opportunity to ask questions of the physician proposing to participate in the trial, and the physician is obliged to answer all questions.
- The patient has the right to receive a copy of the written information about the trial and the informed consent document signed by them and the investigator.
- **The patient may opt out of the trial at any time.** However, they should inform the physician of their opting out and also appear at the appointed date for a follow-up appointment to assess their health after participation in the trial.
- The patient has **the right to obtain information from the physician about their condition at any stage of** the clinical trial and to inspect the documentation concerning them.
- Participation in a clinical trial is at no cost to the patient. The costs of investigational medicinal products, specialised tests and medical care are borne by the clinical trial sponsor.

During the course of treatment, the physician informed us that there was an opportunity to take part in additional trials to develop knowledge for better treatments in the future

- The patient is **entitled to compensation** if they have suffered permanent injury directly related to the medicine or medical procedure required by the clinical trial protocol.
- The patient is entitled to reimbursement for the additional documented costs they incurred while participating in the clinical trial.
- **The cost of treating side effects is covered by the clinical trial sponsor** – usually a pharmaceutical company.
- The patient has **the right to be informed** of any new data that may affect their decision on further participation in the clinical trial.
- The patient has **the right to full anonymity** and protection of their personal data.
- Both during and after the trial, the patient has the right to report to the attending physician any changes in well-being that they notice.
- By signing the informed consent form, the **patient agrees to follow the recommendations of the investigators** in the use of treatment, among other things.
- The patient is obliged to adhere to **the appointment schedule provided for in the protocol**. If a scheduled appointment is changed or cancelled, the patient should inform the investigator in advance.

PATIENT PARTICIPATION IN CLINICAL TRIAL, PRIMARY HEALTH CARE (PHC)

A clinical trial participant is under the constant care of a physician-investigator at the research centre but remains a patient and is entitled to receive standard medical care. In the case of developing any worrisome symptoms and need to use Primary Health Care (PHC), it is necessary to notify the investigator.

Primary Health Care

When qualifying a patient for a clinical trial, it is very important to inform the family physician, who cares for the patient on a daily basis, about participation in a specific clinical trial. This is, of course, a voluntary action, but it has many benefits, mainly for the patient participating in the trial.

Benefits

- Building mutual trust and better cooperation in the future.
- Contact with a physician with whom one can talk freely, address one's doubts and concerns.
- **Avoiding possible interactions between medicines used in the clinical trial and those prescribed in the family physician's office.**
- Possible contact of physicians as part of inter-medical consultations, for the benefit of both the patient, the safety of treatment and the proper realisation of the objectives of the clinical trial.

All decisions taken during the trial, such as changing treatment within the clinical trial or terminating treatment, among others, are made by the physician-investigator, who is responsible for the patient's safety.

A clinical trial participant may withdraw from participation in a clinical trial at any time at their own discretion. The decision to opt out of the trial must not affect further medical care or access to treatment outside the clinical trial.

ADVERSE ACTIONS AND EVENTS

The participant should inform the investigator of worrisome situations and consult with them about the use of other medicines, unrelated to the clinical trial, even if this information seems irrelevant to them. Cases of adverse reactions should be reported immediately to the investigator.

Side effects

Any adverse and unintended reaction to the investigational medicinal product associated with its administration in any dose, such as the occurrence of fever after taking the investigational medicinal product.

Adverse events

Any adverse medical event occurring in a person to whom an investigational medicinal product was administered without the need to demonstrate a causal relationship to that treatment, such as a person's broken leg.

It is the investigator's responsibility to provide adequate medical care to clinical trial participants, particularly in the event of a severe adverse event following use of the investigational medicinal product, including significant deviations in the results of laboratory tests. Adverse events are recorded by the investigator in the clinical trial participant's medical records and in the Case Report Form (CRF).

The investigator is required to report to the sponsor a serious adverse event while taking the investigational medicinal product, unless these were events identified in the clinical trial protocol or the investigator's brochure as not requiring immediate reporting.

According to the GCP principles, each trial participant should be kept informed about the course of the clinical trial, possible risks and side effects of the investigational medicinal product.

RESPONSIBLE INSTITUTIONS AND LEGAL BASES

The institutions responsible for clinical trials in Poland are the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products (URPLWMiPB) and the Bioethics Committees (KB).

Supervision

In Poland, the President of URPLWMiPB supervises clinical trials and the approval of new medicines. The relevant KBs assess whether the study is ethically acceptable, paying particular attention to the rights of the clinical trial participant.

The principles of Good Clinical Practice (GCP) require that all clinical trials be science-based and have a plan (clinical trial protocol). The document is thoroughly reviewed in terms of ethics and content by independent KBs.

The committees pay particular attention to the content of patient information and the language in which the information is conveyed.

In accordance with the rules applicable in the European Union, **the process of ethics review and the registration of a clinical trial in Poland run in parallel. It is possible to start a trial only after obtaining a positive opinion from the KB** and receiving approval to conduct a clinical trial from the President of URPLWMiPB.

THE MOST IMPORTANT LEGISLATION ON CLINICAL TRIALS

§ **Act of 9 March 2023 on clinical trials of medicinal products for human use**

It defines, among other things, the rules for insuring clinical trials and how to protect patients.

§ **Pharmaceutical Law of 6 September 2001**

It defines, among other things, the rules and procedures for authorizing the marketing of medicinal products and the conditions for conducting clinical trials of medicinal products.

§ **Act of 5 December 1996 on the profession of a physician and dentist**

It defines the terms and conditions of the aforementioned professions, including the exclusivity to conduct a clinical trial as an investigator.

§ **Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014**

It defines the rules for conducting clinical trials of medicinal products for human use throughout the European Union.

CLINICAL TRIALS INSURANCE

Every clinical trial must have mandatory investigator and sponsor liability insurance.

Without insurance, the clinical trial will not receive permission from the President of URPLWMiPB and a positive opinion from the KB. The scope of such insurance is defined in the regulations – similar to the mandatory motor third-party liability insurance.

Such insurance always covers liability for bodily injury, health disorder or death of a trial participant caused in connection with the conduct of a clinical trial as a result of an act or omission of the sponsor, investigator or persons for whom they are responsible.

Insurance does not cover:

- damage, destruction or loss of property

- damage resulting from the participant's addiction*

- damage caused by or related to asbestos

- contractual penalties

- damage caused by acts of war, martial law, riots and unrest, as well as acts of terror

*if the possibility of addiction was presented to the participant in writing at the start of the trial

CLINICAL TRIALS COMPENSATION FUND

If a bodily injury, health disorder or death occurs as a result of participation in a clinical trial, it is possible to apply to the Patient Ombudsman for compensation benefits from the Clinical Trials Compensation Fund.

The amount of the benefit depends, among other things, on the nature of health consequences and the degree of ailments resulting from bodily injury or health disorder.

To use the benefit, it is not necessary to initiate legal proceedings and incur the associated costs.

The Fund will not eliminate other avenues of redress.

It is still possible to use other forms, i.e. the right to seek compensation from the insurer, or to take legal action.

If compensation or damages are obtained from the person responsible for the damage, including as part of insurance, the compensation benefit shall be reduced accordingly.

The choice will be yours.

For more information, see:
gov.pl/web/rpp/fundusz-kompensacyjny-badan-klinicznych

CHIEF BIOETHICS COMMITTEE

According to the Act on clinical trials of medicinal products for human use, the Minister of Health appoints the Chief Bioethics Committee (NKB) for clinical trials. Among the thirty members of the NKB appointed for a 4-year term, there are three representatives of patient organisations included in the list of patient organisations maintained by the Patient Ombudsman.

Composition of the Chief Bioethics Committee

15 representatives of scientific disciplines:
- medical sciences
- pharmaceutical sciences

6 representatives of scientific disciplines:
- philosophy
- theological sciences

6 representatives of scientific disciplines:
- legal sciences

3 representatives of patient organisations
- on the list of patient organisations

PATIENT REPRESENTATIVE IN ETHICS REVIEW

Among the NKB's tasks is to prepare an ethics review of the clinical trial, which **involves a patient representative**.

The role of the patient in the ethics review of a clinical trial

1. Opinion on the content of informed consent.
2. Opinion on the clinical trial information prepared for the patient:
   - is it written in a clear manner?
   - is it written in simple language?
   - is it understandable and patient-friendly?

When issuing an opinion, the KB pays special attention to the content of information intended for the patient and the way it is conveyed, in order to fully ensure the dignity, safety and rights of clinical trial participants. The review team is fully autonomous and impartial when conducting an ethics review.

The ethics review conducted with the patients' representative aims to ensure the dignity, safety and full rights of the clinical trial participant.

QUALITY OF CLINICAL TRIALS IN POLAND

To protect the rights and safety of patients participating in a clinical trial and to ensure the reliability of the data obtained, the GCP principles and the Act of 9 March 2023 on clinical trials of medicinal products for human use were developed and implemented. The ethical principles for medical research involving human subjects (the so-called Helsinki Declaration) is also an important regulation in the field of clinical trials.

The principles of Good Clinical Practice (GCP) should be applied to all clinical trials conducted in Poland.

Inspection of clinical trials

Clinical trials are subject to inspection by the URPLWMiPB. Inspection of clinical trials is an official activity conducted by inspectors acting under the authority of the URPLWMiPB President. These actions aim to verify how the clinical trial is conducted.

► Main goals of the inspection:

- Protecting the rights of clinical trial participants.
- Standardisation of conducted clinical trials.
- Caring for a sound research process.
- Verifying the division of responsibilities and duties between the parties involved in conducting the clinical trial (investigator's duties, sponsor's duties).

I was aware that the physician would call me, and I knew that someone was watching over me all the time

WHERE TO LOOK FOR INFORMATION ABOUT A CLINICAL TRIAL?

Contact with a physician.

Contact with other patients.

Clinical trial registries/international databases.

Research centre websites.

Patient organisation websites.

Internet and social media.

How to find a clinical trial?

- Type a phrase with the name of the condition and "clinical trial" into an Internet search engine.

  Check clinical trial search engines:

- Find the data of the centre that offers participation in a particular clinical trial, call and find out what the possibility of qualifying for the program is*.
- Ask your doctor if they know of any clinical trials being conducted for your indication.

*Finding a clinical trial does not guarantee eligibility for participation. In order to check the possibility of participating in a clinical trial, it is necessary to contact the research centre in question and then go through the qualification process for a particular trial.

GLOSSARY

Active comparator medicine (comparator) –	a medicine currently on the market that is considered effective, which is used in a clinical trial for comparison with the investigational medicine.
Investigator –	a physician who conducts and supervises a clinical trial at a research centre (hospital/medical centre). The investigator is responsible for ensuring that the trial is conducted in accordance with the approved clinical trial protocol, takes care of ethics and good clinical practice, as well as the rights and safety of the clinical trial participant.
Clinical trial –	scientific research conducted with human subjects to discover or confirm the efficacy and safety of medicines and medical devices.
Informed consent form –	a document that allows the patient to make an informed decision about participating in a clinical trial. The document outlines the purpose of the trial, the patient's rights and obligations, the procedures performed during the trial, and the benefits and risks of participating in the trial.
Bioethics committee –	an opinion-making body established in accordance with applicable Polish law.
Coordinator of the trial –	the person responsible for adhering to international GCP procedures during the clinical trial, organising the work of the centre and ensuring that the implementation of the clinical trial protocol is followed; they are the liaison between the sponsor and the research centre and are responsible for the first stage of verification of the reliability of the data obtained by the research teams.
Inclusion/exclusion criteria –	criteria to help determine whether a person is eligible to participate in a clinical trial (and will be included in the trial) or not (and will not be qualified for the trial).
Investigational medicinal product –	a substance or mixture of substances whose properties are being evaluated in a clinical trial.
Research centre –	a health care entity, such as a hospital or medical centre, where a clinical trial is being conducted.
Placebo –	a substance that looks the same as the investigational medicine (has the same form, e.g., identical tablets or ampoules), but does not contain any medicine (active substance). Clinical data collected from patients taking the investigational medicine are compared with data from patients taking a placebo, so the efficacy and safety of the investigational medicine can be assessed.
Medicinal product –	a substance or mixture of substances with properties due to which it can be used for the prevention of disease, treatment of diseases occurring in humans or animals, administered for the purpose of diagnosis, restoration, improvement or modification of physiological functions of the body through pharmacological, immunological or metabolic action.
Clinical trial protocol –	a document describing the plan for the clinical trial, its objectives and method of implementation. In Poland, the clinical trial protocol is approved by the Bioethics Committees and the President of the URPLWMiPB.
Randomization –	a process that involves randomly assigning trial participants to a group with the investigational medicine or to a control group (with an active comparator medicine or placebo). Neither the patient nor the examining physician can choose which group the patient will be assigned to.
Sponsor –	an individual, a legal entity or an organisational unit without legal personality, responsible for the initiation, conduct and financing of a clinical trial, which is located in the territory of one of the European Union Member States or member states of the European Free Trade Agreement (EFTA) – a party to the Agreement on the European Economic Area, if the sponsor is not located in the territory of one of the European Economic Area countries, may act only through its legal representative located in that territory.
Medical device –	a tool, instrument, device, software, material or other article, used alone or in combination, including software intended by its manufacturer for use for diagnostic, therapeutic purposes, replacement or modification of anatomical structure or physiological process. The essential intended action of a medical device in or on the human body is not achieved by pharmacological, immunological or metabolic means, but whose action can only be assisted by such means.

FREQUENTLY ASKED QUESTIONS

- What is a clinical trial and why is it conducted?
- What are the risks of participating in a trial?
- What should be considered before entering a clinical trial?
- What are the rights of the patient participating in a trial?
- Can I withdraw from a trial, and if so, do I incur any losses?
- What is information and informed consent?
- What are the benefits of participating in a clinical trial?
- Who can participate in a clinical trial?
- Do I incur any costs for participating in a trial?
- Will I get paid for participating in a clinical trial, and in what case?

Answers to all questions can be found on PwBK's website and Facebook page:

www.pacjentwbadaniach.abm.gov.pl

www.facebook.com/pacjentwbadaniach

*all quotes are from patients who were participants in the clinical trials, the statements can be found in the videos on the PwBK website.

Patient in Clinical Trials

Participation of patients from Ukraine in clinical trials conducted in Poland

In view of the armed conflict in Ukraine, the Medical Research Agency's website provides key data on clinical trials in Poland, which may be useful for Ukrainian citizens wishing to start or continue participation in a clinical trial.

зв'язку зі збройним конфліктом в Україні Агентство медичних досліджень (Agencja Badań Medycznych) зібрало найважливіші дані про клінічні дослідження у Польщі, які можуть бути корисними для громадян України, бажаючих розпочати чи продовжити участь у клінічному дослідженні.

The Ombudsman for Patients
ul. Młynarska 46, 01-171 Warsaw
kancelaria@rpp.gov.pl; www.gov.pl/web/rpp/
The Ombudsman for Patients' Call-Centre: 800-190-590

The publisher of the information folder is the Medical Research Agency.