



CATALOGUE Polish Clinical Trials Network





MEDICAL RESEARCH AGENCY, OCTOBER 2023, WARSAWA, POLAND

Medical Research Agency

The **Medical Research Agency (MRA)** was founded in order to improve the use of potential for development of medical research and health sciences, particularly in the scope of non-commercial clinical trials.

The main goals of non-commercial clinical research development shall include searching for new methods of treatment in the most pressing areas of medicine: oncology and cardiology, and also in the area of rare diseases, as often they are outside the area of interest of private companies. Ensuring the patients with oncology, cardiac and rare diseases the opportunity to participate in clinical research is essential for the whole health care system. In the future it will result in an access to modern medications or in lowering the costs of treatment of particular diseases.

The research conducted by the MRA will be used to assess effectiveness and safety of medications and technologies that have already been on the market, but also to withdraw the technologies that are no longer effective. Verification of effectiveness of the selected technologies in the conditions of the Polish health care system will make it easier for the bodies responsible for reimbursement and tariff setting to arrive at decisions in this area.

The Agency will also support development of population-based and epidemiological studies in various areas of public health. The collected data will be used to prepare expert analyses that will define the causes of various incidence of particular diseases or of mortality ratios due to selected diseases in individual regions of Poland.

Polish Clinical Trials Network

The **Polish Clinical Trials Network (PCTN)** was set up on 11 March 2021 through an agreement between the Medical Research Agency and the Beneficiaries of the 1st edition call for proposals for the establishment and development of Clinical Trials Support Centers. It aims at implementing uniform, systemic solutions for quality and process management at institutions involved in conducting clinical trials in Poland.

The common standards and clinical trial information management models in place within the Network are intended to make the Polish clinical trial market more attractive to sponsors, and particularly encourage them to use public sector institutions as venues for their research.



Continuous implementation of new solutions is expected to have a direct impact on reinforcing Poland's position in the clinical trial industry, boosting the competitive advantage of domestic infrastructure and its potential to support high quality research in order to promote more effective international cooperation. The PCTN is intended to ensure effective country-wide recruitment, streamline the feasibility process, as well as support the training of dedicated clinical trial staff.

Clinical Trials Support Centres

The idea behind creating dedicated **Clinical Trials Support Centres (CTSC)** was to harness the potential of Polish public facilities engaged in clinical trials, create a favourable environment for investigators to initiate non-commercial clinical trials (thus increasing the overall number of clinical trials conducted in Poland) and offer Polish patients better access to innovative technologies.

In 2020 and 2021, the Agency announced two editions of the call for proposals for establishing and developing Clinical Trials Support Centres (CTSCs) and one call for specialised oncology and hematooncology CTSCs (OncoCTSCs). **Twenty-three** public entities have received approx. **PLN 195 million** (42 million euros) in MRA grants.

The principal areas of funding:



Beneficiaries are required to implement CTSC Model Standard – uniform systemic quality and process solutions to standardize the conduct of clinical trials. The purpose of the document is to indicate the minimum requirements, optimal criteria and guidelines for the use of funds in the implementation of projects for the establishment and development of MRA-funded CTSC.

Sponsors Support Center

The **Sponsor Support Center (SSC)** at the MRA is an initiative to assist clinical trial sponsors in the process of identifying and selecting appropriate sites to conduct clinical trials. The SSC serves as a contact point allowing sponsors to access specialized sites collaborating within the Network.

Main tasks and functions of the Sponsor Support Center:

• Advice and support in the trial site selection process:

The SSC offers expert advice to clinical trial sponsors on the selection of optimal study sites within the PCTN. This allows for a focus on the sites that best meet the trial's specific criteria and requirements.

Access to the trial sites database:

The SSC collects and updates a comprehensive database of available sites within the PCTN. This gives sponsors access to the latest information on the sites' infrastructure, specialties and experience.

• Site potential analysis:

The SSC representatives assess the potential and capacity of trial sites to conduct a specific clinical trial. This analysis takes into account both scientific and logistic aspects.

Logistic support and process monitoring during trial:

The SSC assists in the logistic process involved in starting a collaboration with trial sites. Once the sites have been selected, the Center stays in constant contact with sponsors, monitoring the progress of the trial and offering support in resolving any problems.

• Developing cooperation between the public and private sectors:

The SSC encourages cooperation between the public sector (trial sites) and the private sector (clinical trial sponsors), which contributes to promoting innovation and the development of medical research in Poland.

To establish cooperation, please contact:

cws@abm.gov.pl



Polish Clinical Trials Network Members



Multidisciplinary Clinical Trials Support Center

of the Medical University of Gdańsk & University Clinical Center

The Medical University of Gdańsk is a leading medical university in Poland, the only one with the elite status of a Research University. The Medical University of Gdańsk employs over 1,200 academic staff and educates more than 6,000 students (including more than 1,000 international students) at the faculties of medicine, health sciences, pharmacy and biotechnology. Among the ongoing scientific and R&D projects (a total of more than 150 projects worth nearly €80 million) are 17 non-commercial clinical trials.



The University Clinical Center (UCC) is a multispecialty clinical hospital of the Medical University of Gdańsk, the largest in Pomerania and one of the largest in Poland (with more than 4,500 staff and more than 1,200 hospital beds).





The UCC provides comprehensive treatment in most of the specialties covered by the healthcare services, offering comprehensive diagnosis, treatment, rehabilitation and palliative care at the highest level. It is one of the Poland's largest research centers conducting clinical trials, including early phase trials (10% of all trials).



Central Clinical Laboratory
 Early Phase Clinical Trials Center

Laboratory of Clinical Genetics and Laboratory of Hematology

Bio-Bank

• Laboratory of Clinical Immunology and Transplantation



Prof. Rafał Dziadziuszko

Specialist in clinical oncology and radiation therapy; co-author of over 370 full-text scientific publications (papers cited more than 9400 times); medical coordinator of the Early Phase Clinical Trials Center; Principal Investigator in more than 40 clinical trials (including 12 early phase trials).



Prof. Elżbieta Senkus-Konefka

Specialist in clinical oncology and radiation therapy; co-author of over 150 full-text scientific publications (papers cited nearly 13,000 times); expert and co-author of the European Society For Medical Oncology guidelines; Principal Investigator in more than 20 clinical trials.



Prof. Jan Maciej Zaucha

Specialist in internal medicine, hematology and clinical transplantation; co-author of over 200 full-text scientific publications (papers cited more than 3,500 times); Principal Investigator in over 20 clinical trials (including 6 early phase trials and 2 MRA-funded non-commercial trials).

The Medical University of Gdańsk has received over PLN 210 million to carry out 19 projects funded by the Medical Research Agency!

Past inspections and certifications as well as accreditations:

FDA, EMA, URPL
ISO/IEC 27001:2017-06; ISO 9001:2015
ISO 45001:2018; ISO 14001:2015

Medical University of Gdańsk M. Skłodowskiej-Curie 3A, 80-210 Gdańsk

> University Clinical Center Dębinki 7, 80-952 Gdańsk



Non-commercial trials: dnbk@gumed.edu.pl, Tel.: +48 58 349 27 67

Commercial trials: feasibility@uck.gda.pl, Tel.: +48 58 584 64 37

Learn more: www.clinicalresearch.mug.edu.pl

Pediatric Clinical Trials Support Center Children's Memorial Health Institute in Warsaw

Children's Memorial Health Institute (CMHI) in Warsaw is the largest and the most modern tertiary refferal pediatric hospital in Poland & a research institute (A category) contributing to modern pediatrics. Except hematology and orthopedics all fields of pediatrics are represented in the CMHI. Modern diagnostics and treatment options are offered for pediatric patients of all age subsets of pediatric population from all over the country. The CMHI has got more than 45 years experience in pediatric research, including clinical trials. Our pediatric liver and kidney transplantation program is one of the largest in the world.



The Center for Pediatric Clinical Trials Support (CPCTS) is the only one stand alone pediatric facility in Poland. The mission of CPCTS is to increase high quality, ethical research dedicated into medicinal products development for pediatric population.



The CPCTS actively initiates scientific projects using new research tools in drug's development (e.g., modeling and simulation, extrapolation) to obtain more information without unnecessary studies in children. The scope of the CPCTS's activities support the mission of the CMHI "We treat at the highest level. The child is in the Center".

We work with:









Prof. dr hab. n. med. Katarzyna Kotulska-Jóźwiak

Specialist in pediatric neurology, particularly in epileptogenesis and neurocutancous diseases. Member of Board of Members States for European Reference Neuroses. Author of over 200 scientific publications.



Prof. dr hab. n. med. Jarosław Kierkuś

Specialist in pediatric gastroenterology, hepatology and pediatric nutrition, especially in biological treatment and inflammatory bowel disease. Author of over 200 scientific publications.



Prof. dr hab. n. med. Piotr Socha

Specialist in rare metabolic liver diseases (e.g., Wilson's Disease, newly described PGM-1), nutrition in hepatology and gastroenterology (e.g., LCPUFA deficiency). Author of over 400 scientific publications.

In the years 2019-2023, we received a total of PLN 130.7 million in R&D funding from the MRA!

Past inspections and
certifications as well
as accreditations:

- FDA, MRA
- Scientific category A; Certified "Hospital Without Pain"
 - ISO 9001; Accreditation Certificate (No. 2022/60)



Location:

Building Z, Al. Dzieci Polskich 20, 04-730 Warszawa



Contact details:

E-mail: badania.kliniczne@ipczd.pl Tel. +48 22 815 19 43 Feasibility: polpednet@ipczd.pl

Learn more: www.nauka.czd.pl

Clinical Trials Support Center at the National Institute of Geriatrics, Rheumatology and Rehabilitation in Warsaw

The mission statement of the CTSC at the National Institute of Geriatrics, Rheumatology and Rehabilitation in Warsaw with regard to clinical trials is to use its highest competencies and innovative management model in order to provide access to modern forms of treatment for patients in need through the latest scientific advances. The Institute improves the health and quality of life of its patients by using with the highest global standards and contributes to the growth of innovation in the healthcare system.



The center relies on the models and many years of clinical experience gained in the course of the Institute's clinical activities and cooperation with experienced clinicians – Principal Investigators in clinical trials. The Institute is also developing international cooperation with a view to bringing Poland into the mainstream of key research conducted around the world.



We conduct trials on diseases including rheumatology (adults and children), immunology, dermatology, orthopedics, neurology and cardiology. When conducting trials, we combine the work of clinicians with specialists in pharmacy and molecular biology.





Prof. dr hab. n. med. Brygida Kwiatkowska

Over 20 years of experience in clinical trials of rheumatic, dermatological and cardiovascular diseases.



Dr n. med. Piotr Gietka

Over 10 years of experience in clinical trials of rheumatic diseases in the pediatric population.



Dr n. med. Łukasz Artryszuk

A hypertension and internal medicine specialist with several years of experience in working with patients with hypertension and high risk of cardiovascular disease.



Dr n. med. Maria Maślińska

Over 5 years of experience in clinical trials of rare and rheumatoid diseases.

CTSC at the National Institute of Geriatrics, Rheumatology and Rehabilitation in Warsaw guarantees an efficient, safe and professional environment for study participants and accurate, high-quality data for Sponsors. The trials we conduct out are handled comprehensively.

We received nearly PLN 90 million in R&D funding! (from non-commercial projects)



Location:

Spartańska 1, 02-637 Warszawa



Contact details:

E-mail: cwbk@spartanska.pl Tel. +48 22 688 06 32

Learn more: www.cwbk.spartanska.pl

Clinical Trials Support Center at the Cardinal Stefan Wyszynski Institute of Cardiology in Warsaw

The Clinical Trials Support Center at the Institute of Cardiology operates under a shared services model, providing support for commercial and non-commercial clinical trials. It provides patients with access to research and a high standard of healthcare, which gives them the opportunity to undertake modern therapies. Doctors conducting research gain the necessary knowledge, scientific experience and expand their professional networks.



The Clinical Trials Support Center operating within the Institute of Cardiology—in addition to providing a standardized infrastructure, organization and IT systems—has put in place clear operating rules in the form of standard operating procedures (SOPs), which standardize and regulate the processes of conducting clinical trials. All these activities help create an attractive environment for investigators.



The Institute of Cardiology is a reference site for cardiology and cardiac surgery and for many years now has been at the forefront of cardiac medicine in Poland. The highest (A+) category in medical research, particularly in cardiovascular diseases.



Prof. dr hab. n. med. Łukasz Szumowski

Specialist in internal medicine, cardiology and electrophysiology. Member of Polish and international scientific societies, including the European Society of Cardiology and the Polish Society of Cardiology, author or co-author of over 150 scientific publications.



Prof. dr hab. n. med. Katarzyna Biernacka

She has the most experience working with patients with ARVC in Poland. Her scientific achievements include a number of original studies published in such journals as Journal of Electrocardiology, Progress in Interventional Cardiology, Journal of Cardiology and Polish Cardiology.



Prof. dr hab. n. med. Aleksander Prejbisz

Specialist in internal medicine, specialist in hypertension, President Elect of the Polish Society of Hypertension, author or co-author of original domestic and international publications. He earned the title of Clinical Hypertension Specialist awarded by the European Society of Hypertension.

We received a total of PLN 106 million in R&D funding!



Learn more: www.ikard.pl/dzial-badan-klinicznych.html

Clinical Trials Support Center at the National Institute of Oncology – Gliwice Branch

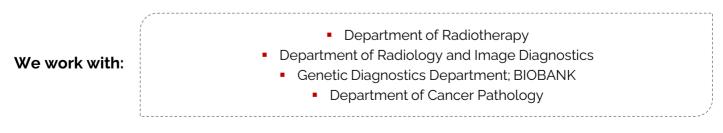
The National Institute of Oncology is a full-profile and the largest oncology center in Poland with the highest level of reference offering comprehensive treatment and diagnostics. Its state-of-the-art apparatus and highly trained staff provide patients with comprehensive world-class medical treatment. The Clinical Trials Support Center is a specialized unit operating according to the highest standards, providing comprehensive support for the implementation of trials.



Over the past 15 years, nearly 200 commercial studies have been conducted at the National Institute of Oncology in Gliwice for leading pharmaceutical and non-commercial companies, e.g. with the European Organization for Research and Treatment of Cancer (EORTC), the Polish Adult Leukemia Treatment Group Association (PALG) and the Polish Lymphoma Research Group.



The CTSC has specialists in radiation oncology, clinical oncology, endocrinology, nuclear medicine, internal medicine, clinical transplantation and chemotherapy.





Dr hab. n. med. Tomasz Rutkowski

Specialist in radiation oncology and clinical oncology. Author of nearly 70 scientific publications, mainly in the field of treatment of head and neck cancer patients. Principal Investigator in 24 clinical trials.



Dr hab. n. med. Daria Handkiewicz-Junak

Specialist in radiation oncology, clinical oncology and nuclear medicine. She has 20 years of experience in isotope treatment of patients with malignancies, including prostate cancer.



Prof. dr hab. n. med. Sebastian Giebel

Specialist in internal medicine, hematology and clinical transplantation. Chairman of PALG and PLRG, author of over 120 scientific publications, mainly in the field of hematology and hematopoietic cell transplantation.

We received a total of PLN 62 million in R&D funding!

Past inspections and certifications as well as accreditations:



Learn more: badaniakliniczne.io.gliwice.pl

Clinical Trials Support Center at the Poznan University of Medical Sciences

The University's CTSC, as a Site Management Organization (SMO), consolidates all clinical trials conducted at 4 clinical hospitals. Thanks to economies of scale, both contracting, recruitment and human resources management processes have been optimized. The Poznan University of Medical Sciences is an entity capable of having an impact on a macro-regional scale, and thus acts as a national leader co-creating a market in Poland for a modern approach to clinical trials.



As one of few centers in the public sector, we operate early phase sites that guarantee full safety for patients (sites in hospitals with access to anesthesiology and intensive care units).



We conduct Phase 1 to 4 trials in the following therapeutic areas: oncology, hematology, cardiology, cardiac surgery, vascular surgery, transplantation, gastroenterology, metabolic diseases, diabetology, pediatrics, neonatology, neurology, endocrinology, pulmonology, gynecology, dermatology, rheumatology, orthopedics and ophthalmology.





Prof. dr hab. med. Barbara Steinborn

Specialist in child and adult neurology. Principal Investigator in over 20 clinical trials. Author of over 633 scientific publications.



Prof. dr hab. med. Jacek Mackiewicz

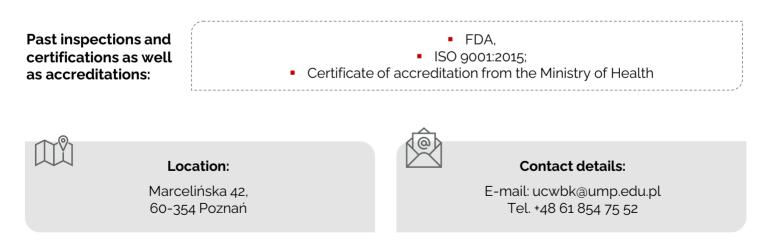
Specialist in clinical oncology. Principal Investigator in over 60 clinical trials. Author of over 100 scientific publications.



Prof. dr hab. med. Maciej Lesiak

Specialist in internal medicine and cardiology. Principal Investigator in over 50 clinical trials. Author of over 388 scientific publications.

We are the first center in Poland to use CAR T-cell therapy!



Learn more: www.badaniakliniczne.ump.edu.pl

University Clinical Trials Support Center at the Wroclaw Medical University

The University CTSC provides comprehensive planning and management services for clinical trials of medicinal products and medical devices as a Sponsor, Site Management Organization, as well as an Early Phase Center. A state-ofthe-art Early Phase Center fitted with innovative equipment allows for more than a dozen studies (16 beds) to be carried out simultaneously, including first-in-human, proof-ofconcept, pharmacokinetics monitoring, pharmacodynamics, bioavailability and bioequivalence, taking into account the evaluation of safety and efficacy of medical devices.



A Scientific Council operating at the Center is composed of highly qualified physicians and scientists specializing in various fields of medicine, which oversees the quality and safety of the conducted trials.



We conduct multi-center and international clinical trials in strategic cooperation with the University Clinical Hospital in the fields of cardiology, hematology and oncology, including pediatric hematooncology, neurosurgery or internal medicine, and others.





Prof. dr hab. Piotr Ponikowski

Expert in the field of heart failure, chairman of the working group preparing European guidelines in this field (2016), co-author of many international expert papers in cardiology. Ranked among the world's most influential medical scientists according to Clarivate Analytics' The World's Most Influential Scientific Minds' ranking.



Prof. dr hab. Anna Czyż

Expert in the field of hematopoietic cell transplantation, acute lymphoblastic leukemia, lymphomas and the application of flow cytometry in the diagnosis and treatment of hematologic malignancies, co-author of international expert papers in this field.



Prof. dr hab. Krzysztof Kałwak

Expert in pediatric transplantation. In 2020, he introduced CAR-T technology for the treatment of children with refractory lymphoblastic leukemia. Since April 2023 Chairman of the European Bone Marrow Transplant Group Pediatric Diseases Working Party.



Prof. dr hab. Ewa Jankowska

Expert in the field of heart failure, co-author of the European Heart Failure Guidelines (2016), co-author of many international expert documents in the field of cardiology. Board member of the Heart Failure Association of European Society of Cardiology.

Past inspections and certifications as well as accreditations:

- ISO Management System Certificate
- Accreditation Certificate for the activities
- of the University Center for Stationary Care
- Biobank accreditation, ISO 20387:2021-01 standard



Location:

Borowska 211A, 50-556 Wrocław



Contact details:

E-mail: ucwbk@umw.edu.pl Tel. +48 71 784 05 89

Learn more: www.ucwbk.umw.edu.pl

Clinical Trials Support Center at the Medical University of Bialystok

The CTSC is a joint venture between the Medical University of Bialystok and the University Clinical Hospital and the University Children's Clinical Hospital. The CTSC's goal is to comprehensively support the conduct of clinical trials. To this end, the Center employs specialized medical staff (physicians, coordinators, nurses) and administrative staff (contracting and billing for trials). The CTSC cooperates with investigators with extensive experience in clinical trials in a wide range of therapeutic areas.



The CTSC has an infrastructure dedicated specifically to conducting clinical trials. In addition, trials can be conducted using the facilities of both teaching hospitals. A particular strength of the CTSC is the establishment of an Early Phase Center enabling Phase 1 and Phase 2 trials to be conducted in complete safety.



Therapeutic areas with the most experience: cardiology, oncology, allergology, psychiatry, infectious diseases, endocrinology, diabetology, neurology, anesthesiology, nephrology, pulmonology.

 Academic Center of Pathomorphological and Genetic-Molecular Diagnostics

 Medical University of Bialystok Biobank
 Medical University of Bialystok Molecular Imaging and Technology Development Laboratory
 Center for Bioinformatics and Data Analysis



Prof. dr hab. n. med. Agnieszka Tycińska

Specialist in cardiology and intensive care. Deputy head of the Department of Cardiology and head of the Cardiac Intensive Care Unit, regional consultant in intensive care.



Prof. dr hab. n. med. Adam Krętowski

Specialist in diabetology, endocrinology and internal medicine. Principal Investigator in over 20 clinical trials. Author of over 250 scientific publications. Rector of the Medical university of Bialystok, head of the CTSC.



Prof. dr hab. n. med Anna Wasilewska

Specialist in pediatrics and nephrology. Head of the Department of Pediatrics and Nephrology, regional consultant in pediatrics. Principal Investigator in over 30 clinical trials. Author of over 150 scientific publications.

We received a total of PLN 80 million in R&D funding!

Past inspections and certifications as well as accreditations:

 Accreditation Certificate of the Ministry of Health for the University Clinical Hospital and the University Children's Clinical Hospital
 "Hospital Without Pain" certificate for the University Clinical Hospital and the University Children's Clinical Hospital



Location:

J. Waszyngtona 17, 15-274 Białystok



Contact details:

E-mail: trials.owbk@umb.edu.pl Tel. +48 85 686 53 86

Learn more: www.umb.edu.pl/owbk

Clinical Trials Support Center at the Medical University of Lodz

Clinical Trials Support Center at the Medical University of Lodz operate as a CRO/ARO and provide comprehensive support as part of the planning, coordination and management of single- or multi-center clinical trials and preclinical studies, drawing on extensive facilities and strong academic support. Our mission is to provide the highest quality clinical research to answer important questions about human health and to help develop increasingly effective therapies.



We are a Leader in 6 projects for the implementation of non-commercial clinical trials and a Consort in another 11. In addition, we are currently conducting with about 40 commercial trials, and this number is constantly growing.



Our research portfolio covers a wide range of diseases, in the fields of: oncology, hematology, cardiology, dermatology, pediatrics, neurology, metabolic diseases, rare diseases.





Prof. dr hab. n. med. Wojciech Fendler

His specialty is statistical data analysis and research in diabetology and oncology. Author of several hundred scientific papers and Manager of several research projects funded by national and EU funds. Recipient of numerous international and national programs and awards for young scientists, including the START FNP scholarship and the Scholarship of the Ministry of Science and Higher Education.



Prof. dr hab. n. med. Wojciech Młynarski

Specialist in pediatrics, pediatric oncology and hematology, as well as pediatric endocrinology and diabetology. Author of over 1000 scientific publications. As of 2019, he is the Leader of the TEAM-NET project, and as of 2020, he is the Manager of the MRA-funded cALL-POL clinical research project.

Prof. dr hab. n. med. Joanna Narbutt

She is a specialized dermatologist-venereologist. A member of many scientific societies at home and abroad. She is a member of, among others, the Polish Society of Dermatology. Author of numerous publications published in recognized national and international medical journals. As of 2020, she is a Principal Investigator in the MRA-funded STEADY Project.

We received a total of 98,776,653.30 million in research funding and 11,222,536.40 million in infrastructure development!



Location:

Pomorska 251, 92-213 Łódź



Contact details:

E-mail: cwbk@umed.lodz.pl Tel. +48 42 272 53 65

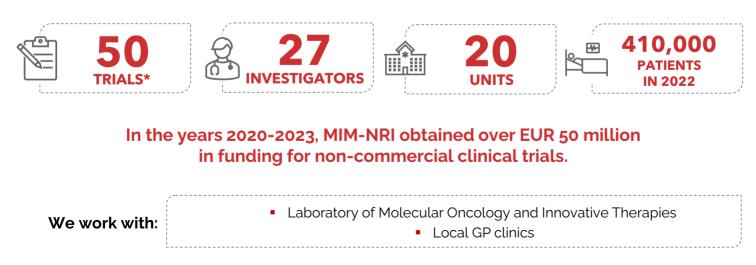
Learn more: www.cwbk.umed.pl

Clinical Trials Support Center of the Military Institute of Medicine (MIM-NRI) in Warsaw

The Clinical Research Support Center (CRSC) was established in January 2022 with funding from the Medical Research Agency. MIM-NRI is one of the largest multispecialty hospitals in Poland, accredited by the Minister of Health and adhering to rigorous quality management systems - ISO 9001 and AQAP 2110. With its extensive infrastructure and an exceptional team of skilled doctors and researchers, we have the capability to conduct clinical trials across a wide range of medical specialties.



The Center excels in conducting both commercial and non-commercial clinical trials of all phases. Notably, we have an exclusive Early Phase Unit dedicated to Phase I and Phase II studies, equipped with ICU-standard hospital rooms. Additionally, all study participants may benefit from access to Hospital's diagnostic facilities, including MR, CT, X-ray, ultrasound, scintigraphy, endoscopy, as well as pathomorphology and laboratory tests in full range.





Prof. Marek Rękas

National Consultant in Ophthalmology and Head of the Department of Ophthalmology. Specialist in ophthalmology, author of ~240 scientific publications, principal investigtor in more than 10 clinical trials.



Prof. Renata Duchnowska

Head of the Department of Oncology. Specialist in ophthalmology, author of ~100 scientific publications, principal investigtor in more than 20 clinical trials.



Prof. Maciej Gonciarz

Head of the Department of Gastrology and Internal Diseases. Specialist in gastroenterology and internal medicine, author of ~140 scientific publications, principal investigtor in more than 20 clinical trials.

To ensure the seamless execution of trials, we have assembled a team of 25 professionals at CRSC. Our medical team consists of highly skilled doctors and nurses. A dedicated Monitoring and Coordination unit guarantees accurate data collection, while the Scientific and Medical team focuses on non-commercial studies. Quality Assurance plays a pivotal role in maintaining rigorous standards throughout the research process, and a Contracting and Settlements section ensures efficient administrative operations.

Currently, clinical trials are conducted at MIM-NRI in approximately 20 therapeutic areas, including dermatology, gastroenterology, hematology, cardiology, nephrology, neurology, ophthalmology, oncology, otolaryngology, and rheumatology.



Location:

Szaserów 128, 04-141 Warsaw



Contact details:

E-mail: badaniakliniczne@wim.mil.pl Tel. +48 26 181 70 13

Learn more: www.wim.mil.pl/o-instytucie/cwbk/

Clinical Trials Support Center

4th Military Clinical Hospital in Wroclaw

The Center has been incorporated into the structures of the 4th Military Hospital in Wroclaw to ensure a uniform standard of clinical research implementation, high quality patient service, and to increase the Hospital's visibility in the field of clinical trials. Our mission is to increase the diversification of the Hospital's income, raise its scientific potential, and establish a network between the scientific, business and clinical communities. We always put patient welfare first.

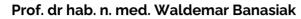


Our scientific activities focus on areas related to evidence-based approach to health policy, finding effective solutions for health promotion and chronic disease prevention, increasing individual mental resilience, or introducing beneficial technological changes in health care.



The Clinical Trials Support Center at the 4th Military Clinical Hospital in Wroclaw meets the standards of a model CTSC set by the Medical Research Agency, bringing together individuals to support investigators and scientists in the execution of clinical trials. It is also one of two military institutions that are part of the PCTN.





Specialist in cardiology. Principal Investigator in over 20 clinical trials. Author of over 200 scientific publications.

Dr hab. n. med. Dariusz Jagielski, Professor of the University

Cardiologist-electrophysiologist. PI and Co-Investigator in both commercial and noncommercial cardiology clinical trials. PI in the MRA-funded Gentle-Pace Study. Deputy Head of the Cardiology Department of the Heart Center. Dean of the Faculty of Medicine of the WUST.

Ppłk dr n. med. Bartosz Krakowiak

Investigator and a Principal Investigator in over 30 clinical trials, national coordinator, steering committee member, manager and protocol author of the MRA-funded ProtectAA clinical trial.

Dr n. med. Artur Milnerowicz

Specialist in vascular surgery. Principal Investigator in a non-commercial clinical trial to evaluate the safety and clinical efficacy of aortic stent-grafts modeled using innovative 3D model printing technology.

Past inspections and certifications as well as accreditations:
 FDA, EMA
 ISO 9001 Certificate
 Polish Quality Award

Learn more: www.4wsk.pl

Clinical Trials Support Center at the National Medical Institute of the Ministry of the Interior and Administration

Clinical Trials Support Center at the National Medical Institute of the Ministry of the Interior and Administration in Warsaw is an innovative institution that plays a key role in the development of medicine and the acceleration of advancement in clinical research. The center provides a platform for cooperation between researchers, doctors, patients and pharmaceutical companies. It provides assistance in planning, legal services, coordination, management and financial settlement of clinical trials.



Our center is equipped with state-of-the-art laboratories, diagnostic equipment and technological facilities to conduct trials research at the highest level. Our knowledge, experience and professionalism make us a reliable partner ready to conduct research in accordance with the highest standards and regulations. The CTSC conducts both non-commercial and commercial clinical trials as well as in-house research. The CTSC creates a research environment for advanced and meaningful trials on new therapies and drugs.

Through cooperation with the MRA the State Medical Institute of the Ministry of Internal Affairs and Administration in Warsaw plans to actively initiate clinical projects using new clinical research directions to become an incubator of ideas and make optimal use of its human and equipment





Prof. dr hab. n. med. dr h.c. Waldemar Wierzba

Head of the National Medical Institute of the Ministry of Internal Affairs and Administration in Warsaw. He participated in the establishment of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products, the Office of International Settlements, and the Agency for Health Technology Assessment. Principal Investigator in non-commercial trials.

Dr n. med. Artur Zaczyński



Deputy Medical Director, Head of the Department of Neurosurgery at the National Medical Institute of the Ministry of Internal Affairs and Administration in Warsaw. Specialist in neurosurgical procedures using Neuronavigation and Stereotaxis. Head of the Humanitarian-Medical Assistance Team. Expert and health advisor to the Union of Employers of Poland. Principal Investigator in non-commercial trials.

Prof. dr hab. n. med. Agnieszka Pawlak



Head of the Clinical Trials Support Center at the National Medical Institute of the Ministry of Internal Affairs and Administration in Warsaw. President-elect of the Heart Failure Association of the Polish Society of Cardiology. Member of the European Heart Academy ESC in Brussels. European Commission's Expert; Expert Panel for the evaluation of research projects. Specialist in cardiology and internal medicine. Clinical trials investigator.

Past inspections and certifications as well as accreditations:

FDA, EMA, URPL
ISO/IEC 27001:2017-06; ISO 9001:2015
ISO 45001:2018; ISO 14001:2015



Location:

Wołoska 137, 02-507 Warszawa



Contact details:

E-mail: cwbk@cskmswia.gov.pl Tel. +48 47 722 20 12

Learn more: www.gov.pl/web/cskmswia/centrum-wsparcia-badan-klinicznych2

Clinical Trials Support Center at the Pomeranian Medical University in Szczecin

The CTSC at the Pomeranian Medical University is a nonfaculty organizational unit of the Pomeranian Medical University in Szczecin, cooperating with scientific and educational faculty units and members of the Consortium, which includes the Pomeranian Medical University in Szczecin—project leader, the Prof. Tadeusz Sokolowski Independent Public Clinical Hospital No. 1 of the Pomeranian Medical University in Szczecin and the Independent Public Clinical Hospital No. 2 of the Pomeranian Medical University in Szczecin.



We hospitalize over 100,000 patients annually in our clinical centers, with a base of 1,078 hospital beds. In 57 outpatient clinics for adults and children, we provide over 350,000 consultations per year.



Patients are cared for in 44 clinics and departments, which offer the conduct of world-class clinical trials by 190 investigators, high-level specialists guided by the principles of Good Clinical Practice (ICH GCP).





Prof. dr hab. n. med. Marek Stefan Brzosko

Specialist in internal medicine and rheumatology. Author of over 463 scientific publications. Principal Investigator in approx. 100 clinical trials.



Dr hab. n. med. Anita Monika Chudecka-Głaz

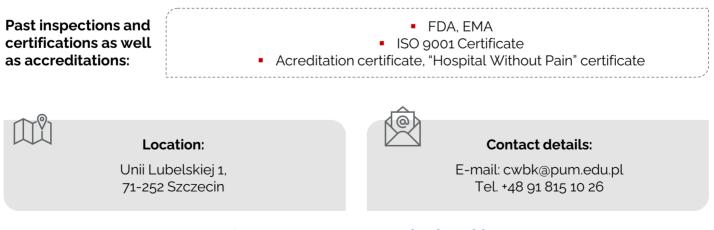
Specialist in gynecology and obstetrics. Author of over 114 scientific publications. Principal Investigator in 14 clinical trials.



Prof. dr hab. n. med. Kazimierz Ciechanowski

Specialist in internal medicine, diabetology, nephrology, clinical transplantology and sports medicine. Author of over 413 scientific publications. Principal Investigator in 71 clinical trials.

Our mission: To increase patient access to innovative medical technologies and therapies by optimizing the collaboration between the investigator, site and sponsor, with simultaneous systemic professional conduct of high standard clinical trials.



Learn more: www.pum.edu.pl/cwbk

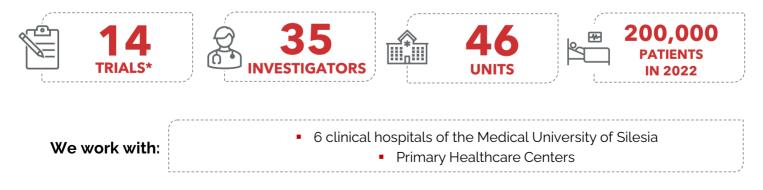
Clinical Trials Support Center at the Medical University of Silesia in Katowice

The Clinical Trials Support Center is established by a consortium of the Silesian Medical University in Katowice and two clinical hospitals: Leszek Giec Upper-Silesian Medical Center of the Medical University of Silesia in Katowice and University Clinical Center of prof. K. Gibiński of the Medical University of Silesia in Katowice. Establishing an Early Phase Center will make it possible to support clinical trials of all phases (1 through 4) across a wide range of therapeutic indications.



The new structure puts in order the process of organizing the trial, the course of the patient's stay at the site and the evaluation of the investigators' ideas. There is one contact point at the Clinical Trials Support Center of the Medical University of Silesia responsible for communicating with sponsors as regards feasibility studies.

The center's activities provide patients with increased access to new, free experimental therapies, ensuring the highest possible safety of clinical trial participation. The Clinical Trials Support Center of the Medical University of Silesia is a place where patients will be given hope conveyed in the form of research offered by top specialists.





Prof. dr hab. n. med. Tomasz Szczepański

Rector of the Medical University of Silesia in Katowice, head of the Department of Pediatrics, Hematology and Pediatric Oncology at the Medical University of Silesia in Zabrze, member of the National Oncology Strategy Team, specialist in pediatrics and pediatric oncology/hematology. Author and co-author of over 660 scientific papers. Principal Investigator Coordinator in the cALL-POL project, which is a clinical research project designed to include all children in Poland with newly diagnosed acute lymphoblastic leukemia.

Prof. dr hab. n. med. Katarzyna Mizia-Stec

Cardiologist, angiologist, specialist in internal diseases. Since 2012, Head of the 1st Department of Cardiology of the Leszek Giec Upper-Silesian Medical Center, at the same time Head of the 1st Department of Cardiology of the Silesian Medical University in Katowice. Co-author of over 250 scientific papers and 67 books. Her main areas of scientific interest are echocardiography, heart failure, cardiac arrhythmias, valvular heart defects and pulmonary circulation diseases.

In the years 2016–2020, the Consortium took part in 52 commercial clinical trials, e.g. in multiple sclerosis, stroke, epilepsy and myasthenia gravis.

We received over PLN 9,322,000 for the establishment of the Silesian Clinical Trials Support Center with an Early Phase Center, for the implementation of commercial and non-commercial clinical trials.



Location:

Ziołowa 45/47, 40-635 Katowice – Ochojec



Contact details:

E-mail: cwbk@sum.edu.pl Tel. +48 32 479 61 14

Clinical Trials Support Center at the Medical University of Lublin

The Clinical Trials Support Center at the Medical University of Lublin was established to provide comprehensive and systemic support in a shared services model for the implementation of clinical trials, both commercial and noncommercial. The CTSC's potential lies in the clinical hospitals of the University, i.e.: Independent Public Clinical Hospital No. 1 in Lublin, Independent Public Clinical Hospital No. 4 in Lublin, and University Children's Hospital in Lublin, which implemented 455 clinical trials in the years 2012–2022.



The CTSC of the Medical university of Lublin constitutes a strategic contribution to the advancement of scientific research through clinical resources and to the development of the Polish healthcare system, which strives to improve results while optimizing the costs of healthcare services.

The establishment of the CTSC, equipped with a suitable infrastructure, a well-ordered and effective organizational structure, clear processes set forth in operating procedures that ensure functionality, continued operations and integrity of activities, as well as good systemic solutions including tools for efficient project management and PR, will be the most important step towards building competitive capacity in clinical trials on a world scale.



Prof. Krzysztof Giannopoulos

Specialist in hemato-oncology. Principal Investigator in 29 commercial and 6 noncommercial clinical trials. Author of numerous scientific publications, with an h-index of 30,

Prof. Konrad Rejdak

Specialist in neurology. Principal Investigator in 48 clinical trials. Author of numerous scientific publications, with an h-index of 30

Prof. Jerzy Kowalczyk

Specialist in haemato-oncology. Principal Investigator in 3 commercial clinical trials. Author of numerous scientific publications, with an h-index of 27.

We received a total of PLN 170 million in R&D funding!

Past inspections and certifications as well as accreditations:

Independent Public Clinical Hospital No. 4 in Lublin

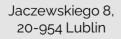
 has a Clinical Trials Manual and management based
 on the PN-EN ISO 9001: 2015 standard

 University Children's Hospital in Lublin – has the Procedure for conducting
 clinical trials of a medicinal product or medical device at the University
 Children's hospital in Lublin, Accreditation Certificate No. 2019/9 CMJwOZ

Independent Public Clinical Hospital No. 1 in Lublin
 has internal Regulations for the conduct of clinical trials



Location:





Contact details:

E-mail: cwbk@umlub.pl Tel. +48 81 448 51 70

Learn more: www.spsk4.lublin.pl/pl/badania-kliniczne/centrum-wsparcia-badan-klinicznych-link

Clinical Trials Support Center of the University Clinical Hospital in Opole

The University Clinical Trials Support Center in Opole provides comprehensive services in the planning, management, coordination, legal services and billing of clinical trials. The Center's team also performs scientific consulting services for planned medical trials. The Center has specialized staff: coordinators, clinical trials assistants, biostatisticians, pharmacists, laboratory diagnosticians, legal and financial and accounting services.



The Center's infrastructure consists of: modern clinical facilities (MRI lab, CT lab, doctors' surgeries), office space, sponsor service rooms, including audiovisual, patient service point, biological material collection and processing point, archive, clinical base of the University Clinical Hospital in Opole with a hospital emergency department and intensive care unit.



We carry out clinical trials of medicinal products and medical devices in the area of broadly defined civilization diseases (cardiology, vascular surgery, allergology, nephrology, intensive care) and pediatric studies (diabetology).





Prof. dr hab. Marek Gierlotka

Cardiology specialist and experienced interventional cardiologist. Expert in the design and analysis of large databases, medical registries and clinical trials. Author of 265 publications with a total IF of 485 and an h-index of 24. He heads the Department and Unit of Cardiology and is the director of the Institute of Medical Sciences at the University of Opole.



Dr hab. Jerzy Sacha

As an invasive cardiologist he specializes in coronary, valvular (TAVI, MitraClip) and LAA, PFO, ASD procedures. He introduces new methods: mechanical circulatory support, non-contrast procedures and virtual reality (VR) surgery. Head of the Hemodynamic Research Laboratory, associate professor at the Opole University of Technology.



Dr hab. Tomasz Czarnik

Specialist in anesthesiology and intensive care. Investigator in many international, multi-center clinical trials. Author and Principal Investigator of non-commercial clinical trials. Head of the Department of Anesthesiology and Intensive Care, Head of the Unit of Anesthesiology and Intensive Care, Deputy Director of the Institute of Medical Sciences of the University of Opole.

Past inspections and certifications as well as accreditations:

ISO 2021/48 Accreditation Certificate
ISO 9001, 14001, 45001, 27001 Certificates

130 9001, 14001, 43001, 27001 Certificati



Location:

Aleja Wincentego Witosa 26, 45-401 Opole



Contact details:

E-mail: badania.kliniczne@usk.opole.pl Tel. +48 77 452 05 73

Learn more: www.usk.opole.pl/944/212/about-the-centre-en.html

Oncology Clinical Trials Support Center at the Lower Silesian Oncology, Pulmonology and Hematology Center

The Oncology Clinical Trials Support Center was established to increase the quality and diversity of the trials offered, as well as its comprehensiveness, thereby influencing faster and more effective therapy. The research conducted at the Center is intended to respond to real needs specified in the treatment framework. The operation of the Center, through the implementation of clinical trials, will facilitate the process of their subsequent implementation, as well as transfer for use in other treatment facilities.



The Oncology Clinical Trials Support Center combines the academia, clinical and business circles, which translates into well-planned and conducted trials which have and will continue to result in new therapies. We view the Oncology Clinical Trials Support Center as a very important part of the development of both the staff and the Center itself, including directing attention to the patient.





The center has extensive experience in the areas of breast cancer, lung cancer (small cell and nonsmall cell), skin cancer (melanoma), stomach cancer, intestinal cancer, prostate cancer, kidney cancer, bladder cancer, head and neck cancer, and in the area of hematology (lymphocytic leukemia, plasmocytic myeloma, lymphoma, myeloid leukemia).



- Institute of Immunology and Experimental Therapy of the Polish Academy of Sciences
- National Information Processing Institute National research Institute
- INNOVATIVE PARTNERSHIP FOR ACTION AGAINST CANCER (iPAAC)
 - EUROPEAN UROLOGICAL FOUNDATION (EAU)



Dr n. med. Aleksandra Łacko

Specialist in clinical oncology. Head of the Breast Chemotherapy Unit at the Lower Silesian Oncology, Pulmonology and Hematology Center. Author and co-author of textbooks and publications on cancer treatment. Principal Investigator in numerous phase 2 and 3 breast cancer trials.



Dr. n. med. Jarosław Dybko

Specialist in hematology and clinical transplantology. Head of the Hematology and Transplant Center and Head of the Hematology Department. Author of numerous scientific publications. He has successfully conducted more than 20 phase 2 and 3 trials.



Dr. n. med. Krzysztof Tupikowski

Specialist in urology with the prestigious European FEBU title. Head of the Urological Tumor Center at the Lower Silesian Oncology, Pulmonology and Hematology Center. He represents Poland in the international EU-funded PRAISE-U project. Principal Investigator in phase 1–3 trials of renal cell carcinoma, phase 1–3 bladder cancer, phase 2 and 3 prostate cancer and other urological conditions.

Past inspections and certifications as well as accreditations:

- ISO 9001 and ISO/IEC 27001
- Certified by iPAAC (General Certificate—Comprehensive Cancer Center, Specific Certificates—Colorectal and Pancreatic Cancer Treatment Center)
- PCA accreditation for the Department of Molecular Cancer Diagnostics
 - EU Certificate "European Quality Assurance (QA) Scheme for Breast Cancer Services across the EU"



Location:

Plac Hirszfelda 12, 53-413 Wrocław Grabiszyńska 105, 53-439 Wrocław



Contact details:

E-mail: badniakliniczne@dcopih.pl Tel. +48 669 220 471, +48 782 999 717

Learn more: www.onkocwbk.dcopih.pl

Oncology Clinical Trials Support Center at the Polish Mother's Health Center Institute in Lodz

It is a one-of-a-kind research institution that provides professional healthcare and is located in a two-building complex housing a gynecology and obstetrics unit and a pediatric unit. The Institute has been involved in medical research and development since 1997. The team of specialists employed at our Center is supporting 100 commercial and non-commercial clinical trials at the moment. We cooperate with various units such as the Medical University of Gdańsk and conduct an international academic trial, the Truffle2, in cooperation with Imperial College London.



Our entity is distinguished from others by its high credentials. Annually, the hospital admits about 90,000 patients. We have specialized units or a Specialized Emergency Department with a helipad.



Prof. dr hab. n. med Ewa Kalinka

Specialist in clinical oncology. She speaks as an international expert. She is currently conducting over 30 active clinical trials.

Prof. dr hab. n. med. Andrzej Lewiński

Specialist in endocrinology, pediatric endocrinology and diabetology, internal medicine and nuclear medicine. Doctor Honoris Causa St. Elizabeth University of Health and Social Sciences in Bratislava.

Prof. dr hab. n. med. Maciej Banach

One of the most experienced researchers in the field of karyology and lipidology, associate professor at the Medical University.

Since 2011 the Polish Mother's Health Center Institute in Lodz has signed contracts for over 100 clinical trials, including two non-commercial projects financed by the Medical Research Agency. Clinical trials focus primarily on the fields of oncology, endocrinology, and metabolic diseases, but also neurology, nephrology, and pediatrics.

Past inspections and certifications as well as accreditations: • In 2016, the European Commission awarded us the scientific category A Image: Contact details: • In 2016, the European Commission awarded us the scientific category A Image: Contact details: • In 2016, the European Commission awarded us the scientific category A Image: Contact details: • In 2016, the European Commission awarded us the scientific category A Image: Contact details: • In 2016, the European Commission awarded us the scientific category A Image: Contact details: • In 2016, the European Commission awarded us the scientific category A Image: Contact details: • In 2016, the European Commission awarded us the scientific category A Image: Contact details: • In 2016, the European Commission awarded us the scientific category A Image: Contact details: • In 2016, the European Commission awarded us the scientific category A Image: Contact details: • In 2016, the European Commission awarded us the scientific category A Image: Contact details: • In 2016, the European Commission awarded us the scientific category A Image: Contact details: • In 2016, the European Commission awarded us the scientific category A Image: Contact details: • In 2016, the European Commission awarded us the scientific category A Image: Contact details: • In 2016, the European Commission awarded us the sc

Learn more: www.iczmp.edu.pl/onkologiczne-centrum-wsparcia-badan-klinicznych/

Oncology Clinical Trials Support Center of the Institute of Hematology and Transfusion Medicine in Warsaw

The Institute of Hematology and Transfusion Medicine represents more than 70 years of tradition, uninterrupted development, modern diagnostics and treatment, and many scientific achievements in Polish hematology and transfusion medicine. We are a reference scientific and clinical unit that conducts scientific and translational research in its title disciplines. Trials are conducted in cooperation with national and international research groups.



Clinical trials conducted at the Oncology Clinical Trials Support Center at the Institute of Hematology and Transfusion Medicine are characterized by high standards. We have the broadest and most modern specialized diagnostic facilities in Poland, allowing precise, comprehensive diagnosis of all hematological diseases. At the Institute, we conduct numerous clinical trials, both commercial and non-commercial.



Our investigators and all medical personnel are highly qualified and are guided by the principles of Good Clinical Practice. The Oncology Clinical Trials Support Center at the Institute of Hematology and Transfusion Medicine in Warsaw conducts phase 1, 2, 3, and 4 clinical trials in hematology and transplantology.



Prof. dr hab. n. med. Ewa Lech-Marańda

Specialist in internal medicine, hematology, clinical transplantology and clinical immunology. Director of the Institute of Hematology and Transfusion Medicine in Warsaw, head of the Department of Hematology and national consultant in hematology. Author of 130 original papers, review papers and book chapters.



Specialist in internal medicine, hematology and clinical transplantation. Deputy Director for Medical Affairs of the Institute of Hematology and Transfusion Medicine, head of the Department of Hematopoietic Cell Transplantation. Principal Investigator in clinical trials

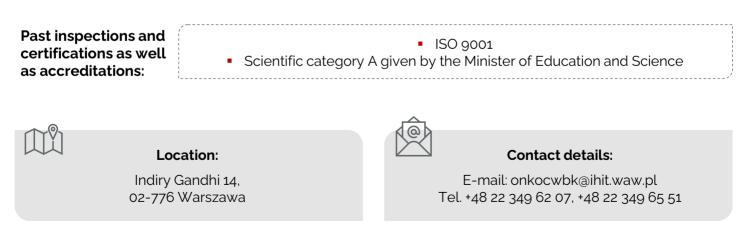
for Medical Affairs of the Institute of Hematology and Transfusion Medicine, head of the Department of Hematopoietic Cell Transplantation. Principal Investigator in clinical trials of hematopoietic stem cell transplantation. Author of numerous scientific papers and articles.



Dr hab. n. med. Bartosz Puła

Dr. n. med. Kazimierz Hałaburda

Specialist in hematology, pending specialization in clinical transplantation. Investigator in clinical trials and leader of a non-commercial trial funded by the Medical Research Agency. Author of 115 original and review papers.



Learn more: www.ihit.waw.pl/badania-kliniczne

Oncology Clinical Trials Support Center at the Dr. Alfred Sokolowski Specialist Hospital in Walbrzych

The Dr. Alfred Sokolowski Specialist Hospital obtained its current shape in 2008 after merging with the Stefan Batory Specialist Hospital in Walbrzych and the Specialist Mother and Child Healthcare Complex in Walbrzych. Currently, the Hospital has 25 wards and 23 specialized clinics providing comprehensive care for patients from all over Poland. The mission of the Hospital is to save, cure, and always give hope.



The main objective of Oncology Clinical Trials Support Center in Walbrzych is to increase access to innovative treatments for patients through the implementation of commercial and non-commercial clinical trials and to provide professional service to patients, sponsors, CROs and investigators.



The Dr. A. Sokolowski Specialist Hospital in Walbrzych has teams with interdisciplinary experience in clinical trials, namely: hematology, cardiology, ophthalmology, infectious diseases, child and adolescent psychiatry. The Hospital's staff cooperates with scientific units in Poland and around the world carrying out commercial and non-commercial clinical trials.

We work with:

- Department of Imaging DiagnosticsDepartment of Laboratory Diagnostics
- Department of Pathomorphology
 - Hospital Pharmacy



Prof. dr hab. n. med. Aleksandra Butrym

Specialist in hematology and internal medicine. Active investigator in recruitment and treatment of patients in clinical trials. Author of over 150 scientific publications. Head of the Oncology Clinical Trials Support Center, physician in charge of the hematology department at the Dr. Alfred Sokolowski Specialist Hospital in Walbrzych.



Dr. n. med. Janusz Lange

Specialist in hematology, clinical transplantology, internal medicine. He graduated from the Faculty of Medicine of Wroclaw Medical University. He gained professional experience in Brisbane, Australia. Author and co-author of 10 full-text publications and 38 abstracts from conference reports.



Lek. med. Anna Łukowiak-Sokołowska

Physician in charge of the oncology department at the Dr. A. Sokolowski Specialist Hospital in Walbrzych. Clinical trials investigator. Specialist in clinical oncology and cancer chemotherapy.



Lek. med. Jolanta Blaszczyk-Mnich

Specialist in clinical oncology and cancer chemotherapy. Doctor in charge of the chemotherapy day unit at the Dr. A. Sokolowski Specialist Hospital in Walbrzych. Clinical trials investigator.

Past inspections and certifications as well as accreditations:

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Location:

Sokołowskiego 4, 58-309 Wałbrzych



ISO 9001:2015 Certificate



Contact details:

E-mail: onkocwbk@zdrowie.walbrzych.pl Tel. +48 74 648 97 36

Learn more: www.zdrowie.walbrzych.pl/dla-pacjentow

Oncology Clinical Trials Support Center of Pomeranian Hospitals LLC

Pomeranian Hospitals LLC is a healthcare facility highly specialized in the fields of radiotherapy, surgical oncology, clinical oncology, hematology, and ambulatory chemotherapy. The establishment of the Pomeranian Oncology Clinical Trials Support Center, equipped with suitable infrastructure, a wellordered and effective organizational structure, clearly defined processes described in operating procedures, which will ensure functionality, continuity and integrity of operations, and thus significantly increase the facility's potential.



The center is among the most active in the Pomeranian region in the implementation of oncology clinical trials. The team responsible for conducting scientific activities has expertise in management, quality assurance, legal services and research coordination.



The modernization and adaptation work within the already existing infrastructure will to a large extent enable us to create an even more efficient and patient-friendly clinical trial center in the region. More than 350 square meters of medical and administrative space will be available to patients and our staff in the near future.

Our strength is the staff experienced in the field of clinical trials, among others: 20 physicians, 8 of them with academic degrees, 12 nurses, 5 pharmacists, 9 people in charge of administrative activities, legal department. The team coordinates trials in indications such as breast cancer, ovarian cancer, endometrial cancer, lung cancer, solid tumors and in the field of hematology.

Dr. n. med. Iwona Danielewicz

Specialist in clinical oncology and radiation therapy. Head of the Clinical Oncology Department. Principal Investigator in over 20 clinical trials.

Dr n. med. Wanda Knopińska-Posłuszny

Specialist in internal medicine, hematology and clinical transplantation. Head of the Hematology Department. Principal Investigator in over 20 clinical trials.

Dr n. med. Joanna Pikiel

Specialist in clinical oncology and chemotherapy, radiation therapist. Head of the One Day Chemotherapy Unit. Principal Investigator in over 20 clinical trials.

Past inspections and certifications as well as accreditations:

ISO 9001:2015 quality certificate and ISO 14001:2015 environmental certificate

 ISO/IEC 27001:2013 information security certificate
 Accreditation from the International Society for Breast Diseases

 Accreditation of the Medical Physics Department of the Oncology Center in Gdynia as a research and measurement laboratory

 PN-EN ISO/IEK 17025:2005
 Accreditation of the European Society of Gynecologic Oncology (ESGO)-"Certification for Advanced Ovarian Cancer Surgery"



Location:

Powstania Styczniowego 1, 81-519 Gdynia



Contact details:

E-mail: info.onkocwbk@szpitalepomorskie.eu Tel. +48 58 726 03 80

Learn more: www.szpitalepomorskie.eu/badaniakliniczne/

Oncology Clinical Trials Support Center at the Holy Cross Oncology Centre in Kielce

The Oncology Clinical Trials Support Center at the Holy Cross Oncology Center provides free and comprehensive care for oncology patients at various stages of cancer progression. A specialized team and modern diagnostic equipment facilitates access to innovative treatments and significantly influences the development and acquisition of expertise in a specific therapeutic areas.



The Oncology Clinical Trials Support Center at the Holy Cross Oncology Center provides free and comprehensive care for oncology patients at various stages of cancer progression. A specialized team and modern diagnostic equipment facilitate access to innovative treatments and have a significant impact on the development and acquisition of expertise in a specific therapeutic areas.





The Oncology Clinical Trials Support Center has the most experience in the following areas: gynecological oncology, hemato-oncology, endocrinology, head and neck cancer, non-small cell lung cancer, melanoma, uro-oncology, and clinical oncology.

We work with:
 Department of Laboratory Diagnostics
 Department of Cancer Markers
 Department of Imaging Diagnostics
 Department of Molecular Diagnostics



Dr n. med. Jolanta Smok-Kalwat

Deputy Director of Clinical Affairs, specialist in clinical oncology, chemotherapy, anesthesiology and intensive care. Principal Investigator with many years of experience in conducting phase 2–4 trials



lek. Paweł Steckiewicz

Internal medicine specialist, hematologist. Principal Investigator in more than 17 hematooncology trials.



Dr. n. Marcin Misiek

Specialist in obstetrics and gynecology, specialist in gynecological oncology, regional consultant in gynecological oncology. Principal Investigator in more than 20 gynecological trials.

Past inspections and certifications as well as accreditations:

ISO 9001:2015 Certificate

ISO 22000:2018 Certificate

Location:

Artwińskiego 3, 25-734 Kielce



Contact details:

E-mail: badania.kliczne@onkol.kielce.pl Tel. + 48 41 367 43 15

Learn more: www.onkol.kielce.pl/pl/centrum/onkologiczne-centrum-wsparcia-badan-klinicznych

Oncology Clinical Trials Support Center of the Copernicus

Memorial Hospital in Lodz Comprehensive Cancer Center and Traumatology

Clinical trials have been conducted at the Center for over 20 years. A total of 574 studies have been conducted since 2012. The enormous potential of the Center is due to the highly qualified staff that are part of the Research Teams, the state-of-the-art infrastructure and highly specialized equipment including: PET-CK, SPECT-CT, CT, MRI, Da Vinci robot, state-of-the-art stereotactic radiotherapy machine (TrueBeam by Varian) and others. In addition, based on the Center's Blood Cell Bank and Genetic Engineering Department, we have the ability to collect, process and distribute lymphocytes for CAR-T therapy.



Medical care is provided in 35 hospital units (917 beds), 58 outpatient clinics and specialist laboratories. The Oncology Clinical Trials Support Center provides professional administrative services for clinical trials, providing comprehensive and systemic support for the implementation of commercial and non-commercial clinical trials. The staff continuously improve their qualifications through participation in training courses, conferences and international scientific projects.

115 TRIALS*	76 INVESTIGATORS	35 UNITS 318,000 PATIENTS IN 2022
We work with:	 Teleradiotherapy Department Department of Imaging Diagnostics Department of Nuclear Medicine Laboratory of Clinical Immunology, Transplantation and Genetics Department of Genetic Engineering 	 Bone Marrow Laboratory Cytogenetics Laboratory Łódź Kopernik Laboratory – Synevo Department of Genetic Diagnostics Hematopoietic Cell Bank, Laboratory of Apheresis and Cell Therapies

*Average number of conducted clinical trials annually from the last 5 years.



Prof. dr hab. n. med. Tadeusz Robak

Specialist in experimental and clinical hematology and internal medicine. Principal Investigator with experience as PI in more than 160 clinical trials. Author and co-author of more than 600 publications, (H-index: 70).



Prof. dr hab. n. med. Agnieszka Wierzbowska

Specialist in hematology and transplantology. With an enormous scientific output (H-index: 25), she has conducted more than 13 clinical trials; she is also currently leading an non-commercial clinical trial project.



Dr. n. med. Agnieszka Brzozowska

Director of the Department of Pediatric Allergology and Internal Medicine. She has experience as Principal Investigator in more than 50 clinical trials.

The areas in which clinical trials are conducted include: Oncology, hemato-oncology, hematology, cardiology, neurology, neurosurgery, infectious diseases (COVID), pediatric allergology, respiratory diseases and cystic fibrosis – in patients up to 18 years of age, immune disorders – in patients up to 18 years of age.

Past inspections and certifications as well as accreditations: • FDA, Office for Registration of Medicinal Products • ISO 9001 2015 Certificate • Polish Quality Award • Polish Quality Award • Decation: • Certificate No. 2023/8 • Contact details: • Pabianicka 62, 93-513 Łódź • Pabianicka 62, 93-513 Łódź • Contact details:

Learn more: www.kopernik.lodz.pl/badania-kliniczne/

PCTN Obesrvers

Jagiellonian University – Collegium Medicum in Cracow

Jagiellonian University – Collegium Medicum in Cracow has extensive experience in conducting non-commercial clinical trials, both in terms of trial design and organization, documentation development and monitoring as well as reporting.

The University has acted as Sponsor in 20 non-commercial Investigator-initiated clinical trials (including one clinical trial of a medical device). The University is currently acting as Sponsor of six non-commercial clinical trials of medicinal products that have received funding from the Medical Research Agency, totalling nearly PLN 80 million.

J. Gromkowski Regional Specialist Hospital in Wroclaw

J. Gromkowski Regional Specialist Hospital in Wroclaw provides comprehensive medical care at the highest level. Commercial clinical trials mainly in the fields of infectious diseases and neurology are carried out at the Hospital, in accordance with GCP requirements, by qualified staff.

The objective of the Hospital as an Observer in the PCTN is to implement proper governance standards in clinical trials. Also, we will adapt internal procedures and structures to increase the efficiency of acquiring and conducting commercial and non-commercial clinical trials.



Medical Research Agency website:

abm.gov.pl



Polish Clinical Trials Network website:

psbk.abm.gov.pl



The Polish Clinical Trials Network (PCTN) was set up on 11th March 2021. It aims at implementing uniform, systemic solutions for quality and process management at institutions involved in conducting clinical trials in Poland.