





WE ARE

KO-MED Clinical Centers is the leader in the field of clinical trials in Poland. It operates mainly in public health care units, institutes and clinical hospitals.

KO-MED's study sites are located in Warsaw, Lublin, Zamość, Biała Podlaska, Staszow and Puławy.

THE LIDER

A specialized organizational structure which includes experienced coordinators, medical assistants, data administrators as well as nurses and laboratory workers is in charge of management, administration and medical support.

KO-MED Clinical Centers has repeatedly been granted status of „TOP RECRUITER”, and monitoring and audits demonstrate the highest quality in running clinical trials.

START-UP

KO-MED Clinical Centers is an organization specializing in clinical trials management. In order to get optimal terms of cooperation with sponsors KO-MED Clinical Centers has launched a START-UP department, which is responsible for obtaining projects for the entire network.

START-UP proceeds with these offers until they are sent for execution (signing the contract) and operationalises the research project to be conducted in a study site.



INNOVATION IN THE START-UP PROCESS

- Effective communication: one point of contact
- Short contract negotiation time (30 days)
- Short response time to feasibility (1-3 days)
- Managing communication with
- Investigators
- Document management for / from Investigators
- Support in assessing the project's feasibility in Poland (pre-feasibility)



ONE POINT OF CONTACT

- Processing an inquiry for each study site in the network
- Swift signing of a confidentiality agreement (CDA) up to 2 days
- Responses from the Investigator / Study Site to feasibility questionnaires
- Handling documents for pre-study and initiation visits
- Central management of all trial and team documentation (CVs, equipment certificates, contracts with subcontractors, etc.)
- Smooth contracting and budgeting

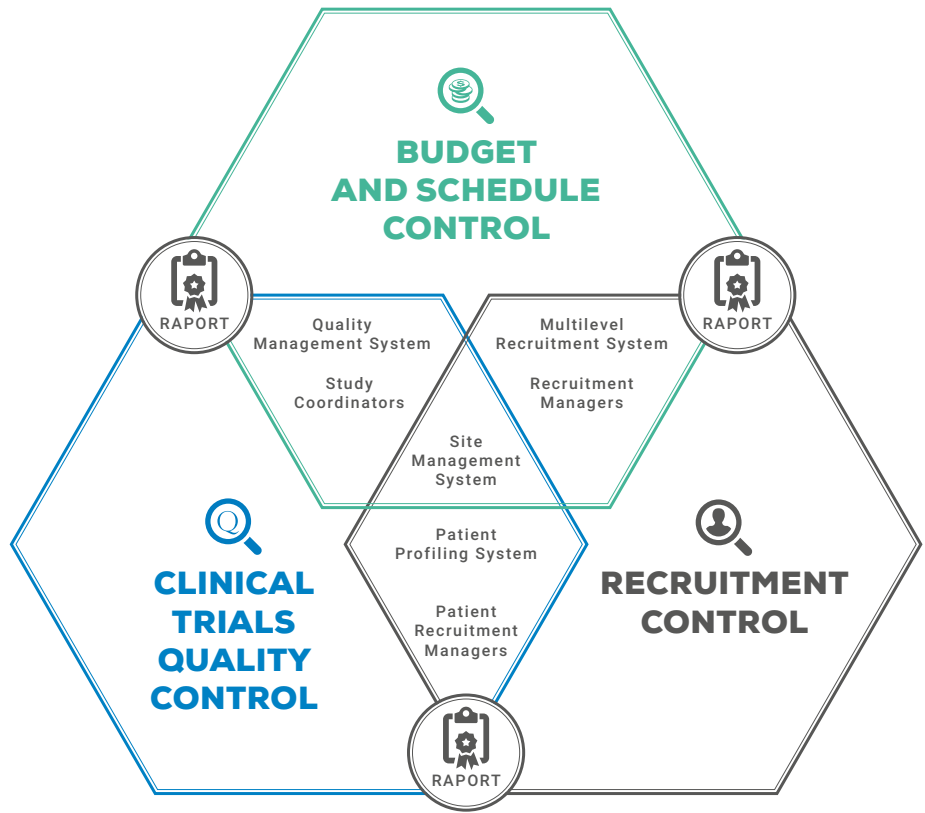


OBLIGATIONS TO SPO/CRO

- Information on the potential of Investigators in the Study Sites (PI / doctors / experience)
- Information about potential and resources of the Study Sites
- Justification in case of rejecting a trial offer
- Bundle pricing - assessment of trial profitability in relation to the total profitability of cooperation (conducting less profitable trials)
- Conducting phase I to IV trials in all indications
- Access to extensive patient databases, including those of hospitals and institutes



RESEARCH PROJECT MANAGEMENT



STUDY SITES OF KO-MED CLINICAL CENTERS

WARSAW

STASZÓW

PUŁAWY

BIAŁA PODLASKA

LUBLIN

ZAMOŚĆ

WARSAW

National Institute of Geriatrics,
Rheumatology and Rehabilitation,
Medical Research Center

 1, Spartanska Street, room 210,
second floor, 02-637 Warsaw

 +48 533 330 824

- Geriatrics
- Pain Management
- Neuroorthopedics and Neurology
- Orthopedics
- Osteoporosis
- Pulmonology
- Rehabilitation
- Cardiological Rehabilitation
- Rheumatology
- Pediatric Rheumatology
- Developmental Rheumatology
- Rheumaortopedy
- Systemic connective tissue diseases
- Gastroenterology

WARSAW

Institute of Psychiatry
and Neurology in Warsaw Medical
Research Center

 9, Sobieskiego Street
02-957 Warsaw

 +48 609 409 803

- Neurology
- Psychiatry

BIAŁA PODLASKA

Regional Specialist Hospital
Study Site

 57-65, Terebelska Street
21-500 Biała Podlaska

 +48 83 306 77 00, +48 603 314 074

- Alergology
- General Surgery
- Internal Diseases
- Diabetology
- Gynecology and Obstetrics
- Hematology
- Cardiology
- Oncology
- Orthopedics
- Otolaryngology
- Pulmonology
- Rehabilitation
- Urology
- Endocrinology

LUBLIN

Military Clinical Hospital
SPZOZ
Study Site

 23, Aleje Racławickie
20-049 Lublin

 +48 533 330 941

- General surgery
- Orthopedic trauma surgery
- Internal diseases
- Dermatology
- Diabetology
- Gastroenterology
- Gynecology
- Cardiology
- Neurology
- Rheumatology
- Urology

LUBLIN

Institute of Rural Medicine
Study Site

 2, Jaczewskiego Street
20-090 Lublin

 +48 500 029 749

- Vascular surgery
- Metabolic diseases
- Internal diseases
- Dermatology
- Diabetology
- Endocrinology
- Obstetrics-gynecology
- Cardiology
- Neurology
- Rehabilitation

LUBLIN

Private Hospital
and Outpatient Clinics
Żagiel Med

 21, Tetmajera Street
20-362 Lublin

 +48 81 440 24 74

- Internal diseases
- Dermatology
- Diabetology
- Gastroenterology
- Gynecology
- Clinical immunology
- Cardiology
- Neurology
- Oncology
- Orthopedics
- Pulmonology
- Rheumatology

LUBLIN

Luxmed
Study Site

 11, Królewska Street
20-109 Lublin

 +48 607 817 050

- Allergology
- Pediatric allergology
- Bariatrics (treatment of obesity)
- Vascular surgery
- General surgery
- Dermatology
- Diabetology
- Dietitian
- Endocrinology
- Gynecology
- Gynecology-endocrinology
- Hematology
- Cardiology
- Pediatric cardiology
- ENT
- Pediatric ENT
- Speech therapy
- Aesthetic medicine
- Nephrology
- Pediatric nephrology
- Neurology
- Pediatric neurology
- Pediatrics
- Proctologist
- Pulmonology
- Pediatric pulmonology
- Rehabilitation
- Rheumatology
- Urology

STASZOW

Independent Public Hospital
and Outpatient Clinic
Study Site

📍 78, 11 Listopada Street
28-200 Staszów

☎ +48 15 864 12 34, +48 533 330 827

- General surgery
- Traumatic and Orthopedic Surgery
- Internal diseases
- Geriatrics
- ENT
- Nephrology
- Neurology (Strokes)
- Orthopedics
- Obstetrics - Gynecology
- Urology
- Diabetology
- Gastroenterology
- Cardiology
- Clinical immunology

PUŁAWY

KO-MED's Clinical Centers
Study Site

📍 34, Sieroszewskiego Street
24-100 Puławy

☎ +48 81 888 63 33, +48 660 241 384

- Internal diseases
- Dermatology
- Diabetology
- Gastroenterology
- Clinical immunology
- Cardiology
- Neurology
- Pulmonology
- Gynecology
- Rheumatology

ZAMOSC

Non-public Hospital
in Zamość
Study Site

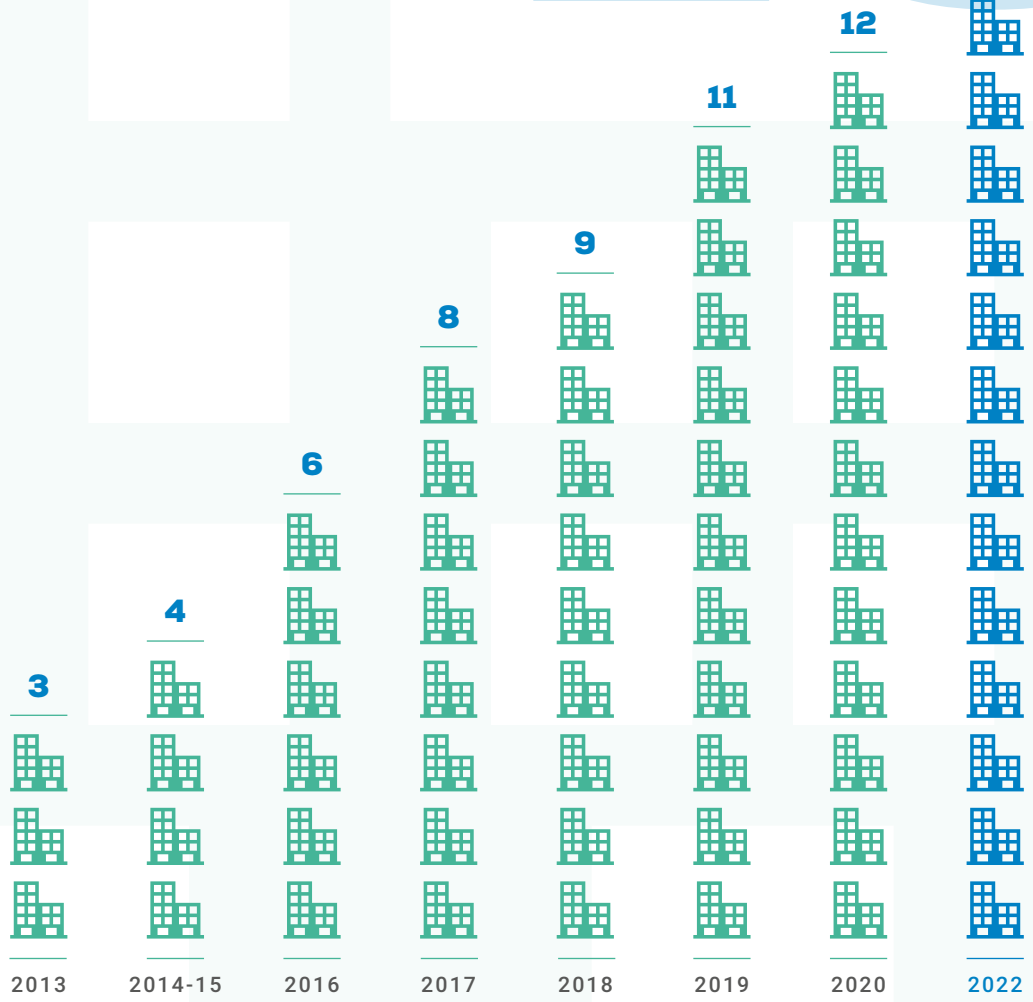
📍 1, Peowiaków Street
22-400 Zamość

☎ +48 84 627 88 87, +48 537 255 100

- Internal Diseases
- Dermatology
- Diabetology
- Gastroenterology
- Cardiology
- ENT
- Nephrology
- Neurology
- Pulmonology
- Urology
- Rheumatology

18 STUDY SITES BY 2022

18



NUMBER OF PATIENTS VS NUMBER OF TRIALS IN SELECTED DOMAINS BETWEEN 2018-2019

IMMUNOLOGY
(VACCINE)  >  **3402 !!!**

DIABETOLOGY  **238**



NEUROLOGY
(HEART FAILURE)  **210**


RHEUMATOLOGY  **201**


NEUROLOGY  **185**


INTERNAL DISEASES
(LIPID METABOLISM DISORDER)  **152**


GYNECOLOGY  **83**


 NUMBER OF PATIENTS
Screenings in 2018-2019

 NUMBER OF PROJECTS
in 2018-2019

RESOURCES AND TRIAL MANAGEMENT SYSTEM



INFRASTRUCTURE

- Doctor's offices
- Treatment rooms
- Diagnostic rooms
- Dedicated CRA room
- Medical archives



SAFETY & SECURITY

- Alarm and fire alarm systems
- 24-hour monitoring and security protection
- Safe (eg. For INDs code cards)
- Access control system
- Electronic code card locks
- Cabinets, fridges, freezers with access control



EQUIPMENT

- 12 lead ECGs
- Fridges (b/t +2°C and -10°C) and freezers (b/t -30°C and -86°C) with a phone alarm system in case of temperature change and maintaining temperature up to 3 days during power cuts)
- Laboratory centrifuges with cooling systems
- Weights with height meter
- Blood pressure monitors with different cuff sizes
- Ultrasound machine with head for echocardiographic, vascular and abdominal examinations
- Exercise test equipment (treadmill, bicycle)
- RR and ECG Holter monitors
- Resuscitation equipment (defibrillator, anti-shock kit)
- Infusion pumps
- Hospitalization option – bed monitoring system
- CT scan
- Magnetic resonance



INFORMATION SYSTEM OF CTMS CLASS

KO-MED's Clinical Centers operational model is **an advanced information system of CTMS class** which enables us to implement effective planning and supervising of clinical trials including costs, resources, staff's schedules, patients' visits schedules and communication management - work standardization, information flow and the reporting standard.

Thanks to the methodology of process management, individual **SMARTrials®** modules correspond to all stages of running a clinical trial, from an offer until closing and billing the study.



QUALITY

KO-MED Clinical Centers is a network of modern and thriving Study Sites that receive dozens of patients every day.

Our mission is to run clinical trials that give patients a chance of recovery and contribute to the development of medicine.

C O U N T S

We have been operating for 20 years, and have conducted hundreds of clinical trials.

KO-MED Clinical Centers is a guarantee of high quality, efficiency and safety of clinical trials.

Patients' well being is always our priority. Study methods used in our sites are compliant with medical, legal, ethical and scientific global standards.

CERTIFICATES



QUALITY IN KO-MED CLINICAL CENTERS



INNOVATION IN PROCESSES RELATED TO QUALITY

- The range of SOPs that includes all stages related to clinical trials from pre-feasibility to archiving
- Creating new procedures or improving existing ones in order to satisfy needs and requirements of CRO and SMO and building competitive advantage
- The concept of quality management focused on meeting the needs and expectations of CRO / SMO
- Regular training of investigating teams in the field of SOP, involvement of all employees in implementing the company's quality strategy and continuous improvement
- Implementing the experience of individual Study Sites throughout the entire KO-MED Clinical Centers network
- Proactive acquisition of information on running the same clinical trial in other Study Sites all over the world in order to identify areas requiring special attention



SUPERVISION OF QUALITY

- Quality Manager in the team
- Monitoring day-to-day timeliness of input data gained in the course of running a clinical trial in the SMARTrials® internal electronic system
- Daily reporting of Site managers to the Quality Manager and Operations Director concerning conducting the trial in accordance with the requirements
- Centralized analysis of all follow-ups from monitoring visits in order to standardize the quality of running trials in all Study Sites, double control of quality and maintaining standards



GCP AND PROACTIVE ACTIONS RELATED TO QUALITY

- Annual stationary training courses organized by KO-MED Clinical Centers for investigating teams
- On-line training
- Verification of the validity of the investigating team certificates
- Analysis of CRO and SMO expectations as well as observation of the market and its changing requirements



RISK MANAGEMENT, AUDITS AND INSPECTIONS

- Periodic internal audits identifying possible threats
- Processes carried out with a double-check system - minimizing the risk of human error
- Regular training in quality and procedures, training diaries for new employees
- Over 25 Sponsor Audits
- 1 URPL inspection
- 1 FDA audit
- 0 Major findings
- 0 Critical findings

PATIENT RECRUITMENT



SHORT TIME FOR THE PATIENT TO JOIN THE TRIAL

In most trials the first patient joins the trial within 2-3 days



UNIQUE PATIENT RECRUITMENT DEPARTMENT

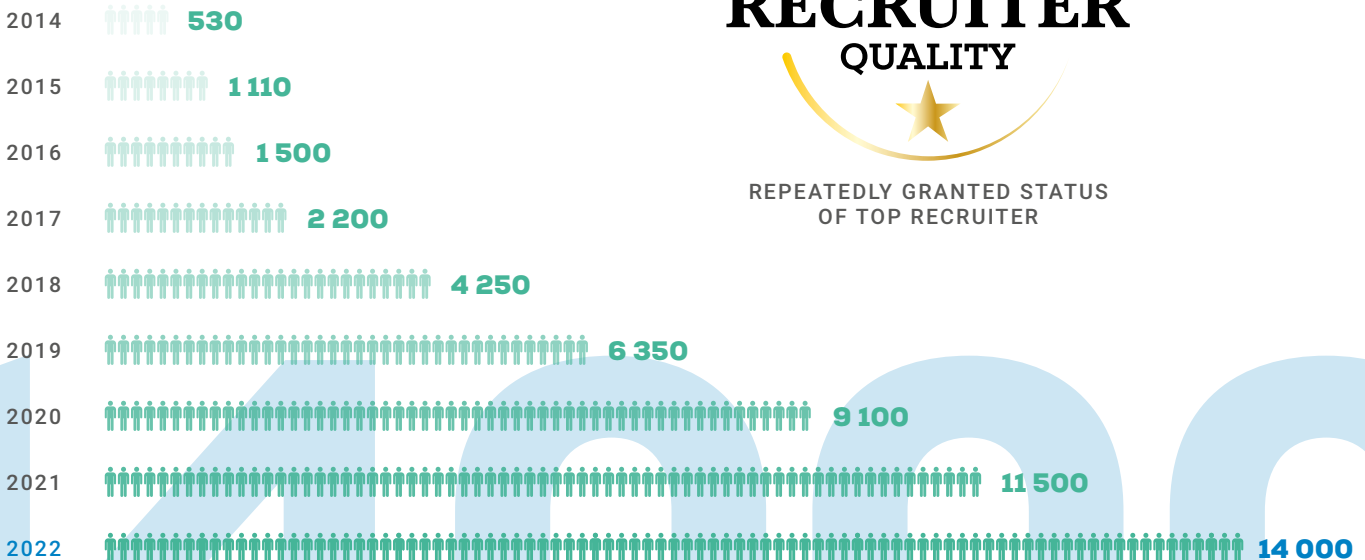
A qualified team of Patient Recruitment Managers operating in the field, responsible for gaining patients



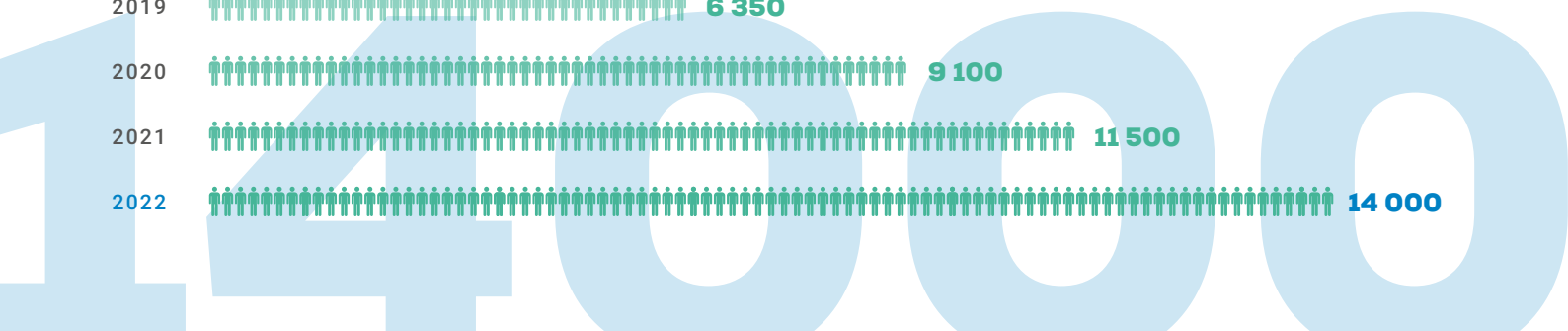
MARKETING DEPARTMENT DEDICATED TO SUPPORT RECRUITMENT

Original system of informing patients about available trials

NUMBER OF PATIENTS IN TRIALS BY 2022



REPEATEDLY GRANTED STATUS OF TOP RECRUITER



EXAMPLE OF RECRUITMENT SUCCESS IN A POPULATION RESEARCH

5508

PATIENTS IN POLAND

=

62%

OUR SHARE OF RECRUITMENT
IN POLAND
SEASON 1+2

3402

PATIENTS
IN KO-MED
CLINICAL CENTERS

12524

PATIENTS GLOBALLY

=

27%

OUR SHARE
IN GLOBAL RECRUITMENT
SEASON 1+2



KO-MED Clinical Centers

START-UP

startup@komed-ck.pl

+ 48 609 409 803

WWW.KOMED-CK.PL