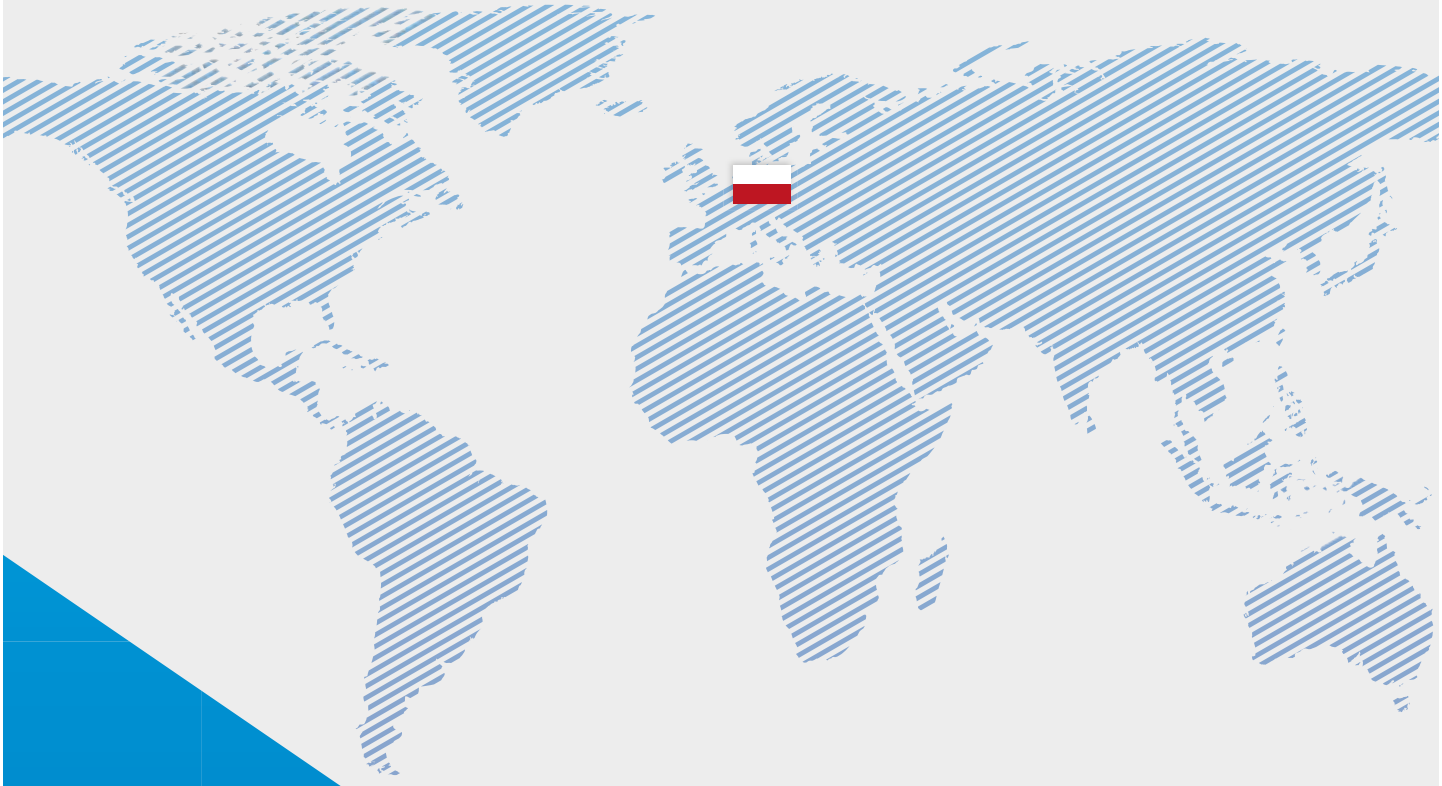
CROMOS™
where the patients are PHARMA



CLINICAL TRIALS IN POLAND

COUNTRY PROFILE #1

CLINICAL TRIALS IN POLAND

Cromos Pharma presents this Country Profile "Clinical Trials in Poland" as one of our forthcoming series of reports about clinical trials in Cromos Pharma's geographic regions and topical issues in clinical research.

Background

Poland is a country located in Central Europe with a population of 38.5 million. Poland is the sixth most populous member state of the European Union. Its largest city and capital is Warsaw. It is a high-income and developed economy and the sixth largest in the EU with an estimated GDP of $1.281 trillion (2019, IMF). Poland has a strong clinical research sector and attracts significant numbers of international sponsors to conduct trials there.

POPULATION OF POLAND
38.5 MILLION

GDP (IMF, 2019)
$1.3 TRILLION

Overall, Poland is perceived as a good place to carry out clinical research due to several advantages, including a large population (38 million) with a significant naïve patient population in a diverse range of clinical areas. Its membership in the EU, advanced economy, and high standard of medical care add to positive perceptions about conducting trials there.

Skilled clinical professionals and strong healthcare infrastructure

A well-educated clinical workforce with experience in ICH GCP-compliant clinical trials allows for efficient recruitment of skilled investigators. Most public hospitals are well disposed towards taking part in trials and have established protocols for working with international sponsors. Poland also boasts excellent access to sophisticated diagnostic tools and laboratory evaluations often required in the conduct of global trials.

Positive patient attitudes to trials

In general, Polish investigators and their patients are favorably inclined to participate in trials as a way of accessing novel therapies not yet available through their national health system. Because of the perceived benefits of patient participation, Polish authorities are actively seeking to grow the clinical research sector e.g. to make site contracting, regulatory approvals and other processes more streamlined, and to encourage patients to take part in global trials. The Polish Ministry of Health, Polish Development Fund and Patient Rights Commission recently established an awareness campaign aimed at informing patients about clinical trial participation and promoting better communications between physicians and patients to further improve patient participation in research.

General information about clinical trial approval process in Poland

Regulatory Agency/Competent Authority (RA) and Ethics Committee (EC) approval is required prior to any new drug or non-CE marked medical device clinical trial initiation in Poland. The Clinical Trial Application (CTA) should be submitted to the RA by the clinical trial sponsor or its authorized representative. Application for drug studies can be made to RA and EC in parallel, however, the CTA for medical devices must be made to the RA after EC approval has been obtained. In October 2018, an amendment of the Polish Pharmaceutical Law Act significantly shortened the process of obtaining a clinical trial's authorization. Instead of submitting fully executed contracts, the sponsor is obliged to submit only a brief description of the financing of a proposed clinical trial, information about compensation paid to participants, investigators and the institutions involved in the study. In addition, the sponsor must also include a description of any agreements between the sponsor and the institution where the clinical trial is being conducted. Contracts will be negotiated and signed during evaluation of an application. From all Principal Investigators participating in the study in Poland a Country Coordinator must be chosen and his/her local EC becomes the Central EC (CEC) responsible for review and approval of the proposed study. If the local ECs gives favorable reviews on the proposed sites or doesn't not respond within 2 weeks, then the study is considered approved for all sites submitted within the application. The 2018 amendment has served to simplify and expedite the approval process and to increase Poland's competitiveness as a site for clinical trials.

Streamlining of regulatory processes

Polish authorities recently announced changes to the regulatory processes for clinical trials aimed at improving e!ciencies in study approval and start-up times. A new agency, the Medical Research Agency (ABM), was established in 2019, aimed at streamlining clinical trial processes and promoting clinical research in Poland. The new Agency is a specialized body of experts who will work on innovation in Polish medicine, focusing on areas related to oncology, hematology and rare diseases. The activities of the Agency will primarily consist of co-financing scientific research and development work as well as interdisciplinary projects, with emphasis on clinical, observational and epidemiological research.

These actions, alongside simplification of the European Union regulatory procedures for clinical trials, have improved the outlook for the Polish clinical trials sector.

A snapshot of clinical trials in Poland **January 2019 – January 2020**

Using https://clinicaltrials.gov our team analyzed the trends in the clinical trials market in Poland between 1 January 2019 and 1 January 2020.

Algorithm of Search at ClinicalTrials.gov.

Search was performed on 20 January 2020. Advanced search option was used with all fields left blank except “Country” (=”Poland”) and “Start date” (=”From 01/01/2019 to 10/01/2020”).

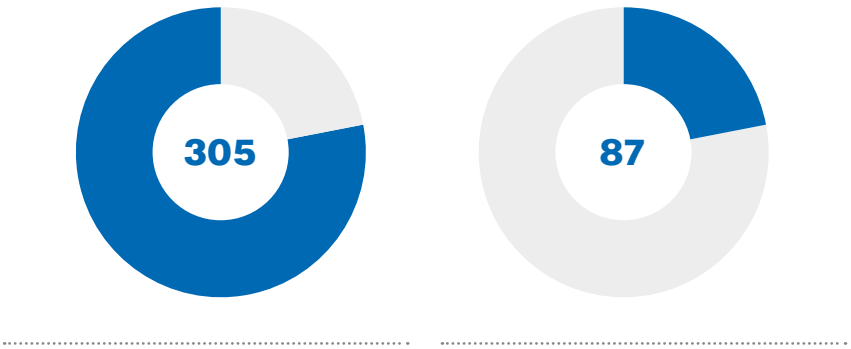
Discussion on limitations of research using ClinicalTrials.gov.

Search results are valid only as of the date of the search. If a sponsor updates information on the study later (e.g. next day or week post search) and adds Polish sites, then the results will differ from those that were obtained.

Clinical Trials in Poland

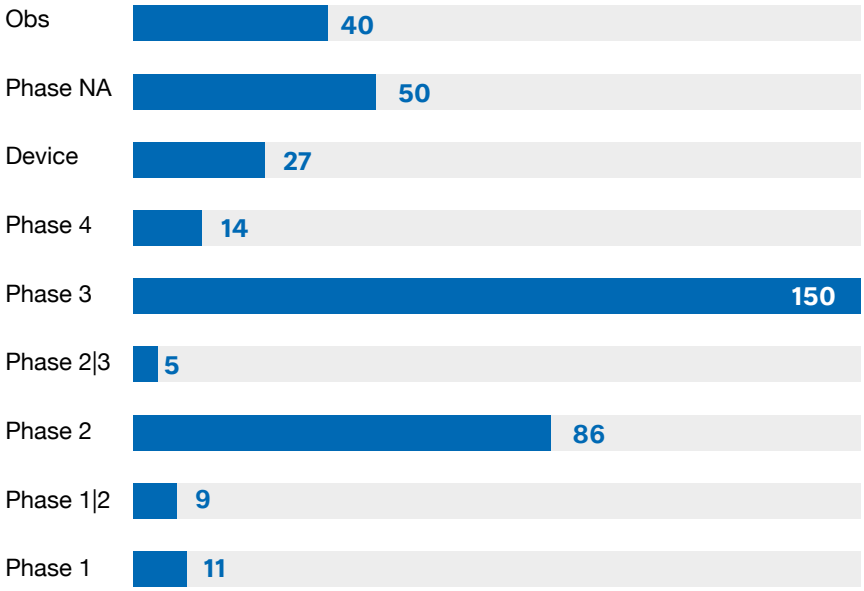
According to data provided by clinicaltrials.gov, a total of 392 clinical trials were initiated in Poland between January 2019 and January 2020. The majority of trials were initiated by international sponsors (305) with 22 per cent (87) led by local sponsors.

Poland clinical trials (Jan 19 - Jan 20) **Local Vs International Sponsors**



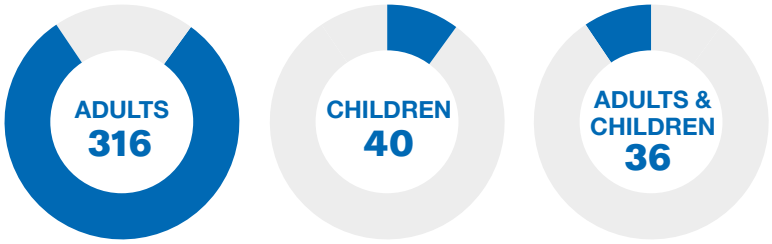
Just over 38 per cent of the trials initiated in this period were Phase 3 (150) and 22 per cent were Phase 2 (86). Very few Phase 1 trials (11) were recorded in this time period while 26 related to medical devices.

Poland clinical trials (Jan 19 - Jan 20) by Phase



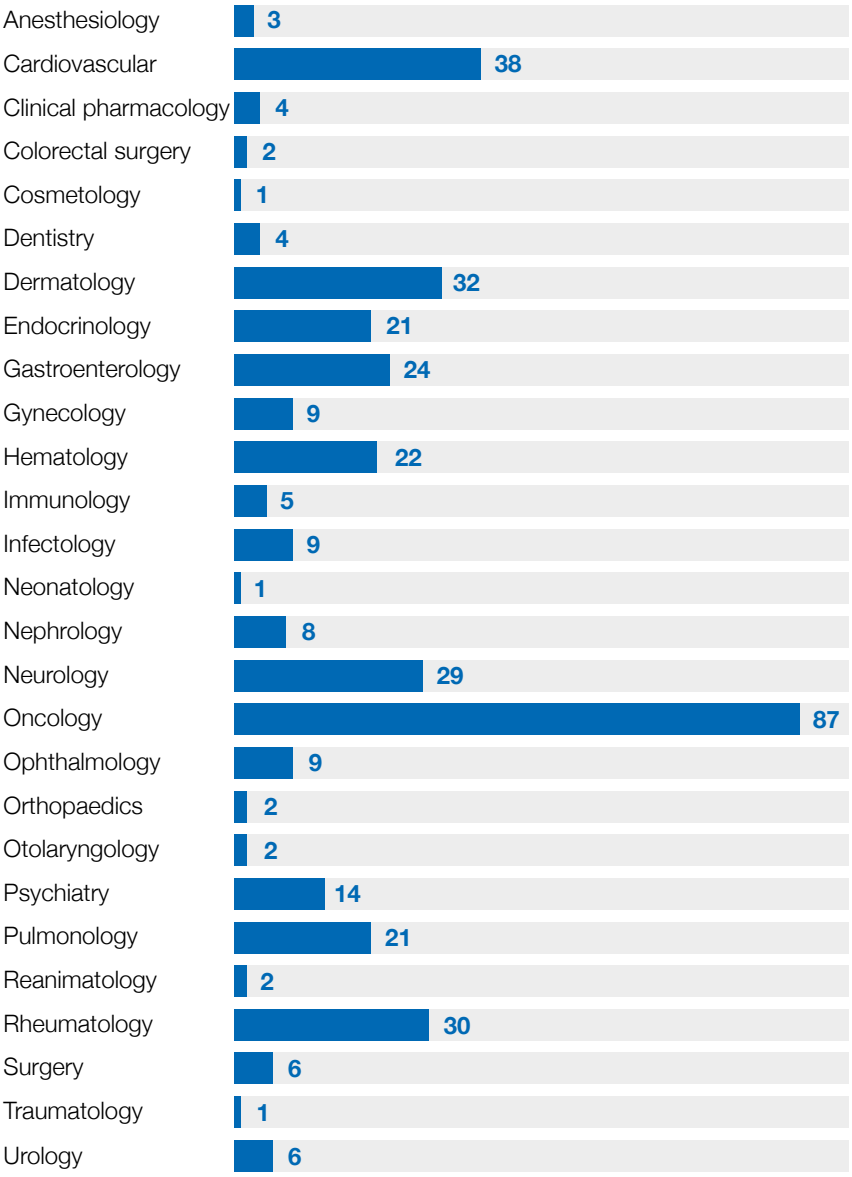
Over 80 per cent of the trials involved adult participants (316). Forty trials involved children and the remaining 36 included adults and children.

Poland clinical trials (Jan 19 - Jan 20) Participant Type



Clinical trials initiated between January 2019 and January 2020 had a diverse range of therapeutic indicators (27 different therapeutic areas in total). Oncology was the leading therapeutic area with over 22% (87). Oncology was followed by cardiovascular (38), dermatology (32) and rheumatology (30).

Therapeutic Indicators



Conclusion

With high levels of patient recruitment, an established framework for conducting clinical trials, a large population of skilled clinical professionals and reputation for producing high quality data Poland remains an attractive site for international sponsors. Recent moves to establish a more streamlined approach to regulatory approval and initiatives to promote patient participation in clinical research have further strengthened Poland's position in the clinical trials sector.

Cromos Pharma has been managing clinical research in Poland since 2015. **If you would like to find out more about how Cromos Pharma can help you with your clinical trials in Poland email: bd@cromospharma.com**

Cromos Pharma provides tailored and effective clinical trial services to support the development of drugs that transform healthcare. It is an international CRO offering fully integrated services with expertise in delivering all aspects of clinical trials in all clinical phases and a range of therapeutic areas. Cromos Pharma delivers rapid recruitment and excellent patient retention as well as expert study design and management. Cromos Pharma has strong regional experience in Central and Eastern Europe. Its European HQ is situated in Dublin, Ireland and its US base is in Portland, Oregon. **Find out more by visiting www.cromospharma.com.**