CROMOS
where the patients are PHARMA

CLINICAL TRIALS IN POLAND

Country Profile Update
May 2022

CROMOS PHARMA IN POLAND

Poland is the largest clinical trials market in Central and Eastern Europe. Cromos Pharma has been managing clinical research in Poland since 2015 and opened a permanent office in Warsaw in February 2020.

WHY POLAND?

20 YEARS — Strong track record, over 20 years, of producing high quality data.

Large population (38.15 million) in comparison with neighboring countries offers great potential for patient recruitment.

Large proportion of treatment-naïve patients in a wide range of therapeutic areas.

Patients are eager to participate in clinical trials as a means of accessing novel therapies.

EU member state since 2004.

Highly skilled, qualified, experienced and motivated investigators and site staff.

Large network of specialized medical facilities located around major urban centres.

Lower costs – on average 30% less than US – due in part to efficiencies in patient recruitment and comparatively lower salaries and fees.

BACKGROUND

- Poland is a country located in Central Europe with a population of 38.151 million.
- It is the sixth most populous member state of the European Union, and its largest city and capital is Warsaw.
- It is however once of the EU economic least affected by the pandemic and the World Bank predicts a return to growth in 2021.
- Poland has a well-diversified economy with a strong clinical research sector and attracts a significant number of International Sponsors to conduct trials there.
- 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 the positive perceptions about conducting trials there. It also has a strong track record, across several decades, for producing high quality data corroborated by regulatory authorities, FDA and EMA.

SKILLED CLINICAL PROFESSIONALS AND STRONG HEALTHCARE INFRASTRUCTURE

Having 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 TOWARDS 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.

GOVERNMENTAL SUPPORT FOR THE SECTOR

Polish authorities are actively seeking to grow its 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.

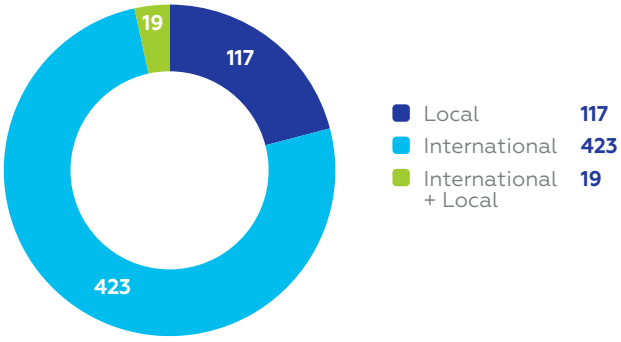
A SNAPSHOT OF CLINICAL TRIALS IN POLAND, JANUARY 2021 – JANUARY 2022

Clinical Trials in Poland

A total of 559 clinical trials were initiated between 1 January 2021 and 1 January 2022. The majority of trials initiated in this period were Phase 3 (203) with a significant number of Phase 2 (144) studies also initiated.

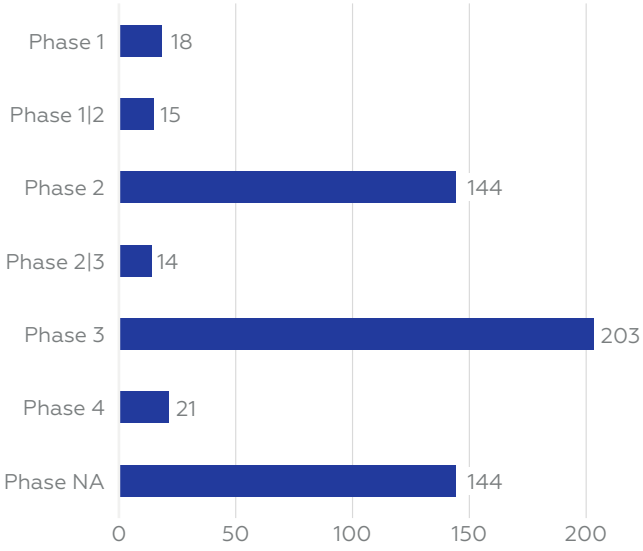
Using https://clinicaltrials.gov our team analyzed the trends in the clinical trials market in Poland between 1 January 2021 and 1 January 2022.

Local Vs International Sponsors



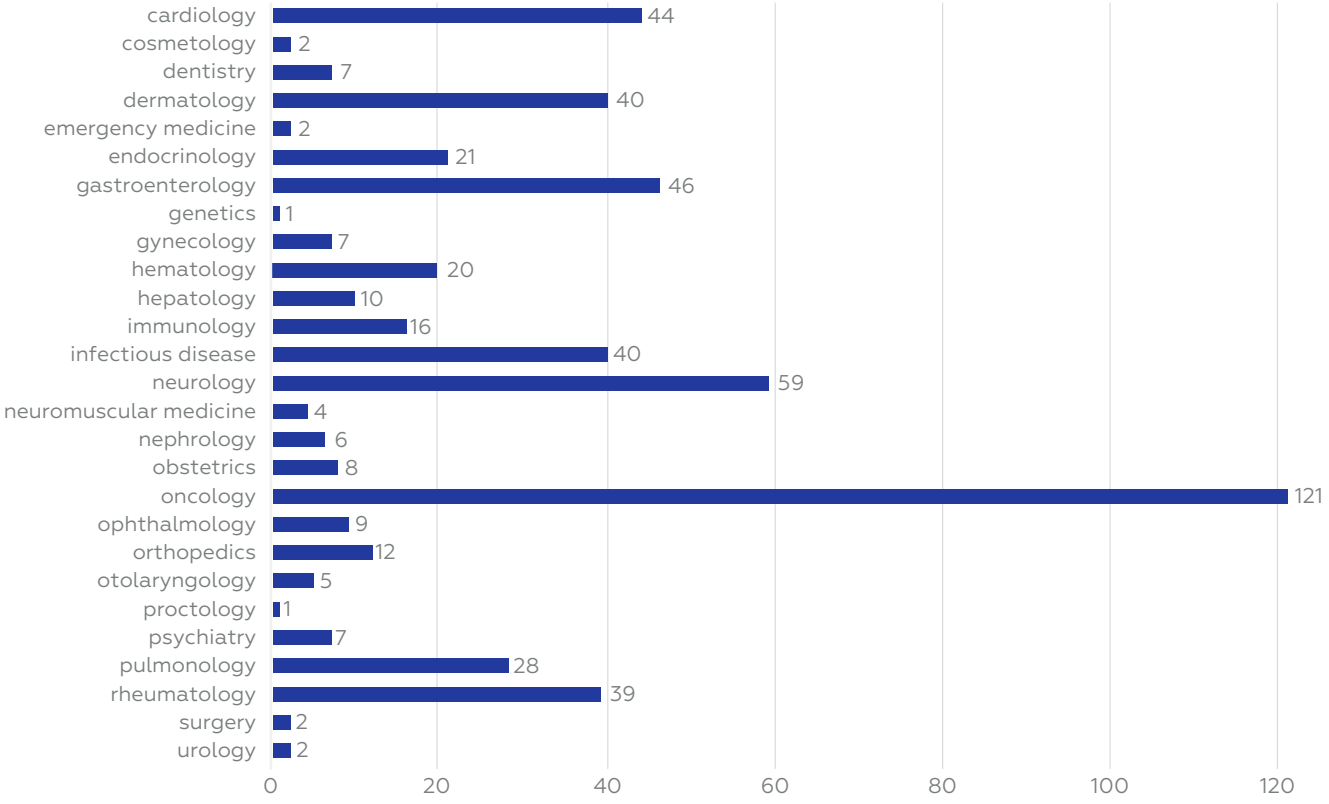
The majority of trials were initiated by International Sponsors 423 with 117 led by Local Sponsors and 19 by both.

Trial Phases



Therapeutic Area

The majority of trials initiated in Poland Jan 2021 – Jan 2022 were oncology (121) followed by neurology (59).



AVERAGE START-UP PERIOD DURATION

Individual stages	Days	Weeks	Months	week 1	week 2	week 3	week 4	week 5	week 6	week 7	week 8	week 9	week 10	week 11	week 12	week 13	week 14	week 15	week 16	week 17	week 18	week 19	week 20	week 21	week 22
Translation of docs and submission dossier preparation	42	6	1.4	●	●	●	●	●	●																
Review & approval by the RA	77	11	2.5							●	●	●	●	●	●	●	●	●	●	●					
Review & approval by the Lead EC (Central EC)*	63	9	2.1							●	●	●	●	●	●	●	●	●							
Review & approval by local ECs**	14	2	0.5									●	●												
Negotiating study budgets with sites	42	6	1.4	●	●	●	●	●	●																
Negotiating & signing study agreements***	–	22	5.1	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Obtaining import/export licenses, importation & distribution of IMP****	28	4	0.9																			●	●	●	●

Summary	Days	Weeks	Months	week 1	week 2	week 3	week 4	week 5	week 6	week 7	week 8	week 9	week 10	week 11	week 12	week 13	week 14	week 15	week 16	week 17	week 18	week 19	week 20	week 21	week 22
From submission till study approval	77	11	2.5							●	●	●	●	●	●	●	●	●	●	●					
From submission till first site initiation	–	16	3.7							●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
From start of work till first site initiation	–	22	5.1	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●

* the EC of the National Study Coordinator is considered to be the Lead EC (Central EC)
** the local ECs are responsible for giving within 14 days an opinion to the Lead EC on the investigator and the site facilities
*** For drug studies the draft of ag reement must be submitted and if not available, statements regarding study funding and financial operations in the study must be submitted
**** No importation license needed if imported from the EU

CONCLUSION

With high levels of patient recruitment, an established framework for conducting clinical trials, a large population of skilled clinical professionals and a reputation for producing high quality data, Poland remains a key location for International Sponsors.

Cromos Pharma has opened its permanent office in Poland (February 2020) to further develop and expand its operations in the country.

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, throughout a wide 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 international HQ is situated in Dublin, Ireland and its US base is in Portland, Oregon.

Find out more by visiting
www.cromospharma.com