

Clinical Trials in Poland

Poland

Capital: Warsaw

Area: 312,679 km²

Population: 38,383,000 people

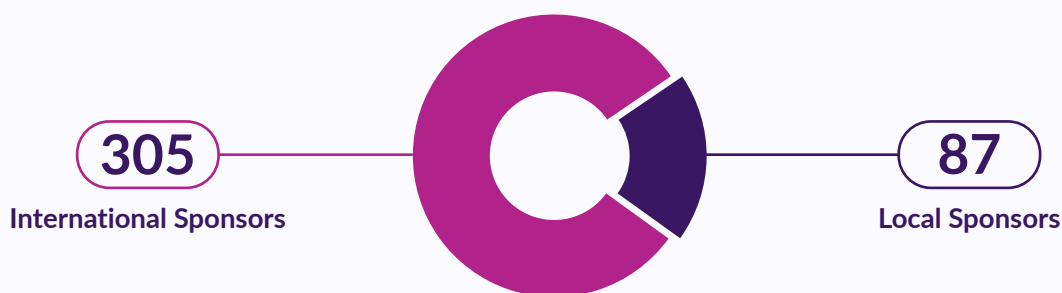
CTA approval timeline: 60 days

Number of ongoing studies at clinicaltrials.gov: 2,189 studies*

Total number of trials registered at clinicaltrials.gov: 7,998 studies*

GDP: USD 1.3 trillion

Clinical Trials Launched in Poland in 2021, International vs Local Sponsors ^[1]



Poland is 10th place in the world by number of research sites (over 1,400). It has had EU membership since May, 2004, and its advanced economy, high standards of medical care and regulatory landscape attract a significant number of international sponsors to conduct clinical trials there.

With a population of 38.5 million people, Poland boasts highly successful patient recruitment rates, reasonable grants, and lower costs per patient than in the U.S., though higher than in such countries as Ukraine, Russia or Georgia. Between January 2019 and January 2020, a diverse range of studies were initiated in 27 therapeutic areas, with Oncology topping the list (87 studies), followed by Cardiovascular (38), Dermatology (32) and Rheumatology (30).^[1]

According to the recent FDA Report^[2] based on a total of 292,766 clinical trial participants, Eastern European countries placed in the top 10. Poland ranked third after the U.S. and Russia, in terms of the number of subjects recruited for studies, while Ukraine, Bulgaria and Romania entered the top 10 of the most recruiting countries.

The attractiveness of the country and the proof of its developed landscape for clinical research can be demonstrated by the FDA data. Of 50 novel drugs approved by the FDA in 2021, 22 have undergone clinical trials at sites in Poland.

FDA-approved New Drugs Tested in Poland, 2021 ^[3]

Drug Name	Active Ingredient	Company Name
Adbry	tralokinumab-ldrm	LEO Pharma
Leqvio	inclisiran	Novartis
Vyvgart	efgartigimod alfa-fcab	Argenx
Besremi	ropeginterferon alfa-2b-njft	PharmaEssentia
Tavneos	avacopan	ChemoCentryx
Livmarli	maralixibat	Mirum Pharmaceuticals
Qulipta	atogepant	AbbVie
Skytrofa	lonapegsomatropin-tcgd	Ascendis Pharma
Korsuva	difelikefalin	Cara Therapeutics
Nexvazyme	avalglucosidase alfa-ngpt	Genzyme
Saphnelo	anifrolumab-fnia	AstraZeneca
Bylvay	odevixibat	Albireo
Kerendia	finerenone	Bayer
Aduhelm	aducanumab-avwa	Biogen
Jemperli	dostarlimab-gxly	GlaxoSmithKline
Ponvory	ponesimod	Janssen
Fotivda	tivozanib	AVEO
Nulibry	fosdenopterin	ORIGIN
Amondys 45	casimersen	Sarepta Therapeutics
Ukoniq	umbralisib	TG Therapeutics
Tepmetko	tepotinib	EMD Serono
Lupkynis	voclosporin	Aurinia Pharmaceuticals

The FDA regularly performs inspections of clinical sites to determine their compliance with applicable regulations and laws. Publicly available statistics of FDA inspection results help biotech and pharmaceutical companies choose the best options for assigning their future clinical studies. The number of international clinical trials in Eastern Europe continues to grow, as does the frequency of FDA inspections. During the last 10 years Poland has had one of the highest NAI rates (68%), which shows that the level of clinical trials conducted appears to be very high.^[4]

1 - ClinicalTrials.gov

2 - FDA. <https://www.fda.gov/media/143592/download>

3 - FDA. <https://www.fda.gov/drugs/new-drugs-fda-cders-new-molecular-entities-and-new-therapeutic-biological-products/novel-drug-approvals-2021>

4 - FDA. <https://datadashboard.fda.gov/ora/cd/inspections.htm>

* as of January 31, 2022

About OCT Clinical

OCT Clinical is one of the leading CROs in Europe. With a team of 130 professionals, the company provides a full range of high-quality clinical research services for phase I-IV and BE studies. With strong local expertise and focus on quality, OCT ensures seamless clinical trial conduct and drug registration on time and within budget. OCT's experienced team delivers both standalone services such as medical writing, consultancy, monitoring, data management, biostatistics and turnkey service for clinical development. Since 2005, OCT Clinical has worked on over 300 full-service and functional service projects in 29 therapeutic areas.

Reach out to OCT experts to explore your clinical trials options in Europe
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