CROMOS
where the patients are PHARMA

CLINICAL TRIALS
IN THE CZECH REPUBLIC

Country Profile
June 2022

CROMOS PHARMA IN THE CZECH REPUBLIC

Cromos Pharma began working in the Czech Republic in 2010 and **established a representative office in Prague in 2015.**

BACKGROUND

- The Czech Republic is a high-income country with a **population of 10.69 million and a GDP of $245.33 billion** (World Bank, 2020[1]).
- Its largest city and capital is Prague with a population of 1.3 million.
- The country has a strong pharmaceutical sector and established clinical research infrastructure.

The Czech Republic is a highly attractive location to conduct clinical trials offering numerous distinct advantages for International Sponsors including:

- Excellent recruitment potential due to its large population of modern treatment-naïve patients in a wide range of therapeutic areas.
- A strong track record for producing high-quality data and lengthy experience in Good Clinical Practices provided by the ICH-GCP.
- A centralized Universal Healthcare System conducive to patient enrollment.
- A large network of public hospitals and clinics as well as specialized centers for patients with specific diagnoses.
- A large pool of highly educated and skilled medical professionals with ten medical faculties in six universities including the internationally renowned Institute of Clinical and Experimental Medicine (IKEM) in Prague and Masaryk Memorial Cancer Institute (MMCI) in Brno.
- An EU member since 2004, its clinical trial regulatory and legislative framework is harmonized with EU directives in relation to clinical research.

CZECH REPUBLIC AS A LOCATION FOR CLINICAL TRIALS

The Czech Republic is a well-established location for the conduct of clinical trials with a strong track record in producing high quality data. In recent years, it has developed a reputation as a good location for niche clinical trials including those for gene and cell therapies and rare diseases.

ADVANTAGES

- Solid clinical research infrastructure;
- High density of clinical sites;
- High standards in education (particularly clinical and medical training);
- Supportive regulatory framework;
- Well-organized centralized healthcare system;
- Large pool of skilled clinical professionals trained in GCP that produces high quality data;
- Significant treatment-naïve patient populations in a diverse range of therapeutic areas.

[1] https://data.worldbank.org/country/CZ

Centralized Health Care System

The Czech Republic has a well-structured centralized healthcare system. Care is provided through a large network of public inpatient and outpatient facilities. There is also a growing number of specialized private clinical institutions which patients can avail of through health insurance contributions. The centralized nature of the health care system assists rapid patient recruitment.

Highly Skilled Staff with a Strong Track Record for Producing High Quality Data

The Czech Republic has a highly skilled clinical workforce. These professionals are very experienced in conducting clinical trials in full compliance with ICH GCP standards and have gained a reputation for producing high quality results confirmed by numerous EMA/FDA inspections.

Significant Naïve Patient Population in a Wide Range of Clinical Indications

With a population of over 10.6 million, the Czech Republic has a positive reputation for patient enrollment with availability of treatment-naïve patient populations in a wide range of therapeutic areas. In general, patients and physicians are positively disposed to clinical trials to access advanced treatments.

Clear and Supportive Regulatory Framework

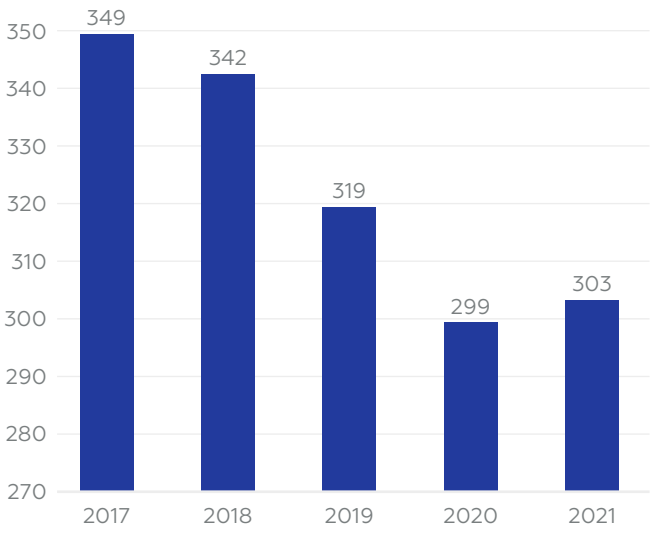
The regulatory authority, the State Institute for Drug Control (SUKL), has a reputation for being open, efficient, and supportive in its approach to clinical research approvals. This allows for quick approval periods and expedited start-up timelines (on average 60 days).

A SNAPSHOT OF CLINICAL TRIALS IN THE CZECH REPUBLIC

Clinical Trials Initiated from Jan 2021 – Jan 2022

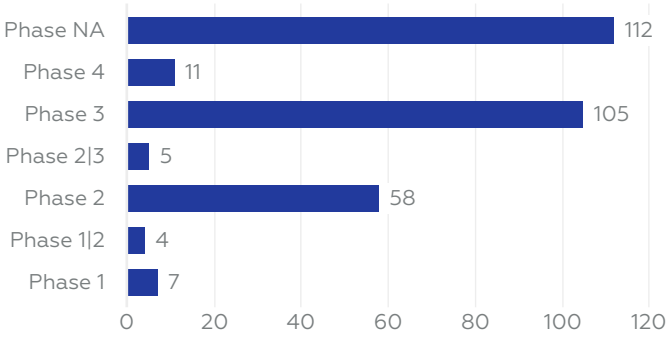
In total 303 clinical trials were initiated in the Czech Republic in the period from January 1, 2021 to January 1, 2022. These included studies in a wide range of therapeutic areas. The largest number is in oncology (64) with neurology (44), infectious disease (24), and cardiology (23) also featuring strongly.

Total number of clinical trials initiated by year 2017 - 2021

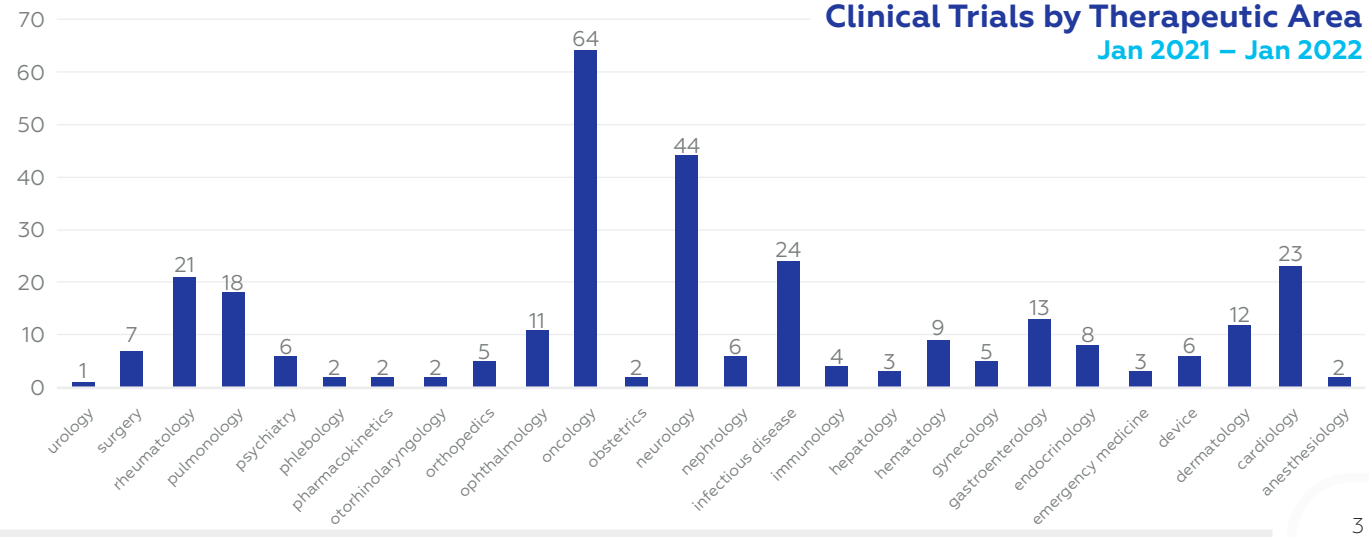


Source: https://clinicaltrials.gov

Clinical Trials by Phase Jan 2021 – Jan 2022



Clinical Trials by Therapeutic Area Jan 2021 – Jan 2022



CLINICAL TRIAL REGULATORY AND APPROVAL PROCESS

The regulatory authority for clinical trials in the Czech Republic is the State Institute for Drug Control (SUKL). The SUKL has a reputation for being open, efficient and supportive in its approach to supporting clinical research. This allows for quick approval periods and expedited start-up timelines (on average 60 days).

IMPACT OF EUCTR ON REGULATION

The way clinical trials are conducted in the EU is undergoing major change due to the full implementation of the new EU Clinical Trial Regulation at the beginning of January 2022. The Regulation harmonizes the assessment and supervision processes for clinical trials throughout the EU via a publicly available Clinical Trials Information System (CTIS; formerly the EU Clinical Trial Portal and Database). The European Medicines Agency (EMA) will maintain the new information system, in collaboration with the member states and the European Commission.

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
Translation of docs and submission dossier preparation	35	5	1.2	●	●	●	●	●														
Review & approval by the RA (State Institute for Drug Control)	77	11	2.5						●	●	●	●	●	●	●	●	●	●	●			
Review & approval by the Central EC	56	8	1.8						●	●	●	●	●	●	●	●						
Review & approval by local ECs	21	3	0.7														●	●	●			
Negotiating & signing study agreements*	119	17	3.9		●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	
Obtaining import/export licenses, importation & distribution of IMP**	28	4	0.9																●	●	●	●
Summary																						
From submission till study approval	77	11	2.5						●	●	●	●	●	●	●	●	●	●	●			
From submission till first site initiation	98	14	3.2						●	●	●	●	●	●	●	●	●	●	●	●	●	●
From start of work till first site initiation	133	19	4.4	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●

* Draft agreements are usually submitted to the EC; then they are negotiated, finalized and signed in parallel with EC/RA review of study docs
** No importation license needed if imported from the EU

FIND OUT MORE

Cromos Pharma has a highly experienced team based in Prague who effectively manage all regulatory and contracting processes to ensure that studies can get up and running in the quickest time possible. Our team also has an impressive track record for rapid patient recruitment and retention, as well as proven relationships with a skilled pool of investigators and staff who consistently produce the highest quality data.

For more information about running your clinical trial in the Czech Republic please **email bd@cromospharma.com** to set up an introductory call.

Find out more by visiting **www.cromospharma.com**