

HUNGARIAN NATIONAL HEALTH RESEARCH AGENCY (HNHRA)

Hungary, located in the heart of Central-Europe, has always been an attractive country for sponsors to conduct clinical trials, due to the highly qualified and motivated investigators/research teams and the positive regulatory environment.

*If you need more information, please contact us.
We are happy to answer your questions in a scheduled
online or offline consultation.*

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Hungary is a highly attractive location for international clinical trials for several key reasons:

- › Quality based attitude and systematic approach, experienced professionals, high ICH-GCP knowledge
- › The Investigators and researchers are well trained, precise and motivated
- › Health care facilities are well equipped with high-tech infrastructure
- › Predictability, transparency
- › Compared to other EU member states, Hungary is known to have a more favourable cost-efficiency
- › The main therapeutic areas with a high-scale patient population are oncology, neurology, cardiology, respiratory, metabolic diseases, paediatrics, vaccine and medical devices
- › Hungary has a significant and fast-growing medical device industry in which both domestic and international companies participate. Consequently, Hungarian clinical trial sites are well prepared for the medical device clinical trials

Hungary is a reliable, trustworthy venue to perform international clinical trials.

High-quality health research is increasingly carried out worldwide through expert agencies that are in close connection with governments.

Hungarian National Health Research Agency (HNHRA) was established by the Ministry of Human Capacities of the Hungarian Government and has a unique position to facilitate excellent cooperation among all actors of the health research sector, such as authorities, therapeutic specific health care institutions, universities and pharmaceutical companies.

HNHRA is responsible for supporting the effective cooperation among key figures of the health care system within a network.

**Predictability,
transparency,
quality-based
attitude and
a demand for
high standards.**

High level education is required for research staff participating in clinical trials in Hungary:

- › GCP certification is mandatory for all Principal Investigators in Hungary, according to the local legislation
- › University-accredited CRA courses
- › Education for Study Nurse/Study Coordinator
- › A special Clinical pharmacology exam is mandatory for Principal Investigators of Phase I Units

Hungary performed with excellent results during the previous FDA inspections, which confirms the quality of the clinical trials data.

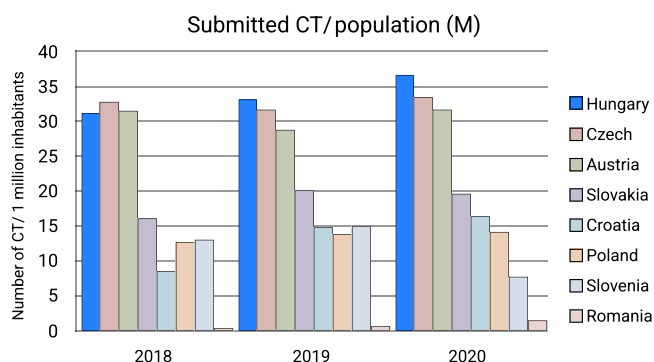
FDA Inspections 2005-2020:

US FDA Inspected Country	Inspections Since 2005	No Action Indicated	Voluntary Action Indicated	Official Action Indicated
Hungary	54	53.7%	46.3%	0.0%

Source: <http://www.fda.gov/cder/regulatory/investigators/cliil.zip>
(Accessed October 18, 2021)

Hungary provides an excellent economic environment for clinical trials and it has become a global leader in the field.

Submitted Clinical Trials per Population in Surrounding Countries:



The clinical trial sites have high-tech infrastructure:

- › 19 accredited Phase I Units equipped with high-tech infrastructure
- › The centralised health care system greatly facilitates efficient patient recruitment
- › Short study initiation time
- › High level of legal/regulatory authority environment – predictable, transparent and conforms to EU guidelines

Compared to other EU member states, Hungary is known to have a more favourable cost-efficiency.

