



01 Newsletter of Smooth Drug Development

January 2023

Dear Colleagues and Friends.
We are happy to present you the
Smooth Drug Development newsletter.





Smooth Drug Development is an ISO certified contract research organization, which offers a full range of clinical trial services and drug registration services in the EAEU region and Europe.



Representative Office in Beijing

Smooth Drug Development together with our partner Summer Atlantic opened a representative Office in Beijing Economic and Technological Development Zone.

Our Chinese office focus is to help Chinese pharmaceuticals and biotechnical companies reach the European and EAEU medical markets by organizing clinical trials and drug registration and increasing the efficiency in both clinical and regulatory process for Chinese bio companies via cutting-edge digital platforms.

Smooth Drug Development advantages:

Experience

We have a vast experience in clinical trials in Europe and other regions. We performed 450+ trials with over 40,000 subjects for different indications or drugs in the EAEU, Europe and in India. We have experience in bringing novel drugs to the market performing full service clinical program development.



Smooth Drug Development advantages:

CTMS

Smooth Drug Development uses a self-developed Clinical Trials Management System (CTMS).



Smooth CTMS is a unified platform for critically important systems needed for a clinical trial and company's operations. Our CTMS has a modular structure and can support company and clinical studies activities. We provide end-to-end software support for clinical trials under one roof (eTMF/eISF, EDC, IWRS, ePRO, Monitoring and Project Management tool) and support for company's operations (QMS, LMS, HR).

Smooth Drug Development advantages:

ICO certified

Our company has proven its high-quality adherence by getting ISO certified in the following area:

ISO 9001:2015 "Quality Management Systems"

ISO 22301 "Societal security – Business continuity management systems – Requirements"

ISO 27001:2013 "Information Security Management Systems"



Smooth Drug Development advantages:

successful
experience

We already have a successful experience with Chinese pharmaceutical companies in conducting clinical trials in EAEU and Europe. We have repeatedly worked with companies from China and Taiwan.



Our achievements for the last year in China include:



Smooth took part in a global clinical trial with a vaccine against Covid-19 conducted by a leading Chinese biotechnology company. We opened 12 sites and enrolled 5000 subjects in two months in Russia. The subjects were followed up for 12 months and the study included immunogenicity part. The vaccine proved its efficiency and was finally registered in China.

In 2023 a leading pharma company from China received its FDA registration for its drug for the treatment of schizophrenia in adult patients. This drug was approved in China in 2021. Smooth Drug Development worked on this project in EAEU and EU and its data generated by Smooth Drug Development sites was used for the registration in USA and China.





Our achievements for the last year in China include:

We organized webinars for Chinese medical companies focused on smooth entrance on the EU market:



Global Expansion and Exit Strategies for Chinese Healthcare Companies hosted together with Summer Atlantic Capital with the support of Beijing local government.

Seminar on European Market Strategy for Medical Device Companies Going Abroad hosted together with Beijing Advanced and Innovative Medical Device Industrialization Alliance, and Summer Atlantic Capital.

Seminar on European Market Strategy for Medical Companies Going Abroad: Technical Pain Points and Digital Intelligence Solutions for Medical Companies Going Abroad hosted together with Beijing Advanced and Innovative Medical Device Industrialization Alliance, and Summer Atlantic Capital.

We would be happy to start
a dialogue with you in 2023.

Sincerely,
Smooth Drug Development



<https://smoothdd.com>



<https://www.summeratlantic.com>