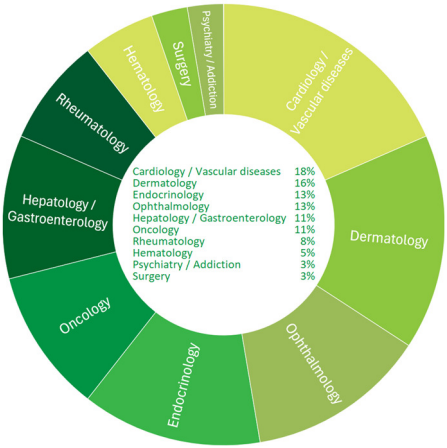
Medical Device Studies
Overview and Case Study

Pharmnet's expertise

Pharmnet Group has over ten years of experience performing medical device (MD) studies across a variety of therapeutic areas. Over the years, we have conducted more than **35 medical device projects**, including significant contribution in diabetes, wound healing and heart failure. Pharmnet Group conducted four first-in-human (FIH) MD studies, including a successful FIH study in GI bleeding, with a total of 30 patients recruited.

Pharmnet Group experience in MD studies:



Experience with the HORIZON EU grant program

Pharmnet proudly positions itself as a key player in the HORIZON EU grant program, contributing as a small to medium enterprise and co-researcher within a diverse research consortium. As a co-researcher, Pharmnet gained expertise in reporting and documenting the progress of various projects under the HORIZON EU framework. This involves meticulous data collection, analysis, and presentation, ensuring that findings are accessible to stakeholders and aligned with the program's objectives. Using this experience, we can support clients in various reporting needs tailored towards investors, grant applications etc.

Regulatory guidance from FIH to Post-Market Clinical Follow-up (PMCF)

Conducting a clinical study of a medical device, that does not bear the CE mark or that is used in a clinical study for a purpose other than its original intended purpose, is permitted only upon the basis of authorisation from Ethics Committee (EC) and relevant Regulatory Authority (RA).

All MD clinical studies are submitted according to Regulation (EU) No. 745/2017 (MDR). An approval from EC (usually 30 days) is required prior the application to RA.

To obtain authorization for a clinical study /performance evaluation, sponsor or an authorized person needs to submit an application, currently through a local registration system. The RA gives a decision on the application within 60 days of the submission. The study documentation is evaluated per harmonised standard EN ISO 14155:2012 Clinical study of medical devices for human use - Good clinical practice. In general, the 60-day evaluation process is split into several steps. Within 10 days of receipt of the application, the RA assesses completeness of the dossier and its correct classification as per MDR. Then in 4-6 weeks the RA issues questions and comments on the submitted documentation that must be addressed by sponsor within a given timeframe.

PMCF studies aim to answer specific questions about the clinical effect or the efficacy and safety of a MD when used in accordance with the approved instructions for use. PMCF studies are conducted under a simpler regime than MD studies, i.e. only the written approval from EC is required, but not RA approval.

PHARMNET

Pharmnet, Peckova 13, 186 00 Prague 8, Czech Republic
pharmnet-cro.com | bd@pharmnet-cro.com

Version: Apr-25

Medical Device Studies
Overview and Case Study

Case study – FIH and pivotal study

Client: A biotech company committed to the innovation and commercialisation of GI sensor technologies to transform and add value to diagnosing and monitoring upper gastrointestinal bleeding (UGIB).

Pharmnet was contracted to a full-service project to evaluate detection of blood in patients with suspected UGIB following a FIH healthy volunteers' cohort. Scope of work included study design, development of investigational plan and study documentation, preparation of all essential investigation documents (excl. manufacturing documentation and IB), feasibility and site identification, regulatory submission(s), obtaining approval(s), site contracting, clinical monitoring – on/off-site, project management, securing of supply chain and the preparation of the paper CRFs to comply with CSN ISO 14155:2012.

Challenge	Pharmnet's solution
The initial study design, as outlined by the sponsor, revealed difficulties in obtaining approval from the RA.	Pharmnet revised the design to create two separate clinical studies: one testing blood detection in healthy volunteers (FIH) and another for patients with suspected UGIB (pivotal).
The sponsor anticipated a challenge from the EC regarding the use of own blood in study with the healthy volunteers.	Pharmnet formulated an informed consent document for healthy volunteers, with a suitable compensation amount stipulated. This was done so that the document aligns with the complexity of the procedure, adhering to ethical standards as outlined by the EC.
Due to COVID-19 travel restrictions, the sponsor was unable to supervise first use of the device in healthy volunteers on site.	Pharmnet proposed a stepwise approach to investigate all 10 volunteers within a single day and provided real-time communication of results to the sponsor.

Real impact

Combining our expert knowledge and creative problem-solving, we successfully overcame challenges in ethical and regulatory compliance. Our client's positive feedback highlighted the effectiveness of our approach, flexibility and our ability to navigate the complexities of the study process. Our high standards led to significant achievements, including publications of first-in-human trial results in the Clinical Endoscopy Journal, successful presentations at the UEG Congress and the sponsor securing FDA registration. This project reinforced our position as a trusted and capable partner in the field of medical device research.