

Investigator-Sponsored Studies (ISS)

Pharmacosmos Therapeutics (PTI) is committed to supporting investigator-sponsored research that promotes the advancement of medical and scientific knowledge involving intravenous (IV) iron products and therapeutic areas of interest.

This type of research may expand our understanding of IV iron products and their potential applications. Plus, it may spark new ideas for further disease-related research.

The PTI ISS program provides an opportunity for academic and community-based physicians and researchers interested in conducting their own research to apply for research support. An ISS may be an interventional or non-interventional study for which PTI provides funding, drug product, or both.

We welcome unsolicited proposals from qualified sponsors with promising ideas in our areas of strategic interest and will support programs that will:

1. Contribute to knowledge in the medical and scientific community,
2. Address unmet needs, and
3. Will be communicated in an appropriate scientific forum, including congresses and peer-reviewed publications.

Established Areas of Interest

Currently our areas of interest include, but are not limited to:

- Real-World Evidence for IV irons, including Health Economics and Outcomes Research and improving patient quality of life,
- Safety of IV irons, including Hypophosphatemia and Infusion Reaction Management,
- Iron Deficiency with or without Anemia in:
 - Special Populations, including patients diagnosed with Hereditary Hemorrhagic Telangiectasia (HHT) and the elderly,
 - Cardiology, including Heart Failure,
 - Oncology, including Chemotherapy-Induced Anemia,
 - Gastroenterology, including Inflammatory Bowel Disease and Upper GI Bleeding,
 - Obstetrics and Gynecology, including Abnormal Uterine Bleeding, Post-Partum, and Pregnancy,
 - Patient Blood Management and Surgery,
 - Nephrology, including Non-Dialysis Chronic Kidney Disease and Peritoneal Dialysis.

How to Apply

If you are a Health Care Professional with an ISS proposal, the first step is to discuss your proposal with your regional Medical Science Liaison (MSL), who will provide you with a Form for completion and submission. If you do not know your regional MSL, please reach out to our Medical Information department via email (MedInfo@Pharmacosmos.us) or phone ([888-828-0655](tel:888-828-0655)), 9:00 am – 5:00 pm Eastern, Monday to Friday.

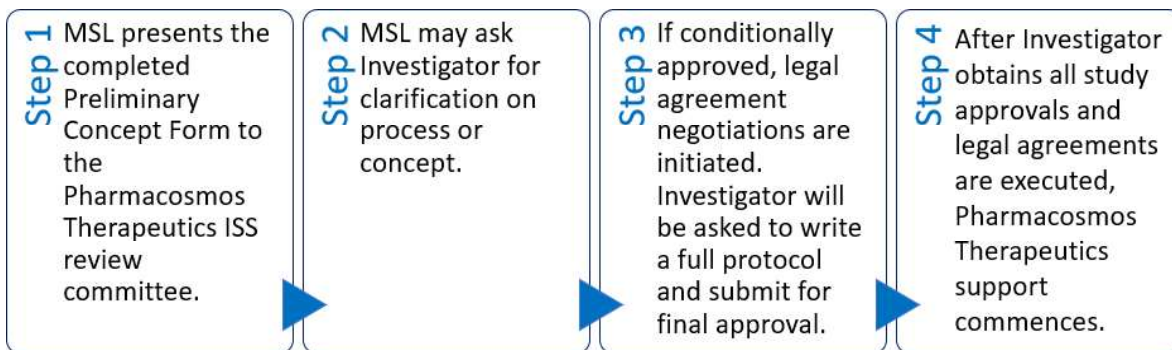
Process

Once we receive the initial proposal, we review it based on the following:

- Scientific, clinical, and medical robustness and merit
- Safety and ethical integrity

- Feasibility of study protocol
- Alignment with existing strategy
- Availability of resources

Applications are reviewed monthly and may require multiple rounds of review. Your MSL will be your best source for updates on the process as your proposal moves through the various stages.



The Investigator assumes responsibility for all aspects of the study, including, but not limited to, study design, initiation and conduct, monitoring and safety reporting, analysis, and publication of the results. The Investigator is also responsible for adhering to agreed-upon timelines and delivery of a final study report to PTI.

Support of an ISS is not intended to encourage the prescription, supply, administration, recommendation, purchase, or sale of any PTI product. PTI is committed to both data and financial transparency. To ensure compliance with relevant laws and regulations, all transfers of value (i.e. payments and product provision) will be reported in accordance with the relevant local regulations. As the study sponsor, the Investigator is also responsible for complying with all applicable regulatory requirements and guidance and this includes registering the study with applicable government agencies and websites (ex: clinicaltrials.gov). We also encourage all Investigators to share and report any support provided to them.

If you have additional questions about the ISS program, please contact your local MSL or write to us at ISS@Pharmacosmos.us