# PharmaNest

## About IND-Enabling Technologies

PharmaNest commercializes breakthrough international IND-Enabling Technologies and Services for the US Markets.

What are IND-Enabling Technologies and the related market opportunities?

**About Enabling Technologies.**

In general terms, an **enabling technology** is an invention or innovation, that can be applied to drive radical change in the capabilities of a user or culture. Enabling technologies are characterized by rapid development of subsequent derivative technologies, often in diverse fields.

In the field of Drug discovery and Pharmaceutical Development enabling technologies are poised to accelerate the discovery of new therapeutic compounds and significantly reduce time to market and safety profiles.

**Why Focus on IND?**

The United States Food and Drug Administration's **Investigational New Drug** (**IND**) program is the means by which a pharmaceutical company obtains permission to ship an experimental drug across state lines (usually to clinical investigators) before a marketing application for the drug has been approved. The FDA reviews the IND application for safety to assure that research subjects will not be subjected to unreasonable risk. If the application is cleared, the candidate drug usually enters a Phase 1 clinical trial.

In short, ***IND is the key milestone prior to testing drug candidates on humans*.**

The IND application to FDA must contain information in three broad areas:

- *Animal Pharmacology and Toxicology Studies* - Preclinical data to permit an assessment as to whether the product is reasonably safe for initial testing in humans. Also included are any previous experience with the drug in humans (often foreign use).

- *Chemistry and Manufacturing Information* - Information pertaining to the chemical composition, manufacturing methods, stability, and controls used for manufacturing the drug substance and the drug product. The chemical stability and activity of the product must also have been tested. This information is assessed to ensure that the company can adequately produce and supply consistent and active batches of the drug.

- *Clinical Protocols and Investigator Information* - Detailed protocols for proposed clinical studies to assess whether the initial-phase trials will expose subjects to unnecessary risks. Information on the qualifications of clinical investigators—professionals (generally physicians) who oversee the administration of the experimental compound—to assess whether they are qualified to fulfill their clinical trial duties. Finally, commitments to obtain informed consent from the research subjects, to obtain review of the study by an institutional review board (IRB), and to adhere to the investigational new drug regulations.

- An IND must also include an *Investigator's Brochure* which is a document intended to educate the trial investigators of the significant facts about the trial drug they need to know to conduct their clinical trial with the least hazard to the subjects or patients who will be enrolled.

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**How will technologies transform the current paradigm?**

Innovative technologies and services have the potential to redefine the workflows, quality and cost structure of the efforts dedicated by pharmaceutical companies and biotechnology companies to more Drug candidates from a "lead" concept to an IND by disrupting conventional and generally accepted process to:

- *Perform Animal Pharmacology and Toxicology Studies*,
- *Develop Compound Chemistry Technologies and Manufacturing processes*
- *Develop Clinical Protocols, with increased Investigator and Patient participation*
- *Create innovative ways to execute clinical trials while increasing the protection of the subject involved.*

There is an increasing amount of innovative technologies around the world that have the potential to enable major improvements in the way these macro-processes are planned and executed. But these technologies are often captive of their local ecosystems and markets and are the victim of slow adoption. In addition, large distances and cultural gaps slow down their adoption, even is the world of technology is become more and more transparent.

Most often, the lack of availability of relevant leadership teams, at the right time, is the key reason why promising technologies do not harvest the success that they deserve. Pertinent and creative business model may be as well one of the manor root causes of failure.

**Some examples of IND-Enabling Technologies**

As an illustration, here is a selection of IND-Enabling technologies developed/supported by PharmaNest for the US markets:
**Fluofarma:** Bioengineering, BioScreening, BioComputing Services (www.fluofarma.com)
**Creapharm:** Formulation, packaging, clinical trial supplies of Cytotoxic compounds (www.creapharm.fr)
**Disposable Lab**: Single-Use BioManufacturing of High Potency Compounds (www.disposable-lab.com)
**GemacBio:** Custom Molecular Engineering Services for Small Molecule Antibodies (www.gemacbio.com)
**LLTECH:** Non Destructive 2D-3D Digital Pathology Imaging for Tissue and Stem Cells (www.lltechimaging.com)
**Atoxigen:** substitute technologies for ADME Tox on Zebra Fish and propritary Imaging (www.atoxigen.com)
**ITEC Services:** Full service CRO specialized in respiratory studies (www.itecservices.com)
**MARS-CT:** a multispectrum Spectroscopic CE scanner for small Animals (http://tiny.cc/h20a4)

**How will PharmaNest change the game**
We believe that the demand for IND-enabling technologies and services (with unique IP) is just emerging and we want to embrace this change and contribute to the acceleration of their adoption in the US. Headquartered in Princeton, NJ, in the heart of the biggest Pharmaceutical and Biotechnology ecosystem in the word, we are in the front row of this transformation.

Last, our team offer a unique combination of highly experienced scientists and commercial leaders. We understand the needs of the industry, of their technical buyers and procurement leaders. Whereas the technologies that we are taking to market will be used in-house or "as-a-service" by pharmaceutical users, PharmaNest will offer a very consultative and scientific "sales process" focused on the development of relevant applications and value creation.

We are eager to be a new player in the industry and are looking forward to sharing growth with our clients and partners.

Mathieu Petitjean, Ph.D,
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