PHARMANET/i3 AT A GLANCE

PharmaNet/i3

INVENTIV HEALTH CLINICAL

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PharmaNet|i3

INVENTIV HEALTH CLINICAL

AT A GLANCE: OVERVIEW

For pharmaceutical, biotechnology, generic drug, and medical device companies of all sizes around the world, *PharmaNet/i3 works for you.* We can partner with you in all phases of product development, from comprehensive Phase I-III clinical trials and bioanalysis, to regulatory submissions and Phase IV post-approval programs. With robust global resources and expertise in virtually all major therapeutic areas, PharmaNet/i3 has the capacity to conduct any clinical trial, from a large multi-country, multi-language clinical trial, to a proof-of-concept trial in a single location.

Part of the inVentiv Health family of companies, PharmaNet/i3 is comprised of more than 7,000 employees dedicated to clinical research in more than 30 countries. We are a trusted partner to our clients, building effective relationships through a philosophy of focused client service, professional integrity, and depth of experience.

For the applied knowledge and intelligent solutions needed to accelerate high-quality product development programs, ***PharmaNet/i3 works for you.***

PharmaNet/i3 offers:

- **PHASE I-IIA**
- **BIOANALYTICAL**
- **PHASE IIB-III**
- **PHASE IV**
- **STRATEGIC RESOURCING**
- **QUALITY ASSURANCE**
- **CONSULTING**
- **THERAPEUTIC EXPERTISE**

AT A GLANCE: PHASE I-IIA

PHASE I-IIA

PharmaNet/i3 has the capacity you need to conduct Phase I-IIa clinical trials quickly and efficiently with a dedicated clinical facility. Our strategic hospital partnerships and extensive centralized database give us access to a significant population of potential participants, including special populations. Advanced technology, including Initiator™ software, expedites studies and provides real-time data for Phase I clinical trials.

A dedicated project manager is assigned to each study, supported by a team of experts including physicians and specialists in participant recruitment, clinical operations, quality assurance, biostatistics, and scientific and regulatory affairs. These experts work with the program manager and sponsors to minimize risks and establish contingency plans, providing robust quality and regulatory controls to ensure protocol compliance and study participant safety. Our bioanalytical laboratories streamline processes with specialized techniques to provide the solutions you need.

All departments and business processes, including data processing and report writing, comply with current GCP and GLP standards, while an independent quality assurance unit validates study data and reports, providing the basis for our exceptional regulatory success.

Phase I-IIa services include:

- Bioavailability/bioequivalence
- Biosimilars
- Cardiac safety clinical trials
- Drug drug interaction clinical trials
- First-in-man clinical trials
- Proof-of-concept clinical trials
- SAD and MAD studies
- Special populations

AT A GLANCE: PHASE IIB-III

PHASE IIB-III

At PharmaNet/i3, our ability to connect the right teams, resources, and expertise across the development spectrum means that sponsors can get the customized product development services they need. We combine comprehensive product development services, a worldwide network of experienced resources, and therapeutic expertise to safely keep study timelines on track.

Having decades of experience with the design and conduct of clinical trials, PharmaNet/i3 offers the flexible management approach that brings together the exact team that sponsors need including therapeutic experts in oncology, cardiology, infectious disease, neuroscience, pain, and a host of other areas. Sponsors get the right resources where they need them with the local insights to successfully complete their product development programs. Our commitment to quality and client service ensures the integrity of every study.

Phase IIb-III services include:

- Biostatistics
- Clinical monitoring
- Data management
- Feasibility studies
- Global safety and pharmacovigilance
- Interactive response technologies
- Investigator recruitment and site management
- Medical and scientific affairs
- Medical writing
- Patient recruitment
- Project management
- Protocol/case report form design
- Rater training

AT A GLANCE: PHASE IV

PHASE IV

PharmaNet/i3 helps world-class biopharmaceutical companies bridge the gap from development to commercialization. By recognizing that Phase IIIb-IV research is undertaken for different reasons than pre-approval studies, post-approval success is achieved through documentation and persuasive demonstration of safety and value. PharmaNet/i3's operational approach reflects these unique characteristics of Phase IV: different goals, different measures, different stakeholders, and different time frames.

As the clinical segment of inVentiv Health, PharmaNet/i3 affords clients research support capabilities in all phases of drug and device development, from pre-approval product development research to post-approval commercialization activity.

Services include:

- Conduct of post-marketing studies by an experienced global team with diversified therapeutic expertise
- Risk evaluation and mitigation strategies
- Pricing and market access
- Patient access and reimbursement
- Product commercialization and brand deployment
- Adherence programs
- Product optimization
- Regulatory affairs consulting

Our goal is to support our clients through a balanced and operationally cost-efficient approach that recognizes the specific attributes of the post-approval landscape.

SAFETY ← → VALUE

CLINICAL	HUMANISTIC	ECONOMIC
• Observational (non-interventional) studies and patient registries • Comparative effectiveness research • Interventional studies • Safety surveillance studies • Risk management/epidemiology • Endpoint studies • Compassionate use programs • Label extension studies	• Patient-reported outcomes research • Quality-of-life instrument development and validation • Quality-of-life studies • Direct-to-patient disease registries	• Cost-effectiveness studies • Economic models • Global value dossier development • Health technology submissions • Meta- and database analyses • Pricing and reimbursement support

AT A GLANCE: STRATEGIC RESOURCING

STRATEGIC RESOURCING

Today, drug development companies are under intense pressure to accelerate the development of innovative products with improved efficiency and quality, while simultaneously lowering costs and adjusting to evolving regulatory environments.

PharmaNet/i3 offers not only full-service clinical trial outsourcing, but robust strategic resourcing capabilities with a complete range of functional service provider and clinical staffing services.

These capabilities give us new ways to tailor resourcing solutions on a global scale. We work to anticipate and alleviate your business pressures, address competing demands, and help you achieve your clinical and financial objectives.

We use a flexible business model and adjustable strategy that can quickly adapt to evolving business needs. We deliver the right resources at the right time, and continually look for ways to reduce costs, eliminate redundancy, and deliver timely results.

The 200,000 professional candidates in our global network and our 3,500 employees have experience in a wide variety of therapeutic categories and stand ready to rapidly staff any size program.

Our core services include:

- Data management
- Biostatistics
- Statistical programming
- Clinical operations
- Medical writing
- Pharmacovigilance
- Regulatory
- Project management

PharmaNet/i3
Strategic Resourcing
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AT A GLANCE: BIOANALYTICAL

BIOANALYTICAL

At its core, PharmaNet/i3's bioanalytical services are built to deliver on our commitment to meet project schedules and provide high-quality data. Through our GLP-compliant laboratories, an extensive list of more than 1,000 validated assays, knowledgeable scientists, and skilled technicians, PharmaNet/i3 provides bioanalytical services in all stages of product development.

We combine our significant experience with small and large molecules, peptides, immunochemistry, LC/MS/MS, HRMS, GC/MS/MS, and ICP-MS, and blend innovative science with efficient, validated processes to deliver quality data on time.

Our experience in the development and validation of immunoassays for large molecules and biomarkers gives PharmaNet/i3 scientists special insight into biotechnology product development. A variety of proprietary and non-proprietary pharmacokinetic and immunogenicity assays, as well as a wide range of cell-based and enzymatic assays, have been developed. By rapidly providing specialized immunogenicity testing for the presence of antibodies to biologic and biosimilar products, PharmaNet/i3 can help move your large molecule development programs forward quickly and smoothly.

Bioanalytical services include:

GLP method development, validation, and analysis

- Biomarker support
- Immunoassays
- Large molecule

Non-GLP method development and analysis

- Dried blood spot analysis
- Fast PK
- High-quality tissue analysis
- Lead optimization
- Plasma protein binding studies
- Semi-quantitative and quantitative metabolite analysis

AT A GLANCE: QUALITY ASSURANCE

QUALITY ASSURANCE

At the heart of every PharmaNet/i3 product development program is an independent team of dedicated quality assurance specialists who ensure the credibility of your data. Our senior-level auditors assess all aspects of each study, including auditing clinical sites, associated databases, and vendors; validating software; and ensuring the quality of individual reports, study files, tables, and listings. We can also provide training to prepare investigator sites for regulatory inspections.

Because of our global footprint, we have personnel fluent in a multitude of languages and have conducted quality assurance audits across multiple countries, ensuring all aspects of our work are accurate, consistent with GLP, GCP, and GMP standards, and in full compliance with regulatory requirements.

You have the security knowing our expert quality assurance team is prepared and is keeping your objectives top-of-mind through meticulous attention to detail.

Quality assurance services include:

Auditing

- Clinical and analytical laboratories
- Drug packaging and distributors
- Institutional Review Boards
- Investigator sites
- Phase I units
- Suppliers/vendors

Validation

- Computer systems
- Databases

Study deliverables

- Clinical study reports
- CRFs
- Protocols
- Study files
- Tables and listings

Regulatory inspection preparedness

- Assist preparing responses to inspection findings
- Conduct FDA and MHRA mock regulatory inspections
- Provide training to prepare investigator sites for regulatory inspections

AT A GLANCE: CONSULTING

CONSULTING

Changing pharmaceutical development regulations represent a complex environment in which to develop new therapeutics. To assist you in addressing these requirments, PharmaNet/i3 has assembled an exceptional team of international regulatory and pharmaceutical experts, physicians, and biostatisticians. Whether you have a product in preclinical or clinical development, PharmaNet/i3's in-house experts are proficient in the planning and execution of clinical trials and regulatory submissions.

PharmaNet/i3 professionals begin by understanding your objectives and goals, and then build a cohesive strategic plan to meet your specific needs. By getting involved early we can help anticipate potential issues and regulatory risks and build contingencies into the plan.

Expert advice backed by direct experience — it's just one more reason why PharmaNet/i3's regulatory and pharmaceutical consulting ***works for you.***

Consulting services include:

- 505(b)(2)
- Biostatistics
- Business plan services
- Chemistry, manufacturing, and controls (CMC)
- Clinical and product development
- Global safety and pharmacovigilance
- Life sciences investments
- Pharmacology and toxicology
- Regulatory services
- Toxicokinetics and clinical pharmacology

Consulting expertise includes:

- Biosimilars/follow-on biologic proteins
- Cell, gene, and tissue therapies
- Combination products
- Small molecules
- Large molecules; including therapeutic proteins such as monoclonal antibodies, and vaccines

AT A GLANCE: THERAPEUTIC EXPERTISE

THERAPEUTIC EXPERTISE

PharmaNet/i3 was one of the first CROs to establish dedicated therapeutic teams. Our staff has specialized operational and therapeutic experience to conduct clinical programs in several key therapeutic areas.

By concentrating the attention of experienced medical and scientific professionals in specific areas, we have gained a depth of knowledge that allows us to apply new insights and innovative science to clinical trials. PharmaNet/i3's therapeutically focused teams include experienced medical monitors, project managers, clinical research associates, data management professionals, biostatisticians, and medical writers.

From small to large molecule programs in a clinical environment or laboratory, PharmaNet/i3 can execute programs wherever patient populations, economic conditions, and regulatory environments are most favorable. Seamless trial management is ensured across multiple centers in the Americas, Europe, and the Asia-Pacific. Our relationships with leading academic institutions and study centers bring global resources to the forefront. From designing a regulatory strategy and meeting with health authorities, to gaining agreement on the study design — PharmaNet/i3 conducts therapeutically sound trials within the program timelines.

Therapeutic indications

- Cardiovascular
- EMD (endocrinology and metabolic disease)
- Dermatology
- Infectious diseases/vaccines
- Nephrology
- Neuroscience
- Oncology
- Ophthalmology
- Pain
- Rheumatology
- Women's health

Clinical development expertise

- Biosimilars
- Cell, gene, and tissue therapies
- Combination products
- Drug-delivery systems
- Generics
- Pediatrics
- Small molecule therapeutics
- Therapeutic proteins

AT A GLANCE: GLOBAL ADVANTAGE

GLOBAL ADVANTAGE

With offices and clinical trial experience from around the world and 7,000 employees in more than 30 countries, PharmaNet/i3 has the resources, access to patient populations, and therapeutic expertise to efficiently recruit, conduct, and complete projects ranging from a single study to a comprehensive product development program.

Although we are a worldwide enterprise with a comprehensive range of services, PharmaNet/i3 custom fits a team of top scientists and clinical research professionals to your project. This team is specifically chosen to meet your precise research objectives. Even though the size of your trials may vary, the quality of the science, the level of customer service, and the availability of cogent advice from the industry's leading experts remain the same.

This unique ability to scale our resources to your needs, without compromising quality, is what drives your success and ours — ***PharmaNet/i3 works for you.***

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Visit www.pharmanet-i3.com for a list of all our global locations.


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