AT A GLANCE

inVentiv Health clinical

inVentivHealthclinical.com

» TRANSFORMING PROMISING IDEAS INTO COMMERCIAL REALITY

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Overview

inVentiv Health Clinical is a top provider of global drug development services to pharmaceutical, biotechnology, generic drug, and medical device companies offering comprehensive Phase I/bioequivalence, Phase II-III, Late Stage (Phase IV) clinical development and clinical staffing services from a single clinical professional to an entire functional team.

We realize that healthcare companies are challenged every day to accelerate their pipelines while controlling costs. With 6,500 passionate employees operating in more than 70 countries, inVentiv Health Clinical conducts high quality drug development programs of all sizes around the world, delivering results for our clients and the patients they serve. Our global footprint and deep and diverse therapeutic expertise allows us to craft custom solutions to meet the specific needs of our clients now, while being flexible enough to change over time as their needs evolve.

As part of the inVentiv Health family of companies, we link our clinical expertise to the commercial and consulting services across the organization to ***transform promising ideas into commercial reality***.

INVENTIV HEALTH CLINICAL OFFERS:

- Phase I-IIA
- Bioanalytical
- Phase IIB-III
- Late Stage
- Strategic Resourcing
- Quality Assurance
- Consulting
- Therapeutic Expertise

Phase I-IIA

At inVentiv Health Clinical we have the ability to expedite clinical programs and build the foundation for continued development of the product. With more than 15 years of experience, we provide our sponsors with the appropriate talent, experience, processes and infrastructure to successfully conduct your clinical study. We offer a full range of services, from protocol development to report preparation, to help sponsors reduce costs, shorten timelines and achieve quality data.

Our broad exposure to different types of studies, therapeutic areas and dosage forms allows us to develop a creative and innovative design for studies, including first-in-man, proof-of concept, drug-drug interaction, single ascending dose/multiple ascending dose (SAD/MAD) and cardiac safety.

A dedicated project manager is assigned to each study, supported by a team of experts, including physicians and specialists in patient recruitment, clinical operations, quality assurance, biostatistics and clinical pharmacology. These experts work with sponsors to minimize risks and establish contingency plans, providing robust quality and regulatory controls to ensure protocol compliance and patient safety.

Strategic hospital partnerships and an extensive centralized database give us broad access to a significant population of potential participants, including special populations. This, along with our ability to develop efficient processes in all study areas, means we can effectively expedite the conduct of any study, regardless of its size or complexity.

All departments and business processes comply with current GLP, GCP and ICH standards, while an independent quality assurance unit validates study data and reports, providing the basis for our exceptional regulatory success. Advanced technology expedites studies and provides real-time data.

inVentiv Health Clinical's extensive experience, streamlined processes and state-of-the-art facilities can help mitigate risk in your Phase I-IIa programs. It's just one more way inVentiv Health Clinical is ***transforming promising ideas into commercial reality***.

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

Phase IIB-III

At inVentiv Health Clinical, 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, inVentiv Health Clinical 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

Late Stage

inVentiv Health Clinical Late Stage leaders help world-class companies bridge the gap from development to commercialization. The key is recognizing that Phase IIIb/IV research is undertaken for different reasons than pre-approval studies. Post-approval success is achieved through documentation and persuasive communication of safety and value, and through an operational approach that reflects the unique characteristics of Late Stage: different goals, different measures, different stakeholders, and different time frames.

Through the inVentiv Health family of companies, inVentiv Health Clinical 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

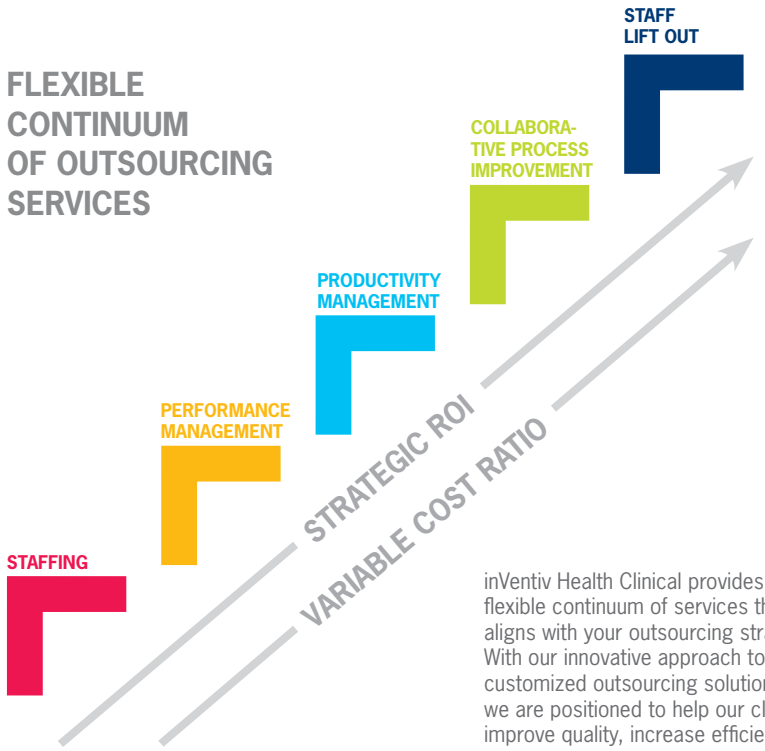
Strategic Resourcing

inVentiv Health Clinical provides a flexible continuum of services that aligns with our clients' outsourcing strategies. With our innovative approach to customized outsourcing solutions, we are positioned to help our clients improve quality, increase efficiency and manage cost. By offering the most experienced team in the industry, inVentiv Health Clinical provides expert clinical resources in customized solutions whether you need a single professional or an entire functional team.

Our dedicated functional teams have the experience to be your partner in clinical research. With experience in biostatistics, statistical programming, clinical monitoring, data management, medical writing, project management and pharmacovigilance, we deliver clinical development services customized to fit your objectives; whether you need support within a single function, multiple functions within a single therapeutic area or across your entire portfolio. We also have significant expertise in staff lift outs of clinical development functions to further significantly reduce our clients' fixed costs.

Working closely with each client, our team will determine the right level of service for your specific program.

- **Staffing:** Whether our clients need a single resource or a multinational team to work across one or more programs, we can provide professionals with experience in all phases of development, therapeutic areas, functional services and geographies. Our global staffing and recruiting division represents the convergence of more than 40 years experience in contract staffing, permanent placement, retained search and resource management. We have access to and continuously replenish our worldwide database of more than 300,000 clinical professionals to meet our client's resourcing needs.
- **Performance Management:** Our team can handle all aspects of day-to-day employee management including on-boarding, training, priority setting and workflow management. Our highly experienced team uses industry best practices, while permitting clients to determine the level of management control they want to retain.
- **Productivity Management:** We can manage resources and productivity and report back metrics and key performance indicators to help identify process inefficiencies and ways to streamline execution within our sponsor's program.
- **Collaborative Process Improvement:** Through shared governance of our sponsor's program we work closely with the client's team to analyze existing SOPs, identify bottlenecks and make recommendations that lead to more efficient processes.
- **Staff Lift Out:** When clients transfer their resources to us, we can dramatically lower their fixed cost. We can assume complete management of their team and focus on delivering the agreed upon outcomes. In this option, our clients have realized cost savings up to 30% compared to an "in house" approach.



inVentiv Health Clinical provides a flexible continuum of services that aligns with your outsourcing strategy. With our innovative approach to customized outsourcing solutions, we are positioned to help our clients improve quality, increase efficiency, and manage cost.

Bioanalytical

inVentiv Health Clinical provides high quality bioanalytical services across the entire continuum of drug development. Our significant experience with small and large molecules, peptides, immunochemistry, LC/MS/MS, HRMS, GC/MS/MS and ICP-MS, combined with having one of the largest capacities in the industry, allows us to blend innovative science with effective, validated processes to deliver quality data on time, every time.

Our approach to bioanalytical study management includes a project management team of knowledgeable scientists, regulatory resources and support staff that can rapidly respond to changing project needs and deliver results. Through our two GLP-compliant laboratories, we offer more than 1,000 validated assays, extensive method development and rapid data handling capabilities.

BIOANALYTICAL SERVICES INCLUDE:

GLP METHOD DEVELOPMENT VALIDATION AND ANALYSIS

- Biomarker support
- Large molecule
- Immunoassays

EXPLORATORY BIOANALYSIS

- Lead optimization
- Semi-quantitative and quantitative metabolite analysis
- High-quality tissue analysis
- Protein mass spectrometry and antibody drug conjugates
- Fast PK
- Dried blood spot analysis

Quality Assurance

At the heart of every inVentiv Health Clinical 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 of 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

Consulting

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

inVentiv Health Clinical 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 inVentiv Health Clinical's regulatory and pharmaceutical consulting help ***transform promising ideas into commercial reality***.

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

Therapeutic Expertise

inVentiv Health Clinical 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. inVentiv Health Clinical'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, inVentiv Health Clinical 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 — inVentiv Health Clinical 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

Global Advantage

With offices and clinical trial experience from around the world and 6,500 employees operating in more than 70 countries, inVentiv Health Clinical 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, inVentiv Health Clinical 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 — ***transforming promising ideas into commercial reality***.

PHASE I-IIA CLINIC

Quebec City, Quebec, Canada	+1 418 527 4000

BIOANALYTICAL LABORATORIES

Quebec City, Quebec, Canada	+1 418 527 4000
Princeton, New Jersey, USA	+1 609 951 0005

PHASE IIB-IV REGIONAL OFFICES

Princeton, New Jersey, USA	+1 609 951 6800
Maidenhead, Berkshire, UK	+44 1628 408408
Singapore	+65 6594 3570

STRATEGIC RESOURCING REGIONAL OFFICES

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