

**THERAPEUTIC EXPERTISE**



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➤➤ TRANSFORMING PROMISING IDEAS INTO COMMERCIAL REALITY



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# >> Overview

## APPLIED KNOWLEDGE. INTELLIGENT SOLUTIONS.

As one of the first CROs to establish dedicated therapeutic teams, we have specialized resources with the necessary operational and therapeutic expertise to conduct clinical programs in key therapeutic areas.

By concentrating the attention of experienced medical and scientific professionals in specific areas, we have gained a depth of knowledge that has allowed 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 programs in a clinical environment or laboratory, our therapeutic expertise is just one way we are **transforming promising ideas into commercial reality.**

### THERAPEUTIC INDICATIONS

- Cardiovascular
- Dermatology
- Infectious Diseases/Vaccines
- Nephrology
- Neuroscience
- Oncology
- Ophthalmology
- Pain
- Rheumatology
- Women's Health

### CLINICAL DEVELOPMENT EXPERTISE

- Biosimilars
- Cell, Gene, Tissue Therapies
- Combination Products
- Drug-Delivery Systems
- Generics
- Pediatrics
- Small Molecule Therapeutics
- Therapeutic Proteins

# Indications

## **CARDIOVASCULAR**

Because cardiovascular diseases claim millions of lives around the world each year, new and innovative therapies are in high demand. inVentiv Health Clinical's dedicated cardiovascular team offers expertise in all stages of program design and development. In late stage, inVentiv Health Clinical's cardiovascular team offers extensive clinical trial experience, expanded access programs, patient registries, and global safety and pharmacovigilance.

Our established relationships with many of the world's leading cardiovascular centers and specialists enable access to a large network of investigators and patient populations so that even large, multi-center global trials can be conducted effectively and on time. For clinical trials studying acute coronary syndromes, thrombosis, pulmonary hypertension, arrhythmia, diabetes, heart failure, hypercholesterolemia and many other conditions, inVentiv Health Clinical is transforming promising ideas into commercial reality.

## **DERMATOLOGY**

The inVentiv Health Clinical dermatology team is made up of clinicians and clinical research associates with extensive experience in dermatological studies. In hundreds of dermatologic trials involving tens of thousands of patients, inVentiv Health Clinical's dermatology team has studied topical, systemic, transdermal, transmucosal, inhaled, antibacterial, anti-fungal, anti-inflammatory, anti-viral, dry skin and wound-care products.

In addition to extensive ties with a global network of leading dermatological investigators, we are thoroughly familiar with both the objective and subjective ratings used to evaluate dermatological study results, including lesion counts and skin changes, such as color, roughness, moisture content and elasticity. Our extensive experience in products for skin and skin-structure infections includes NDA, AN DA and 505(b)(2) submissions; GMP, GLP and cGCP audits; and regulatory liaison.

## **INFECTIOUS DISEASES/VACCINES**

inVentiv Health Clinical experts in infectious disease and vaccine clinical trials offer a broad range of therapeutic expertise in bacteriology, virology, mycology, and associated diseases and syndromes. We have a proven record of success with all forms of regulated anti-infective and immunologic agents, including drugs, biologics and devices. We have significant experience with all commonly studied populations, including pediatric, as well as with populations with unique clinical issues, such as HIV infection, stem cell transplantation, chronic hepatitis, multidrug resistance, sepsis/septic shock and trauma.

To ensure the success of your vaccine study, our flexible monitor resourcing plans address short or lengthy follow-up recruitment periods. We have expertise in a variety of therapeutic indications for all age groups, including HIV and HPV infections, meningitis, pneumococcus, influenza and therapeutic vaccines. inVentiv Health Clinical's immunology monitoring service offers multiplexed flow-cytometry to provide assays with up to 15 different parameters, working with both fresh and preserved blood specimens. We can also perform immunology assays simultaneously, analyzing multiple immune response measurements to provide a broad and more sophisticated evaluation of patient response to the vaccine.

## **NEPHROLOGY**

Chronic Kidney Disease (CKD) devastates millions of lives every year. The board-certified nephrologists and other specialists that make up the inVentiv Health Clinical nephrology team have significant hands-on experience, including studies of factors influencing the morbidity and mortality of patients on hemodialysis, studies of treatments for hypertension and investigations into patients with glomerulonephritis, diabetes, hypertension and other nephropathic conditions. Our strong clinical relationships with leading nephrology centers and specialists mean inVentiv Health Clinical's nephrology team has access to specialized patient populations, including renal transplants, ESRD and pre-ESRD, and patients on hemodialysis and peritoneal dialysis.

# >> Indications

## NEUROSCIENCE

With significant unmet medical needs in the treatment of Alzheimer's disease, cognitive disorders, stroke, multiple sclerosis, Parkinson's disease, seizure disorder, schizophrenia and other major neuroscience disorders, the demand for innovative therapies is high and expected to grow. inVentiv Health Clinical's neuroscience team is led by board-certified physicians, neurologists and other neuroscience-experienced clinicians.

By maintaining strong relationships with leading psychiatrists, neurologists and neuroscience investigators worldwide, inVentiv Health Clinical has conducted more than 150 neuroscience trials from Phase I through Phase IV programs, from single-site Phase I studies to large, global programs.

## ONCOLOGY

inVentiv Health Clinical's strong global oncology project teams have conducted hundreds of regional and global oncology trials involving tens of thousands of patients and many different classes of therapeutics, including cytotoxic chemotherapies, monoclonal antibodies, targeted therapeutics, immunotherapies, pathway inhibitors and therapeutic vaccines.

We have successfully conducted programs in all stages of development, including eleven registration programs that resulted in five NDA/MAA approvals. inVentiv Health Clinical has extensive experience in First-in-Man (FIM) through Expanded Access Protocols (EAPs) in most solid tumor types, including breast, lung, prostate, NHL, and colorectal and hematological malignancies (such as multiple myeloma and leukemias). Project sizes range from regional to large, global programs.

## WE HOLD SPECIFIC KNOWLEDGE IN THE DEVELOPMENT OF NEUROLOGICAL THERAPEUTICS, INCLUDING:

- Acute and Chronic Pain
- Addiction
- Alcohol Addiction
- ALS
- Alzheimer's Disease
- Anxiety
- Bipolar Disorder
- Depression
- Eating Disorders
- Epilepsy
- Fibromyalgia
- Migraine
- Multiple Sclerosis
- Neurology
- Pain Management
- Parkinson's Disease
- Peripheral Neuropathy
- Schizophrenia
- Sleep Disorders

# >> Indications

## OPHTHALMOLOGY

inVentiv Health Clinical's ophthalmology team comprises ophthalmic-experienced clinicians and other team members providing expertise in all key areas, including the objective evaluation of examinations and procedures to assess visual acuity, intraocular pressure, automated perimetry, biomicroscopy, ophthalmoscopy and other eye care tests. Our ophthalmology professionals are also well-versed in the requirements of ophthalmic product development programs and provide current knowledge of competitive compounds, therapeutic practices, protocols and case report forms.

In addition to evaluating data submitted by study staff, the team offers expertise in managing independent vendors that provide certification, such as certifying visual acuity examiners. They can also act as reading centers to certify fundus photographers, fluorescein angiographers and optical coherence tomography (OCT) technicians.

inVentiv Health Clinical's ophthalmology team has strong relationships with more than 500 investigator sites and a large pool of appropriate study participants in addition to experience on hundreds of ophthalmology studies involving ethical pharmaceuticals, devices and over-the-counter products.

## PAIN

inVentiv Health Clinical's team of pain management specialists conducts a wide variety of analgesic-related studies for small and large molecules targeted at post-surgical pain, neuropathy, cancer pain, headaches, dermal and laser procedure, migraine, osteoarthritis and back pain.

Specialized project teams are familiar with pain measurement scales, including headache records, likert, visual analog, and pediatric scales and observer scoring.

## EXAMPLES OF STUDIES THE OPHTHALMOLOGY DIVISION HAS PARTICIPATED IN:

- Devices
  - Contact lenses
  - Intraocular lenses
  - Lasers
  - Ocular implant lubricants
  - Punctal plugs
  - Silicone oils
  - Viscoelastics
- OTC Products
  - Anti-infectives
  - Artificial tears
  - Contact lens care products
  - Lubricants

## ETHICAL PHARMACEUTICALS ADDICTION STUDIES WE HAVE EXPERIENCE WITH:

- Aldose reductase inhibitors
- Alphasblockers
- Anti-angiogenics
- Anti-bacterials
- Anti-cataract medications
- Betablockers
- Carbonic anhydrase inhibitors
- Cycloplegics
- Immunosuppressants
- Mast cell stabilizers
- Monoclonal antibodies
- Mydriatics
- NSAIDs
- Prostaglandins
- Retinoids
- Steroids
- VEGF inhibitors

# >> Indications

## RHEUMATOLOGY

inVentiv Health Clinical's rheumatology team has extensive experience in standard scales for osteoarthritis and in developing treatment options for osteoarthritis, rheumatoid arthritis, osteoporosis and undifferentiated connective tissue disease. inVentiv Health Clinical's rheumatology team has extensive experience in standard scales for osteoarthritis and in developing treatment options for osteoarthritis, rheumatoid arthritis, osteoporosis and undifferentiated connective tissue disease. Our studies have included a variety of treatments administered orally or via injection (intra-articular, subcutaneous and intravenous). Studies have included a variety of treatments administered orally or via injection (intra-articular, subcutaneous and intravenous).

inVentiv Health Clinical's large network of experienced investigators provides timely recruitment for rheumatology studies on a global basis.

## WOMEN'S HEALTH

In many different areas of health and medicine, women's needs are wholly different from men's. But just knowing the gender differences in disease patterns is not enough to do breakthrough research – firsthand experience in running these unique trials is vitally important. inVentiv Health Clinical offers a dedicated team of professionals focused solely on the clinical investigation of pharmaceuticals, biologicals and medical devices that hold promise for improving women's health.

## WOMEN'S HEALTH EXPERTISE INCLUDES:

- Breast Carcinoma
- Breast Implantation
- Contraception
- Fertility
- Gynecological Infections
- Gynecological Malignancies
- Hormonal Therapies
- *In Vitro* Fertilization
- Menstrual Disorders
- Osteoporosis
- Pregnancy and Labor
- Sexual Dysfunction
- Urinary Incontinence
- Uterine Disorders

# Clinical Development

## **BIOSIMILARS**

The U.S. Food and Drug Administration is exploring new regulatory pathways for the development of generic versions of biologics, also known as biosimilars. Although many factors impacting the regulatory pathway in the U.S. are still being assessed and evaluated, Europe and Asia have defined pathways in place.

The nature of biologics means biosimilar development requires a specific skill set, including immunochemistry expertise, clinical development experience with biologics, pharmacovigilance capabilities, regulatory relationships and expertise, and a thorough understanding of existing generic drug development approaches. inVentiv Health Clinical excels in all of these areas.

## **CELL, GENE AND TISSUE THERAPIES**

Cell, gene and tissue therapies offer unprecedented opportunities to both biotechnology companies and life science investors. inVentiv Health Clinical's consulting professionals provide expert guidance on predicting commercial feasibility, complying with GMP guidelines and evolving regulatory requirements, controlling biomaterial sources and analyzing key issues in business opportunities.

inVentiv Health Clinical's pharmaceutical and regulatory consulting team includes senior-level expertise from the Office of Tissue, Cell/Gene Therapy (OTCGT). Our consulting services provide assistance with study design, regulatory strategy, Chemistry/Manufacturing Control (CMC) issues, assessment of long-term risks, and interpreting actions and policies of worldwide regulatory agencies.

## **COMBINATION PRODUCTS**

The challenges involved in the development, manufacture and regulation of combination products can be exponentially more difficult than those faced by the drug or device alone. inVentiv Health Clinical professionals can assist in their development, having been involved in designing and conducting clinical trials for drug-device and drug-drug combination products, assisting with manufacturing issues, preparing and submitting marketing applications for these products, and helping to develop the approach taken by international regulatory agencies to combination product jurisdiction, regulation and technical/clinical evaluation.

## **DRUG-DELIVERY SYSTEMS**

inVentiv Health Clinical's professionals offer significant experience in designing and conducting clinical studies for drug delivery systems, as well as providing regulatory and technical consultation in preparing and submitting regulatory documents for these products. Delivery system categories in which inVentiv Health Clinical has assisted sponsors include oral, inhalation, transdermal, needlefree injection, catheter and implantable.

## **GENERICS**

inVentiv Health Clinical offers a comprehensive range of services, advanced facilities and equipment, and highly trained personnel for conducting bioequivalence studies across a broad spectrum of therapeutic areas. During more than a decade of providing these services, inVentiv Health Clinical has developed a deep understanding of the unique requirements of generics, including utilizing the 505(b)(2) pathway, as well as strong relationships with international regulatory agencies, such as FDA, EMEA, HPFB, AN VISA and TGA.

# Clinical Development

## **PEDIATRICS**

Studies in infants, children and adolescents require special expertise in a wide variety of areas. In addition to regulatory advice on the FDA's Modernization Act (FDAMA), Pediatric Rule, U.S. Pediatric Research Equity Act, the Best Pharmaceuticals for Children Act (the FDA's Amendment Act, or FDAAA), and the EU Regulation on Medicinal Products for Paediatric Use, we provide medical oversight of active clinical trials, with special attention given to patient eligibility and monitoring of efficacy and safety in pediatric populations, age-specific informed consent and assent issues, and age-appropriate chemical formulations. Many of our clinical research associates have experiences with pediatric clinical trials.

inVentiv Health Clinical's experienced professionals can provide input into study reports and regulatory filings, including interpretation of age-dependent laboratory and other data. We have proven methodologies to enhance enrollment, consistent with applicable ethical and age-based standards. Our database of pediatric investigators, including investigators affiliated with Pediatric Pharmacology Research Units, allows us to quickly fill and complete pediatric trial programs in the Americas, Europe and Asia Pacific regions.

## **SMALL MOLECULE THERAPEUTICS**

Well-planned regulatory strategies – including Chemistry/Manufacturing Controls (CMC), pharmacological and toxicological studies – are critical for drug development programs. inVentiv Health Clinical pharmaceutical and regulatory consulting experts can assist you with regulatory strategy, CMC preparation, clinical trial design issues and other technical considerations to gain marketing approval for your products.

## **THERAPEUTIC PROTEINS**

inVentiv Health Clinical consulting professionals can assist you with many aspects of developing therapeutic proteins, monoclonal antibodies and biosimilar products. inVentiv Health Clinical pharmaceutical and regulatory consultants call on their experience as senior-level FDA officials to offer advice on every stage of the regulatory process, from planning a biologics license application (BLA) to establishing a post-marketing registry to track product safety.





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