

Respiratory and infectious disease trials are complex and fast-paced, and sponsors need a CRO that understands the unique demands of these categories. As therapeutic specialists, i3 Respiratory and Infectious Diseases has been there. Our experience since 2001 includes 69 studies at over 10,000 sites with more than 97,000 patients. Our medical and scientific specialists and operational staff have proven experience in respiratory and infectious diseases. We apply this therapeutic expertise to understand, anticipate, adapt, and deliver, staying attuned to the therapeutic nuances of each indication—and our clients' goals.

Strategic thinking, operational excellence

Our dedication to respiratory and infectious diseases means we provide in-depth scientific insights and tailor our processes and teams to meet the demands of the project—maintaining speed, precision, and quality. Senior management not only offers strategic thinking, but also stays involved in study execution. On the operational level, our project managers and CRAs have substantial expertise in respiratory and infectious disease trial management, and therapeutic knowledge shapes every aspect of a trial.

Respiratory experience

Narrow time windows, seasonal and regional factors, constant change: i3 RID has the expertise to handle respiratory trials and their challenges. We have managed all phases of clinical trials in respiratory medicine, including design, execution, analysis, and interpretation.

We understand the unique operational aspects that affect respiratory trials:

- Use of medication delivery systems (MDI, DPI, SVN, Injectable)
- Quality of life, symptom assessment, and patient diary data collection instruments
- Patient-reported outcomes
- Collection of pulmonary function measures, such as spirometry (including centralized) home peak flow measurement (including electronic and remote data collection)
- Impact of seasonal factors on study logistics and timelines (i.e., impact on disease exacerbation)

Respiratory indications:

- Allergic rhinitis (seasonal and perennial)
- Asthma
- Bronchitis
- COPD (chronic bronchitis, AECB, emphysema)
- Rhinitis (common cold)
- Cystic fibrosis (pulmonary infections)
- Respiratory syncytial virus infections

Respiratory therapies evaluated:

- Anti-inflammatory (inhaled corticosteroids, leukotriene inhibitors, anti-IL4)
- Bronchodilators (short- and long-acting beta agonists, anticholinergics, PDE4 inhibitors)
- Antihistamines
- Combination products

Infectious disease expertise

Whether it's finding the right patient populations anywhere on the globe or understanding sponsor and site challenges, i3 has experience managing the complexities of infectious disease trials. Our infectious disease experience spans multiple important indications and most phases of research.

INFECTIOUS DISEASE INDICATIONS:

- HIV/AIDS
- Hepatitis B and C
- Gastroenteritis
- Bronchitis
- Rhinitis (common cold)
- Urinary tract infection
- Oropharyngeal candidiasis
- Cryptococcal meningitis
- Vaccines
- Cystic fibrosis (pulmonary infections)

INFECTIOUS DISEASE THERAPIES:

- Antiviral drugs for treatment of HIV, HBV, HCV, influenza, and respiratory syncytial virus infection
- Vaccines
- Antibacterials
- Antifungals
- Genetically recombinant antibodies

Expanded access, patient registries

In addition to managing Phase I–III programs, we also have experience with late phase trials, including expanded access and patient registry studies. Our detailed understanding of these programs enables us to plan, launch, and run them with great efficiency. We work to balance the needs of the investigative sites with the needs of the sponsor, adapting as required.

Global reach

We have been on the ground in six continents—recruiting investigators, establishing enrollment goals, monitoring sites, managing data, providing regulatory support, and pursuing our clients' objectives. We have field-based teams in eight countries and capabilities in more than 45 countries, and we have provided comprehensive services from investigator selection to site close-out for trial sites on a global scale. Our experience managing complex trials has helped clients speed their infectious disease treatments to market to help patients around the world.

Find out what i3's specialized approach can do for your next respiratory or infectious disease study.

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