

Infectious Disease

At INC Research, we understand that infectious disease research in areas such as HIV, hepatitis, malaria, influenza, nosocomial pneumonia, intra-abdominal infections and other pressing illnesses present unique challenges for successful study conduct. Complex considerations include:

- Difficult populations for enrollment, both adult and pediatric
- Intensity of laboratory measures
- Global locations
- Accelerated timelines due to pressing illnesses
- Loss to follow up of long duration study patients

We understand and anticipate those challenges to offer our customers creative solutions from our highly-seasoned team. We direct Phase I-IV adult and pediatric clinical trials in infectious disease leveraging our Trusted Process® methodology to deliver actionable results on time and on budget.

Hundreds of projects successfully completed

We've conducted hundreds of projects over the years from full-service clinical trials to partial service programs. A high percentage of these projects were completed through repeat services and long-term relationships – some of which have lasted more than 10 years and are a true testament to our customers' satisfaction.

With one customer, over the course of 10 years, INC Research successfully completed more than 15 trials and numerous FDA submissions for a quinolone. These studies were all conducted on time and on budget and more than 40 percent of the trials completed enrollment prior to the targeted timelines.

All the studies were full-service projects including submission and liaison work with the FDA. The repeat business from this client is a testimony to the quality of work and timeliness of approvals from the regulatory agency.

Comprehensive infectious disease experience

INC Research's Infectious Disease team has experience in all stages of infectious disease research from initial clinical plan development and Phase I-IV study conduct to the filing of INDs, NDAs, sNDAs and ex-U.S. submissions. Our experience spans both pediatric and adult trials of all levels of complexity, from Phase I to highly-complex Phase II and III clinical trials, and from treating everyday infections to fighting highly-resistant pathogens in an intensive care setting.

Our therapeutically-focused team of physicians and operations staff have the experience, passion and knowledge crucial to delivering your projects on time and on budget.

Experience includes work in the areas of:

- Antivirals:
 - HIV, RSV, hepatitis B, hepatitis C, orthopoxvirus
 - Antibacterials:
 - Community-acquired pneumonia
 - Healthcare-associated pneumonia
 - Complicated skin and soft tissue infection
 - Febrile patients with neutropenia
 - Sinusitis
 - Urinary tract infection (UTI)
 - Prostatitis
 - *C. difficile* infection
 - Bronchitis
 - Intra-abdominal infection
 - Traveler's diarrhea
 - Bacteremia
 - Otitis externa
 - Otitis media
 - Nongonococcal urethritis
 - Acne, rosacea
 - Shigatoxin-producing *E. coli*
 - Sepsis
 - Bacterial vaginosis
 - Antifungals:
 - Aspergillosis, candidemia, zygomycosis, onychomycosis
 - Vaccines:
 - Viral – influenza, dengue fever, encephalitis, meningitis, herpes, smallpox, HIV, rotavirus, Ross River virus
 - Bacterial – tuberculosis, anthrax, *S. pneumoniae*, *H. influenzae*, *C. difficile* toxin, *E. coli*, *C. jejuni*
 - Combination vaccines
 - Antiprotozoal – malaria, chagas disease
 - Other – pediculosis
 - INC Research also has extensive experience in the clinical development of products for biodefense
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Access to infectious disease investigators and patient populations worldwide

Success requires planning with foresight of the end goal. Our proactive and detail-oriented project planning leverages our extensive database and well-nurtured relationships with key physician investigators specializing in infectious disease drug development in both private practice and academic settings across the globe.

Our long-standing relationships with experienced physician investigators provide access to a vast population of both adult and pediatric patients, as well as immunocompetent and immunocompromised patients for both in-patient and out-patient Phase I-IV trials.

Global reach, individualized solutions

At INC Research, our infectious disease team provides strategic access to sites, opinion leaders and authorities worldwide. Well connected and supported by the most advanced technology, our international project teams are dedicated to meeting and often exceeding each customer's unique research, development and regulatory needs. Leveraging our Trusted Process, we focus our energies, expertise and resources where and when you need them to meet your individual infectious disease drug development research goals.

AECB Phase III study

Our infectious disease team provided full-service support for a Phase III global trial in acute exacerbations of chronic bronchitis (AECB), the first of its kind being conducted under the new FDA guidelines requiring placebo-controlled superiority trials for antibacterial treatment of AECB.

We were asked to rescue the study from another CRO due to slow subject recruitment and low evaluability rates, which threatened to increase the required sample size. We ensured the appropriate subjects were enrolled, which afforded the customer every opportunity to show superiority of their drug as compared to placebo.

Enrollment increased more than two fold in less than half the time. The quality of data and evaluability rate also increased. By leveraging our infectious disease expertise, global reach and Trusted Process methodology the study achieved a QualityFinish. The customer was very pleased and able to submit results at a key scientific meeting.

For more information

about INC Research's capabilities in infectious disease, please contact us at info@incresearch.com or at one of the telephone numbers below:

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