



IMMUNOLOGY AND INFLAMMATION CLINICAL RESEARCH SERVICES

Your Global Partner in Phase I-IV Immunology & Inflammation Studies Powered by Patients, Technology Tools & Data, and Operational Excellence

Immunology and inflammation clinical research is rapidly advancing. Despite these innovations — such as adaptive and basket trial designs — sponsors still face significant challenges. High screen failure rates, unpredictable treatment responses and the need for interdisciplinary collaboration can complicate trial success.

Expert Solutions for Immunology & Inflammation Trials

At Advanced Clinical, we understand the challenges emerging biotechnology and pharmaceutical companies face in bringing innovative therapies to market. Our flexible, patient-centered operational strategies and expert planning help companies incorporate country-specific and regulatory requirements into clinical trials from the start, ensuring efficient and successful studies.

Leveraging global expertise across Phase I-IV trials, the Advanced Clinical team incorporates patient and site insights to align site selection and recruitment with study objectives, while utilizing data and tools to optimize each trial for success. With deep operational experience, our team is committed to delivering precise, results-driven solutions tailored to the requirements of each study.

Why Partner With Advanced Clinical?

With operations around the globe, our team is well equipped to provide you with localized support for immunology and inflammation clinical trials.

1. Optimized Patient Recruitment & Retention

Our team targets specific barriers in immunology and inflammation trials with tailored communication strategies, ensuring efficient recruitment and retention. According to a recent survey that Advanced Clinical conducted with [StuffThatWorks](#) and [Know Rare](#), patients with immune-inflammatory conditions were significantly more likely to search for information about clinical studies related to their condition, underscoring the need for targeted outreach. Additionally, these patients were more likely than others to say that an online app with study information would have improved their trial experience, highlighting the importance of accessible digital resources. Our partner, AI-powered health crowdsourcing platform StuffThatWorks, with a 3 million patient engaged community, allows Advanced Clinical and our sponsors to gain patient and caregiver insights, while access to medical claims and social determinants of health data sources and an EMR system with over 132 million active patients boosts site and patient reach.

2. Comprehensive Trial Support

Advanced Clinical offers robust and detailed operational and logistical planning, from epidemiology and diversity review, standard of care overview and study time lines to patient visit schedules, ensuring seamless trial execution. Patient responses expressed a preference toward learning about clinical research opportunities early in the disease journey rather than later in their experience when there are no other options. That is why early planning and trial recruitment are crucial aspects of the trial support we provide.

“One of our immunology studies had some complexities that required special submissions. Although the EU CTIS (Clinical Trials Information System) submission process is intended to streamline submissions in EU countries, each country has its own authorization procedure for ATMP (Advanced Therapy Medicinal Product) and GMO (Genetically Modified Organism) products. We were able to provide our sponsor with trainings on ATMP/GMO submissions in the countries in question and had successful submissions and approvals.”

Kirsten Krusche-Ziemann, Principal
Global Study Start-Up Lead, EU



3. Maximizing Trial Value

Our comprehensive patient engagement and support services, including awareness and education, travel assistance and expense compensation, enhance satisfaction and retention, minimizing patient burden. In our patient survey, numerous immune-inflammatory patients also responded that travel support, compensation for time off work or compensation for study-related expenses could have improved their experience.

4. Tailored Approaches for Complex Conditions

Advanced Clinical specializes in immunology and inflammatory clinical trials, customizing study designs and recruitment strategies based on condition-specific expertise and real-world data. Our experience in complex studies, such as cell and gene therapies, ensures compliance with regulatory standards. Approximately 25% of immune-inflammatory respondents to our survey, compared to 21% of non-immune-inflammatory respondents, have participated in clinical research. The survey also provides some evidence to suggest that in the context of immune-inflammatory conditions, as the prevalence of a condition increases, the likelihood that a patient with that condition has participated in clinical research decreases. Providing tailored approaches for these complex conditions goes hand in hand with providing a comprehensive patient experience in immunology and inflammation clinical research.

“As a Medical Monitor and former investigator, I understand the challenges clinical sites face. Acting as the sponsor’s local and regional representative, I focus on balancing clinical measures with patient-reported outcomes in rheumatoid arthritis (RA) trials. Accurate joint assessments and ACR response rates can be challenging due to the variability of PROs. By focusing on both clinical and patient-centered endpoints, we can better evaluate therapeutic efficacy.”

Ana Regina Madrid, Senior Medical Monitor, Australia

ADVANCED CLINICAL IMMUNOLOGY AND INFLAMMATION EXPERIENCE BY PHASE

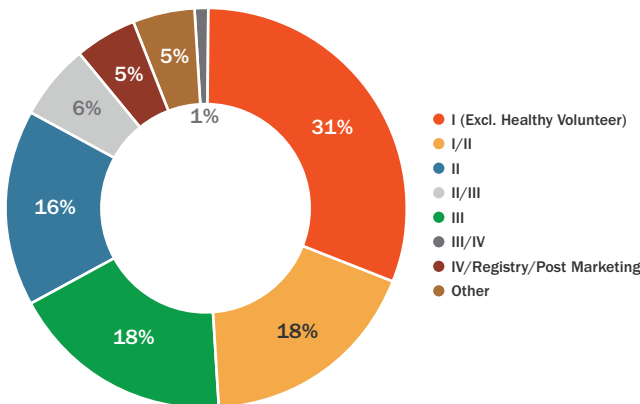


Figure 1: Our team has extensive experience across all phases of complex studies, including cell and gene therapies, with deep expertise in navigating regulatory and adhering to stringent safety guidelines.

ADVANCED CLINICAL'S IMMUNOLOGY AND INFLAMMATION THERAPEUTIC EXPERTISE

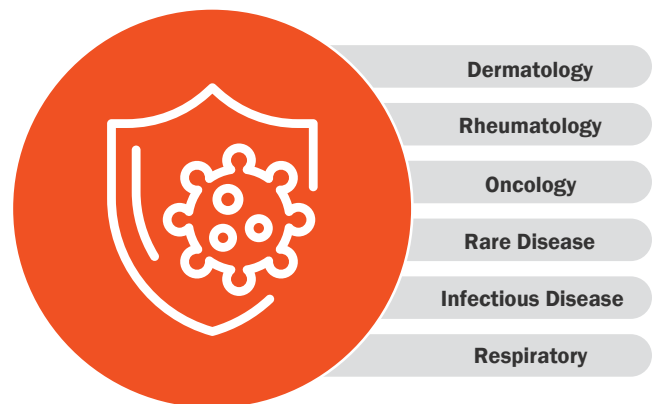


Figure 2: Our team has experience across a wide variety of indications, including rheumatology, oncology, rare disease, metabolic-endocrinology, dermatology, respiratory and infectious disease.

Partner With Us to Drive Success in Immunology and Inflammation Clinical Trials — Let's Collaborate.

ABOUT ADVANCED CLINICAL

Advanced Clinical is a clinical development and strategic resourcing organization committed to providing a better clinical experience across the drug development journey. Our goal is to improve the lives of all those touched by clinical research – approaching each opportunity with foresight, character, resilience and innovation. Based on decades of experience, we help our clients achieve better outcomes by conducting candid conversations and anticipating potential issues through our customized solutions.

Visit our website to learn more: www.advancedclinical.com