Immune-Mediated Inflammatory Diseases
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The new inflammation paradigm

Growing markets, increasing opportunities

IMIDs: Immune-Mediated Inflammatory Diseases

Global impact of IMIDs

A new understanding of inflammation has changed the drug development landscape for several major diseases affecting millions of people worldwide. These include:

- Asthma
- Chronic obstructive pulmonary disease (COPD)
- Psoriasis
- Rheumatoid arthritis (RA)
- Systemic lupus erythematosus (Lupus)
- Inflammatory bowel disease (IBD) (includes ulcerative colitis and Crohn’s disease)

Drug development has traditionally focused on treating the symptoms of each disease separately, with limited integration of research and clinical trial design.

Today, the discovery that these conditions share a common underlying immune system response mechanism is driving a new, interconnected approach: targeting these immune-mediated inflammatory diseases (IMIDs) as a unified area focused on mechanism-based disease modification.

Growing markets, increasing opportunities

IMIDs represent a significant and escalating global threat in terms of morbidity, mortality, and quality of life.

This represents a growing opportunity to develop new treatments designed to modify these disease states; enter new markets; and expand market share.

Covance has aligned our medical, scientific, and operational resources to support your drug development needs under this new IMID paradigm.
Solutions to your IMID drug development challenges

Solutions for your success

Integrated capabilities aligned with your needs

To gain competitive advantage in the IMID drug development market, you need to overcome the operational challenges that can slow your progress and reduce the possibilities for understanding your compound’s safety and efficacy.

Covance’s integrated capabilities span the full range of services, resources, and expertise you need to conduct effective and cost-efficient IMID studies that enable you to make better decisions faster—based on high-quality primary data.

- Placebo response rates
- Investigator interest
- Patient retention
- Patient compliance
- Site performance
- Objective endpoints
- PRO reporting

Challenge:
If your trial is conducted at a low-performing site, it can have a detrimental effect on your study timelines, data quality, and clinical ROI.

Covance solution:
Using our Xcellerate® platform, we will provide customized recommendations for selecting and monitoring the most appropriate site, investigator, and location to deliver patient enrollment—helping to reduce the drain on your resources, decrease your trial timelines, and enhance your clinical ROI. With our robust network of clinical trial sites and investigators, we can also quickly deploy standby sites to keep your trial on track, even when unexpected problems arise.

Challenge:
High placebo response rates observed in IMID trials (e.g., psoriasis 14-20%; RA 30%; ulcerative colitis >30%) can mask treatment effects, putting the success of your drug at risk.

Covance solution:
High placebo response rates in IMID trials are often related to “eligibility creep”—a significant risk in trials when disease severity is evaluated using subjective self-reporting or investigator assessment methods. Covance helps you reduce placebo response rates through careful study evaluation, investigator training, and by monitoring investigator and site performance using our Xcellerate® platform.

Challenge:
Patient reported outcomes play a crucial role in the differentiation of new products in the crowded IMID market. Improper selection of PROs can result in missed opportunities for differentiation, PRO label claims, and accurate patient assessment.

Covance solution:
Drawing on our combined GHEOR and clinical development experience and resources, Covance offers an integrated approach to PRO strategy and management. We help identify PROs which are targeted at creating differentiation and guide our clients through the PRO label claim process. We also offer PRO management in the clinical trials to ensure translation and ePRO readiness for any clinical trial scenario.

Challenge:
Because many new IMID therapies are injectable biologics, self-administration can be challenging for patients, leading to noncompliance and/or reduced drug efficacy.

Covance solution:
As your clinical trial partner, we ensure that your study subjects are properly trained and monitored throughout the screening period and entire trial.

Challenge:
The use of objective endpoint measurements in IMID clinical trials (e.g., radiographic imaging (RA) and lesion photographs (psoriasis)) can enhance the precision and accuracy of your data, but they often require specialized assessment techniques.

Covance solution:
Leveraging our imaging experience in oncology studies, Covance can perform a centralized review and analysis of images obtained for your objective endpoints to reduce data variability.

Challenge:
In the highly competitive IMID clinical trial arena—where the demands on investigators are high, the pool of subjects is limited, and study durations are often long—investigator interest may be lacking and difficult to maintain.

Covance solution:
Covance will provide customized recommendations for recruiting and retaining qualified investigators. We have the experience needed to tailor your study protocol, sample size requirements, investigator remuneration, and other elements to drive instructor engagement throughout your clinical trial.

Challenge:
IMID clinical trials are often lengthy and involve complex protocols, making it difficult to retain subjects for the entire duration of the study.

Covance solution:
Covance proactively “pressure tests” each protocol and study and recommends a customized mix of approaches and tools to promote continued study participation.
An interconnected perspective

Integrated capabilities across IMIDs and a full range of drug development services

Like you, Covance targets IMIDs as an interconnected area that requires an interconnected approach—commercially, medically, and operationally.

Our unique integrated approach offers valuable opportunities to leverage our medical and operational experience across related diseases, enabling you to benefit from our strategic insight and obtain faster, high-quality results. Our broad range of integrated Phase I-IV drug development services includes:

- Clinical trial monitoring and project management
- Site services
- Data management
- Biometrics and medical writing
- Central laboratory services
- Quality assurance and control
- Patient safety
- Regulatory submissions
High-quality data—for better answers, sooner

Enhance site selection, reduce waste, and improve ROI

You depend on high-quality, reproducible data to get the answers you need early in the drug development process—so you can make the right decisions about what steps to take and what opportunities to pursue.

Xcellerate® is Covance’s unique, proprietary approach to forecasting, investigator and site selection, and clinical trial management. We will help you:

• Efficiently evaluate each potential study.
• Engage investigators likely to help you meet patient enrollment goals from the start.
• Obtain faster clinical outcomes, less waste, and more consistent and predictable on-budget studies.

As your IMID partner, we will also help you avoid scope creep and cost overruns while proactively preventing resource waste.
Our approach: aligned with your perspective and your needs

Targeting IMIDs as a cohesive area

Faster decision-making and results

Increased clinical ROI

Reduced risk

Global studies

Your partner for a new IMID paradigm

Creative, customized solutions to your IMID clinical trial needs

As your IMID drug development partner, our goal is to provide creative, customized solutions to your clinical trial needs. You will benefit from our deep and broad expertise of IMIDs and related diseases. We are medically, scientifically, and operationally aligned with the new IMID paradigm and your drug development goals and requirements.

For more information, contact your account executive or visit us online at www.covance.com/inflammation.