Immune-Mediated Inflammatory Diseases
Accelerating drug development starts here

Rigorous lab testing that produces consistent clinical data—and drives the success of your clinical trial

Immune-Mediated Inflammatory Diseases: IMIDs

A new understanding, a new approach

There has been a paradigm shift in our understanding of inflammatory disease and the immune system. In the not-too-distant past, drug developers focused on therapies targeting specific organs and symptoms.

Now, research has revealed the underlying immune system response mechanisms shared by some of these seemingly unrelated conditions.

New opportunities for success

The revolutionary change in our understanding of immune-mediated inflammatory diseases (IMIDs) offers unique opportunities for pharmaceutical companies and their future R&D efforts.

This approach may lead to:

• Future mechanistic applications vs. single disease state usage

• Enhanced value of your clinical portfolio

• Extended commercialization potential for existing therapies

The leader in IMID drug development

Covance experience includes 14 of 15 top IMID drugs.

The IMID revolution is here:

New targets for therapy

Expanding markets for your products

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Over the past five years:

- 450+ IMID trials
- 75+ countries
- 18,000+ investigator sites
- 150,000+ patients

Experience inspires innovation

Covance delivers excellence, so you can deliver life-changing treatments

New challenges—and a partner with the experience to help you overcome them

The choice of a central lab can have a significant impact on the success of your IMID drug development efforts.

The lab you choose must:

- Ensure high-quality end-to-end sample management
- Maintain tightly controlled, rigorous testing practices
- Produce globally consistent, reliable data
- Balance the demands of trial complexity with global patient populations and diverse assay requirements

Covance Central Laboratory Services can help you overcome these challenges and achieve success—and your patients always come first.

Partner with Covance for assured data consistency—every day, every trial, every site.

We offer:

- Globally consistent testing platforms and SOPs
- Global automated kit production
- Customized training materials & tools based on the specific requirements of your protocol
- Dedicated oversight of your investigators and your trial sites
- In-house capabilities for more than 550 assays
- Extensive assay validation capabilities

Sites are located in convenient areas with easy access to research institutions, study populations, and transportation routes.

Covance CLS offers access to diverse study populations around the world, including treatment-naive potential study subjects.

- Rheumatoid Arthritis (RA): 169 studies
- Lupus: 30 studies
- Chronic Obstructive Pulmonary Disease (COPD): 66 studies
- Asthma: 97 studies
- Psoriasis: 52 studies
- Inflammatory Bowel Disease: 42 studies
In-house capabilities:

Medical and scientific consultation

More than 550 assays

CAP/CLIA assay validations

Powerful results depend on reliable data

Data consistency drives your success

Rigorous SOPs enable better decisions

Data consistency is critical to FDA approval and successful commercialization of your IMID drug. Achieving data consistency is a challenge in any clinical trial—but especially when your trial is conducted globally, with constant pressures of tight budgets and short timeframes.

To ensure that your study produces consistent data meeting all regulatory compliance requirements, you need a partner with proven methodologies and experienced technical staff. Our innovative laboratories process more clinical trial samples than any other central lab in the business.

In-house capabilities: Key IMID assays

Delivering global data consistency

Covance CLS offers unique in-house capabilities and dedicated support for a variety of key IMID assays to ensure that you obtain consistent data—and help accelerate your clinical trial.

Anti-Nuclear Antibody Indirect Fluorescence Assay (ANA-IFA)
Lower cost, improved turnaround time, unmatched data consistency.

Erythrocyte Sedimentation Rate (ESR)
Consistent assays for improved patient screening and better decision-making.

QuantiFERON®-TB Gold Assay (QFT-G)
Focused investigator training and project management support ensures site compliance and reportable results.

Fluorescent micrograph used with permission—Bio-Rad Laboratories and the University of Washington
Data quality control and assurance:

- Leverage clinical trial best practices
- Access diverse study populations worldwide
- In-house assays minimize risk and cost
- Automation reduces TAT and ensures consistency

Uncover the full potential of your data

Data quality that exceeds your expectations—and yields enhanced results

Covance offers the highest level of data quality control and assurance, with:

- The most IMID clinical trial experience
- The greatest number of global clinical trial sites
- The most tightly controlled, end-to-end sample management, with the ability to perform assay validations in-house
- Automated lab processes to maximize consistency and scalability while minimizing costs

14 of 15 top IMID drugs developed with Covance data quality

Covance CLS has automated many lab processes for maximum data consistency, scalability, and cost-effectiveness. This approach ensures that we can optimize the volume of samples processed at each of our labs and provide you with reduced turnaround time and a lower cost per sample.

Covance CLS offers high-quality end-to-end sample management services to ensure sample stability, data consistency, and valid results. Your trial will benefit from our highly experienced technicians, global in-house coverage, and consistent SOPs.

We understand that your IMID trial may have specific testing needs not covered by previously validated assays. Covance offers extensive in-house assay validation capabilities to minimize the expense, risk, and uncertainty of sending your samples to a referral lab. In 2012 our labs validated more than 50 assays in immunology alone. We also provide unique capabilities and dedicated support for a variety of key IMID assays to ensure that you obtain consistent data.

Covance’s in-house capabilities can help you reduce costs and accelerate your clinical trial.

Covance CLS has five central labs worldwide: Indianapolis, U.S.; Geneva, Switzerland; Shanghai, China; Tokyo, Japan; and Singapore. We provide testing services for clinical trials at more than 18,000 investigator sites in 75 countries across the globe—more than any other central laboratory in the world. Our global reach gives you unparalleled access to many difficult-to-recruit populations, so you can avoid the time and expense of launching additional standalone studies. Our centralized global data management capabilities ensure that your study produces consistent data you can rely on.

Because we have strong relationships with couriers, referral labs, storage facilities, and other partners in all the regions in which we operate, we can maintain sample stability and assure you of consistent, timely, cost-efficient service across all your trial sites.

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Covance approaches IMID research the same way you do: as one interconnected area of diseases sharing common underlying immune system response mechanisms. This makes it possible for us to leverage best practices across a range of diseases and assays. As your central laboratory partner, we’ll put our exceptional experience to work for you—ensuring that your study produces consistent data and yields maximum value.
We put the whole world in your hands

Worry-free, cost-effective global logistics and operations

Global solutions for IMID clinical trials

- Five central labs with the ability to transfer samples for specific assays quickly to preserve the stability of your samples

- Expanded facilities in Shanghai, China, offering an extensive population of treatment-naive potential

- Strong, long term relationships with couriers and referral labs deliver consistent service and flexibility for your clinical trials

Weathering the storm—and delivering sample stability

Data consistency during a natural disaster

Learn more about how Covance CLS responded to “Superstorm” Sandy
Every patient counts

Empowering you to change people's lives

We handle the samples, so you can help the patients

We understand that developing a new IMID drug is more than a market decision. It represents your commitment to helping people live healthier lives. As your partner, Covance provides the support and resources you need to develop critical treatments that can alleviate patients' pain, manage their symptoms, and give them new hope.

Covance recognizes the value and dignity of every patient, and the significant contributions made by every person enrolled in your clinical trials. We conduct and manage every trial with this in mind, ensuring that our practices maintain your patients as the priority.

Covance is here to serve all your clinical trial needs—and we will always put the needs of your patients first.