

Position Your Lupus Clinical Trial for Success

Overcome Eligibility and Endpoint Evaluation Challenges

PPD
Part of Thermo Fisher Scientific

To successfully bring your lupus treatment to market, the challenges of lupus studies, including issues related to data quality, patient eligibility, placebo responses and efficacy signal detection rates, must be met head on.

With a large number of compounds in development, choosing a CRO partner with the right experience, patient focus, site networks and relationships is essential to effectively support and deliver your lupus therapy to the market quickly.

PPD has the right experience, resources and data quality strategies to advance your lupus compounds.



23 lupus studies
enrolling **4,000+**
patients



Strategies to
confidently
assess disease
activity



350 lupus-experienced
operations staff,
including in-house
rheumatologists



Partnerships
with **Lupus**
Therapeutics and
Clinical Ink

High-quality Sites and Hands-on Management

Identifying and engaging the right sites globally will ensure enrollment speed and data quality. Of the **2,000+ rheumatologists** we have worked with, PPD has more than **440 top-tier clinical trial sites** for lupus studies with proven enrollment capabilities and strong experience with lupus endpoint assessments.

Our teams will:

- Guide the selection of the right sites for your study
- Leverage existing relationships, contracts and budget specifications
- Save time, money and produce shortened start-up timelines

In fact, our most recent Phase II and III lupus studies exceeded industry benchmark enrollment rates. And our ultra high-touch customized management plans for each site ensure the right frequency and type of contact to best support enrollment and operations at each site.

Additional Specialized Sites through Lupus Therapeutics

PPD actively collaborates with Lupus Therapeutics (LT). This partnership not only provides enhanced protocol and trial optimization capabilities for your study, but you will also benefit from access to preferred investigators and Lupus Clinical Investigators Network (LuCIN) sites to expand and strengthen lupus-focused clinical trials.



PPD has the staff, sites and experience in every region, including China and Japan, needed to support your lupus program.

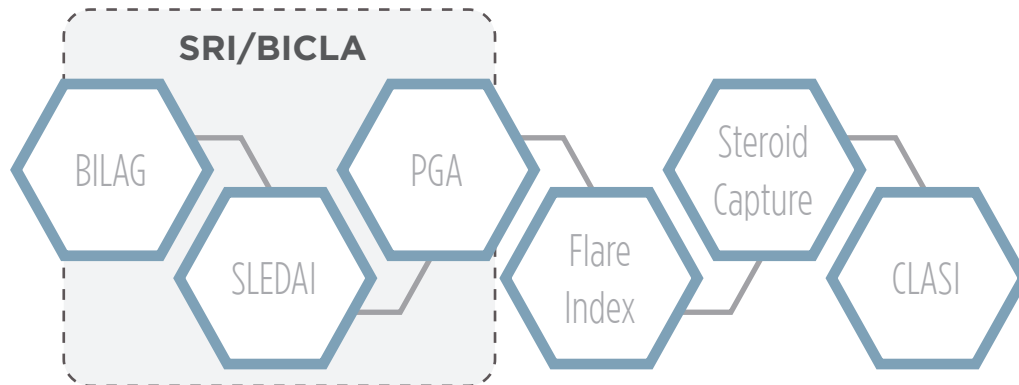
Our unique combination of more than **2,000 rheumatologists** and **440+ top-tier sites** ensures the right country/site strategy for your study.

Mitigating Eligibility Issues, Ensuring Data Quality

Through our specialised eligibility confirmation process we decrease eligibility issues, ensuring the right patients are enrolled in your study. Our trained and experienced central review team, along with our partner, Clinical Ink's, proprietary technology platform, Electronic Lupus Assessment Suite (eLAS), enable near real-time adjudication of efficacy data.



We are able to integrate eLAS data along with other data sources, including EDC and lab data, into our Preclarus® data review tool. This gives PPD teams better and more efficient access for individual patient and cross study trend reviews, identifying issues earlier on, enabling us to resolve them.



Our in-house rheumatologists support our lupus studies through:

- A focus on site and patient burden reduction
- Accurate disease assessment through consistent training and convenient job aids
- Robust systems and clear expectations for source documents
- Automated and standardized query text to manage query volume
- Focus on consistency to reduce data variability
- Automated entry checks/timely central review

PPD is well-positioned to overcome the challenges of lupus programs, including eligibility and endpoint complexities. Our teams are ready to leverage our proven strategies, experienced teams and specialized network of lupus sites to support your study. **Together, we will bring new treatments to lupus patients who need them.**