indero

The Rheumatology Trial Readiness Checklist

Is Your CRO Truly Equipped for Rheumatology Trials?

Rheumatology clinical trials are among the most complex in clinical development. Disease heterogeneity, multidimensional endpoints, placebo response, and rater variability can quickly undermine otherwise strong protocols.

This checklist helps you assess whether your current CRO setup is built to manage that complexity, or whether hidden gaps may be putting your trial at risk.

Instructions:

Answer **Yes** or **No** to each question below based on your current or planned rheumatology study.

1. Scientific & Medical Expertise

Rheumatology trials demand deep, indication specific expertise that goes beyond general inflammatory disease experience.

Yes	No	
☐	☐	Do you have indication specific inclusion and exclusion criteria designed to reduce placebo response and PRO noise?
☐	☐	Are key confounders (e.g., uncontrolled fibromyalgia) explicitly excluded to protect signal detection?
☐	☐	Are background therapies (csDMARDs, NSAIDs, corticosteroids) stabilized with clearly defined tapering rules?
☐	☐	Do your investigators and raters have documented expertise in rheumatology specific assessments (joint counts, enthesitis, dactylitis, mRSS, SLEDAI, BILAG)?
☐	☐	Is formal rater training and recertification planned at predefined intervals?
☐	☐	Is inter-rater reliability actively monitored, with a target ICC ≥ 0.80?
☐	☐	Does your trial design anticipate dermatology–rheumatology overlap (e.g., joint–skin discordance in PsA)?
☐	☐	Are endpoints structured to capture total disease burden (e.g., ACR responses combined with PASI or DLQI)?

2. Outcome Assessment & Data Integrity

Reliable outcomes in rheumatology depend on standardization, real-time oversight, and bias control.

Yes	No	
☐	☐	Are patient reported outcomes collected via time stamped ePROs with enforced completion windows?
☐	☐	Are PRO completion windows actively audited to reduce recall bias?
☐	☐	Are composite outcomes governed by predefined rules to ensure consistent interpretation across sites?
☐	☐	Is there a formal adjudication framework for outcome changes?
☐	☐	Are imaging endpoints (ultrasound, MRI) supported by centralized quality control and adjudication?
☐	☐	Is rater drift monitored centrally and addressed proactively?
☐	☐	Do your outcome processes support regulatory ready, interpretable data rather than just data collection?

3. Risk Management & Trial Governance

In rheumatology, risk is closely tied to disease heterogeneity and assessment complexity. Proactive control is essential.

Yes	No	
☐	☐	Are scientific and operational risks systematically identified early in trial planning?
☐	☐	Are risks prioritized and mapped to predefined mitigation strategies?
☐	☐	Are monitoring systems designed to detect variability trends in near real time?
☐	☐	Do governance structures allow for rapid, blinded safe decision-making?
☐	☐	Are roles and escalation pathways clearly defined across scientific, operational, and medical teams?
☐	☐	Is quality by design embedded into trial execution rather than retrofitted after issues arise?

4. Operational & Scientific Infrastructure

Strong infrastructure is what turns a well designed protocol into a successfully executed trial.

Yes	No	
☐	☐	Does your CRO infrastructure support multidimensional rheumatology endpoints beyond standard operational models?
☐	☐	Are centralized imaging, biomarker handling, and data oversight integrated seamlessly?
☐	☐	Is your infrastructure scalable for rapid geographic expansion if enrollment shifts?
☐	☐	Are biomarker and translational components (PK/PD, immunogenicity, exposure–response) fully planned and operationalized?
☐	☐	Are biological sample logistics (serum, PBMCs, biopsies, biobanking) validated end to end?
☐	☐	Do cross functional teams have real-time access to data needed for proactive decision-making?

Scoring & Interpretation

How many "No" boxes did you check?

- **0-5 No's**
  Your trial foundation appears strong. You likely have many of the right structures in place, but even high performing programs can benefit from specialized rheumatology optimization.
- **6-10 No's**
  There are meaningful gaps that could impact data quality, interpretability, or timelines. These are early warning signs that warrant expert review.
- **11+ No's**
  Your trial may be exposed to significant scientific and operational risk. This level of complexity typically requires a CRO with dedicated rheumatology leadership and infrastructure.

What This Means for Your Program

If you found yourself answering "No" more often than expected, it's not a reflection of effort, it's a reflection of how demanding rheumatology trials truly are.

Rheumatology studies require:

- Deep therapeutic specialization
- Rigorous outcome control
- Integrated scientific and operational oversight

These are not add ons. They are foundational.

How Indero Can Help

Indero is purpose built for complex, immune mediated disease trials, including rheumatology. Our teams combine:

- Dedicated rheumatology medical leadership
- Proven rater training and monitoring frameworks
- Integrated translational and biomarker strategies
- Infrastructure designed for multidimensional endpoints and proactive risk control

If this checklist surfaced potential gaps in your current approach, a focused discussion with our rheumatology experts can help you determine next steps before those gaps become trial level issues.

SPEAK WITH AN INDERO RHEUMATOLOGY EXPERT

About Indero

Indero is a dual-focus CRO for dermatology and rheumatology, with over 25 years of experience in clinical research and trial delivery. Our full-service approach which includes everything from protocol design and patient recruitment to trial monitoring and biometrics provides biotech and pharmaceutical sponsors with the rigorous scientific foundation and tailored expertise their studies need to reach the finish line efficiently and effectively. With capabilities in North America, Europe, Latin America, and Asia-Pacific; vast, continuously growing relationships with investigators and patients; and a dedicated research clinic through which we design and execute our own studies, Indero is the ideal partner for clinical needs at global scale.

inderocro.com