PRA Health Sciences

SLIP SHEET

Central Review Services

Systemic Lupus Erythematosus, Lupus Nephritis, & Primary Sjögren's Syndrome

Service Description

PRA's Central Review Services (CRS) comprises a group of experienced physicians and managers dedicated to supporting SLE research and clinical trial development for systemic lupus erythematosus and lupus nephritis. Our review and query processes increase the scoring accuracy of activity indices, improve overall trial data quality, and enhance the ability of efficacy measures to detect treatment response. We also provide and enter British Isles Lupus Assessment Group (BILAG) grades in a variety of electronic data capture (EDC) systems. Our review service has expanded to include primary Sjögren's syndrome (pSS), an autoimmune condition facing similar challenges in clinical trials, such as complex multi-organ involvement, varied clinical picture, no clear biomarkers correlating with activity or prognosis, and evolving optimal composite endpoints.

Associated Services

Our physician group confirms participant eligibility and correlates activity captured on the physical exam, vital signs, joint count, Systemic Lupus Erythematosus (SLE) Disease Activity Index (SLEDAI), BILAG, Physicians Global Assessment (PGA), and Cutaneous Lupus Erythematosus Disease Area and Severity Index (CLASI) to assure consistency, accuracy, and conformity with definitions and protocol-specific clarifications across instruments. We verify SLE classification criteria per protocol specifications and review to ensure damage and activity are precisely scored.

In a similar manner, for pSS, CRS confirms participant eligibility, verifies the 2016 American College of Rheumatology (ACR)/ European League Against Rheumatism (EULAR) primary Sjögren's syndrome classification criteria, and correlates activity and/or damage captured on the physical exam, vital signs, joint count, EULAR Sjögren's Syndrome Disease Activity Index (ESSDAI), PGA, lacrimal gland function, and salivary gland function electronic case report forms (eCRFs).

CRS Experience

- 26 SLE studies since 2006
- 1 LN trial since 2018
- 1 pSS study since 2019

Current trials include:
- 3 Phase II trials
- 1 long-term safety/efficacy trial

- 3600 lupus subjects' data reviewed and correlated across all study visits at more than 400 sites globally
- 124,000+ BILAG visits graded
- 84,000 SLEDAI visits scored
- 27,000 CLASI assessments

Next Steps

For more information, contact Ionela Gheorghiu, Director of Therapeutic Expertise at GheorghiuIonela@prahs.com or Kate Oechsner, Senior Manager, Central Review Services at OechsnerKate@prahs.com

Central Review Services include:

Study Start-Up Support

- Protocol design analysis and protocol specification recommendations for Phase I-IV trials
- Efficacy analysis guidance: BICLA, SRI-4, DORIS, LLDAS, SRI-50
- Case report form (CRF) design and edit check input
- Enrollment rate projections based on protocol-specific requirements
- Experienced-based country and site selection recommendations
- Investigator meeting training and certification through audiovisual training for lupus assessments (ATLAS)

Ongoing Support

- Confirmation of patient eligibility during screening and prior to randomization
- Eligibility and stratificaton on information added to interactive voice/Web response system (IxRS)
- BILAG grading and data correlation at screening and during study
- Correlation of CLASI entries with clinical photographs
- Programmatic QC of efficacy data through our proprietary BILAG Electronic Scoring Tool (BEST) program
- Physician-led data review with queries to ensure consistency and accuracy across activity and efficacy instruments
- Flare review
- Ongoing training support for clinical research associates (CRAs) and site personnel
- Intensive site data review to optimize quality
- Protocol amendment guidance

Post-Trial Support

- Efficacy clinical trial results interpretation and communication
- SLE false flare analysis
- Ad hoc re-adjudication