PEDIATRIC RHEUMATOLOGY COLLABORATIVE STUDY GROUP (PRCSG)
DESCRIPTION OF SERVICES

PROJECT SPECIFIC SERVICES:

Protocol Development/Execution:

- Development of Pediatric Study Plans (PSP) for the Food and Drug Administration (FDA)
- Development of Pediatric Investigational Plan (PIP) for European Medicines Agency (EMA)
- Consult and advise the sponsor on the clinical, scientific and operational issues relevant to the trial
- Consult and advise the sponsor on any issues affecting scientific integrity and ethical conduct that may arise during the course of the study
- Assist in Case Report Form development
- Assist in decisions about early termination or "mid-course" corrections.
- Actively support Subject recruitment
- Answer day-to-day study related questions (protocol interpretation, subject eligibility, case report forms completion, etc.)
- Assist in reporting of adverse events according to the protocol
- Assist in development of Subject recruitment and retention plans
- Attend face-to-face meetings, as requested by the Sponsor
- Participate in teleconferences as needed
- Interact with study investigators, as needed, regarding study development, conduct and reporting
- Assist in collection of Essential Documents

Study Feasibility Survey:

- Assist in the identification of pediatric rheumatology sites interested in participating in each particular clinical research study
- Estimate the potential number of enrolled patients per center
- Encourage and help problem solve at low enrolling sites
- Assist with replacement of non-performing sites
- Perform follow-up feasibility surveys for important protocol changes or to identify additional sites

Investigator Meeting:

- Assist in the development of oral presentations and written instructional materials
- Present study materials

Determination of ACR pediatric 30/50/70/90 response to therapy, JADAS 10/27/71, flare, disease activity and clinical inactive disease status, types of Clinical Remission, as well as, guidance for steroid tapering

- Various Quality Assurance methods to ensure accurate response
- Capable of producing real time turn-around of the response to the Site
- Adequate staffing to fulfill protocol requirements
- Develop study specific SOPs / Working Instructions for assessing response

Set-up and validation of a web-system data collection

- Ensure and document that the electronic data processing system conforms to the Sponsor's requirements and is compliant with the study protocol for completeness, accuracy, reliability and consistency (i.e. validation)
- Maintain SOPs for using and updating the system
- Ensure that the system is designed to permit data changes in such a way that the data changes are documented and that there is no deletion of entered data
- Maintain a security system that prevents unauthorized access to the data
- Maintain a list of the users who are authorized to make data changes
- Maintain adequate backup of the data

Database reconciliation

- Comparisons between the sponsor data and PRCSG data are completed as determined by the sponsor
- Data capture of key outcome measures to serve as part of the sponsor study database

Site Support:

- Assist in site specific IRB submission
- Assist in collection of regulatory document via Central Regulatory Document Resource
- SAE adjudication

Data Analysis/Reporting:

- Assist in interim reporting of data
- Assist in preparation of tables needed for DSMB meetings
- Assist in the data analysis and preparation of abstracts and full publications of the study results
- Assist in review of the clinical study report
- Preparation of publications compliant with the ICMJE guidelines