



ALBUQUERQUE  
CENTER FOR  
RHEUMATOLOGY

Albuquerque Center for Rheumatology has been providing superior Rheumatology care to the residents of the State of NM since 1997. Our private practice has a **combined clinical research experience of greater than 30 years**. We are able to successfully recruit and **often exceed our enrollment expectations** due to day-to-day patient interactions and our extensive database of clinic patients. Up to ninety five percent of our subject recruitment is from our own clinic. Additionally, we conduct on-site quarterly Research Department meetings.

We have greater than 30 collaborative years experience in conducting Phase II-IV clinical trials and our site has conducted over 70 clinical trials in Rheumatology since 1999. We have extensive experience in **Biologic** and **Biosimilar** drug clinical trials.

## Advertising

- Central Campaign
- Local Television, paper, radio and Billboard
- Outside Clinic Referrals

## Record Storage

- On-Site Record Storage



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## Experience and Staff

Our Phase II-IV Clinical Drug/Device Trial Experience includes but is not limited to the following indications:

- Rheumatoid Arthritis (RA) Early, Moderate, Severe
- Psoriatic Arthritis (PsA)
- Systemic Lupus Erythematosus (SLE) (CLE)
- Ankylosing Spondylitis (AS)
- Gout
- Sjogren's Disease
- Osteoarthritis (Pain)

## Research Certification & Training

Our Investigative staff as well as support staff maintain current certification/training in the following:

- GCP (CITI training every 2 years)
- IATA certified Study Coordinators
- Phlebotomy and IV certified Study Coordinators
- ACRP Certified or ACRP Eligible Study Coordinators
- ACRP/SOCRA membership
- On Site Standard Operating Procedures (SOPs)
- BLS certification

## Site Equipment

- Two dedicated Investigational Product Refrigerators
- Dedicated Ambient IP storage
- Dedicated Exam room
- Dedicated Infusion Room
- Scheduling
- Emergency Medications
- Dedicated Monitoring Area
- Centrifuge
- Incubator
- -20 freezer
- Xray, MRI & Nuclear Imaging (off site)
- Access to dry ice
- ECG

## Site Equipment (cont.)

- Urgent Care/Hospital 1 mile away
- Wireless Internet Access
- Fax/Copier
- Document Shredder
- Electronic and Paper medical records
- \*SOP for monitor/auditor access\*
- Secure source document storage
- Equipment calibration annually

## Informed Consent (ICF)

- Dedicated private room for consent discussion
- SOP for consent procedures
- GCP guidelines are strictly enforced and followed for the informed consent process

## Outcomes & Efficacy Assessment Experience

- Patient reported outcomes and study specific questionnaires
- Experience with paper blinded independent and tablet questionnaires
- Physicians are experienced with performing joint counts
- Experience with the following site and subject questionnaires/assessments:  
PGA sPGA SF-36 HAQ EQ-5D 5L QUIDS-SR-16 SPARCC LDI -B NAPS1 PASI Itch NRS SLEDAI BILAG SLICC DLQI WPAI-SHP DAS SDAI FACIT PROMIS-29 LEI SPARCC BASDAI ESSDAI ESSPRI
- RA and PsA assessments

## Investigational Product

- On site drug destruction per site SOP
- 24 hour min/max ambient and refrigerator temperature monitoring
- SOP for power outage

## Lab Collection and Processing

- PK and Serial PK collection and processing
- TruCulture collection and processing
- Quantiferon TB Gold collection and processing
- Safety lab collection and processing
- PBMC, Flow cytometry, PAXGENE, BNP UA dipstick/Pregnancy Testing
- On Site ESR
- Cytodelic sample collection/processing
- Access to Dry Ice and Shipping

## On-Site IV (infusion) Facility

- Area to accommodate IV and serial PK subjects comfortable for extended period of time.
- IV bag preparation and administration experienced staff
- Continuous subject monitoring

## Regulatory/IRB

- On site regulatory management
- Site is able to utilize a Central IRB
- Experience in electronic submission and reporting

## Contract/Budget Negotiations

- Handled at the site level
- Average time to contract execution 4-8 weeks

## Electronic Data Capture/EDC/IWRS

Site experience with the following applications:

ERT/Clario	Firecrest	BioClinica
Oracle	Medidata	InForm
Bracket	Intralinks	SIP
SIS	Greenphire	Sponsor system
Calyx	Almac	Conduit
DrugDev		
Safety Reporting systems		Veeva