Early Clinical Research

Why DaVita Clinical Research?

Unlike most CROs, DaVita Clinical Research® (DCR) is part of an integrated company that provides healthcare. This unique structure enables us to integrate real-world experience, expertise in pharmacology and clearance studies, and unmatched proprietary data and analytics to further the design of and recruitment for complex studies that support regulatory submissions. Operational excellence, superior customer service, flexibility, and quality data make DCR a leading choice for outsourced research.

With two hospital-based facilities dedicated to early-phase research, DCR brings a track record of success to your Phase I studies. For more than 30 years, we have helped over 175 biopharmaceutical and device clients successfully manage and execute early-phase clinical trials in both healthy normal volunteers and patient populations. Our integrated clinical data analysis and reporting services allow for informed and timely decisions about safety and efficacy.

Experience and Expertise

- More than **500 early-phase clinical trials** for more than 175 pharmaceutical and biotech companies
- Leadership with extensive experience in **drug development and clinical pharmacology**
- Extensive **Phase I trial experience** in the last 3 years, including:
  - Studies in **healthy normal volunteers and patient populations**, including FIH/SAD/MAD studies
  - **Cardiovascular studies**
  - More than **115 renal and hepatic** clearance trials enrolling more than 1,000 patients
- **Hospital-based facilities** in Denver and Minneapolis with **122 total beds** operating under common SOPs and ready access to numerous, physicians, and ancillary services and patient populations available for trial feasibility and potential trial enrollment
- Site capabilities for performing ADME (mass balance) studies
- Industry-leading pharmacy services USP 797-compliant and meeting USP high-risk standards/guidelines
- **Full range of data services** including protocol development, data programming, PK/PD analysis, biostatistics, medical writing, and reporting

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Put our pharmacology expertise to work on your next trial

Our DaVita® Early Clinical Trials (ECT) team has extensive experience in the development of new compounds within specialty populations and populations with comorbid conditions.

Clinical Studies for Regulatory Submission

- First in human
- Single and multiple ascending dose
- Adaptive trial designs
- Drug/Drug interaction
- Food effect
- Mass balance (ADME)
- Pharmacokinetic/ Pharmacodynamic
- Bioavailability/ Bioequivalence
- QT/QTc
- Sleep studies
- Smoking studies

Specialty Populations

- Chronic kidney disease
  - Mild, moderate, severe
- End-Stage Renal Disease
  - Hemodialysis and peritoneal dialysis
- Hepatic
  - Mild, moderate, severe
- Cardiovascular
  - NY classification II, III, IV
- Diabetes
  - Types I and II
- Hypertensive
- Elderly
- Postmenopausal
- Obese

Special Procedures Available

- Echocardiograms
- Bio-Z® cardiac monitoring
- Bronchoscopy
- Biopsies
- Hypoxia induction
- Actual renal function measurement via PAH
- Ophthalmic studies
- Full suite of imaging
- Pulmonary function
- Blood transfusions

> A look into the composition of subjects in Phase I trials further illustrates the trend of moving away from use of healthy volunteers only to use of patients only or a mix of patients and healthy volunteers.

Source: ISRreports.com

Certifications and Licensing

- Mortara Certified Partner and meeting
- USP 797-compliant and meeting USP high-risk standards/guidelines
- 3rd-Party ISO Certified: ISO Class 5, 6, and 7/8 areas
- APPI-certified physician investigator
- ACLS-certified nursing & medical staff
- State-licensed pharmacy
- DEA license for schedule I-IV drugs
- Nuclear medicine license
- iCardiac Certified

Comprehensive Pharmacy Services

- Clean room (ISO Classes 6 & 7)
- USP 797-certified for high-risk compounding
- Vertical flow hood (ISO Class 5, high risk)
- Radiolabeled medications (MSP only)
- Controlled access with continuous monitoring
- All routes of administration
- Oncology agents
- Nonsterile to sterile products
- Four storage temperatures: room temp, refrigerated, -20° C, -70° C

DaVita Clinical Research®

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Late Phase Clinical

Real-World Healthcare Data

Health Economics & Outcomes Research

Medical Communications

Learn more about our flexible approach to early clinical studies, and let us start something quickly for you.

Call **1-888-345-2567** and see how quickly we act.

www.davitaclinicalresearch.com

DaVita Clinical Research®

All statistics current as of October 2015

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