DaVita Clinical Research Data Analysis and Reporting Services

DaVita Clinical Research® (DCR) Data Analysis and Reporting services offer an array of data management and biometric solutions for Phase I studies.

Our services are designed to meet your needs and include data management, biostatistics and programming, medical writing, and pharmacokinetics (PK) and pharmacodynamics (PD). We offer customized, cost-effective, and flexible solutions, and our team can help enable you to make effective decisions about the safety, tolerability, and PK/PD properties of your compound more quickly.

- Good clinical data management practices
- Customized, cost-effective, and flexible approach to meet your needs
- Integrated services—seamless data flow and communication throughout project
- Dedicated teams, shared knowledge, and consistent processes within and across projects
- Focused project management - one point of contact

Data Management	BioStatistics	Medical Writing	PK and PD Reporting
• CRF design • Data management plans • Database design • Query management • Electronic data transfer and reconciliation • Medical coding	• Sample size calculations • SDTM and ADaM data sets in CDISC-compliant format • Randomization • Statistical analysis plan development • Interim analysis • Statistical design for protocols • Statistical analysis of PK/PD endpoints • Data tables, figures, listings • Statistical reports and contribution	• Protocol development • Fully integrated study reports in ICH E3-compliant format • Scientific posters and papers • eCTD format	• Bioanalytical data review • Rapid interim PK analysis • Noncompartmental PK and PD analysis • PK reports and contribution • Population PK

DaVita Clinical Research®

Research Data Analysis and Reporting

The data you need, delivered timely and accurately

We support you with integrated services and fully validated systems.

- Electronic data capture using Oracle® Clinical RDC 4.6.6

- JReview® integrated data review and reporting tool

- Medical terminology coding using Oracle® TMS 4.6.6

- MedDRA® and WHO DDE™ coding dictionaries

- Statistical programming using SAS® 9.2

- CDISC validation (WebSDM™ and OpenCDISC)

- PK services using Phoenix® WinNonlin® 6.3

- Full validation documentation

- Study documentation maintenance

- Integrated services project management

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JReview® is a registered trademark of Integrated Clinical Systems, Inc.

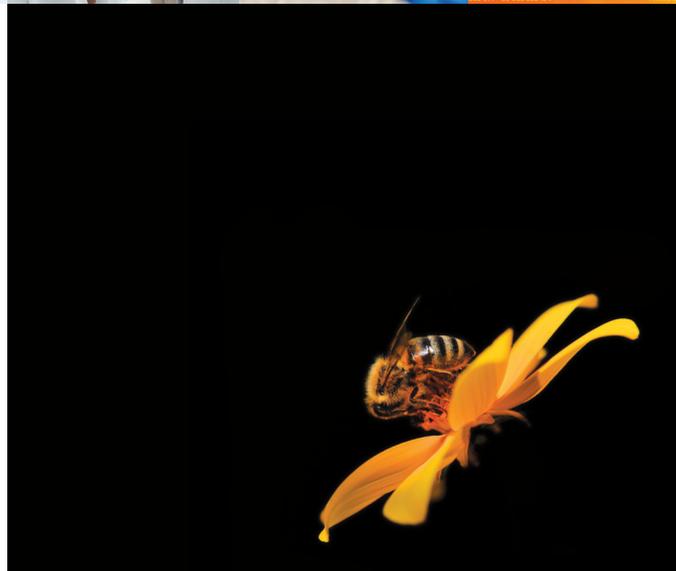MedDRA® trademark is owned by IFPMA on behalf of ICH.

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® indicates USA registration.

We have built a dedicated and integrated team of experts with 20+ years of experience providing operational excellence by delivering timely and accurate clinical trial data.

Call **1-888-345-2567** to learn more about our integrated clinical data analysis and reporting capabilities.

www.davitaclinicalresearch.com

DaVita Clinical **Research** ®

All statistics current as of October 2015.