Biostatistics & Programming Service Model

The focus of Biostatistics and Programming Services is on developing a stronger biostatistics infrastructure and addressing previously unmet biostatistical needs of investigators conducting FDA-regulated clinical trials across the Command.

MeRITS and USAMMDA have jointly developed a Biostatistics and Programming Service Model for both individual and clinical studies, which currently provides the following services:

- Representation and guidance on protocol teams;
- Protocol review;
- Review of CRFs;
- On-site training for implementation of randomization and documentation procedures;
- CRO selection for statistical services;
- Management of CROs providing statistical services, including direction, review, and feedback on deliverables;
- Assistance to the USAMRMC Quality Management Office for biostatistics auditing of CROs and other partner organizations;
- Assistance with the implementation and review of biostatistics documentation (e.g., randomization, study blinding, unblinding procedures, and drug labeling);
- Statistical programming and analysis through a validated implementation of Statistical Analysis Software (SAS®);
- Support and advice on formulation of testable research hypotheses;
- Data collection methods to address hypotheses;
- Study methodology, design, and logistics;
- Calculation and review of sample size determination and power analysis;
- Development of statistical analysis plans (SAPs);
- Interpretation of results, and preparation of study tables, listings, figures and graphs;
- Final Clinical Study Report preparation;
- Abstract and manuscript preparation; and
- Attendance with the Investigator team at FDA meetings to provide a biostatistical representative for the Sponsor.

Through this service model we will be supplementing the current services with the addition of:

- Journal club to review statistical methods relevant to clinical investigators;
- Seminars on the essentials of clinical trials and biostatistical topics; and
- Introduction of a two-day workshop on the Essentials of Biostatistics for the Clinical Trial Investigator.

Protect, Project, Sustain

MeRITS PMO

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MeRITS PMO CDPS

Clinical Data Process & Systems Project

General Information & FAQs

Released June 2007

MeRITS PMO

What is the CDPS?

The Clinical Data Process and Systems (CDPS) Project is comprised of the functional areas of Clinical Data Management (CDM), Biostatistics, and Clinical Safety.

CDPS is focused on the improvement of the effectiveness, efficiency, and regulatory compliance of these functional areas through the use of widely-accepted, good clinical data processes and standards; qualified and experienced personnel; and technology solutions within USAMRMC to manage our clinical data.

CDPS solutions and support include:

- A Clinical Data Management System (CDMS), which will be the core capability for handling data electronically whether the source is paper or electronic –
  - The CDMS, selected by the Command in the near future, will possess the capability and flexibility to capture clinical data from paper and subsequently entered into an electronic format, as well as directly into an electronic format using an Electronic Data Capture (EDC) capability;
- Serious Adverse Event Reporting System;
- CDISC (Clinical Data Interchange Standards Consortium);
- MedDRA® (Medical Dictionary for Regulated Activities);
- Request for proposal development and outsourcing management support for CDM;
- Clinical project team support and consultation;
- Standing Operating Procedures, work instructions, and templates; and
- Education and training on a variety of topics related to clinical data and systems.

What is the goal of the CDPS Project?

The goal of the CDPS project is to support on-line input, inquiry, and retrieval of clinical information and records from a central database while providing a diversity of output/reporting functions. The highest priority of this project is to reduce regulatory risk of clinical studies due to inadequate data management processes. Therefore, the MeRITS office is first working with study teams to provide standardized, well-designed Case Report Forms (CRFs) and training on good data management practices. We are also providing compliant data management capabilities for FDA-regulated studies through three Contract Research Organizations (CROs) that have been audited to insure compliance with FDA regulations.

Some objectives to help achieve our goal are:

- Identify differences in processes, standards, and systems between representative laboratories in USAMRMC;
- Identify, develop, and implement a best practice process architecture (common procedures, templates, and forms to use across the Command);
- Ensure quality control is integrated from the onset and throughout the process;
- Develop and implement training programs for processes, standards and technology; and
- Develop and implement an overall process and systems architecture change-control mechanism.

Clinical Data Management Service Model

The CDPS project team has developed a service model and continues to support CDM activities on clinical project teams. The CDM Service Model for individual studies currently provides the following services:

- Representation and guidance on protocol teams;
- Protocol review;
- Development and printing of case report forms (CRFs) and CRF instructions;
- A step-by-step training for site personnel and guide for Monitors on the completion of study-specific CRFs (both leader-led and CD with voice-over);
- CRO selection for CDM services;
- Management of CROs providing CDM services, including direction, review, and feedback on deliverables (e.g., database design and development, Data Management Plans, Data Validation Plans, data review, MedDRA® coding review, etc.);
- Clinical safety training, assessments, and reporting;
- Assistance to the USAMRMC Quality Management Office in CDM and other partner organizations;
- Assistance with the implementation of CDM documentation (e.g., Data Management Plans, Data Validation Plans, annotated CRFs, CDM Study Binders, CDM procedures, Clinical Safety procedures, etc.); and
- Training and education on widely accepted, good CDM practices.