

BIostatistics & DATA MANAGEMENT CORE

Grant Boilerplate

The BDMC provides biostatistical and data management support to investigators at The Children's Hospital of Philadelphia (CHOP) for studies ranging from small, bench science projects to large, multi-site clinical trials. The BDMC currently supports more than 30 funded studies spanning multiple subspecialties of pediatric medicine, and collaborates with investigators on dozens of grant applications each year. The BDMC staff is comprised of professionals with expertise in project management, biostatistics, statistical programming, data management, site management, and site monitoring.

The Biostatistics group includes doctoral and master's level statisticians and statistical programmers. The biostatistics group provides consultative and analytic support services to investigators interested in basic, pre-clinical, clinical, and epidemiological studies. The biostatistics group offers the following services: study design (observational studies, conventional randomized parallel group comparison designs, and various adaptive designs); selection of primary and secondary study endpoints for hypothesis testing; randomization; sample size and power calculations; statistical analysis (planning, data analysis and report writing); statistical analysis and generation of tables, figures and listings (TFLs) for Data and Safety Monitoring Boards (DSMB); statistical support for grant applications; statistical support for abstracts and manuscripts; statistical methodological research; and statistical consulting. The BDMC statistical programmers are also proficient in creating analysis datasets including Clinical Data Interchange Standards Consortium (CDISC) Study Data Tabulation Module (SDTM) and Analysis Data Model (ADaM) datasets and preparing the documentation required for submission to the Food and Drug Administration (FDA). In addition to traditional office and project management software, BDMC staff have expertise using the following commercially available software packages for statistical analysis, sample size calculations, and data file conversions: SAS, R, and G*Power.

The Data Management (DM) group includes data managers, database developers, data research associates, and systems administrators. The DM team provides services ranging from consultation through full-service data management. Data management services include: study database creation, maintenance, backup and/or archiving (using REDCap, REDCap Cloud, and Medidata Rave); case report form design; remote data capture; data review and query management; medical coding; and data audits. Thorough documentation tailored to meet each project's DM needs is created and maintained by the BDMC staff for the life of each project.

The BDMC has the capability to support 21 CFR Part 11 compliant clinical trials with data submission to the Food and Drug Administration (FDA). For these regulated studies, two solutions are available. Medidata Rave is a clinical database management system (CDBMS) designed specifically for use in FDA-regulated trials. Medidata Rave provides a highly secure environment with full data management functionality, including built-in data cleaning and validation tools, clinical coding tools, and external data integration capabilities. Medidata Rave is a widely recognized and respected CDBMS routinely used in many clinical trials by the National Institutes of Health and other agencies worldwide. The CHOP REDCap Part 11 instance

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is another secure web application designed for data collection and management in regulated research studies and is available in collaboration with the CHOP REDCap team.

For studies not requiring 21 CFR Part 11 compliance, the preferred electronic data capture system is the REDCap Academic instance, a secure, web-based remote data capture application hosted by CHOP's Research IT Servers. REDCap is flexible enough to be used for a variety of types of research and provides an intuitive user interface that promotes real-time validation rules, easy data manipulation, audit trails for reporting, monitoring and querying patient records, and an automated export mechanism to common statistical packages (SPSS, SAS, Stata, R).

The BDMC is operated and supported by Westat, a large health research organization with extensive project management, biostatistics, data management, site management, site monitoring, and information technology capabilities. Westat, an employee-owned company headquartered in Rockville, MD, has more than 50 years of experience implementing clinical trials, epidemiological, and other health studies for the National Institutes of Health, the Centers for Disease Control and Prevention, foundations, and pharmaceutical companies. Westat's Clinical Research Practice has approximately 200 staff members, including: project directors; project managers; site monitors; database developers and data managers; doctoral and master's-level biostatisticians, epidemiologists, and statistical programmers; and information technology specialists. This entire capacity is available to support the BDMC as needed.