A Unique Collaboration For A Data Coordinating Center

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Background: UW DCC

- Established in 2016 as a component of the Clinical Trials Program in the Department of Biostatistics and Medical Informatics (BMI) in the UW School of Medicine and Public Health.
- Supports and is engaged in collaborative clinical research projects which are NIH- or industry-funded data coordinating centers.
- Plays a critical role in coordinating and implementing large multi-center randomized controlled trials (RCTs) and other types of clinical research studies, bringing expertise in planning, conduct, monitoring, analysis and reporting and in data management, quality control and quality assurance, and information technology support for trial monitoring and communication, all needed to complement the clinical investigators’ content expertise.

Strengths

- Provides case report forms (CRFs)
- Data management
- Collaborates in manuscript preparation
- Coordination and quality assurances
- Coordination of the activities of the data and safety monitoring board (DSMB), the protocol review committee (PRC), the executive and steering committees, and other standing committees.
- Support of ancillary study activities
- Support for study drug distribution
- Development and maintenance of websites or online resources for the studies.

Statistics

- Provides the statistical expertise in randomization
- Preparation of statistical analysis plans for interim and final analyses
- Monitoring of trial conduct
- Interim analysis for review of safety and efficacy by the DSMB
- Final analysis and production of the final report
- Interpretation of findings from analysis
- Preparation of results for presentation and publication of findings from the trial
- Development of new/novel statistical methods for analysis of complex time to/recurrent events

Safety Reporting

- Report findings to the DSMB

### Benefits of the Collaboration:

- Ideally staffing would lend itself for all aspects of data management to be done by one team at one institution/organization but given space and resource limitations this does not always occur
- Sometimes partnerships outside one’s own institution are necessary to accomplish the end goal
- UW has a long-standing relationship with Frontier Science and Technology Research Foundation dating back to the 1970s
- Together both teams formed one stronger team to the benefit of the researchers that engage with them to answer important clinical questions
- Uniquely combines the strengths of the UW and Frontier Science in statistical methods for randomized controlled trials and data management and quality control/assurance

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### Background: Frontier Science

- Engaged in clinical trials collaboration and support for 40 years, providing accurate and cost-effective data management as well as statistical software development and maintenance for the collection and analysis of data to research networks, pharmaceutical companies and investigators.
- Has participated in numerous multi-site, multi-trial networks including the AIDS Clinical Trials Group (ACTG), the Pediatric AIDS Clinical Trials Group and its successor, IMPAACT; the Eastern Cooperative Oncology Group (ECOG) and International Breast Cancer Study Group (IBCSG) and the Pediatric HIV/AIDS Cohort Study (PHACS).
- Collaborates with scientists and technicians in more than 800 laboratories, universities and medical centers around the world engaged in clinical trials and observational studies.
- Funded by the U.S. National Institutes of Health, pharmaceutical companies and other organizations, Frontier’s main focus has been on studies related to cancer and HIV although Frontier has also participated in a broad spectrum of other clinical studies and has gained extensive experience in a wide range of studies, involving all Phases.

**Strengths**

- Database design and management
- Data collection including case report form (CRF) and patient reported outcomes (PRO)
- Data quality control/assurance
- Medical coding
- Programming and reporting
- Statistical research and analysis
- Laboratory data analysis, specimen collection and mobilization, and repository tracking
- Create CDISC compliance datasets

**Training**

- Customizable comprehensive training curriculum
- Various methods of delivery
  - Onsite
  - At Frontier Science’s facilities
  - Group meetings
  - Webinars
  - E-learning
  - User Guides and Reference Guides for Frontier Science supported systems

**Communication**

- 24/7 User Support
- Online data management forum for sites
- Network coordinator meetings
- Newsletter items
- Committee involvement: Executive and Steering
- DCC weekly meetings

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**Data Management**

- OpenClinica is used for electronic data capture and data management
- Data is processed into a central database (Ingres)
- Generate study reports
- Used by the statistical group for analysis
- Subjects are randomized using a Web-based subject enrollment system (SES) that is available 24/7

**Adjudication**

- Patient data relating to events securely transferred from OpenClinica to eSOCDAT
- SOCAR prepares packages for Endpoint Committee review
- SOCAR transfers adjudicated data back to Frontier Science

**Quality Control/Quality Assurance**

- Standard Operating Procedures
- Limited access to OpenClinica
- Account management policies
- Real time data checking and verification
- Automated and manual queries
- Site evaluation reports
- Clinical sites are monitored using remote and risk based monitoring during the conduct of the trial

**Safety Reporting**

- Investigators complete an SAE eCRF in OpenClinica
- DCC alerts necessary study personnel, network medical monitor, and CCC co-PI who alerts health authorities
- DCC maintains SAE database