How Data Managers Support Prospective Research

CIBMTR Data Managers Meeting

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Prospective Clinical Research
Agenda

• Background - Prospective Research (RCI BMT)

• The Clinical Trial Life Cycle

• Importance of Data Management in Prospective Research Trials

• Survey Research Group (SRG) and ePRO
Background
RCI BMT

Resource for Clinical Investigation in Blood and Marrow Transplantation (RCI BMT) conducts prospective research within CIBMTR

- Provides HCT researchers:
  - Clinical trial infrastructure and expertise
  - Support and coordination for a wide array of studies including multicenter trials, survey assessments, laboratory evaluations

- GOAL: To help investigators to generate data allowing novel and innovative ideas for application in trials of all phases
Clinical Trial Lifecycle

- Development
- Review
- Activation
- Conduct
- Analysis
- Publication
- Closeout
RCI BMT Key Functions

- Funding proposal assistance
- Protocol development and approvals
- Site selection
- Contractual and financial administration
- Study conduct management
- Sample management
- **Data collection and management**
- **Regulatory oversight**
- Coordinate unrelated donor data
- Survey research support
- Monitoring
- Analysis
RCI BMT Current Clinical Trials

- Total of 16 studies
  - 6 in development
  - 6 currently enrolling
  - 8 completed enrollment
    - 1 Follow up
    - 3 Manuscript write-up ongoing
    - 3 Manuscript submitted
    - 1 Manuscript recently published
## Data Management - Reporting

<table>
<thead>
<tr>
<th>Medidata Rave</th>
<th>FormsNet3</th>
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</thead>
<tbody>
<tr>
<td>• Prospective data</td>
<td>• Observational data</td>
</tr>
<tr>
<td>• Clinical Trial Forms</td>
<td>• SCTOD required forms and Comprehensive forms</td>
</tr>
<tr>
<td>• Entered by Study Coordinators</td>
<td>• Entered by Data Managers</td>
</tr>
<tr>
<td>• Monitored for accuracy of data and safety of trial participants</td>
<td>• Audited to ensure quality and integrity</td>
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Clinical Trial Lifecycle

1. Development
2. Review
3. Activation
4. Conduct
   - DATA MANAGEMENT
5. Analysis
6. Publication
7. Closeout
Data Management

• Clinical Data Management is an important phase in a clinical trial

• It is a cycle of collecting, cleaning and managing data

• Leads to generation of high quality, reliable and statistically sound data for clinical trials
Data Management

• Missing data, missing values, outliers may lead to misleading results, bias and may result in lack of confidence in a study
Data Management

Why is Quality Data Important?

• Research results in data to be analyzed which supports or refutes a study hypothesis.

• Poor data results in a waste of effort and resources and may put subjects and patients at risk of harm.
Data Managers Support: Data Collection

- Data managers support study safety surveillance and monitoring
  - Adverse events, serious adverse events, unanticipated problems are reported to investigators, study sponsors, Data Safety Monitoring Boards (DSMB) or Data Safety Monitoring Committee (DSMC), FDA, Institutional Review Boards (IRB)
  - This reporting ensures the highest level of subject protection
Data Managers Support: Data Collection

• Quality data entry by data managers and study coordinators in FormsNet3 and Medidata Rave help us prepare accurate data reports in a timely manner.
Data Managers Support: Generation of Data Report

What is a Data Report?

- A summary of study analyses results which are reported in an abstract or manuscript

  - Prepared by RCI BMT study staff and study statisticians

  - RCI BMT scientific director oversees activities of RCI BMT staff and Associate Scientific Director oversees statisticians activities in development of this report
Data Managers Support: Generation of Data Report

What activities are involved in Data Report Development?

• Cleaning
  – Screening for data error (outliers, inconsistencies)
  – Diagnosing and editing suspected data abnormalities
  – Data error (inliers)

• Data points generated by error but falling within the expected range
  – Identified during monitoring of study specific forms
Clinical Trials: Monitoring and Auditing Activities

- Monitoring visit (Study specific forms)
  - Review progress of a clinical study
  - Ensure protocol is conducted in adherence to protocol
  - Assure accuracy of data
  - Assure safety of subjects
  - Regulatory Compliance (CFR & GCP)

- Audit visit (CIBMTR forms)
  - Ensure quality and integrity of data collected
Data Managers Support: Data Report Development

- **Data Auditing and Monitoring**
  - Screening for:
    - Missing forms
    - Missing values
    - Unavailability of information
Regulatory Management
Clinical Trial Lifecycle

Development → Review → Activation

Conduct → Analysis → Publication

Closeout
Regulatory Management

Prior to site activation and during lifecycle of a study.

- Data managers help with collection of regulatory documents e.g., FDA form 1572, CV, medical licenses, human subjects protection training, financial disclosure forms, delegation logs.

- Documentation of site IRB protocol and consent approval.
Impact of Data Management

• In conclusion, data managers play a key role in clinical trials that goes beyond data entry into a role that contributes to generation of quality data

• This leads to research publication in the medical and scientific community with a goal of increasing access to HCT and to improve outcomes
Pop Quiz for Prizes!
When your table knows the answer stand up as a group. First table with the right answer wins a prize
Survey Research Group (SRG) and electronic Patient Reported Outcomes (ePRO)
Survey Research Group Key Functions

• Support research studies that involve direct contact with participants, usually by phone
  – Many studies within RCI BMT but other partnerships as well such as NMDP Health Services Research and Bioinformatics and the BMT CTN.

• Participants include related and unrelated donors, transplant survivors, patients awaiting or not going to transplant, registry members and families

• Contact participants to complete a survey over the phone or to follow up on materials sent
  – Consent forms, paper surveys, buccal swab kits, blood draw kits
Pop Quiz for Prizes!
Get ready to stand up as a table
SRG and Data Managers

The work of data managers is critical to our success

• Providing accurate and timely data is important for study accrual estimates and study selection, recruitment and arm assignment

• Efforts to stay in contact with patients and donors provides critical information for SRG contact and follow-up
Patient Reported Outcomes (PRO)

• Patient reported outcomes (PRO) are any report of the status of a patient’s health condition that comes directly from the patient.
  – Assessments like health-related quality of life, financial hardship or pain diaries
  – Health metrics tracked through wearable devices like heart rate or sleep patterns
• Electronic PRO (ePRO) are collected through online survey tools, mobile apps, in-clinic tablets, or wearable devices.
PRO relevance to transplant and cellular therapy outcomes

- PRO are accurate measures of a patient’s experience with disease and treatment
- PRO can be ‘biomarkers’ of disease activities
- Collecting PRO data helps expand the breadth with which we can meet long-term follow-up deliverables for our federal grants
CIBMTR ePRO collection system
(in development)

• ePRO allows for most direct, cost effective and efficient way to collect data.

• CIBMTR ePRO system will
  – Securely collect and store PRO data from patients; single time point and long term follow-up studies
  – Allow the CIBMTR Survey Research Group (SRG) to follow-up with non-responders
  – Store PRO scores alongside clinical outcomes data for center and researcher access
CIBMTR ePRO collection system

- Set of standard PRO measures
- Patient interface for completing PROs
- Patient interface for completing PROs
- CIBMTR outcomes database
- SRG’s CRM system.

PROMIS measures

Qualtrics

IDW

Salesforce
CIBMTR ePRO collection system

- Set of **standard PRO measures** that evaluate physical, mental, social health, developed by Northwestern University through NIH-Roadmap for Medical Research Initiative
- **Item Response Theory** – each question directs a more precise score with more confidence
- **Computer Adaptive Test** methodology – after first question in a measure, algorithm picks the next to display that is relevant to patient and leads to precise score. Each patient sees different questions, but their scores are comparable
CIBMTR ePRO collection system

- Cloud based online survey tool – patient interface for completing PROs
- Connects with Salesforce to streamline ePRO administration
- Connects with PROMIS to display correct questions and responses after Q1
- Receives and stores PROMIS scores

PROMIS measures
Qualtrics
IDW
Salesforce
CIBMTR ePRO collection system

- SRG’s CRM system to track studies, participants, time points, activities
- Task management and assignment, phone scripts
- Integrate with Qualtrics to streamline and automate processes
  - Adding a subject to Salesforce will push information to Qualtrics
  - A subject completing their ePRO in Qualtrics will conclude SRG follow-up
CIBMTR ePRO collection system

- Integrated Data Warehouse where outcomes data from multiple sources (FN, RAVE) are stored for research retrieval
- ePRO data and scores will be uploaded to IDW to be linked with clinical data by CRID or study ID
- Future plans to make web connection between Qualtrics and IDW
Thank you!

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