International Consultation on Research to Combat Nipah Virus Disease
Clinical Data Management – Day 3

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Agenda

- Dataflow and regional collection strategies (3 options)
- Data Management Tasks
- Data collection “hot zone” considerations
- Data sharing agreements
- Safety and SAE reporting - by whom, frequency, to whom
- Data Safety Monitoring Board
- Randomization
- Future outbreak(s) – Data Management critical tasks
- Data management / SOPs
- Data analysis
- Case Report Form Review
Dataflow and regional collection strategy (1)

- ICMR administer clinical database (1 global database)
- CRFs electronically transferred (scanned/photos) to ICMR for entry
- ICMR (centrally) responsible for data entry and data management activities
Dataflow and regional collection strategy (2)

- ICMR administer clinical database (1 global database)
- All sites have access to clinical database
- CRFs entered by sites directly into clinical database
- Data management activities shared across sites
Dataflow and regional collection strategy (3)

- Site specific database
- All sites have access to their own site database
- CRFs entered by sites directly into site clinical database
- Data management activities managed at each site
- Data transfers (sharing) required to ICMR
## Data Management Tasks

<table>
<thead>
<tr>
<th>Data Management task</th>
<th>Data Management strategy</th>
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<tbody>
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<td></td>
<td>1</td>
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<tr>
<td>CRF Transmission</td>
<td>Sites</td>
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<tr>
<td>Data Entry</td>
<td>ICMR</td>
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<tr>
<td>Query Management</td>
<td>ICMR</td>
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<tr>
<td>Query Resolution</td>
<td>Sites</td>
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<tr>
<td>Data Reporting</td>
<td>ICMR</td>
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<tr>
<td>Quality Control</td>
<td>ICMR</td>
</tr>
<tr>
<td>Data Transfers</td>
<td>NA</td>
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</tbody>
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### Data Strategy
- **1** – Central ICMR DB
- **2** – Central ICMR DB with direct site entry into DB
- **3** – Multiple Site DBs
Data collection “Hot zone” considerations

• Ensuring efficient way of getting data out of the “hot zone”
• Data transmission equipment & procedures
  ▪ Scanners / photos
  ▪ Identifying a secure online storage service (other than google drive)
  ▪ External hard drive to store downloaded files
  ▪ File electronic naming conventions
  ▪ Storing of potentially “contaminated” CRF & source documents
  ▪ Data connectivity (wifi equipment outside of “hot zone” however coverage within the “hot zone”).
Data sharing agreements

- Formal data sharing agreements between Indian Council of Medical Research (ICMR) all participating countries / sites
- Frequency of data transfers to be agreed-upon
- IMPORTANT: Data to remain "blinded" post-outbreaks
- Country specific regulatory issues regarding data sharing agreements to be addressed asap.
Safety and SAE Reporting

- Recording of Grade 3/4 AEs on CRFs
  - *DAIDS Table for Grading the Severity of Adult and Pediatric Adverse Events Version 2.1, July 2017*

- Recording & reporting of all SAEs
  - Reported on the SAE CRF
  - Deaths and immediately life threatening to be reported within 1 business day to ICMR data center
  - All other SAEs to be reported within 3 business days to the ICMR data center
  - SAEs (possibly, probably, or definitely related) to the research will be reported to the IRB within 7 calendar days
  - Investigators are responsible for reporting according to their IRB/Regulatory requirements
Data Safety Monitoring Board (DSMB)

- Independent DSMB will review the study at least twice a year (additional reviews might be required)
- All SAEs, Unanticipated Problems, and all Safety Reports will be reported by the ICMR data center to the DSMB
- The PI will submit the DSMB summary open reports (with the DSMB recommendations) to the IRB
- DSMB will monitor safety and may pause enrollment in the event of study-related deaths or SAEs that are considered study-related
- DSMB will review the completeness of follow-up and other aspects of study conduct
- DSMB will recommend continuing the study, modification, or terminating the study
Randomization

REDCap Randomization

Treatment code is provided – ensuring the treatment is blinded
## Future outbreak(s) – Data Management critical tasks

<table>
<thead>
<tr>
<th>Data Management (future outbreak) critical task</th>
<th>Data Management strategy</th>
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<tbody>
<tr>
<td></td>
<td>1</td>
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<tr>
<td>CRF completion training</td>
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<tr>
<td>Data Management Plan training</td>
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<tr>
<td>Database entry training</td>
<td>-</td>
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<tr>
<td>Query resolution training</td>
<td>X</td>
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<tr>
<td>Database (user) access</td>
<td>-</td>
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<tr>
<td>Database replication / implementation</td>
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<tr>
<td>Data transmittal infrastructure (“hot zone”)</td>
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</tbody>
</table>

**Data Strategy**

1 – Central ICMR DB
2 – Central ICMR DB with direct site entry into DB
3 – Multiple Site DBs
Data Management Plans / SOPs

- CRF completion
- CRF transmission / storage (“Hot zone”)
- Data entry
- Randomization
- Query management and management of CRF updates
- Quality control
- Data transfers
- Database lock
- User management and access control
## Data Analysis - RACI

<table>
<thead>
<tr>
<th>Data Analysis</th>
<th>ICMR</th>
<th>NIAID</th>
<th>WHO</th>
<th>Clinical Site</th>
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</thead>
<tbody>
<tr>
<td>Statistical Analysis Plan</td>
<td>R</td>
<td>C</td>
<td>C</td>
<td>I</td>
</tr>
<tr>
<td>DSMB Reporting (Tables and listings)</td>
<td>R</td>
<td>C</td>
<td>I</td>
<td>I</td>
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<tr>
<td>Randomization schema</td>
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<tr>
<td>Unblinding</td>
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<tr>
<td>Final Analysis</td>
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<td>C</td>
<td>C</td>
<td>I</td>
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Case Report Form Review

CRF Review

Refer to handouts
Questions