International Consultation on Research to Combat Nipah Virus Disease

Nipah Treatment Protocol Team Meeting

ICMR New Delhi
August 6-8, 2018

NIAID Perspective
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U.S. Health and Human Services

• CDC and NIH both come under the U.S. Health and Human Services
**Relevant organizational background**

**NIAID Mission:** Leading research to understand, treat, and prevent infectious, immunologic, and allergic diseases
Context: WHO Reform & NIAID Role

• Creation of WHO Health Emergencies Program (HEP)
• WHO Research and Development Blueprint focused on priority pathogens with Epidemic potential – Nipah on the list
• Each pathogen has a development product roadmap working group
• Separate vaccine & therapeutic Protocol Development teams for Pathogen X

WHO & NIAID Signed MOU for Collaboration and Facilitation for Outbreak Preparedness and Research Response
<table>
<thead>
<tr>
<th>Date</th>
<th>Event Description</th>
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<tbody>
<tr>
<td>6/5/2018</td>
<td>m102.4 in India</td>
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<tr>
<td>6/18/2018 - 7/13/2018</td>
<td>NIAID IRB Review/Approval</td>
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<tr>
<td>5/23/2018</td>
<td>WHO requests NIAID Participation</td>
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<td>5/18/2018</td>
<td>3 Nipah Deaths Reported, Kerala State, India</td>
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<td>4/20/2018</td>
<td>WHO / NIAID MOU</td>
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**New Delhi Meeting:**
- WHO
- CDC
- ICMR
- NIAID

**Protocol Developed** (5/25-6/5)
Background & Rationale

- Kerala, India Nipah Outbreak, No previous outbreaks
- Person to person, primarily encephalopathic, ARDS presentation
- 9.6 days from contact to clinical symptoms
- 2HCW, 2600 people under surveillance

- WHO Asked Dr. Higgs/NIAID (5/23) under WHO/NIAID MOU to facilitate WHO R&D Blueprint Nipah Therapeutics protocol Development Working Group: Chair Ed Cox
  - Met 5/24 & 5/25
  - Based on road map, NHP, Phase I data and status of pipeline m102.4 selected as lead product
  - Leverage MCM design except extend across outbreaks
Desired purpose of collaboration and scope of involvement collaboration

• DCR collaboration (mostly as a consultant) can facilitate the rapid research response necessary to capture important Nipah data available only at the identification of an outbreak, or during a very small window of opportunity. Combining resources will facilitate the most rapid path to effective prevention or treatment of Nipah.

• **Desired outcomes/ deliverables / measures of success**
  • ICMR/Bangladesh/Malaysia/Philippines with support from SEARO can immediately initiate the Nipah RCT protocol upon recognition of a new outbreak in the region with a large percentage of eligible participants enrolled (>80%).
  • Facilitate licensure and Incorporation novel POC diagnostic
  • Definitive answer for m1024 and then add another agent to the study
  • Data analyzed and published in high quality journals
  • Inform public health policy and practice
  • Regional EID Clinical Trials Consortium collaboratively develops through the development and execution of the study
Identified critical success factors &/or potential barriers to success

• Regional collaboration/consortium for trial with central DMC
• Protocol in place: e.g. IRBs and regulatory approvals in place
• Efficient and rapid launch of trial once outbreak is identified
  • Rapid response teams
  • POC diagnostics
  • Trained operational teams
• Prepositioned drugs at time of outbreak
• Prevent looks at data between outbreaks
High level next steps and timeline envisioned

- Regulatory and ethics approvals of regional protocol
- Finalize plans for*
  - Data management
  - Site initiation
  - Staff training
  - Laboratory
  - Drug manufacturing and distribution
  - International collaboration
  - Safety monitoring
  - Study monitoring
- Transition of protocol responsibility/accountability from NIAID to ICMR/Regional consortium
  *NIAID to consult as needed