Ebola therapeutic clinical trials

In MSF

Annick Antierens – OCB OR day 2015
Why would MSF engage in a phase II clinical trial?
Liberia

Sierra Leone

Conakry

Epidemiology
Mortality

- CFR 50–60%
- Effect of improved supportive care?
Lack of treatment options

- No registered treatment existing
- No experimental intervention passed Phase II trials
- Candidates
MSF’s position

- 6 ETC + transit centres
- 570 hospital beds
- > 50% of total patient care
- others MOH

Liberia: Monrovia Elwa 3
Equity

Evacuated expatriates have access to compassionate use of experimental products

Global push

Ethical considerations for use of unregistered interventions for Ebola virus disease (EVD) - Summary of the panel discussion
WHO statement
12 August 2014

Topics:

R&D
Biotechs find themselves in R&D spotlight as Ebola hits the headlines
August 4, 2014 | By John Carroll
How would MSF engage in a clinical phase II type trial?

- Ethical and feasible
- Expertise and support
- Independence
Ethical and feasible

Additionally to Ethical benchmarks

• Maximum of inclusion
  – No randomization
  – Compassionate use if exclusion

• No negative impact on care
  – Simple protocol, simple outcome
  – No additional interventions

• Rapid shared results

• Post trial access
Expertise and support

- Identification of intervention
- Design
- Engaging in partnerships
- Dosages and Pharmacovigilance
- Laboratory test
- Statistics and analysis
- Sharing institutional risks

Partner with Research Institutes/Consortia
Independence

- Keep medical responsibility
- Co-decisional on protocol– product– site
- Pull out if issues of patients’ best interest, acceptability, operational constraints
- No funds linked to military or pharmaceutical industry
Which intervention?

- Pre-selected list STAC-EE
  - Efficacy and safety data

- 2\textsuperscript{nd} round of selection:
  - Direct virus effect
  - Availability
  - Way of administration
What was done?
<table>
<thead>
<tr>
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<th>Brincidofovir</th>
<th>Convalescent Plasma</th>
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<tr>
<td>Antiviral</td>
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<td>IV – 2 units- one day</td>
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<td>Stop after 3 patients</td>
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Thanks to

Heroic and undestructable health and frontline workers

INSERM – Denis Malvy

Oxford U / ISARIC – Peter Horby

ITM – Johan Van Griensven
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