Expanded Access

MSF rVSV Contingency Plan

Geneva, 26th April 2017

epicentre
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Compassionate use or rVSV during EVD flare-ups in *Guinée forestière*, February–April 2016

1 day

Index case confirmed on **17/03/2016**

2 days

Report to WHO & to Ring Trial coordination

1 day

Study protocol approval NRA & Ethics Commitee

1 day

Organization of 4 teams including 4 people Logistics, cold chain preparations

TRANSPORT to Forest area by air and road

WFP support

2 days

FIELD ACTIVITIES / 4 Teams
35 team members in total

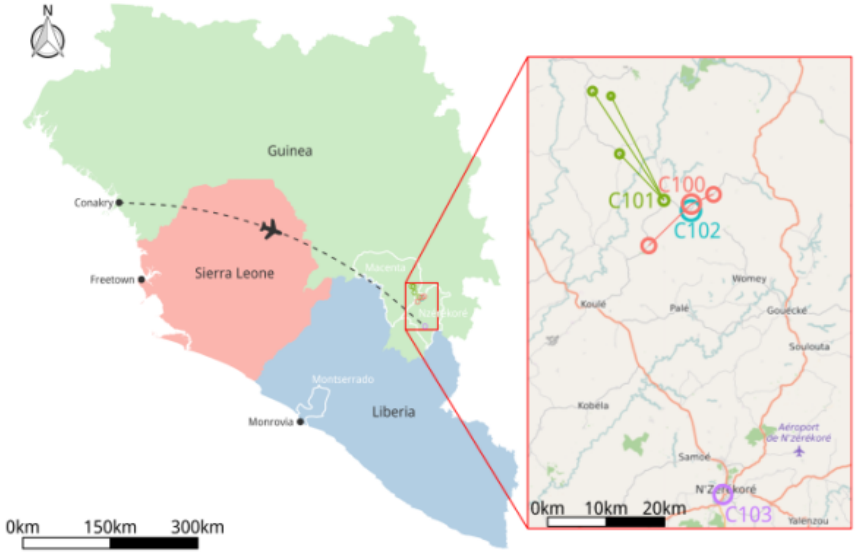
Under GCP conditions and with IC

Vaccination completed on

06/04/2016

1 month in the field to complete scheduled follow up visits

11 days



13 EVD cases in total, of which 10 confirmed (included 3 in Liberia)

4 rings
1510 persons eligible were vaccinated
(6 years of age and older)

No cases reported among vaccinees 10 or more days after vaccination

Note: Similar activities were done Sierra Leone (end of 2015,) and in Liberia in (November 2015 and April 2016).

Source= WHO, April 2017, partially supported by Gavi

Pre- Licensure access to rVSV ZEBO

- rVSV is an investigational product
- No Emergency Use Assessment and Listing (EUAL) or licensure has been obtained yet
- The investigational product can only be exported & used in the framework of a study protocol (Expanded Use)

Study Protocol & Contingency Plan

Phase 3b trial: “Open-label, non-randomized, single arm study of one dose of rVSV vaccine to prevent EVD when implemented in a ring vaccination strategy”

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MSF rVSV Contingency Plan

Countries where MSF is present and willing to intervene

Sierra Leona	Guinea	DRC	Liberia
Mali	Gabon	Guinea Bissau	Senegal
Niger	Nigeria	Sud Sudan	Ivory Coast
Uganda			

Limiting the MSF interventions to:

a) countries with **no contingency plan** for expanded use or **limited resources** to assume the coordination and costs of such intervention
b) during the estimated **period of 9 to 12 months** until the registration for emergency use of this vaccine.

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Preparation - Interactions

MERCK

SPONSOR:
Micaela Serafini, MSF-Geneva

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Rebecca Grais – Sponsor representative
GCP – Research Implementation Mobile Team
- Coordination
- Clinical research ref
- Support lab and vaccine aspects
- Support
- Support & review

HEADQUARTERS 5 SECTIONS:
Medical/Operational Directors
Focal point
Desk
Technical referents

FIELD:
Head of Mission
Medical Coordination
…

Country Representatives
National ERB/Regulations

Preparation – Protocols and SOPs

- Primary objective:
  - **Incidence** of laboratory-confirmed EVD cases 84-days after vaccination

- Secondary objectives:
  - **Serious Adverse Events** over 84 days of follow-up
  - **Adverse Events** over 28 days
  - **Pregnancy outcome**
  - **Effectiveness**

Preparation – National Level

- Contingency Plan **presentation** to relevant national authorities
- Definition of the **inclusion** of age group/pregnancy in the study
- **ERB** submission & follow up and approval
- Negotiations with **regulatory agencies**, producer and projects

Preparation: Materials

- **Study documents**
  - Protocol
  - Case Report Forms
  - Standard Operating Procedures

- **Training & Information**
  - Briefings at HQ and Mission levels
  - Information Material available
  - GCP/Protocol implementation mobile team

- **List of medical and logistical needs**
  - Study Kits – eg 20 cases
  - Cold chain modules

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Preparation: State of affairs

- ERB approvals for few countries
- MoUs under discussion for some others
- Some countries expressed no need for MSF support
- Some countries expressed their interest but MSF in not present in the country
- Further negotiations (internally and externally) on going

This contingency plan is open to new vaccines as they advance in their phase of research

Questions?

Thank you!

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