

#### UN EBOLA RESPONSE MPTF FINAL PROGRAMME<sup>1</sup> NARRATIVE REPORT - VERSION 1 DATE: 12 OCTOBER 2016

<b>Project Number(s) and Title(s)</b>	Recipient Organization(s)			
#54 – Vaccination Cohort Study: Preventing late transmission of Ebola from survivors to close contacts – Phase 1 Project ID: 00098865	RUNO : World Health Organization Project Focal Point: Name: Ana Maria Henao-Restrepo E-mail: <u>henaorestrepoa@who.int</u>			
Strategic Objective & Mission Critical Action(s)	Implementing Partner(s)			
Strategic Objective 2 MCA No 3: Care for persons with Ebola and infection control Strategic Objective 5 MCA 13: Multi-faceted preparedness	Government of Guinea and a team of national and international experts, including rom Italy, UK, US, France, Germany			
Location:	Sub-National Coverage Area:			
Guinea	Basse-Guinee			
Programme/Project Cost (US\$)	Programme Duration			
Total approved budget as per project proposal document: MPTF <sup>2</sup> : US\$ 299 547	Overall Duration (3 months) Project Start Date <sup>3</sup> : 23.02.2016 Originally Projected End Date <sup>4</sup> : 31.03.2016			
Government Contribution: <i>n/a</i> Other Contributions (donors): <i>MPTF financing for Phase II of</i> <i>the study (US\$1 199 603)</i> <b>TOTAL: US\$ 1 499 150</b>	Actual End date <sup>5</sup> 30.06.2016 Agency(ies) have operationally closed the programme in its(their) system Yes No $\Box \blacksquare$ Expected Financial Closure date <sup>6</sup> : 31.03.2017			
Programme Assessment/Review/Mid-Term Eval.	Report Submitted By			
Evaluation Completed       □     Yes       ■     No       Evaluation Report - Attached       □     Yes       ■     No	<ul> <li>Name: Kerstin Bycroft</li> <li>Title: RM Officer</li> <li>Date of Submission: 12 October 2016</li> <li>Participating Organization (Lead): WHO</li> <li>Email address: bycroftk@who.int</li> </ul>			
	Signature:			

<sup>&</sup>lt;sup>1</sup> Refers to programmes, joint programmes and projects.

<sup>&</sup>lt;sup>2</sup> The amount transferred to the Participating UN Organizations – see <u>MPTF Office GATEWAY</u>

<sup>&</sup>lt;sup>3</sup> The date of the first transfer of funds from the MPTF Office as Administrative Agent. The transfer date is available on the online MPTF Office GATEWAY.

<sup>&</sup>lt;sup>4</sup> As per approval of the original project document by the Advisory Committee.

<sup>&</sup>lt;sup>5</sup> If there has been an extension, then the revised, approved end date should be reflected here. If there has been no extension approved, then the current end date is the same as the originally projected end date. The end date is the same as the operational closure date, which is the date when all activities for which a Participating Organization is responsible under an approved project have been completed. As per the MOU, agencies are to notify the MPTF Office when a programme completes its operational activities. Please see <u>MPTF Office Closure Guidelines</u>.

<sup>&</sup>lt;sup>6</sup> Financial Closure requires the return of unspent funds and the submission of the <u>Certified Final Financial Statement and Report.</u>

## PROJECT/PROPOSAL RESULT MATRIX

Project Proposal Title: Vaccination Cohort study : Preventing late transmission of Ebola from survivors to close contacts							
Strategic Objective to which the project contributed	SO2: Treat the infected SO5: Prevent outbreaks in countries currently unaffected.						
MCA 3, MCA 13 <sup>7</sup>	MCA3: Care for Person With Ebola and Infection Control MCA13: Multifaceted Preparedness						
Output Indicators	Geographical Area	Target <sup>8</sup>	Budget	Final Achievements	Means of verification	Responsible Organization(s).	
Number of participants recruited for the initial phase of the vaccination programme	Guinea	1000	200 000	1629	Interim report produced	WHO, Government of Guinea	
% blood samples of selected participants systematically collected and analysed at 28 day period	Guinea	100% blood sample collected and analysed at 28 days	79 950	78%	Interim report produced	WHO, Government of Guinea	
Effect Indicators	Geographical Area Guinea	Baseline <sup>9</sup> In the exact area of operation	Target	Final Achievements	Means of verification	Responsible Organization(s)	
% reduction in Ebola disease incidence among the vaccinated group of Survivors and close contacts in Guinea as result of the vaccination programme	Guinea	To be collected at start of trial	More than 50%	Information not yet available (phase II of the study is ongoing)	Study protocols, results	WHO	
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<sup>7</sup> Project can choose to contribute to all MCA or only the one relevant to its purpose.
<sup>8</sup> Assuming a ZERO Baseline.
<sup>9</sup> If data is not available, please explain how it will be collected.

### FINAL PROGRAMME REPORT

#### EXECUTIVE SUMMARY

Transmission linked directly to the original outbreak of Ebola in West Africa was declared to have ended in all three affected countries at the end of December 2015. However, further cases were expected as a result of the re-emergence of Ebola virus from a small proportion of survivors for whom the virus remained present in some bodily fluids.

One such outbreak was detected on 17 March in N'Zerekore, southeast Guinea. In early April a linked cluster of three cases was reported in Monrovia, Liberia. By 30 April, thanks to the rapid response of Guinean and Liberian authorities supported by WHO, all contacts in both countries had completed follow up, and all patients treated for EVD had tested negative for virus in their blood.

The Ebola outbreak in West Africa 2014-2016 has shown that late transmission of the virus from survivors to close contacts due to viral persistence is a significant challenge to stopping all cases of Ebola in the region, and that there is significant residual risk of further outbreaks caused by the re-emergence of virus that had persisted in a small proportion of survivors. Liberia, supported by WHO capacity in country, had recently had to respond rapidly to an isolated cluster of two cases, and on 14 January 2016 had just confirmed the end of transmission linked to that cluster when Sierra Leone announced the detection of and rapid response to what would also prove to be a two-case cluster. Transmission linked to that cluster would be declared to have ended on 17 March – the same day that Guinea announced that its surveillance system had detected a cluster of two confirmed and three probable cases in the southeast of the country.

The March 2016 outbreak in Guinea meant that all three countries had recorded cases of EVD since the end of Ebola transmission directly linked to the original outbreak had been declared. In most cases the exact cause of these outbreaks has been impossible to pin down, but through a combination of traditional field-based epidemiological investigation, real-time viral genome sequencing, and ongoing studies into the persistence of virus in bodily fluids, the most likely cause in each instance was determined to have been exposure to Ebola virus that had persisted in individuals who had survived a previous infection. WHO is collaborating with partners on several studies of viral persistence in individuals who have survived infection with Ebola virus. Preliminary results have shown that, in rare cases, Ebola virus fragments can be detected in some bodily fluids of individuals up to 12 months after the onset of symptoms. There also seems to be the possibility of disease relapse in some individuals, although there are currently very few documented cases. The risks posed by such cases of viral persistence are small, and decrease over time as survivors continue to clear the virus, but the potential consequences of any reintroduction of EVD are considerable

A landmark study examining viral persistence in survivors has shown that some men still produce semen samples that test positive for Ebola virus nine months after onset of symptoms. Better understanding of viral persistence is important for supporting survivors to recover and to move forward with their lives. It is also crucial for the prevention of the re-introduction of Ebola virus. Post-recovery transmission events (PRTEs) due to Ebola virus carriage in semen or other body fluids of Ebola survivors have the potential to trigger clusters of disease and restart wider transmission. A particular concern is male-to-female sexual transmission, because the virus can persist in semen for many months, with documented transmission. Ending Ebola requires diminishing the potential risk of late transmission from survivors to their close contacts.

This study is designed to test the effectiveness of a vaccination program in preventing the transmission of Ebola from survivors to close contacts. It will determine the effect of natural seropositivity on the immunogenicity and safety of the VSV-ZEBOV vaccine. The study is using rVSV-ZEBOV (Merck), following the very promising efficacy results in the interim analysis of the WHO-led ring vaccination trial (suggesting 100% protection, and unlikely to be less than 75% protective), and early indications of safety from the ring trial and studies in non-outbreak settings.

# • Key Achievements:

- Good clinical practice training was organized from February 11th to 13th. This training also focused on protocols, SOPs, and a specific training on counseling was directed to the teams in charge of survivors.
- Recruitment of Ebola survivors and vaccination of their contacts started on 23 May 2016. By 13 August 2016, a total of 48 survivors have been enrolled in the study with their samples successfully taken.
- In addition, 114 rings have been established with a total of 1631 participants recruited among which 1629 contacts of survivors were effectively vaccinated. Each ring having an average of 14.2 participants per ring
- Phase II of the study is ongoing until 2017, with preliminary results to be expected by March 2017

# • Delays or Deviations

• The recruitment of Ebola survivors and vaccination of their contacts started only in May 23rd due to the comments and suggestions from the Ethics Review Committees that needed to be addressed, thus delaying the approvals and the start of the study. The holy fast period of Ramadan and the rainy season slowed down the recruitment process, but did not have any impact on the follow-up rate. The inclusion period of new participants for vaccination stopped at the end of August 2016. The follow up period will last until the end of September 2016.

### • Gender and Environmental Markers (Please provide disaggregated data, if applicable)

No. of Beneficiaries		
Women	509	
Girls	231	
Men	989	
Boys	322	
Total	2051	

Environmental Markers			
n/a			

- Best Practice and Summary Evaluation (will be completed at end of Phase II))
- **Lessons learned** *study still ongoing (this report covers Phase I of the study)*
- Story on the Ground *-http://www.who.int/features/2014/ebola-survivor-stories/en/*

**Report reviewed by** (MPTF M&E Officer to review and sign the final programme report)

- Name: GBAPPA Gobo Serge
- o Title: Ebola MPTF Planning, Monitoring and Evaluation Officer
- Date of Submission: October 12, 2016
- Email address: gobo.serge.gbappa@undp.org

Signature: