Joint Coordination Group Meeting
Summary of Proceedings
Transcorp Hilton Abuja, 18 January 2019

Meeting Co-Chairs (In alphabetical order)

- Peggy Hamburg (JCG Chair)
- Chikwe Ihekweazu (Director General, Nigeria Centre for Disease Control)

Member institutions represented by (In alphabetical order)

- Dicky Akanmori (WHO/AVAREF)
- Marion Gruber (FDA)
- Frank Mahoney (IFRC)
- Vasee Moorthy (WHO)
- Robin Nandy (UNICEF)
- Els Torreele (MSF)
- Charlie Weller (Wellcome Trust)

Working groups represented by

- Daniel Brasseur (Regulatory WG Chair)

CEPI Secretariat (In alphabetical order)

- Richard Hatchett
- Frederik Kristensen
- Nicole Lurie
- Gunnstein Norheim
- Dawn O'Connell
- Shannon Quinlan
- Jodie Rogers
- Melanie Saville
- Nadia Tornieporth

Nigerian Colleagues (in alphabetical order)

- Obi Adigwe (Director General, Nigerian Institute of Pharmaceutical Research and Development)
- Liasu Ahmed (Chief Medical Director, Federal Medical Centre, Owo)
- Kayode Amuda (Nigeria Food and Drug Administration and Control)
- Daniel Asogun (Head, Public Health Department, Irrua Specialist Teaching Hospital)
- Zubairu Iliyasu (Chairman, National Health Research Ethics Committee of Nigeria)
- Elsie Ilori (Head, National Lassa Fever Technical Working Group, NCDC)
- Onwe Ogah (Chief Medical Director, Federal Teaching Hospital Abakaliki)
- Sylvanus Okogbenin (Chief Medical Director, Irrua Specialist Teaching Hospital)
- Adebola Olayinka (WHO/NCDC Lassa Fever Research Lead)
- Oyeronke Oyebanji (Technical Assistant to the Director General, Nigeria Centre for Disease Control)
- Oyewale Tomori (Chair, National Lassa Fever Steering Committee)

Lassa Vaccine Developers (in alphabetical order)

- Kate Broderick (Inovio)
- Sarah Gilbert (Oxford)
- Swati Gupta (IAVI)
- Katrin Ramsauer (Themis)
- Lisa Welch (Emergent)
- Rong Xu (Profectus Biosciences)

Document Administration

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ITEM 1: Welcoming and Opening Remarks

ITEM 2: Frameworks, Roles and Responsibilities

Nigeria and Lassa

Presentation (see more in slides).

- NCDC provided a comprehensive overview of Lassa fever in Nigeria.

JCG's Role in Vaccine Development and Deployment

No slide presentation.

- The Joint Coordination Group (JCG) is an institutional roundtable made of up outside partners that each have a vested interest in the success of CEPI's vaccine candidates. Members include: WHO, GAVI, UNICEF, FDA, EMA, MSF and the International Federation of the Red Cross.
- The JCG works to advance CEPI's portfolio of vaccines by enhancing coordination of effort across the community of stakeholders and by addressing challenges related to the research and development, regulation, stockpiling, and delivery of these products.
- This JCG meeting is unique because it brings together vaccine manufacturers, JCG members and Nigerian authorities to set the stage for collective decision making and future work around CEPI's Lassa vaccine candidates.

ITEM 3: Lassa Vaccine Technical Components

Lassa Vaccine Development Updates and Timeline

Presentation (see slides).

Comments and Questions

- Standardized data collection and study sites across West Africa is needed.
- By using sera from survivors, specific immune responses can be studied. Serological assays can be used to bridge efficacy. Functional immune responses will need to be studied.
- Reference sera and antigens need to be standardized as much as possible. Concern has been expressed by some developers that this will take too much time.
- All agreed on the need to develop vaccines quickly, while highlighting that there are trade-offs between acceleration and getting the right products.

ITEM 4: Clinical Trials from the Sponsor's Perspective

No slide presentation.

- This discussion encompassed developers' concerns regarding, clinical trial design, capacity at clinical trial sites, and regulatory issues.

Comments and Questions

- In Nigeria, the ethical and regulatory review of protocols are separate.
- Ethics submissions are electronic.

- Nigeria Food and Drug Administration and Control (NFDAC) requires that vaccines must be licensed in Nigeria before undergoing the registration process. NFDAC reviews application submissions, as well as monitors and visits the sites. Additional information is provided on their website.
- Pre-review of vaccine applications is encouraged before submission.
- WHO/AVAREF will continue to facilitate joint review of protocols. EMA and FDA offered their continued support.
- Capacity building is needed at all levels, including at clinical trial sites and within the regulatory agencies.
- Genetically modified organism inquiries are handled by the National Biosafety Initiative and addressed within the specific committees or agencies that can respond to each inquiry.
- Consent forms should be provided in relevant languages besides English. Translators will be available.

ITEM 5: Special Populations

No slide presentation.

- The definition of special populations needs to be widened to the broadest possible use of the term to include children, pregnant women, lactating women, and the elderly.
- PREVENT recommendations are attached.
- Each vaccine candidate should be considered for administration to these special populations as safety information becomes available.

ITEM 6: Community Engagement

Presentation (see more in slides)

- It is important to remember that what happens with one vaccine candidate will affect the whole vaccination program. The immunization program must be engaged at the outset.
- Communication approaches must be tailored to the audience. What will work in Nigeria may not work in other countries.
- Messages must be well crafted to avoid miscommunication and negative perceptions. Community leaders play a large role in convincing the communities to obtain the vaccinations.
- Community engagement should begin with the epidemiological studies.
- Regarding Nigeria, as a result of Polio eradication efforts, UNICEF has 20,000 fixed stipend-based volunteers and a support a network of 44,500 traditional leaders that support vaccination campaigns.

ITEM 7: Regulatory Issues

- NFDAC has posted guidance documents on its website regarding acceptable submission details to the agency. www.nafdac.gov.ng/resources/guidelines/
- Nigeria has few clinical trials compared to other countries. The ethical and regulatory functions have improved over the past few years. Nigeria hopes to begin more clinical trials in the future.
- The desire for vaccine manufacturing in Africa was discussed as were the regulatory implications that would come along with such manufacturing.
- The FDA's Priority Review Voucher (PRV) program was discussed as a potential incentive.
- Benefit sharing occurs in many forms, including clinical trial capacity strengthening, conduct of clinical trials (jobs), and access to vaccine. CEPI has a strong focus on benefit sharing with low-and-middle income countries.

ITEM 8: Working Together

- This unique opportunity to bring together the JCG, Nigerian stakeholders, and CEPI's Lassa vaccine developers, has highlighted our collective capabilities and responsibilities for doing things differently to reach a successful outcome.
- Additional opportunities have been identified in the areas of: early regulatory engagement, targeted workshops, task forces, and existing working groups.
- What we discussed today are all critical elements of advancing the Lassa vaccine candidates. No one can do this alone; we must work together.