Call for concept notes:

Manufacturing, Supply and Logistics modelling for CEPI target pathogens

Background

CEPI is currently investing in the development of a number of vaccine candidates and platforms, as well as undertaking planning exercises around the manufacturing and future deployment of vaccines candidates, which are at a late stage of development and approval.

Launched in September 2018, CEPI's Sustainable Manufacturing Working Group is a sub-group of CEPI's Joint Coordination Group, with the task to find a long term sustainable manufacturing solution for CEPI vaccines beyond 2022. The Sustainable Manufacturing Working Group provided the following recommendations, which were approved by the CEPI Board:

1. Engage epidemiology research groups to model epidemiology of targeted diseases to better understand stockpiling requirements
2. Engage with CMOs, MNCs, DCVMs, equipment manufacturers, etc. to secure needed capacities for CEPI
3. Engage end users, regulators and any relevant authorities to define the minimum requirements for drug product presentation/stability criteria
4. Develop an "end-to-end" supply chain model
5. Explore which CEPI vaccine development and manufacturing processes can be standardised
6. Explore possible new business models, clarify funding requirements, identify financing solutions

The Manufacturing, Supply and Logistics (MSL) workstream of the Sustainable Manufacturing Working Group will cover recommendations 3 and 4 from the above list.

The scope of the manufacturing, supply and logistics modelling for CEPI target pathogens is to cover the development of an end-to-end supply chain model.

The MSL workstream will coordinate with the Epidemiology workstream of the Sustainable Manufacturing Working Group to better understand demand, stockpiling and supply requirements.

Aims and objectives

Aim:

CEPI aims to engage supply chain modelling groups from interested parties (including universities, technical experts, & non-profit organisations) with experience in:

a) supply chain delivery systems, and;

b) international transit requirements for vaccines on an end-to-end approach for supply chain.

Selected groups will undertake modelling exercises to understand the logistics and controls required to ensure delivery of the CEPI target pathogen vaccines.

These initial modelling studies will need to be completed by August 2019. The findings will inform the decision-making processes of the CEPI Board.

Objectives:

1. Model the optimal approach for designing lead time, capacity, and stockpile (regional stockpile vs central-hub model vs bulk vs drug product and potential use of filling regional hubs) for MERS, Lassa and Nipah and for protein, BSL 2 recombinant virus and Nucleic acid vaccines.

2. Model the optimal approach for deployment of investigational stockpile (Phase II, Phase III) vs approved vaccines.

3. Use supply and logistic models to understand the requirements and durations for deployment of a pathogen vaccine against MERS, Lassa and Nipah considering the following variables:

    a. Collection of temperature controlled drug product (DP; basis: up to 100,000 units) from manufacturing facility (target locations: Germany, Italy, UK, Maryland USA, China) to:
        i. Nigeria (Lassa)
        ii. Bangladesh (Nipah)
        iii. Saudi Arabia or Qatar (MERS)
    b. Including but not limited to carriers, regulatory import requirements, duties and tariffs, temperature monitoring and control, security, and quality systems
    c. Last-mile deployment required to the healthcare facilities.

4. Collaborate with the epidemiology workstream of the Sustainable Manufacturing Working Group in order to establish a set of agreed scenarios for vaccination strategies and focus on response to specific scenarios and determine if the supply chain can meet the overall demand.

5. In addition, as an aspirational objective, the ideal approach will have clear controls and mechanisms that can be easily modified by users to allow for changes in pathogen characteristics, numbers of doses and destination locations so that the modelling scenarios can be adapted to a future, unknown pathogen.

In order to support the development of a supply chain modelling, the awarded modelling group will work closely with selected CEPI partner consortia currently developing vaccine candidates against MERS, Lassa and Nipah.

Workplan

Deliverables:

1. Scenario for the optimal approach for designing capacity, lead time and stockpile of CEPI vaccines for rapid intervention in terms of:
    a. Stockpile of drug product *vs* stockpile of drug substance
    b. Differences in classes of vaccines (nucleic acid, BSL1, BSL 2 recombinant virus vaccine, protein)
    c. Fill finish logistics (in house at bulk manufacturer or separate CMO)
    d. Temperature stability requirements (WHO Target Product Profile *vs* worst-case -20 °C / -80 °C)
    e. Need for regional *vs* centralised storage and fill-finish operations
    f. Investigational stockpile (Phase II-III) *vs* approved product
2. Developed model scenario for the delivery of up to 100,000 doses of Drug Product as investigational stockpile and as approved vaccine product in multi-dose vials (10 mL) to health centre targeted locations in: Central Africa (Nigeria) for Lassa, Bangladesh for Nipah and Saudi Arabia/Qatar for MERS
3. Estimates for minimum and maximum durations of supply-chain based on outbreak response (incorporating defined vaccination strategy in collaboration with the epidemiology group of CEPI).

All deliverables need to be completed according to the timeline below.

Timeline (2019):

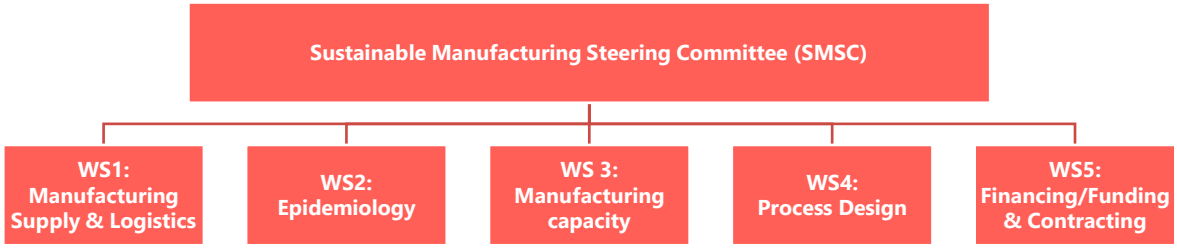
- Project commencement, definition of assumptions and key parameters, 30 April 2019
- Modelling workshop, June-July 2019
- Compilation of report and draft issued for review and approval, 15 August 2019
- Final outcomes reported to Sustainable Manufacturing Working Group, 22 August 2019
- Submission of final project report to CEPI, 30 September 2019

Governance structure

Groups engaged to undertake these modelling exercises will work directly with the CEPI Manufacturing Supply & Logistics workstream of the Sustainable Manufacturing Working Group, and the Project Manager, as a main points of contact (see figure below). Results from these exercises will inform the overall work of the Sustainable Manufacturing Working Group.

Groups engaged to undertake these modelling exercises will be expected to work in collaboration with Epidemiology modelling working group as required.

Group leaders and representatives will also be asked to participate in a workshop focussed on vaccination strategy in Summer 2019 (date TBC).



How to submit a proposal

Develop a concept note (max. 3 pages + appendices) including:

1. Description of proposed plan/modelling approach that will address the objectives described above
2. Principle investigators and research staff background
3. Track record in supply, logistics and delivery modelling
4. Track record in supply chain supply modelling
5. Experience (if any) in research/modelling of any CEPI target pathogens (Lassa, MERS Co-V, Nipah) and/or Pathogen X
6. Total cost / proposed budget and planning

The concept notes will be evaluated based on the above criteria. Evaluation will be weighted (quality of items 1-5 weighted (90%), and cost (10%).

A fully completed CEPI tenderer declaration form and CEPI tender information sheet should be included in the submission.

You can find these forms by going to www.cepi.net/tenders and then filtering by category 'Supporting Documents'.

Note: Use of figures/tables and published references or reference to publicly available work is encouraged.

Concept notes are due to CEPI by **April 17th, 2019 15:00 CET**.

In case of questions, it could be possible to contact CEPI at:

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Concept notes should be submitted via email to tenders@cepi.net.We plan to notify applicants of the of the evaluation outcome soon after the application.