IMI2 Ebola and other filoviral haemorrhagic fevers programme

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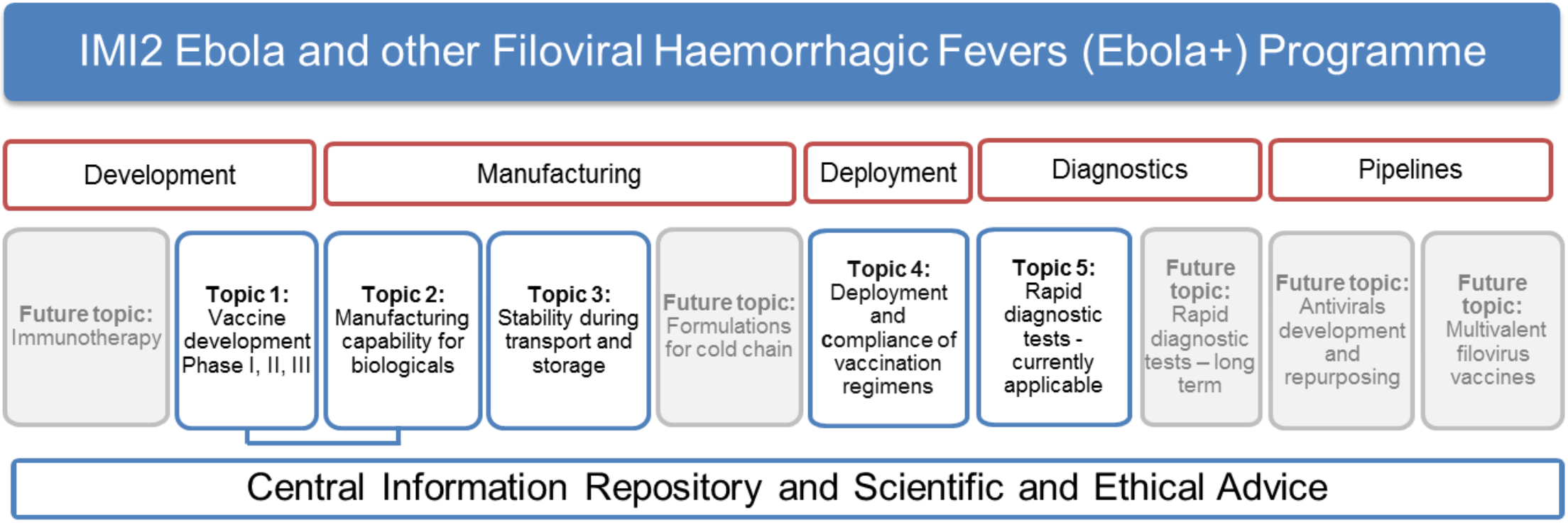
On behalf of EFPIA

Ebola+ programme overview



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Topic 1: Vaccine development Phases I, II, III

The progression of vaccine candidates currently in development is an urgent public health need (WHO)

- Design and implementation of Phase I, II, or III clinical development of vaccine candidates, including prime boost combinations against Ebola virus disease (Zaire), to start in early 2015
- The applicants must demonstrate the ability to roll out clinical trial vaccination programmes in EU / Africa / US, and to conduct studies in areas where Ebola virus disease is endemic
- The clinical development programme(s) need(s) to be aligned with the global effort coordinated by the WHO

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Topic 2: Manufacturing capability

Ebola vaccines are recombinant adenovirus or other viral-based vaccines and need to be produced in facilities meeting an appropriate biosafety level

- Scaling up currently available production techniques to the necessary scale
- Fully compliant with good manufacturing practices (GMP) and biological safety level requirements
- Generation of additional data to provide the necessary scientific, technical and regulatory justifications to seek a reclassification of current vaccine vectors

Topic 3: Stability of vaccines during transport and storage

Maintaining very low temperature required for the stability of currently available vaccine candidates in areas targeted for vaccination is challenging

- Development of tools and technologies to allow distribution of Ebola vaccines requiring very low temperatures
- Stability testing and supporting analytical capabilities to be applied at all stages of the shipping, storage and deployment process

Future topic: *Development of alternative formulations to improve the thermo-stability of clinically active vaccines*

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Topic 4: Deployment and compliance of vaccination regimens

Ensuring vaccination coverage and adherence to potential prime-boost vaccination regimen is challenging

- Development of technologies and tools that augment vaccination coverage and adherence to the vaccination regimen
- Environmental factors that impact compliance
- Projects might look at how to exploit mobile telecommunication and use of mobile apps in West Africa

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Topic 5: Rapid diagnostic tests

Rapid detection of Ebola infections is an urgent need in the current crisis and will remain important in the future

- Development of rapid diagnostics to detect EVD at acceptable costs and with high sensitivity and specificity
- Need to be able to be deployed at decentralised health care facilities under conditions with minimum laboratory infrastructures available
- Includes clinical validation in current endemic regions, registration and launch

Future topic: *Follow-up of current topic to allow long-term surveillance (would include new tests and early development)*

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