Writing a Clinical Development Plan

Working groups exercise

DCVMN Training Clinical Development 18 July 2016
Vaccine Candidate 1

- Chikungunya measles-virus-based vaccine (Chik-Meas Based Vaccine)

Dose and schedule as selected in Phase I?

Regulatory strategy

- To license the world first Chikungunya vaccine in 1-65 years old in endemic countries
- To license the vaccine in the country of origin: your country in Asia
- Possibly, to license in selected Chikungunya endemic countries
  - You select according epidemiology, market access, others?
- To obtain WHO PQ
Vaccine Candidate 2

- DTwPHibHBV is the first in the world full liquid vaccine
- First clinical study already conducted in infants in Turkey
- Satisfactory results obtained
  - See paper
- At the time only GSK DTwPHBV +Hib Lyo was the only one commercially available
Regulatory strategy

- To license the full liquid DTwPHibHBV vaccine in infants and toddlers in the country of origin: your country in Asia

- Possibly to license in other regional countries

- Obtain WHO PQ
CDPlan Sections

- For each section of the CDPlan as per template prepare 4-5 slides as appropriate