

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?

[Ramsauer K et al. Immunogenicity, safety, and tolerability of a recombinant measles-virus-based chikungunya vaccine: a randomised, double-blind, placebo-controlled, active-comparator, first-in-man trial..Lancet Infect Dis. 2015 May;15\(5\): 519-27.](#)

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