

COVID VACCINE EFFECTIVENESS

Platform based in the DRIVE lessons learnt

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Javier Díez-Domingo
FISABIO, Spain

PPPs and the European regulations.



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

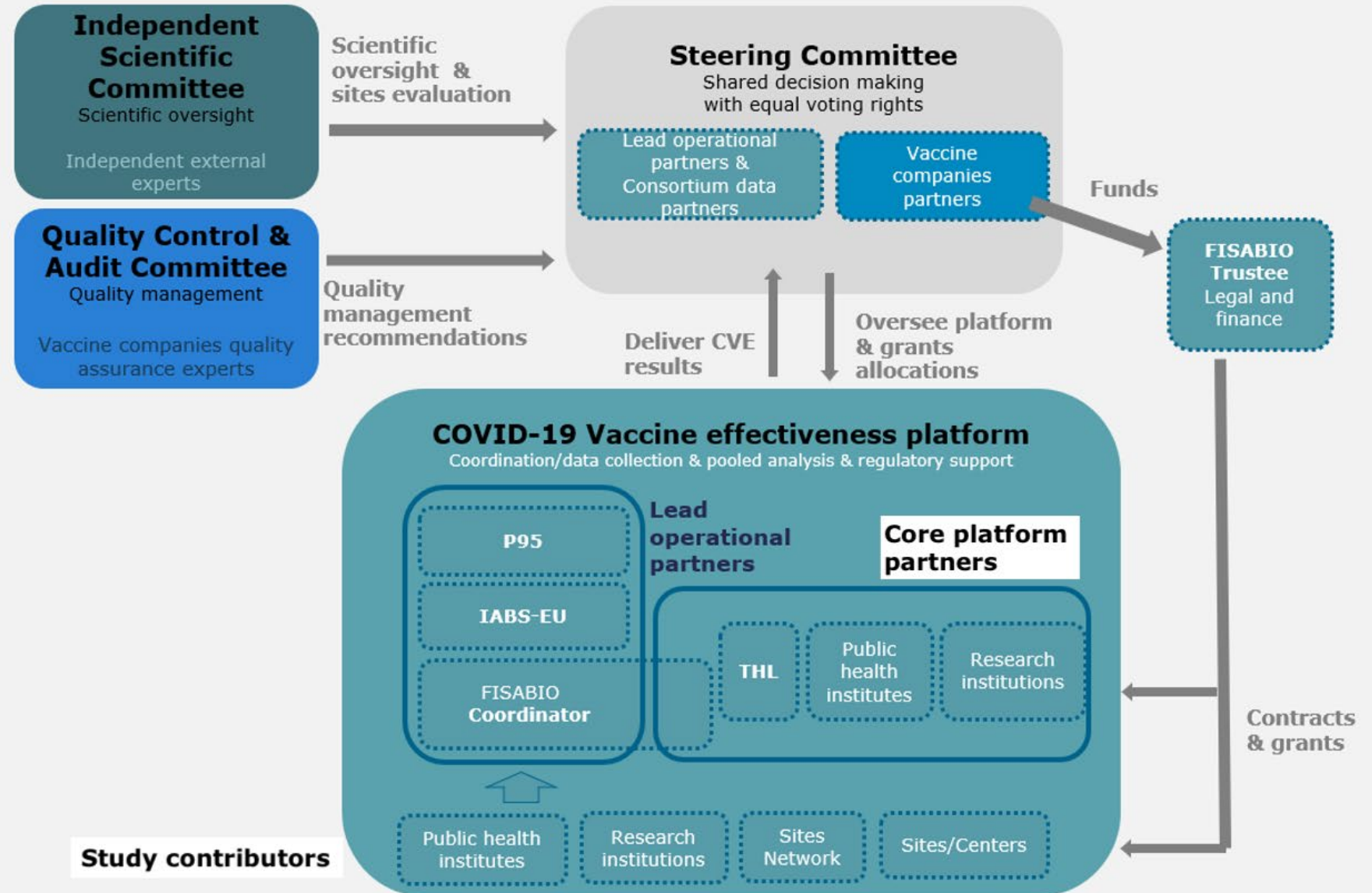
21 July 2016
EMA/CHMP/VWP/457259/2014
Committee for Medicinal Products for Human Use

Guideline on Influenza Vaccines

Non-clinical and Clinical Module

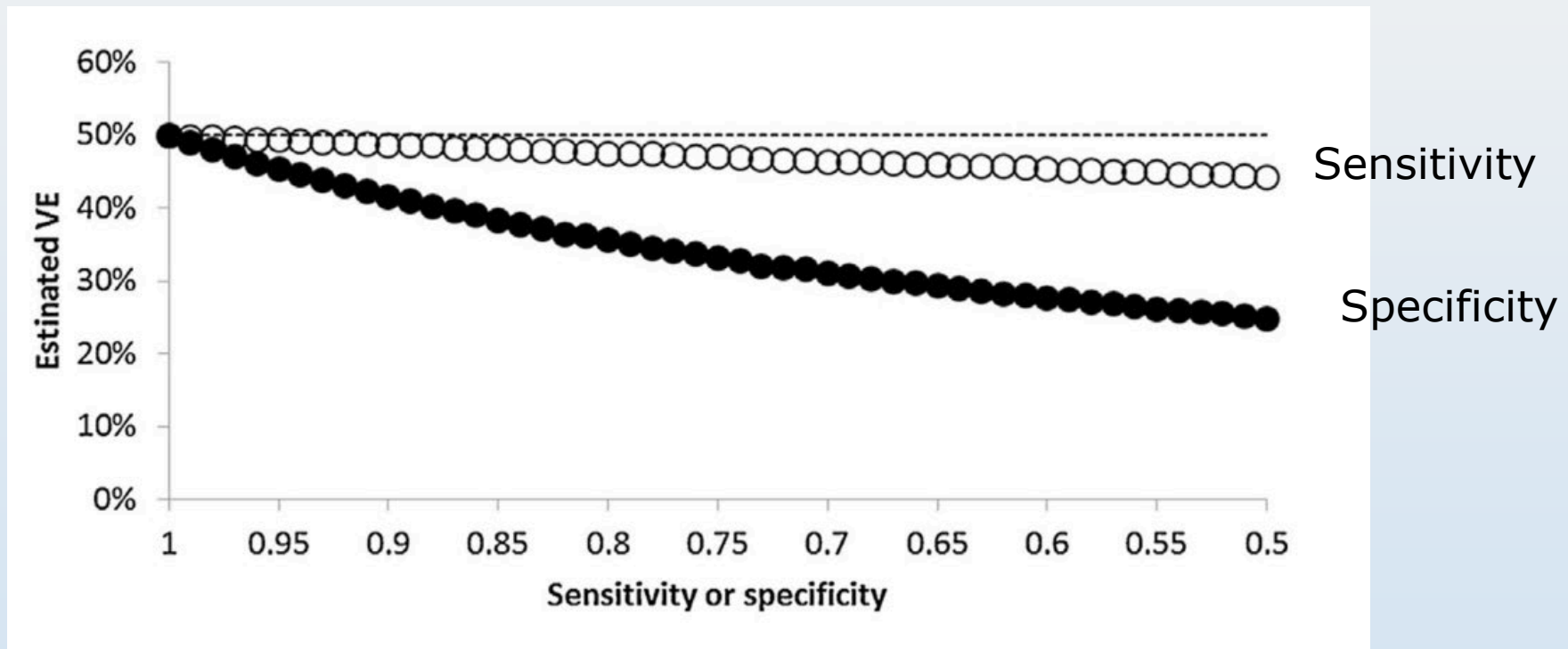
Studies will have to be conducted in accordance with Good Epidemiological Practice (GEP) guidelines and with guidelines of ENCePP. Applicants are encouraged to liaise with organisations/institutions/public health authorities who have experience in influenza effectiveness studies and who have implemented a functioning infrastructure to conduct multicentre studies.

Governance –draft proposal-



STUDY PROTOCOL. TND?

SC2 PCR: Lower sensitivity than influenza PCR



Jackson ML, 10.1016/j.vaccine.2015.01.069.