EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

26 September 2017

Submission of comments on Concept Paper on revision of the Guideline on clinical development of vaccines (EMA/CHMP/VWP/124350/2017)

Comments from:

Name of organisation or individual
ACRO (Association of Clinical Research Organizations)

Please note that these comments and the identity of the sender will be published unless a specific justified objection is received.

When completed, this form should be sent to the European Medicines Agency electronically, in Word format (not PDF).

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1. General comments

Stakeholder number *(To be completed by the Agency)*	General comment (if any)	Outcome (if applicable) *(To be completed by the Agency)*
	The Association of Clinical Research Organizations (ACRO) represents the world's leading, global clinical research organizations (CROs). Our member companies provide a wide range of specialized services across the entire spectrum of development for new drugs, biologics and medical devices – from discovery, pre-clinical, proof of concept and first-in-man studies through post-approval and pharmacovigilance research. With more than 130,000 employees engaged in research activities around the world (including 57,000 in Europe), ACRO advances clinical outsourcing to improve the quality, efficiency and safety of biomedical research. Each year, ACRO member companies conduct more than 7,000 clinical trials involving 1.3 million research participants in over 100 countries. On average, each of our member companies works with more than 700 research sponsors annually. ACRO welcomes the EMA's intention to revise and update the 2007 guideline on clinical development of vaccines. This is a welcome and rapid response to scientific changes since approval of the original Guideline. ACRO notes that, earlier this year, the World Health	

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	Organization published revised and updated guidelines on clinical evaluation of vaccines: regulatory expectations (WHO Technical Report Series No. 1004, Annex 9, 2017). In view of the global challenges related to antimicrobial resistance and the increasing importance of vaccines, and to facilitate their global development, ACRO urges the EMA to ensure that the planned EU guidance is aligned with that of the WHO. ACRO has no specific comments on the text of the EMA's Concept Paper, and fully supports the inclusion of the various points discussed in the Concept Paper. Additionally, ACRO recommends that guidance on the following important topics should also be included in the planned revision of the guideline: • A more detailed discussion (than in the current guideline) on issues associated with assay methodology, especially in relation to bridging trials where the assay method may have changed or cannot be directly compared to the original assay used during the efficacy trial. • More detailed guidance on when human challenge studies should be performed, and on the design of these trials.	

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	• More detailed guidance on the use and role of placebo in efficacy trials. • Guidance on ring vaccination trial designs. • Guidance on when clinical trials are needed to support manufacturing changes, both pre- and post-marketing authorisation. • Recognition that the collection of data on routine laboratory tests (e.g., haematology, chemistry and urine analysis) is not necessary in many clinical trials of vaccines. • Guidance on minimum considerations for the safety assessment of vaccines data in clinical trials versus the post-approval safety setting. • Guidance on factoring multi-faceted approaches in the safety assessment of vaccine data and minimum considerations for evaluating safety data generated from exposure to new vaccines or vaccine variations, including consideration of the potential impact of vaccine variations on the safety trends of a vaccine's adverse event data. • A discussion of challenges in the application of statistical data mining approaches post-approval	

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	for early detection of safety signals in vaccines data. • A discussion of critical and other important considerations in post-marketing vaccine safety surveillance in specific disease populations, healthy populations, paediatrics, elderly, and other sub populations. • A discussion of challenges in the assessment of paediatrics vaccines and rare diseases safety data. • Recognition of the particular issues which affect the pregnant population would also be welcomed. To assist the assessment of teratogenic vaccine injury, consideration should be given to a system of mandatory follow-up and reporting at a period to be determined by the relevant experts. • A discussion of the importance of registries to capture details of vaccine use in specific populations post-authorisation. • Consideration should be given to the implementation process for this Guideline,	

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	particularly the impact upon extant development programmes. ACRO thanks the Agency for the opportunity to comment on this concept paper. Please do not hesitate to contact ACRO if we can answer any questions at all (knoonan@acrohealth.org).	