



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

21 May 2013
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Human Medicines Development and Evaluation

Agenda - Workshop on Correlates for Protection and Serological Assays for Influenza Vaccines

30-31 May 2012: European Medicines Agency, London, United Kingdom

Chairs: Michael Pfleiderer and Jean-Hugues Trouvin

Wednesday 30 May 2012

Time	Topic	Presenter
09:00-09:10	Welcome and introduction	Chairs
Morning session: Predicting clinical efficacy for seasonal TIV vaccines		
09:10-09:40	Sero-epidemiology of influenza	Katja Hoschler
09:40-10:45	State of the science: correlates of protection for influenza vaccines (adj/unadj)	Katja Hoschler
	Basic principles to establish correlates for protection	Sara Thomas
	Research update on parameters to predict clinical efficacy: a) Industry views b) antibody against viral HA and NA, and protection c) assays suitability: SNA and HI assays	Mélanie Saville/Andrew Dunning Walter Beyer Marta Granstrom
10:45-11:00	Coffee break	
11:00-11:40	Factors impacting on correlates in various age groups:	



Time	Topic	Presenter
	d) young children e) elderly (>60 years)	Susanna Esposito Janet McElhaney
	Industry views	Martine Denis
11:40-12:45	How to improve prediction of clinical efficacy for seasonal vaccines (adj/unadj), in all age groups	discussion
Lunch Break 12:45- 13:45		
I Afternoon session: Predicting clinical efficacy for pandemic vaccines		
13:45-14:00	Use of animal models for predicting the efficacy of pandemic vaccines in humans	Kanta Subbarao
14:00-14:30	Research update on parameters to predict clinical efficacy in a pandemic vs. seasonal context: a) immunogenicity endpoints in a pandemic context and impact of residual immunity on post-vaccination responses	Ernst Soethout
	Industry views	Dominique Descamps
14:30-15:45	- How to improve prediction of clinical efficacy in children, adults and elderly - Factors impacting extrapolation from seasonal to pandemic: gaps in knowledge	discussion
15:45-16:00	Coffee break	
II Afternoon session: Strains with pandemic potential and pre-pandemic vaccination		
16:00-16:50	Circulating strains with future pandemic potential and pre-pandemic vaccination	Derek Smith Jacky Katz
16:50-17:00	Concluding remarks	Michael Pfleiderer

Thursday 31 May 2012

Time	Topic	Presenter
I Morning session: Live attenuated vaccines / Efficacy & effectiveness studies		
08:30-09:25	Live attenuated influenza vaccines:	
	a) can correlates of protection be identified?	Raburn Mallory
	b) potential for use of LAIV during pandemics	Kanta Subbarao

Time	Topic	Presenter
09:25-10:40	Issues with clinical efficacy studies from recent experience: • Endpoints for efficacy • Optimisation of study design • Extrapolation of study results, e.g. among strains	Michel Stoffel
10:40-10:50	Coffee break	
10:50-11:25	The role of effectiveness studies in seasonal and pandemic vaccination: an update	Bruno Ciancio
II Morning session: Development of novel influenza vaccines - a research update		
11:25-12:30	• Universal influenza vaccine, where do we stand? • Alternative adjuvanting systems Industry views	Albert Osterhaus Rebecca Jane Cox Giuseppe del Giudice
Lunch Break 12:30- 13:30		
Afternoon session: Serological assays for measuring immunogenicity - conclusions based on current knowledge		
13:30-13:45	Summary of the laboratory group conclusions (Seroepidemiology meeting, Stockholm, Dec 2011)	Othmar Engelhardt
13:45-15:55	Achieving the standardisation of serological tests for influenza vaccines: • EMA sera retesting experience • Technical proficiency monitoring - Use of standardised protocols and reagents - Use of antibody standards • Industry views • Use of a reference laboratory for serological issues • Discussion on standardisation issues	Ralph Wagner Jim Robertson / Karl Buchheit Martine Denis Othmar Engelhardt
15:55-16:05	Coffee break	

Time	Topic	Presenter
16:05-16:25	Alternative anti-HA assays	Jacky Katz Discussion
16:25-17:00	Detection of NA-specific antibodies in sera from vaccinated humans and animals	Ralph Wagner Mark Galinski Discussion
17:00- 17:20	Assays to measure CMI	Stefan Kostense Discussion
17:20- 17:30	Concluding remarks	Chairs