



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

01 October 2014
EMA/149595/2014
Human Medicines Research & Development Support Division

Agenda - Regulatory Workshop on Clinical Trials Designs in Neuromyelitis Optica (NMO) and Spectrum Disorders

10 October 2014; 30 Churchill Place, Canary Wharf, London E14 5EU

A broadcast of the workshop can be viewed by clicking on the 'multimedia' tab on the [event page](#) on the EMA website¹.

09.00 -10.40 Session 1; Background and setting

Chair: J Müller-Berghaus, CHMP, SAWP, Paul-Ehrlich-Institut, DE

Topic	Speaker	Mins
Population	J Palace, John Radcliffe Hospital Oxford Multiple Sclerosis and Neuromyelitis Group, UK	15
Natural History	F Paul, Department of clinical neuroimmunology, NeuroCure Clinical Research Centre, Charité University Medicine Berlin, DE	15
Diagnosis: New Criteria	B Weinshenker, Mayo clinic, US	10
Discussion		10
Current Standard of Care – clinical view	R Marignier, Service de Neurologie A and EDMUS Co-ordinating Center, Hôpital Neurologique Pierre Wertheimer, Hospices Civils de Lyon, FR	15
Current standard of Care – industry view	E Katz, MedImmune	15
Discussion		15

Coffee 10.40-11.00

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11.00-13.00 Session 2; Trial designs

Chair: L Pani, CHMP, SAWP, Agenzia Italiana del Farmaco, IT

Topic	Speaker	Mins
Consideration for Non Placebo/Add on Clinical Trial Designs for NMO	W Wasiewski, Alexion	20
Consideration for Placebo Clinical Trial Designs for NMO	B Cree, UCSF, US	10
Detailed methods to manage risk in a placebo trial	S VanMeter, S Kavanagh, GSK	15
Discussion		15
Patient's view	Irene Wilson	5
The Ethical Consideration of Placebo Study Design in NMO	S Woods, Policy Ethics and Life Sciences Research Centre (PEALS) Newcastle university, UK	10
FDA view	W Chambers, FDA, US	10
EMA View	MM Rosa, Faculdade de Medicina de Lisboa, SAWP, Infarmed, PT	5
EU Clinical view	MI Leite, NMO and autoimmune encephalitis Services, University of Oxford, UK	10
Discussion		20
Exit Poll on placebo comparator (anonymous by broad group)		
Lunch 13.00-14.00		

14.00-15.00 Session 3; Endpoints		
Chair: MM Rosa, Faculdade de Medicina de Lisboa, SAWP, Infarmed, PT		
Topic	Speaker	Mins
Endpoints - clinical view	A Jacob, The Walton Centre – Liverpool, UK	20
Endpoints - industry	A Perera, Chugai	20
Discussion		20
Coffee 15.00-15.15		
15.15-16.15 Session 4; Paediatric development		
Chair: D Mentzer, PDCO chair, Paul-Ehrlich-Institut, DE		
Topic	Speaker	Mins
Development of drugs in paediatric NMO- clinical	C Hemingway, Great Ormond Street Hospital, UK	20
Development of drugs in paediatric NMO- industry	J Glover, Independent pharmaceutical physician	20
Discussion		20
16.15 Wrap up		
Chair: R Hemmings, CHMP, SAWP Chair, Medicines and Healthcare products Regulatory Agency, UK		
Topic	Speaker	Mins
Exit poll results	EMA	15
Wrap up comments from panel of regulators	Regulators	
Way forward (report)		
16.30 End		

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