EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

11 December 2015
EMA/350683/2015
Corporate Stakeholders Department – SME Office

Draft Agenda - Workshop for Micro, Small and Medium-Sized Enterprises: statistical perspectives in regulatory clinical development programmes

Friday 5 February 2016, 09:00-16:00, Meeting Room 3-A

Chair: David Wright, BSWP Chairperson & MHRA

Registration and Coffee

08:30 – 09:00

	Welcome and Introduction	
	Welcome address and opening remarks by Chair • Background of SME Workshops – *David Wright, BSWP Chairperson & MHRA*	10' (09:00-09:10)

Session 1	**Introduction to general statistical considerations in clinical trials**	
	• Topics: common types of clinical trial design, study objectives, randomisation and blinding, hypothesis testing, p-values and confidence intervals, sample size calculation. – *David Brown, MHRA & BSWP 50'* • Questions and answers *25'*	75' (09:10-10:25)

Coffee Break

10:25-10:40

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Session 2	Statistical considerations in exploratory studies	
	• Topics: phase I dose escalation, phase II proof-of-concept and dose finding, modelling and simulation, predictive power and decision making, adaptive dose finding designs – *Byron Jones, EFSPI 50'* • Questions and answers *25'*	75' (10:40-11:55)

Lunch

11:55 – 13:00

Session 3	Statistical considerations in confirmatory clinical trials I	
	• Topics: study population, endpoints and estimands; superiority, non-inferiority and equivalence; choice of control group, multiple comparisons. – *Norbert Benda, BfArM & BSWP 50'* • Questions and answers 25'	75' (13:00-14:15)

Coffee Break

14:15 – 14:30

Session 4	Statistical considerations in confirmatory clinical trials II	
	• Topics: interim analysis and data monitoring committee, sample size re-estimation, adaptive designs, exploratory and confirmatory subgroup analyses, missing data. – *Oliver Keene, EFSPI 50' TBC* • Questions and answers 25'	75' (14:30-15:45)

Closing remarks by Chair