

19 September 2017
EMA/620344/2017

Agenda – Forum on bioequivalence inspections

5 October 2017 – Continental Hotel Budapest, 14:00-18:00, Budapest, Hungary

Chair: Olivier Le Blaye (ANSM)

Co-Chair: Maria Bonafonte (EMA)

Item	Preliminary draft agenda	Initials	Mins
1.	Welcome and practical information	Introduction	14:00-14:05
2.	Data integrity – early signal detection - data patterns/trends in data - similar PK profiles - etc.	Presentation	14:05-15:35
3.	Statistic applied to BE trials	Presentation	15:35-16:05
	Picture and coffee break		16:05-16:20
4.	eCRF and other electronic systems	Presentation	16:20-17:00
5.	Inspections of Ligand Binding Assays (in particular ELISAs)	Presentation	17:00-17:30
6.	Q&A	Discussion	17.30-17.45
7.	AOB	Discussion	17.45-17.50
8.	End of Forum		17:50-18:00

For preparation of the Forum: please bring any useful inspection tools (excel, word etc based, on USB stick) with you, if you like to present and share them.