EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

8 November 2012
EMA/INS/GCP/720678/2012
Compliance and Inspections

2012 EU GCP Inspectors Working Group workshop PROGRAMME

12-14 November 2012, room 2A, EMA, London (UK)

Chair: Ana Rodriguez

Day 1 – Monday 12 November 9:00-17:25

Item	Topic
	Welcome
	Introduction with training purpose and objectives
1.	EMA GCP inspections
1.1	CHMP evaluation process - where / when do the inspections fit in?
1.2	The revised procedure on Reporting EMA requested inspections-what are the new expectations
2.	Inspections of Oncology trials-inspectors' and assessors' perspective
2.1	Oncology trials- Assessors' and Inspectors' perspective • factors that affect the risk benefit balance • examples of findings that (may) affect the risk benefit balance
	BREAK OUT Session A – practice with writing the IIR for oncology trials with a focus on the impact of different findings on the risk benefit balance.
3.	Inspections of Cardiovascular clinical trials- inspectors' and assessors' perspective
3.1	Cardiovascular trials- Assessors' perspective • factors that affect the risk benefit balance • examples of findings that (may) affect the risk benefit balance
3.2	Cardiovascular trials- Inspectors' perspective
	BREAK OUT Session B – practice with writing the IIR for cardiovascular trials with a focus on the impact of different findings on the risk benefit balance.

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Day 2 – Tuesday 13 November 9:00-18:00

Item	Topic
4.	Inspection findings- Grading and Impact
4.1	Short presentations on inspection findings from EU/EEA countries
	BREAK OUT Session C - case studies/discussion points on grading of findings with practical examples
5.	GCP and ethical standards in non EU/EEA Countries
5.1	Clinical Trials in resource-limited settings outside of the EU
5.2	Ethics Committees' perspectives
5.3	Non EU/EEA Countries - Presentations on practical experiences in GCP inspections
	Round table and Q&A
6.	International cooperation on GCP inspections
6.1	Roadmap to Promote Good Clinical Practice Inspection- the APEC initiative
6.2	Other initiatives

Day 3– Wednesday 14 November 9:00-15:45

Item	Topic
7.	Data Management and Statistical Analysis
7.1	Inspecting Clinical Data Management and Statistical Analysis –common issues for inspectors to watch out for
7.2	Computer validation-practical steps for inspectors
	BREAK OUT Session D - case studies/discussion points on data collection and validation systems
8.	Inspections of BE trials
8.1	Specificities of BE trials- most common findings and how to identify them; practical examples
8.2	Short presentation on inspection findings identified in BE trials
	BREAK OUT Session E - case studies/discussion points on inspections of BE trials
General discussion and Conclusions of training course.	