EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Federal Institute for Drugs and Medical Devices

24 September 2018
EMA/INS/GCP/658233/2018
Committees and Inspections

Programme – 2018 European Union Good Clinical Practice Inspectors Working Group workshop

09-11 October 2018 in Bonn (Germany)

Chair: Federal Institute for Drugs and Medical Devices (BfArM)

Co-Chair: European Medicines Agency (EMA)

Day 1 – Tuesday, 09 October 09:00-18:00

Time	Topic
09:00-09:15	Welcome and introduction with training purpose and objectives
	1. Risk proportionate approaches in clinical trials
09:15-10:45	• Overview of documents related to the implementation of Regulation (EU) No 536/2014 • Risk-based monitoring - Points to consider for GCP inspections • A practical approach to computer systems validation
10:45-11:15	Coffee break
11:15-12:30	BREAK OUT session A– Case studies on risk based monitoring and risk based approach to computer systems validation *Groups:* *Rooms:*
12:30-13:30	Lunch break
13:30-14:00	Feedback session

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 8400 Facsimile +44 (0)20 3660 5535
E-mail info@ema.europa.eu Website www.ema.europa.eu

Time	Topic
	2. A practical view on GCP inspections at sponsor sites
14:00-15:15	Inspection planning: • Scope of the inspection • Selection of the site/facility to be inspected • Aspects to be considered during planning • Tools to prepare the inspection Inspection conduct: Presentation covering among other aspects: • Procedures and processes (and correct behaviour) • Basic principles to keep in mind • Examples and potential reactions / and options how to deal with • Some tips in the end
15:15-15:30	Introduction to BREAK OUT session B
15:30-16:00	Coffee break
16:00-17:15	BREAK OUT session B–Applying soft skills and interviewing strategies: role play sponsor – inspectors *Groups:* *Rooms:*
17:15-17:45	Feedback session: lessons learned and impressions from the role play
17:45-18:00	Conclusions and feedback on day 1

Day 2 – Wednesday, 10 October 09:00-17:30

Time	Topic
09:00-09:05	Introduction to day 2
	3. Clinical and statistical evaluation of trial data
09:05-11:15	• Handling of protocol deviations • Statistical models to handle missing data • Controlling bias in clinical trials • Inspection of clinical trials with interim analysis (incl. novel design trials, real world studies)
11:15-11:45	Coffee break

Time	Topic
11:45-12:30	BREAK OUT session C–Discussions on case studies on statistical evaluation of clinical trials and adaptive design of protocols *Groups:* *Rooms:*
12:30-13:15	Feedback session
13:15-14:15	Lunch break
14:15–16:00	4. Safety reporting in clinical trials • Reporting requirements for SUSARs[1], medical events of special interest, important medical events, treatment related AEs[2] • Inspections of clinical trials for which data safety monitoring boards (DSMB) have been implemented
16:00–16:45	Poster Session I (incl. coffee break)
16:45-17:00	Conclusions and feedback on day 2

Day 3 – Thursday, 11 October 09:00-13:45

Time	Topic
09:00-09:05	Introduction to day 3
	5. Electronic media used in clinical trials
09:05-11:40	• Overview of the updated guidance on TMF[3] • Direct entry of data in e-source, e-CRF[4]
	Panel discussion
11:40-12:00	Poster session II (incl. coffee break)
12:00-12:30	Plenary Q&A session
12:30-12:45	Conclusions of the workshop and distribution of certificates
12:45-13:45	Lunch
	End of workshop

[1] Suspected unexpected serious adverse reactions
[2] Adverse events
[3] Trial master file
[4] Electronic case report form