DDF33+34c
08/05/2019
Clinical study reports - mastering the essential skills (double workshop) (Drug Development — FOUNDATION)
08:45 until 17:00
Sarah Hopwood (Scinopsis)
Monica Milani (Apropos Science)

Participant profile
This course is intended for medical writers with no or little experience of writing clinical study reports (CSRs).

Objective
The objective of this workshop is to equip you with the essential skills required for the management and preparation of high-quality CSRs. This includes in-depth sessions on both the writing of CSRs as well as their project management. The workshop will include group exercises and discussions so that participants can develop new skills attained and learn from each other's experiences.

This double workshop brings together different aspects of knowledge and medical writing skills required (covered in depth in other workshops) for the production of CSRs.

Workshop content (8:15)
The course will cover:
- CSR project preparation and timelines
- Writing a CSR according to International Conference on Harmonisation (ICH) E3 guidelines and CORE reference
- Writing the methods sections: brief overview and advice
- Interpreting data, describing results: demography and baseline characteristics
- Interpreting data, describing results: efficacy; using the statistical report
- Interpreting data, describing results: safety and safety narratives
- Different types of CSRs: abbreviated CSR, full CSR, post-marketing reports, medical device reports
- CSR review and quality control
- Appendices: an overview

Pre-workshop assignment 1:00 hour
Post-workshop assignment 2:00 hours

Monica Milani
Apropos Science
Monica has been a medical writer since 2011. She began her career in a busy medical writing company, moved to the pharmaceutical industry, and recently transitioned into freelancing. She has experience in a wide range of regulatory and medical communication documents covering various therapeutic areas. Prior to medical writing, she worked in academia and authored numerous articles in the immunology and oncology fields. She was editor-in-chief of the open access journal

Drug Target Insights from 2008 to 2011, and served as a reviewer for several peer-reviewed journals. Monica holds degrees in biological sciences, biotechnology and scientific/technical communication.

Sarah Hopwood
Scinopsis
Sarah is head of medical writing at Scinopsis, a consultancy based in France and the UK. Sarah began her medical writing career in 2006, initially working in a busy international medical communications agency before joining the Scinopsis team in 2009. Prior to medical writing, she worked as a post-doctoral research scientist and authored numerous scientific publications in the field of neuroscience. Sarah is very experienced at writing a wide range of regulatory documents and medical communications covering many different therapeutic areas. She has been an active member of EMWA since 2007.