

Module 12: Data Management and Digitalisation in Regulatory Affairs
Date: 18-20 November 2025



Module Leader: Peter Embley

Location: TOPRA OFFICE, LONDON, UK / ONLINE

Date: Tuesday 18 November 2025

| Time | Activity | Speaker |
|-------------|--|--|
| | Registration | |
| | Welcome & Introduction to Module 12 | Peter Embley Ariello |
| | Lecture 1: Data Management and Data Governance (DM/DG) <ul style="list-style-type: none">• Background, History and Legal Basis<ul style="list-style-type: none">○ Electronic Data Capture (EDC)○ Data Input/Output○ Data Querying○ Data Management Plans• Data Standards• Regulatory Involvement in DM/DG | Gill Penrose & Tabitha Sleaf Chaucer |
| | Lunch | |
| | Lecture 2: Regulatory Information, Intelligence and Knowledge Management <ul style="list-style-type: none">• RIM Systems and Capabilities• Regulatory Intelligence• Regulatory Knowledge and Management | Dennie van de Voort & Amy Williams Deloitte |
| | Refreshment Break | |



- Lecture 3: Technical Specifications and Compliance
- ISO IDMP and EMA SPOR
 - XEVMPD
 - ePI

Dorien de Vries & Dennie van de Voot
Deloitte

Date: Wednesday 19 November 2025

| Time | Activity | Speaker |
|-------------|---|---|
| | <p>Lecture 4: Introduction to Artificial Intelligence</p> <ul style="list-style-type: none">• Introduction to Artificial Intelligence and Foundational Ideas• Artificial Intelligence Concepts• The Challenge of Artificial Intelligence Compliance• Q&A Session | <p>Paul Fletcher-Dyer Cognetivity Neurosciences Ltd</p> |
| | Refreshment Break | |
| | <p>Lecture 5: EU Telematics Strategy</p> <ul style="list-style-type: none">• EMA SPOR• Electronic applications forms (eAF)• Update on EMA 2025 Roadmap• Global IDMP implementation approaches and Health Authority collaborations | <p>Amy Williams & Dorien de Vries Deloitte</p> |
| | Lunch | |



Module 12: Data Management and Digitalisation in Regulatory Affairs
Date: 18-20 November 2025

Lecture 6: Electronic Common
Technical Document

Remco Munnik
Deloitte

- Update on Worldwide Use
- Current Technical Specifications
- Electronic applications forms (eAF)
- eCTD Demo
- Future version of eCTD

- Electronic applications forms (eAF)

Refreshment Break

Lecture 7: US Regulatory
Requirements

Nancy Pire-Smerkanich
University of Southern
California

- US Data Standards and
Resources
- CDISC
 - ADaM
 - SEND
- Reviewer's Guides
- Data Traceability and
Accountability
- eLabeling - SPL
- US FDA KASA System

Workshop Activity

Peter Embley
Ariello

Date: Thursday 20 November 2025

Lecture 8: Medical Device Related
Presentation

Monir El Azzouzi
Easy Medical Devices

- Medical Devices Regulation



- Basics & Overview of the MDR

Refreshment break

Lecture 9: Medical Device & Digital Health

Monir El Azzouzi
Easy Medical Devices

- Quality and Regulatory Application of software devices
- Overview of SaMD and SiMD
- Review of legislation changes

Lunch

Lecture 10: The Look to the Future

Paul Fletcher-Dyer
Cognetivity Neurosciences Ltd
Peter Embley
Ariello

- Machine Learning
- Artificial Intelligence
- Big Data
- RWD/E
- *AI & Data Governance*