

Module 12: Data Management and Digitalisation in Regulatory Affairs
13/01/2026 - 15/01/2026

Location: TOPRA Office: 3rd Floor, City Reach 5, Greenwich View Place, London, E14 9NN

Module Leader: James Pink

Date: 13th of January 2025

Time	Activity	Speaker
10:30	Registration	
11:00 – 11:15	Welcome & Introduction to Module 12	James Pink JPA
11:15 – 12:15	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"> o Electronic Data Capture (EDC) o Data Input/Output o Data Querying o Data Management Plans • Data Standards Regulatory Involvement in DM/DG Technical Specifications and Compliance <ul style="list-style-type: none"> • ISO IDMP and EMA SPOR • XEVMPD • ePI 	TBC
12:15 – 13:00	Lunch	
13:00 – 14:15	Lecture 2: Regulatory Information, Intelligence and Knowledge Management <ul style="list-style-type: none"> • RIM Systems and Capabilities • Regulatory Intelligence • Regulatory Knowledge and Management 	Victor Goncharuk Sanofi
14:15 – 14:30	Refreshment Break	
14:30 – 16:00	Lecture 3: Global medical device nomenclature <ul style="list-style-type: none"> • Structure Medical device ontologies and purpose	Graham Nash Gmdn
16:00	Close	

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Date: 14th of January 2026

Time	Activity	Speaker
9:15 – 10:15	Lecture 4: Introduction to Artificial Intelligence <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	Abhishek Shivkuma Element Materials
10:15 – 10:45	Refreshment Break	
10:45 – 12:30	Lecture 5: EU Telematics Strategy <ul style="list-style-type: none">• EMA SPOR• Electronic application forms (eAF)• Update on EMA 2025 Roadmap• Global IDMP implementation approaches and Health Authority collaborations	Grzegorz Kojro Perrigo
12:30 - 13:30	Lunch	
13:30 – 15:00	Lecture 6: Electronic Common Technical Document <ul style="list-style-type: none">• Update on Worldwide Use• Current Technical Specifications• Electronic application forms (eAF)• eCTD Demo• Future version of eCTD• Electronic application forms (eAF)	Daniel Langa <i>Asphalion</i>
15:00 – 15:30	Refreshment Break	
15:30 – 17:00	Lecture 7: US Regulatory Requirements <ul style="list-style-type: none">• US Data Standards and Resources• CDISC<ul style="list-style-type: none">o ADaMo SEND• Reviewer’s Guides• Data Traceability and Accountability• eLabeling - SPL• US FDA KASA System	TBC
17:00 -17:30	Workshop Activity	

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Date: 15th of January 2026

Time	Activity	Speaker
9:00 – 10:130	Lecture 8: Medical Device-Related Presentation <ul style="list-style-type: none">• Medical Devices Regulation• Basics & Overview of the MDR	Michael M. Kania Meddevo
10:30 – 10:45	Refreshment Break	
10:45 – 12:15	Lecture 9: Medical Device & Digital Health <ul style="list-style-type: none">• Quality and Regulatory Application of software devices• Overview of SaMD and SiMD• Review of legislation changes	Sorcha Murphy GSK
12:15 - 13:15	Lunch	
13:15 – 15:00	Lecture 10: The Look to the Future <ul style="list-style-type: none">• Machine Learning• Artificial Intelligence• Big Data• RWD/E• AI & Data Governance	James Pink JPA
15:00 – 15:30	Close	
