Module: Clinical Evaluation of Medical Devices
Date: 29/06/2026 - 01/07/2026

Location: TOPRA Office: 3rd Floor, City Reach 5, Greenwich View Place, London, E14 9NN
Module Leaders: Adrian Keene
Day 1: 29/06/2026

Time	Activity	Speaker
12:55 – 13:00	**Registration** **Welcome & Introduction to the Module**	**Adrian Keene** **NAMSA**
13:00 - 14:00	**Lecture 1: Current status of the EU Medical Device Regulation 2017/745**	**Adrian Keene** **NAMSA**
14:00 - 15:00	**Lecture 2: Clinical Evaluation – moving from MEDDEV 2.7.1 Rev 4 to MDR – scope of work and who performs it**	**David Mandley** **NAMSA**
15:00 – 15:30	**Refreshment break**	
15:30 -16:30	**Lecture 2 (cont'd): Clinical Evaluation – moving from MEDDEV 2.7.1 Rev 4 to MDR – scope of work and who performs it**	**David Mandley** **NAMSA**
16:30 – 17:00	**Wrap up day**	**Adrian Keene**

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Day 2: 30/06/2026

Time	Activity	Speaker
08:55 - 09:00	Introduction	Adrian Keene
09:00 - 10:00	Lecture 3: The Place of Clinical Evaluation Within Device Live-Cycle and Technical Documentation	Adrian Keene NAMSA
10:00 - 10:30	Refreshment Break	
10:30 - 11:30	Lecture 4: The Notified Body Perspective on Clinical Evaluation – the Notified Body Clinical Evaluation Assessment Report	Rachel Gibbs NAMSA
11:30 - 12:30	Lunch	
12.30 – 13.30	Lecture 5: The Summary of Safety and Clinical Performance	Rachel Gibbs NAMSA
13.30 – 14.30	Case Study	Adrian Keene/ David Mandley NAMSA
14.30 - 15:00	Refreshment Break	
15:00 - 16:00	Case Study discussion	Adrian Keene/ David Mandley NAMSA

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Day 3: 01/07/2026

Time	Activity	Speaker
09:00	Introduction	Adrian Keene
09:00-10:00	Lecture 6: The relationship between clinical evaluation and post market surveillance/post market clinical follow-up	David Mandley NAMSA
10:00 - 10:30	Refreshment Break	
10:30 – 11:30	Lecture 7: The Equivalence Assessment under MDR: When and how can this be leveraged?	David Mandley NAMSA
11:30 – 12:30	Lunch	
12:30 - 13:30	Lecture 8: Clinical Investigations under MDR:	Dan Whitter NAMSA
13:30 - 14:30	Case study	Adrian Keene/ David Mandley NAMSA
14:30 – 15.00	Refreshment Break	
15:00 – 16:00	Lecture 9: Clinical Global Strategy Requirements – Focus on US FDA Specifics	Aine Duffy NAMSA
16:00 - 16:30	Wrap up	Adrian Keene NAMSA