



25 June 2021
EMA/363108/2021
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How sponsor organisations can prepare for CTIS

Date: 29th July 2021

Date: Thursday 29th July 2021
Time: 14:00-16:30 (CEST)
Event chair: Fergus Sweeney

Topic	Speaker	Time
Introduction and welcome	Fergus Sweeney EMA	14.00 - 14.05 5 mins
The CTR: what, when, why and how?	Sylvain Giraud European Commission	14.05 - 14.15 10 mins
CTIS: harmonising the submission, authorisation and supervision of clinical trials	Pieter Vankeerberghen EMA	14.15 - 14.25 10 mins
What is needed to work in CTIS: Organisation, Administrator and User Registration	Ana Rodríguez EMA	14.25 - 14.40 15 mins
CTIS personas and sponsor organisation modelling for sponsor preparedness	Sarah Scales EMA	14.40 - 14.50 10 mins
Member State support for sponsor preparedness and adoption	Maria Elgaard Sørensen Danish Medicines Agency	14.50 - 15.00 10 mins



Topic	Speaker	Time
Coffee break		15.00 – 15.15
		15 mins
Sponsor Preparedness: The Sponsor perspective	Andrea Seidel-Glaetzer ECRIN Trine Birgitte Moulvad EUCOPE Rose-Marie Swallow EFPIA	15.15 – 15.45 30 mins
EMA training and support for sponsors	Fia Westerholm EMA	15.45 – 15.55 10 mins
Panel discussion and Q&A	All Speakers Panel chair: Fia Westerholm	15.55 – 16.25 30 mins
Closing remarks	Fergus Sweeney EMA	16.25 – 16.30 5 mins