



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

18 January 2021

CTIS Programme

SME and Academia Clinical Trials Information System (CTIS) two-part training webinar – Day 2 draft agenda

Day 2

Date: 4 March 2021

Chair: EMA and Stakeholder representatives

Time	Preliminary draft agenda
13:30 – 13:40 10 min	Welcome and session overview
13:40 – 13:50 10 min	Recap of Day 1
13:50 – 14:25 35 mins	Submission of an initial Clinical Trial Application in CTIS – structure, data and documents of an initial application dossier
14:25 – 15:00 35 mins	• Update of an initial application through other applications ◦ Substantial modifications with scope - Part I only, Part II only or Part I and II ◦ Addition of a new Member State Concerned • Use of responses to Requests for Information (RFI) applicable across applications • Non-substantial modifications
15:00 – 15:20 20 min	Panel discussion and Q&A
15:20 – 15:30 10 mins	Break
15:30 – 15:40 10 mins	Sponsor activities during the life-cycle of a clinical trial • Submission of notifications
15:40 – 15:55 15 mins	Submission of trial results and layperson summary
15:55 – 16:10 15 min	Transparency – publication of clinical trial information contained in CTIS

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Time	Preliminary draft agenda
16:10 – 16:20 10 mins	Break
16:20 – 16:35 15 mins	Work-planning and management tools
16:35 – 16:55 20 mins	Panel discussion and Q&A