

19 March 2024  
Information Management

## Agenda – eCTD v4.0 Vendor Workshop

27 March 2024 (13:00 – 17:00) – WebEx meeting

The electronic Common Technical Document (eCTD) is the standard norm for industry submissions for over 20 years and currently implemented by regulators and industry in version 3.2.2. Version 4.0 of eCTD was published in December 2015 with its most recent Implementation Package v1.5 endorsed at the May 2022 ICH meeting.

This workshop, organised and facilitated by the eCTD v4.0 SME Group (EMA, NCAs and Industry), is intended for all eCTD Vendors that are interested in better understanding changes to the EU regional eCTD Specification. The event aims at fostering a discussion around the key sections of the new version of the Implementation Guide, the technical understanding of the implementation of the new standard, including the grouped submissions, document re-use and controlled vocabularies. At the moment, the focus will be on the Centralised Procedures only.

Moreover, during the workshop, the scope and timeline of the pilot, as well as the timeline for the updates of the Implementation Guide, will be discussed.

This session also offers an invaluable opportunity for participants to ask questions and provide feedback on pertinent matters.

Register for this [workshop](#).

After registration you will receive a confirmation e-mail with the link and password to access the workshop. Please make sure to save those to be able to participate to the workshop.

Item		Time	
1	<b>Introduction</b> Kristiina Puusaari, eCTD Product Owner, EMA	13:00- 13:10	5 mins
2	<b>Discussion on relevant sections of the new draft EU Module 1 Implementation Guide (Version 1.1)</b> Facilitated by Mihaela Pereteatcu and Kristiina Puusaari	13:10 – 13:55	45 mins

Item		Time	
3	<b>Technical Understanding on EU IG</b> Facilitated by Mihaela Pereteatcu and Kristiina Puusaari	13:55 – 14:25	30 mins
4	<b>Proposed scope of the Pilots (Technical and Production)</b> Facilitated by Mihaela Pereteatcu and Kristiina Puusaari	14:25 – 15:00	35 mins
Break	15:00 – 15:20		20 mins
5	<b>eCTD v4.0 tool availability</b> Facilitated by Mihaela Pereteatcu and Kristiina Puusaari	15:20 – 15:50	30 mins
6	<b>Implementation Guide and Pilot Timelines</b> Facilitated by Mihaela Pereteatcu and Kristiina Puusaari	15:50 – 16:20	30 mins
7	<b>Any other questions</b> Moderator: Cristina Pepato, eCTD Change Manager	16:20 – 16:40	20 mins
8	<b>Closing</b> Kristiina Puusaari, eCTD Product Owner, EMA	16:40 – 17:00	20 mins