

# M8 eCTD Vendor Group

July 17, 2024

# Welcome to the M8 eCTD Vendor Group

## ■ Agenda

- Objectives
- Group Communications
- Discussion Topics
- Next Steps



# eCTD Vendor Group Objectives

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- Objectives:
  - To create an ongoing forum to raise eCTD v4.0 implementation questions – e.g., specification details, etc.
  - To understand the current availability of eCTD v4.0 Tools available to Regulated Industry

# eCTD Vendor Group Communications

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- Please feel free to raise topics *before, during* or *after* the meetings
  - Agendas will be drafted to address any **ongoing** or **new** topics
  - Topics may include:
    - How to use this eCTD Vendor forum
    - Clarifications on Implementation specifications
    - Implementation status across regions
    - New requirements
- We aim to discuss implementation questions in general
  - Questions should focus on the specifications and not how specific tools are implemented
  - If you have a region-specific question, please contact the region directly
- The vendor group is solely intended to facilitate collaborative discussion on the eCTD v4.0 Implementation Specification and timelines.
  - This is not an opportunity to share product offerings

# eCTD Vendor Group Logistics

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- Meeting Agendas
  - Open call for questions or topics
  - Announcements of updates to eCTD
- Meetings Invitations
  - Invites will be sent to the eCTD Vendor Group Distribution List
    - Vendors must Opt-in to the group by sending contact information (see [eCTD v4.0 webpage](#))
  - Next meeting date: September 11, 2024
    - Otherwise, meetings will be ad-hoc as topics and feedback are received

# How to Communicate with M8

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EMAIL: [ICHM8VENDORS@ICH.ORG](mailto:ICHM8VENDORS@ICH.ORG)



- All correspondence related to the *eCTD Vendor Group activities* should be sent to the designated email.

Examples include:

- Feedback related to eCTD v4.0 topics in the eCTD Vendor Group
- Suggestions for future topics

EMAIL: [ADMIN@ICH.ORG](mailto:ADMIN@ICH.ORG)



- Official *Change Requests* to the ICH eCTD v4.0 Implementation and Controlled Vocabulary specifications
- These request will result in a change request at the specification level and be included in the next version of the eCTD v4.0 Q&A document.

# Discussion Topics

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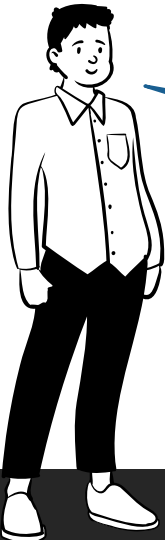
- Questions about eCTD v4.0 Implementation
- M8 Resources
  - [eCTD v4.0 Webpage](#)
    - Includes information about eCTD v4.0 Specifications and Implementation Status
- Future Topics
  - M4Q (R2) Updates
  - Smart Hyperlinking

# Next Steps

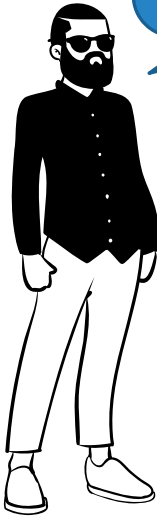
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Any Topics for future meetings?



Should we conduct outreach to other vendor groups?



Any Action Items for the group?



Is there a preferred meeting frequency?