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SCIENCE MEDICINES HEALTH

Anvisa Workshop on Regulatory Perspectives

e-CTD Version 4.0 – Current Challenges and Learnings

Regulator perspective on eCTD v4.0 implementation

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Benefits of eCTD (regulators and industry)

- Allows electronic eSubmission workflows and processes eliminating need for physical shipping and storing. This results faster turnaround times for validation and evaluation and also faster resubmission/submission of corrections
- Familiar CTD format but quicker to compile and review submissions. Reuse of documents brings further benefits!
- Validation criteria to ensure that required documentation is included and to enhance consistency

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Tips for successful implementation

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- The importance of **highlighting** the **benefits** to all stakeholders
- Clear **regional specification** (Implementation Guide) and detailed **practical implementation** guide (ideally with examples of different scenarios)
- Technical validation criteria (automated rejection)
- Change Management and communication strategies in place ensuring timely communication to all stakeholders including channels for stakeholder communication to EMA (user groups, webinars, publications etc)

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Tips for successful implementation

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- Clear **baseline requirements** (moving from non-electronic/NeeS formats to eCTD)
- **Tool vendor readiness**! Importance of good guidance to support the tool vendors to ensure aligned/harmonised implementation of validation rules across tools
- Announcement of a date for **Mandatory use** with preceding transitional steps
- Training of **reviewers/assessors** – ensure readiness with change management

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eCTD v4.0 challenges and opportunities

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- Tool dependency – Vendor readiness – Tool maturity
- Learning by doing – learning from each others
- Flexibility, flexibility, flexibility..
  - Quicker and easier updates
  - Flexibility on submission types
  - Improved lifecycle management
  - Reuse of documents/potential reduce the need for multiple submissions

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THANK YOU

Further information

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