Beyond **eCTD 4.0** eSubmission

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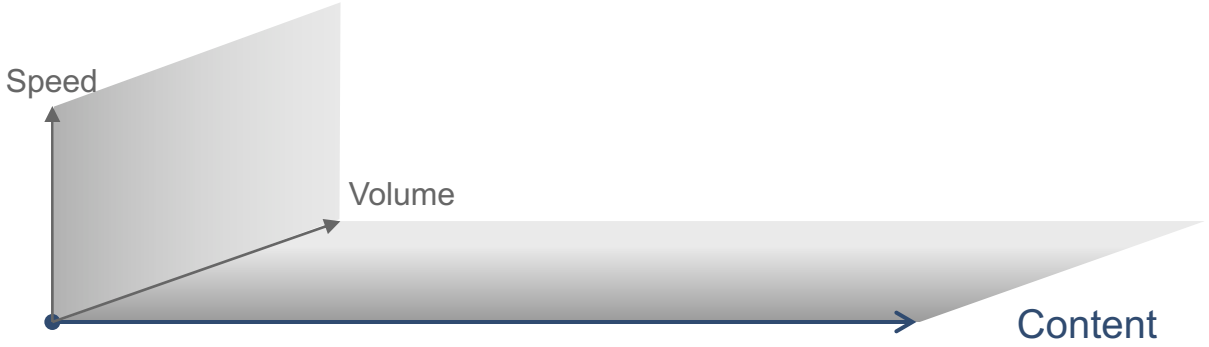
Overview – Evolution of Content



Specification

eSubmission
- CANDA
- DAMOS
- eNDA
- .
- .

eCTD 3.2
- EU, JP, US
- AU, CA, CH
- CN, KR, TH, TW
- GCC, JO, ZA

eCTD 4.0
- JP
- US

Format

Paper

Multi Formats
- TIFF
- XLS, DOC
- PDF
- .

Electronic Paper
- PDF

Data Files
- Datasets
- Media Formats

Structured Content

- The general trend is from paper to documents to data.
- eCTD 4.0 (RPS - HL7 v3) is designed for electronic documents and data files.
- FHIR - HL7 v4 is the standard for structured content – including data update in regulatory filings.

Dynamic Submission Management, DSM

Dynamic Submission Management

represents the next stage in the evolution of pharmaceutical regulation, providing flexibility to the world of filed submissions to meet the challenges of the future

LORENZ White Paper: https://lorenz.cc/dsm.cfm

Overview – Published Dates

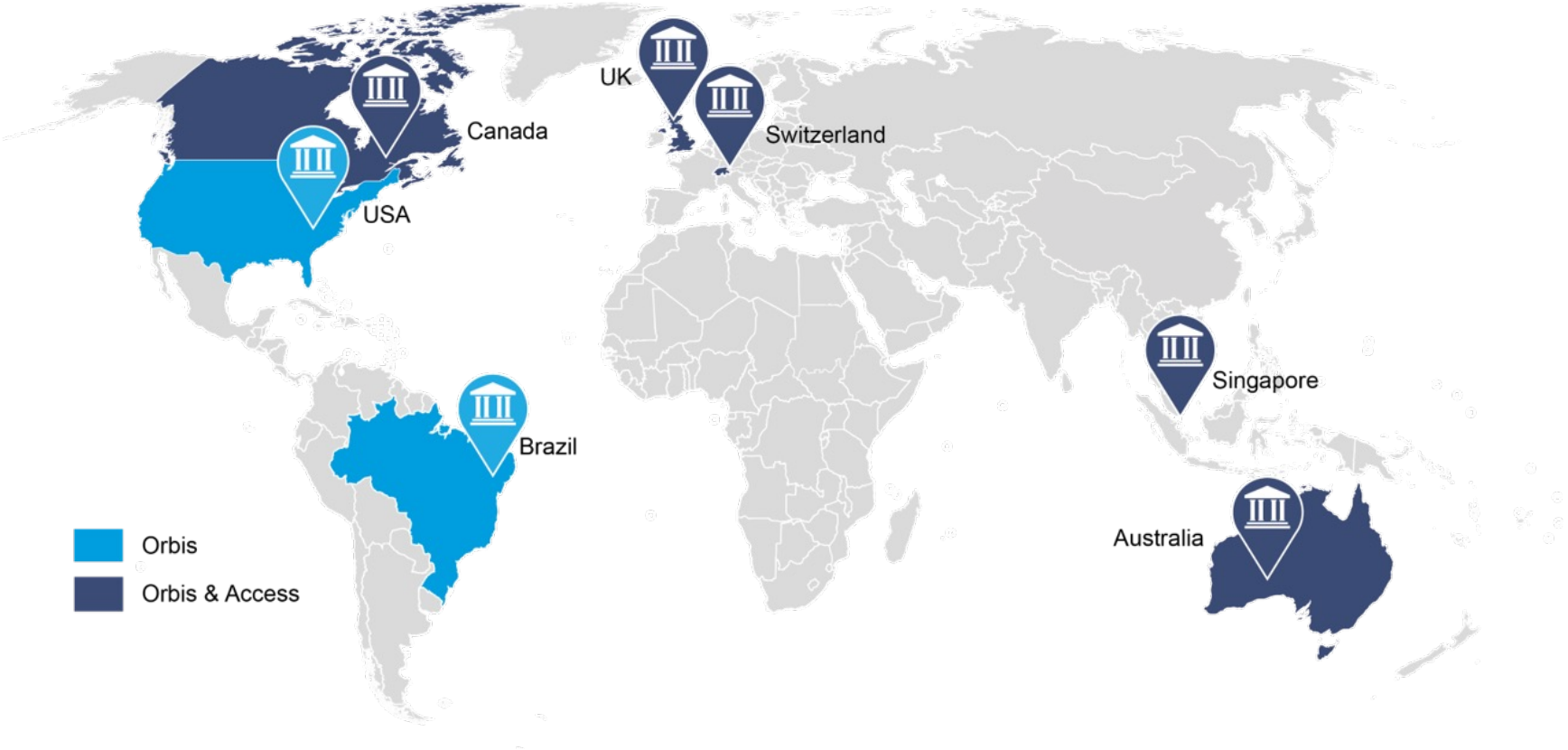
Region	Technical Pilot	Implementation Dates	
 ANVISA, Brazil	2Q 2023 (Planned)	3Q 2023 (Production Pilot)	2023 (Voluntary)
 EC, Europe	2024 CAPs (Planned)	2024 (Voluntary for CAPs) 2026 (Voluntary for NAPs) TBC (Mandatory for MRP/DCP)	2025 (Voluntary for MRP/DCP), 2026 (Mandatory for CAPs),
 FDA, United States	2022 - IQ 2023 (In Progress)	2023 (Voluntary)	2028 (Mandatory)
 Health Canada, Canada	2023 (Planned)	2024 (Voluntary)	2027 (Mandatory)
 MHLW/PMDA, Japan	2Q 2021 (Completed)	2022 (Voluntary)	2026 (Mandatory)
 Swissmedic, Switzerland	2024 (Planned)	2024 (Voluntary)	2028 (Mandatory)
 TGA, Australia	TBD	2023 (Voluntary)	

https://ich.org/page/ich-electronic-common-technical-document-ectd-v40 (updated 2023-Apr)

Forward Compatibility – Advantages and Challenges

- ✓ No need of a TMM with separate XML schema
- ✓ No separate Validation Criteria needed
- ✓ Seamless continuation from Applications of 3.2.2 format without the need to conclude all Regulatory Activities – switch to 4.0 at any time
- ✓ Enables document reuse of 3.2.2 content, including applications that have not transitioned to 4.0
- ✗ Historic Application Sequences management needs to be continued
- ✗ Vendors must modify their software

Cooperation of International NCA



ACCESS Consortium Process

- **Pipeline**
  - Early notification and enquiries regarding potential submission
- **Pre-Filing Planning**
  - Submission of EOI form
  - Consideration of EOI by ACSS Consortium
  - Division of labour for Module 3, 4 and 5
  - Evaluation plan tailored to each submission
  - Coordinated filing
- **Screening**
  - Submission filing and processing
  - Country specific screening requirements
- **Review**
  - Shared Mod 3-5 + country specific requirements
- **Sovereign decision-making by each jurisdiction**

Conclusion

- Regulatory Filing follows a constant evolution
- Items discussed today frequently:
  eCTD 4.0, FHIR, One Platform, Collaboration, etc.
  are supporting technologies
- The main challenge remains change in regulations
  and legal frameworks

Future of Electronic Submission

- White Paper 2022

  https://lorenz.cc/dsm.cfm

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