



# ICH Implementation at Anvisa

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## Anvisa as a Regulatory Member from ICH

Osaka meeting (Nov/2016) → Anvisa accepted as a Regulatory Member

**Tier I Guidelines – Immediate Implementation**  
Q1; Q7; E6



**Tier II Guidelines – 5 years**  
**November 2021 -**  
E2A; E2B; E2D; **M4; M1**

**Tier III Guidelines – Medium to long term**  
Adopt other ICH Guidelines in a near future

### Concluded and in progress activities

- Creation of a WG Responsible for the Implementation of the Tier II Guidelines → **concluded Jan/2017;**
- Mapping the resolutions that will need to be revised → **concluded**
- Establishment of a specific flow for implementation of ICH Guidelines → Regarding Regulatory Flow, activity **in progress**
- Translation (and validation) of ICH Tier II Guidelines, **in progress**
- Discussions with the Productive Sector:  
Biannual meetings with Industry to give a feedback about the implementation and assess stakeholder implementation difficulties, **in progress**
- Acquisition and Parameterization of Technological Tool → (E2B - ICSR) and M1 (MedDRA) implementation, **in progress**

**Not the main focus,** but initial discussions about the implementation of tier III guidelines have started. Efforts are concentrated **on Tier II** guidelines and active EWG



# Implementation of M4: The Common Technical Document and M8: Electronic Common Technical Document (eCTD)

- **Benchmarking:**

Conducting Visits / Conference Calls and surveys with other Regulatory Agencies that implemented CTD and eCTD → learn about their experience, main challenges and IT tools in use;

- **Pilot Project for Submission in CTD Format**

Translated Guideline including Module 1 Definition → March/April 2018;

Meeting with industry to present the pilot (paper + external media in CTD format) → March/April 2018

- **Evaluation of the results**

Assess main challenges and opportunities obtained from the Pilot experience

Define a transition period based on industry capacity and challenges (CTD format not mandatory to mandatory)

- **Acquisition of the IT Solution for the implementation of eCTD (M8)**

Adopt e-CTD to enable the maximum benefits of CTD format

Internal phase (elaborate the purchase documentation – 2018/2019) and external phase (request for tenders launch and conclusion)

- **Implementation of the IT Solution along e-CTD Submission Guideline;**

Pilot project to be expected by 2022







Thank you!

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