



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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ICH guideline M2 on eCTD - file format criteria

Step 5

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|-------------------------|---------------|
| Transmission to CHMP | December 2014 |
| Release for information | January 2015 |

ICH M2 EWG pursued the challenging task of recommending international solutions by identifying the key areas (domains) that demanded M2's immediate attention.

ICH M2 EWG concluded that the best approach would be to recommend a technological framework consisting of open international standards and interoperable products, or to identify proprietary solutions that are de facto standards, since the products offer all the required functionality.

The process of developing the technological framework and recommending solutions followed the logical path of gathering requirements, assigning specific tasks, evaluating international standards and products, and recommending a functional architecture. The M2 EWG has developed a **file format criteria** document which describes required and desired aspects and functionality to be considered in the evaluation of a file format as acceptable for the exchange of regulatory information. This document is not intended to be a prescriptive set of criteria to be met.

Link to: [ESTRI](#)

