



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

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Committee for Medicinal Products for Human Use (CHMP)

## ICH guideline M8 on eCTD – questions and answers

### Step 5

|                                      |               |
|--------------------------------------|---------------|
| Transmission to CHMP for information | December 2013 |
| Release for information              | January 2014  |

In November 2010, the ICH steering committee endorsed the establishment of an Expert Working Group (EWG)/Implementation Working Group (IWG) for the eCTD and assigned the topic code "M8". Work in relation to the eCTD had previously been undertaken by the M2 EWG.

Under the M8 remit is the support of the progression of the eCTD through the Standards Development Organisation (SDO) process to develop the eCTD as an international standard. This is in accordance with the 2008 steering committee decision that the next major version of the eCTD be developed in collaboration with SDOs, with development first as a Health Level Seven (HL7) standard, and then as an International Organization for Standardization (ISO) standard.

Also under the M8 remit is work to maintain the current ICH specifications for the eCTD and study tagging file. This work is a continuation of that undertaken by the eCTD IWG sub-group which was previously a part of the M2 EWG.

Link to document: [Questions and answers](#)



## M8 eCTD questions and answers

| Document Change History |               |                                                                                                      |
|-------------------------|---------------|------------------------------------------------------------------------------------------------------|
| Version Number          | Date          | Description                                                                                          |
| Version 1.0             | January 2003  | Initial Baseline after reviewing questions submitted to ICH                                          |
| Version 1.1             | February 2003 | ICH Steering Committee Meeting in Tokyo                                                              |
| Version 1.2             | July 2003     | ICH Steering Committee Meeting in Brussels                                                           |
| Version 1.3             | July 2003     | ICH Steering Committee Meeting in Brussels FDA Lawyer Comments                                       |
| Version 1.4             | July 2003     | Following ICH Steering Committee Meeting in Brussels                                                 |
| Version 1.5             | November 2003 | ICH Steering Committee Meeting in Osaka                                                              |
| Version 1.6             | January 2004  | Following IFPMA notification of formatting problems                                                  |
| Version 1.7             | June 2004     | ICH Steering Committee Meeting in Washington                                                         |
| Version 1.8             | November 2004 | ICH Steering Committee Meeting in Yokohama                                                           |
| Version 1.9             | May 2005      | ICH Steering Committee Meeting in Brussels                                                           |
| Version 1.10            | November 2005 | ICH Steering Committee Meeting in Chicago                                                            |
| Version 1.11            | June 2006     | ICH Steering Committee Meeting in Yokohama                                                           |
| Version 1.12            | October 2006  | ICH Steering Committee Meeting in Chicago                                                            |
| Version 1.13            | May 2007      | ICH Steering Committee Meeting in Brussels                                                           |
| Version 1.14            | November 2007 | ICH Steering Committee Meeting in Yokohama                                                           |
| Version 1.15            | June 2008     | ICH Steering Committee Meeting in Portland                                                           |
| Version 1.16            | November 2008 | ICH Steering Committee Meeting in Brussels                                                           |
| Version 1.17            | June 2009     | ICH Steering Committee Meeting in Yokohama                                                           |
| Version 1.17.1          | August 2009   | Correction of layout issues for Q&A 49 and 5 retired Q&A (6, 11, 15, 25 & 28) - no change of content |
| Version 1.18            | October 2009  | ICH Steering Committee Meeting in St. Louis                                                          |
| Version 1.19            | June 2010     | ICH Steering Committee Meeting in Tallinn                                                            |
| Version 1.20            | June 2011     | ICH Steering Committee Meeting in Cincinnati                                                         |
| Version 1.21            | November 2011 | ICH Steering Committee Meeting in Seville                                                            |
| Version 1.22            | June 2012     | ICH Steering Committee Meeting in Fukuoka                                                            |
| Version 1.23            | November 2012 | ICH Steering Committee Meeting in San Diego                                                          |
| Version 1.24            | June 2013     | ICH Steering Committee Meeting in Brussels                                                           |
| Version 1.25            | November 2013 | ICH Steering Committee Meeting in Osaka                                                              |