



23 July 2015
EMA/CHMP/ICH/820/2003
Committee for Medicinal Products for Human Use (CHMP)

ICH guideline M8 on eCTD – questions and answers

Step 5

Transmission to CHMP for information	20 July 2015
Release for information	4 August 2015

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](#)



1 M8 eCTD questions and answers

2

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
Version 1.26	June 2014	ICH Steering Committee Meeting in Minneapolis
Version 1.27	June 2015	CH Steering Committee Meeting in Fukuoka