

February 2015
EMA/CHMP/ICH/143002/2015 Rev.1

ICH Electronic Common Technical Document (eCTD) v4.0 DRAFT ICH Implementation Guide v2.0

Step 2

Transmission to CHMP	February 2015
Release for consultation	March 2015
End of consultation (deadline for comments)	22 May 2015

Background

The ICH M8 EWG was formed in November 2010 to assume responsibility for the continued development of the next major version of the eCTD. The M8 EWG has developed the draft of the ICH eCTD v4.0 Implementation Guide. This guide is now being made available as DRAFT Version 2.0 along with the draft ICH Code Lists developed by the M8 EWG.

At the November 2014 ICH meeting, the ICH Steering Committee endorsed the M8 EWG to post the ICH eCTD v4.0 DRAFT Implementation Guide v2.0 and related files for regulatory consultation.

ICH Step 2

ICH Step 2 is an ICH step where the DRAFT Guideline is agreed by the ICH Parties and adopted by the ICH Regulatory Parties.

ICH eCTD v4.0 DRAFT Implementation Guide v2.0 and related documents are being made available for regulatory consultation until May 22, 2015.

The documents are available in the Step 2 document package below.

To download the package, [click here](#).

Comments should be provided using this [template](#). The completed comments form should be sent to Step2comments@ich.org