

**EWG M2 Recommendation to the ICH Steering Committee**  
**Electronic Standards for the Transfer of Regulatory Information (ESTRI)**  
**General Recommendation - Procedure**

Version 3.0 - 11JUN2015

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**Title:** General Recommendation - Procedure

**Background:**

The Expert Working Group (EWG) of ICH M2 (ESTRI) has determined that certain M2 activities will result in recommendations and will not be subjected to the ICH Step process. These recommendations may be subject to frequent change as both science and technology advance. Therefore, it is proposed that the M2 recommendations be made available to ICH regions in a manner which will facilitate periodic updates.

**Recommendation:**

The M2 EWG proposes that the following procedure relating to recommendations made to the ICH Steering Committee be adopted by the Steering Committee.

The recommendations:

- Are categorized according to the list on the ESTRI web site. These categories may change over time to reflect the needs of ICH
- Are an agreed product from the M2 EWG
- Are presented (in person or writing) to the Steering Committee for approval and sign off
- Are published on the ESTRI web site
- Are implemented by coordinating among the Regulatory Authorities to ensure compatibility

**Conditions:**

- Each recommendation will be written using the attached template
- The header contains the version number and SC approval date of the recommendation

**Remarks:**

None

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**Attachment - Recommendation Template**

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**EWG M2 Recommendation to the ICH Steering Committee  
Electronic Standards for the Transfer of Regulatory Information (ESTRI)  
“Category” Recommendation – “title”**

Version x.x - ddmmmyyy

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**Conditions:**

**Remarks:**

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