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

Version 4.0 - 14JUN2021

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 Assembly be adopted by the Assembly.

The recommendations:
- Are identified by any ICH member parties to the M2 EWG for discussion and development
- 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 Assembly for approval
- Are published on the ESTRI web site
- Are implemented by coordinating among the Regulatory Authorities to ensure compatibility
- Are reviewed periodically and updated as needed, typically every 2 years or when changes impacting them are identified, to ensure they remain relevant and valid
- Are retired when the they are superceded or are no longer relevant

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

Remarks:
None

Attachment - Recommendation Template

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EWG M2 Recommendation to the ICH Assembly
Electronic Standards for the Transfer of Regulatory Information (ESTRI)
"Category" Recommendation – "title"

Version x.x - ddmmmyyyy

Title:

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Conditions:

Remarks:

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