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ICH guideline M5 on data elements and standards for drug dictionaries

In November 2003, the ICH Steering Committee endorsed a concept paper for topic M5 and subsequently formed an M5 expert working group (EWG) to develop ICH requirements for the standardisation of medicinal product identifiers and related terminology. In particular, a need was identified to harmonise product information that would facilitate the electronic exchange of individual case safety reports (ICSRs) within and across ICH regions using the ICH E2B format in post-marketing pharmacovigilance.

In May 2005, an M5 consensus draft guideline containing ICH business requirements for medicinal product identifiers, along with lists of controlled vocabularies for routes of administration and units of measurements was published for public consultation at step 2 of the ICH process. To support the electronic exchange of the M5 data elements proposed by the M5 EWG, technical messaging specifications were needed. Electronic messaging development for utilization by the ICH parties had been the domain of the ICH M2 EWG, but in June 2006 the ICH Steering Committee took a key decision to develop electronic specifications in collaboration with standards development organisations (SDOs). This would enable wider interoperability across regulatory and healthcare communities.

The M5 draft guideline, updated to reflect feedback from the public consultation, was subsequently submitted to the International Organization for Standardization (ISO) for development of electronic messaging specifications in February 2007. Work was conducted as a joint initiative with several other SDOs, including Health Level 7 (HL7), and various global stakeholders, including experts with experience on the ICH M5 EWG, were active participants. Abbreviated regional testing was performed by the ICH parties and five international standards for identification of medicinal products (IDMP) were finalized and published by ISO in November 2012. These five ISO standards not only meet the original ICH needs for electronic exchange of ICSRs in post-marketing pharmacovigilance, but also support broader functionality.

Having successfully finalised the international standards for IDMP, the ICH Steering Committee acknowledged the considerable achievements of the M5 EWG and agreed to the sunset of the M5 EWG in June 2013. Subsequently, the ICH Steering Committee formed a new E2B implementation working group (IWG) to facilitate implementation of the new E2B(R3) standard for electronic ICSR exchange. The remit of the E2B IWG includes the use of the five ISO IDMP standards (ISO11238:2012, ISO11239:2012, ISO11240:2012, ISO11615:2012, and ISO11616:2012) only for the purpose of electronic ICSR exchange. Therefore, IDMP maintenance and publication requirements are outside the scope of the E2B IWG.

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