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Planning for and complying with the IDMP standard for Europe

The ISO standards for the Identification of Medicinal Products (IDMP) were established in 2012 and updated in 2017. The first region to implement them will be the European Medicines Agency (EMA), which plans to use it to replace their current drug registration system called XEVMPD. Compliance with IDMP will require gathering data that is mostly locked up in narrative documents and systems outside of regulatory control, but has great potential to serve as a master data management system for EMA for improving public safety through better adverse event signal detection, reduction in prescribing errors, and prevention of counterfeit or contaminated product reaching the market. This session will discuss the progress being made toward implementing the standard in Europe as well as in other regions, and will demonstrate the approach needed to gather the information required for compliance.

Biography

Joel Finkle is the Director of Regulatory Innovation and IDMP Strategy for ACUTA. In this role, he brings new technologies and regulatory data standards to ACUTA's bio/pharmaceutical customers to ensure compliance and process improvements, as well as providing the focal point within the company for other industry standards and regulatory guidance. He came from a background of pharmaceutical industry with software and consulting vendors, with over 30 years' of experience in software development and support of electronic submissions, publishing, and document. He is currently a Member of the HL7 Regulatory/Clinical Information Management group, and the IRISS Forum.

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