
IRISS

GENERAL DESCRIPTION

Implementation of Regulatory Information Submission Standards (IRISS) (pronounced 'Iris' – the flower) is conceptualized to be a global, open, multidisciplinary, non-profit organization dedicated to robust implementation of regulatory submission standards and consideration of industry, agency and technical business requirements for current and next generation electronic regulatory submissions.

MISSION STATEMENT

The mission of IRISS is to enable successful implementation and practical usage of a paperless regulatory submissions environment which supports current regulatory processes and enables efficient and effective assembly, review and maintenance of required regulatory information in support of clinical trial applications and marketing applications around the globe. The current ICH eCTD specification is the cornerstone of this effort, but other electronic regulatory submissions standards, such as CDISC and HL7 standards are also in scope.

JUSTIFICATION

- There is currently no organization that provides a forum for all stakeholders (pharma of all sizes, generics, control submissions vendors, software vendors) to discuss implementation and interoperability issues
- The commenting and requirements processes for new versions of eCTD (and other electronic submissions specifications) is often siloed – comments and requirements are not thoroughly vetted within an inclusive environment to determine impact
- Electronic submissions standards are “owned” by a variety of organizations (ICH, HL7, CDISC) with no central forum for stakeholder discussion of requirements and/or implementation issues

GOALS AND OBJECTIVES:

GOALS

- Establish a quorum of expertise through our leaders and members such that we are recognized by the industry as a credible resource of knowledge and expertise
- Such that we can influence standards development organizations
- Can provide input to decision making bodies for electronic regulatory submission policy

OBJECTIVES

- Contribute robust technical and business requirements for eCTD v 4.0 and RPS v 2.0
- Address eCTD interoperability issues
- Provide a forum for discussion of eCTD and other electronic submission standards implementation experiences