

***IRISS* Forum Overview**

Implementation of Regulatory Information
Submission Standards

www.iriss-forum.org

The Need

IRISS is a neutral forum, open to all regulated human and animal health-care product industries in all regions that use e-CTD or its successors.



The *IRISS* concept

- ▶ To be a new voice for a multi-industry, multi-national, stakeholder membership.
- ▶ To establish a global, open, multidisciplinary, non-profit organization dedicated to the successful adoption, implementation, and technical advancement of electronic regulatory submission standards.
- ▶ To be led and managed by experts in their fields without bias or commercial gain.

The *IRISS* focus

- ▶ Initially focused on eCTD and progressing to its successors and related standards (CDISC, HL7, PIM, RPS, SPL, etc.)
- ▶ Concentrate on clear requirements, universal functionality, smooth implementation, and broad interoperability.
- ▶ Encourage and assist data standards that speed the submissions process worldwide.

The *IRISS* membership

- ▶ Professional and academic individuals.
- ▶ Corporations from small-, mid-, and large pharmaceutical companies, generics, biotechnology, medical device, diagnostics, animal health, and other industries.
- ▶ Software developers and consultants.

IRISS will not

- ▶ Develop new standards
- ▶ Sell or endorse electronic submission tools, software, or services.
- ▶ Recommend specific vendors or publish comparisons of their products or services.

The *IRISS* philosophy

- ▶ Work collaboratively with regulators and existing organizations.
- ▶ Communicate the needs and suggestions of all stakeholders to regulatory agencies and standards development organizations.
- ▶ Share implementation experiences and voice concerns and constructive ideas for improvements to feed the standards development process.

The *IRISS* structure

- ▶ IRISS will have a governance and operational structure that includes:
 - A Board of Directors (three year terms)
 - A CEO and an Executive Committee
 - Several Work Groups (project completion terms)
- ▶ Have a small administrative function.
- ▶ Have a sliding scale, annual membership fee structure to support ongoing operations.

IRISS early projects

- ▶ **Member priorities welcomed NOW.**
- ▶ Initial suggestions are:
 - 1. CMC
 - Align current industry practices for compilation of eCTD-Q
 - Explore the use of controlled terminology to better enable an electronic CMC regulatory environment
 - Provide a neutral interface to collaborate with health authorities on eCTD-Q
 - Publish position papers and draft working documents which may be leveraged by SDOs or Agencies on development of Quality topics or guidance

IRISS early projects (2)

- 2. eCTD Next Major Version
 - Monitor progress, share common concerns and provide input as it progresses through requirements, development, testing and implementation phases
- 3. eCTD vendor/industry collaboration
 - Share common concerns on interoperability
 - Possibly establish a benchmark for tool certification based on ETICS studies

IRISS depends on you

- ▶ We would like to hear from any individual or organization who would like to be involved.
- ▶ We recognize that everyone is busy and we envision several levels of involvement.
- ▶ Please e-mail us at info@iriss-forum.org