Regulatory Submissions, Information, and Document Management Forum

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IRISS: How far the Village has Come in 10 Quick Years

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DIA

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- IRISS Description
- In the Beginning
- Turning an idea into reality
- The first year
- Growing the Organization
- IRISS Today

IRISS
Implementation of Regulatory Information Submission Standards

PURPOSE

IRISS Forum is a global, open, multidisciplinary, non-profit organization dedicated to robust implementation of regulatory information and submission standards around the world. IRISS represents a neutral forum for industry, vendors, government agencies, consultants, etc. to share information and work towards improving interoperability of tools and systems for the mutual benefit of industry, agencies and ultimately, public health.

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 product development and marketing around the globe.

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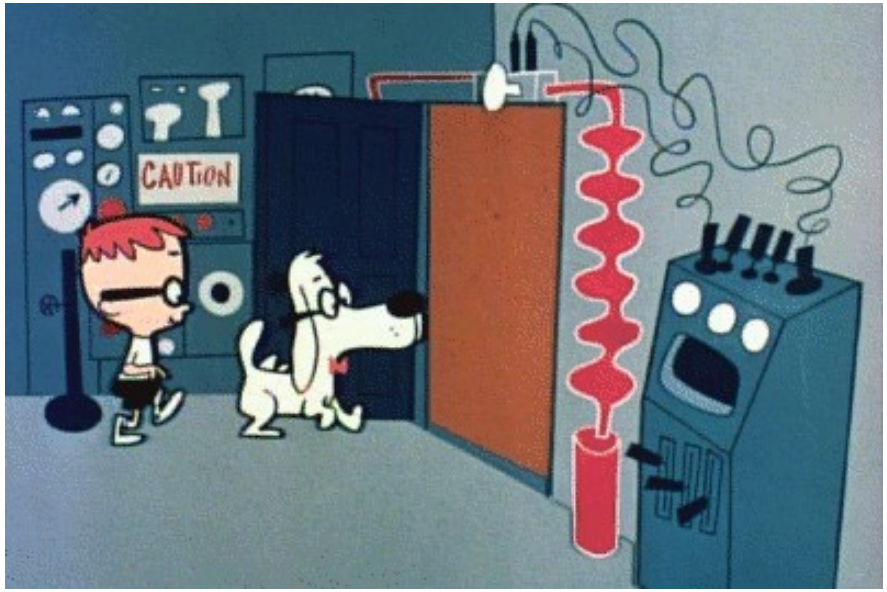
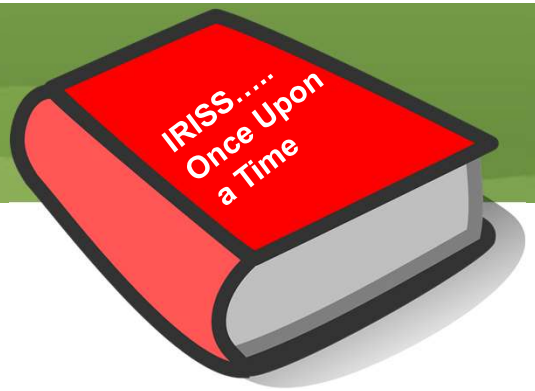
In the Beginning……..



The story starts in 2002……



- eCTD standards are published!
  - Now what – when will it be used?
- ETICS (***e***CTD ***T***ools ***I***nteroperability ***C***ompliance ***S***tudy)
  - ICH M2 subgroup formed, led by Harv Martens
    - 2006: ETICS I for US & EU
    - 2008: ETICS II includes Japan and Canada
- By 2008 approx. 14 eCTD vendors…. but:
  - With no ICH approved validation test – specs were interpreted
  - eCTD created in one tool couldn't necessarily be imported into another tool
- eCTD still open to interpretation; still open issues and questions

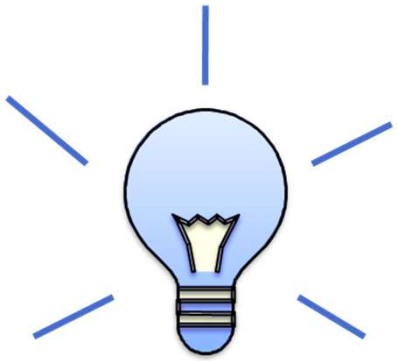
2007/2008 - Meeting of the Minds….

- Various Pharmaceutical Trade Organizations met to discuss eCTD issues
  - Meetings were closed to consultants and vendors
- Enter….. Harv Martens and Deanna Beckett
  - Wanted to see an open forum
    - Industry – Agencies – Consultants – Vendors
    - Sharing concerns, knowledge, and ideas
    - Reaching consensus on interoperability resolutions

Making the idea a reality……. March 2008

- The Idea:

A neutral, non-profit, consortium of experts and stakeholders across the pharmaceutical domain who have an interest in contributing to the further success and development of electronic regulatory submissions



Why do this…….

- Why:

A neutral forum does not currently exist to collaborate and share experience and needs from research & development, vendors and services community

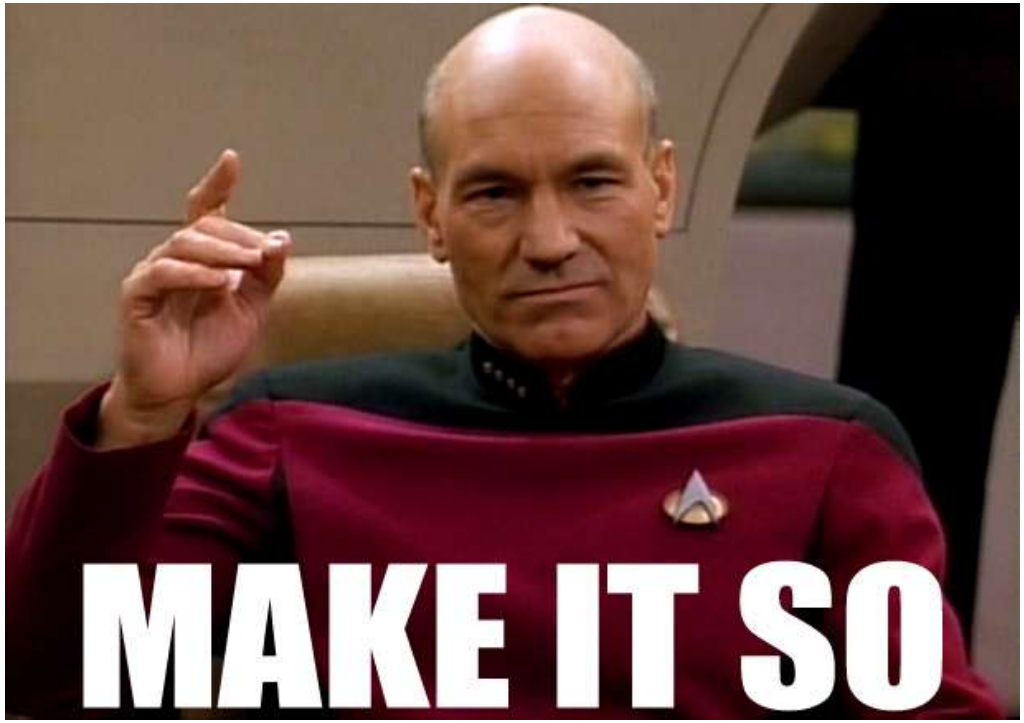
What would be our Charter…….

- Charter:

A neutral, non-profit, consortium of experts and stakeholders across the pharmaceutical domain who have an interest in contributing to the further success and development of electronic regulatory submissions

What would be our initial goals…….

- Initial Goals:
  - Topic Group Team: Contribute robust technical and business requirements for eCTD v 4.0; Address eCTD 3.x interoperability issues
  - Forum: 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



April 2008 – The Village Grows….

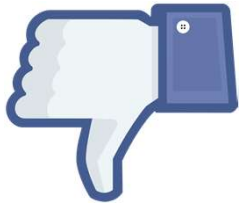
Establishing a Core Team:

- Deanna Murden
- Ron Celeste
- Betsy Fallon
- Harv Martens
- Lenore Palma
- Don Palmer
- Peggy Zorn

The First Year…….

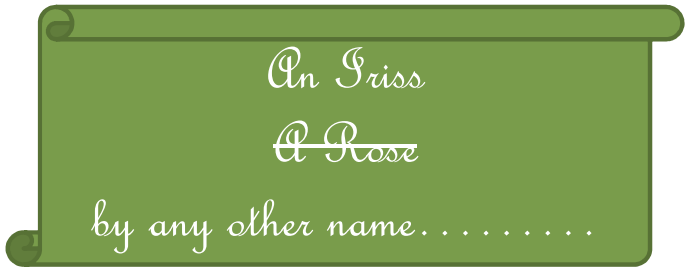
- Defining what the organization is:
  - Non-commercial
  - Global
  - Open
  - Multidisciplinary
  - Non-profit
  - Inclusive

- And is not:
  - Developer of new standards
  - Seller of electronic submission tools, software or services
  - Supporter for specific vendors or products



Coming up with a Name…….

- IRISS (pronounced ‘Iris’ – the flower) International Regulatory Information Submission Standards
- FIRSS (pronounced ‘firs’ = the tree) Forum for International/Implementation Regulatory Submission Standards
- CEEC = (say – ‘seek’) CTD Electronic Exchange Consortium
- CEIC= CTD Electronic Implementation Consortium
- EIC = eCTD Implementation Consortium (just “E-I-C”)
- I2C = International Implementation Consortium/Group/Forum
- LEIG = Life sciences eCTD Implementation Group
- FFRITS = Forum for Future Regulatory Information Transfer Standards



The First Topic Group…….

- eCTD Tool Interoperability Group (ETIG)
  - Open forum following on from ETICS outcomes
    - Industry and agencies – now adding vendors and consultants
    - Sharing knowledge to reach consensus on interoperability issues
    - Produce a best practice guideline and agreed to test scripts for vendor testing
    - Produce feedback and input into the eCTD standards as they progress forward

Fast Forward to 2010……

- 300+ members and 6 Topic Groups!
- Working on becoming a 501(c)(6) not for profit organization
- Call for Corporate Sponsorship to help fund growth and sustainability of IRISS
- Creation of IRISS-Forum.org
- Thank you Founding Sponsors for your support!

AstraZeneca
Bristol-Myers Squibb
Extedo
Liquent
Pfizer
Sanofi

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IRISS Initial Board of Directors

- By 2011 the first BoD was established
  - Donna Whiting (Chair)
  - Joe Cipollina
  - Harv Martens
  - Cindy Piccirillo
  - Rick Riegel
- Deanna Murden was officially elected to CEO/President and Executive Committee lead

10+ Years – Growing the Organization

- Steering Committee (SC) was officially established in 2011
  - Serves as the operational arm of IRISS
    - Everything from member retention, new programs, strategy execution to efficiency improvements and more
  - Includes the an SC Chair, Topic Group leads, Special Project leads, Webinar leads, and the System leads
- Our village (BoD, EC, and SC) has seen over 25 leaders over the past 10+ years
  - With some that have been with us from the beginning! (ahem – Harv, Lenore, and Gina…..)

We are all volunteers committed to maintaining IRISS's success

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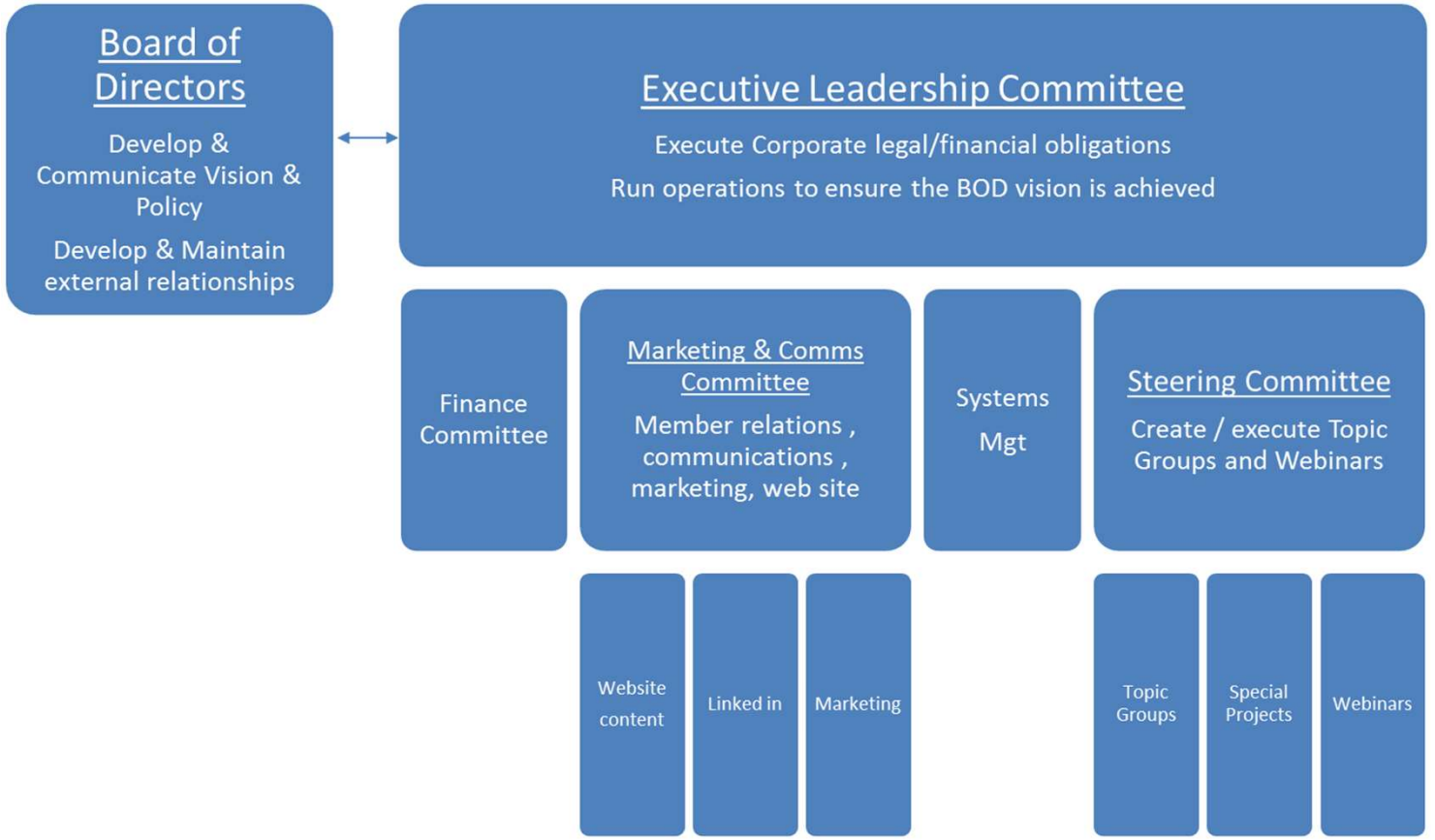
A word about our Topic Groups

- Current Topic Groups: AdPromo, CMC, Med Device, Global Submissions Operations, IDMP
  - Topic Groups meet 1x per month
- Topic Group Meetings have agendas…. but:
  - Agendas are driven by the members
  - Discussions and updates are typically delivered by members and/or experts (ex: EMA, FDA, Industry experts, etc.)
  - Meetings are interactive and open

IRISS Today

- 650+ members….. and growing!
- Looking to expand membership with our Corporate Membership and Sponsorship offerings
- In discussion about additional Topic Groups
- Communications Team soon to begin recruiting for volunteers!
- Webinars are scheduled most months with relevant and timely topics
  - Webinars are not TG specific – topics are usually of interest to many IRISS members
- Website enhancement planning is under way

IRISS High Level Governance Structure



IRISS Leadership Team

Executive Committee:
- Sue Metz (Pres./CEO)
- Kelly Hnat (VP)
- Gina Ross (Treasurer)

Board of Directors:
- Hans van Bruggen (Acting Chair)
- David Berglund
- Jake Doran
- Jim Hanly
- Karen Towns

Steering Committee:
- Kelly Hnat (Chair)
- Doug Kent (AdPromo)
- Marie Parrish (CMC)
- Karin Sailor (EMDS)
- David Ross (GSO)
- Frits Stulp (IDMP)
- Harv Martens (Special Project)
- Lenore Palma (Website)
- Kelly Hnat (Communications)

IRISS-Forum.org

Go to

www.iriss-forum.org/sign_up

to join now!

It Takes a Village……..

To the Village of IRISS…….

THANK YOU!!!!

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Types of Memberships

- Individual Membership - $99 US yearly subscription
  - Subscribe online with a credit card
    - Individual Membership of Founding Sponsor - 20% discount
      - BMS, Extedo, Liquent, Pfizer, Sanofi
- Corporate Membership – contact IRISS to arrange
  - Platinum ($4000) – unlimited individual memberships for a period of one year
  - Gold ($2000) – 25 individual memberships for one year
  - Silver ($1000) – 12 individual memberships for one year

Corporate Sponsorships

- Diamond Sponsor - $5000 annually
  - Company logo on IRISS Forum website
  - 10 individual memberships
  - Use of IRISS logo on company site and marketing materials
  - Sponsorship of up to 3 webinars for IRISS members
- Emerald Sponsor - $2500 annually
  - Company logo on IRISS Forum website
  - 6 individual memberships
  - Use of IRISS logo on company site and marketing materials
  - Sponsorship of 1 webinar for IRISS members
  - 1 mailing to IRISS members
- Ruby Sponsor - $1000 annually
  - Company logo on IRISS Forum website
  - 3 individual memberships

For more details, contact **leadership@iriss-forum.org**