OASIS DITA Pharma

Initial Meeting – 30 July 2009
Agenda – DITA PCSC

• Welcome
• Objectives of today’s meeting
• Introductions – Round Robin
• Expectations of the Group – Round Robin
• Story Boards of Opportunity – DITA in Pharma
Welcome

The OASIS DITA Pharmaceutical Content Subcommittee (DITA Pharma SC) will define DITA topics, maps, associated metadata properties and terminology to streamline design and creation of the complete body of pharmaceutical documentation required to represent a product for scientific and regulatory purposes throughout its lifecycle.

Initial objectives are to define topics and maps as required to implement:

– ICH CTD (Common Technical Document) content specification
– US IND (Investigational New Drug) content specification
– EU CTA (Clinical Trial Authorization) content specification
– FDA Structured Product Labeling content specification
– EU Product Information Management content specifications.

To optimize the value of DITA it is an objective to consider additional topics and maps for facilitating the internal business processes of content design, authoring, document review, submission assembly and regulatory portfolio management.
Vision: A Common Base Format

Publishing/presentation tier
- SPL
- eCTD
- CTA
- NN
- PDF
- Open Xml
- IND
- ODF
- PIM
- NN

Working tier
- E-Learning
- Paper
- HTML
- Framework
- Custom Apps
- Browser
- InDesign
- Arbortext
- Quark
- Word
- FrameMaker
- Excel
- XMetaL
- NN

Repository/database tier
Common Base Format
Common Base Metadata Architecture

DITA Pharma SC
Requirements for a *Common Base Format*

- Non-proprietary, open standard
- Cross-media/platforms/products/vendors/companies/time
- Tools support and availability
- Handle *existing* special pharma standards
- Adapt to *future* special pharma standards
- Handle special company requirements
- Modular to support re-use
- Advanced metadata capabilities
- Field proven
- Industry acceptance
Why *DITA* as the Common Base Format?

- Open standard
- Cross-media/-platforms/-products/-vendors/-companies/-time
- Tools support and availability
- Handle *existing* and *future* special pharma standards as well as *special* company requirements
- Topic-oriented to support re-use
- Advanced metadata capabilities
- Field proven
- Industry acceptance
- *YOU* can influence this!
DITA: Handling Special Requirements

- “D” as in “Darwin”: Evolution and inheritance:
  - Specialize and Generalize
- Built-in flexibility:
  <data>, <foreign>, and <unknown> elements
- Extensible: Specializations:
  - Domain vocabularies
  - Domain metadata architectures
  - Domain topic types:

![Diagram of domain vocabularies and architectures]

Domain vocabularies
Domain metadata architecture
DITA provides a content supply chain for Regulatory documents.

“Darwin Information Typing Architecture”

DITA

OASIS DITA Pharma SC
“in pharma today, topic and document based content must co-exist”

With DITA, submission management begins with the content supply chain...

Approved Topics

- Reusable Topics
  - * .dita

Clinical Protocols and Report Topics

- Indications (Target Labeling)
- Study Design: Method of Assigning Patients
- Study Design: Evaluation Criteria-Efficacy
- Study Design: Evaluation Criteria-Safety
- Study Design: Dosage Special Populations

Content “Design to Re-use” or “Re-purpose”

New Features

- New Topics for Clinical Study Report
  - Reusable Topics

- New Topics for Clinical Study Report
  - Disposition of Patients (summary)
  - Protocol Deviations (summary)
  - Efficacy Results – Primary (full)
  - Safety Results – Exposure Table (full)
  - Safety Results – Serious AE Table (full)

New Documents

- New Documents
  - Medical Writing - Internal
  - Medical Writing - External

“Pre-“ Review & Approval

- "Darwin Information Typing Architecture"
- DITA

DITA Stewardship

Take A Supply Chain Approach To Authoring Tasks

Project Stewardship

“On Demand” Review & Approval

In pharma today, topic and document based content must co-exist

With DITA, submission management begins with the content supply chain...
planning and content design of the clinical content supply chain begins when a drug candidate is being considered for continuation into clinical development and continues throughout the product’s lifecycle.
planning and content design for topic-based content continues through each regulatory submission and is integrated with that of the functional areas and content design.