

Structured Content Management [SCM]

*Lessons learned from
SCM implementations*

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The DITA Information Architecture dates back (2000's)



Life Sciences is picking up too...



- User Adoption is priority 1, 2 and 3
 - Familiar and easy to use tools
 - Be there with your users every step of the way
- Iterative & Agile approach is a must
 - Start small
 - Collect successes, present achievements
 - Drive adoption across the enterprise - scale up
- Address Change Management Proactively
 - Process changes
 - Opportunities to improve current processes; challenge “business as usual” where necessary

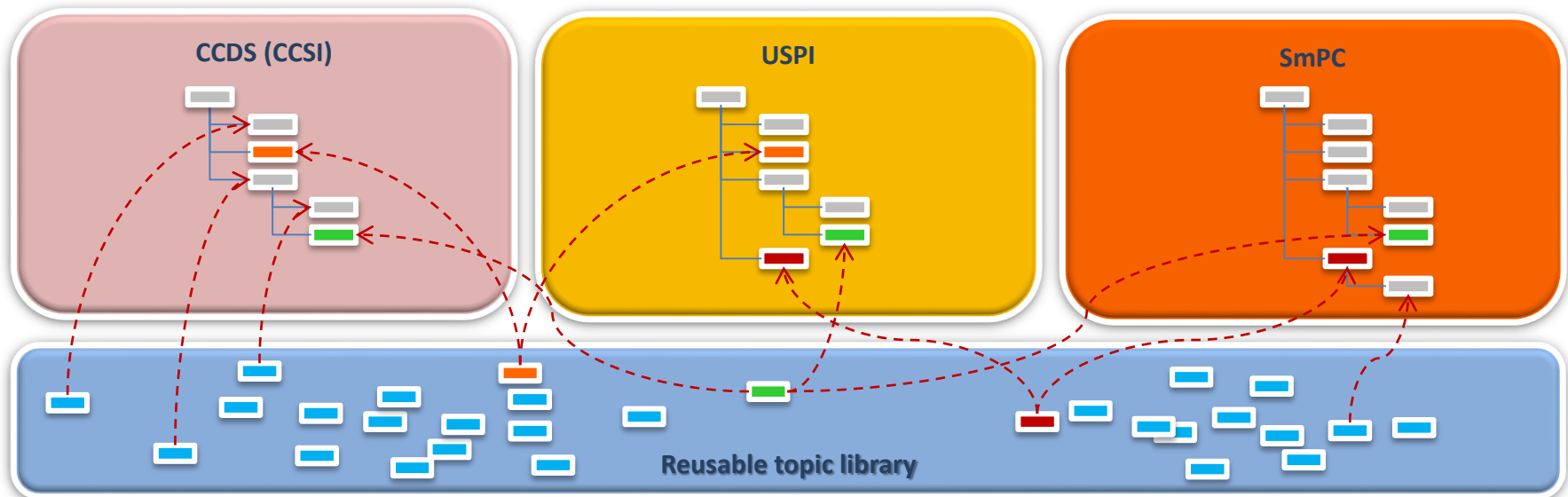
Complexity kills – Simplicity succeeds!

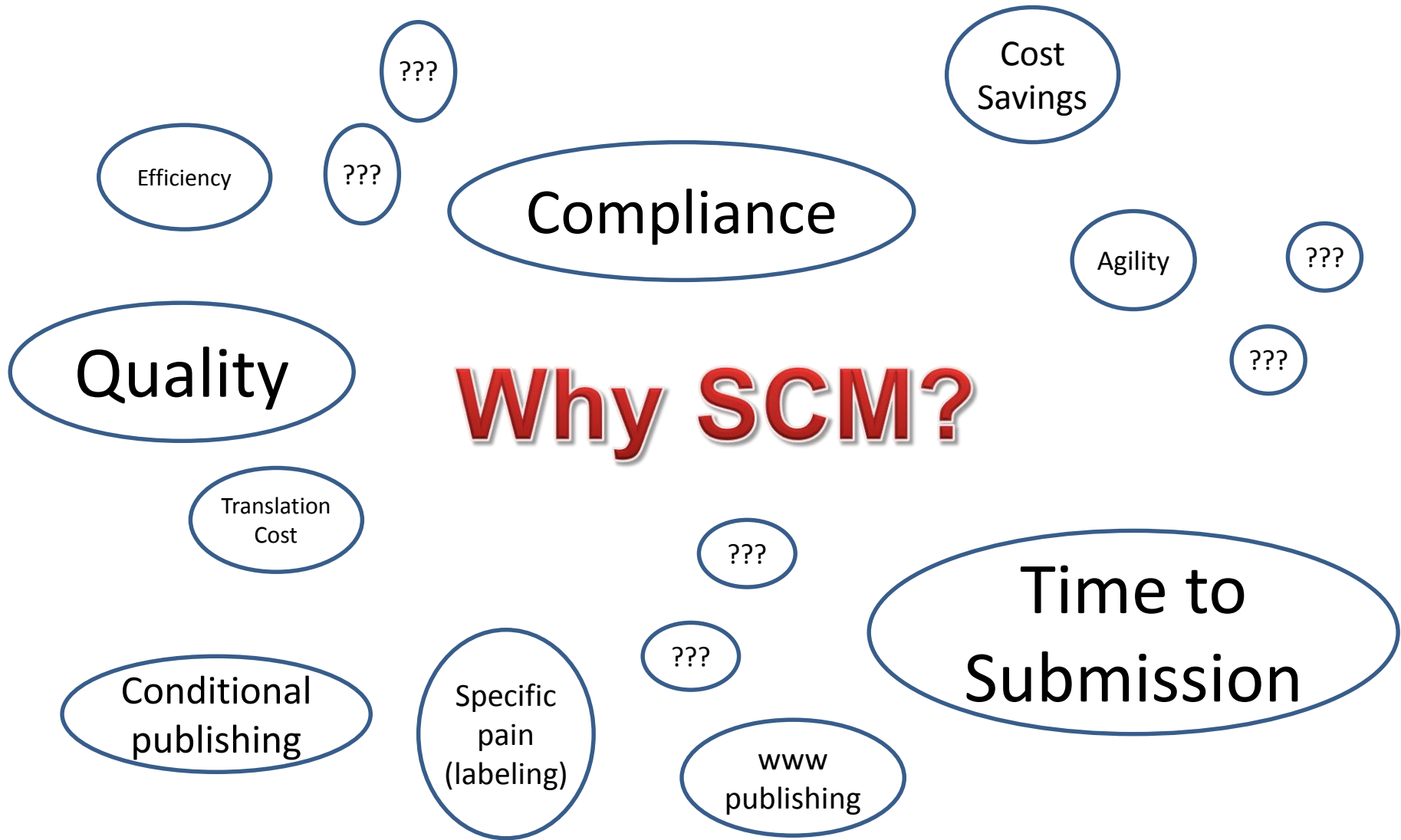
What you need to succeed with enterprise SCM

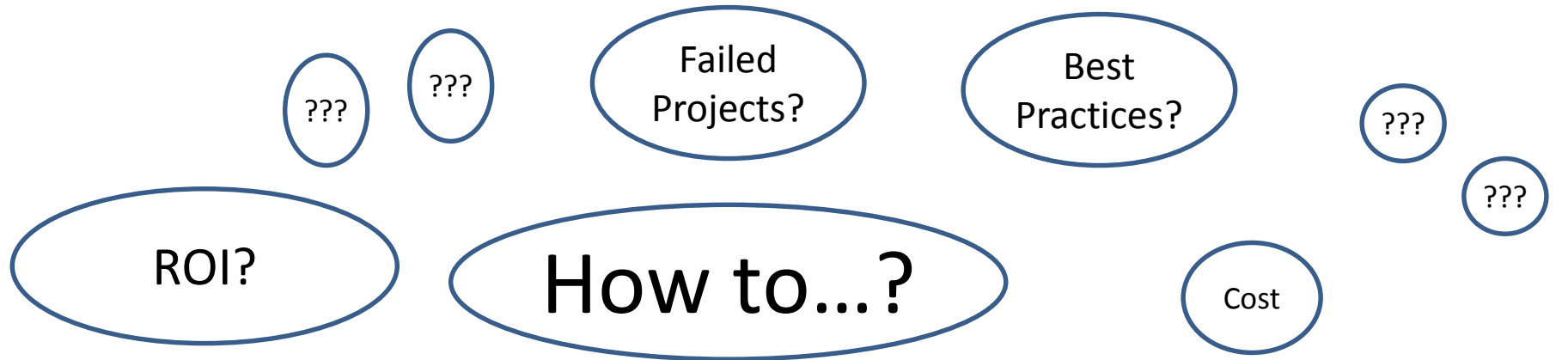
1. Familiar authoring interface; Microsoft Word is the norm
2. A mechanism for handling and evolving information structure
3. A strong Collaboration and Content Management (CMS) platform

What is SCM?

- Structured, well described information model
- Modularized or topic based to promote reuse
 - Different types of reuse
- Facilitate output to multiple audiences and formats





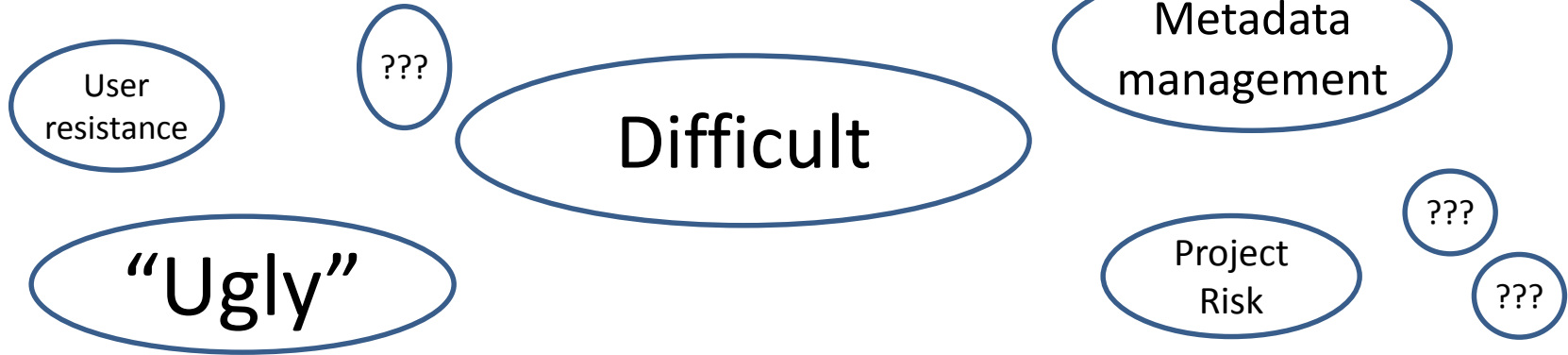


So many good reasons for SCM Why hesitate?

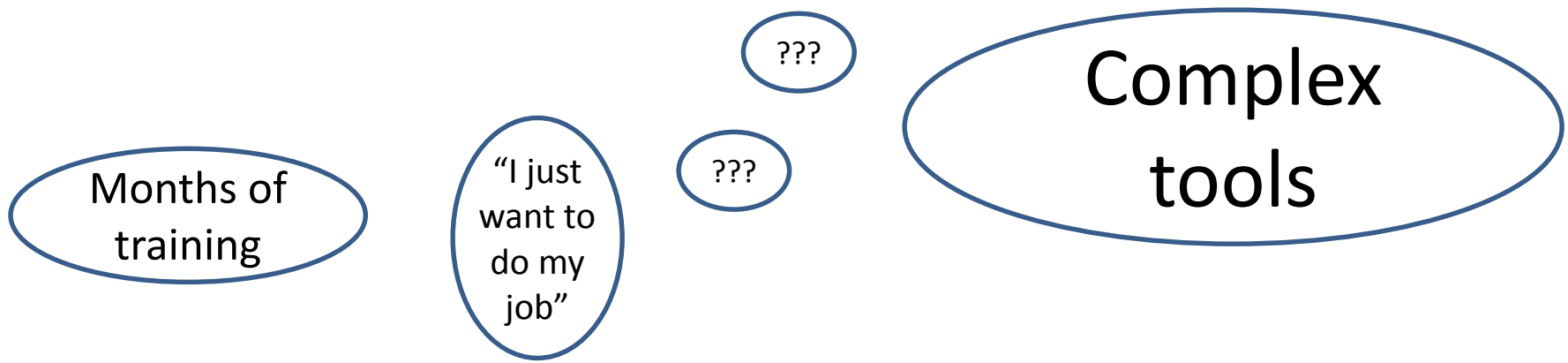


The problem is no longer the tools

**The problems is how the users
interface with the tools,
and how we govern the content
at the enterprise level**



One significant problem is XML!

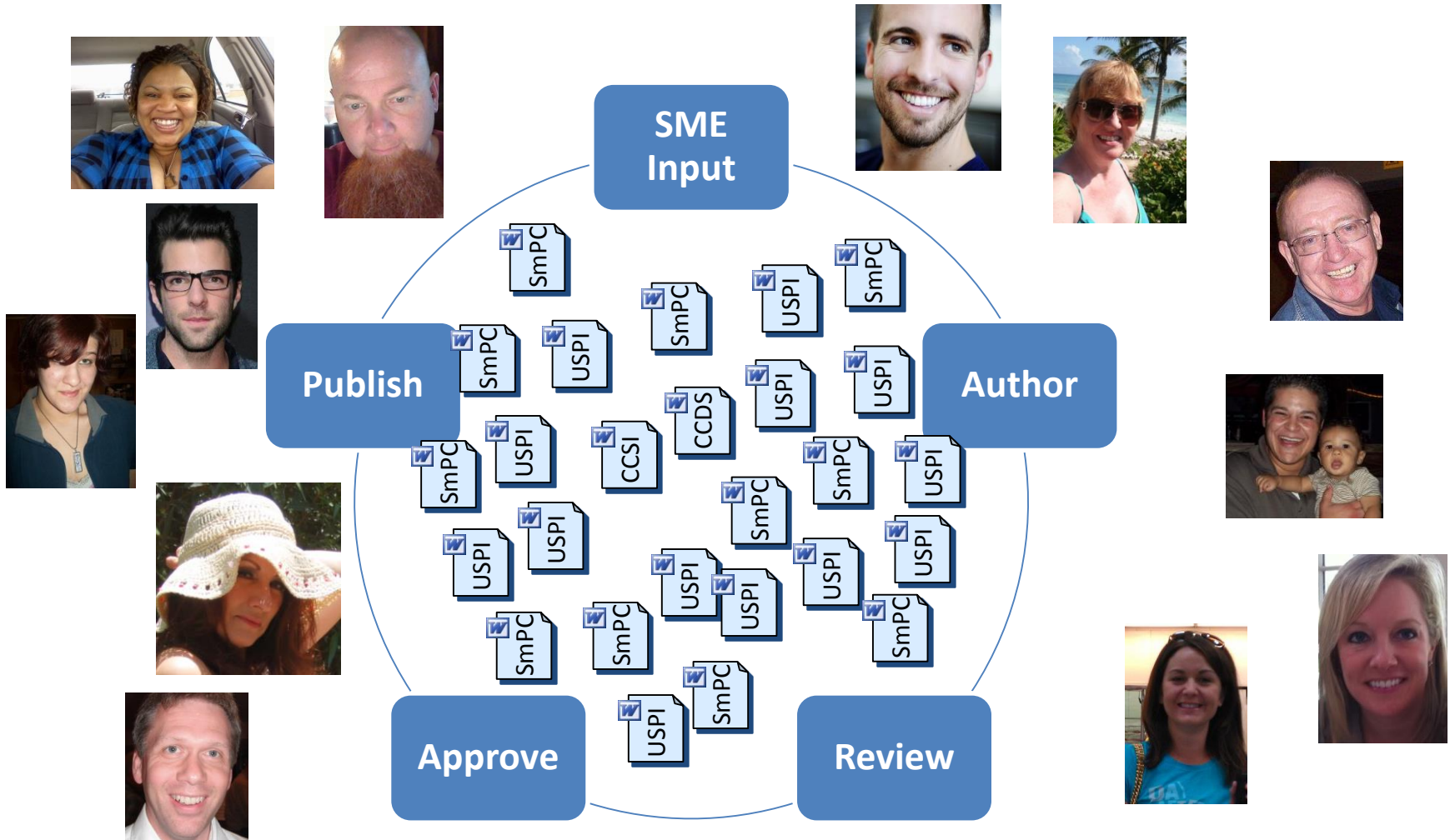


DITA XML is an open
source standard
governed by OASIS

The good news; you are using XML already!

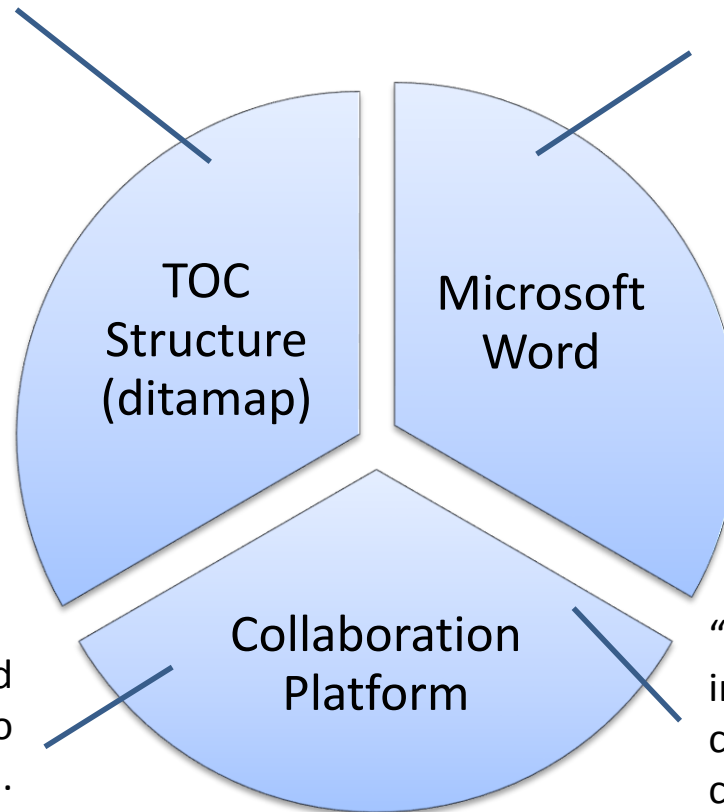
Office Open XML
(OOXML) is an ISO
standard (ISO 29500)
used for e.g. Word,
Excel...

The Challenge in Enterprise Global Labeling



So, what do we need?

Enabling content reuse in a user friendly and easy to understand way are essential for all “users” involved and we all embrace and understand the concept of the TOC



“Users” want to author in Microsoft Word – and nothing else. There is significant resistance to learning XML and using specialist tools

Users need governance and understandable procedures to work in a modern world. That job requires change: “The Enterprise Content Architect”

“Users” will need familiar interface, collaborative and content management capabilities such as metadata, version history, conditional publishing, workflows...

Let's Look at Some Examples

Mailings Review View Developer DITA EXCHANGE EnCORE

Aa ▾ Paragraph Styles

AaBbCcDc AaBbCcDc **AaBbCc** AaBbCc AaB AaBbCc. AaBbCcDc AaBbCcDc AaBbCcDc AaBbCcDc AaBbCcDc

¶ Normal ¶ No Spaci... **Heading 1** Heading 2 Title Subtitle Subtle Em... Emphasis Intense E...

Formulation Appearance

Clopidogrel hydrogen sulfate is available as either pink, round, biconvex, film coated tablets debossed with “75” on one side^{1,2} and “1171” on the other, or pink, oblong, debossed film-coated tablets with “300” on one side and “1332” on the other. Clopidogrel hydrogen sulfate 75 mg for oral administration contains 97.875 mg of clopidogrel hydrogen sulfate which is the molar equivalent of 75 mg of clopidogrel base.^{3,4} Clopidogrel hydrogen sulfate 300 mg for oral administration contains 391.5 mg of clopidogrel hydrogen sulfate which is the molar equivalent of 300 mg of clopidogrel base.⁵

¹ 2.4 (CMC Summ) IND 34,663; SN 170 1/15
² 3.2.5 (DP) IND 34,663; SN 170 2/22
³ 3.2.5 (DP) IND 34,663; SN 170 2/22
⁴ 3.2.1 (DP) IND 34,663; SN 170 2/10
⁵ 300 mg; Module 3.2.P.1 Description and Composition

ISCOVER – 75 & 300mg Tablets
Formulation Appearance
Iscover is available as either pink, round, biconvex, film coated tablets debossed with “75” on one side and “1171” on the other, or white, round, biconvex, film coated tablets with “300” on one side and “1332” on the other. See local dossier for packaging information.

PLAVIX USP Tablets
Formulation Appearance
Plavix is available as either pink, round, biconvex, film coated tablets debossed with “75” on one side and “1171” on the other, or white, round, biconvex, film coated tablets with “300” on one side and “1332” on the other. See local dossier for packaging information.

Clopidogrel Zentiva – 75mg Tablets
Formulation Appearance
Clopidogrel Zentiva is available as either pink, round, biconvex, film coated tablets debossed with “75” on one side and “1171” on the other, or white, round, biconvex, film coated tablets with “300” on one side and “1332” on the other. See local dossier for packaging information.

More Brands, Dosages, Revisions..

PLAVIX – 75 & 300mg Tablets

Formulation Appearance

Plavix is available as either pink, round, biconvex, film coated tablets debossed with "75" on one side and "1171" on the other, or pink, round, biconvex, film coated tablets debossed with "300" on one side and "1332" on the other. Plavix 75 mg film coated tablets contains 391.5 mg of clopidogrel hydrogen sulfate which is the molar equivalent of 75 mg of clopidogrel base.

PLAVIX – 75 & 300mg Tablets

Formulation Appearance

Plavix is available as either pink, round, biconvex, film coated tablets debossed with "75" on one side and "1171" on the other, or pink, round, biconvex, film coated tablets debossed with "300" on one side and "1332" on the other. Plavix 75 mg film coated tablets contains 391.5 mg of clopidogrel hydrogen sulfate which is the molar equivalent of 75 mg of clopidogrel base.

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Clopidogrel Tablets

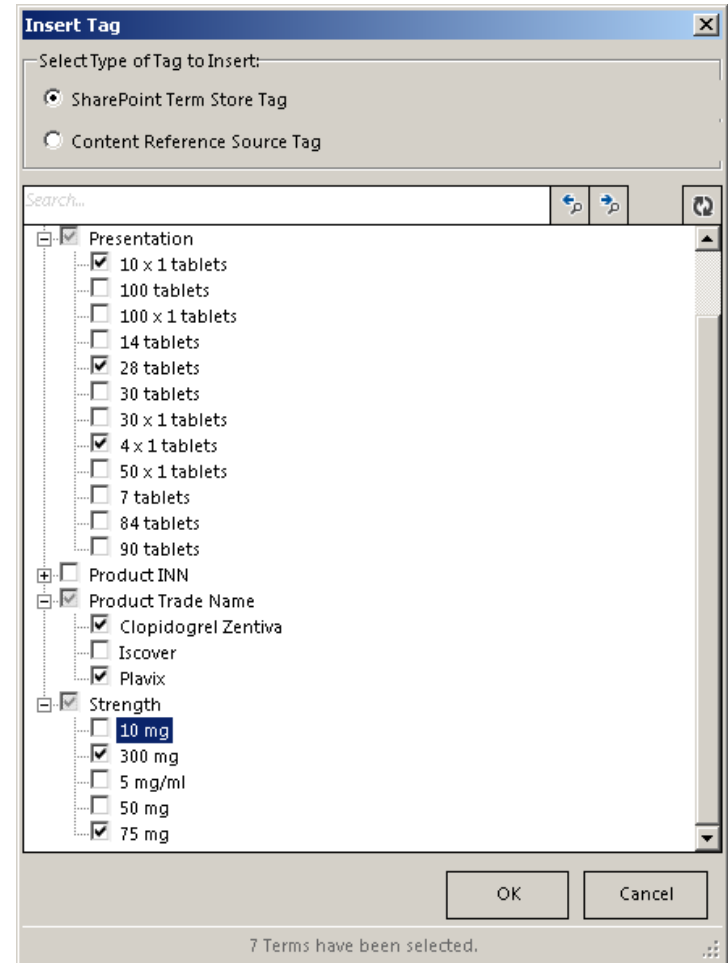
Clopidogrel Tablets

Clopidogrel Tablets

Clopidogrel Tablets

Clopidogrel Tablets

- Apply SCM Principles
 - Topic Reuse
 - Substitution Reuse
 - Conditional Reuse
- Write Once, Publish Many



- Use Variables
 - Trade Names, Dosages, Formulation, etc.
- Tag other content for each condition or scenario

Select tagged content to display:

- Strength
 - 75 mg
 - 300 mg
- Content Scope
 - CCDS Reference

Add New Tag

Tags in the selected content:

75 mg		
CCDS Reference		
300 mg		
CCDS Reference		

Trade Name is available as either 75 mg pink round, biconvex, film coated tablets debossed with "75" on one side^{1,2} and "1171" on the other, or pink, oblong, debossed film-coated tablets with "300" on one side and "1332" on the other. Trade Name 75 mg for oral administration contains 97.875 300 mg clopidogrel hydrogen sulfate which is the molar equivalent of 75 mg of clopidogrel base.^{3,4} Trade Name 300 mg for oral administration contains 391.5 mg of clopidogrel hydrogen sulfate which is the molar equivalent of 300 mg of clopidogrel base.⁵

Formulation Appearance

Clopidogrel hydrogen sulfate is available as either pink, round, biconvex, film coated tablets debossed with “75” on one side^{1,2} and “1171” on the other, or pink, oblong, debossed film-coated tablets with “300” on one side and “1332” on the other. Clopidogrel hydrogen sulfate 75 mg for oral administration contains 97.875 mg of clopidogrel hydrogen sulfate which is the molar equivalent of 75 mg of clopidogrel base.^{3,4} Clopidogrel hydrogen sulfate 300 mg for oral administration contains 391.5 mg of clopidogrel hydrogen sulfate which is the molar equivalent of 300 mg of clopidogrel base.⁵

See local dossier for packaging information.



Clopidogrel Zentiva 75 mg

Clopidogrel Zentiva is available as pink, round, biconvex, film coated tablets debossed with “75” on one side and “1171” on the other. Trade Name 75 mg for oral administration contains 97.875 mg of clopidogrel hydrogen sulfate which is the molar equivalent of 75 mg of clopidogrel base.

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² 3.2.5 (DP) IND 34,663; SN 170 2/22

- ✓ CCDS
- ✓ Plavix 75mg USPI
- ✓ Plavix 300mg USPI
- ✓ Iscover 75mg
- ✓ Iscover 300mg
- ✓ Zentiva 75mg

- **Structure Content Authoring techniques**
 - Reduce duplication of content
 - Reduce non-value add activities
 - Reduce cycle times
 - Improve quality and efficiency
- **Challenges and other Considerations**
 - Parallel or Concurrent Submissions
 - Translations
 - Lineage Reporting

Questions?