

Technical Perspective for FDA

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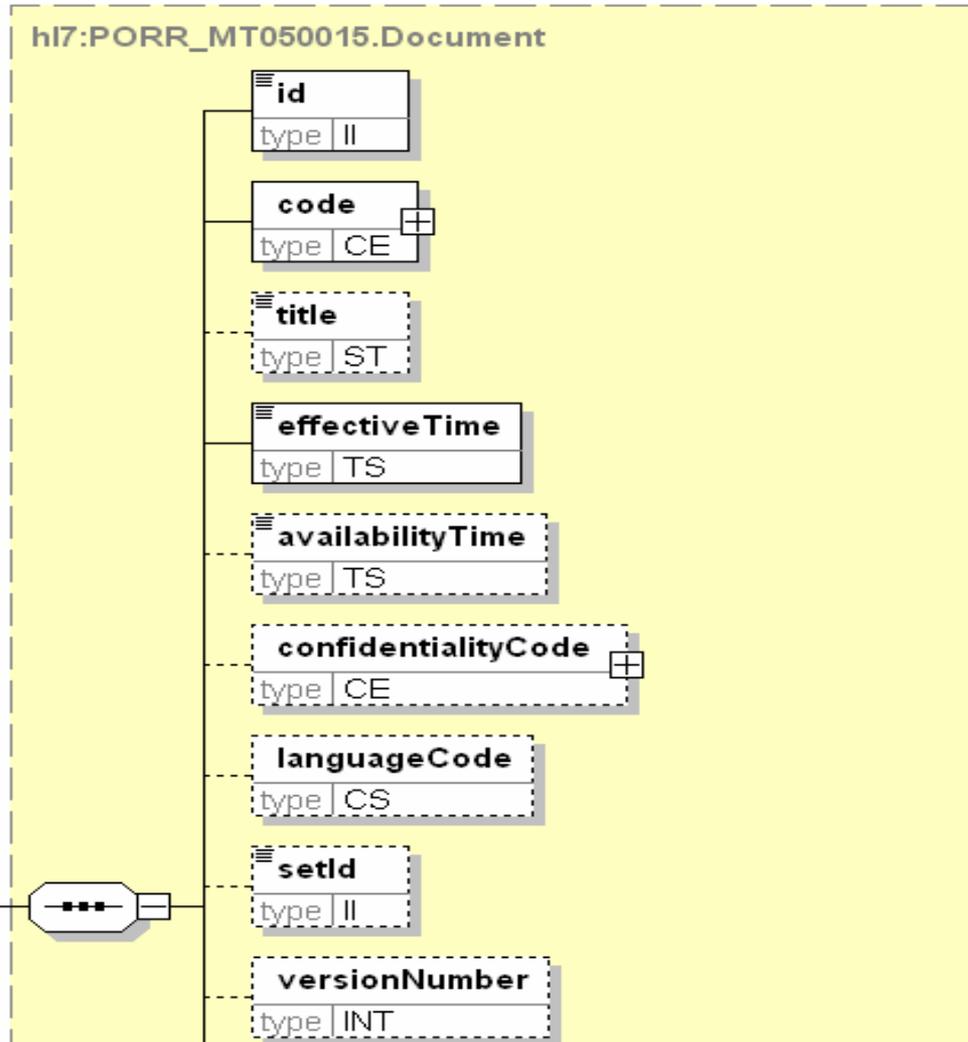
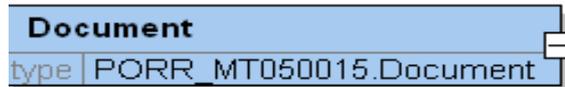
FDA Technical Perspective Reflects Realization of an HL7 Standard

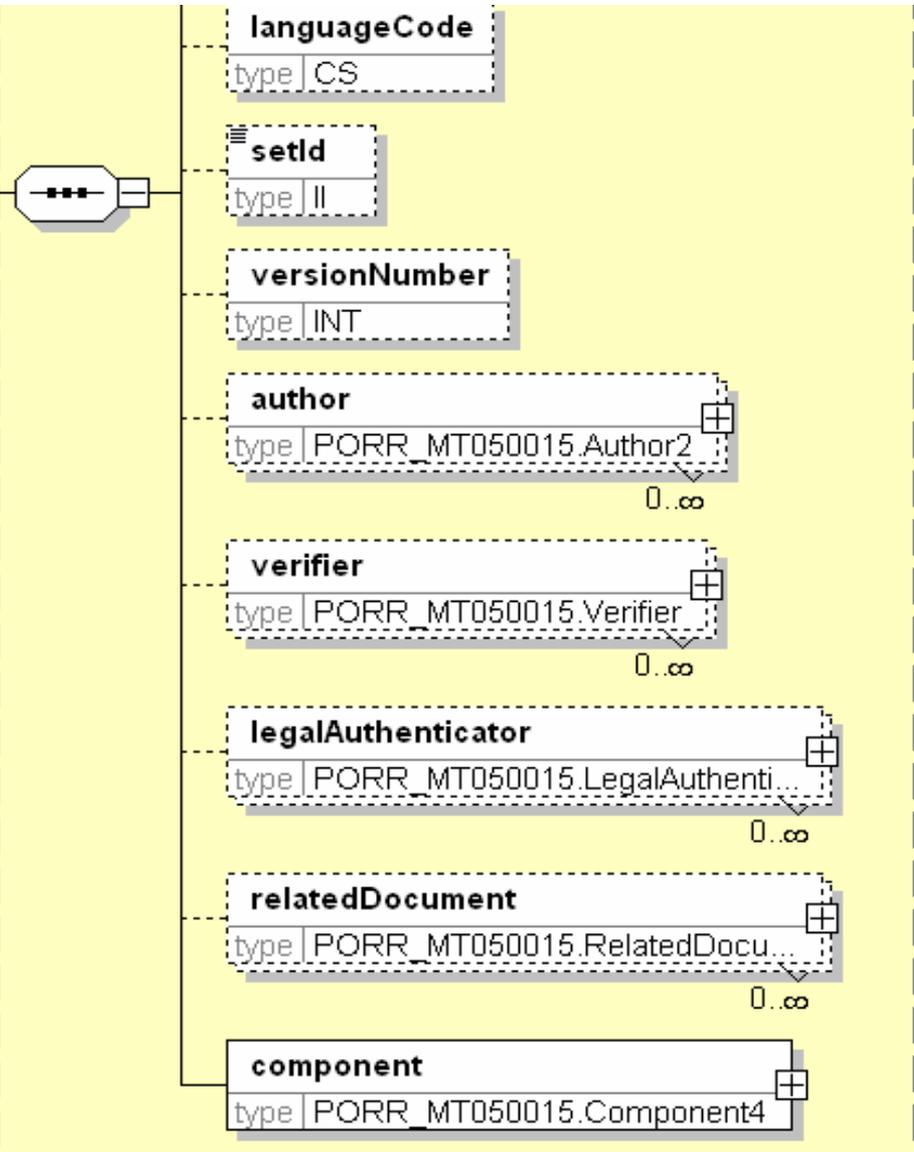
- HL-7 **Balloted** Standard (Version 1) of SPL Exists - **XML schema** via HL7 tools (available from HL7 Website)
- Companion **stylesheet** under development
- **Implementation guide** under development
- **FDA companion** implementation document under development
- Vendor **tools** under development

SPL

- These pieces interact to yield a technical solution that will allow ‘relatively’ easy, unambiguous, consistent development of SPL by (for) industry and other interested parties
- SPL contains the **content** of the package insert; it is not the PI

Header





Information Sufficient to Create Valid SPL

“Every <Document> has a required, globally-unique instance identifier, ‘id’ (which is different from the XML element identifier); an optional identifier, ‘setId’, that remains constant across all document revisions that derive from a common original document, and an optional version number, ‘versionNumber’. These identifiers may be useful in document management, including management of replacements.”

“Every <Document> has a required document type code, ‘code’. This code identifies the type of product labeling document (e.g., prescription drug label or over-the-counter prescription drug label). The externally-defined vocabulary domain for ‘Document.code’ is preferentially drawn from LOINC.”

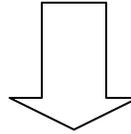
Header Elements Summary

- Discussed in ballot
- Will need some further explanation and discussion in implementation guide(s)
- Unambiguously defined (yes)
- Reusable (yes)/cost (low)
- Tool implementation (high)
- **FUD factor (low)**

Body



Labeling



Boxed warning

Indications and Usage

Dosage and Administration

How Supplied

Contraindications

Warnings and Precautions

Drug Interactions

Pregnancy

Labor and delivery

Lactating women

Pediatric use

Geriatric use

Adverse reactions

Drug abuse

Overdosage

Description

Mechanism of action

Pharmacodynamics

Pharmacokinetics

Other pharmacology

Carcinogenicity

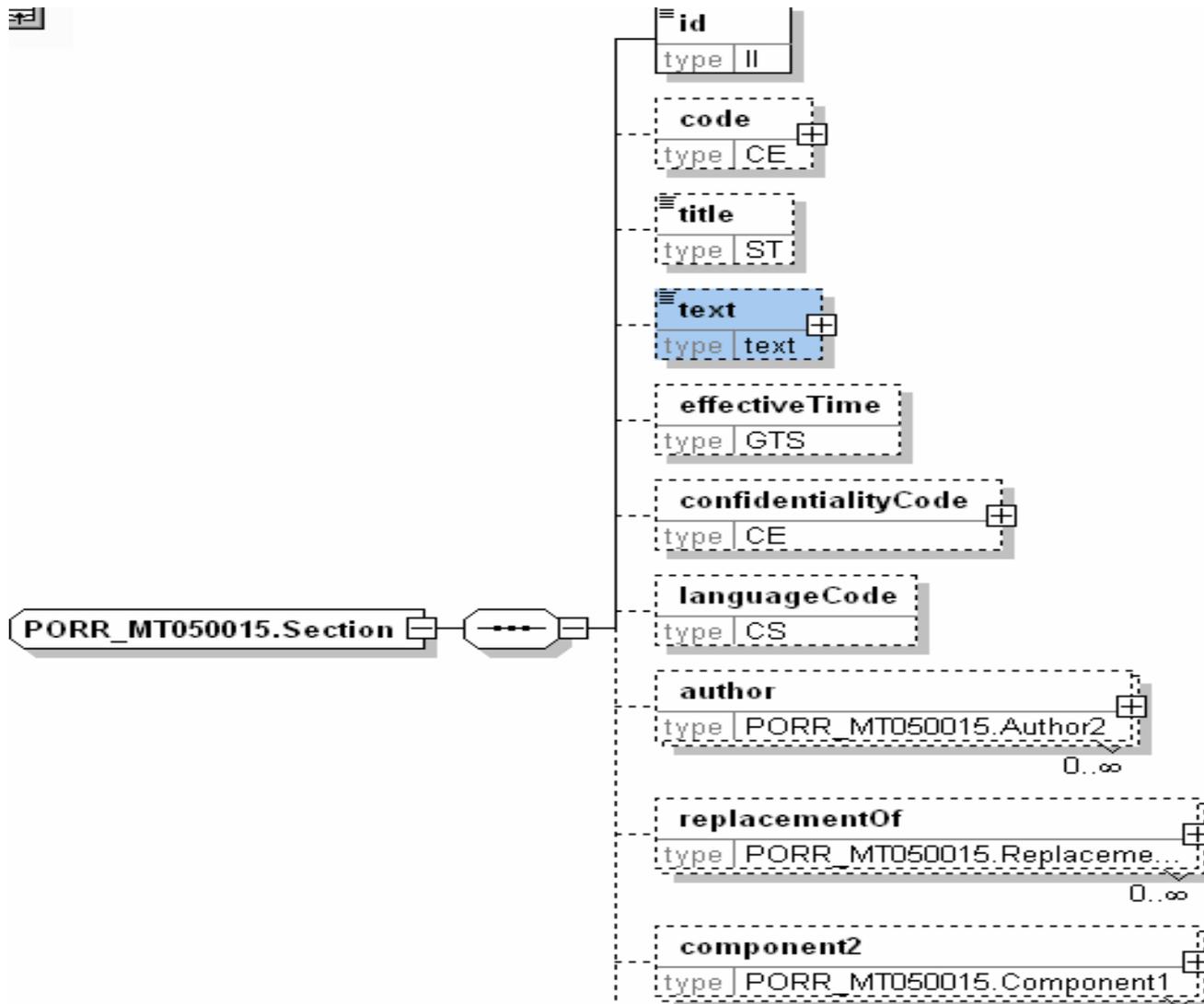
Animal toxicology

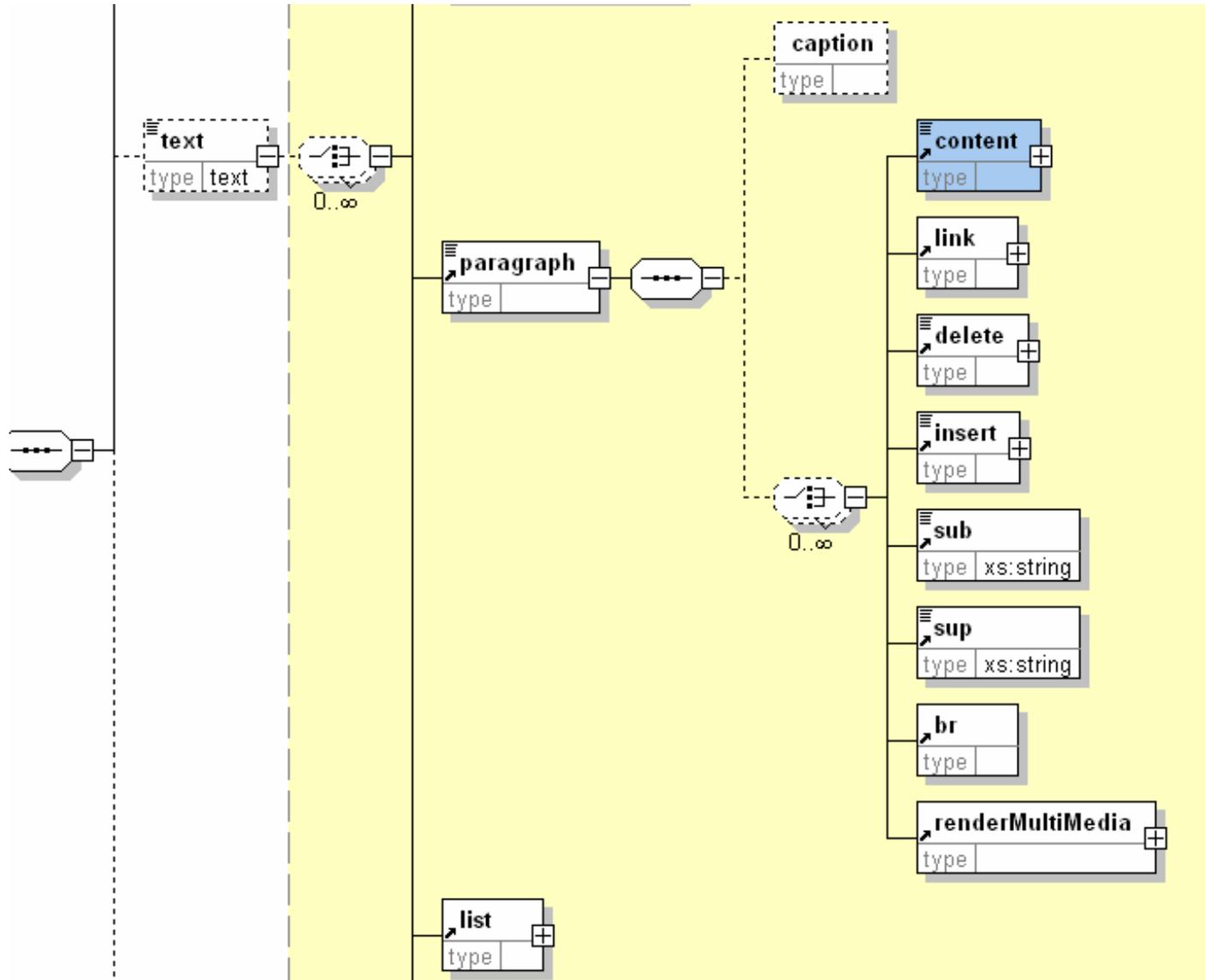
Clinical studies

Patient counseling

References

SPL Schema





Body Sections

Discussed in Ballot:

1.1.1.1.1 Paragraph

A <paragraph> is similar to the HTML paragraph, which allows blocks of narrative to be broken up into logically consistent structures. A <paragraph> element contains an optional caption (see *4.2.2.2.4.10 Caption*).

1.1.1.1.1.2 List

A `<list>` is similar to the HTML list. A `<list>` has an optional caption (see *4.2.2.2.4.10 Caption*) and contains one or more `<item>` elements. The required 'listType' attribute specifies whether the `<list>` is ordered or unordered (with unordered being the default). Unordered lists are typically rendered with bullets, whereas ordered lists are typically rendered with numbers, although this is not a requirement of a receiver. An `<item>` also has an optional caption.

Pregnancy:

Teratogenic Effects: Pregnancy Category B:

Reproduction studies have been performed in pregnant mice given antitaxime intravenously at doses up to 1200 mg/kg/day (0.4 times the recommended human dose based on mg/m²) or in pregnant rats when administered intravenously at doses up to 1200 mg/kg/day (0.8 times the recommended human dose based on mg/m²). No evidence of embryotoxicity or teratogenicity was seen in these studies. There are no well-controlled studies in pregnant women. Because animal reproductive studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed

Body Elements (Label Sections)

- ‘Discussed’ in ballot
- Will need reasonable further explanation and discussion in implementation guide(s)
- Unambiguously defined (no) – could be validly implemented in various ways
- Reusable (no)/cost (higher)
- Tool implementation (**high**)
- **FUD factor (low)**

Where's the Rub...

- **Tables**

- Difficult to model 'content', i.e., content can be ambiguous when current labels are modeled
- Formatting may be important
- Can be in any section
- Sufficiently important to warrant a prominent part of today's agenda

FDA Take...

- Can be addressed in the stylesheet unambiguously
- Possible (likely) role in FDA guidance/'maintainance' with industry
- 'Informative' – not strict part of standard
- FUD factor (high)
- Tool implementation (?)

Data Elements in Current Ballot

- ‘Primarily’ data content of narrative but can be distinct
- Model is unambiguous
- Support FDA medication model (and other systems)
- Well-defined information
- Example: manufactured product

Data Elements (CMC)

- Discussed' in ballot
- Will need 'reasonable' further explanation and discussion in implementation guide(s)
- Unambiguously defined (no - codes evolving/ potentially yes)
- Reusable (yes)/cost (variable)
- Tool implementation (**high** – may be separate 'tool')
- **FUD factor (medium)**

Summary

- Various distinct aspects to SPL
- Different parts lead to different FUD
- Implementation guides important, will be done, and will evolve for V1 – SPL standard for V1 will not
- Tool(s) can/should reduce FUD substantially
- The PhRMA contribution to technical aspects of SPL has been phenomenal

Thank-you for your attention.

“More than any time in history mankind faces a crossroads. One path leads to despair and utter hopelessness, the other to total extinction. Let us pray that we have the wisdom to choose correctly.”

Woody Allen (1992)