



HL7 Standards Development Process for UDI

GS1 Collaboration with HL7



GS1 and HL7 Join Forces to Develop Global Standards to Improve Patient Care

Two complementary global standards organizations will collaborate to develop global healthcare standards to reduce medical errors and to increase the effectiveness of the healthcare supply chain.

**Memorandum of Understanding (MOU)
GS1 and HL7 signed May, 2007**



Health Level Seven

Health Level Seven International (HL7) is a not-for-profit, ANSI-accredited standards organization providing a comprehensive framework and protocol for the development of healthcare informatics standards. These standards are used in **healthcare data exchange, integration, storage and retrieval** among diverse data acquisitions, processing and handling systems.

Health Level Seven International (HL7) is the global authority on **standards for interoperability of health information technology** with members in over 55 countries.



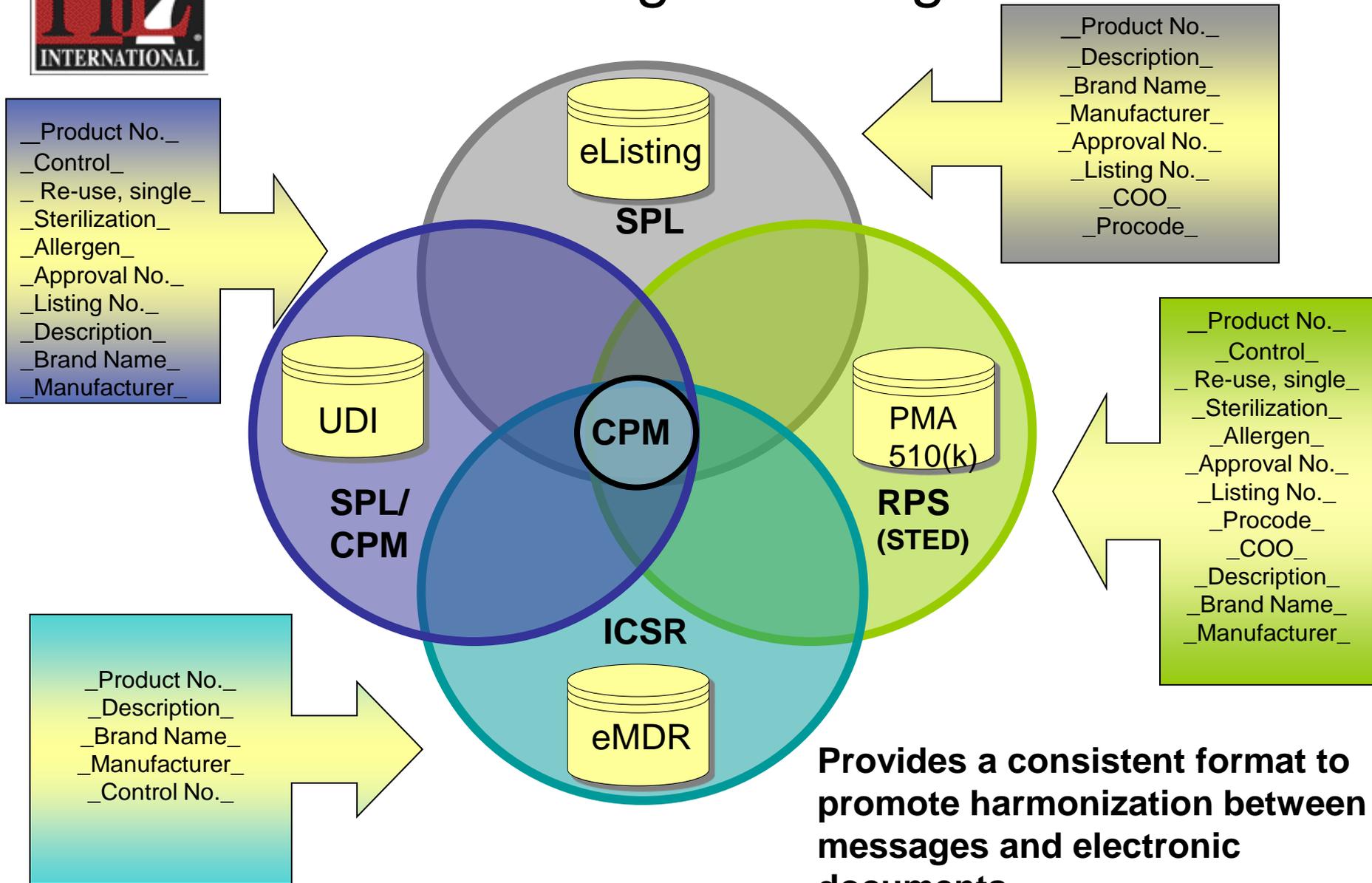


Standards for UDI Submission

- Structured Product Labeling (**SPL**) R5
 - Current release (R4) in use for Drug Establishment Registration and Listing
<http://dailymed.nlm.nih.gov/dailymed/about.cfm>
- Common Product Model (**CPM**) in use for
 - Current release in use for electronic medical device reporting and will be used for market authorization submission and approvals (used to transmit product specific data).
- Other related HL7 standards for FDA submissions:
 - Individual Case Safety Reports (**ICSR**) – used for eMDR
 - Regulated Product Submissions (**RPS**) – used for electronic market authorization submission and approval (STED)



Data Exchange Messages



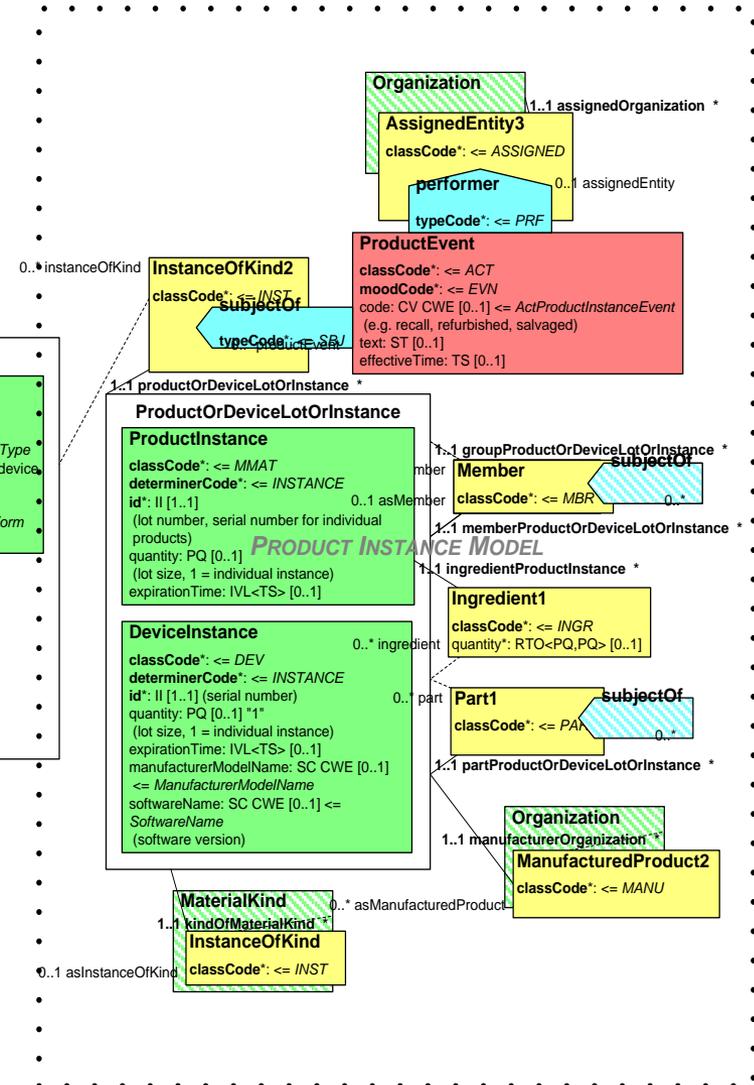
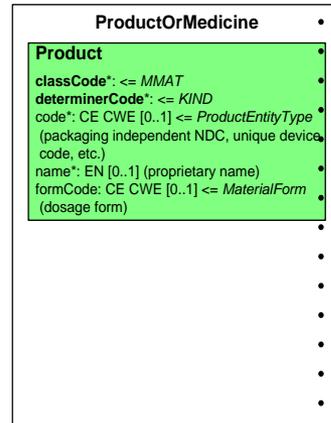


Data and Data Relationships

What:

Global standards for electronic exchange of required Regulatory data

- Content
- Structure
- Data Relationships
- Vocabulary





Enabling Interoperability

How:

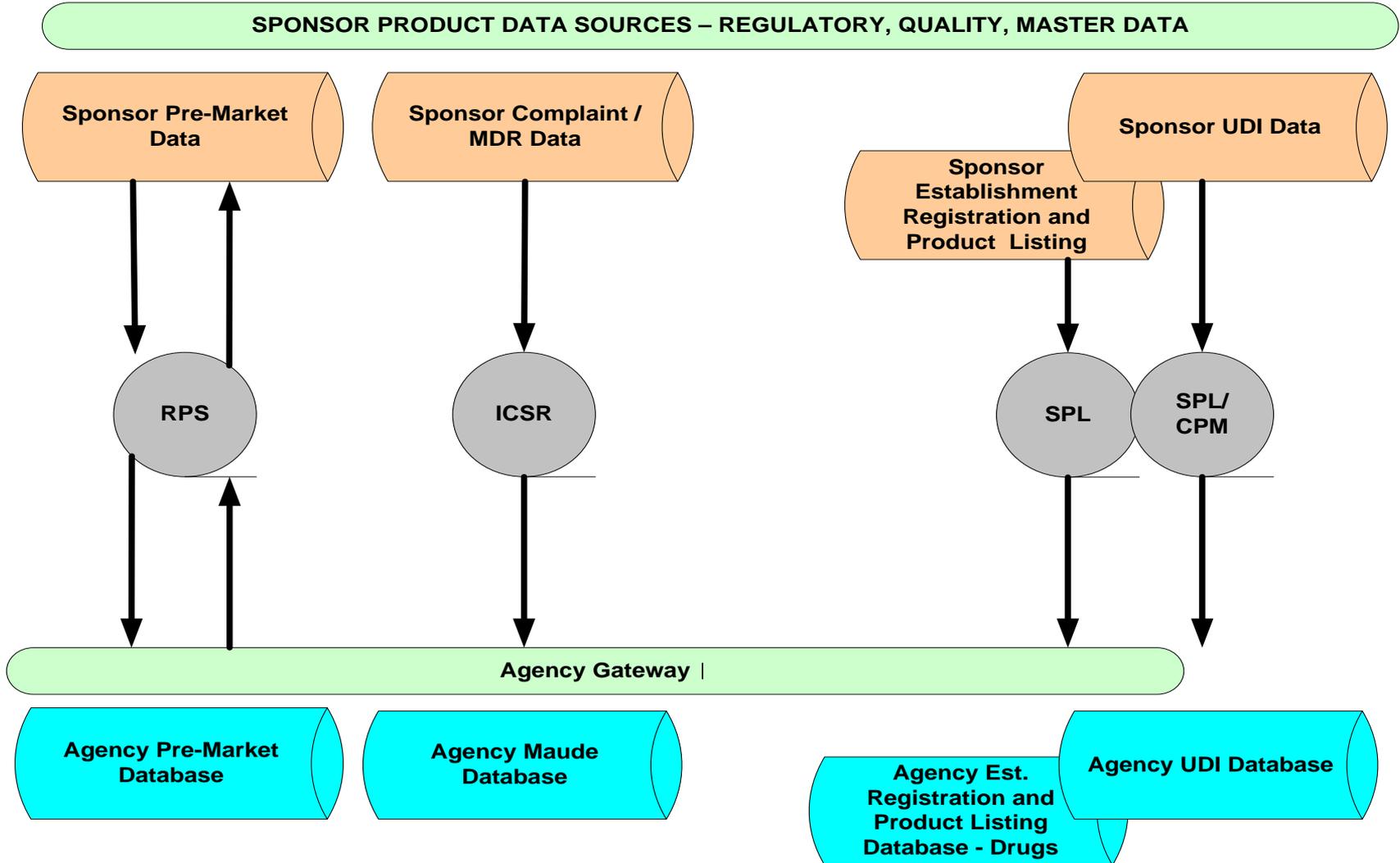
The HL7 standards **enable disparate Healthcare applications to exchange key sets of clinical, product, administrative data to further the *interoperability*** of the systems and their applications using XML based formats.

Elements of Interoperability

- Technical - Moving data from A  B
- Semantic - Ensuring A & B understand the data in the same way
- Process - Enabling business process and systems (A & B) within and across organizations to work together



International Messaging Standards in Use





SPL Standard Update

- The SPL (r5) now in Draft Standard for Trial Use (DSTU) until sufficient pilot testing has occurred. Expect the Standard / Data Model to be ready for the September 2011 Ballot Cycle.
- Implementation Guide for SPL (r5) published

XFORMS Style Sheet Pilot – Web Based Editor by Pragmatic Data

<http://pragmaticdata.com/spl/form/>

<http://www.fda.gov/downloads/ForIndustry/DataStandards/StructuredProductLabeling/UCM237103.zip>

Tool includes templates for device and drug submissions (Home Use Medical devices, UDI submission, Labeler Code Request, Establishment Registration, Drug listing, Substance Indexing).

Load / Save files to your local drive using the software located on the Pragmatic server (use w/ Internet Explorer > 5.0 ,Google Chrome, **Firefox**, Safari).



Medical Device Sub-Team

[http://wiki.hl7.org/index.php?title=Medical_Product_Information_\(SPLr\)](http://wiki.hl7.org/index.php?title=Medical_Product_Information_(SPLr))



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Medical Product Information (SPLr5)

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Project Scope

The project will extend the SPL model to develop a message that will allow transmission of a regulatory product information submission (labelling, listing, registration, unique device identifier and associated attributes) as specified by the Global Harmonization Task Force (GHTF) ad-hoc working group on (UDI.) submissions. The project will further provide references to other standards and external terminology resources required to populate the data elements defined in the standard. The work is based on existing work efforts: ISO/TC 215/SC WG6 N 547 (Health Informatics: IS#11615 Identification of Medicinal Products – Data Elements and Structure for the exchange of product information for drug dictionaries) and HL7 Structured Product Labeling and GHTF. This project will revise SPLr4 to leverage the data elements defined in the Common Product Model and reduce the SPL standard to the description of Header and Text information.

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THANK YOU!

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