





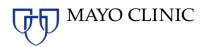


Case Study: Terminology Services as eHealth Enablers

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Who are we?

Phast

- Association of French Healthcare Professionals now including IT administrators, vendors, government.
- Based in Paris, mandated by French Ministry to set basis for unambiguous exchange of information in healthcare facilities concerning medication, extended later to medical devices.
- National interoperability implementation guides, one of which is CIOsp (Codification Interopérable des Spécialités Pharmaceutiques) or Interoperable Medication Coding

Mayo





Case Study: ClOsp - Interoperable Medication Coding

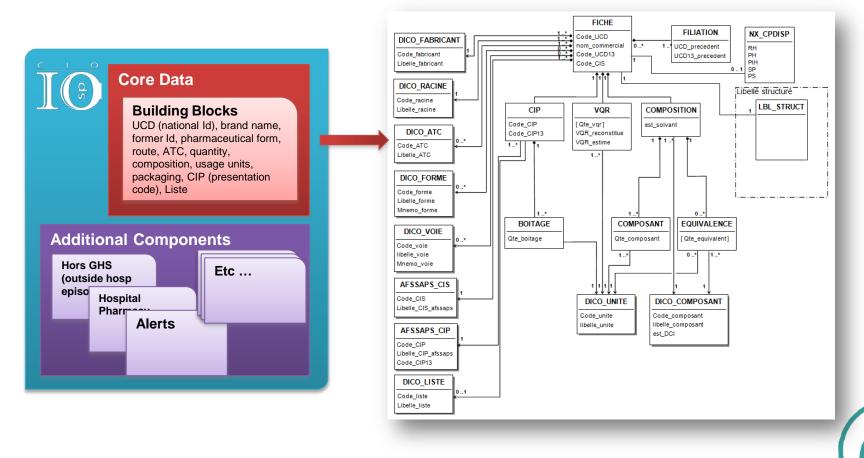
- Aiming to improve interoperability between different systems and applications involved in *Electronic Medication Management*.
- Medication is a complex object, with many properties.
- CIOsp provides a means to interchange medication information via coded attributes with values based on a multitude of terminologies published by many sources of truth. (all medication regulated in France -10655 as of 22/03/2103).







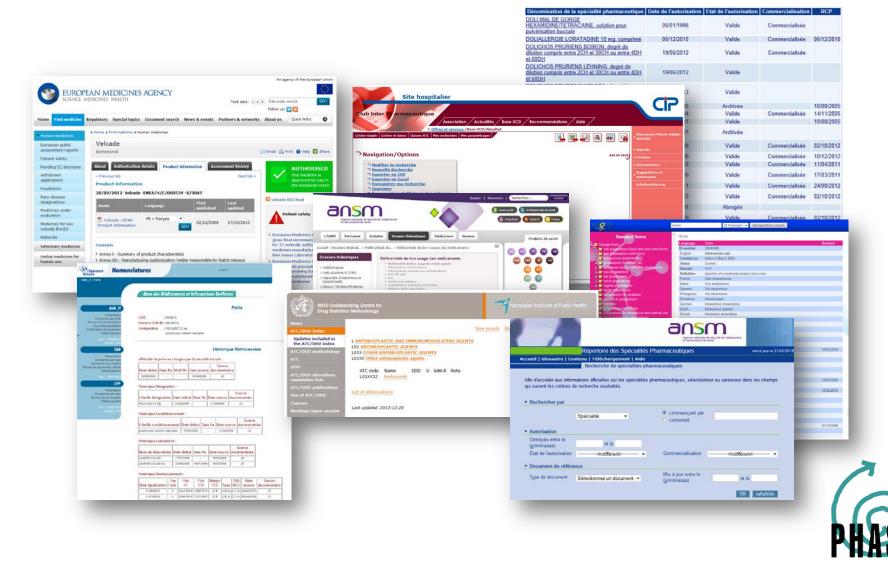








CIOsp Terminologies





Fiche CIO

CIOsp provides

Code UCD: 9260010

Code CIS: 62438913

Fabricant: JANSSEN CILAG

Composants: * BORTEZOMIB DCI - 3,5 milligramme

Code UCD précédent(s) : Néant

Code UCD suivant(s): Néant

Code UCD13: 3400892600109

Libellé: VELCADE 3.5 mg, pdr pr sol inj

Formes: Poudre pour solution injectable



Velcade 1 mg, poudre pour solution injectable et VELCADE 3,5 mg, poudre pour solution injectable - Janssen-Cilag - Retrait de lots

25/11/2011

MED 11/841



En accord avec l'Afssaps, Janssen rappelle :

- tous les lots de la spécialité dénommée VELCADE 1 mg, poudre pour solution injectable (CIP :
- les lots: 9AZSY00 pér déc 2011, 9AZSY01 pér déc 2011, 9DZSB00 pér jan 2012, 9DZSB01 pér jan 2012, 9DZSB02 pér jan 2012, AGZSH00 pér jun 2013, AGZSH01 pér jun 2013, AGZSH02 pér jan 2013, BAZ\$100 pér déc 2013, de la spécialité dénommée VELCADE 3,5mg, poudre pour solution injectable (CIP 564.957.3).

Ce rappel fait suite à une inspection sur le site de Ben Venue Laboratories, Inc. Bedford (Ohio, Usa ; fabricant des lots cités ci-dessus) qui a révélé plusieurs manquements aux bonnes pratiques de fabrication, notamment en termes d'assurance de la stérilité. Ben Venue a décidé de cesser toute la production de son site, pour enquêter sur les manquements identifiés

Les autres lots de VELCADE 3,5 mg, poudre pour solution injectable ne sont pas concernés par le rappel car ils n'ont pas été fabriqués sur le site de Ben Venue.

Voice district to the Conference of the	.7)	Los lots utilisés pour los os	Les lots utilisés pour les agrais cliniques font l'objet d'un avamen particulier									
Voies d'administration (DE	7): Voie intraveineuse Voie sous-cutanée	Les iots duises pour les es	Les lots utilisés pour les essais cliniques font l'objet d'un examen particulier.									
Volume / Quantité référen		Lire aussi	Hors GHS									
Volume / Quantite referen	1 flacon (RECONSTITUE)	VELCADE 1 mg, poud	de	Date d'effet 11/5/2005			Date de radiation NEANT					
A	TC: L: ANTINEOPLASIQUES ET IMMUN			Date d'application	Date de fin	Tarif de respo	nsabilité HT	Date de publication de prix				
	L01: ANTINEOPLASIQUES L01X: AUTRES ANTINEOPLASIQUES L01XX: AUTRES ANTINEOPLASIQUES			1/9/2009	NEANT		1098,79€	16/7/2009				
					Date d'application	Date de fin		Tops établissement				
	L01XX32 : BORTEZOMIB				11/5/2005	NEANT		Établissement Privé				
Conditionneme	nt: Code CIP: 5649573 > LISTE Code CIP13: 3400956495733	1			11/5/2005	NEANT		Établissement Public				
Libellé CIP AFSSAPS : 1 flacon(s) en verre de		e de 38,5 mg		Code CTOM		Date d'application	Date de fin	Majoration				
	- 1 flacon			971		21/5/2005	NEANT	1,16				
Mise à jo	ur: 22/11/2012			972		21/5/2005	NEANT	1,16				
	Retrait de lot		i i	973		21/5/2005	NEANT	1,16				
Velcade 1 mg, poudre pour solution injectable et VELCADE 3,5 mg, poudre pour solution injectable - Janssen-Cilag - Retrait de l			ı	974		21/5/2005	NEANT	1,16				
Réf. : MED11B41	Date : 25/11/2011	Mise à jour : -	N° G	Grp* Indication				Validité				
N° Lot / Sous-lot	Da	te de péremption	4	En association au melphalan et à la prednisone pour le traitement des patients atteints de myélome multiple non traité au								
De 9AZSY00 jusqu'à 9AZSY01	31,	/12/2011	1 1 préalable, non éligibles à la chimiothérapie intensive accompagnée d'une greffe de moelle osseuse Expression CIMX: 1^1^^C900			NEANT-NEANT						
De 9DZSB00 jusqu'à 9DZSB02	31.	/1/2012	4	En monothérapie pour le traitement du myélome multiple en progression chez des patients ayant reçu au moins 1 traitement			ns 1 traitement					
De AGZSH00 jusqu'à AGZSH02	30,	/6/2013	2 1	1 antérieur et qui ont déjà bénéficié ou qui sont inéligibles, pour une greffe de moelle osseuse NEA Expression CIMX: 1^1^^C900								
BAZS100	31,	/12/2013	4									

p* : Groupe d'indication : = indications reconnues par l'AMM situations scientifiquement acceptables



CIOsp Distribution

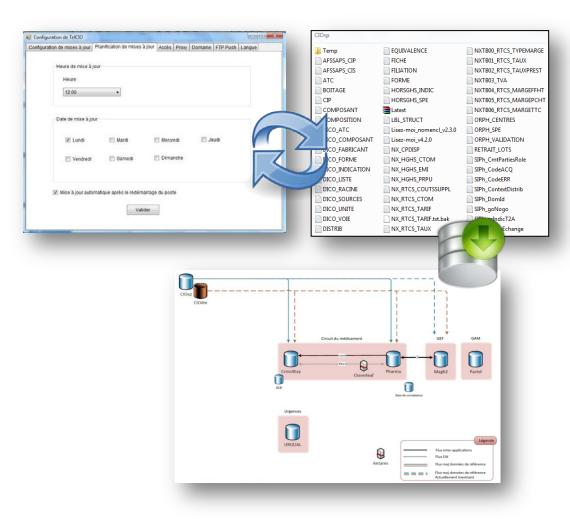
- Administrative procedures
- Initial mapping done by Phast
- Downloading updates via proprietary mechanism TelCIO

Internal	Healthcare Facility	Supplier (Healthcare Facility			ClOsp (Phast
Code	Name	File)	UCD	CIOsp Display Name	file)
		BRISTOL MYERS SQUIBB			
N0213113	ABILIFY 10MG CP	LABORATOIRE	9261274	ABILIFY 10mg cpr	OTSUKA PHARMA
N0213041	ABILIFY 15MG CP	BRISTOL MYERS SQUIBB LABORATOIRE	9261280	ABILIFY 15mg cpr	OTSUKA PHARMA
	ACETYLCYSTEINE 200MG			ACETYLCYSTEINE 200mg EG pdr pr sol buv	
N0211056	SACHET EG	CSP LABORATOIRE	9294291	sachet	E.G. LABO
N0212262	ACICLOVIR 200MG CP SANDOZ	Z SANDOZ LABORATOIRE	9263706	ACICLOVIR 200mg SANDOZ cpr	SANDOZ
N0211628	ACICLOVIR 250MG INJ SANDO2	Z SANDOZ LABORATOIRE	\$248486	ACICLOVIR 250mg SANDOZ pdr pr sol pr perf	SANDOZ
N0211114	ACICLOVIR 500MG INJ SANDOZ	Z SANDOZ LABORATOIRE	9248492	ACICLOVIR 500mg SANDOZ pdr pr sol pr perf	SANDOZ
N0213291	ACLASTA 5MG/100ML SOL INJ	NOVARTIS PHARMA LABORATOIRE	9279179	ACLASTA 5mg/100mL sol pr perf flac	NOVARTIS PHARMA
		Healthcare			
thcare Facility D	atabase	Facility	CIO		
		Formulary	o. osp	0	





CIOsp Distribution



CIOsp updates

- Tool for download: TelCIO
- Can be programmed to suit user needs

Shortcomings and Challenges:

- EACH healthcare facility is handled individually (pull mechanism).
- EACH application integrates individually potential differences in versions
- Large volume of files is being transferred
- Facility must ask for mapping of internal codes
- Handling of versioning must be done with care and is very time-consuming

NOT PRACTICAL, TIME- and RESOURCES-consuming

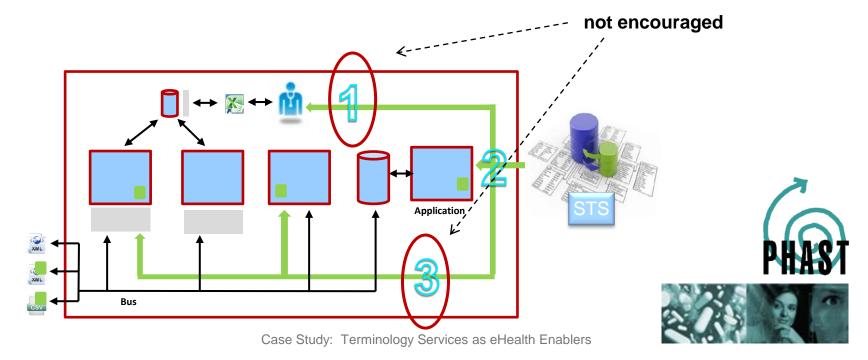






Standard Terminology Service (STS) as a Solution

- Terminology service based on the Common Terminology Services (CTS2) functional model.
- Purpose: offer web services for the applications using ClOsp, ClOdm (equivalent of ClOsp for medical devices), eliminating the need for local import, storage and verification of synchronization, centralized management of terminologies in general.





Common Terminology Services 2 (CTS2)





What is CTS2?

- Started off as functional specifications for handling terminologies in healthcare (HL7 CTS2 Services Functional Model –SFM) in WG Vocabulary, then SOA).
- The goal of CTS2 is to provide a standardized interface for the use and management of terminologies.
- Model and set of functions to read, query, search, exchange and update and map terminological content.
- Modular approach implement only what is needed.





What is CTS2?

 Technical specifications published by OMG under the HSSP auspices respond to these functional specifications, but not only to these, addressing a much larger community – Semantic Web

OMG Standard:

- XML Schemas for Code Systems, Maps, Value Sets and Concept Domain Bindings.
- URL formation rules for Reading, Querying, Importing and Updating the XML Documents.
- Rules for representing XML in JSON, RDF, Java, Python, and others.
- API provides a software blue print





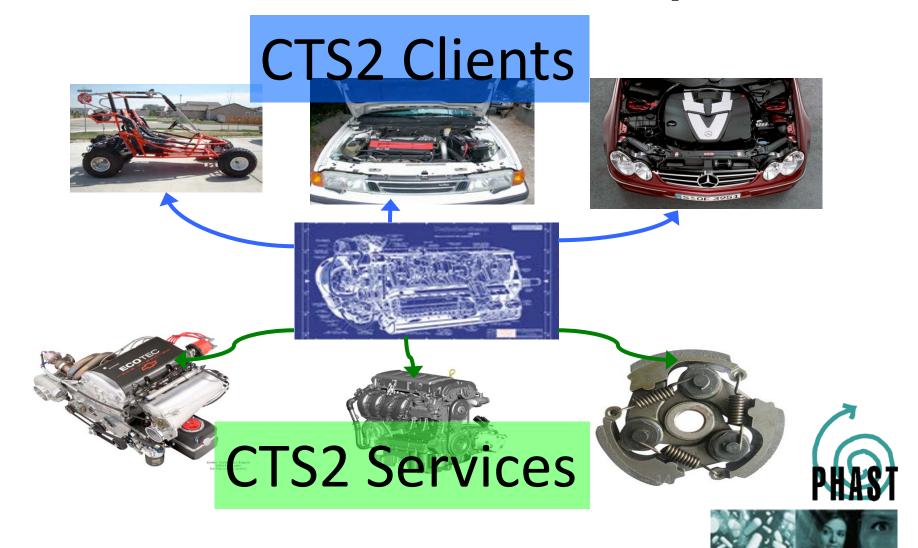
Why CTS2?

- STS provides single access point for terminologies
- Enables generic clients plug-ins, "widgets", etc.
- But how do I replicate STS functionality?
- UMLS, CDC Phin Vads, Mayo Terminologies, BioMedical ontologies ...
- How do I integrate PHAST content, UMLS, HL7, ... and re-use clients, plug-ins, widgets?





CTS2 Standard as a Blueprint





Lessons Learnt: Challenges in STS Deployment

Got two running implementations but not full services, uptake is low.

Possible reasons:

- Some financial costs to integrate the web services but not that significant.
- Legacy systems not allowing direct integration of web services
- Requests to develop "dedicated functions" takes away resources from deployment
- Industry adoption of CDA documents level 3 is very low political and financial reasons (value sets).
- Misunderstanding of the benefits of the value a terminology server can bring
- Data stored in STS is not personal data (no patient data), yet big push back about security and privacy (even if not an issue)
- Psychological barrier in accepting "outside" data
- Misunderstanding of SOA-based services, "palpable interface" also needed, education is needed, OMG can help
- Resistance to change





More information:

- http://wiki.phast.fr (EN) or
- http://www.phast.fr (FR)
- http://informatics.mayo.edu/cts2
 - http://www.omg.org/spec/cts2

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