The Global Language of Business

Standards organisations – together we are stronger

Prof. Sylvia Thun, Charity Visiting Professor, Stiftung Charité, BIH University of Applied Science Niederrhein, Germany

Standards organisations – together we are stronger

Prof. Sylvia Thun
Stiftung Charité

Øyvind Aassve
Norwegian Directorate of eHealth

Robert Stegwee
Health & Health Tech, CGI

Michael van der Zel
Univ. Medical Center Groningen

Erik Zwarter
Erasmus Medical Center

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CORE UNIT EHEALTH & INTEROPERABILITY

STANDARDS ORGANISATIONS – TOGETHER WE ARE STRONGER

PROF SYLVIA THUN PhD MD

GS1 Amsterdam, 03/26/2019

BERLIN INSTITUTE OF HEALTH
Charité & Max Delbrück Center

Motivation

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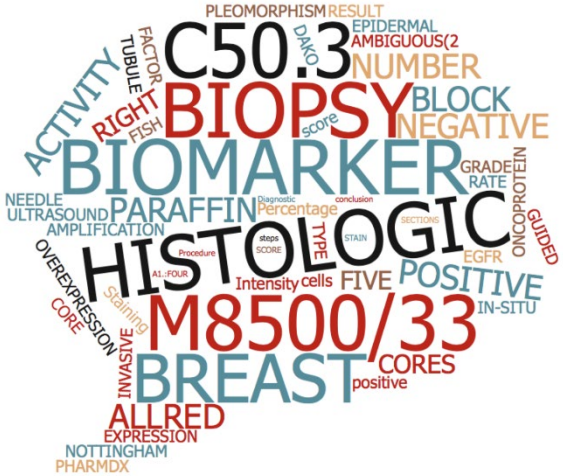
“The whole art of language is to be understood.”

Konfuzius (551-479)



Data-Driven Medicine

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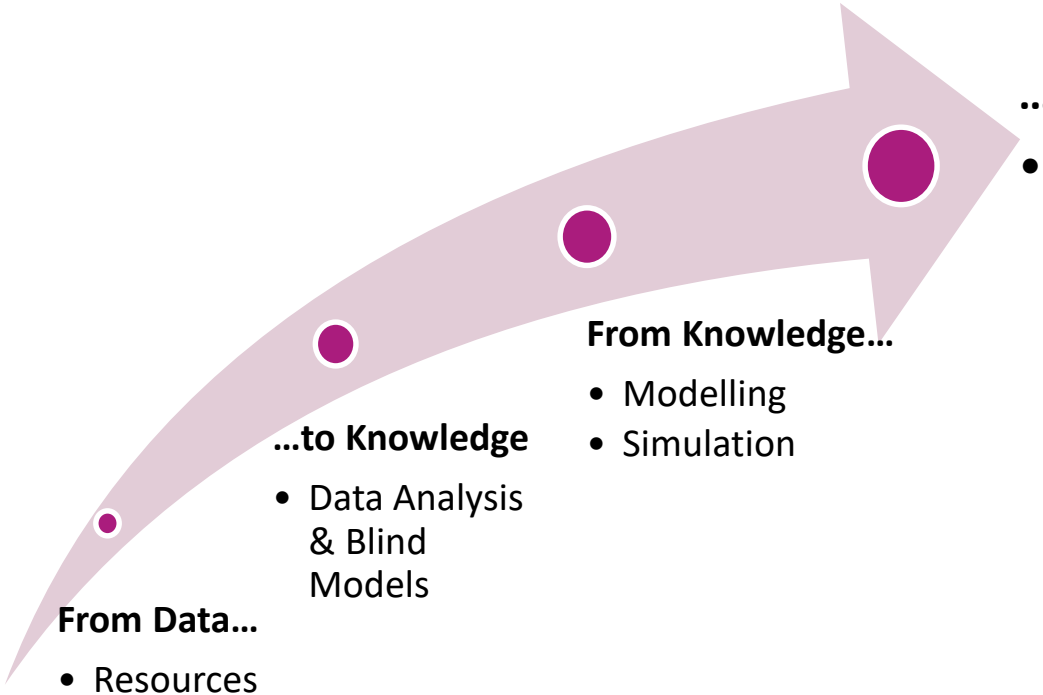


From Data…

- Resources
- Standards
- Integration

…to Knowledge

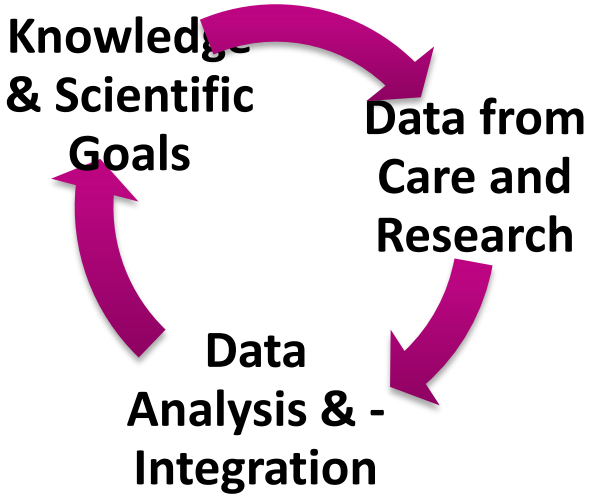
- Data Analysis & Blind Models

From Knowledge…

- Modelling
- Simulation

…to Action

- Decision



Core Unit eHealth & Interoperability (CEI)

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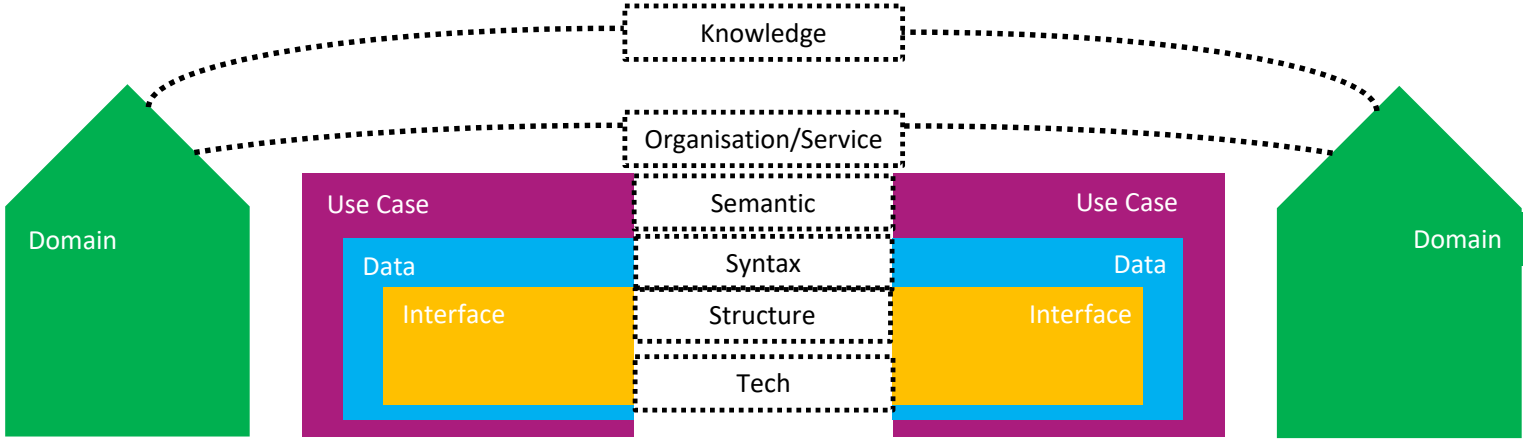
Goals:

- Promote the use of international standards and terminologies
- Enable communication and analysis of medical data across institutions
- Advance the use of digital technologies in medical research, patient care (mobile health applications, big data analytics, precision medicine) and eCommerce

"Our vision is an interconnected digital health infrastructure that enables new technologies (AI, Smart Data Analytics) to predict disease more accurately, develop personalized treatments and diagnostics, promote active patient participation, and ensure high data security."

Interoperability

Interoperability is the ability of different information systems, devices or applications to connect,
in a coordinated manner, within and across organizational boundaries to access,
exchange and cooperatively use data amongst stakeholders,
with the goal of optimizing the health of individuals and populations. *HIMSS*



Worlwide Cooperations (Ministries, Science, E-Health Competence, EU, APPLE, IBM, Amazon, GOOGLE, MS,..)

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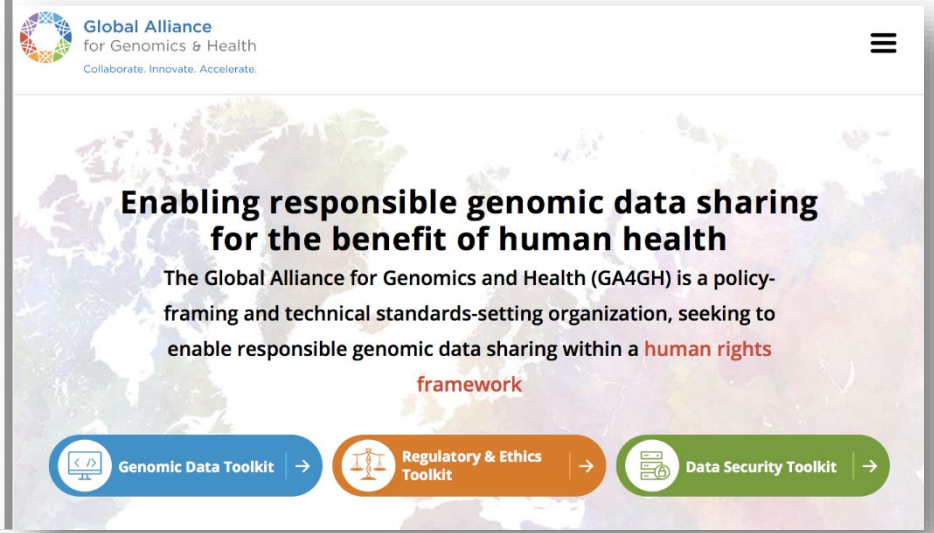
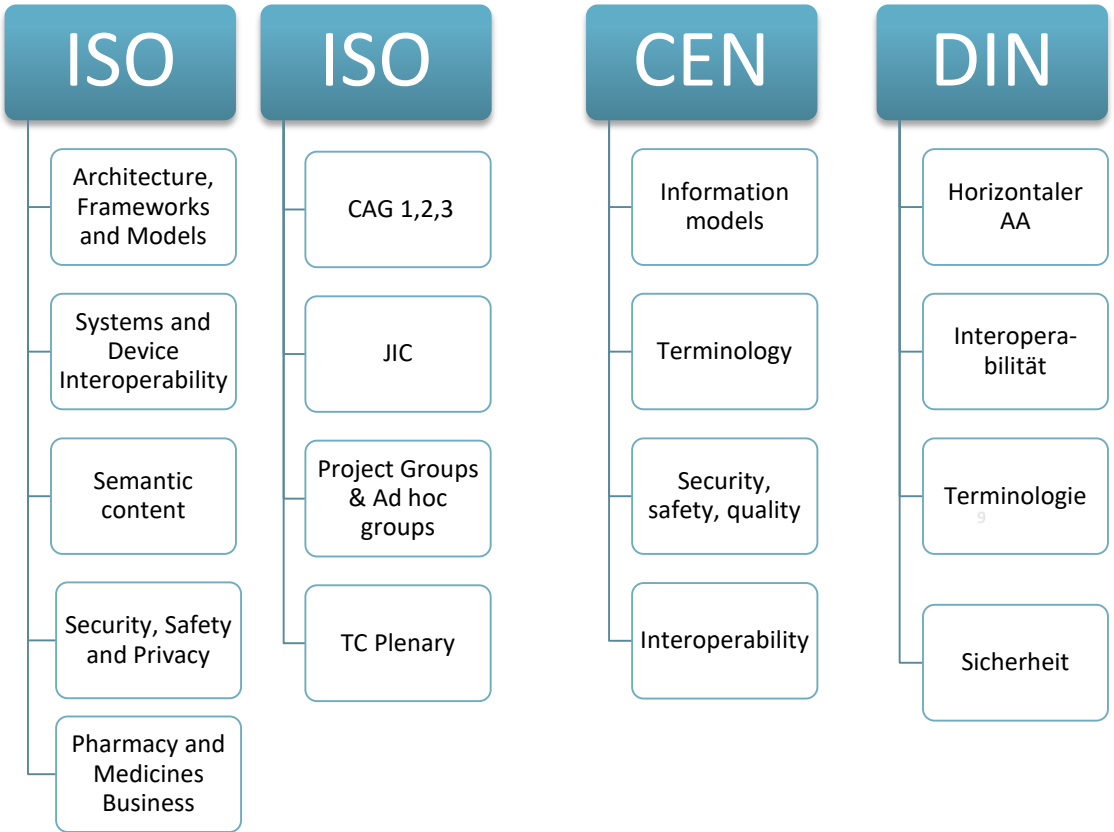
"The JIC will contribute to better global patient health outcomes by providing strategic leadership in the specification of sets of implementable standards for health information sharing."



Quellen: JIC, GA4GH

ISO TC Medical Informatics



Solution: Transparency, Standards und Community

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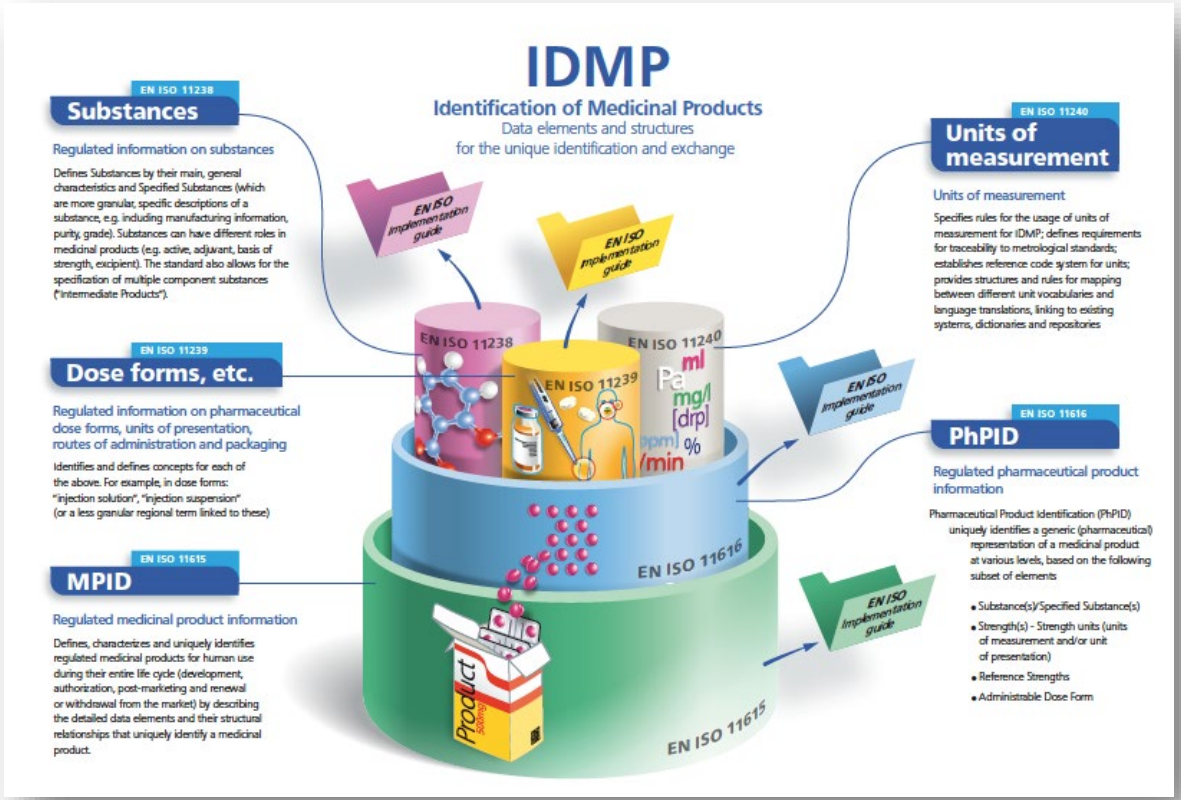

Quelle: ISO

ISO Standards Semantic Content / Terminology / Pharmacy

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- ClaML Classification exchange format
- OID – Object Identifiers
- UCUM – Units of measure
- Principles of Decision Support Systems
- Structure of Anatomy
- Terminology model for nursing
- IDMP – Identification of medicinal products
- Requirements for ePrescription
- Individual case safety reports
- Mapping, Maintenance and structural requirements for terminologies

SITIG

BERLIN INSTITUTE OF HEALTH
Charité & Max Delbrück Center

SITiG

Home | Verband | Mitglieder | Satzung | Datenschutz

Willkommen beim Spitzenverband SITiG

Vorstand
Vorsitzende: Prof. Dr. Sylvia Thun
Stellvertretender Vorsitzender: Alexander Ihls

Spitzenverband IT-Standards im Gesundheitswesen (SITiG)

Anna-Louisa-Karsch-Str. 2

10178 Berlin

Email: info@sitig.de

Standards work together

BERLIN INSTITUTE OF HEALTH
Charité & Max Delbrück Center

- F = Fast
- H = Healthcare
- I = Interoperability
- R = Resources

HL7® FHIR®

& Terminologies
(IDMP, OMICS, LOINC, HPO, SNOMED CT, ICD-10...)

& IDs (GS1)

& Testing, Implementation, Products (IHE)

Together we are strong!

BERLIN INSTITUTE OF HEALTH
Charité & Max Delbrück Center

CONTACT

Sylvia Thun
Director Core Unit eHealth & Interoperability
Berlin Institute of Health (BIH)

Anna-Louisa-Karsch-Str. 2
10178 Berlin
sylvia.thun@bihealth.de
www.bihealth.org

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The Norwegian
Directorate of eHealth

Standardization in Norway

Global GS1 healthcare conference 2019

Øyvind Aassve
Senior advisor
Norwegian Directorate of e-health

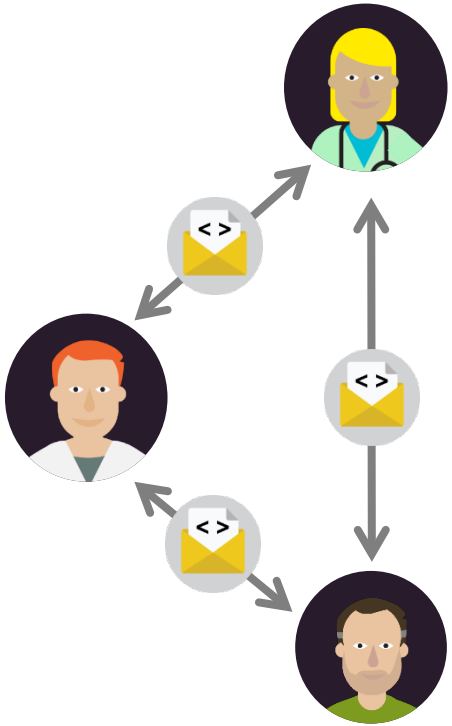
Use of international standards - Norway

Focus in this presentation:

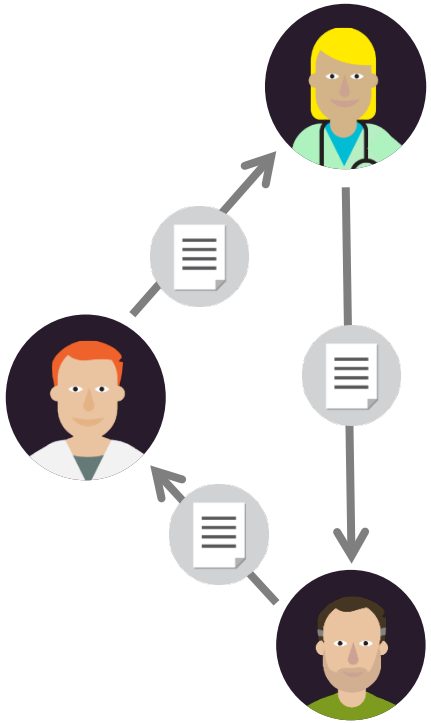
- Data sharing/ APIs
- FHIR
- Roadmap for international standards

Exchange paradigms

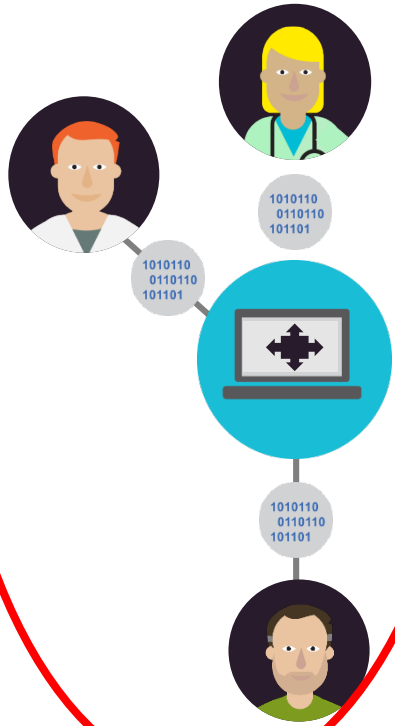
Messaging



Document sharing



Data sharing/ API



Data sharing/ APIs

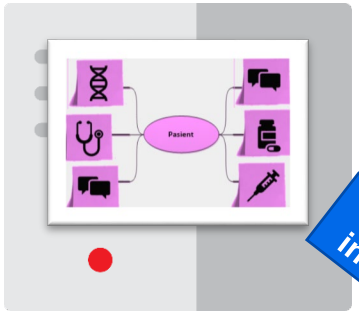
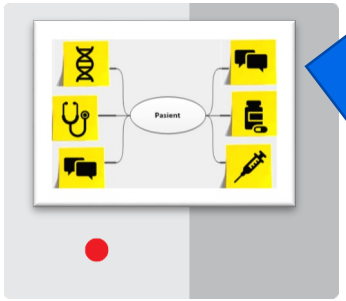


Image-information



Diagnosis

Systems can retreive necessary information on-demand…

Fast Healthcare Interoperability Resources

- FHIR is a free and open standard developed by HL7 International.
- FHIR describes information content that is exchanged between clinical systems.
- FHIR was developed for use in APIs, but the information structures can also be used for messaging and document sharing.
- FHIR representss a more agile approach to standardization.
- FHIR can be adapted to most use-cases
- FHIR has a broad and very active international community
- FHIR focus support on common scenarios (80%)
- Basic principles - ease of use for developers

Standardized APIs = reuse

Patient

Condition

Patient

Condition

Hospital A EHR

Patient

Condition

Hospital B Radiology

Patient

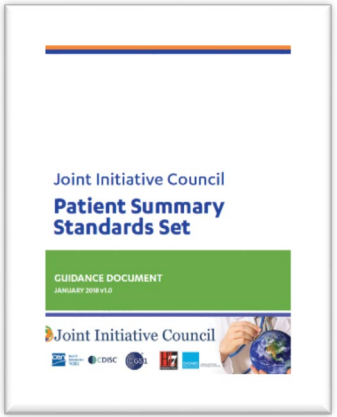
Condition

Nursing home Municipality X

International adoption FHIR

The traditionals

The newbies



CEN EN 17269

FprCEN/TS17288

Guidance for European Implementation

International Pasient Summary

HL7 FHIR

HL7 CDA

SNOMED CT
The global language of healthcare

IHE

GS1

Areas in development

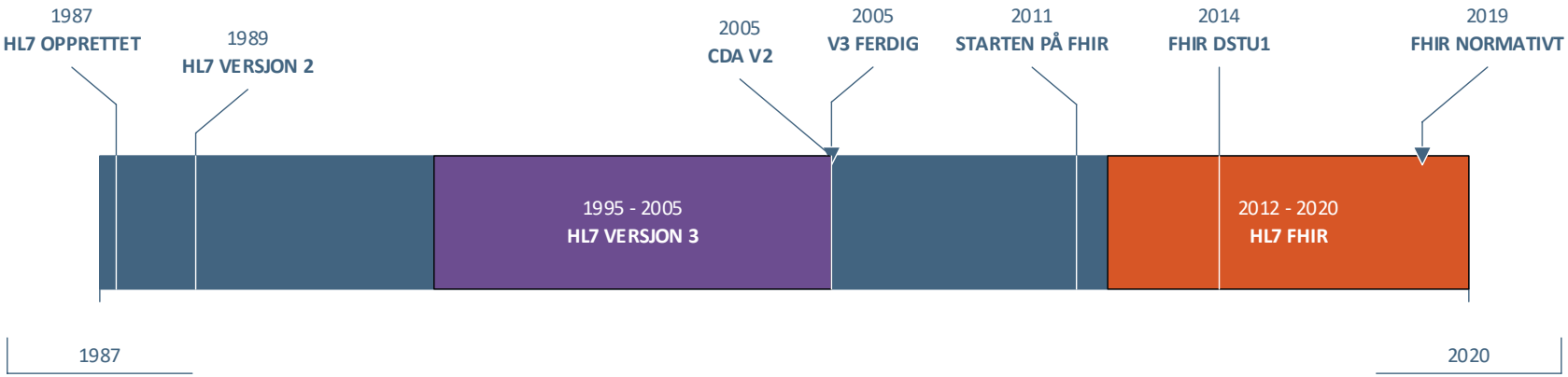
- Building a national community of regulator, sector and vendors to work together on standards development.
- Developing more specific guidance on how to use international standards in some functional areas:

  - Health- and quality registries
  - Medical devices
  - Logistics and supply chain
  - Questionnaires
  - Use of standard information models with ontologybased terminologies (SNOMED CT)

The Norwegian
Directorate of eHealth

Questions?

HL7 standards



Experience from the Netherlands

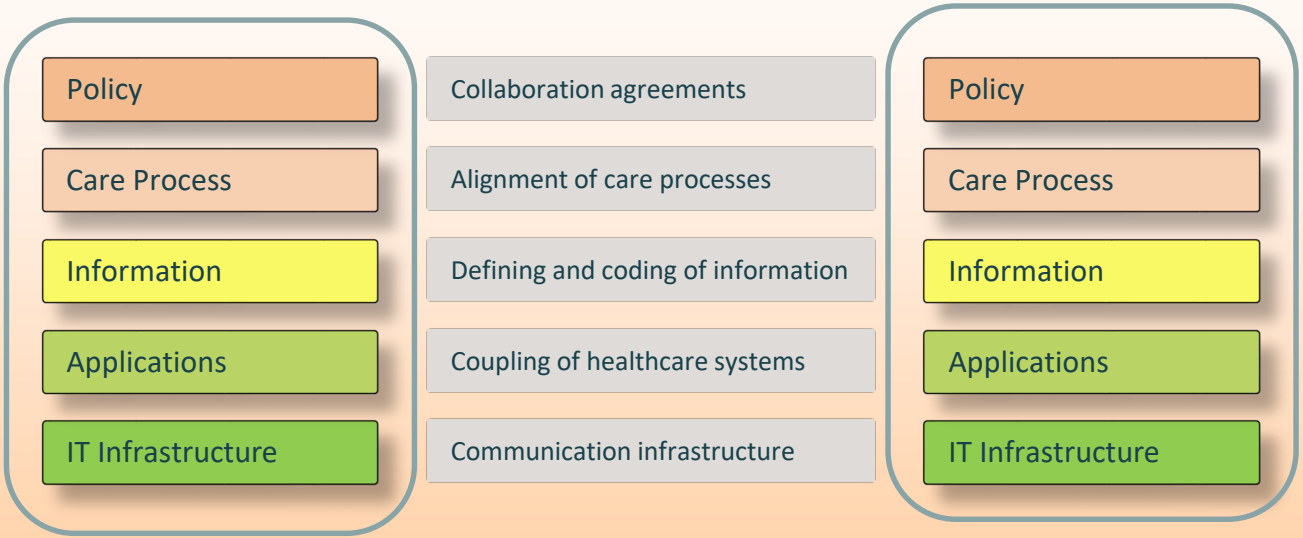
Dr Robert A. Stegwee
Board Member, HL7 Netherlands
Chair, CEN/TC 251 Health Informatics
Member, Joint Initiative Council

CGI
Experience the commitment®

Director Consulting,
Health & Health Tech,
CGI, the Netherlands

Standards Developing Organizations

No single standard is sufficient



National goals are being set

- Policy
- Care Process
- Information
- Applications
- IT Infrastructure

Healthcare Information Council

SDO Council

Main goals of the SDO Council

- To have an environment in which to have an efficient and effective standards debate

1. Coordinate, because multiple standards will usually contribute to a single solution
2. Identify *overlaps* between standards and agree to actions to avoid them
3. Identify *gaps* between standards and agree to actions how to solve them
4. Provide insight into the dependencies between standards
5. Provide (independent) advice to stakeholders

Aligned with the global JIC

(a) promote interoperability and seek to avoid overlaps between standards used in health informatics;
(b) achieve greater coordination and consistency of health informatics standards development;
(c) identify gaps in meeting the needs of members and their stakeholders for health informatics standards

…

Agreement for the SDO Council

1. Inform each other of new initiatives, allowing the other members to question and comment
2. Agree on actions in support of the goals
3. Inform each other of international developments
4. Bring key NL developments to the attention of the international standards community
5. Create and maintain an overview of actions
6. Be open to participation of other organizations contributing to standards when and where needed

A few key achievements

- Uniform Barcode Processing (UBP)
  - Orthopedic Implant Registry
  - Medication Administration

- More awareness of and involvement in European activities
  - International Patient Summary – CEN/HL7

Questions?

Panel II – Standards organisations – together we are stronger

IHE Barcode Processing (UBP) Profile
“An easy recipe with 4 ingredients”
&
Vision on standardised exchange with registries

Michael van der Zel, University Medical Center Groningen, Netherlands

The Use-Case

Medical devices
(High risk) medication
ZzZz
• Electronic Medical Record (EMR)
• Enterprise Resource Planning (ERP)
• Inventory Management System (IMS)
External: Implant registries

The Recipe

- If we want to make a nice dish, you need a recipe
- We need ingredients from more then one shop
  - SDO's are like a grocery store, a toko, a butcher, ...
- But where is the restaurant? Were can we taste? That is were a Tasting Room is for… The Demonstrator

Shopping list

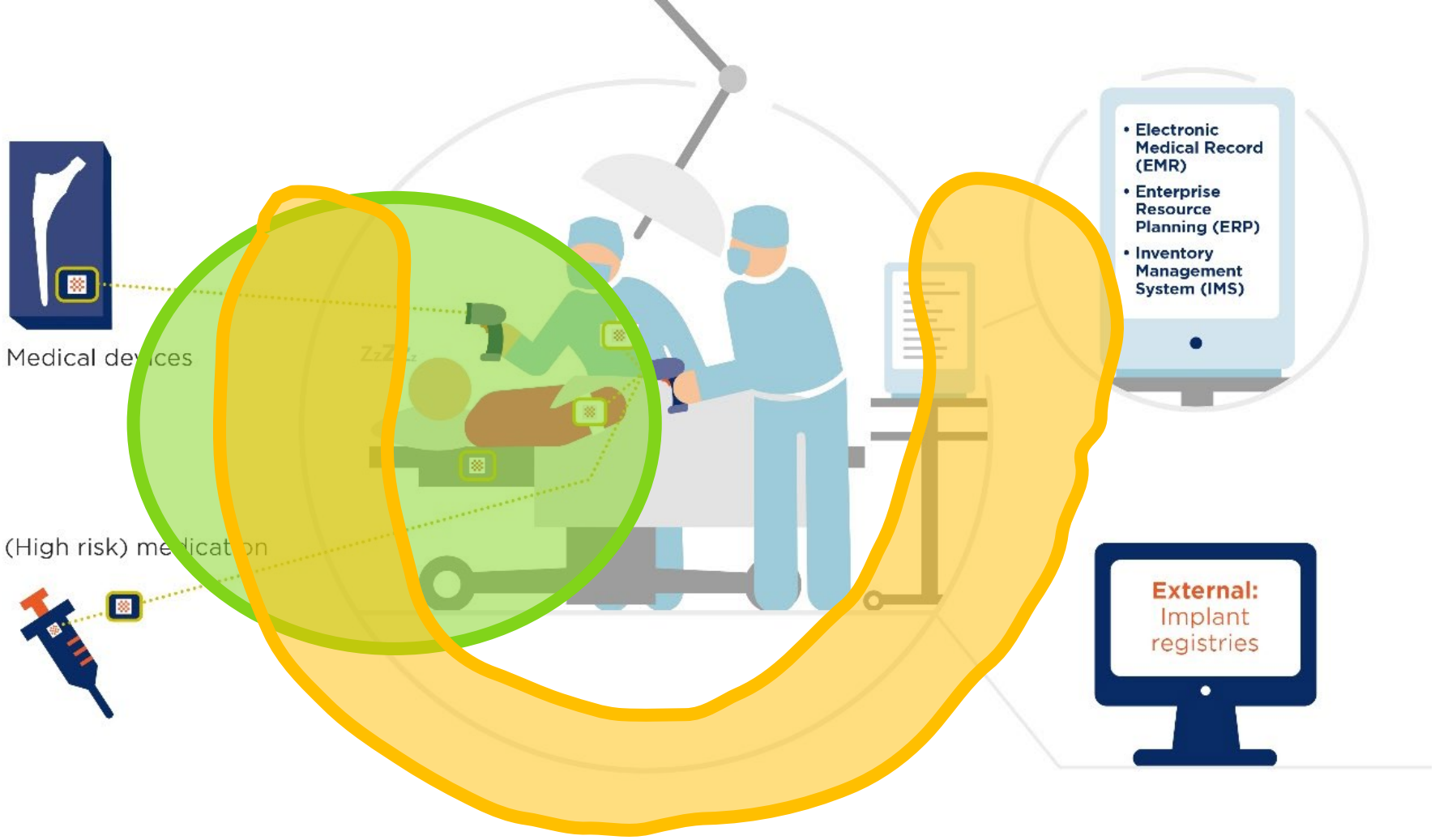
the recipe → IHE Profile

meat → HL7 FHIR Impl. Guide

vegetables → GS1 Barcode

spices → DCM(s)

- Government
- IHE UBP Profile
- DCM + GS1
- FHIR Impl. Guide
- IT Infra


Medical devices
(High risk) medication
• Electronic Medical Record (EMR)
• Enterprise Resource Planning (ERP)
• Inventory Management System (IMS)
External: Implant registries

Recipe

Integrating the Healthcare Enterprise

IHE

IHE Pharmacy Technical Framework Supplement

10

Uniform Barcode Processing (UBP)

15 HL7® FHIR® STU 3

Using Resources at FMM Level 2-5

Rev. 1.1 – Trial Implementation

20 Date: December 4, 2017

Author: IHE ITI Technical Committee

Email: pharmacy@ihe.net

25 **Please verify you have the most recent version of this document.** See here for Trial Implementation and Final Text versions and here for Public Comment versions.

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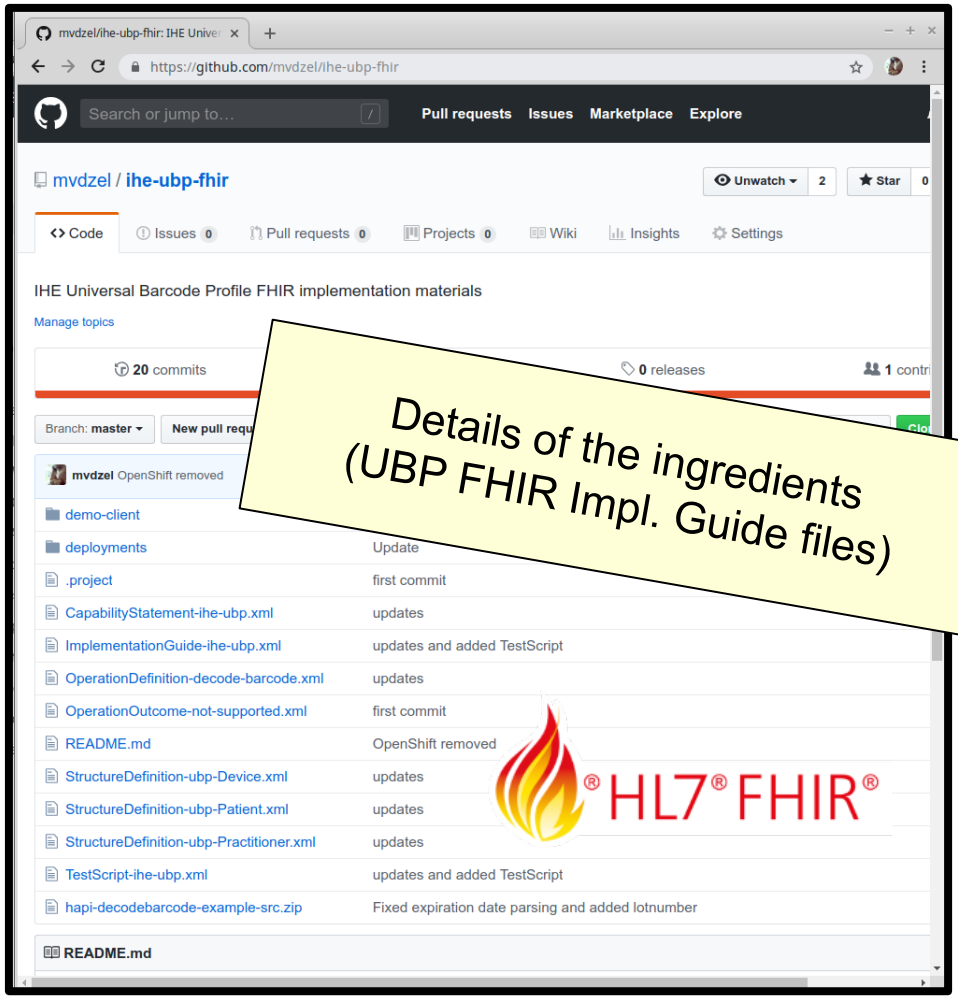


Details of the ingredients (UBP FHIR Impl. Guide files)

HL7® FHIR®

https://www.ihe.net/uploadedFiles/Documents/Pharmacy/IHE_Pharm_Suppl_UBP.pdf

Secure | https://vdzel.home.xs4all.nl/ihe-barcode-demo/index.html

IHE Integrating the Healthcare Enterprise — UBP - Universal Barcode Processing Profile FHIR Demo

Barcode: 010871234567020617270620801710101010101010101080180123456789012345678 Decode

Example: 010871234567020617270620801710101010101010101080180123456789012345678

Care Provider Lookup @EPD

big: 12345988912
name: Lucas van der Spegel

Patient Lookup @EPD

id: 1587965423
name: Piet Jansen
birthDate: 1942-11-15

Device Lookup @EPD Lookup @GS1

udi: {01}00844588003288{17}141120{10}7654321D{21}10987654d321
device: Coated femoral stem prosthesis, modular
manufacturer: Acme Devices, Inc
model: PM/Octane 2014

Create Implant Notification

Medication Lookup @EPD Lookup @GS1

medication: Capecitabine 500mg oral tablet (Xeloda)

Create Statement Create Administration

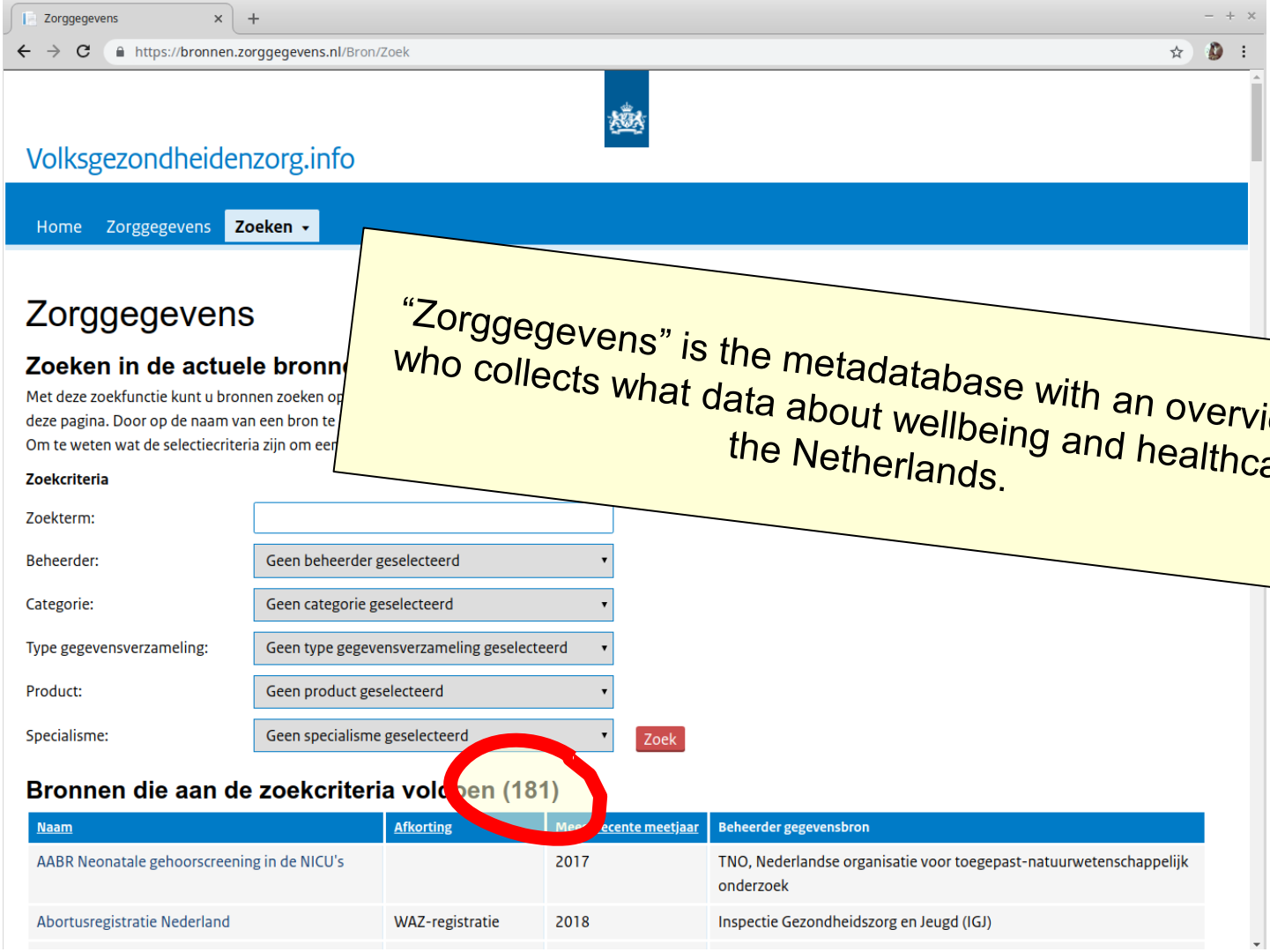
FHIR json


```
{
  "resourceType": "Medication",
  "id": "medexample015",
  "meta": {
    "versionId": "c95ecfb6-a491-4c17-949f-d0bf93c26d19",
    "lastUpdated": "2018-03-28T12:57:05.053+00:00"
  },
  "contained": [
    {
      "resourceType": "Organization",
      "id": "org2",
      "name": "Gene Inc"
    },
    {
      "resourceType": "Substance",
      "id": "sub04",
      "code": {
        "coding": [
          {
            "system": "http://snomed.info/sct",
            "code": "386906001",
            "display": "Capecitabine (substance)"
          }
        ]
      }
    }
  ],
  "code": {
    "coding": [
      {
        "system": "http://www.nlm.nih.gov/research/umls/rxnorm",
        "code": "213293",
        "display": "Capecitabine 500mg oral tablet (Xeloda)"
      }
    ]
```

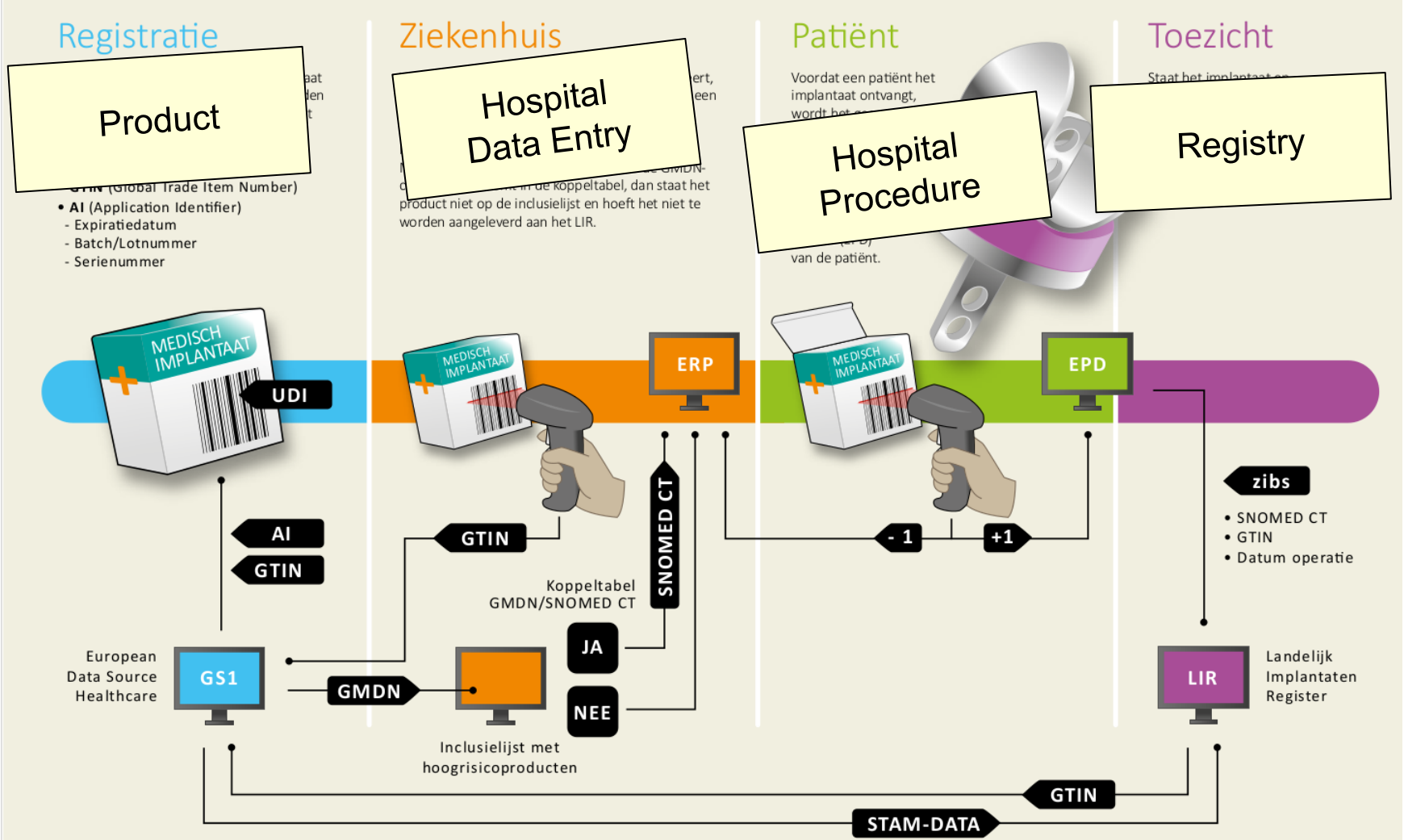

Powered by: HL7 FHIR Vonk FHIR Server heroku

Why SDO governed specs

- As a hospital we need the specs (recipe) so we can tell the vendors what we want in e.g. tenders
- Currently every hospital asks the vendor and we have a system full of proprietary stuff that is not maintainable and can become very expensive
- **We want SDO governed specs, so a vender has to implement only once**
- Scanning and storing in EHR – the standard is here, now implement it
  - takes time to get the stakeholders (hospitals and software vendors) involved and ready to implement
- Then we can move on to the specs for registries



"Zorggegevens" is the metadatabase with an overview of who collects what data about wellbeing and healthcare in the Netherlands.


Registratie
Ziekenhuis
Patiënt
Toezicht
Product
Hospital Data Entry
Hospital Procedure
Registry
• AI (Application Identifier)
- Expiratiedatum
- Batch/Lotnummer
- Serienummer
product niet op de inclusielijst en hoeft het niet te worden aangeleverd aan het LIR.
van de patiënt.
MEDISCH IMPLANTAAT
UDI
ERP
EPD
AI
GTIN
GTIN
SNOMED CT
- 1
+1
zibs
• SNOMED CT
• GTIN
• Datum operatie
Koppeltabel GMDN/SNOMED CT
JA
NEE
European Data Source Healthcare
GS1
GMDN
Inclusielijst met hoogrisicoproducten
LIR
Landelijk Implantaten Register
GTIN
STAM-DATA

Office of the Inspector General/Department of Veterans Affairs photo

THE IMPLEMENTATION OF STANDARDS

Erik Zwarter

Implementation of our EHR

Introduction of next generation of a Electronic Medical Record on June 23, 2017

Erasmus MC

Moving in

Moving into our new hospital on May 18, 2018

Erasmus MC

Introduction

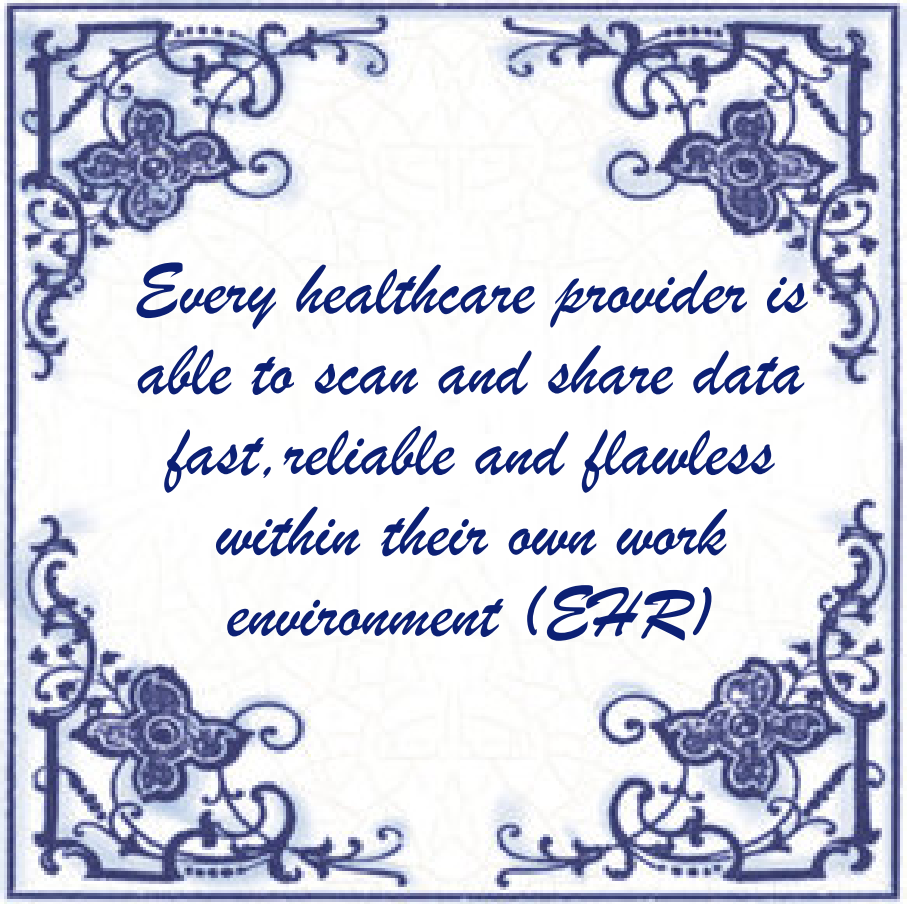
information manager working on

- *eHealth,*
- *digital information exchange of medical data*
- *Automatic Identification and Datacollection (AIDC).*

Working for 15 years in different functions and several departments in Erasmus MC.

For the last 2 years in the central IT department.

Erasmus MC


Every healthcare provider is
able to scan and share data
fast, reliable and flawless
within their own work
environment (EHR)

Why barc

17 JAN 2012

Ziekenh

miljoe

barcc

PATIËNTVEILIGHEID

07 FEB 2017

21,4 miljoen baten van barcodes in ziekenhuizen

Het ministerie van VWS heeft vorige week de Tweede Kamer geïnformeerd over de uitkomsten van het onderzoek van Capgemini Consulting over barcodering op de verpakking van geneesmiddelen. Eén van de belangrijkste conclusies is dat bij

Ziekenhuizen in
euro besparen door in
bij medische hulpmiddelen.
'Patiëntveiligheid en efficiency in

21,4 miljoen Euro's per year saving on medication

170 miljoen Euro's per year savings on medical devices

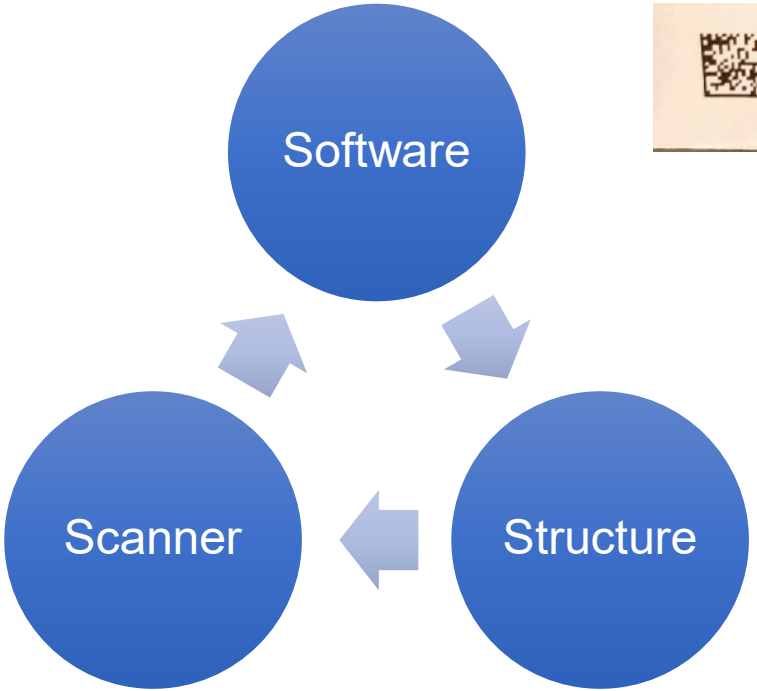
Erasmus MC

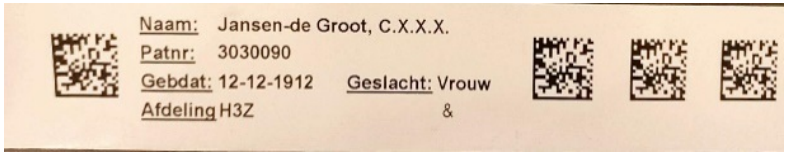
Why a brilliant failure?

Brilliant Failure 2012

Erasmus MC

Trinity





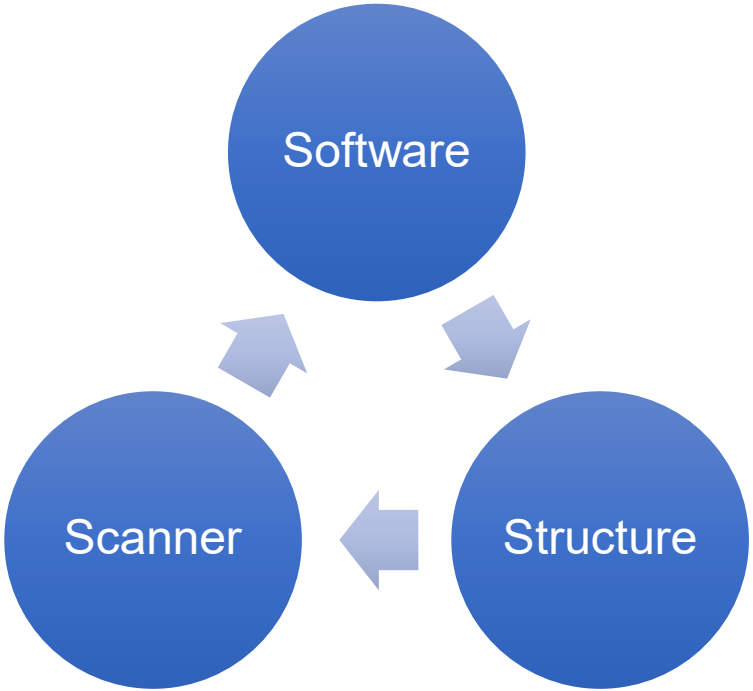
Issue:

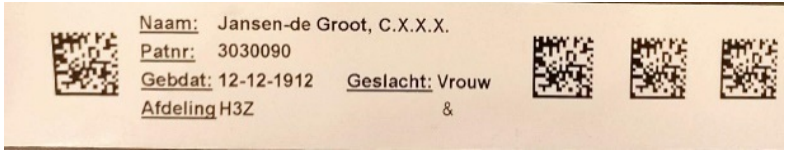
The software could handle patient numbers up to 12 digits

Briljant Failure 2015

Erasmus MC

Trinity



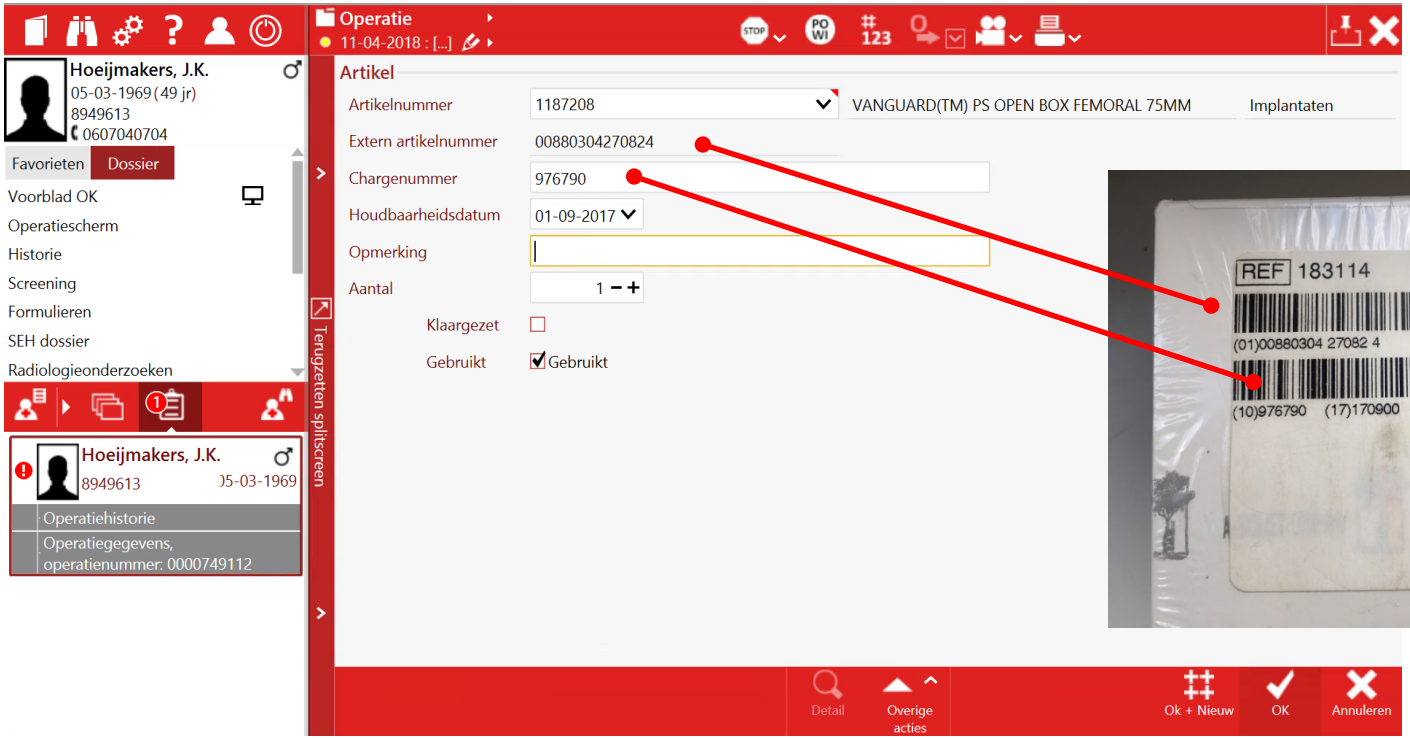


The software couldn't handle GS1 compliant codes. Please at this in your barcode…

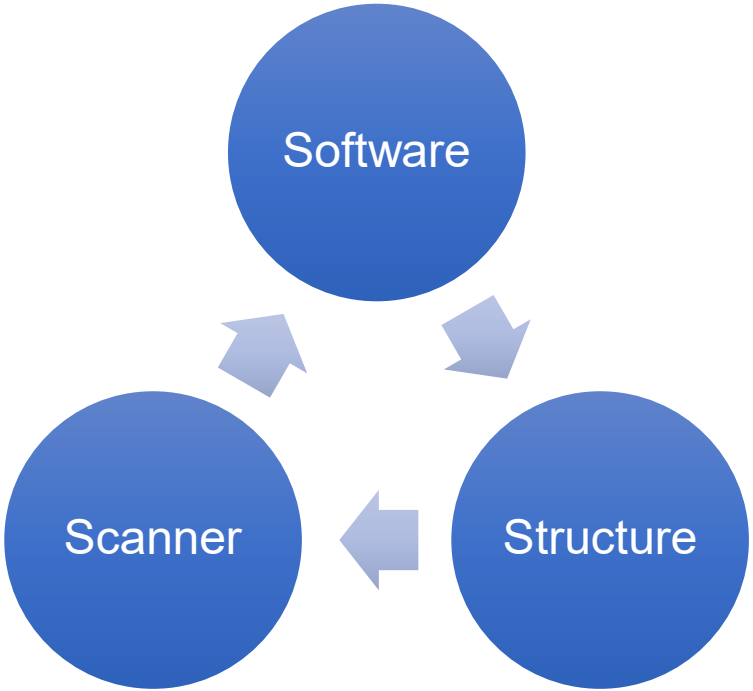
#4 to identify patients
#5 to identify high risk medication

Erasmus MC

Briljant Failure 2017



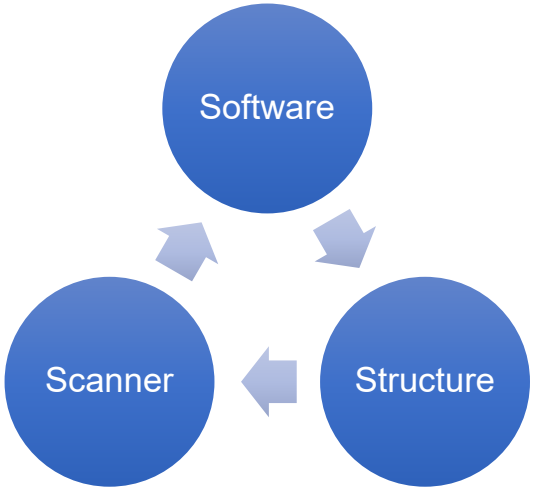
Trinity



The software couldn't handle all GS1 formats.

Datamatrix, GS1-128 please fill in by hand.

Triple Constraint



9201 80188714054000303009O8

Why a IHE UBP profile?

The datastructure from the barcode is processed in the right way

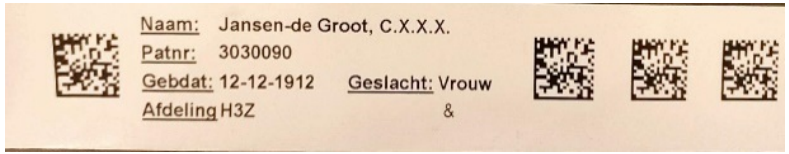
Reliable data interchange without datatransformation.

Interoperability

(Uniform Barcode Processing)

Wristband

AI	Carrier	AI	Company Prefix	Service Reference	Check Digit
92	01	8018	8714054	0003030090	8



UBP - Uniform Barcode Processing

Input from product scanning

Barcode system A	*SDO-ID*	*BatchID*	*ItemID*	*Exp.Date*	*Serial Number*
Barcode system B	*BatchID*	*Exp.Date*	*ItemID*	*SDO-ID*	*Serial Number*
Barcode system C	*SDO-ID*	*ItemID*	*BatchID*	*Exp.Date*	*Serial Number*

Input from scanning of patient, staff, location or document

PatientID	*CaregiverID*	*LocationID*	*DocumenttypeID*

Functional data definition

SDO_ID	12345
BatchID	23456
ItemID	34567
Exp.Date	21/02/2017
PatientID	123456789
CaregiverID	876543
LocationID	56262727
Document-typeID	1234543

GS1	*generic*
HIBCC	*generic*
ICCBBA	*only medical products of human origin*

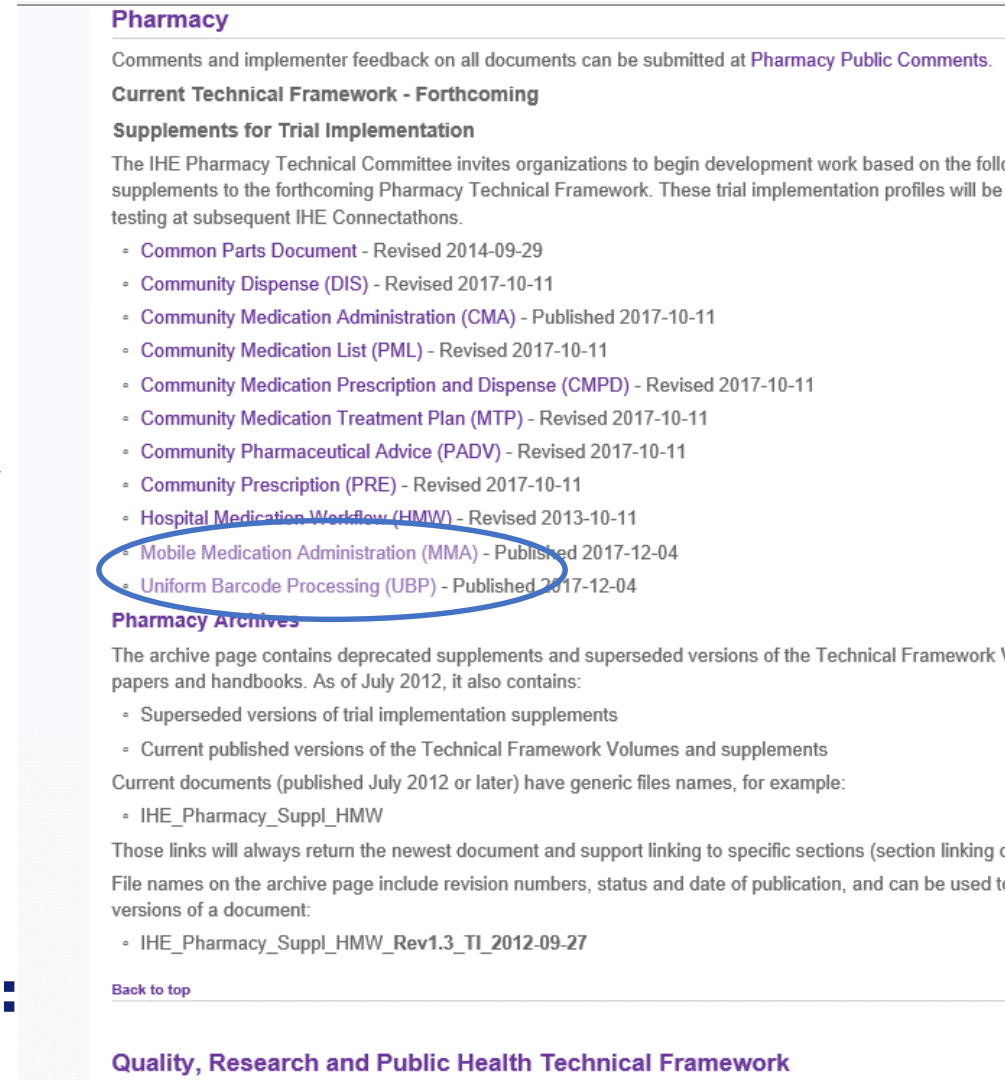
SDO *Standard Developing Organization*

Technical communi-cation templates

HL7 FHIR *HL7 CDA* *Edifact* *ebXML*

To find UBP …

http://www.ihe.net/Technical_Frameworks/#pharmacy



Pharmacy

Comments and implementer feedback on all documents can be submitted at Pharmacy Public Comments.

Current Technical Framework - Forthcoming

Supplements for Trial Implementation

The IHE Pharmacy Technical Committee invites organizations to begin development work based on the follo
supplements to the forthcoming Pharmacy Technical Framework. These trial implementation profiles will be
testing at subsequent IHE Connectathons.

- Common Parts Document - Revised 2014-09-29
- Community Dispense (DIS) - Revised 2017-10-11
- Community Medication Administration (CMA) - Published 2017-10-11
- Community Medication List (PML) - Revised 2017-10-11
- Community Medication Prescription and Dispense (CMPD) - Revised 2017-10-11
- Community Medication Treatment Plan (MTP) - Revised 2017-10-11
- Community Pharmaceutical Advice (PADV) - Revised 2017-10-11
- Community Prescription (PRE) - Revised 2017-10-11
- Hospital Medication Workflow (HMW) - Revised 2013-10-11
- Mobile Medication Administration (MMA) - Published 2017-12-04
- Uniform Barcode Processing (UBP) - Published 2017-12-04

Pharmacy Archives

The archive page contains deprecated supplements and superseded versions of the Technical Framework
papers and handbooks. As of July 2012, it also contains:

- Superseded versions of trial implementation supplements
- Current published versions of the Technical Framework Volumes and supplements

Current documents (published July 2012 or later) have generic files names, for example:

- IHE_Pharmacy_Suppl_HMW

Those links will always return the newest document and support linking to specific sections (section linking
File names on the archive page include revision numbers, status and date of publication, and can be used t
versions of a document:

- IHE_Pharmacy_Suppl_HMW_Rev1.3_TI_2012-09-27

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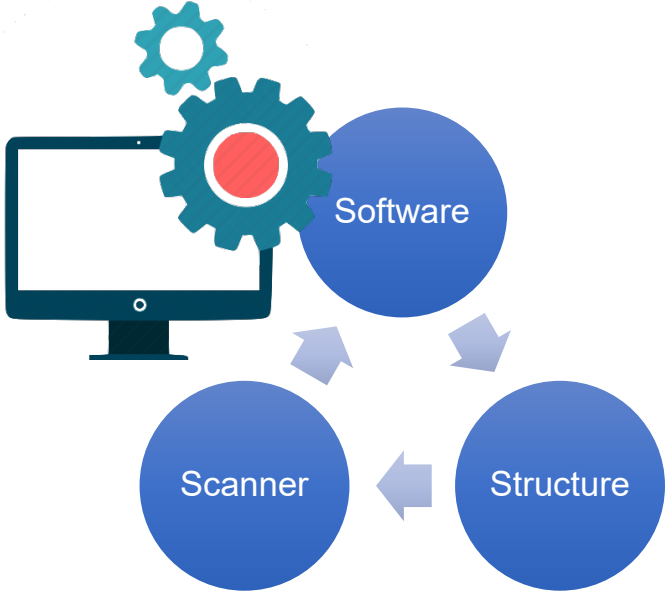
Quality, Research and Public Health Technical Framework

Change the software



Change the datastructure for each IT system

Reprogram barcode scanners

Huge maintenance costs

2018018871405400030300908

...with UBP profile

GS1 standards policy in Erasmus MC

Product identification	(GTIN)
Expiry date	(AI 17)
Batch/lot	(AI 10)
Serial number	(AI 21)
Patient	(GSRN)
Healthcare Professional	(GSRN)
Global Location Number	(GLN)

Use of GS1 ID Keys in Erasmus MC

Global Trade Item Number (GTIN)

Global Location Number (GLN)

Global Returnable Asset Identifier (GRAI)

Global Individual Asset Identifier (GIAI)

Global Service Relation Number (GSRN)

Global Document Type Identifier (GDTI)