22. Międzynarodowy Kongres
Ogólnopolskiego Systemu Ochrony Zdrowia
Innowacyjna Ochrona Zdrowia

4-5 kwietnia 2017 | KATOWICE
MIĘDZYNARODOWE CENTRUM KONGRESOWE

Recent developments in Semantic Interoperability in health and care

Motto 1: Do **NOT** reinvent the wheel

Interoperability

It is all in the semantics

This presentation makes use of slides kindly provided by:
CENTc251 wg1, EN13606 Association, ERS, KPMG, CIMI

Gerard Freriks

- **Active in IT** since 1972
- **General Practitioner** for 20 years
- **Standards (NEN, CEN, ISO, HL7, CIMI)** since 1999
  - past-chairman CEN TC251-WG1
  - Active: Standards for EHR-systems, and Information Security
- **EHR company ERS** (co-director, owner) 9 years
- **Recent topics**:
  - Information Architecture, advanced Semantic Interoperability

What is the problem

Topics
Communication in health and care

What is the problem: It is the Semantics, stupid!

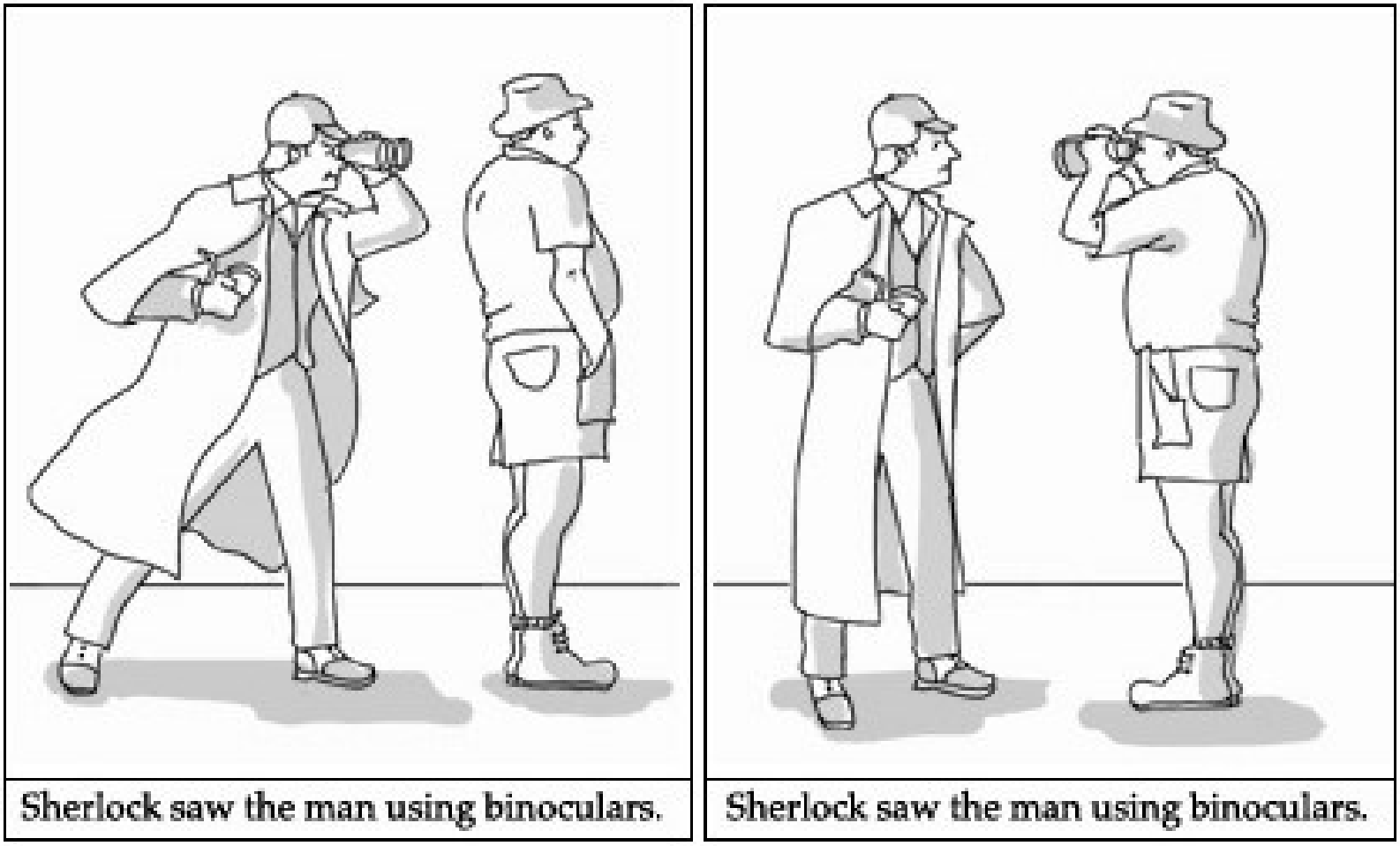
What we need to talk about:

- Semantics
- Standards
- Bakery as metaphor
- Semantic Stack
- Epistemology
- Available standards - Concurrent use of standards
- Information Architecture

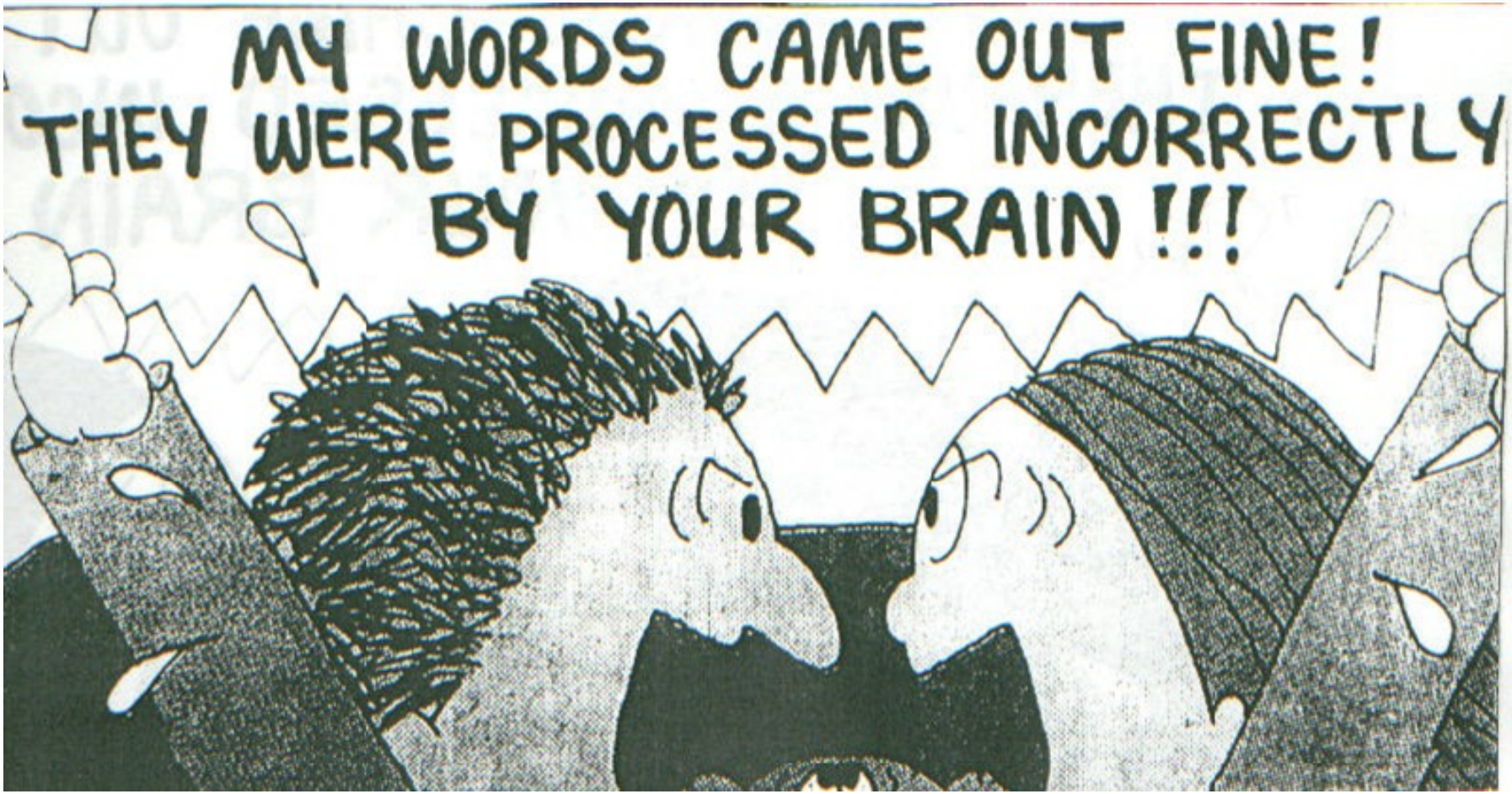
Recent developments: ISO, HL7, CIMI

Pharma developments

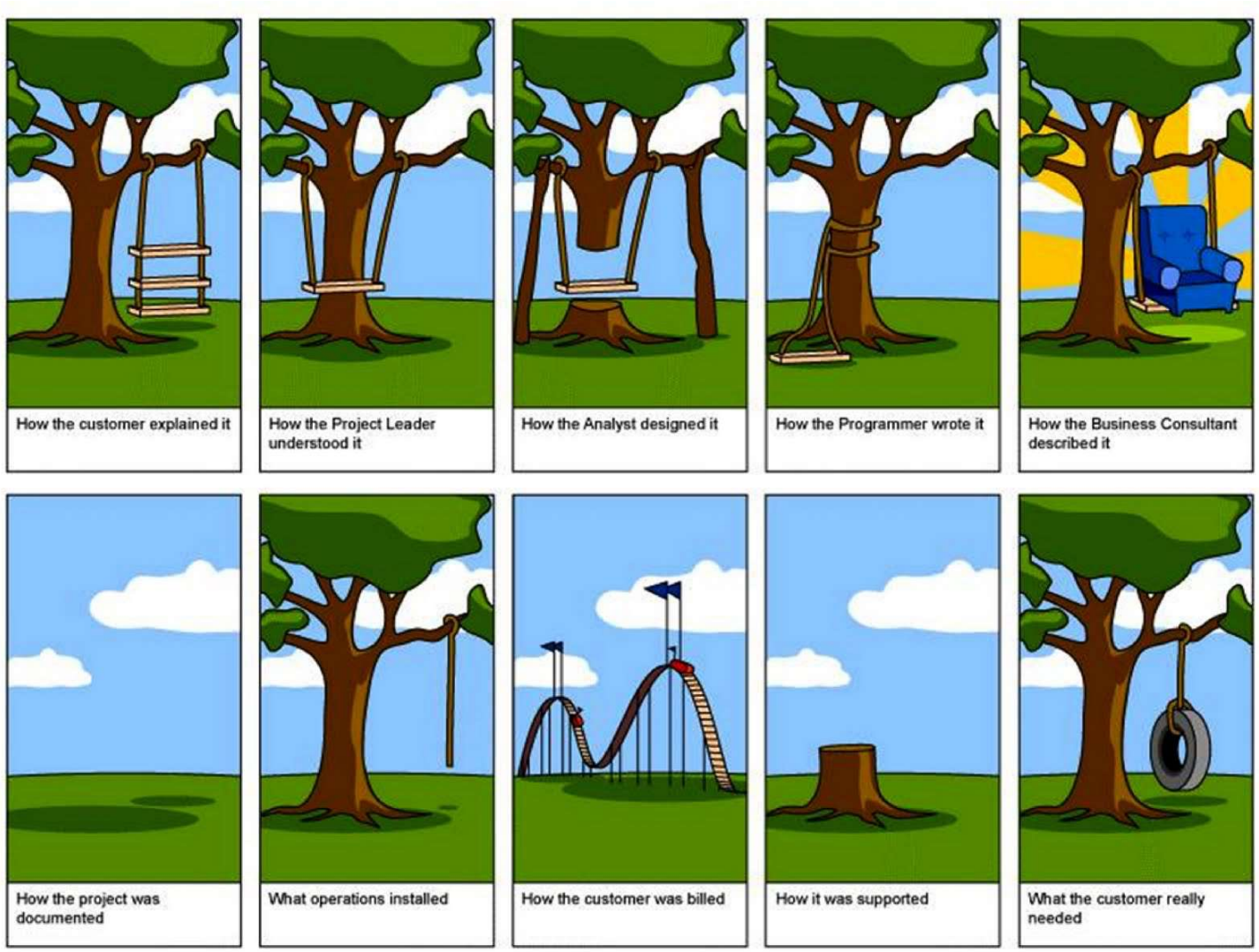
What is the problem



What is the problem



What is the problem



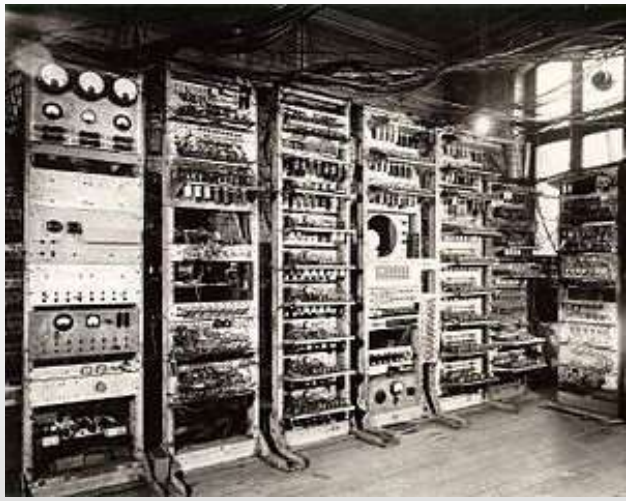
What is the problem

We use for computers since 1949

Can we ubiquitously exchange:

- *Name*
- *Data of birth*
- *Address*

between all kinds of computer systems?



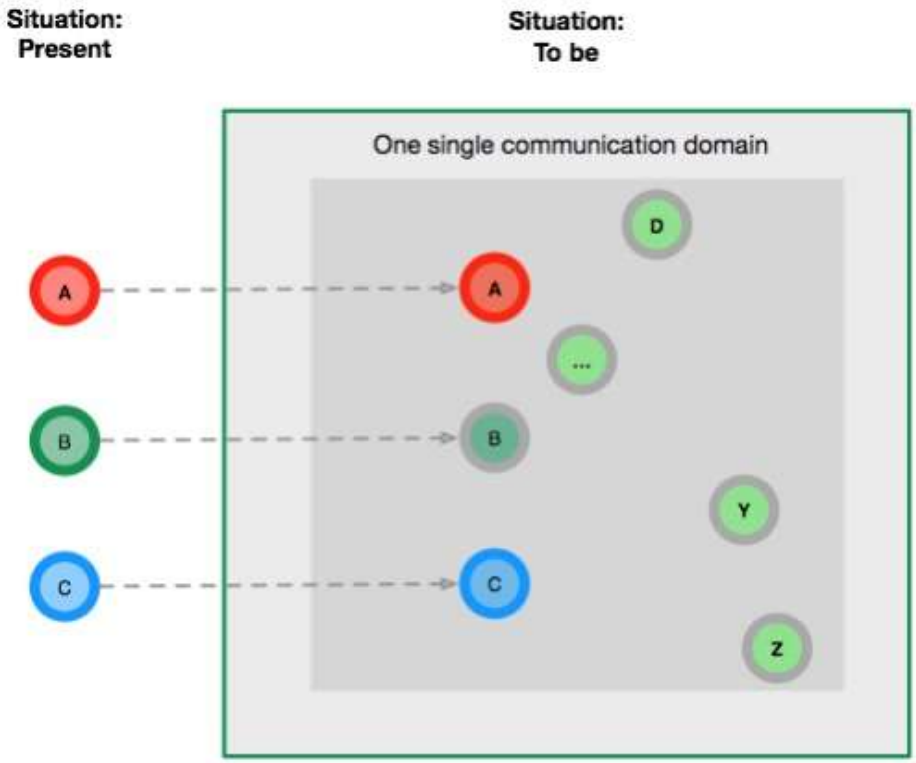
(Mark 1 - 1949)

What is the problem

Answer:

It is the shared semantics, stupid

What is the problem



patients, carers,
nurses,
doctors,
care facilities,
pharmacists,
physiotherapists,
insurers,
registries
research

From a collection of disconnected systems

to connected systems

What is the problem

Definition: Semantics

- [si-**man**-tiks]
- noun, (*used with a singular verb*)
- 1.
- *Linguistics.*
- a **the study of meaning**.
- b the study of linguistic development by classifying and examining changes in meaning and form.
- 2.
- Also called **significs**. The branch of semiotics dealing with the relations between signs and what they denote.
- 3.
- the meaning, or an interpretation of the meaning, of a word, sign, sentence, etc.: Let's not argue about semantics.

What is the problem

How can we document the provision of health and care such that:

- when health data is stored now
- that health data can be safely and
- fully understood
- now and in the future
- by persons yet to be born
- using computer systems that have yet to be designed

What is the problem

Examples

Language: '*Geslacht is mannelijk*'
('Sex is male')

Meaning: Sex?
Biological sex, administrative sex

Coding system: Sex: M (or F)
Sex: 1 (or 0)

Free text / codes: 'Diabetes', 'Suikerziekte', 123.45

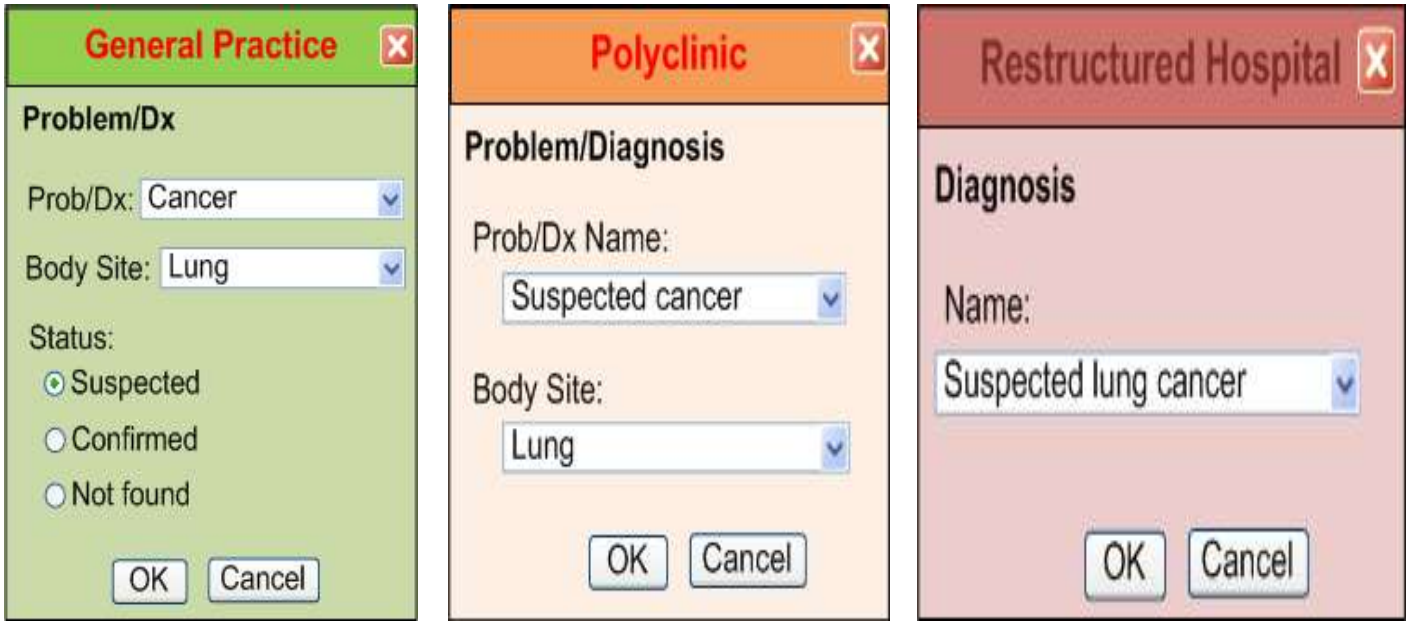
Coding Boundary:
Eyecolor = *brown*
Iriscolor = *brown*
Topic = *Brown-eye-color*
Topic = *iris*, Color = *brown*

Boundary Problem

IsoSemantic Models – Example of Problem

(from Dr. Linda Bird)

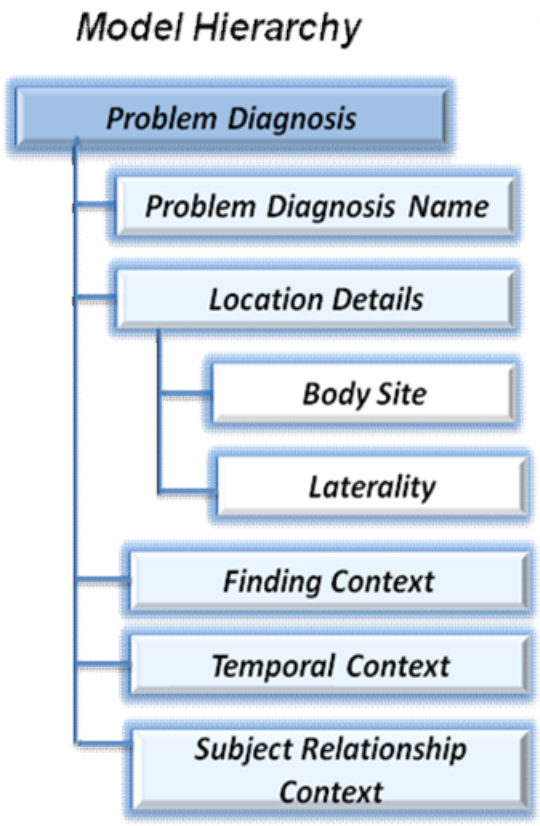
e.g. “Suspected Lung Cancer”



Boundary Problem

IsoSemantic Models – Example Instances *(from Dr. Linda Bird)*

e.g. “Suspected Lung Cancer”



General Practice	Polyclinic	Hospital
Cancer	Suspected Cancer	Suspected Lung Cancer
Lung	Lung	
Suspected		

Topics
Communication in health and care

What is the problem

What we need to talk about:

- Semantics
- Standards
- Bakery as metaphor
- Semantic Stack
- Epistemology
- Available standards - Concurrent use of standards
- Information Architecture

Recent developments: ISO, HL7, CIMI

Pharma developments

Standards - norms

- **Standards:**
  parties decide with whom to make agreements
- **Example:**
  Agreement about Healthcare messages

- **Norms**:
  according to the principle ‘All parties concerned’
- Sometimes referred to by laws
- **Example**:
  Norm NEN 7510 Medical Data Security in Healthcare

Norms/standards

National SDO

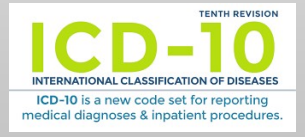
European SDO

World wide SDO

National standards

Each country has its own standardisation development organisation (SDO)
that takes part in:

- **CEN (European Standardisation organisation**
- **ISO the worldwide standardisation organisation**



INTERNATIONAL STANDARDS

- EU law and regulation: CEN norms become automatically National norms in Europe
- Vienna agreement: formal co-operation between ISO and CEN
- Countries vote via national Standard Developing Organisations (SDO's)
- Other Standards developers can take part via liaison status

INTERNATIONAL STANDARDS

- **ISO technical Committee 215**
  Standardization in the field of health informatics to facilitate the creation, interchange and use of health-related data, information, and knowledge to support and enable all aspects of the health system
- **CEN technical Committee 251**
- **Liaisons:**
  - HL7
  - IHE
  - GS1
  - SNOMED
  - EN13606 Association

INTERNATIONAL STANDARDS

ISO TC251 Health Informatics

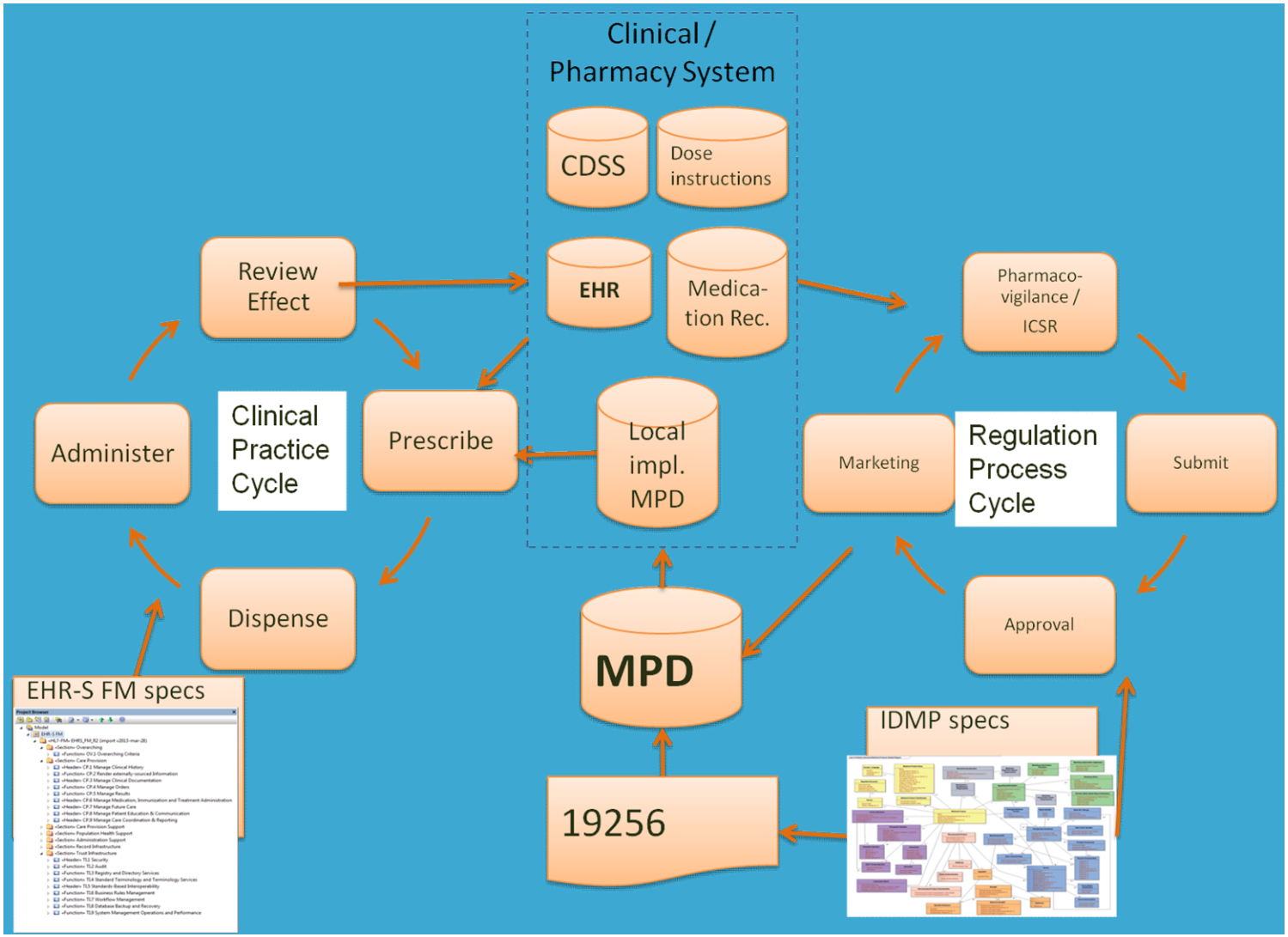
- WG 1 Architecture, Frameworks and Models
- WG 2 Systems and Device Interoperability
- WG 3 Semantic Content
- WG 4 Security, Safety and Privacy
- **WG 6 Pharmacy and Medicines Business**
  Standardization related to the application of information and communication technology in the domain of pharmacy and medication, including standardization to improve patient safety and the efficiency and interoperability of information systems used in researching, developing, regulating, supplying, using and monitoring pharmaceutical products.
- IEC/62A/JWG 7 Application of risk management to information technology (IT) networks incorporating medical devices

INTERNATIONAL STANDARDS

Topics under discussion in ISO TC215 WG6

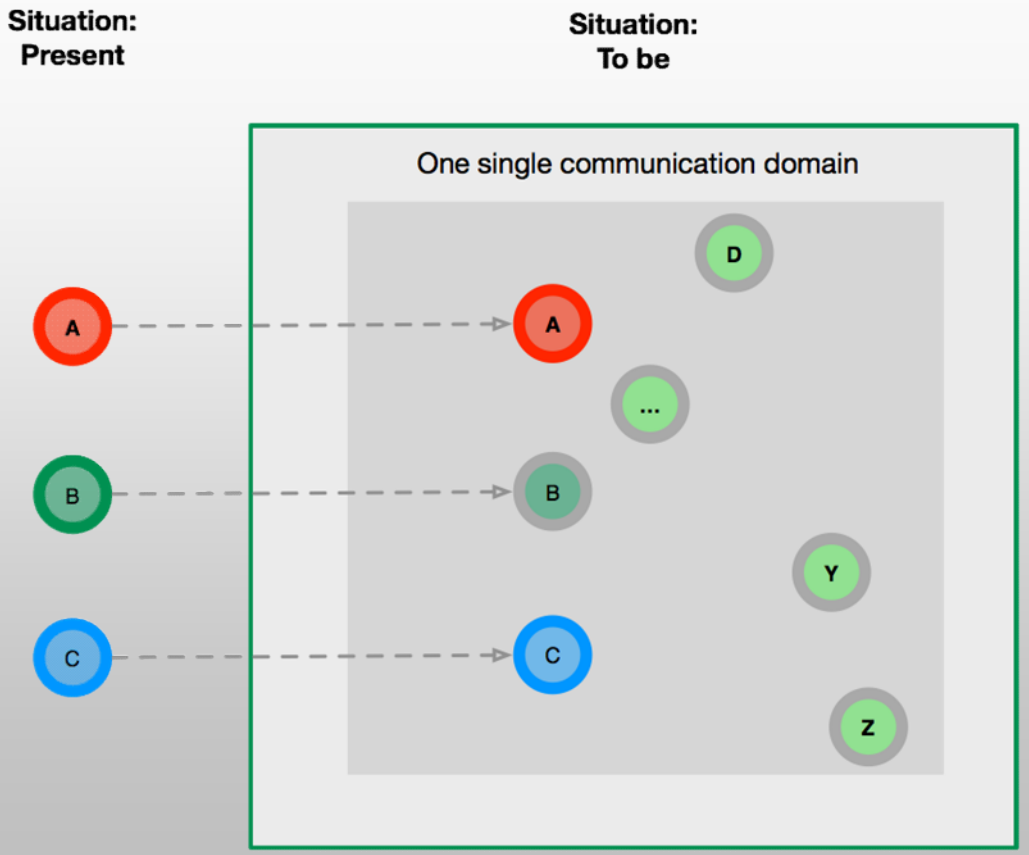
- ICSR, Individual Case Safety Report
- IDMP, Identification of Medicinal Products
- Machine readable codes
- Dose instructions
- Electronic prescriptions
- Medicinal product dictionaries
- Dispense record
- Medication management concepts
- Clinical decision support – knowledge base
- Big Data?

INTERNATIONAL STANDARDS



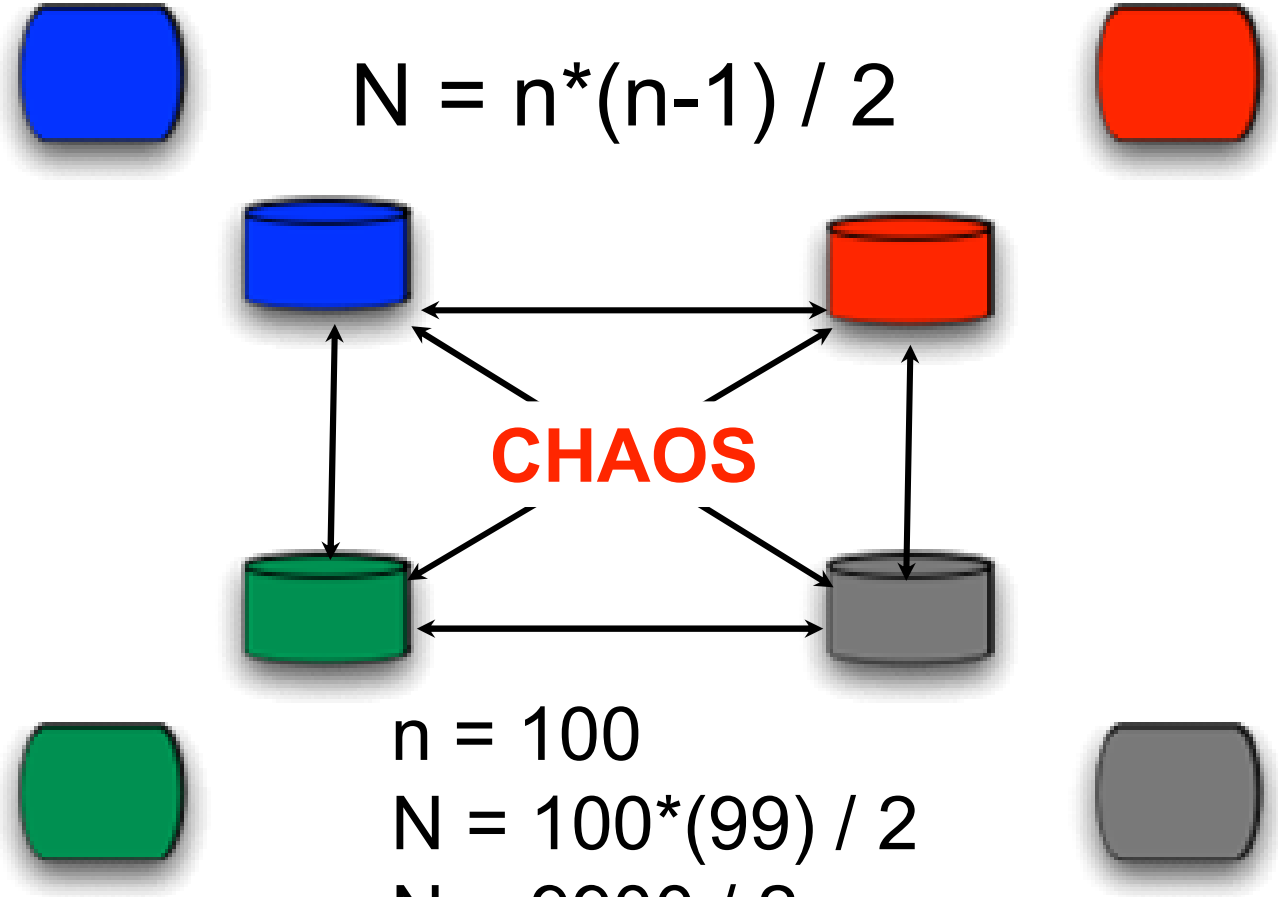
Why standards

Remember



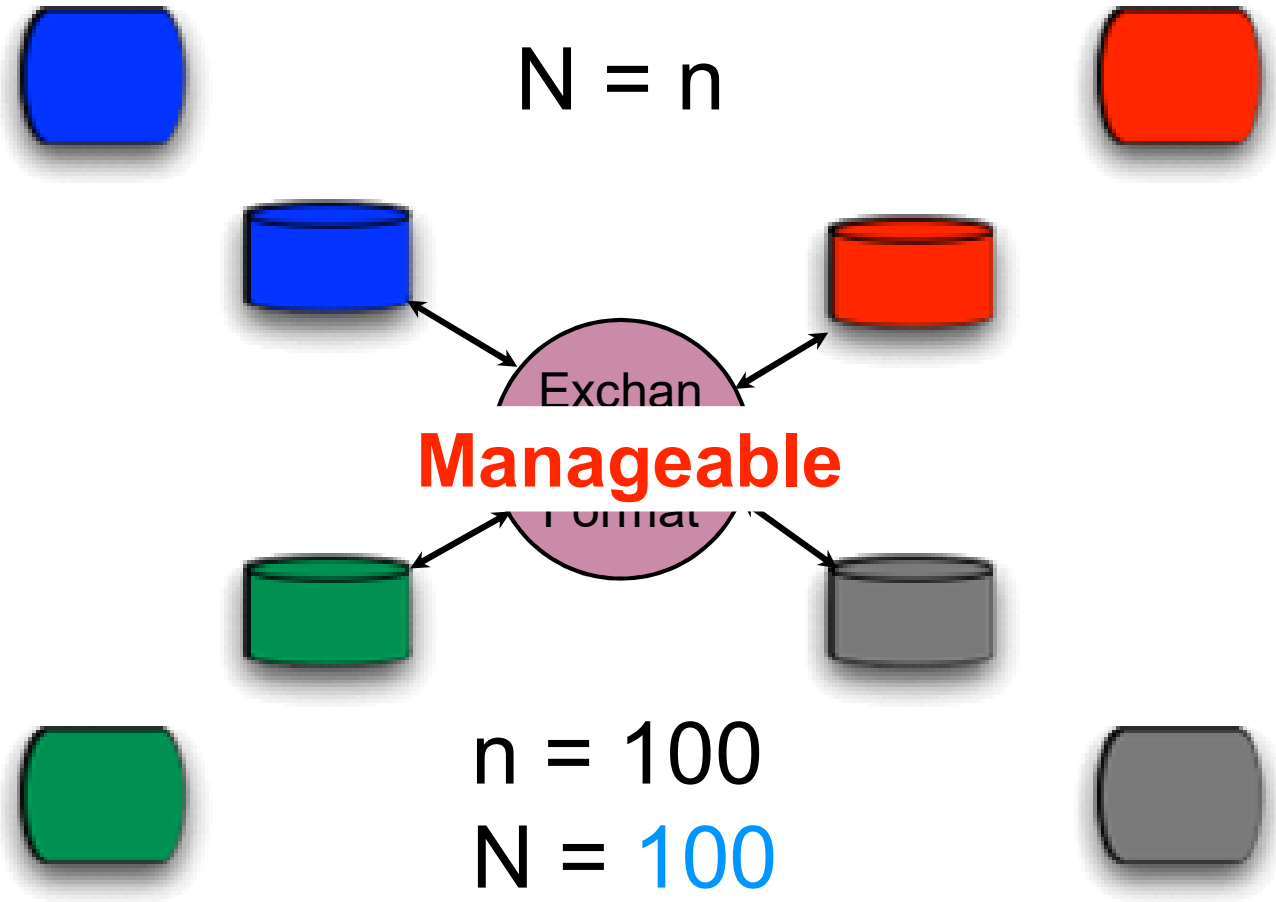
Why Standards

NO STANDARDS : Chaos



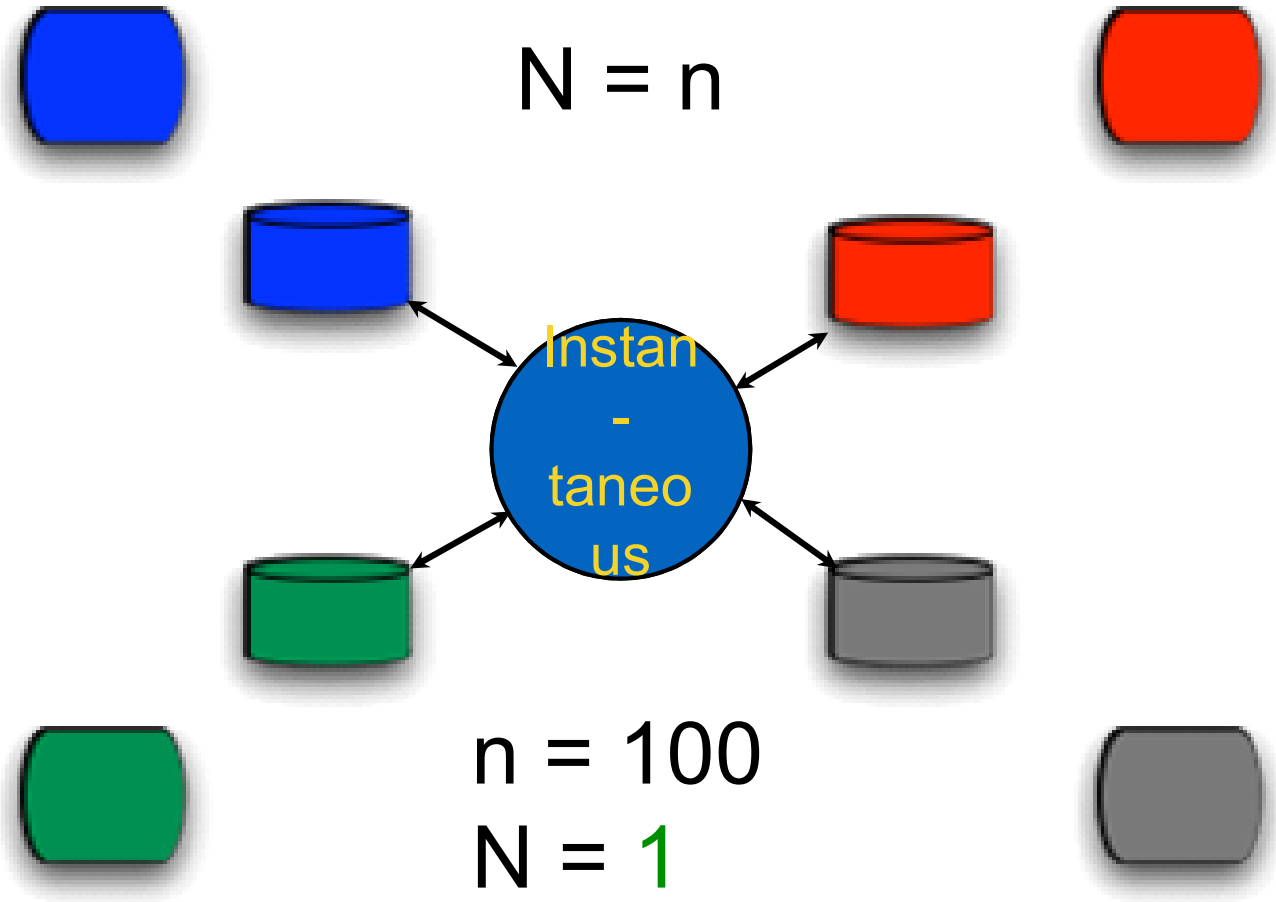
Why Standards

Message STANDARD



Why Standards

CIMI / SIAMM STANDARD



What standards

- The Bakery metaphor
- The Semantic Stack
- The Standards: again

Bakery

Recipe

Ingredients

Moulds

Kitchen machines

Oven

Pastry

Bakery / EHR expectations

Recipe	Ingredients	Moulds	Kitchen machines	Oven	Pastry
					
					
Rules	Information	Presentation	Software	Hardware	EHR

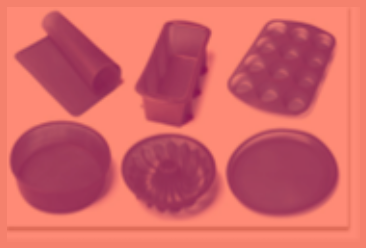
EHR's now

Instructions | Ingredients | Moulds | Kitchen machines | Oven | Pastry










Rules | Information | Presentation | Software | Hardware | EHR

EHR systems now

EHR-systems we need

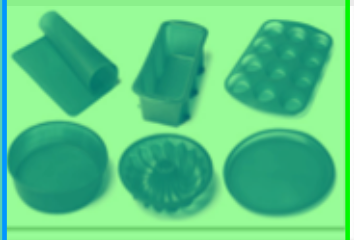
Instruction

Rules

Ingredients

Information

Moulds



Presentation

Kitchen tools

Software

Oven

Hardware

Pastry

EHR

Semantic Stack

Humans	Human Tools	**Standards**	Health IT Tools	Health IT
Meaning	Encyclopedia	**W3C**	Ontology	**Ontology systems**
Words	Dictionary	**SNOMED/LOINC/ Drugs database**	Terminology	Coding system
Phrases	Scholing	**CIMI**	Logical Clinical Information Models	Patterns
Sentences	Local needs	**local needs**	Data sets	Data sets
Syntaxis	Scholing	**ISO EN13606-2 OMG - HL7**	Editors	Models
Letter types	Pencil	**ISO**	Character set	Fonts
Medium	Paper	**vendor specific**	EHR/Database	**Storage Messages**

Epistemology

When documenting health and care such that it can be fully understood
it is necessary that we document the **context**,
the **epistomology**:

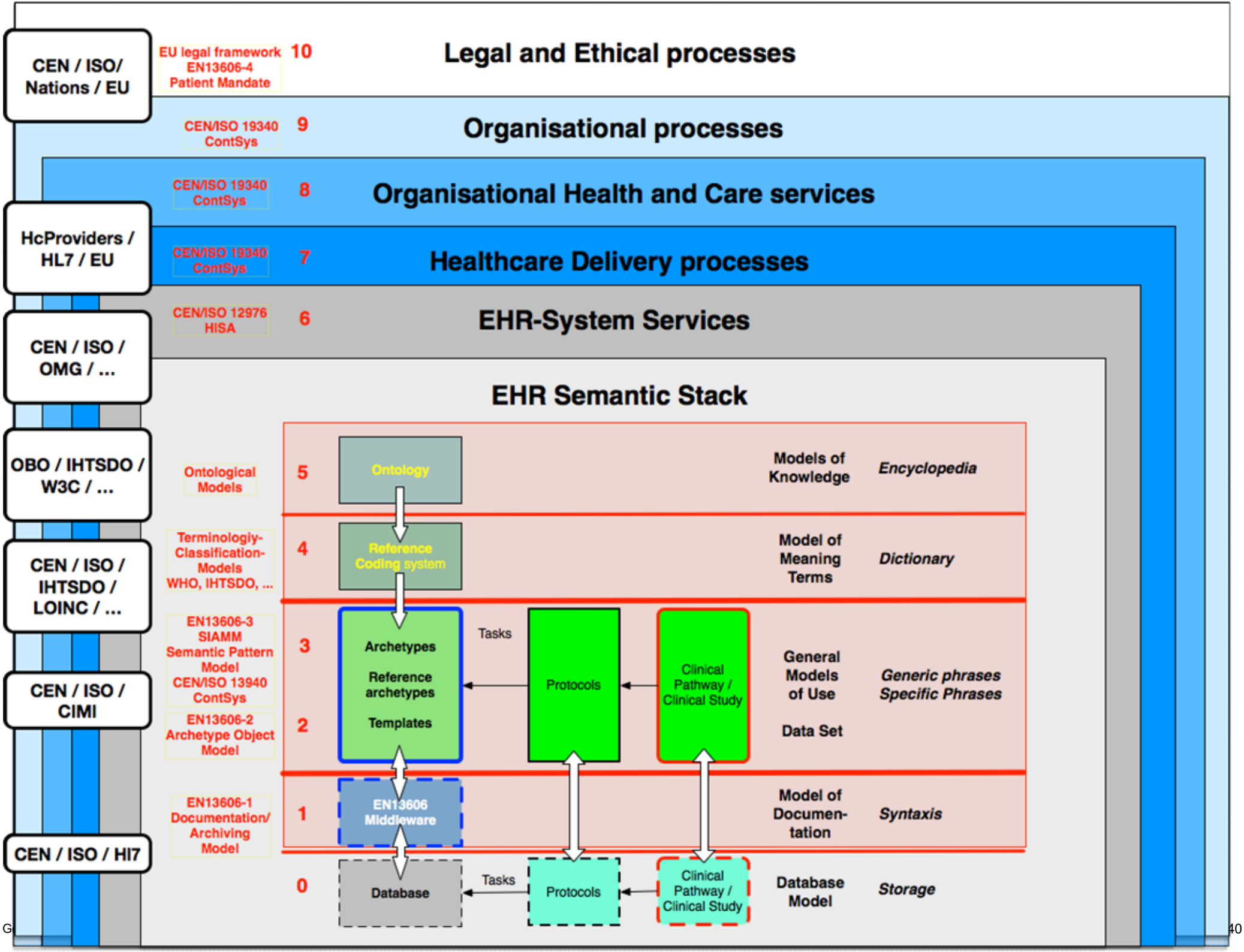
- **What**: topic
- **When**: date, time
- **Where**: location
- **Who**: author, involved parties
- **Why**: reasons
- **How**: methods, confounding factors

Epistemology

Present systems
do **NOT** systematically record
these items (context / epistemology)

People, and Clinical Reasoners
can **NOT** safely re-use data

Available standards for the Semantic Stack

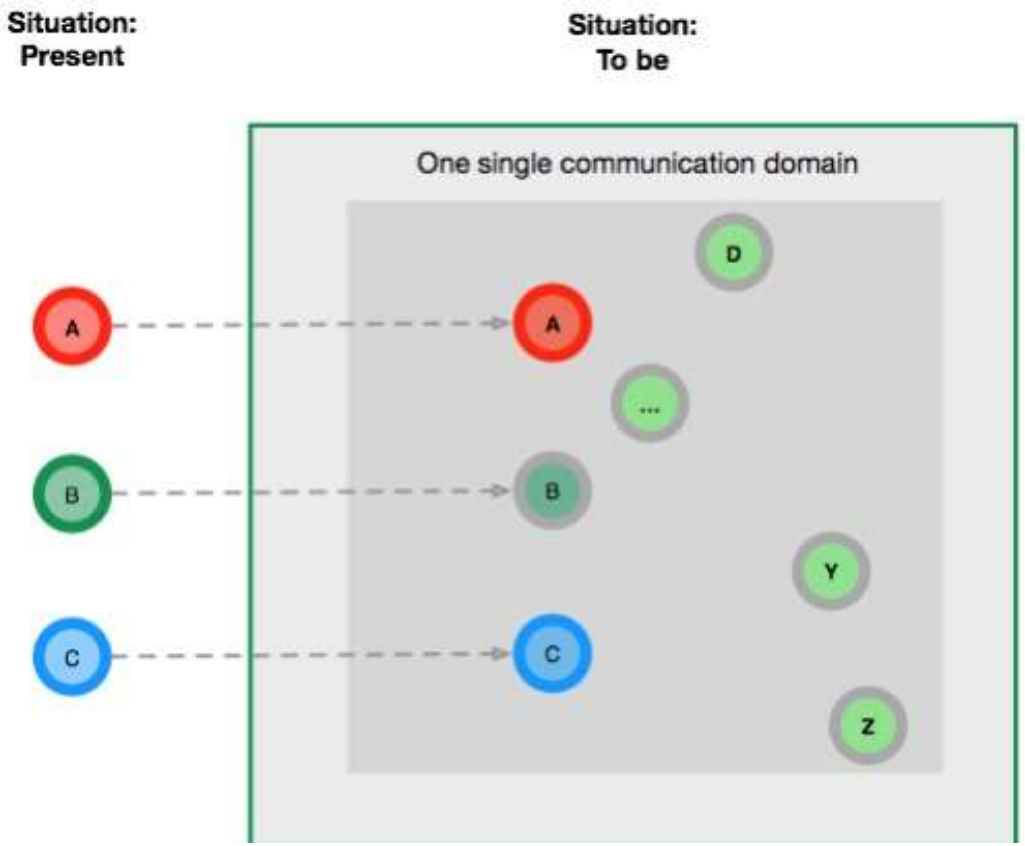

CEN / ISO/ Nations / EU
EU legal framework EN13606-4 Patient Mandate
10
Legal and Ethical processes
CEN/ISO 19340 ContSys
9
Organisational processes
CEN/ISO 19340 ContSys
8
Organisational Health and Care services
HcProviders / HL7 / EU
CEN/ISO 19340 ContSys
7
Healthcare Delivery processes
CEN/ISO 12976 HISA
6
EHR-System Services
CEN / ISO / OMG / ...
EHR Semantic Stack
OBO / IHTSDO / W3C / ...
Ontological Models
5
Ontology
Models of Knowledge
Encyclopedia
CEN / ISO / IHTSDO / LOINC / ...
Terminologiy-Classification-Models WHO, IHTSDO, ...
4
Reference Coding system
Model of Meaning Terms
Dictionary
CEN / ISO / CIMI
EN13606-3 SIAMM Semantic Pattern Model CEN/ISO 13940 ContSys
3
Archetypes
Reference archetypes
Templates
Tasks
Protocols
Clinical Pathway / Clinical Study
General Models of Use
Generic phrases
Specific Phrases
EN13606-2 Archetype Object Model
2
Data Set
CEN / ISO / HI7
EN13606-1 Documentation/ Archiving Model
1
EN13606 Middleware
Model of Documen-tation
Syntaxis
0
Database
Tasks
Protocols
Clinical Pathway / Clinical Study
Database Model
Storage

3 Concurrent ISO standards

Semantic Stack

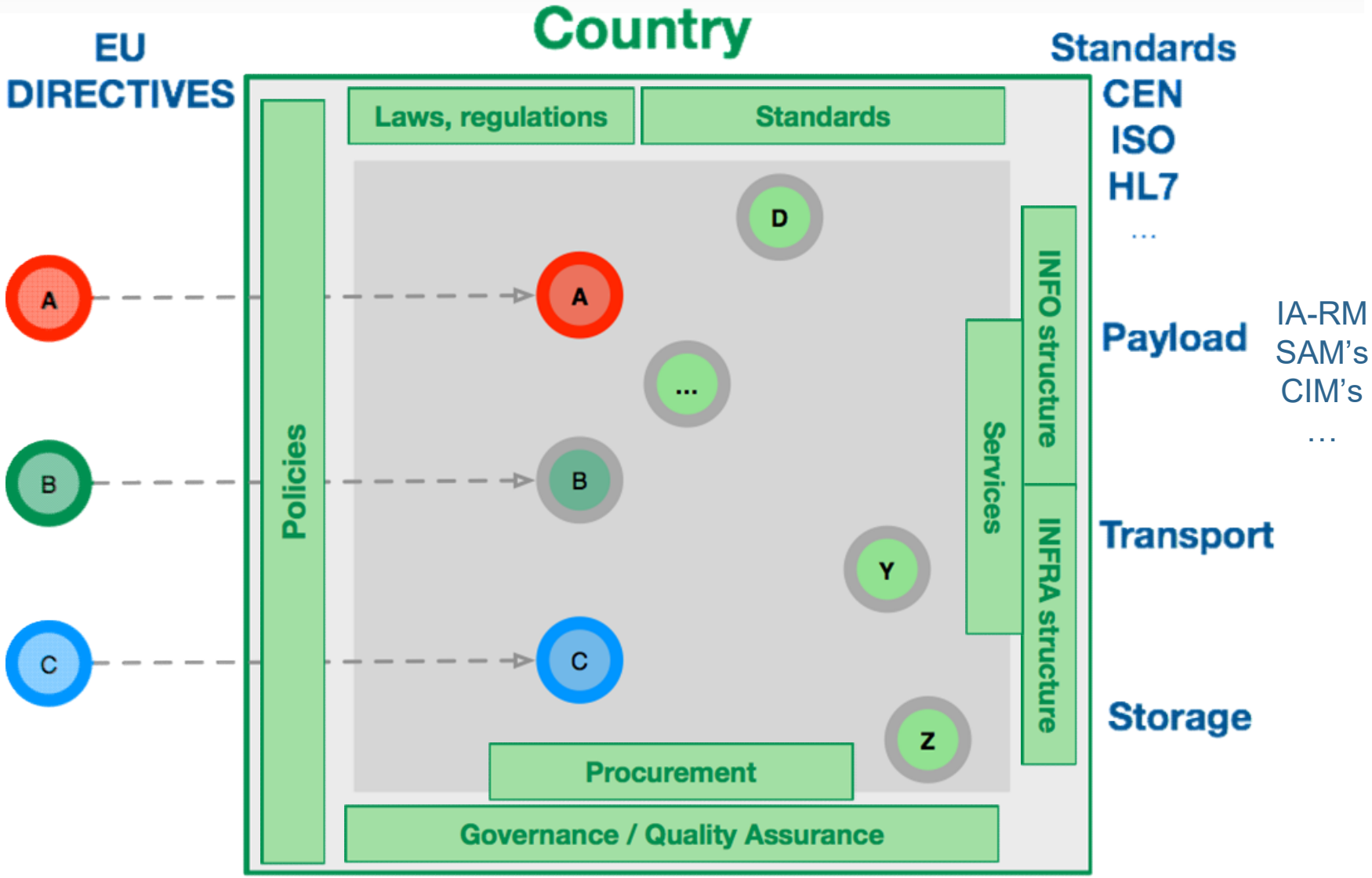
Humans	Human Tools	**Standards**	Health IT Tools	Health IT
Meaning	Encyclopedia	**W3C**	Ontology	**Ontology systems**
Words	Dictionary	**SNOMED/LOINC/ Drugs database**	Terminology	Coding system
Phrases	Scholing	**CIMI**	Logical Clinical Information Models	Patterns
Sentences	Local needs	**local needs**	Data sets	Data sets
Syntaxis	Scholing	**ISO EN13606-2 OMG - HL7**	Editors	Models
Letter types	Pencil	**ISO**	Character set	Fonts
Medium	Paper	**vendor specific**	EHR/Database	**Storage Messages**

What is needed

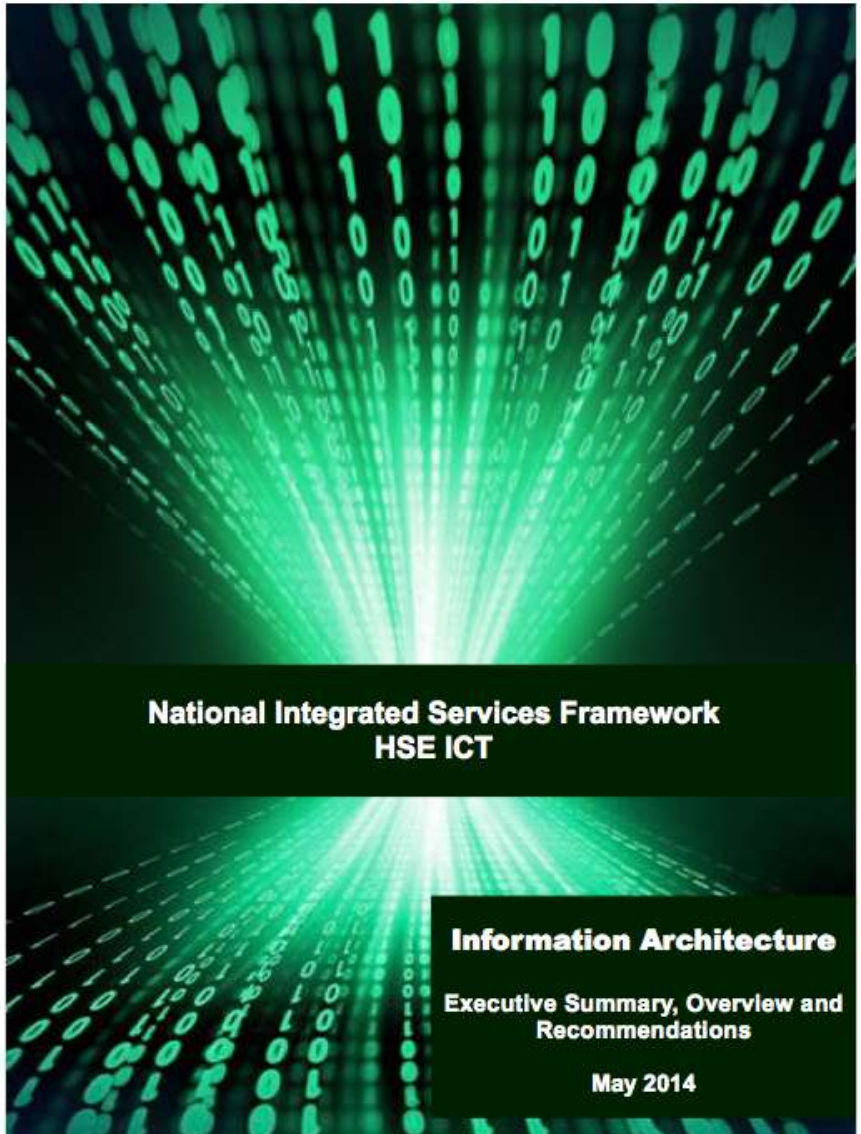


(Inter-) National Information Architecture

Information Architecture



Information Architecture



Owner:
Irish Republic

Author:
ERS bv

Topics

Communication in health and care

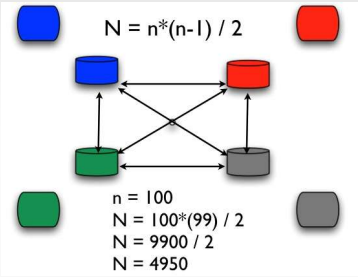
What is the problem: It is the Semantics, stupid!

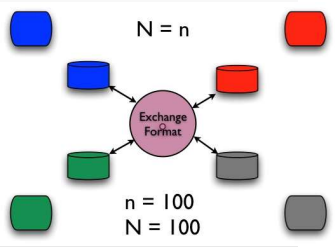
What is needed:

- **Standards**
- **Bakery as metaphor**
- **Semantic Stack**
- **Epistemology**
- **Available standards - Concurrent use of standards**
- **Information Architecture**

Recent developments: ISO, HL7, CIMI

Developments





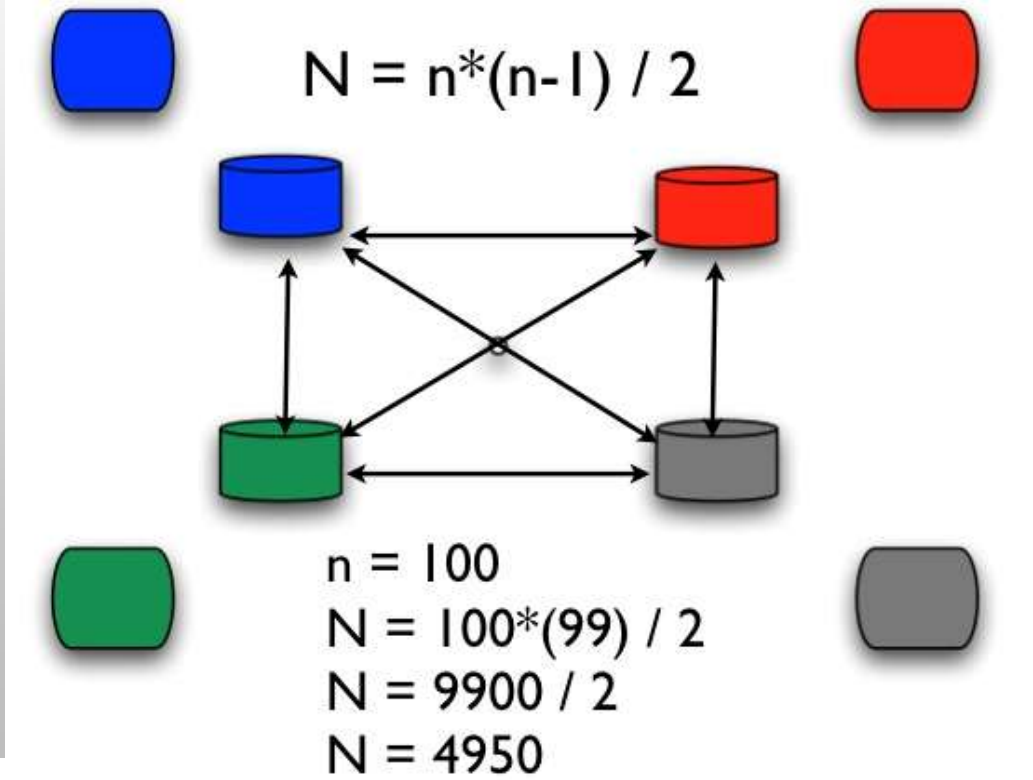
1.Unique proprietary connections

2.Standardised Messages updating field databases:
Edifact messages, HL7v2, HL7v3,
HL7 v3 CDA (*Clinical Document Architecture*), IHE,
FHIR (*Fast Healthcare Interoperability Resources*)

3.CIMI (*Clinical Information Modelling Initiative*)
Collection of Logical standardised components dealing with data in context

Developments

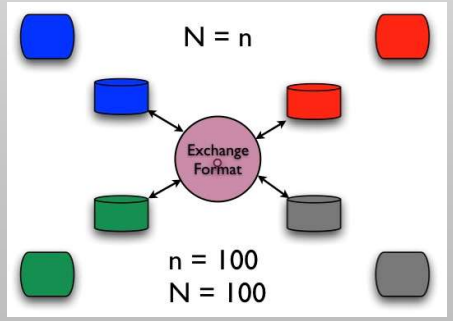
1. CHAOS
Unique proprietary connections

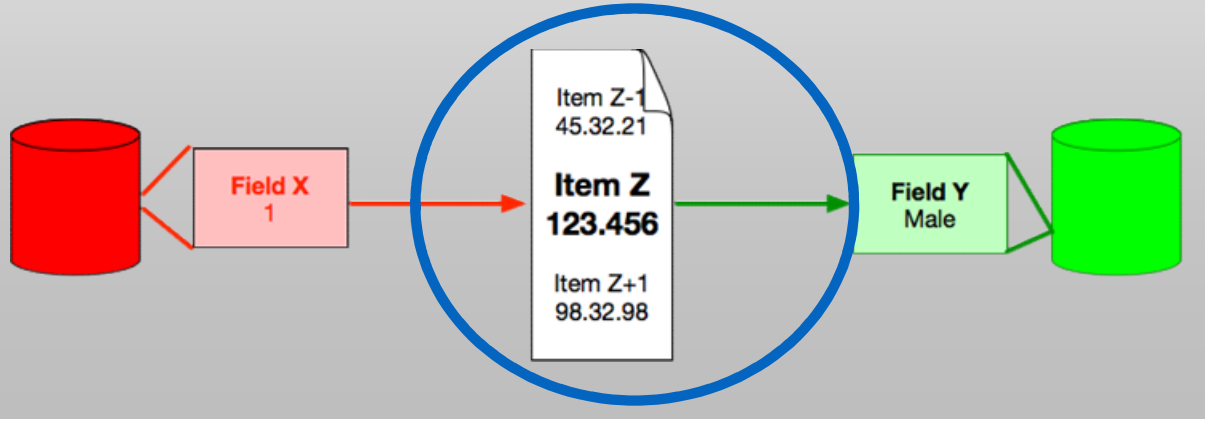


Developments

2.Standardised Messages

updating fields in databases:
Edifact messages, HL7v2, HL7v3,
HL7 v3 CDA (*Clinical Document Architecture*),
IHE,
FHIR (*Fast Healthcare Interoperability Resources*)

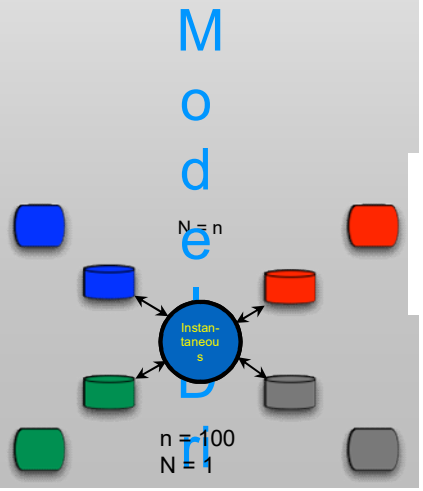




Developments

3. **CIMI (*Clinical Information Modelling Initiative*)**
Clinical Information Models: CIM's
Shared Logical Clinical Models that:
- standardise data sets,
- the way data sets are defined and used
- are created based on shared standards, models and principles
- two model paradigm

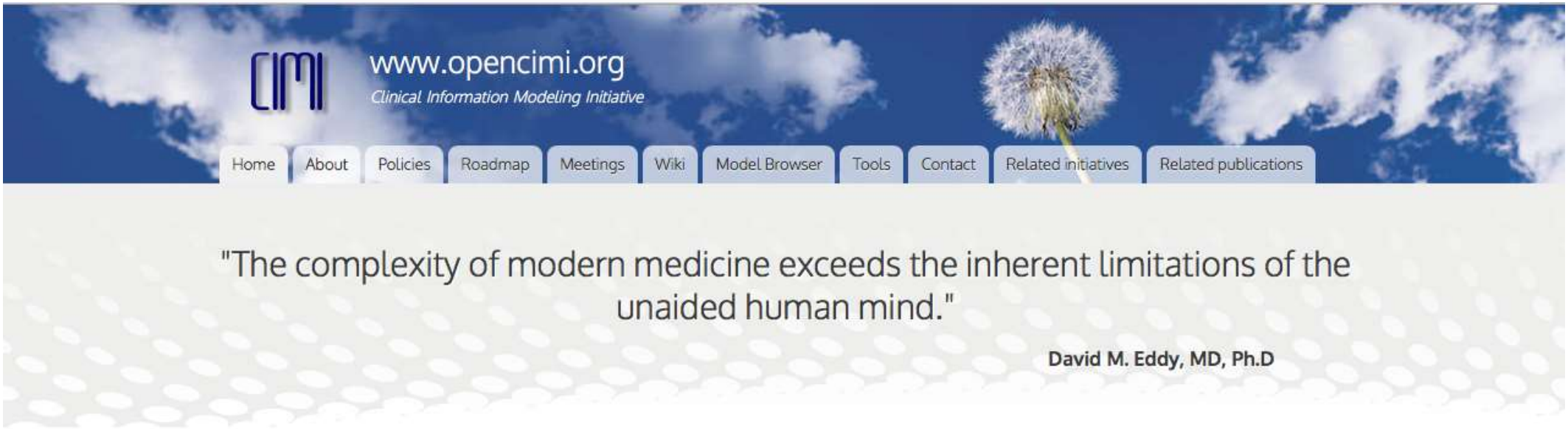
CIM's can be used in:
- interface specifications in general
- including messages, documents



CIMI

- The Clinical Information Modelling Initiative (CIMI) is an HL7 Work Group that is producing detailed clinical information models to enable interoperability of health care information systems
- CIMI was initiated during a “Fresh Look” session at an HL7 meeting in 2011
- CIMI models are free for use for all purposes
- See http://www.opencimi.org/ for more details

CIMI



Mission and Goals

Published by Virginia Riehl, May 2015

Mission

Improve the interoperability of healthcare systems through shared implementable clinical information models.

(A single curated collection)

Strategic Goal

Download the official CIMI presentation as

- Portable Document (PDF)
- MS-Powerpoint (PPTx)

CIMI Member Organizations

- Canada Health Infoway
- Caradigm
- CDISC
- CEN/TC215
- HL7
- IHTSDO
- Intermountain Healthcare
- Kaiser Permanente
- Mayo Clinic
- NEHTA Australia
- NHS
- OpenEHR
- Results4Care
- SMART
- South Korea
- Tolven
- US Government
- EN 13606 Association

CIMI Goals

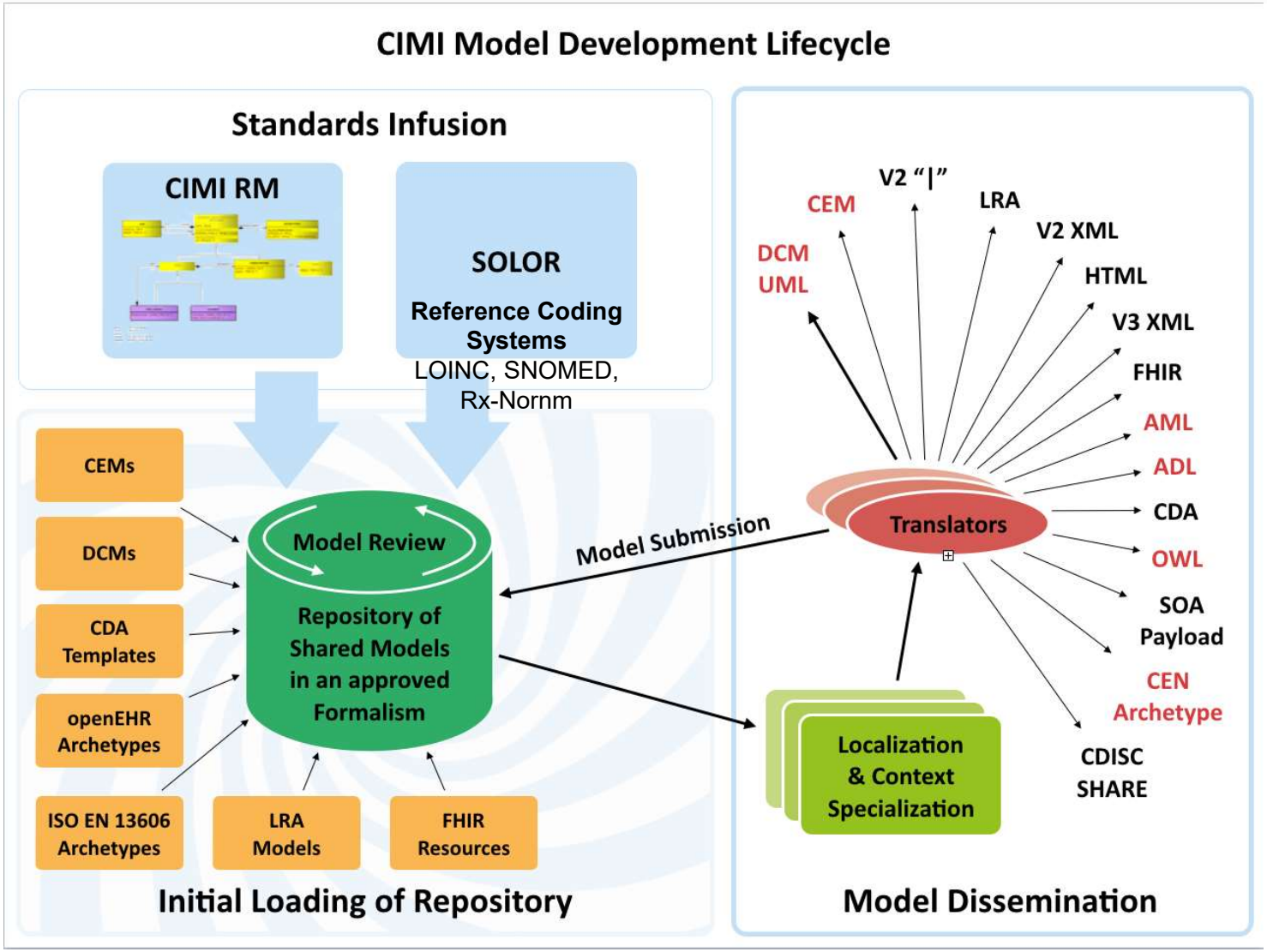
Create a shared repository of detailed clinical information models, as standardised building blocks

Repository is open to everyone and models are licensed free for use at no cost

Where the models:

- Are expressed in an approved formalism
- Archetype Definition Language (ADL)
- Archetype Modelling Language (AML)
- Are based on a core reference model, including a set of base data types
- Have formal bindings to standard coded terminologies

CIMI and data formats



CIMI Accomplishments

- CIMI core principles
- CIMI Reference Model
- Data types
- Core constructor types – clusters, elements
- Reference patterns
- 3,529 CIMI clinical laboratory models

Healthcare Services Platform Consortium
HSPC

HSPC Mission:

Improve health by creating a vibrant,
open ecosystem of interoperable applications,
content, and services

HSPC Membership

3 Benefactor members

- Veterans Administration
- Louisiana State University Health
- Intermountain Healthcare

Key alliances

- Center for Medical Interoperability (C4MI)
- OSEHRA

3 Associate (organizational) members

- Regenstrief
- Motive
- Allscripts

11 Individual members

Society Members: AMA, MHII and ACOG

HSPC Initiatives

- Be a provider led collaboration agent
- Create a reference implementation of common SOA
- Develop terminology and information models for true semantic interoperability
- Support authoring and sharing of knowledge content
- Obtain implementation and adoption of approved standards
- Create a shared technical environment to enable simple and efficient development

Pharma ISO Standards

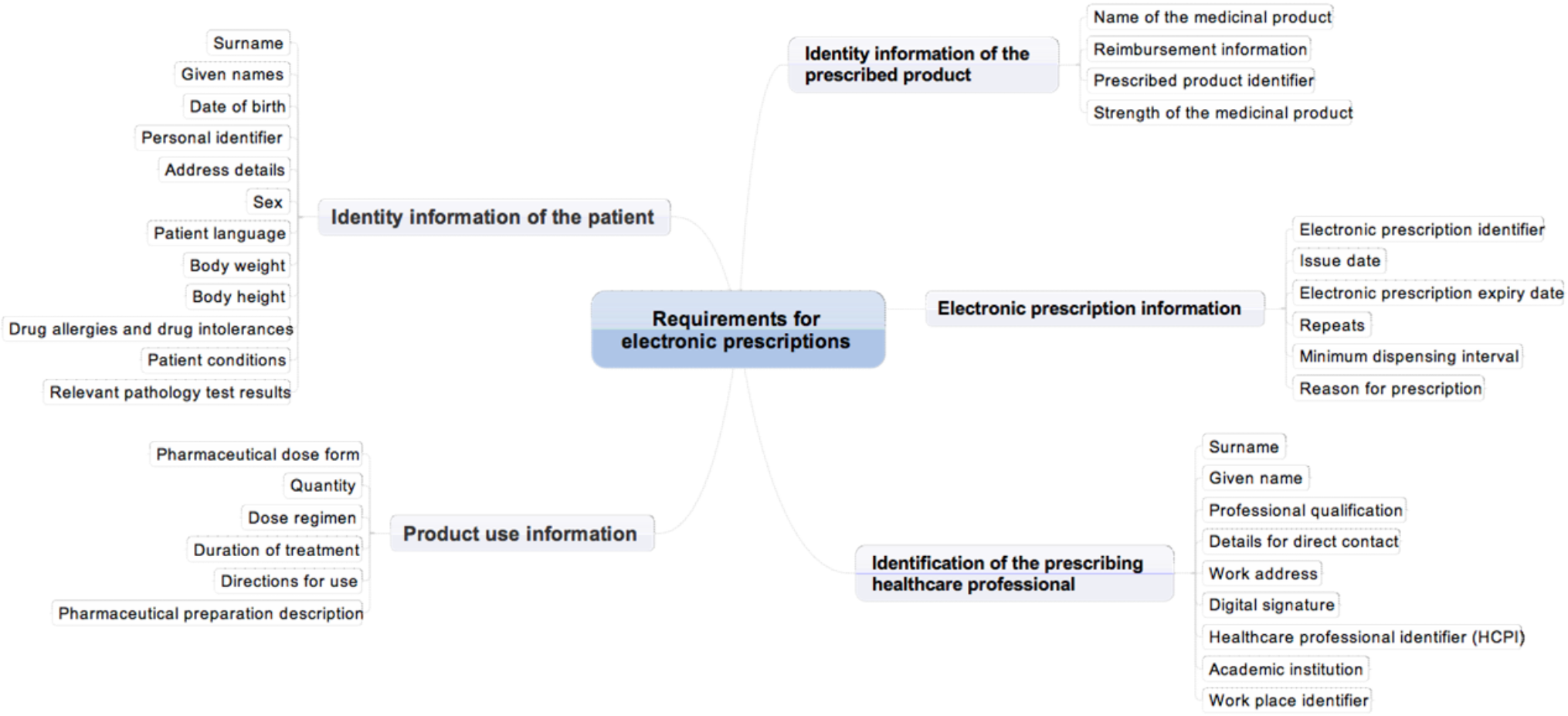
Substantial input from the Netherlands

GP's and Pharmacists co-operate for 30 plus years

Based on the dutch G-standard and Dutch standards a complete national services supporting:

- GP's, Hospitals, Specialists
- Pharmacists
- Whole sale, im-/exporters
- Pharma industries
- Insurers

CONTENT ELECTRONIC PRESCRIPTION



Machine Readable Codes

ISO/TS 16791:2014 Health Informatics

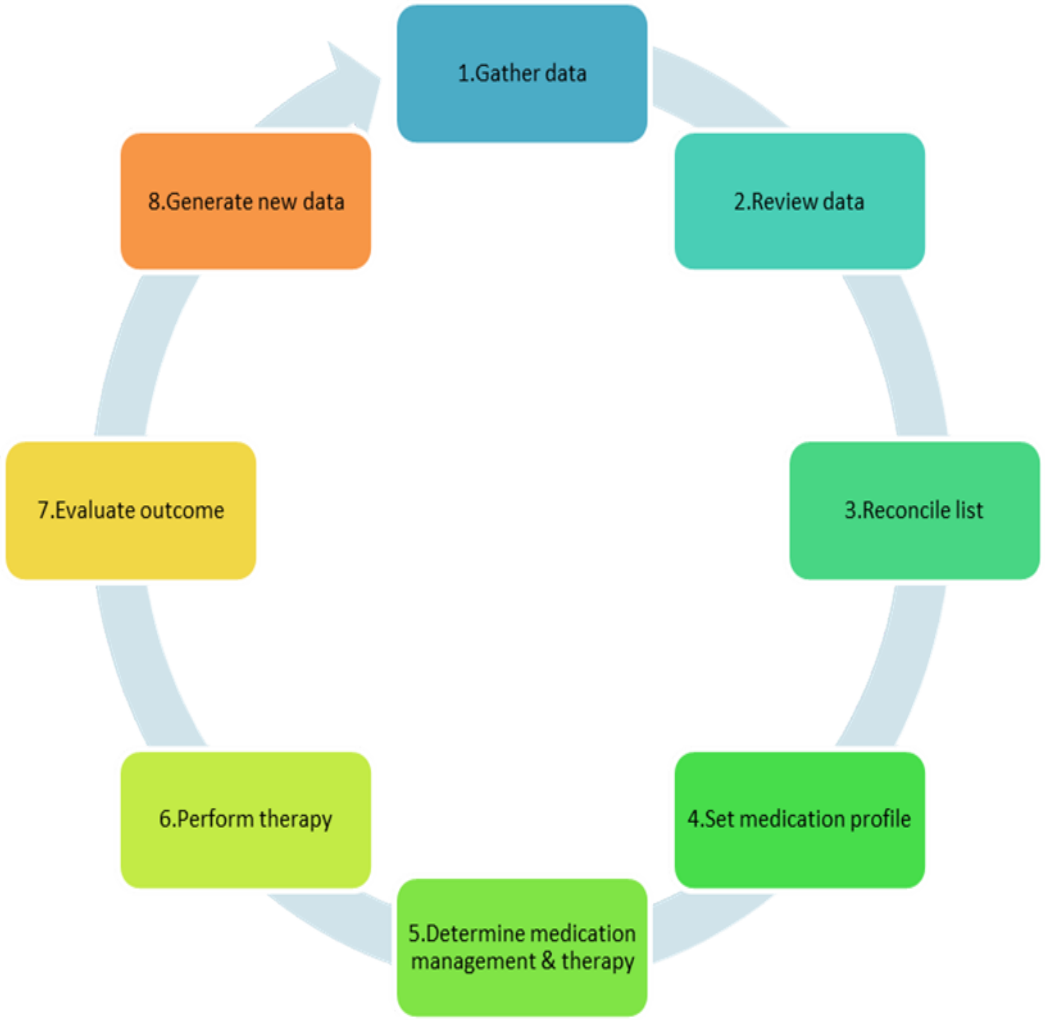
- Requirements for international machine-readable coding of medicinal product package identifiers
- Barcodes for medicinal products
- Identification from production to dispensing
- GS1 plays a prominent role for GS1
- Dutch Z-Index served as input

Medication management concepts

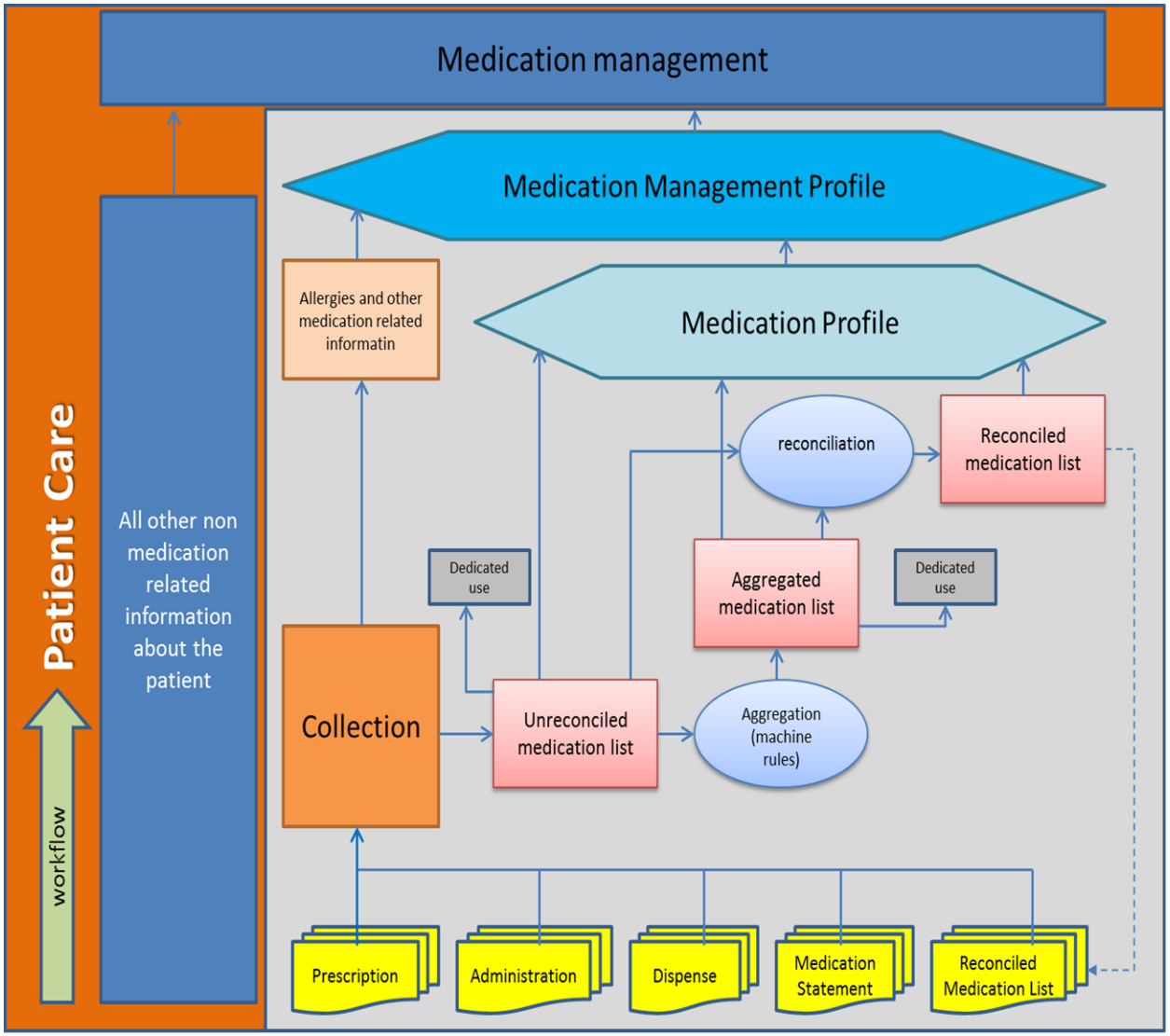
ISO/PDTR 20831 Health informatics Medication Management concepts

- Describes the process steps for medical product therapy
- Defines concepts in this domain
- Input/consensus between: IHE Pharmacy, HL7 Pharmacy and ISO TC215 WG6

Medication management concepts



Medication management concepts



IDMP
Identification Medical Products

IDMP

- **Started by Registration Authorities of Europe, VS and Japan and submitted to ISO TC215**
- **Goal:**
  - one terminology for Medicinal products
  - exchange of associated side effects

IDMP

Substances

Very extensive information about substances

Per kind of substance characte

- proteines
- Vaccins
- simple substances
- etc

Worldwide 5-10 experts, world leader is the Netherlands

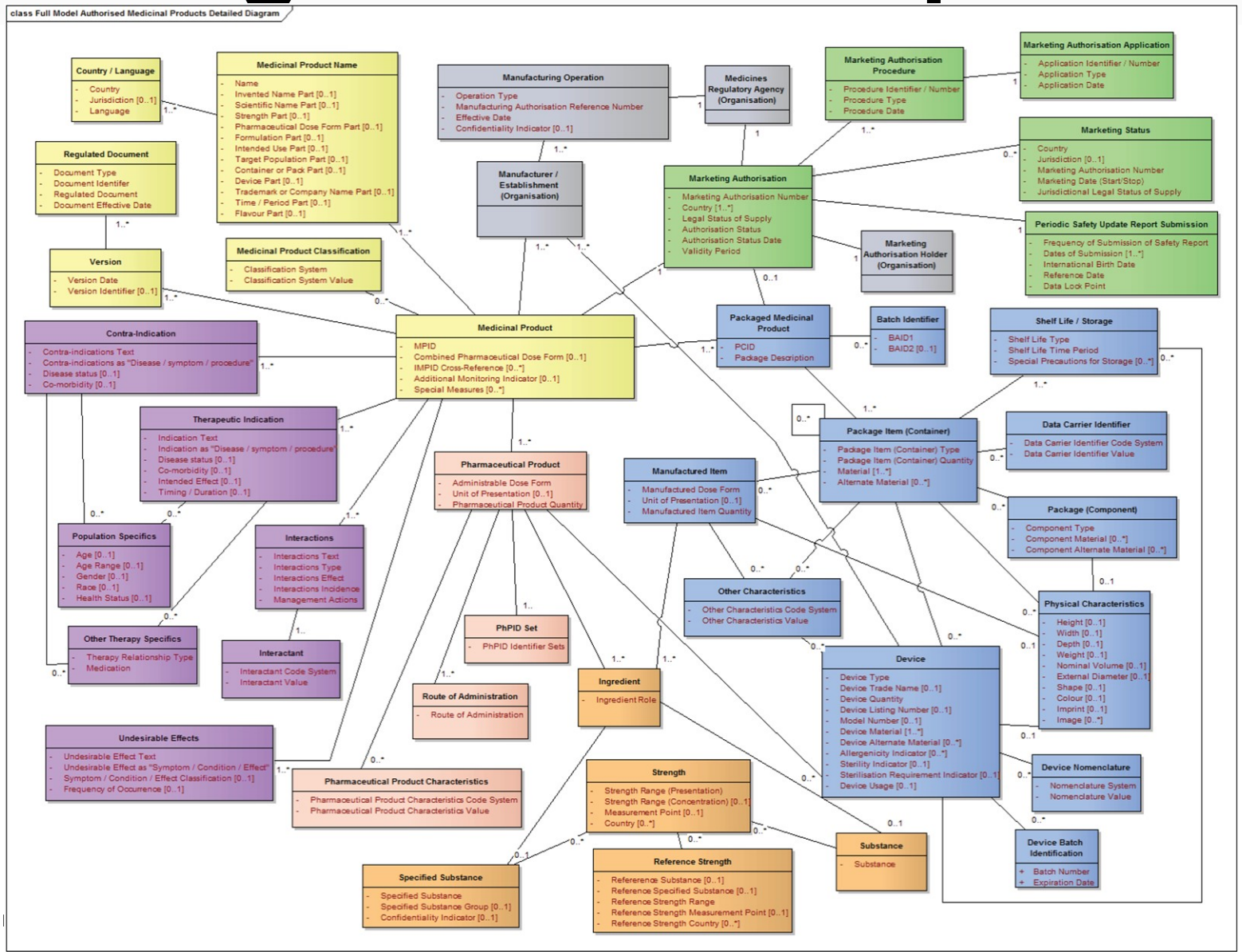
IDMP

Packaged Medicinal product

- Many, many details
- Registration procedure
- Manufacturer, production pr
- height, diameter, kind material, color, weight of emballage
- etc

IDMP

Packaged Medicinal product



Implementations

Physical data base: NL / EMA / VS

Pharm. Products: algorithm in development

Packaged Med. Products: unclear at this moment

Pharmaceutical form: EDQM - European Directorate for the Quality of Medicines

Units of Measurement: HL7 UCUM

Implementation

COMMISSION IMPLEMENTING REGULATION (EU) No 520/2012

of 19 June 2012

on the performance of pharmacovigilance activities provided for in Regulation (EC) No 726/2004 of the European Parliament and of the Council and Directive 2001/83/EC of the European Parliament and of the Council

Article 25

Use of internationally agreed terminology

1. For the classification, retrieval, presentation, risk-benefit evaluation and assessment, electronic exchange and communication of pharmacovigilance and medicinal product information, Member States, marketing authorisation holders and the Agency shall apply the following terminology:

(c) the terminology set out in EN ISO 11615:2012, Health Informatics, Identification of Medicinal Products (IDMP) standard, 'Data elements and structures for unique identification and exchange of regulated medicinal product information' (ISO/FDIS 11615:2012);

72

… and more ISO IDMP standards

Implementation

- EU regulation
- Changes in national existing implementations
- Vendors, Importers/exporters, whole sale, pharmacists, clinicians, registrations

IDMP
Substances

Input from Dutch G-Standard:

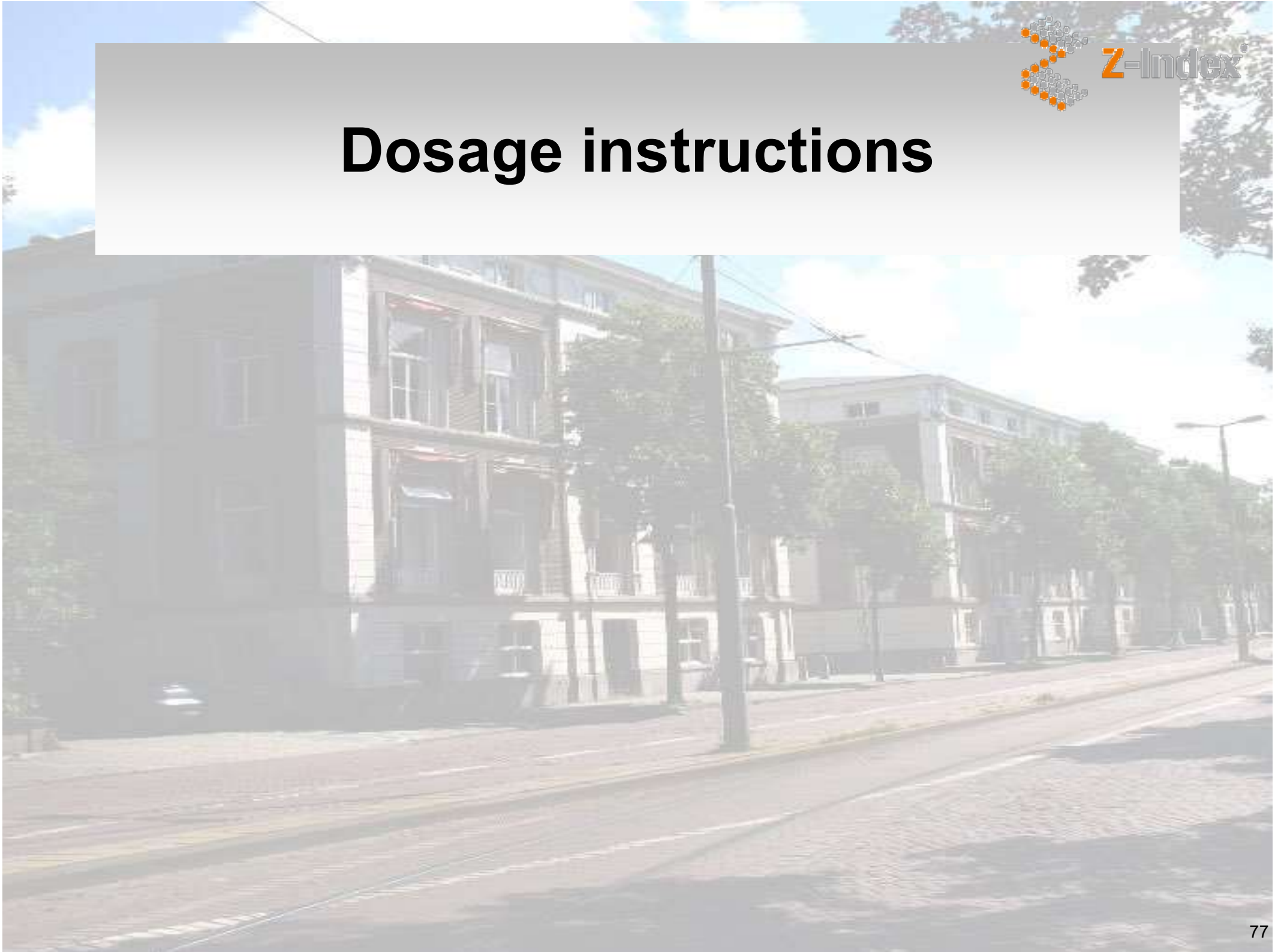
- active substance
- pharmaceutical form
- strength
- administration kind

Medicinal Product Dictionary

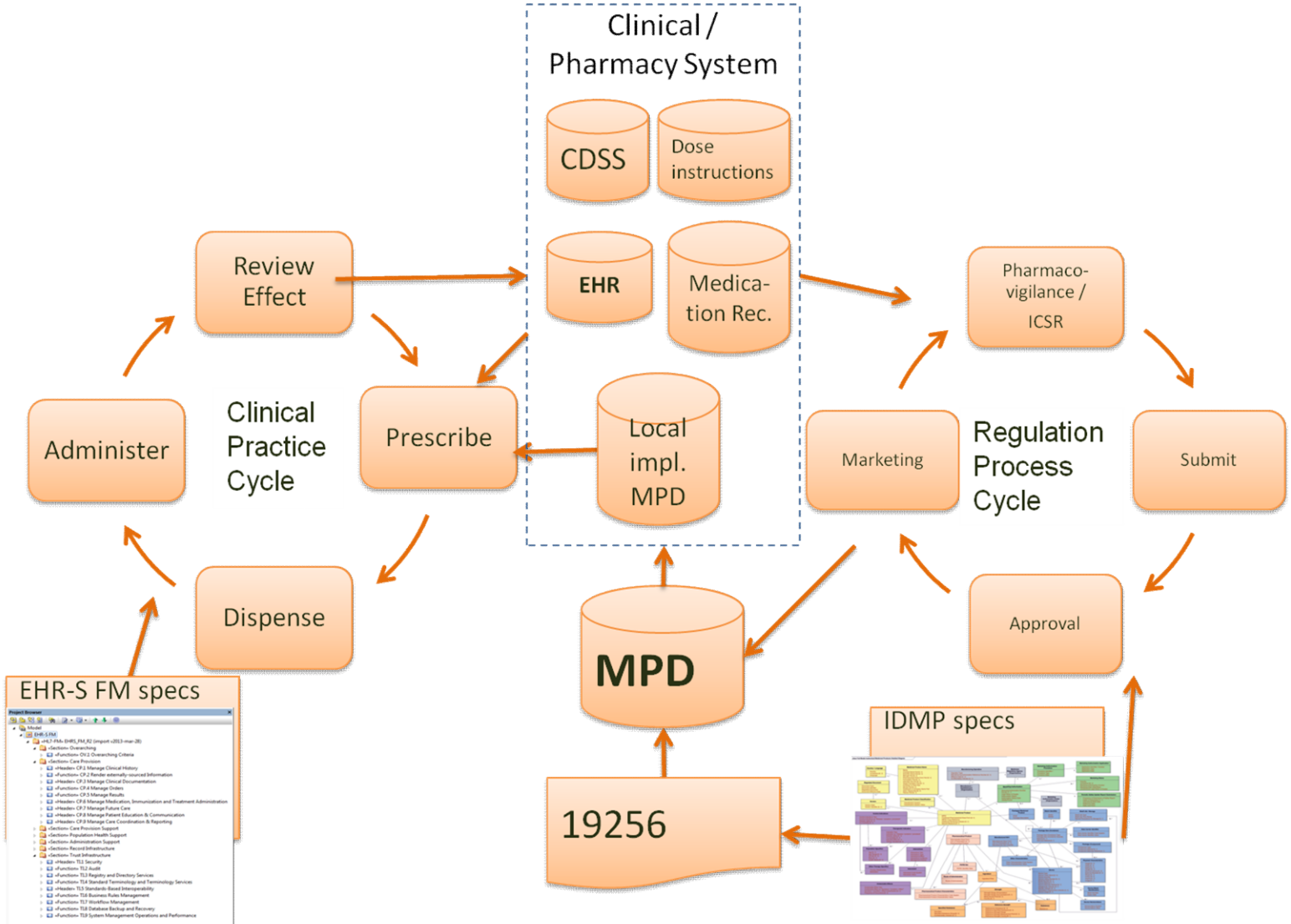
MPD
What is it

- The ISO norm describes requirements for a drug dictionary that is annex the IDMP
- To be used by EHR-systems, clinicians
- Several levels
- It is based on the Dutch G-standard (NEN7507)

Dosage instructions



Dosage Instructions



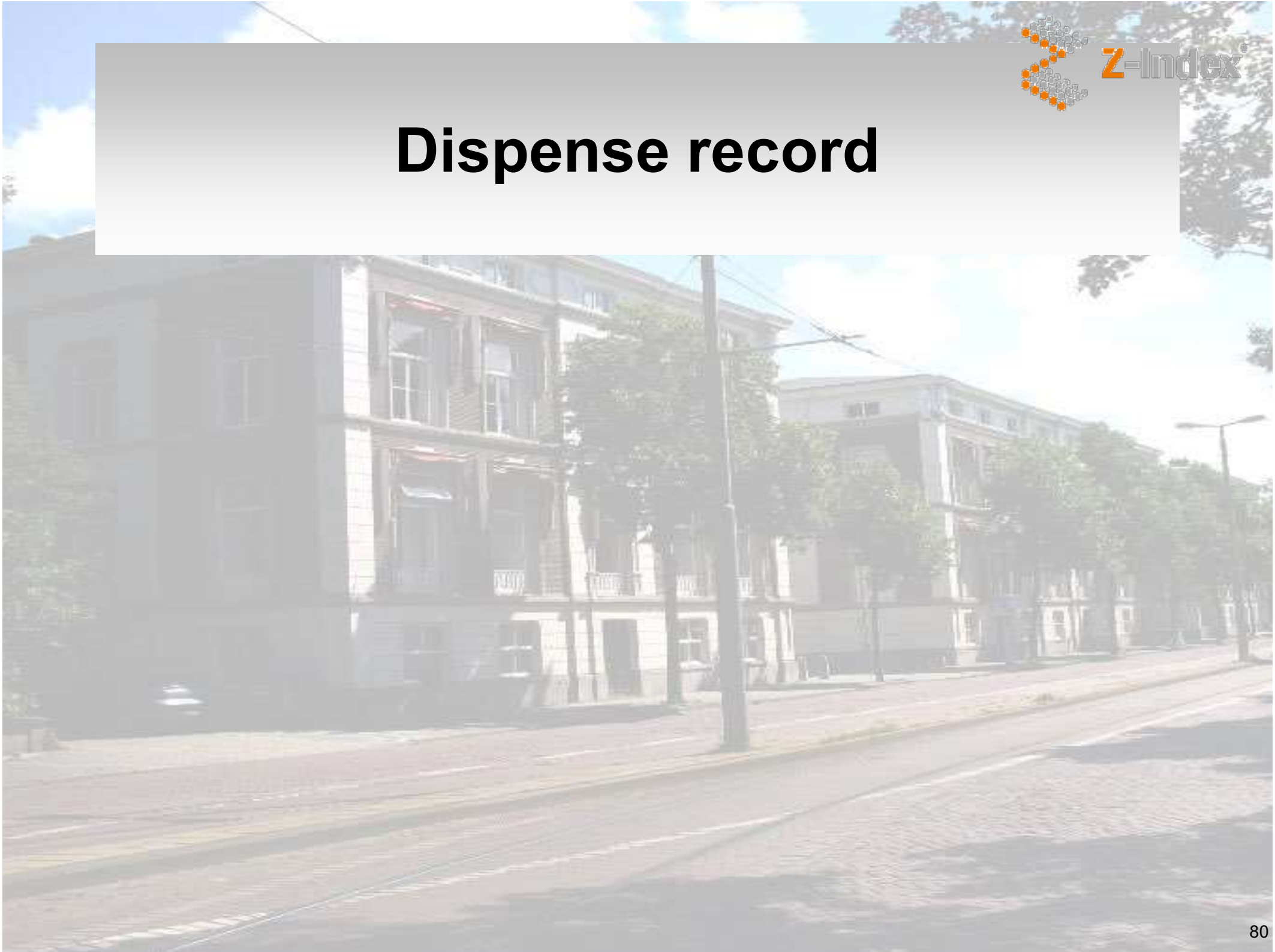
Dosage Instructions

Example

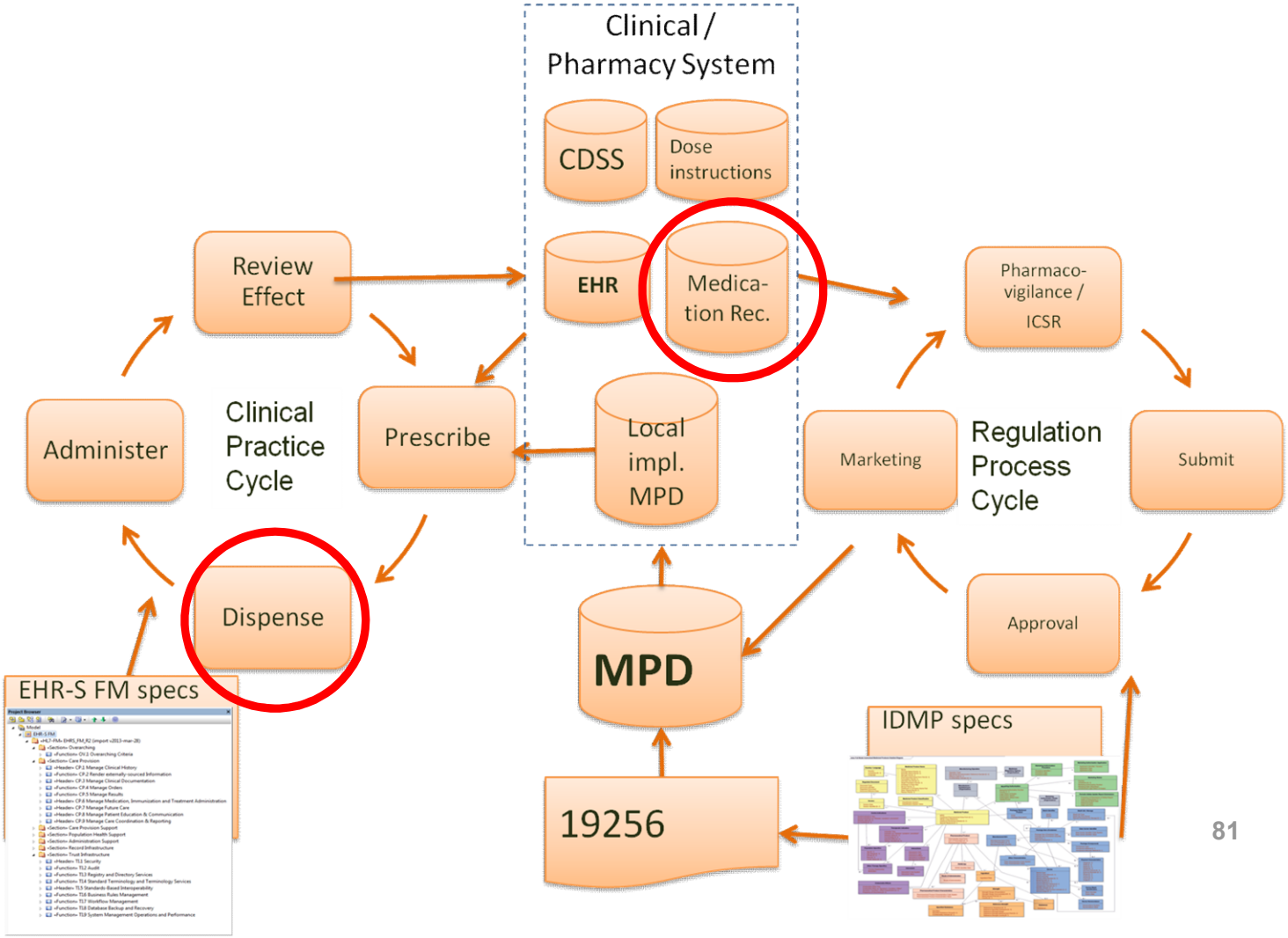
- ‘1 tablet per day’
- Day part (‘morning‘)
- Time (’22:00’)
- Label text (‘take with water’)
- Therapy duration
- Infusion: administration duration, administration speed
- etc, etc

Dutch GP organisation and Pharmacists have experience for 30+ years

Dispense record



Dispense Record



Dispense Record

Why

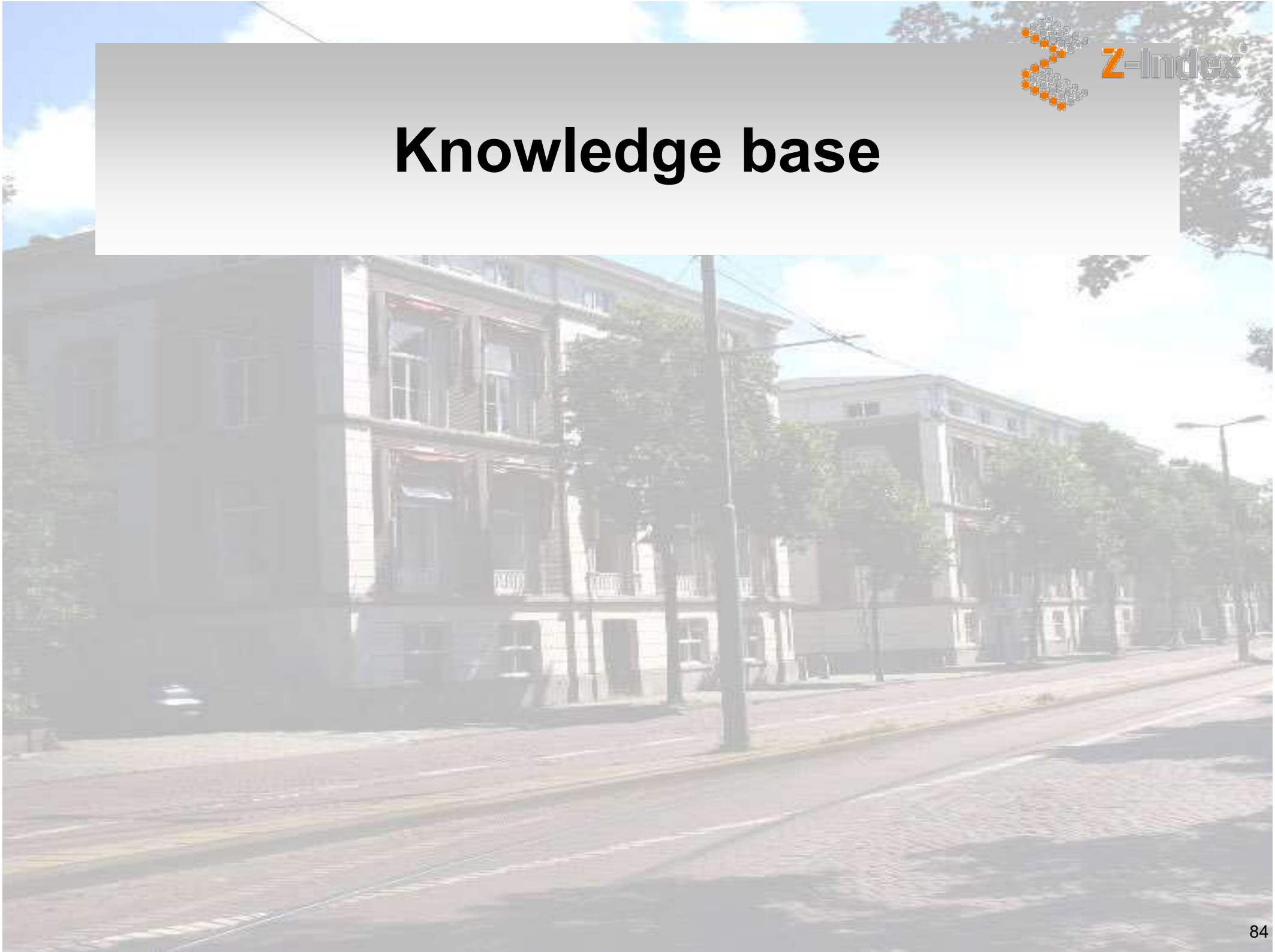
- Data to be used for medication surveillance, billing, etc
- Exchange data about a dispensed medicinal product
- etc

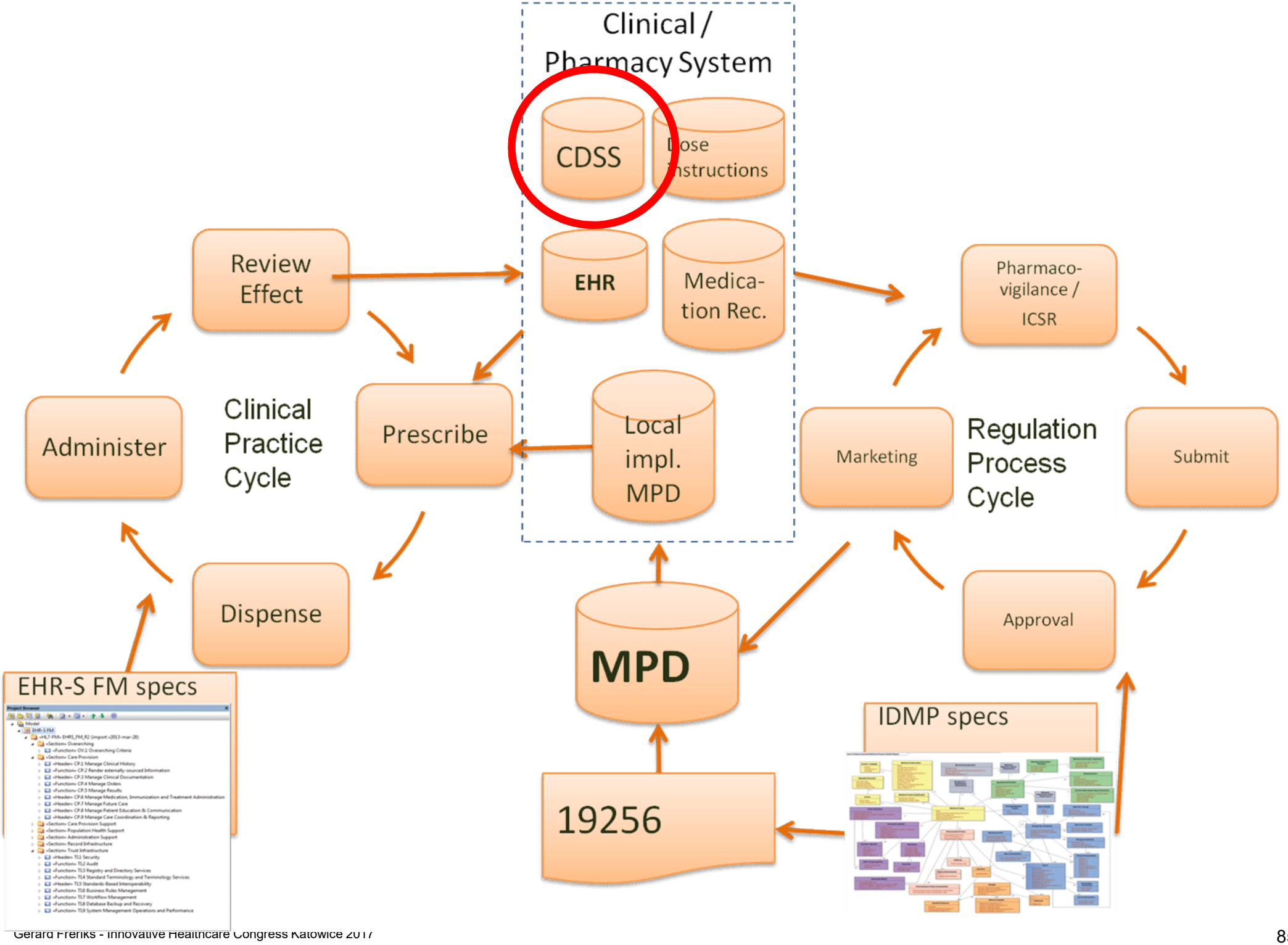
Dispense Record

Content

- prescriptions , and Over-the-Counter
- Patient, Pharmacist accountable
- medicinal product, dosage, label text
- amount and repeats
- Link to prescription / order
- Billing, insurance information
- etc

Knowledge base




Clinical / Pharmacy System
CDSS
Dose instructions
EHR
Medica-tion Rec.
Review Effect
Pharmaco-vigilance / ICSR
Administer
Clinical Practice Cycle
Prescribe
Local impl. MPD
Marketing
Regulation Process Cycle
Submit
Dispense
Approval
MPD
EHR-S FM specs
IDMP specs
19256

CDSS
Knowledge base

- Content and decision rules for medication surveillance
- Netherlands actively involved

Take home messages Pharma I

1. Shared care impossible without full and safe Semantic Interoperability (including pharma)
2. Do NOT re-invent the wheel
3. Standards: many International standards that have to be used
4. Developments Semantic Interoperability:
   Chaos -> Messages -> Documents -> Logical Clinical Information Models (CIM's)
5. Semantic Stack: each layer driven by only one shared standardised model
6. Epistemology / Context are very important for full and safe semantic interoperability

Take home messages Pharma 2

7. Model driven CIM's (Logical Clinical Information Models)
   with the full epistemology / context influenced by EU standards
8. Each country its own Information Architecture based on the same International standards
9. ISO actively is producing various pharma standards
10. EMA and the EU will legislate
11. Using ISO standards national drug databases can be supported and stay interoperable internationally