Yokohoma, Japan 2008

EHR STANDARDS: ISO13606 AND *OPEN*EHR

My background

- 1983-2002, Academic general practitioner

- 1991-1994, Clinical lead, Good European Health Record (GEHR)

- 1999 - Chair, Standards Australia EHR Committee

- 2002-2005 Chair, HL7 EHR Technical committee

- 2002 - Deputy-chair, *open*EHR Foundation

2004- CEO, Ocean Informatics Sydney

Acknowledgements

- Dr Dipak Kalra, PhD
  - Senior Lecturer, University College London
  - Head of the European EHRcom taskforce which has lead the 13606 development
  - Director , *open*EHR Foundation
- Prof. David Ingram
  - Head of CHIME, University College London
  - Chair, *open*EHR Foundation
- Thomas Beale
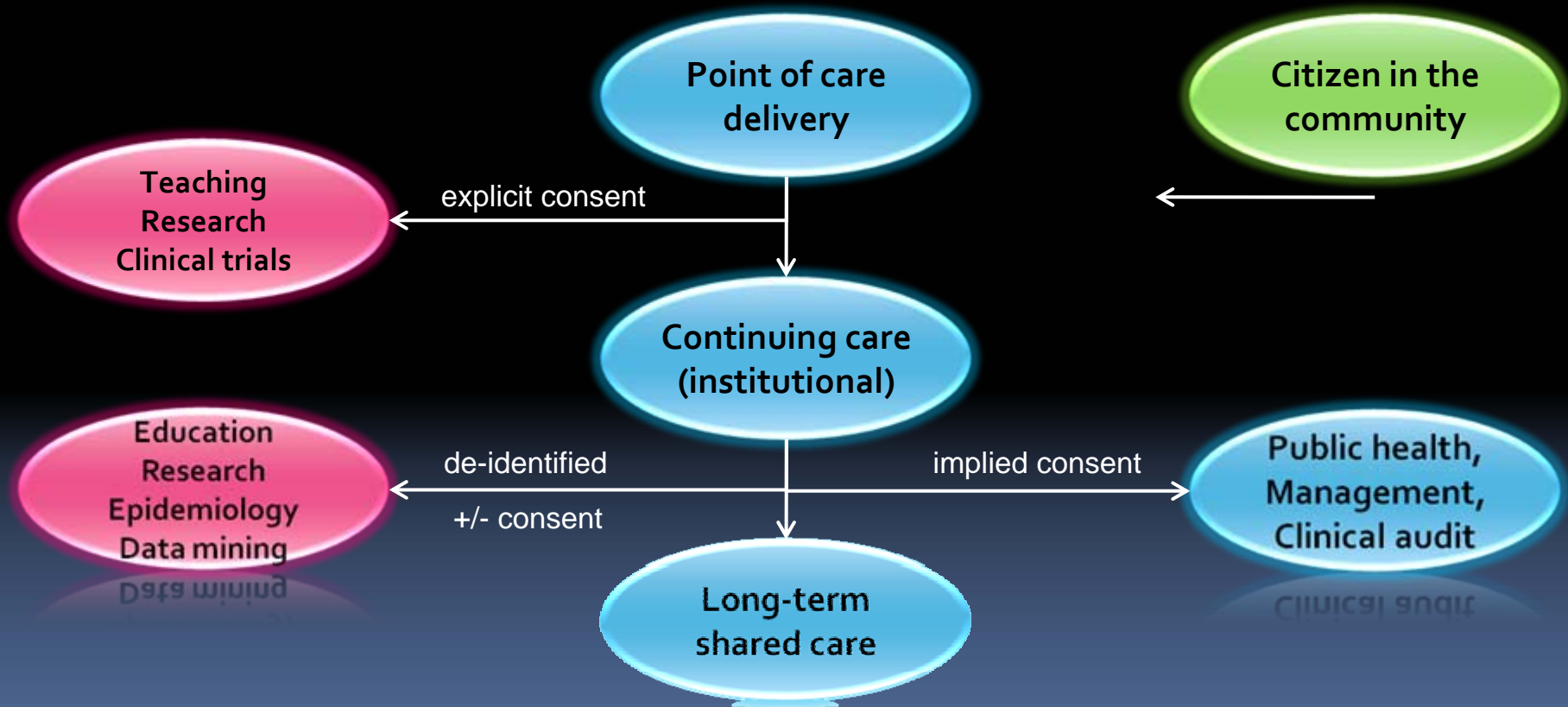 - CTO, Ocean Informatics
  - Technical lead, *open*EHR

What is an Electronic Health Record?

- "A repository of information regarding the health status of a subject of care in computer processable form, stored and transmitted securely, and accessible by multiple authorised users.

- It has a standardised or commonly agreed logical information model which is independent of EHR systems.

- Its primary purpose is the support of continuing, efficient and quality integrated health care and it contains information which is retrospective, concurrent, and prospective."

- Schloeffel P, Editor. Electronic Health Record Definition, Scope and Context. ISO/TR 20514. International Organisation for Standardisation, Geneva, 2005
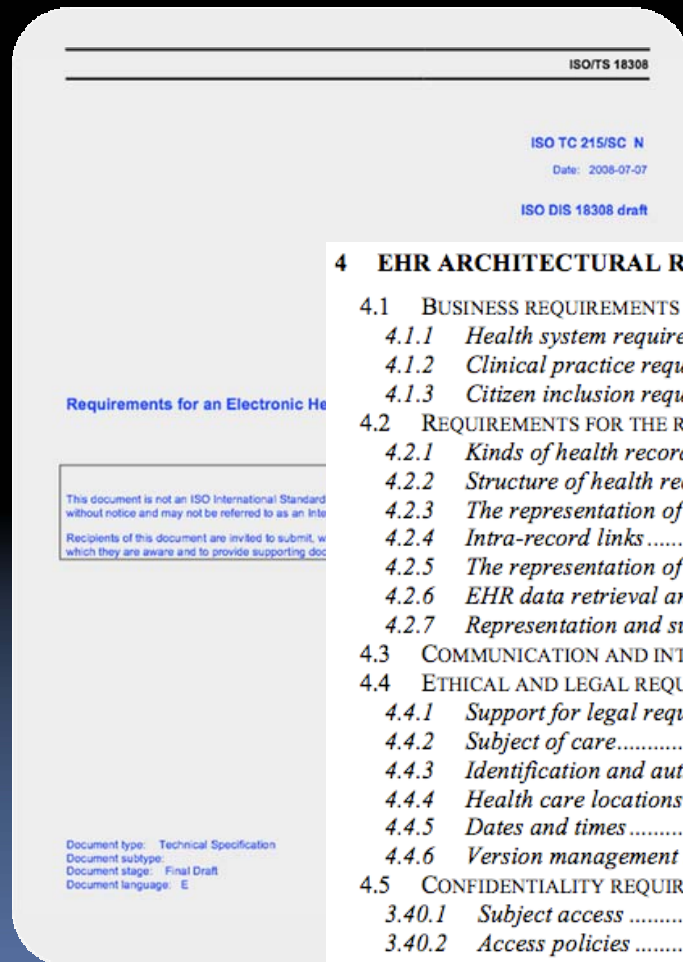
What problems does it help us solve?

- Manage increasingly complex clinical care
- Connect multiple locations of care delivery
- Support team-based shared care
- Deliver evidence-based health care
- Improve safety
  - reduce errors and inequalities
  - reduce duplication and delay
- Improve cost effectiveness of health services
- Manage health care resources more effectively
- Underpin population health and research
- Empower and involve citizens
- Protect patient privacy

Where is EHR information needed?

Requirements the EHR must meet: ISO 18308

ISO/TS 18308

ISO TC 215/SC N
Date: 2008-07-07

ISO DIS 18308 draft

Requirements for an Electronic He

This document is not an ISO International Standard
without notice and may not be referred to as an Inte

Recipients of this document are invited to submit, w
which they are aware and to provide supporting doc

Document type: Technical Specification
Document subtype:
Document stage: Final Draft
Document language: E

The EHR shall preserve any explicitly defined relationships between different parts of the record, such as links between treatments and subsequent

The EHR shall preserve the original data values within an EHR entry including code systems and measurement units used at the time the

The EHR shall be able to include the values of reference ranges used to interpret particular data values

The EHR shall be able to represent or reference the calculations, and/or formula(e) by which data have been

The EHR architecture shall enable the retrieval of part or all of the information in the EHR that was present at any particular historic date and time
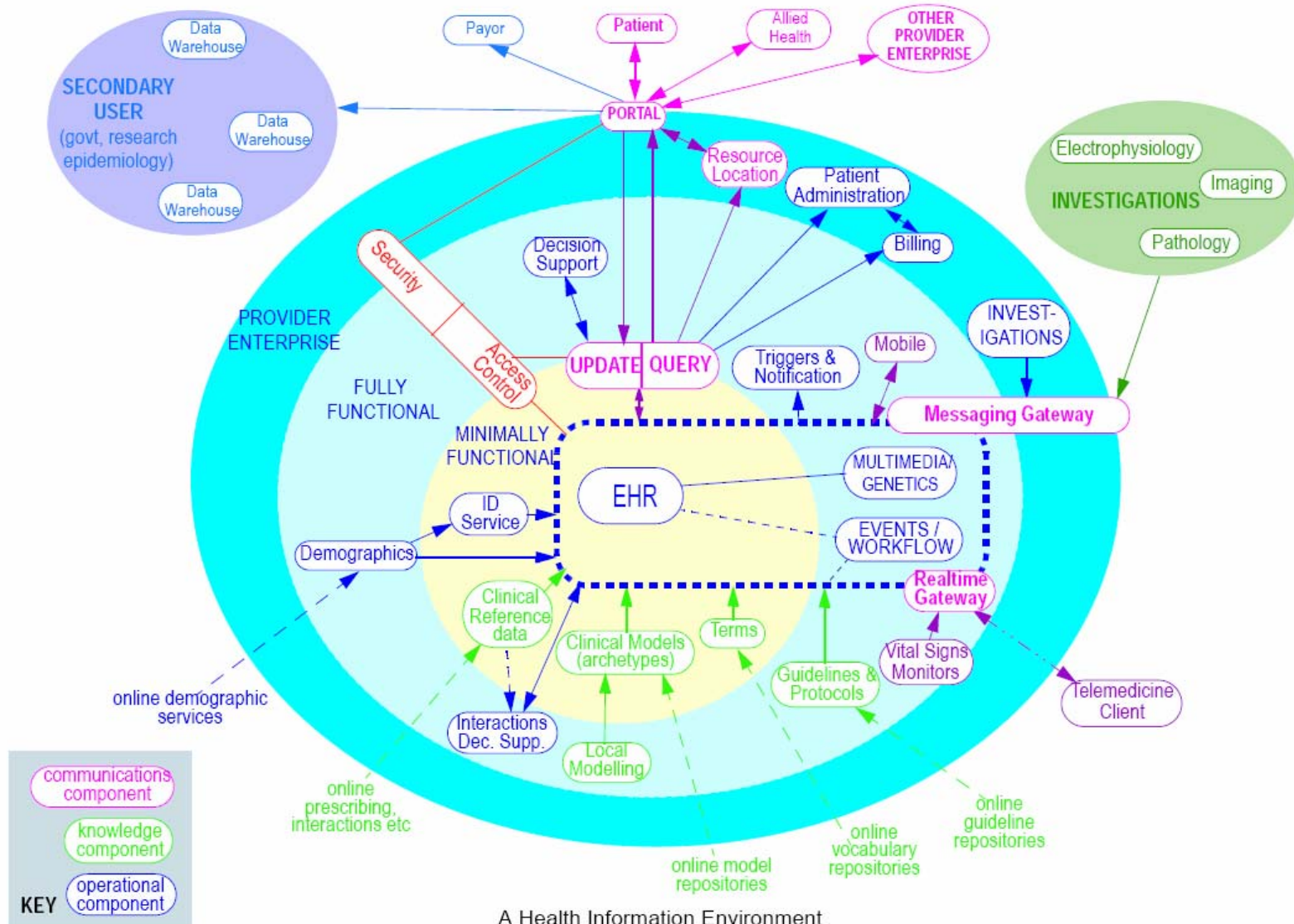
EHR and EHRS

EHR

- SERVICE
- Logical EHR
- Defined interfaces to:
  - Demographics
  - Identity management
  - Security
- Stores and makes available clinical documentation

EHRS

- SYSTEM
- Fully function clinical application
- Broad scope
  - Demographics
  - Billing
  - Ordering
  - Bed management...

The small eHR

EHR and EHRS

A Health Information Environment

Standards v. Specifications

Standards

- ANSI or ISO process
- Inclusive
- Sale of standard
- National or international
- Documentation template
- Balloting
- Risks:
  - Compromise without technical basis
  - Meeting stacking

Specifications

- Community
- Controlled by expert group
- No business model
- International
- Process to suit product
- Cohesive group with clear aims
- Risks
  - Irrelevant
  - Not sensitive to needs

13606 - standard

- ISO and CEN
  - Developed by committee meeting every 3 months
    - Enthusiasts
    - Academics
    - Industry
  - Based on past work
  - Theoretical
  - Balloted
    - Political process

*open*EHR - specification

- Develop by enthusiasts collaborating on web
    - Academics, Engineers, Industry
- Implementation trials
- Engineering processes
    - Change request
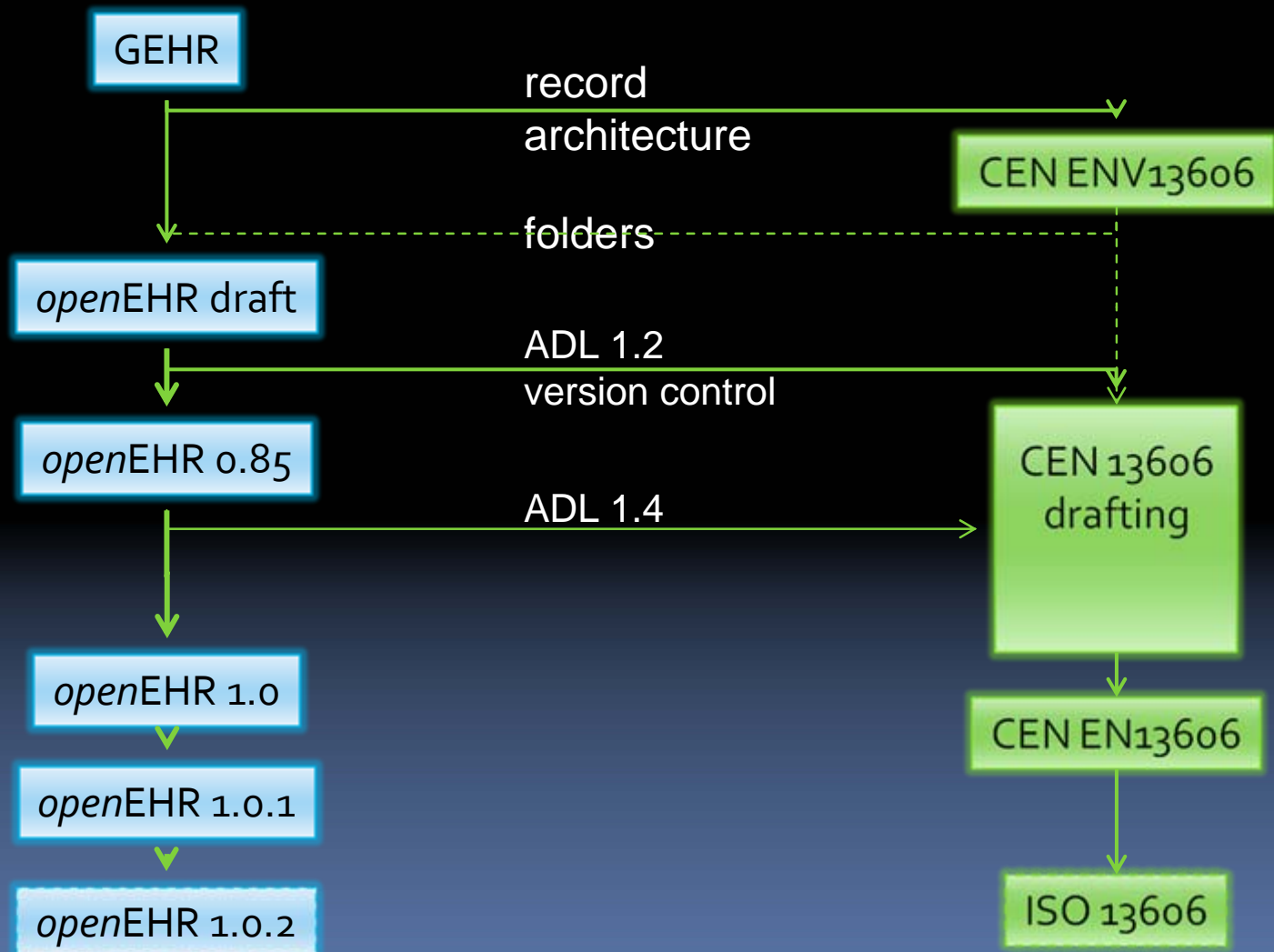   - Expert group decides changes

ISO 13606 and *open*EHR

- 13606
  - Standard in 5 parts
  - 5 years work and input from European volunteers in TC251
  - Some difficult negotiations and changes
  - 2007: Acceptance by the majority of European States
  - 2008: Undergoing ISO process
- *open*EHR
  - Community generated specifications based on implementation experience over 10 years
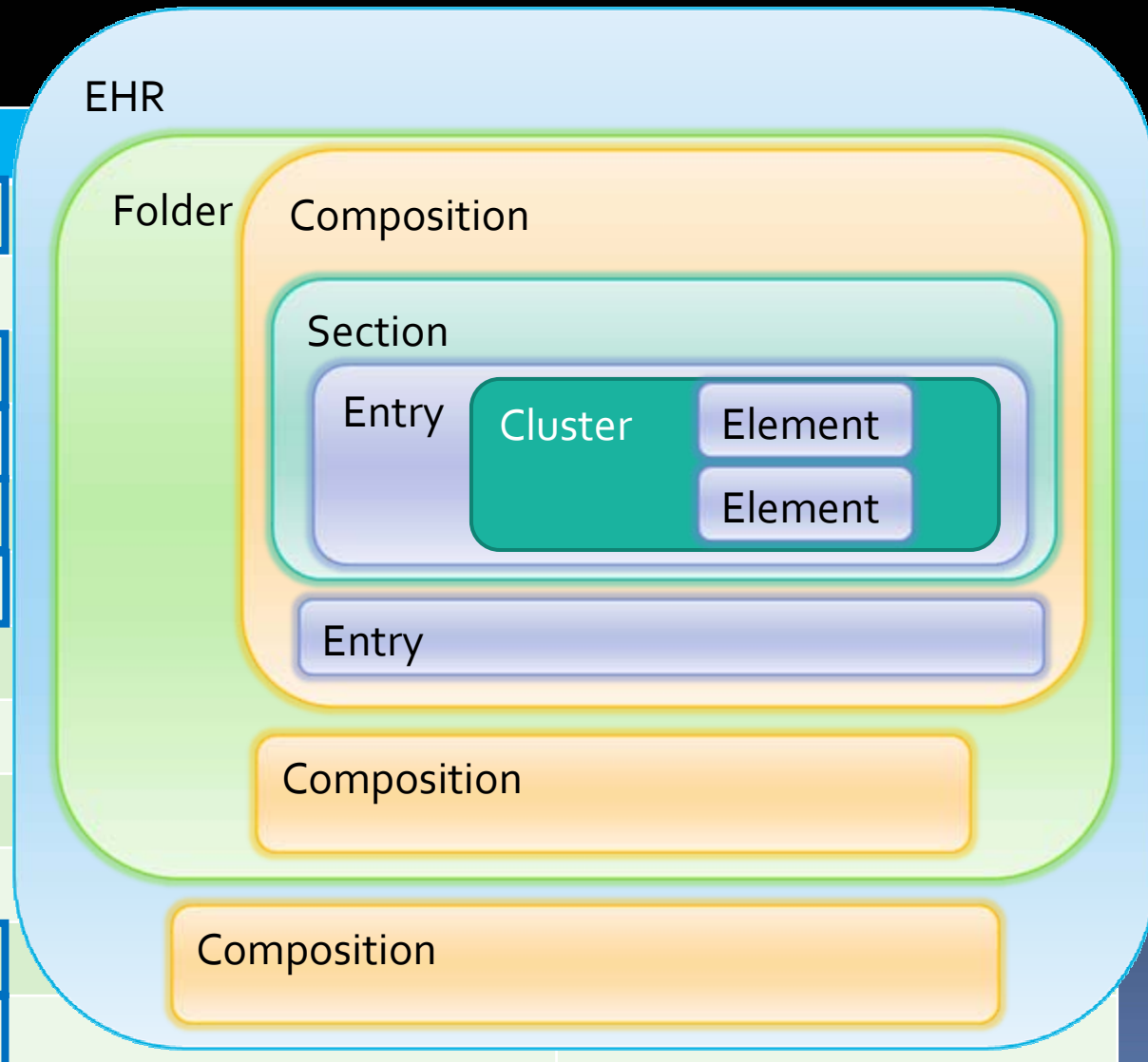 - Ongoing development, 2006 (1.0), 2007 (1.0.1)

History

1991

GEHR

record
architecture

CEN ENV 13606

folders

*open*EHR draft

ADL 1.2
version control

*open*EHR 0.85

ADL 1.4

CEN 13606
drafting

*open*EHR 1.0

CEN EN 13606

*open*EHR 1.0.1

*open*EHR 1.0.2

ISO 13606

The features of the EHR

openEHR
Electronic Health Record
An extract of an EHR
Folder
Composition (versions)
Section
(ENTRY)
• Observation
• Action
• Evaluation
• Instruction
Cluster
Element

EHR

Folder

Composition

Section

Entry

Cluster

Element

Element

Entry

Composition

Composition

Commonalities

openEHR	CEN/ISO 13606	
Health Record		
An extract of an EHR	Extract of EHR	
Folder	Folder	
Composition (versions)	Composition (+/- versions)	
Section	Section	
(ENTRY)	Entry	
• Observation		
• Action		
• Evaluation		
• Instruction		
Cluster	Cluster	
Element	Element	

Commonalities

*open*EHR	CEN/ISO 13606	HL7 CDA
Health Record		
An extract of an EHR	Extract of EHR	Multi document message
Folder	Folder	
Composition (versions)	Composition (+/- versions)	Document (Version number)
Section	Section	Section
(ENTRY)	Entry	*(ENTRY)*
• Observation		• Observation
• Action		• Act
• Evaluation		• Substance administration
• Instruction		• Supply
Cluster	Cluster	
Element	Element	

Commonalities

openEHR	CEN/ISO 13606	HL7 CDA
Health Record		
An extract of an EHR	Extract of EHR	Multi document message
Folder	Folder	
Composition (versions)	Composition (+/- versions)	Document (Version number)
Section	Section	Section
(ENTRY)	Entry	(ENTRY)
• Observation		• Observation
• Action		• Act
• Evaluation		• Substance administration
• Instruction		• Supply
Cluster	Cluster	
Element	Element	

Specialised entry classes

measurable or observable

Observations
1

Investigator

Published evidence base

Personal knowledge base

Patient

4
Actions

recording clinical activities

2 **Evaluation**
- assessment
- summary
- opinion
- goals

clinically interpreted findings or summary

initiation of a workflow process

3
Instructions

Investigator's agents
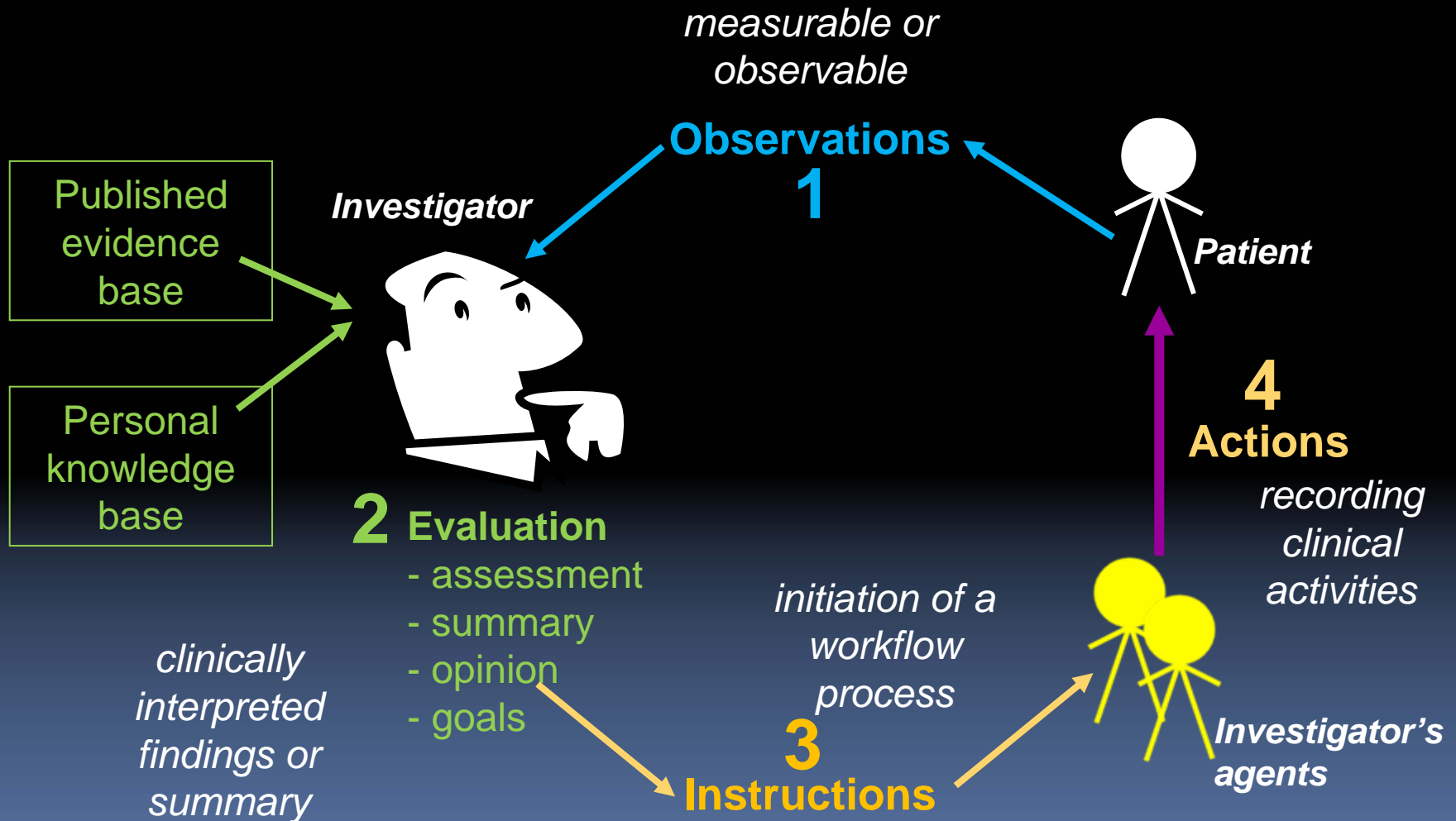
*open*EHR RM
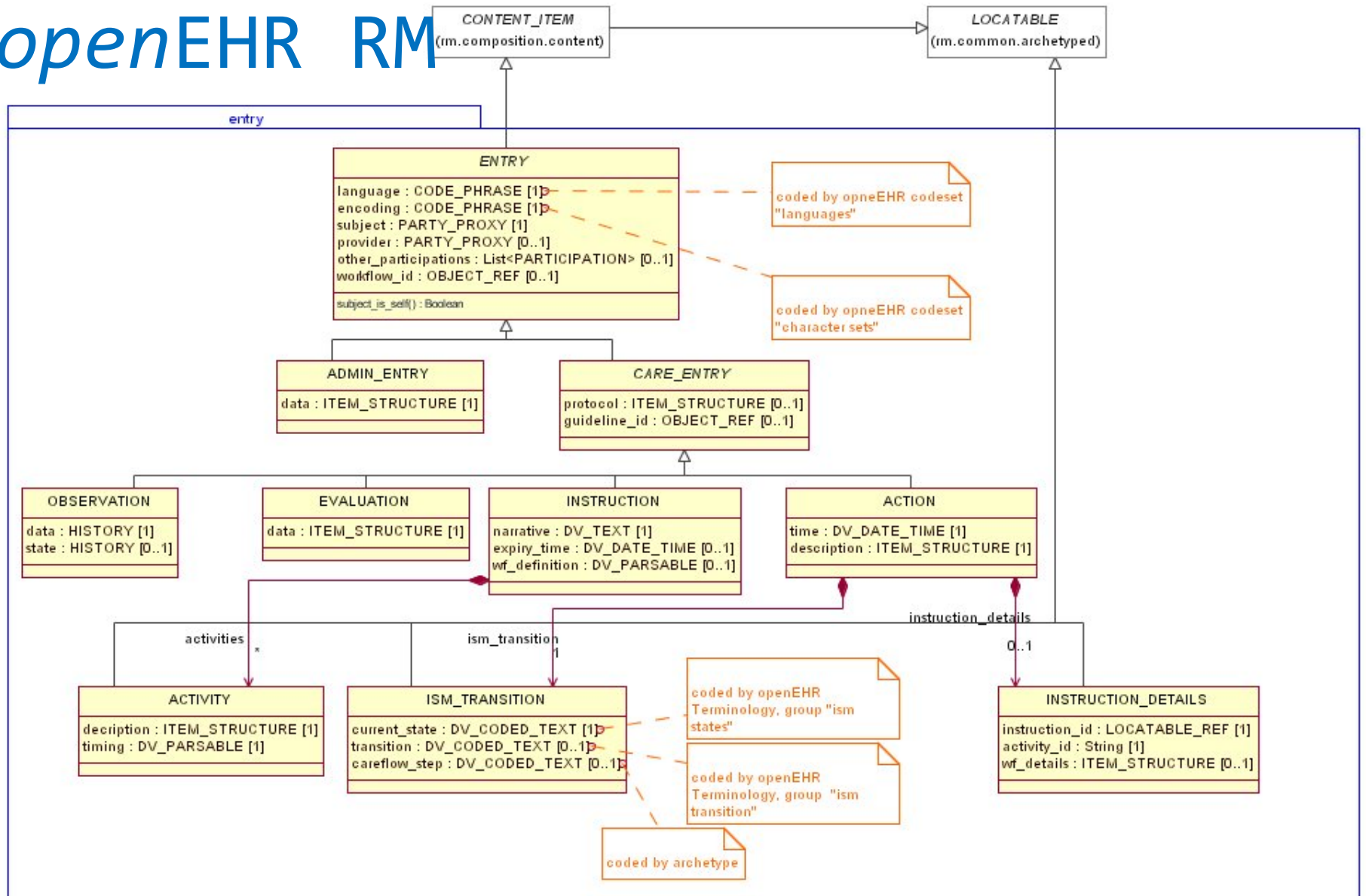
13606
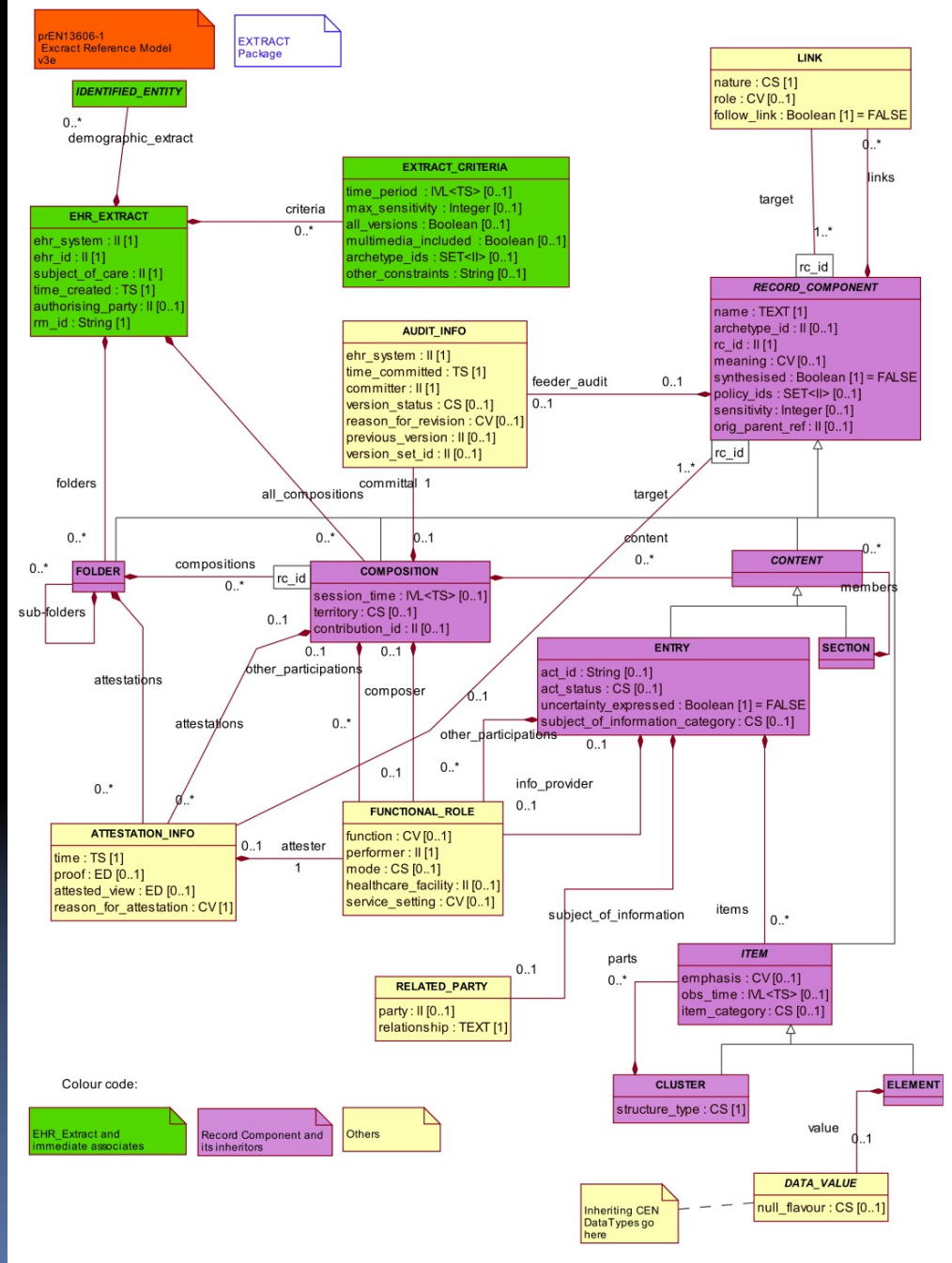
Core properties of the logical EHR model

- the compositional record hierarchy

- the representation of persons, such as the record subject, authorship, signatures and the information provider

- the representation of dates and times, when events occurred and the time-stamping of when details were recorded

- version management

- data types to represent coded terms, quantities, dates and times, images etc. consistently

- a role based access control approach, with options for jurisdictional profiles of these

The *open*EHR Model features

Things you might ask:

- When a composition was created and by whom

- At what site the composition was first committed

- When it was added to this record

- Who has changed the composition and what changes were made

but, no clinical domain knowledge (deliberately)

- Reconstruct the record exactly as it was at

Archetypes are the means to achieve this

a particular time in the past

What is a clinical archetype?

- A clinical archetype is an agreed, formal and interoperable specification for a clinical entity
  - such as a clinical observation, a finding, a plan or a treatment within an electronic health record

Invented and maintained by *open*EHR

  - ratified by CEN: EN 13606 Part 2
  - being balloted by ISO
  - being quality labelled by the EuroRec Institute

Archetype Attributes

- Constrain data entry → **improving data quality**
- Include the **maximum and minimum value** that could possibly be sensible
- Determine the **allowed units**, with associated **numeric ranges** which are unit dependent
- Incorporate the set of terms from a **terminology** that could be used to populate a data point
- Define an **internal value set** that is allowed permitted in the archetype
- Establish whether a data point is **mandatory or optional**
- Quantify the number of times a data point or data set might be **repeated**

LEGO® design analogy

RM components	= individual LEGO bricks
Archetypes	= instructions for creation of meaningful structures

Reference Model

Archetype A
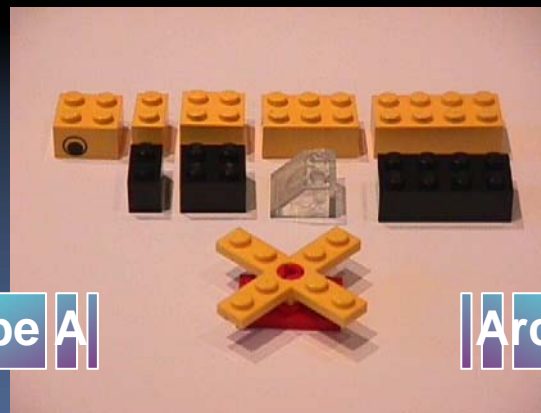
Archetype B
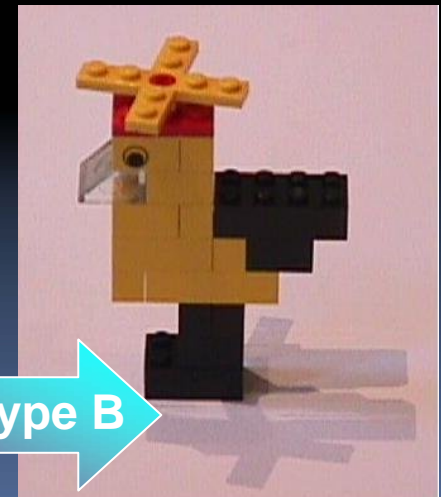
Archetypes put clinicians in the drivers seat!

Archetypes are constraints on the reference model

Archetypes are constraints on the reference model

Archetype as constraint

Archetype as constraint

openEHR-EHR-OBSERVATION.blood_pressure.v1

ヘッダ 定義 用語体系 表示 インターフェース 詳細

☑ プロトコル　　　☐ 参加(Participation)　　　☐ 身体の状態と病歴

データ プロトコル

☑ 身体の状態

List Event 身体の状態

☑ 整列　　　　　　　　　　　　at0004

Q 収縮期

```
ITEM_LIST[at0003] matches {   -- blood pressure
    items cardinality matches {0..*; ordered} matches {
        ELEMENT[at0004] occurrences matches {0..1} matches {  -- Systolic
            value matches {
                C_DV_QUANTITY <
                    property = <[openehr::125]>
                    list = <
                        ["1"] = <
                            units = <"mm[Hg]">
                        >
                    >
                >
            >
        >
    >
>
```

Constraint | Details

Occurrence

分: 0　　　最大: 1　　　☐ バインドされて いない(Unbound)

詳細 | 1つ以上の脈の間で最高値を示す全身の動脈圧 - 心機図の収縮期で測定される

Runtime name constraint | ...

プロパティ

圧(Pressure)

単位

＋ mm[Hg]
－

数量　　　☐ Limit decimal places

☐ 最小値を設定

☐ 最大値を設定

Archetype as constraint

openEHR-EHR-OBSERVATION.blood_pressure.v1

ファイル　編集　言語　用語体系　ツール　ヘルプ

ヘッダ　定義　用語体系　表示　インターフェース　詳細

☑ プロトコル　　　☐ 参加(Participation)　　　☐ 身体の状態と病歴

データ　プロトコル

☑ 身体の状態

List　Event　身体の状態

☑ 整列　　　　　　　　　　　　　　　　　　　at1007

Q 収縮期
Q 拡張期
Q 平均動脈圧
Q 脈圧
T コメント

Constraint | Details

Occurrence

分: 0　　最大: 1　　☐ バインドされて
いない(Unbound)

詳細　1回の収縮サイクルでの血圧の変動

Runtime name
constraint　　　　　　　　　　　　...

量

プロパティ

圧(Pressure)

単位

➕ mm[Hg]

➖

数量　　　　　　☑ Limit decimal places　　0

☑ 最小値を設定　　　　>=　　　0

☑ 最大値を設定　　　　<=　　　750

openEHR-EHR-OBSERVATION.blood_pressure.v1

ファイル　編集　言語　用語体系　ツール　ヘルプ

ヘッダ｜定義｜用語体系｜表示｜インターフェース｜詳細｜

☑ プロトコル　　　☐ 参加(Participation)　　　☐ 身体の状態と病歴

データ｜プロトコル｜

☑ 身体の状態

List｜Event｜身体の状態｜

Eventリスト

◉ 開く (Ctrl + O)

☐ 固定 (Fixed)

☐ 一定期間ごとの Event

? 任意イベント
◉ 基準測定
◉ 5分後測定
◉ 10分後測定
H 姿勢変化
H 奇脈

Event詳細

Occurrence

分:　0　　　最大:　☑ ハイノド されて いない(Unbound

詳細

呼吸による血圧変動

Runtime name constraint

☐ Point in time (事典)
◉ Interval (区間)
☐ 任意のイベント (Event)

Duration (期間)
☐ 固定区間

変異(Variation)

ファイル　編集　言語　用語体系　ツール　ヘルプ

openEHR-EHR-OBSERVATION.blood_pressure.v1

ヘッダ｜定義｜用語体系｜表示｜インターフェース｜詳細｜

☑ プロトコル　　　☐ 参加(Participation)　　　☐ 身体の状態と病歴

データ｜プロトコル｜

☑ 整列　　　　　　　　　　　　　　　　at0014

- **T** カフサイズ
- **T** 測定部位
- **T** コロトコフ音

Constraint｜Details｜

Occurrence

分: 0　　最大: 1　　☐ ハイソトでれに いない/Unbound

詳細　血圧を測定する部位

Runtime name constraint

☐ フリーあるいはコード化さ　　◉ 内部コード　　☐ 用語体系

- 右腕
- 左腕
- 左脚
- イントラ動脈

ファイル　編集　言語　用語体系　ツール　ヘルプ

openEHR-EHR-OBSERVATION.blood_pressure.v1

ヘッダ | 定義 | 用語体系 | 表示 | インターフェース | 詳細 |

☑ プロトコル　　　　☐ 参加(Participation)　　　☐ 身体の状態と病歴

データ | プロトコル |

☑ 身体の状態

List | Event | 身体の状態

☑ 整列　　　　　　　　　　　　　　　　　　　at0008

- **T** 体位
- **T** 運動レベル
- **Q** 労作レベル
- **Q** 傾斜

Constraint | Details

Occurrence

分: 0　　　最大: 1　　☐ バインドされて いない(Unbound)

詳細　血圧を測定するときの患者の体位

Runtime name constraint

☐ フリーあるい はコード化さ　　◉ 内部コード　　☐ 用語体系

- 血圧
- 立位
- 座位
- 斜位
- 臥位

仮定(Assumed)値を設定　　座位

What value do archetypes add?

- A user friendly means to capture and collate professional consensus on how clinical data should be represented

- A formal model of clinical domain concepts
  - e.g. "blood pressure", "discharge summary", "fundoscopy"

- Can be published and shared within a clinical community, or globally

- Can be imported by vendors into EHR system data dictionaries

- Defines a systematic EHR target for queries and for decision support

Layered approach

- Level 1
  - Recording health information
  - Versioning
  - Information currency
  - URL access
  - Granularity for attestation
  - Designed to support re-use

1. Recording model

Information model
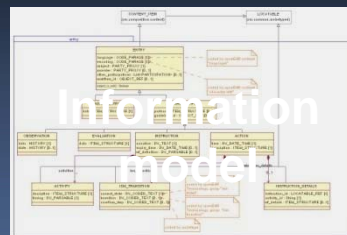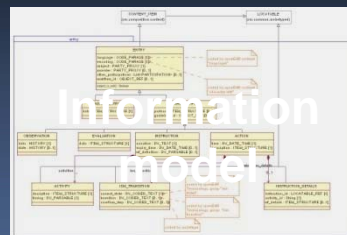
Repository

Layered approach

- Level 2
  - Clinical specifications – whole recurring concepts
  - Allow specialisation
  - Maximum data sets
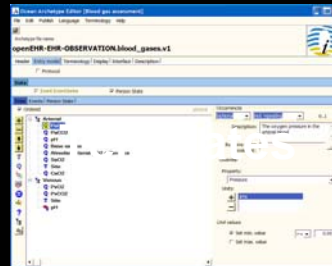 - All data is archetyped
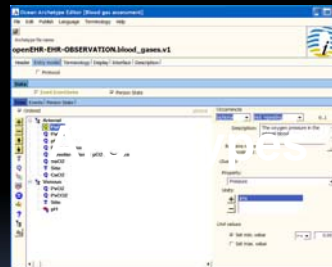
2. Knowledge model
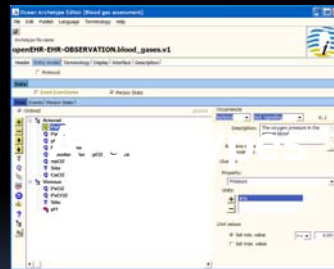
Archetypes

1. Recording model
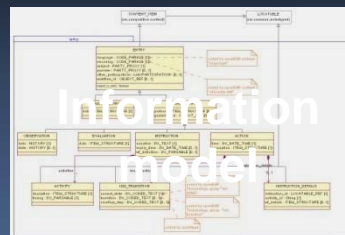
Information model

Repository

Layered approach

3. Implementation

2. Knowledge model

1. Recording model

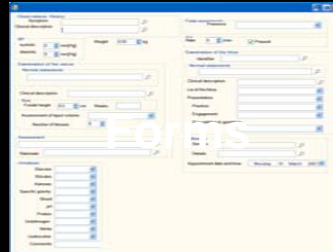

Localised models for use

Clinical models

Repository

Information model

Archetypes and Templates
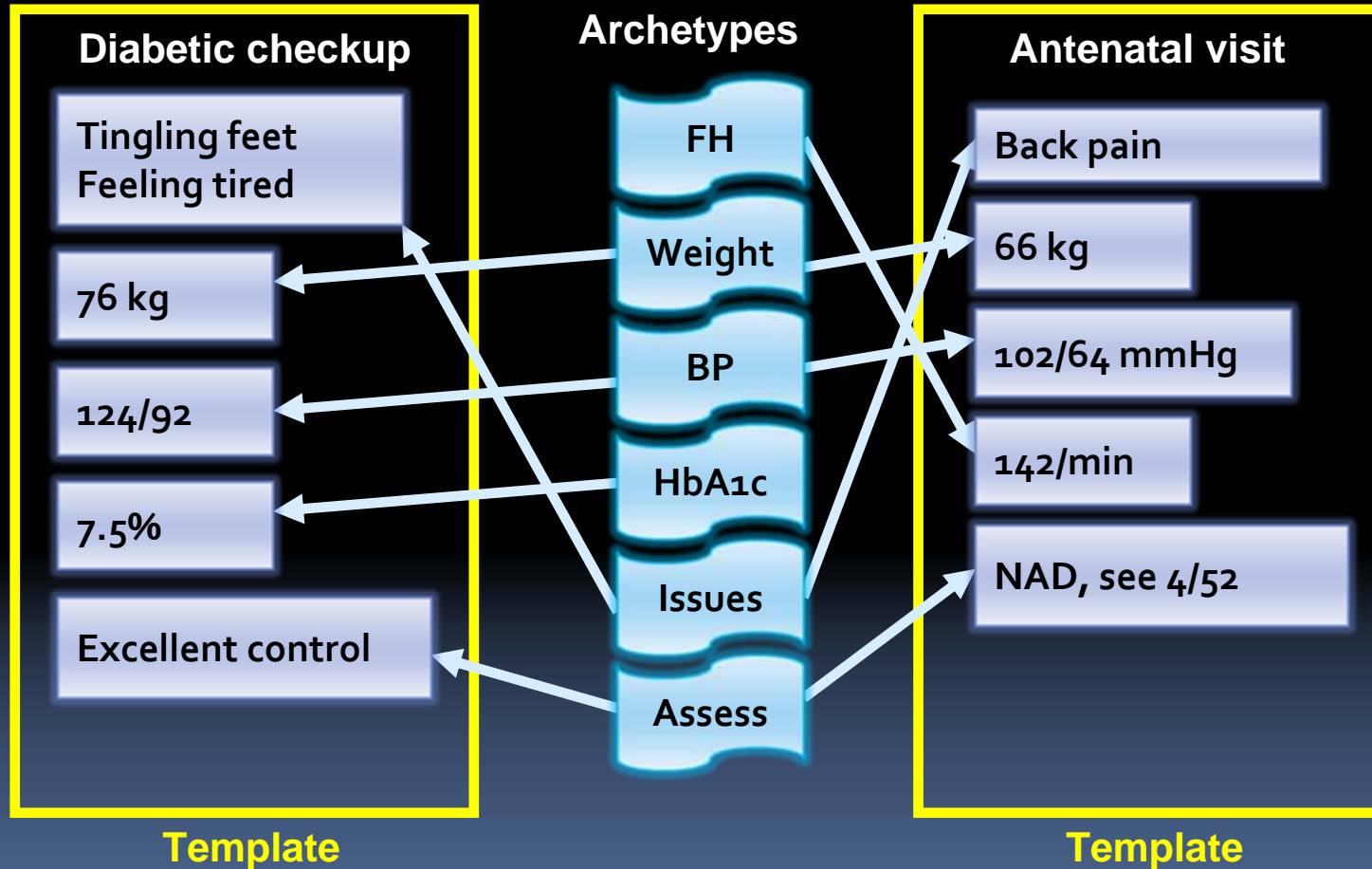
Layered approach

4. Application level

3. Context specifications
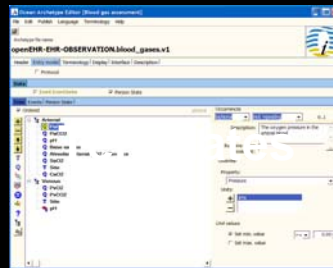
2. Knowledge model

1. Recording model

Implementation

Localised
models for use
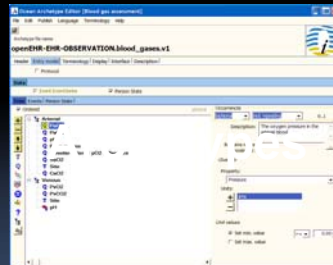
Clinical models
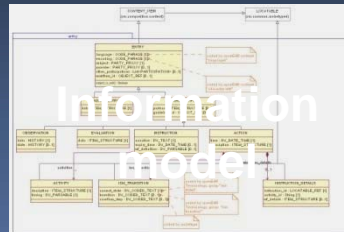
Repository

Observations: History

Symptom [_____] 🔍

Clinical description [_____] 🔍

Fetal movements

Presence [_____▾]

BP

systolic [0 ▾] mm[Hg]

diastolic [0 ▾] mm[Hg]

Weight [0.00 ▾] kg

FH

Rate [0 ▾] /min   ☑ Present

Examination of the uterus

Normal statements

[_____] 🔍

Clinical description [_____] 🔍

Size

Fundal height [0.0 ▾] cm   Weeks [_____]

Assessment of liquor volume [_____▾]

Number of fetuses [0 ▾]

Examination of the fetus

Identifier [_____] 🔍

Normal statements

[_____] 🔍

Clinical description [_____] 🔍

Lie of the fetus [_____▾]

Presentation [_____▾]

Position [_____▾]

Engagement [_____▾]

Size relative to gestation

[_____▾]

Assessment

[_____] 🔍

Rationale [_____] 🔍

Follow up

Service [_____] 🔍

Details [_____] 🔍

Appointment date and time   [Monday . 19 March 2007 ▾]

Urinalysis

Glucose [_____▾]

Bilirubin [_____▾]

Ketones [_____▾]

Specific gravity [_____▾]

Blood [_____▾]

pH [_____▾]

The *open*EHR artefact ecosystem

The universal EHR

HL7v2 → openEHR Repository
HL7v2 (archetyped) → openEHR Repository
CDAr2 (text) → openEHR Repository
CDAr2 (structured) → openEHR Repository
13606 Extract → openEHR Repository
openEHR Extract → openEHR Repository

Clinical Archetypes

openEHR Repository → XML
openEHR Repository → PDF
openEHR Repository → CDAr2 (generated)
openEHR Repository → 13606 Extract
openEHR Repository → openEHR Extract

Who is using it?

- Primary care/Office
  - StatHealth (Australia)
  - McCauley Software (Australia)
  - CHIME (UK)
  - Zilics (Brazil)
- Hospital
  - Cambio (Sweden)
  - Unusu@lvisions (Netherlands)

- Registry/Research
  - Cancer Council of Victoria (Australia)
- Regional clinical repository
  - Extensia (Australia)
    - Queensland Health
    - Division of General Practice

Who is using it?

- Connecting for Health (UK)
  - Clinical data specifications
- Connected Digital Health in Denmark
  - Clinical data specifications for import into vendor systems
  - Specification of terminology use
  - Message schema
- Swedish National Board of Health
  - Basis for national program
- IHTSDO – in discussions

International authoring

- op
- Co
- Cl
- Tr

Next steps

- Improved specification of terminology requirements

- Publish and subscribe interface for national archetype and template repositories

- System vendor engagement with knowledge management

- National programs based on clinical content specification (rather than terminology and messages)

Semantic interoperability

Requires

Where to go to participate..

http://openEHR.org/knowledge

sam.heard@oceaninformatics.com

Thank you