The *open*EHR Foundation

- Some Lessons of Experience in Standardising the EHR

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Founder and President of the *open*EHR Foundation
Director of Charing Systems Ltd

Patient-Centred Approaches to R&D
PRISME Forum , May 22nd 2012

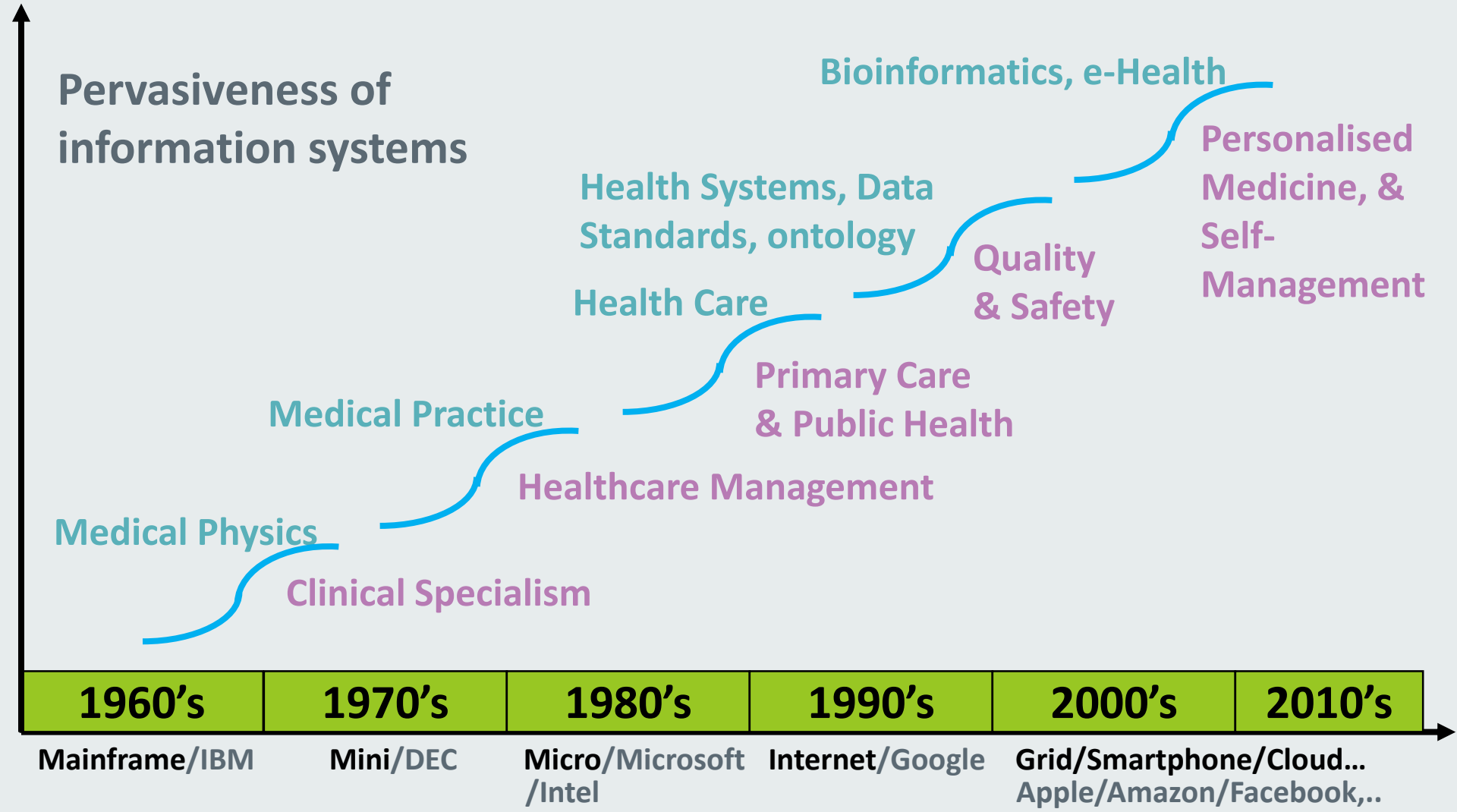
The *open*EHR Foundation

- Some Lessons of Experience in Standardising the EHR

- Context - five decades of innovation in health care and IT
- The openEHR Foundation - working towards EHR standards, experimentally
- Some related new open source and open data initiatives

Context - Five decades of innovation in health care and IT

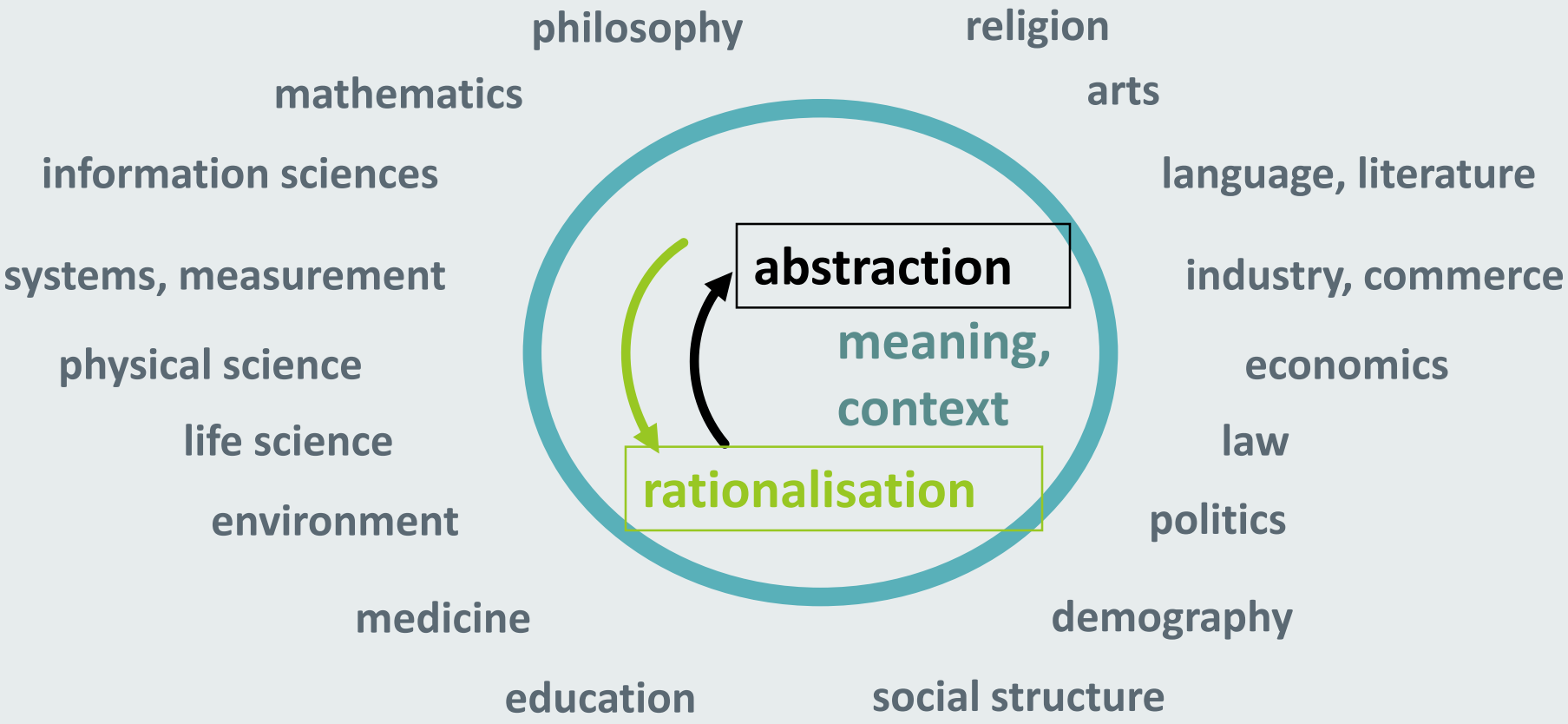
Co-evolving health care and informatics focus over 5 decades



The current scene

- Biomedical science is being transformed
  - ‘bioinformatics is core discipline of biology’ – Royal Society 2005
- Health care and research are increasingly technology and information intensive
  - ‘information is the heart of medicine’ – BMA 1994
- Multiple legacy information systems and frameworks are in use
  - supporting and linking health care, research and industry
- Governments want a pervasive and standardised (open source) ICT infrastructure for health care
- Many initiatives, commercial and public domain, are creating relevant infrastructures

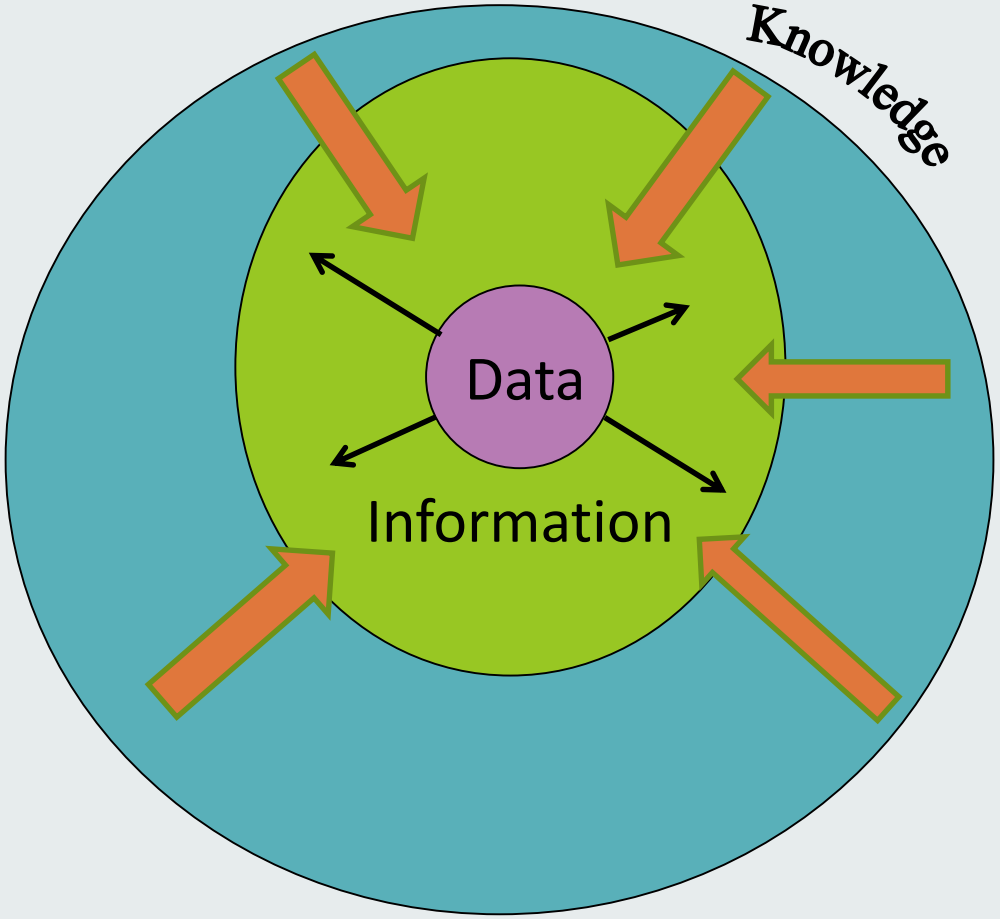
The Circle of Knowledge



The Circle of Knowledge: encyclopaedia, Ranganarthan, 1950

UNESCO, The Basic System of Order

Records capture and organise knowledge and data to represent and communicate facts, opinions and events, in context and with implied meaning



Common usage of these terms is loose and varied, although Latin and Greek roots help to preserve some clarity

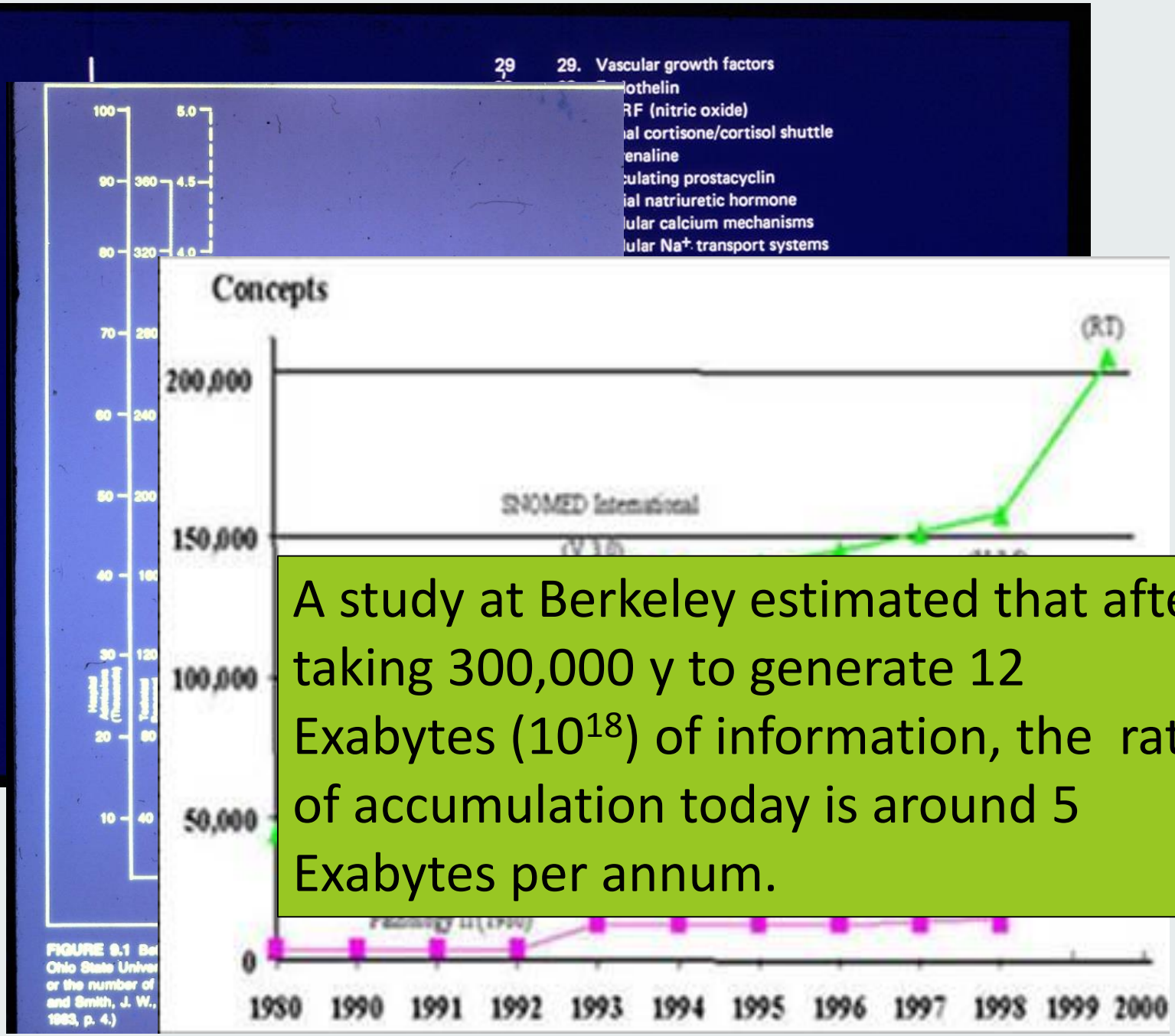
Information - has specialist meanings in physics and engineering.

'Knowledge for the purpose of effective action' is an interesting one here. Also:

Data -

'Facts, given, from which others may be inferred'

The purposes for which the record is captured, organised and communicated, reflect in both its structure and its meaning



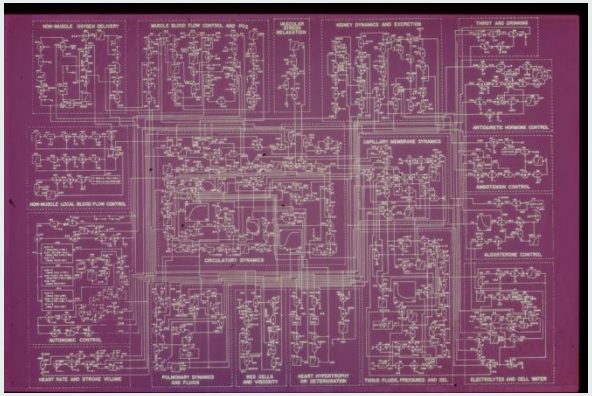
A study at Berkeley estimated that after taking 300,000 y to generate 12 Exabytes (10^{18}) of information, the rate of accumulation today is around 5 Exabytes per annum.

In summary

- Massive change in pretty well all aspects of health care and IT
- Continuing fragmentation and re-integration of professional discipline and teamwork
- Knowledge/information/data overload coupled with loss of focus on patients and care
- Repeating failure to align national information policy with the state of the art of what is computable and implementable
- Health IT characterised by local successes, dependent on visionary innovators, but global failures

Oxfam – Think globally, act locally
Health IT spending has tended to do the opposite

Amazing pioneers

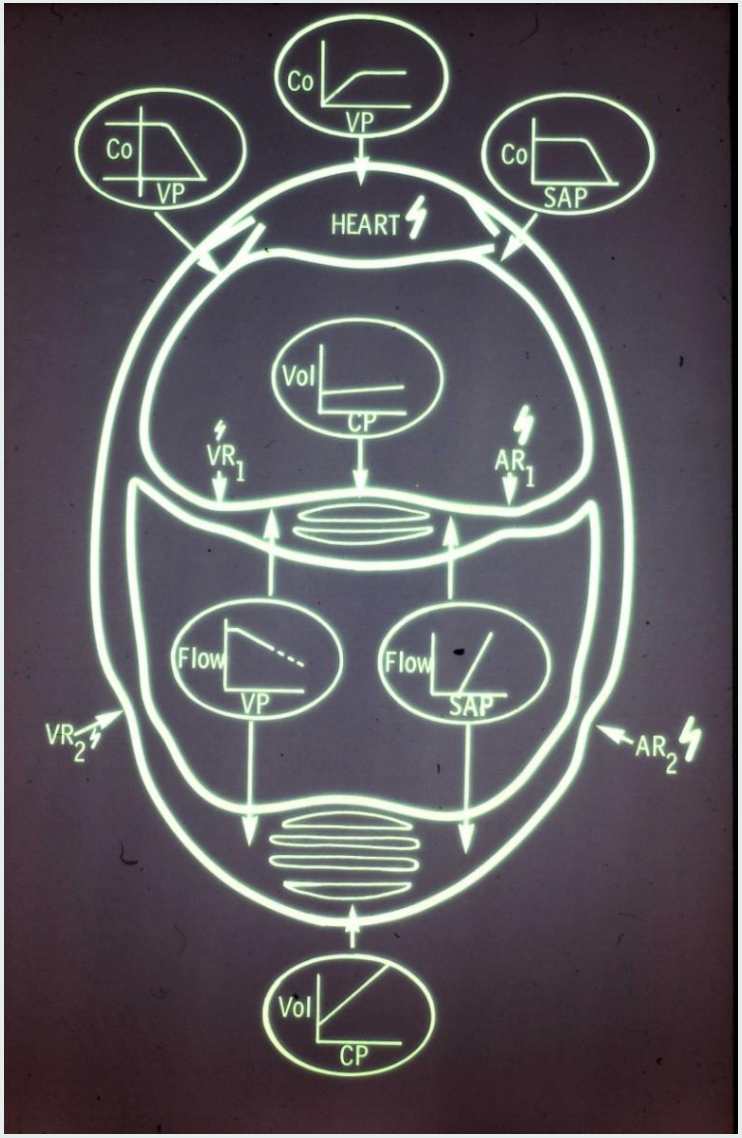


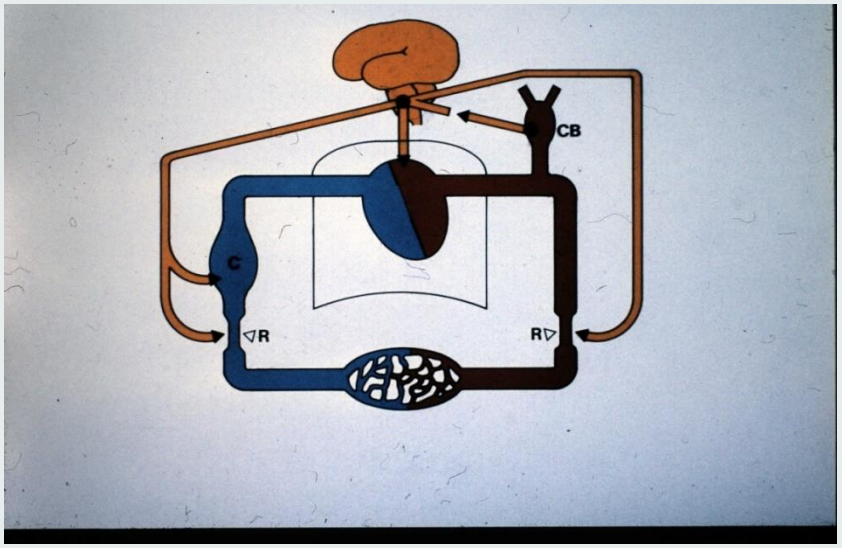
Guyton, 1974 !

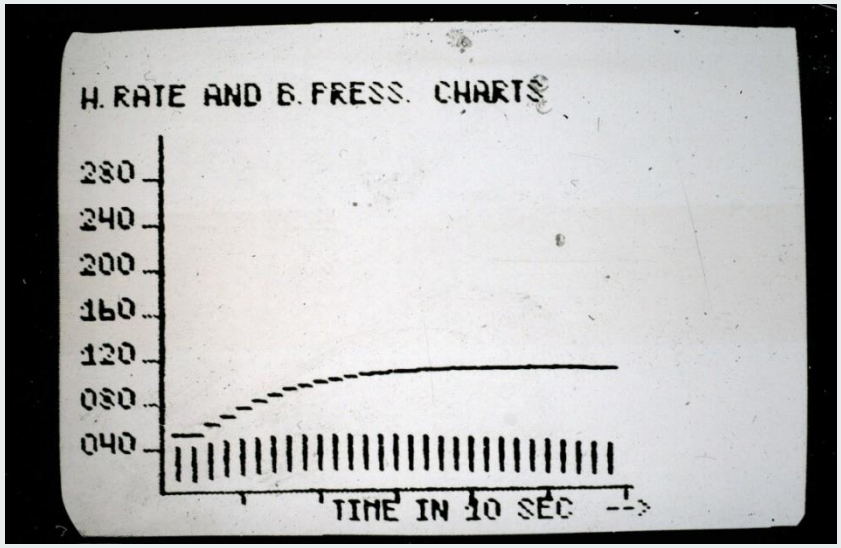
Arthur Guyton (with Ruth), President of the American Physiological Society, who transformed quantitative analysis of the circulatory system – forerunner of the Virtual Physiological Human

Octo Barnett, Professor of Medicine and Computer Science, who conceived and developed MUMPS at Harvard Medical School, underpinning the most successful period of innovation in hospital IT systems, worldwide

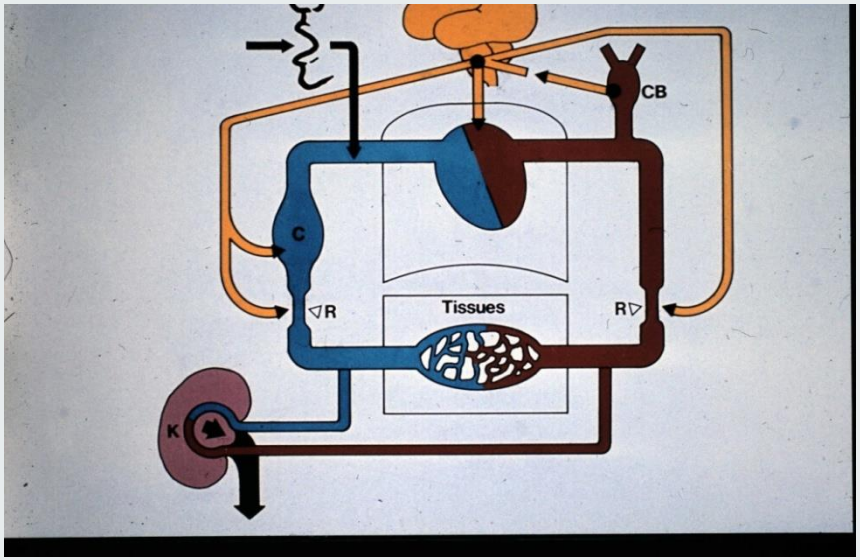
Successful pioneers combine attention to detail, leadership, courage and ability to work across boundaries. This is the pathway from local excellence to achieving global impact and change







Ingram and Dickinson, 1971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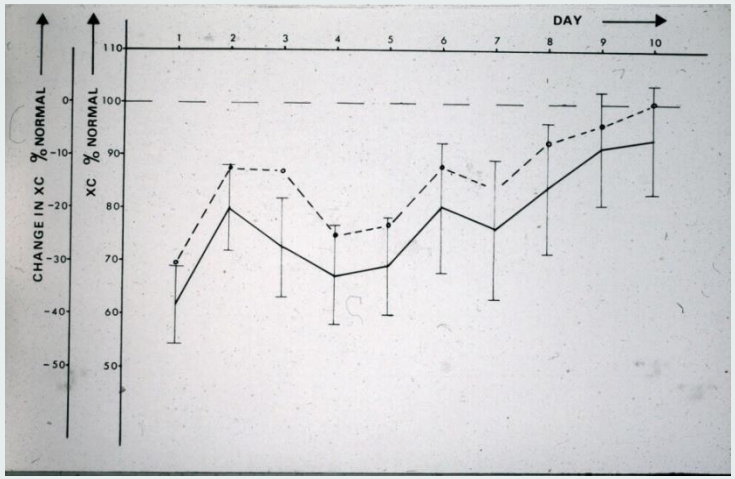
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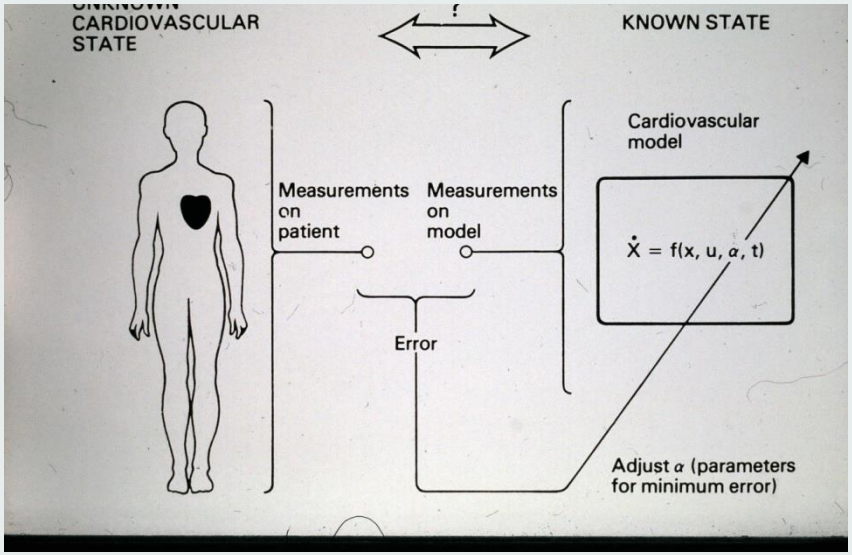
CARDIOVASCULAR STATE
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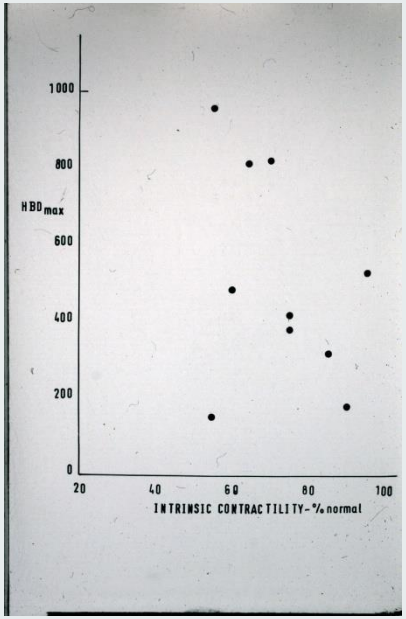
KNOWN STATE
Measurements on patient
Measurements on model
Error
Cardiovascular model
$\dot{X} = f(x, u, \alpha, t)$
Adjust α (parameters for minimum error)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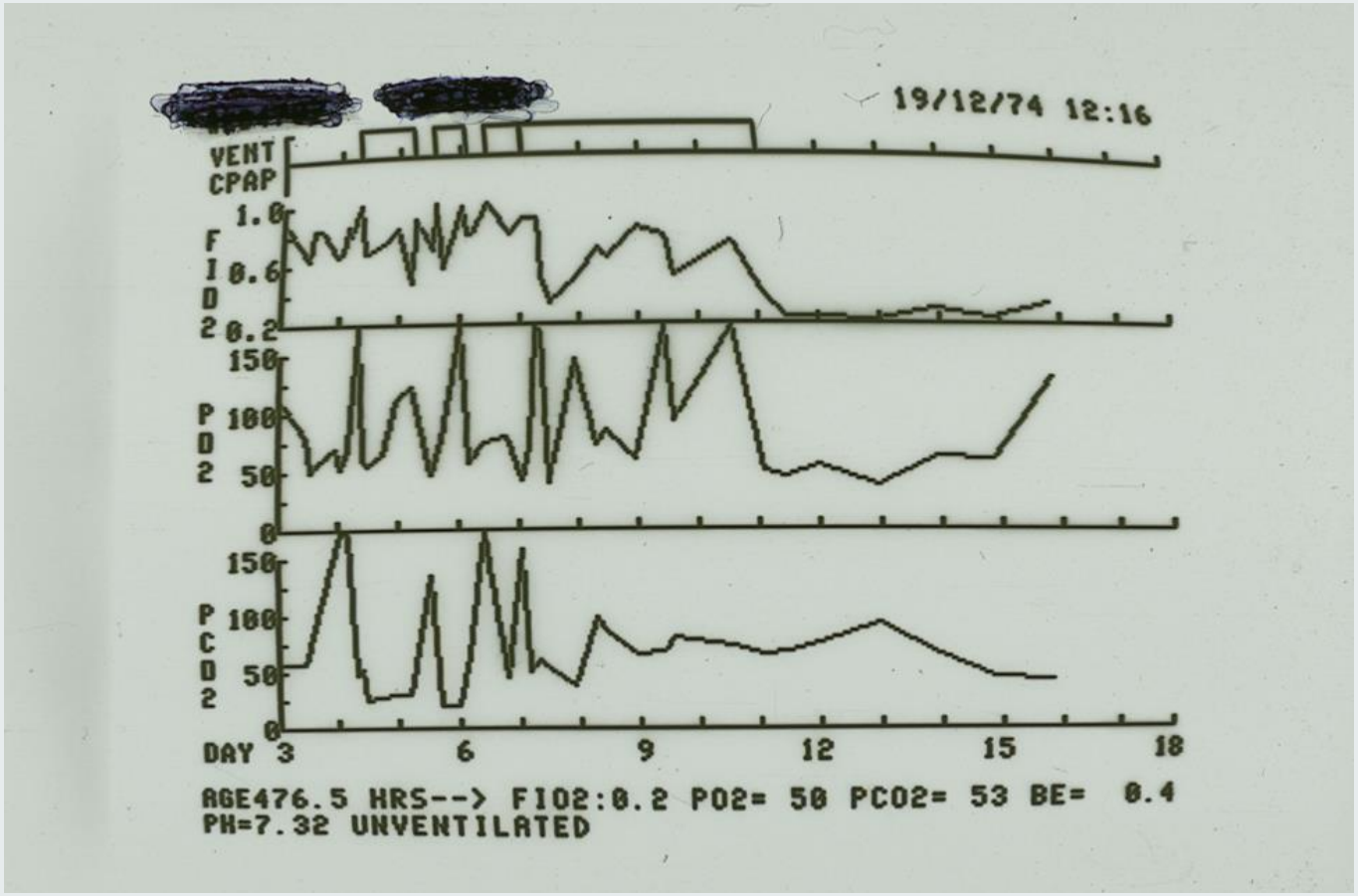
Ingram, 1973

First encounter with electronic health records

University College Hospital, London - Neonatal Unit, 1974

Electronic record of neonatal artificial ventilation management



Ingram and Allan, 1974 – Gas exchange and acid-base balance in neonates

A successful research and development project

But none of this work exists or could run today, due to factors such as:

- obsolescence of the hardware and software technologies
- inability to sustain, develop and improve innovation to the level of viable product

First Digital Equipment Corporation PDP11/45, RSX11-D system in UK.

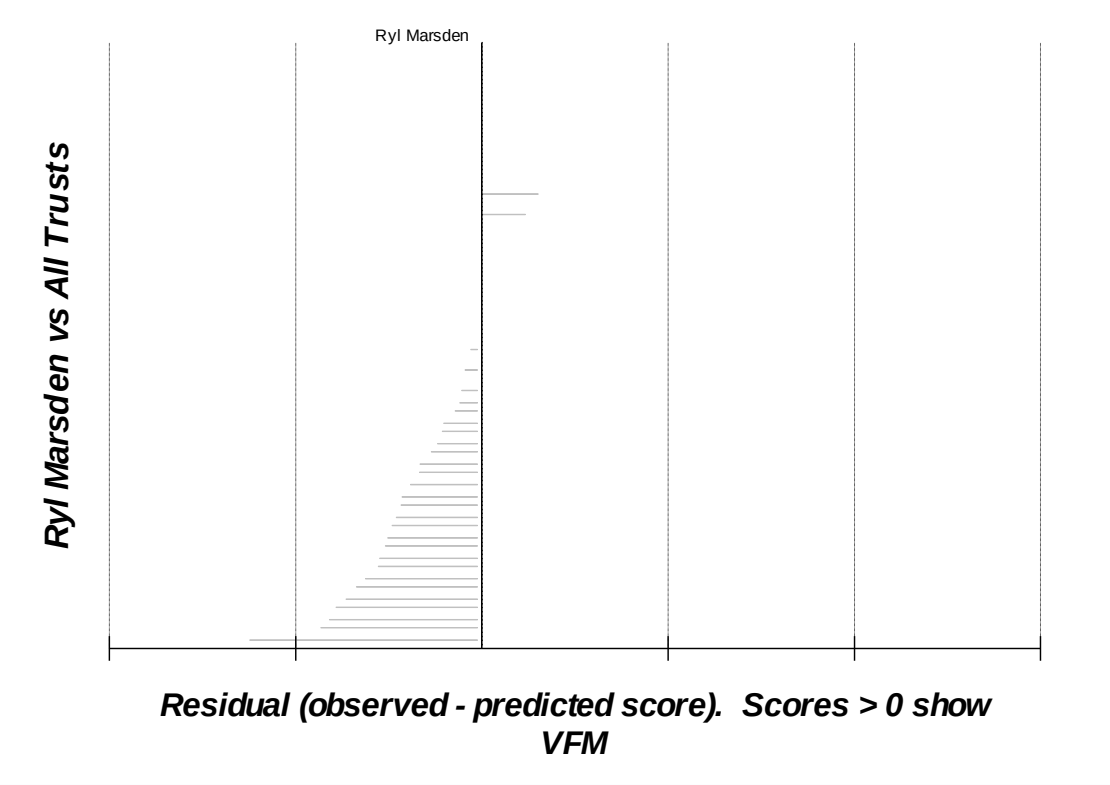
Providing 24x7 clinical service for several years

IT can help the good get better - and the bad get worse !

Escher: Order and Chaos

"To err is human, to really mess things up use a computer"!

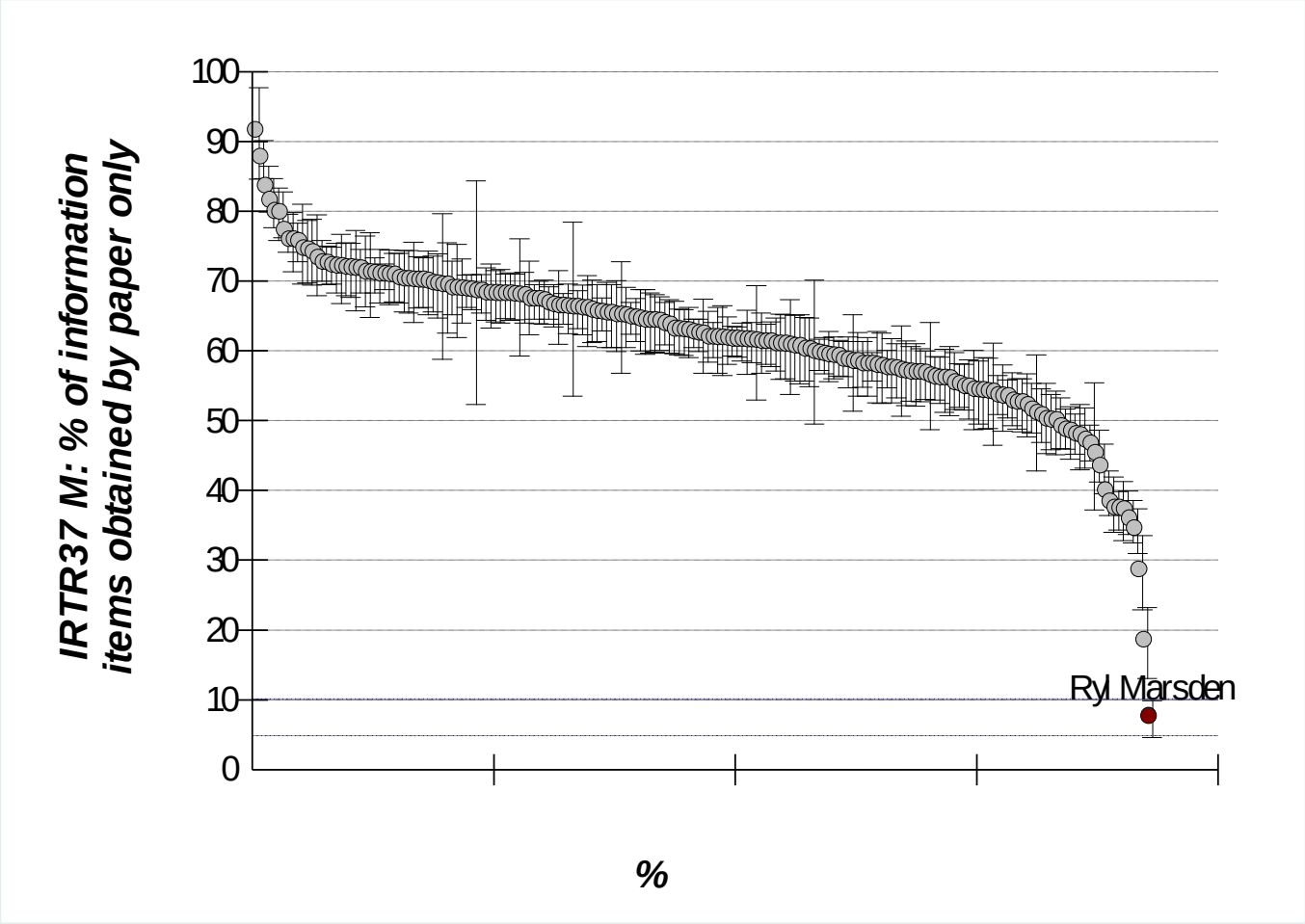
The Best -
Health IT in all NHS acute hospital trusts c 2000
- Clinical approval and value for money



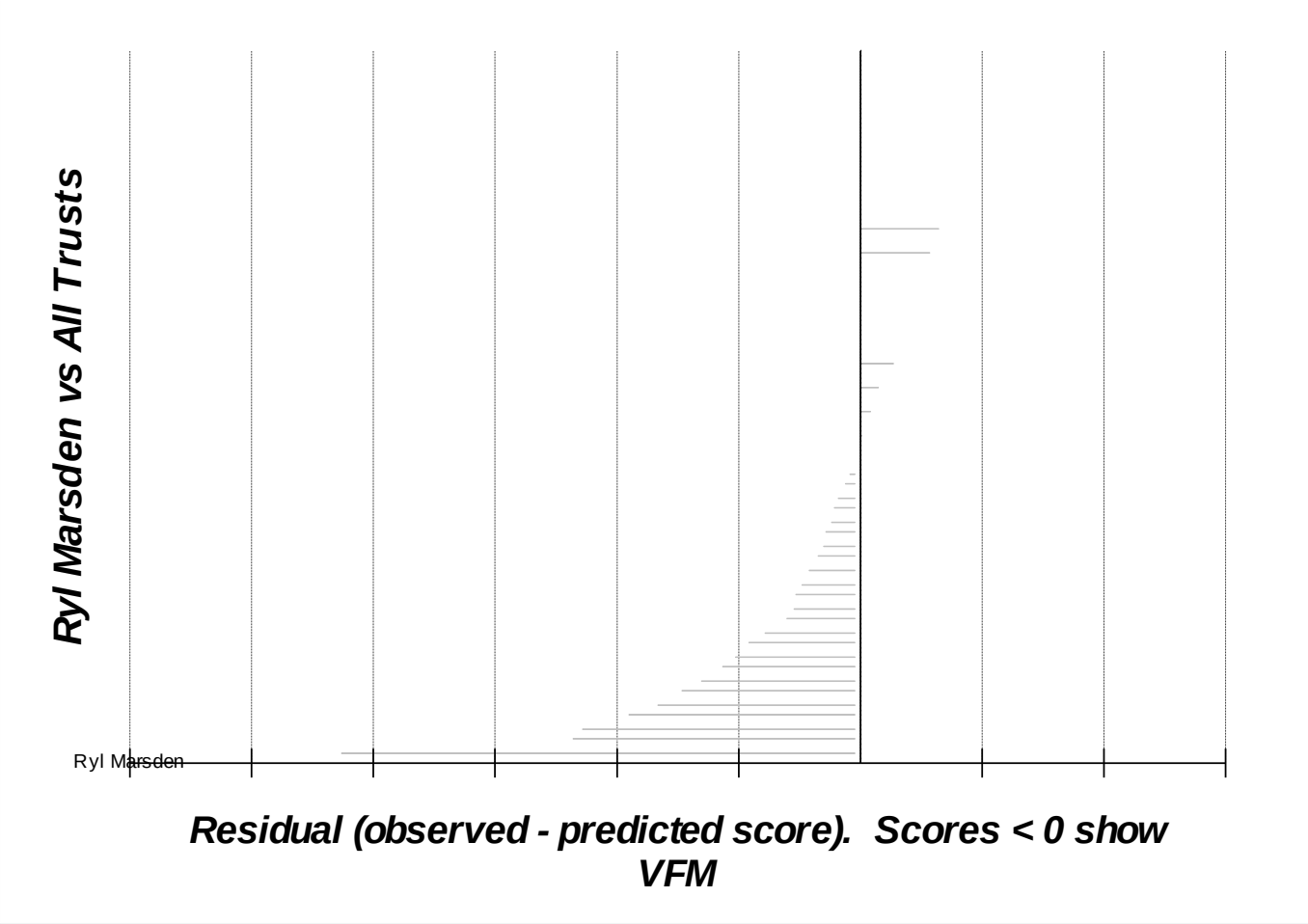
30 years experience of tertiary cancer institute IT systems development and operation at Royal Marsden Hospital, London

Demonstrating the importance of sustained innovation

Health IT in all NHS acute hospital trusts c 2000 - % of information items obtained by paper only



Health IT in all NHS acute hospital trusts c 2000 - Total expenditure and obtaining information



Communication and integration of services, across patient communities tells a different story

Survey of 750 patients with chronic conditions in each of USA, UK, Canada, Australia, New Zealand

- UK: 2/3 of patients not engaged in discussion about own treatment and care; 40% did not have goals of treatment made clear; 20% received conflicting information from different professionals
- UK: 20% were victims of medical error in past 2 years, 9% with serious consequences
- UK: 13% (US 22%) sent for duplicate tests, 1/2 have to repeat health history for different professionals, medical records not reaching consultation on time

Health Affairs, May 2003

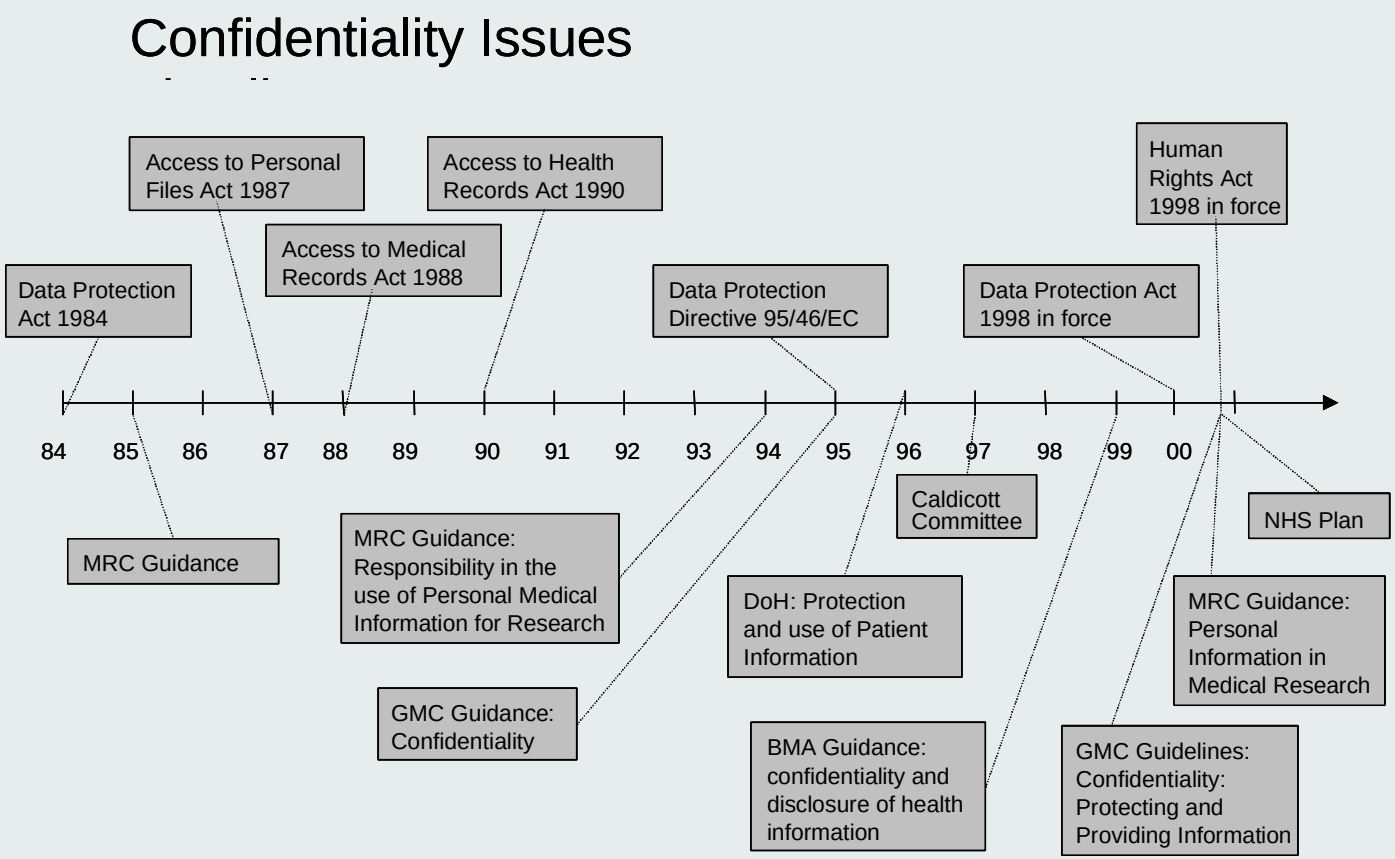
State of patient records leaves a lot to be desired

UK Audit Commission report on Patient Health Records, 1995

- 36% of case notes not immediately available
- Multiple records for patient in 75% of hospitals
- 40% of records poorly kept or not up-to-date
- 30% of history sheets inadequate
- 20% of prescriptions illegible
- 90% of discharge summaries contain no reference to information given to patients or relatives

US Institute of Medicine reported similar findings

Regulation - the letter of the law

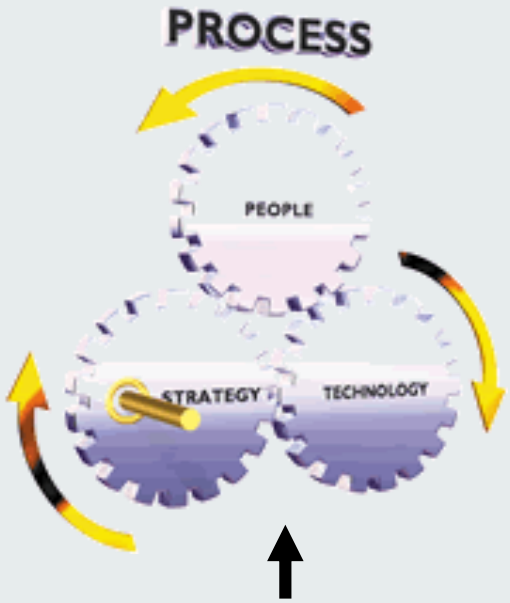


Meanwhile private investigators can acquire personal medical records within days

Loose talk!

!

A consultant writes:‘ Our approach towards CRM stems from the interaction of 4 key elements: **Strategy, People, Technology** and **Process**. These 4 elements combine in a **"Cogwheel process"** that drives the organisation.‘
CRM=Customer Relationships Management



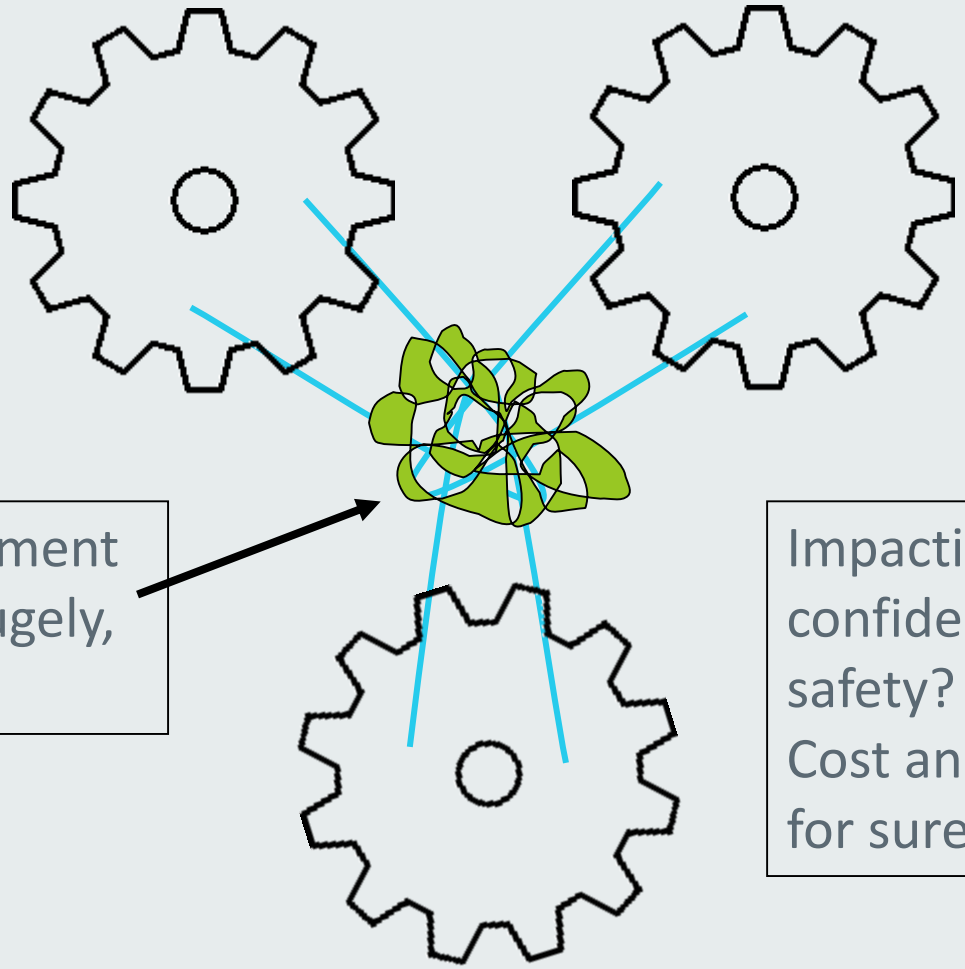
These gearwheels can’t turn
Try too hard and one will surely break the system

Loose talk, based on little or no evidence, purporting to integrate policy, requirements, and design & implementation of systems causes trouble – this is aspirational engineering

There's a lot around and it has led to health care information systems that are dangerously opaque and entangled

Clinical aspects

Technical aspects



This entanglement costs us all, hugely, in many ways

Impacting: confidentiality? safety? efficiency? Cost and efficiency for sure!

Organisational aspects

Barriers to progress

- Data standards
- Global – local requirements
- Governance
- Sustainability
- Multi-level, competing initiatives, lacking common strategy
- Restrictive IP – much that needs to be openly shared, debated and learned from is hidden from view

An international, on-line community, pooling efforts so that clinicians, developers and patients, everywhere, can work towards and benefit from compatible and high quality electronic healthcare records, based on an open, freely sharable, tried and tested common approach

www.openEHR.org

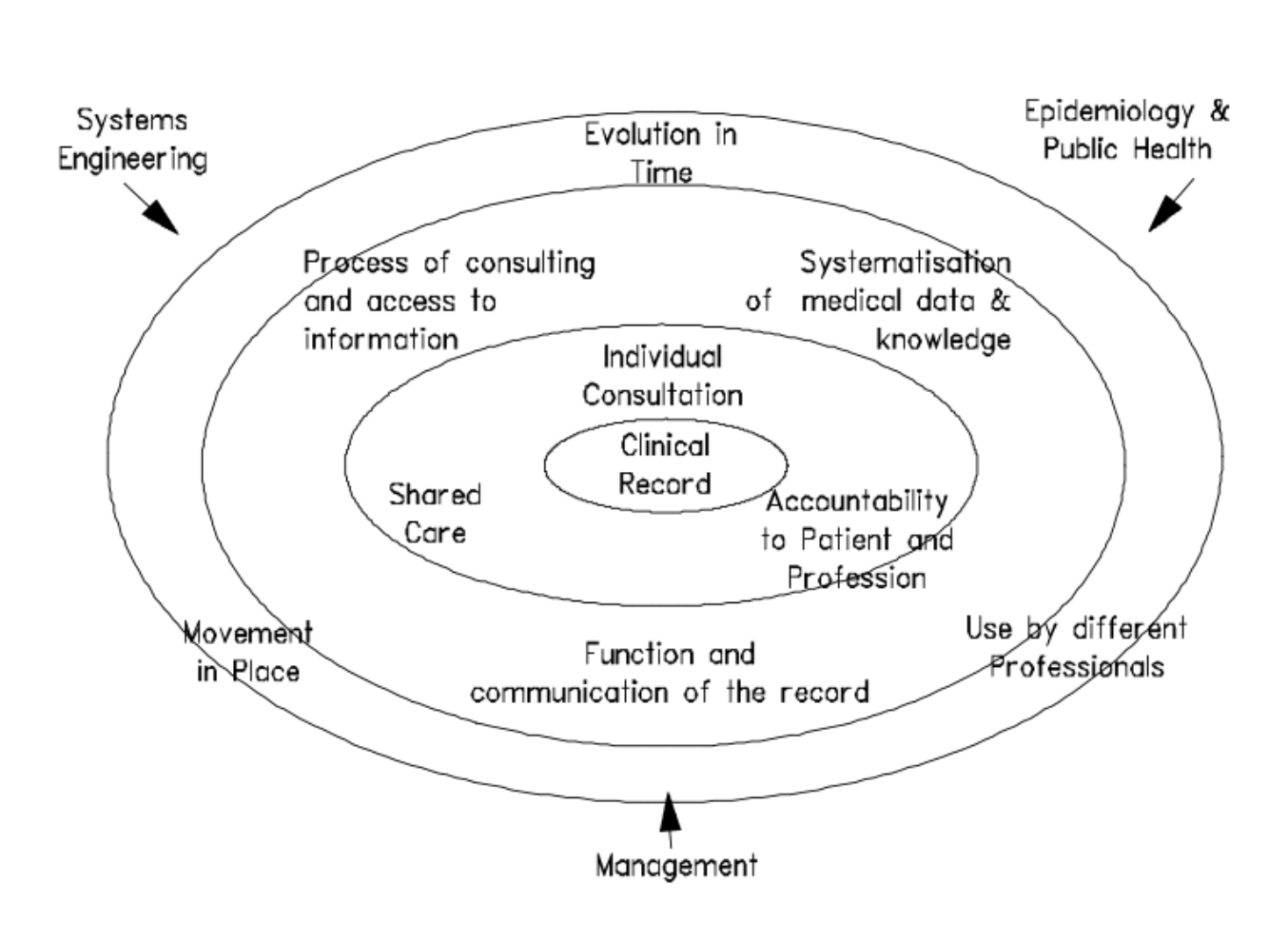
*The open*EHR Foundation - Working towards EHR standards, experimentally

EU Framework Programme: Objectives for Health Care, 1989

- Unify European activities by providing the means for efficient communication of medical records and knowledge so that these may be understood and compatible, thereby permitting the integration of health information systems
  - Strengthen competitiveness ... , Improve the quality of life ...
- AIM Framework 4, The GEHR Project, 1991-1994; to research and prototype the foundations of electronic health record architecture
- FP5, Services for Citizens; FP6, Knowledge Centres and the GRID; FP7, Integrated projects, Networks of Excellence

Niels Rossing, DG of AIM

An overview of requirements



Ingram, EU GEHR Project, 1991

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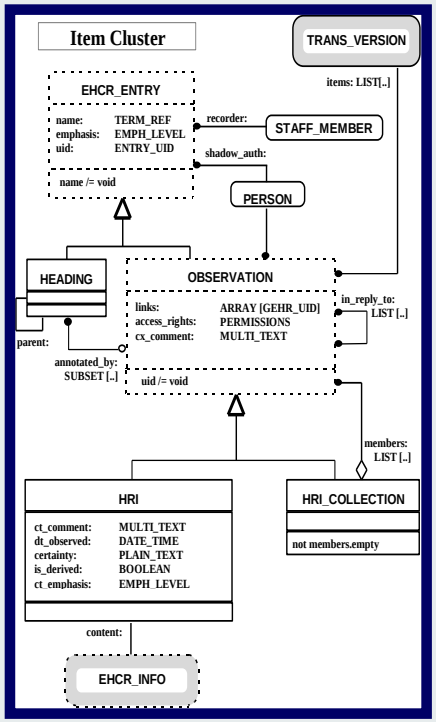
Taking forward the GEHR results

GEHR



GEHR architecture & object model

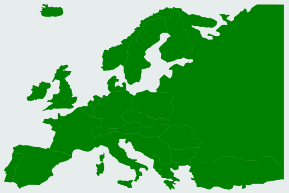
European standardisation

Env 12265

Local implementation, evaluation, refinement and dissemination

Ongoing research & development

CEN TC/251



En 13606

6WINIT

MEDICATE Innovation in Health

SynEx

EHCR SupA

Synapses

E-Science CLEF

International Standardisation
ISO-HL7-IHTSDO

ISO En 13606

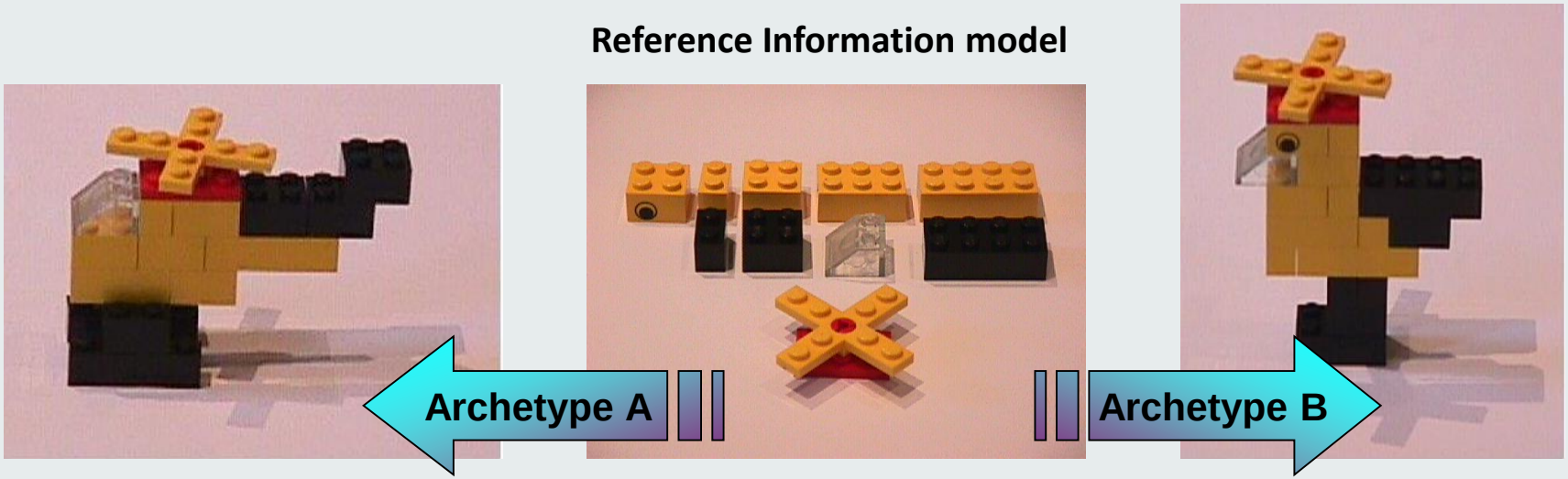
CIMI

*open*EHR

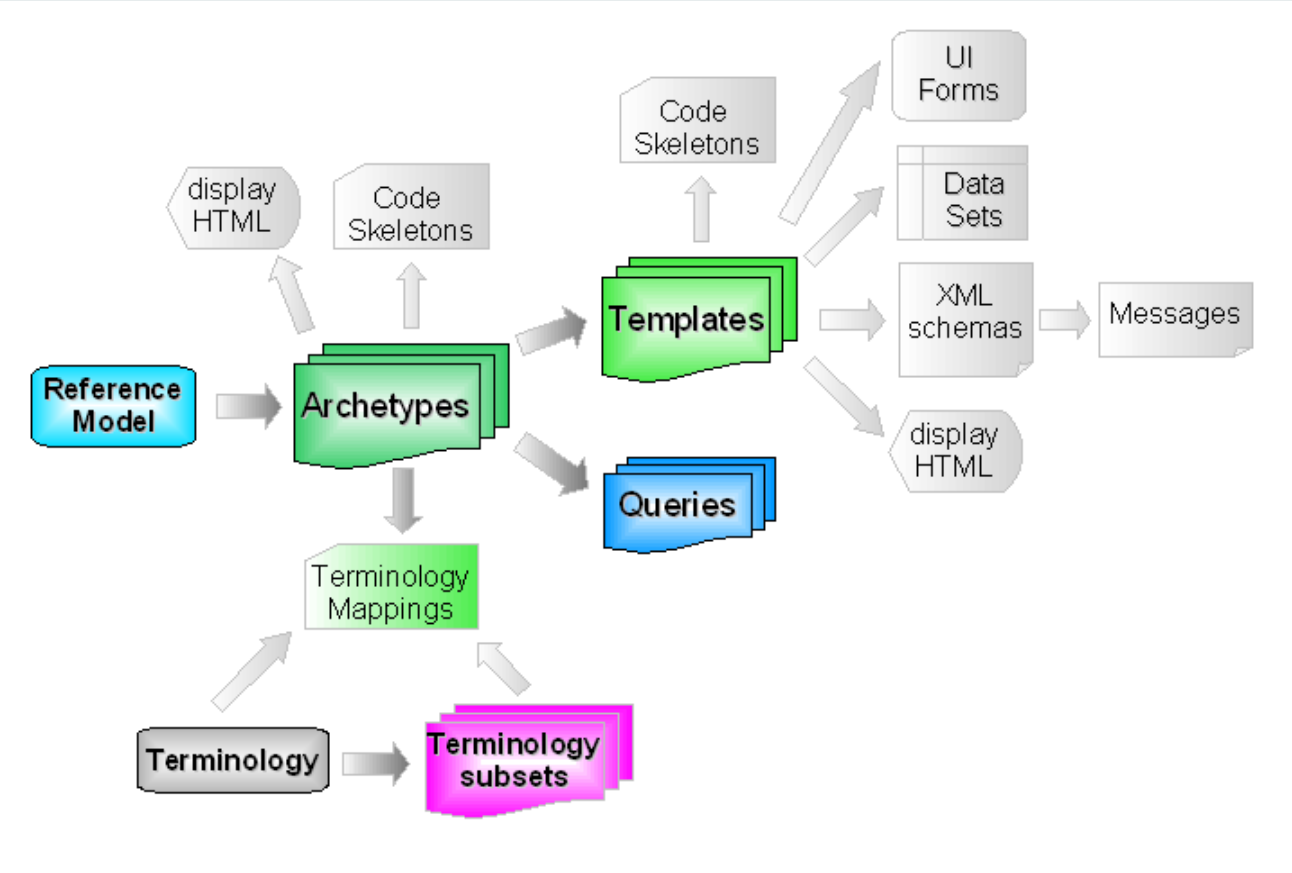
Australian GEHR & Ocean Informatics

LEGO® design analogy

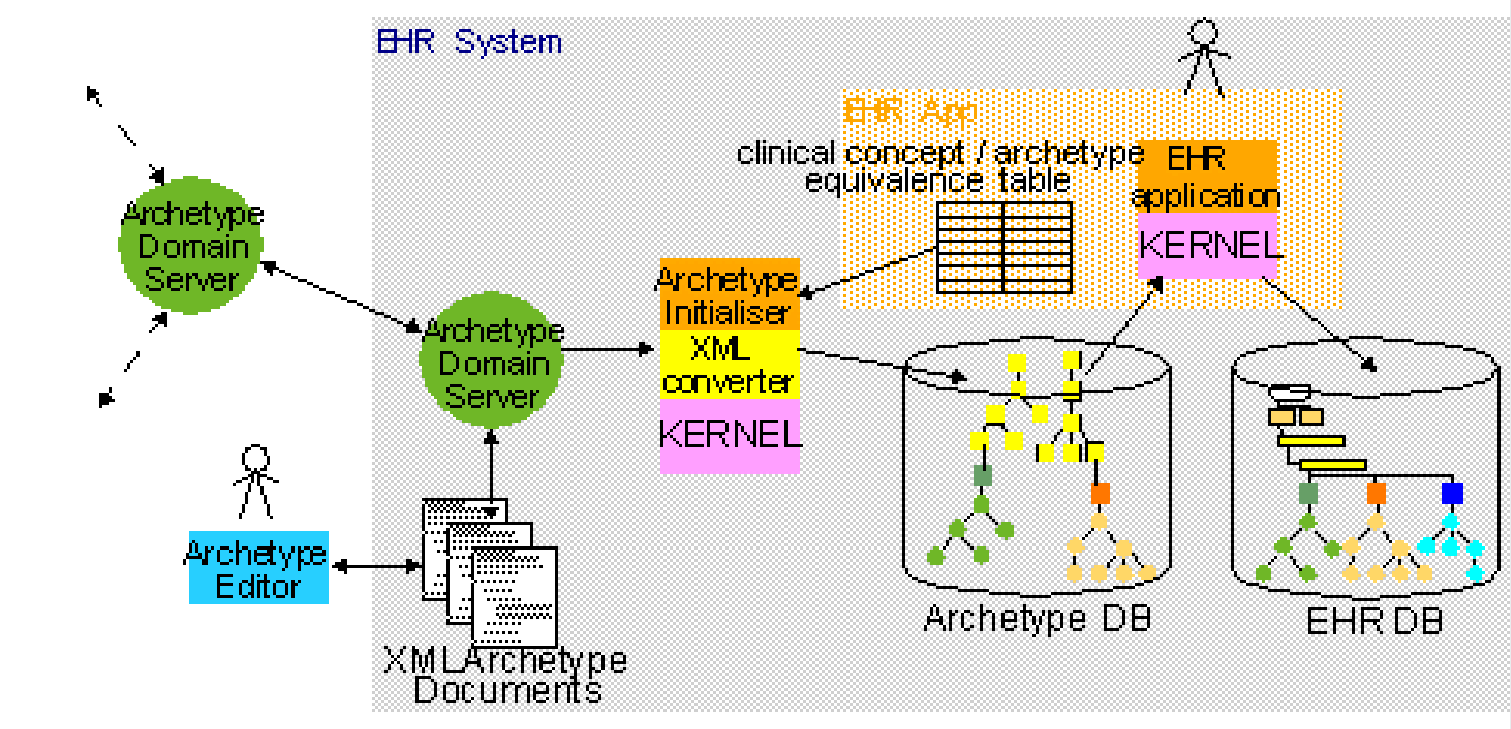
- The components of the *open*EHR Reference Model are like LEGO bricks
- openEHR Archetypes are instructions/designs constraining the use of LEGO bricks to create meaningful structures



*open*EHR artefact ecosystem



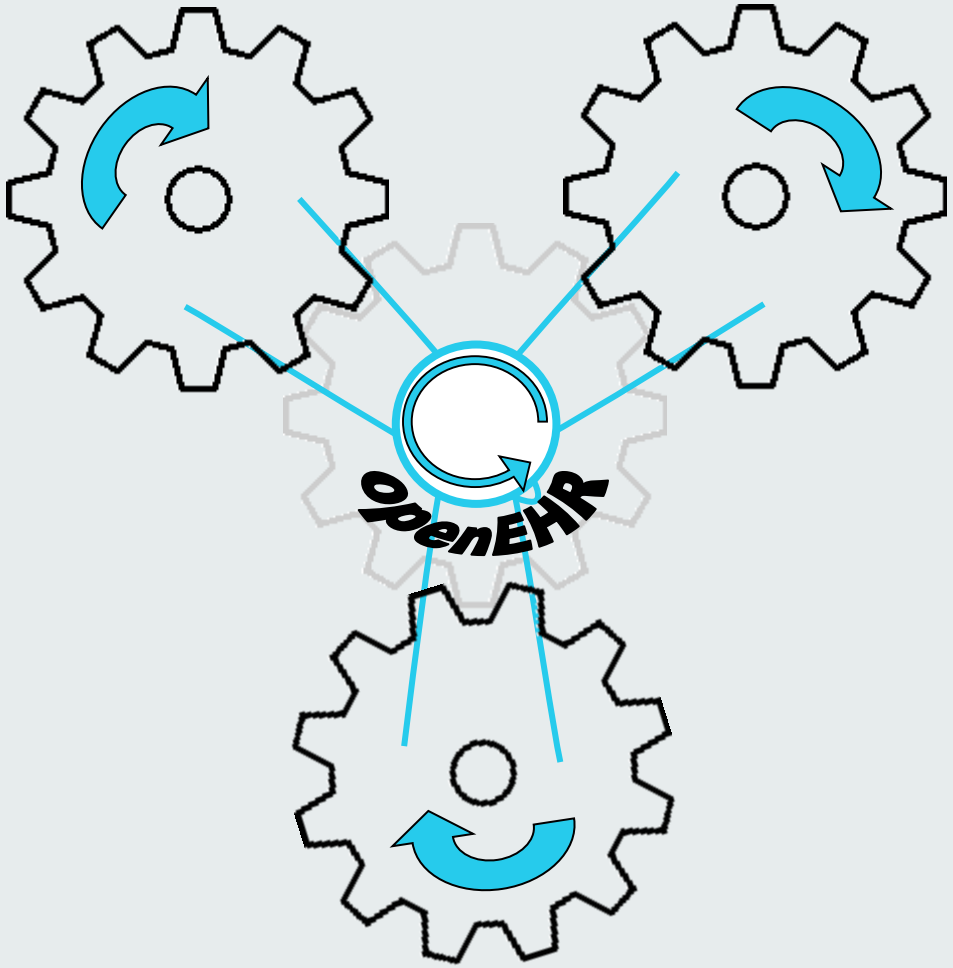
The essence of *open*EHR architecture



Locally customised (templated) clinical information archetypes, managed by generic clinical record middleware.

*open*EHR exists to help untangle clinical systems, so they can work better

Clinical aspects



Technical aspects

Organisational aspects

Responding to the challenge of communicating EHRs

Current attempts to standardise the capture, representation and communication of clinical data rely upon:

- generic models for representing clinical data
  - e.g. *open*EHR RM, ISO/EN 13606-1, HL7 CDA Release 2
- agreed clinical data structure definitions
  - e.g. *open*EHR/13606 archetypes, templates, data sets
- clinical terminology systems
  - e.g. SNOMED-CT, LOINC

The challenge is how to combine these most effectively to achieve the faithful and consistent sharing of clinical meaning

Structure and membership

- Not-for-profit organisation, based at University College London (UCL)
- Established by UCL and Ocean Informatics in 2002, to own the specifications and other collective intellectual property (IP). Based on 16 years of R&D
- Now a worldwide collaboration overseen by
  - Foundation Board – 5 strong, 4 clinical
  - Specifications Group – CEN, ISO, CIMI, IHTSDO
  - Software Group – JAVA, Ruby, .NET, Python
  - Clinical Editorial Group – 800 clinicians using CKM
  - Localisation Group – Japan, New Zealand, Brazil, Europe

Technical motivation of *open*EHR

The *open*EHR approach has been to develop a technical and semantic *platform* for health information systems which addresses four challenges:

- **Meaning preservation** - throughout systems and communications
- **Information sharing** – among systems and applications
- **Information aggregation** - leading to computability
- **Evolution** - of systems and information over time

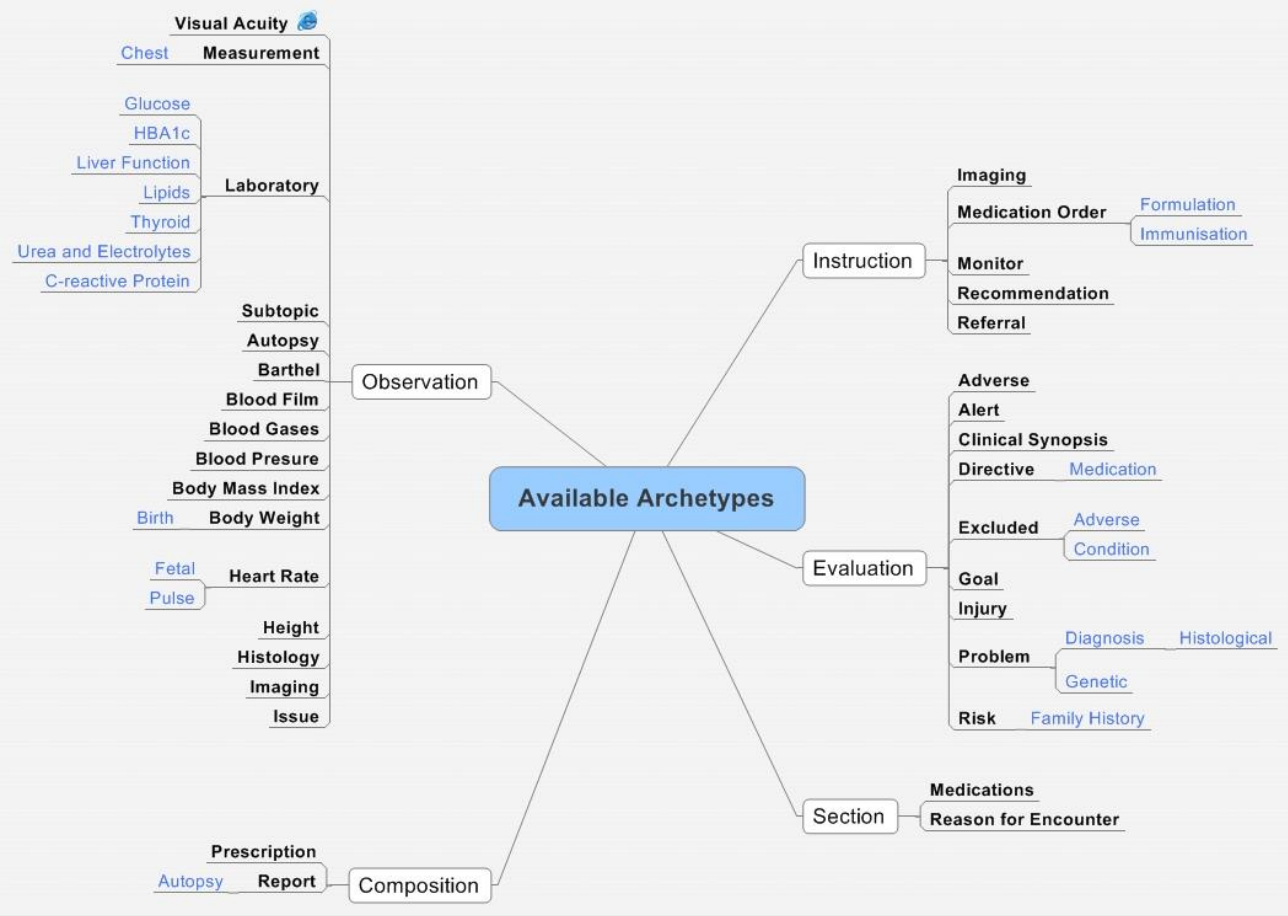
Technical approach of openEHR

- A semantic framework within a services architecture
- Development by engineering design team with open review and formal change management
- All specifications are implemented and tested before release
- Specifications all mutually consistent
- *Living* specifications – a programme for maintenance

Technical deliverables

- A powerful reference information model
- *open*EHR archetypes: software-independent clinician-authored models of content
- *open*EHR templates: a formal basis for localised re-use of content models
- Practical and bounded use of terminologies
- Control over data entry quality
- Portable query language for health records
- A knowledge-enabled service interface to the EHR

Banks of curated, clinician-define archetypes



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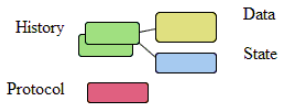
Archetype structure

Blood gas assessment: *Observation*

Generated by the Ocean HTML generator: 18/05/2006 *Comments to* Ocean Informatics

Concept	Archetype Id	Structure
The assessment of blood gas concentrations and acid-base balance in blood	*Id*: openEHR-EHR-OBSERVATION.blood_gases.v1 *Reference model*: EHR ADL	

Data: *TREE*

Arterial, Arterial readings. ***Cluster*** (0..1) optional

Concept	Description	Type	Cardinality	Values
Q **PaO2**	The oxygen pressure in the arterial blood	***Quantity***	optional 0..1	*Property* = PRESSURE *Units*: kPa, (>= 0)
Q **PaCO2**	The carbon dioxide pressure in the arterial blood	***Quantity***	optional 0..1	*Property* = PRESSURE *Units*: kPa, (>= 0)
Q **pH**	The negative logarithm of the Hydrogen ion concentration in blood	***Quantity***	optional 0..1	*Property* = CONCENTRATION *Units*: [pH], (0..14)
Q **Base excess**	The relative excess of alkaline	***Quantity***	optional 0..1	*Property* = CONCENTRATION *Units*: mmol/l, (-30..30)
Q **Alveolar-arterial pO2 difference**	The difference between the pressure of oxygen in the alveolar and the artery	***Quantity***	optional 0..1	*Property* = PRESSURE *Units*: kPa, (0..1000)
Q **SaO2**	The saturation of haem binding with oxygen	***Quantity***	optional 0..1	*Property* = PROPORTION *Units*: %, (0..100)
T **Site**	The site of sampling	***Coded text***	optional 0..1	*Terminology* Any term that 'is_a' artery or cavity
Q **CaO2**	The oxygen content of arterial blood	***Quantity***	optional 0..1	*Property* = CONCENTRATION *Units*: {VOLUME/VOLUME}, (>= 0)

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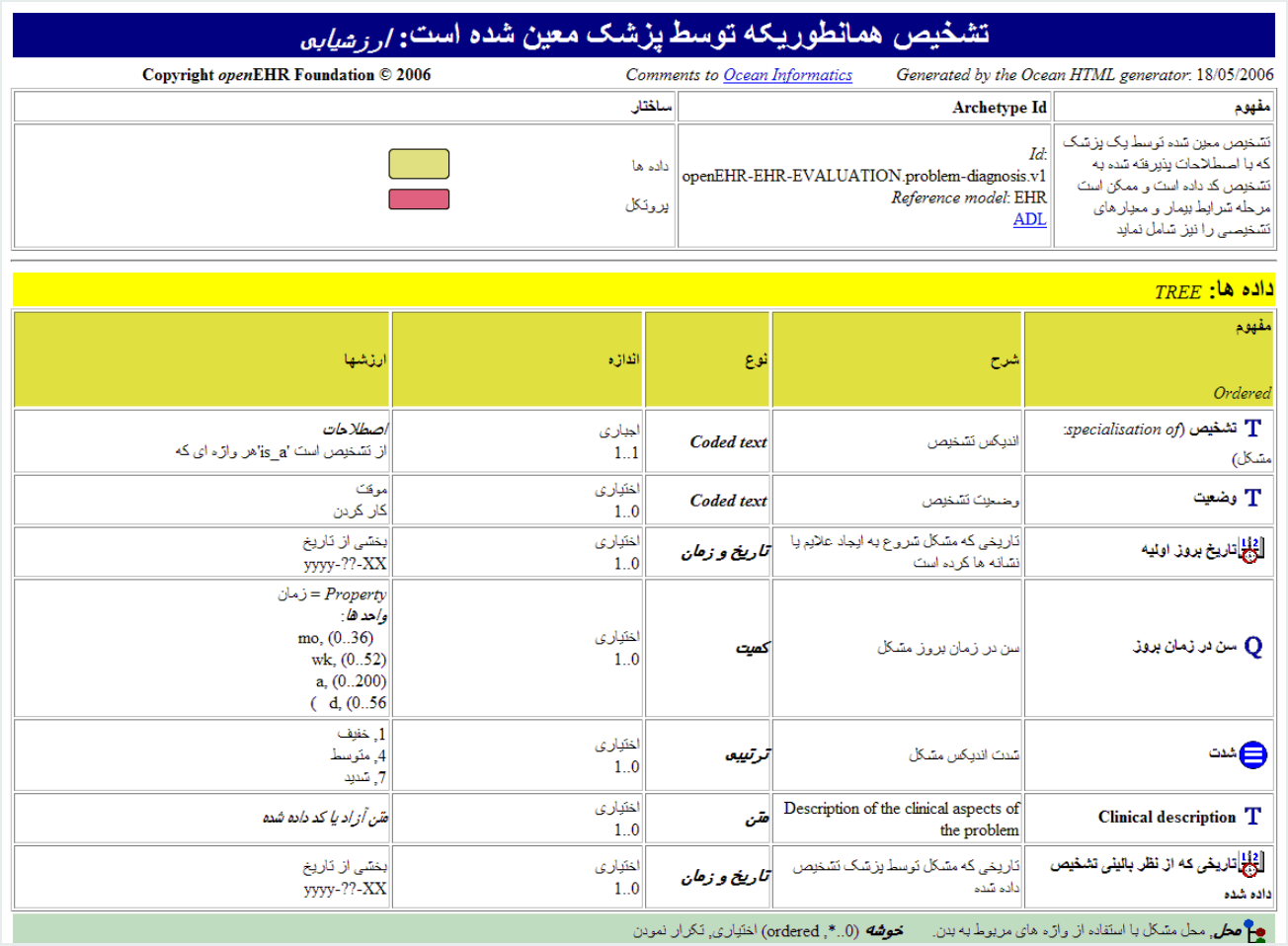
Multi-lingual capability



تشخیص همانطوریکه توسط پزشک معین شده است: *ارزشیابی*

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مفهوم	Archetype Id	ساختار
تشخیص معین شده توسط یک پزشک که با اصطلاحات پذیرفته شده به تشخیص کد داده است و ممکن است مرحله شرایط بیمار و معیارهای تشخیصی را نیز شامل نماید	*Id*: openEHR-EHR-EVALUATION.problem-diagnosis.v1 *Reference model*: EHR ADL	داده ها پروتکل

داده ها: *TREE*

مفهوم *Ordered*	شرح	نوع	اندازه	ارزشها
T **تشخیص** (*specialisation of*: مشکل)	اندیکس تشخیص	***Coded text***	اجباری 1..1	***اصطلاحات*** از تشخیص است 'is_a'هر واژه ای که
T **وضعیت**	وضعیت تشخیص	***Coded text***	اختیاری 1..0	موقت کار کردن
تاریخ بروز اولیه	تاریخی که مشکل شروع به ایجاد علایم یا نشانه ها کرده است	***تاریخ و زمان***	اختیاری 1..0	بخشی از تاریخ yyyy-??-XX
Q **سن در زمان بروز**	سن در زمان بروز مشکل	***کمیت***	اختیاری 1..0	*Property* = زمان ***واحد ها***: mo, (0..36) wk, (0..52) a, (0..200) (d, (0..56
شدت	شدت اندیکس مشکل	***ترتیبی***	اختیاری 1..0	1, خفیف 4, متوسط 7, شدید
Clinical description T	Description of the clinical aspects of the problem	***متن***	اختیاری 1..0	***متن آزاد یا کد داده شده***
تاریخی که از نظر بالینی تشخیص داده شده	تاریخی که مشکل توسط پزشک تشخیص داده شده	***تاریخ و زمان***	اختیاری 1..0	بخشی از تاریخ yyyy-??-XX

محل: محل مشکل با استفاده از واژه های مربوط به بدن. ***خوشه*** (0..*, ordered) اختیاری, تکرار نمودن

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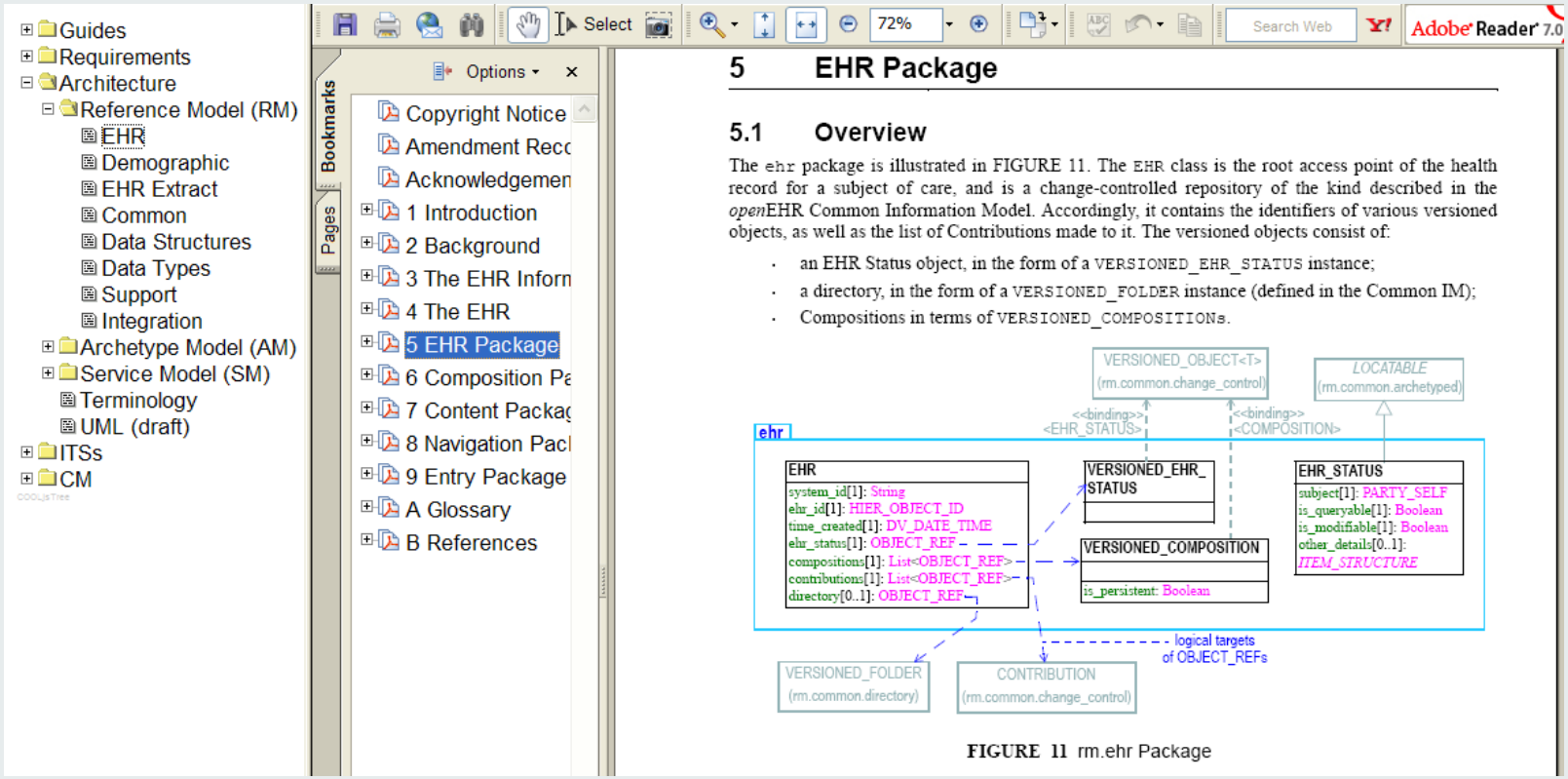
Architecture specifications



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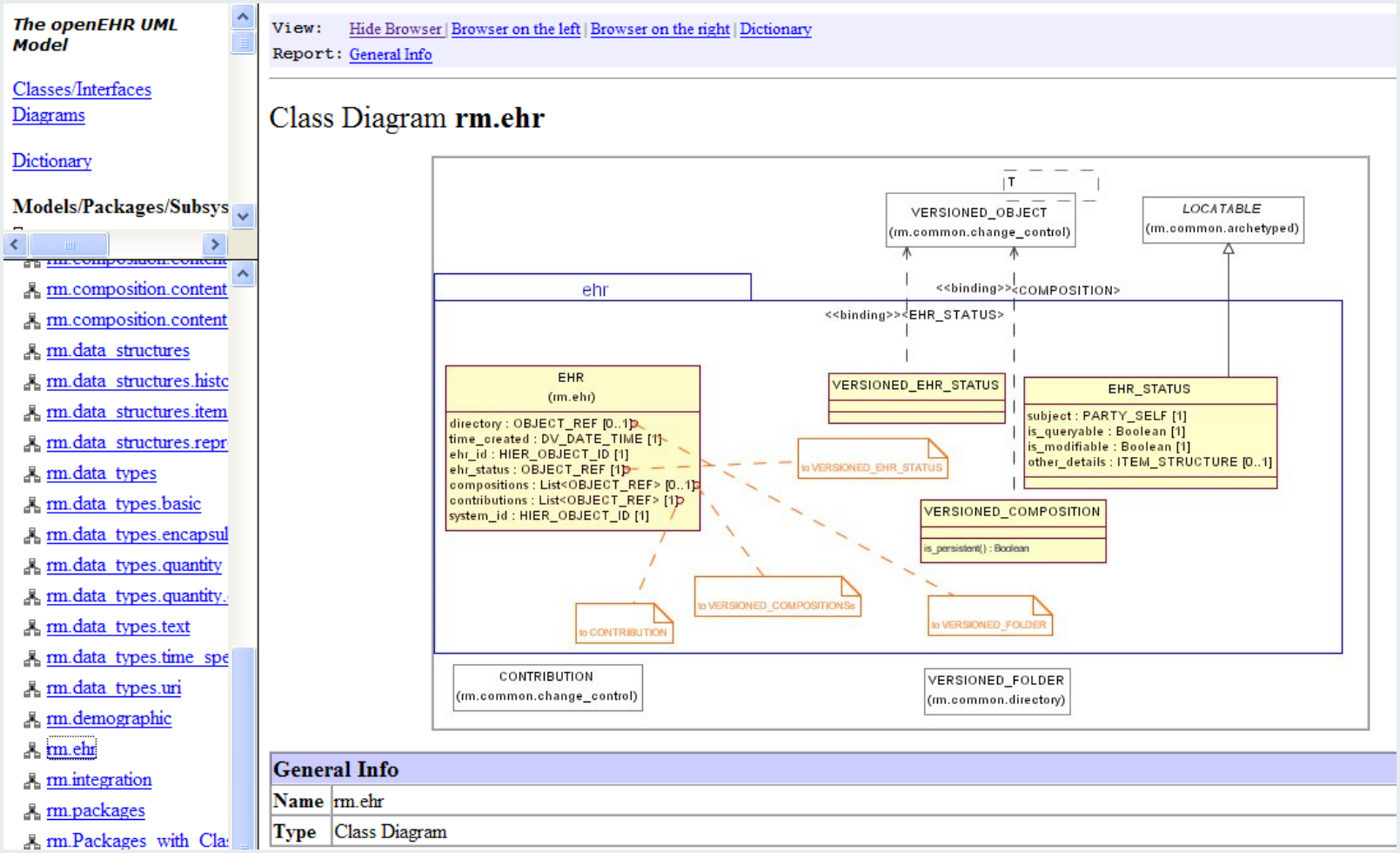
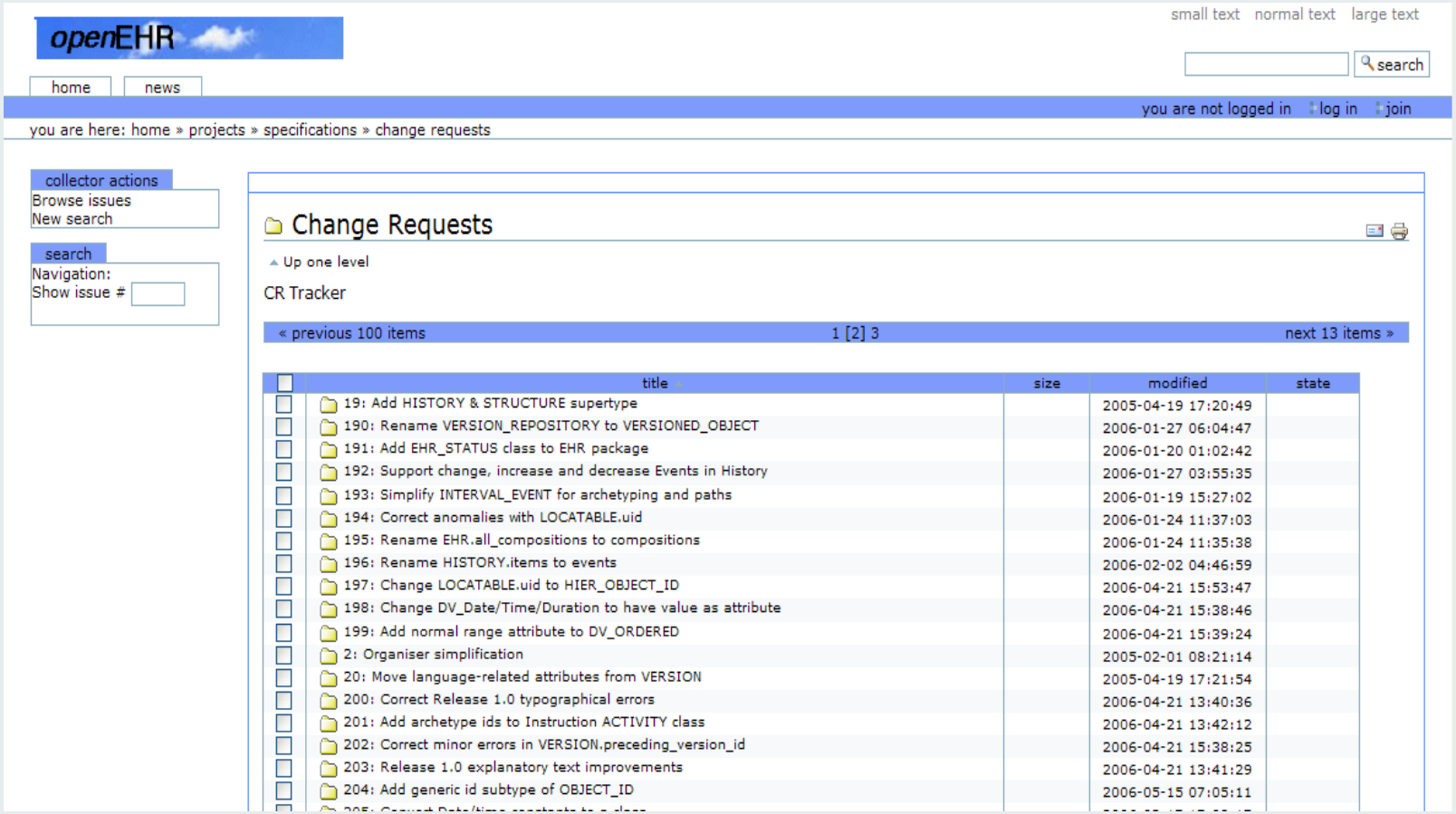
UML representation

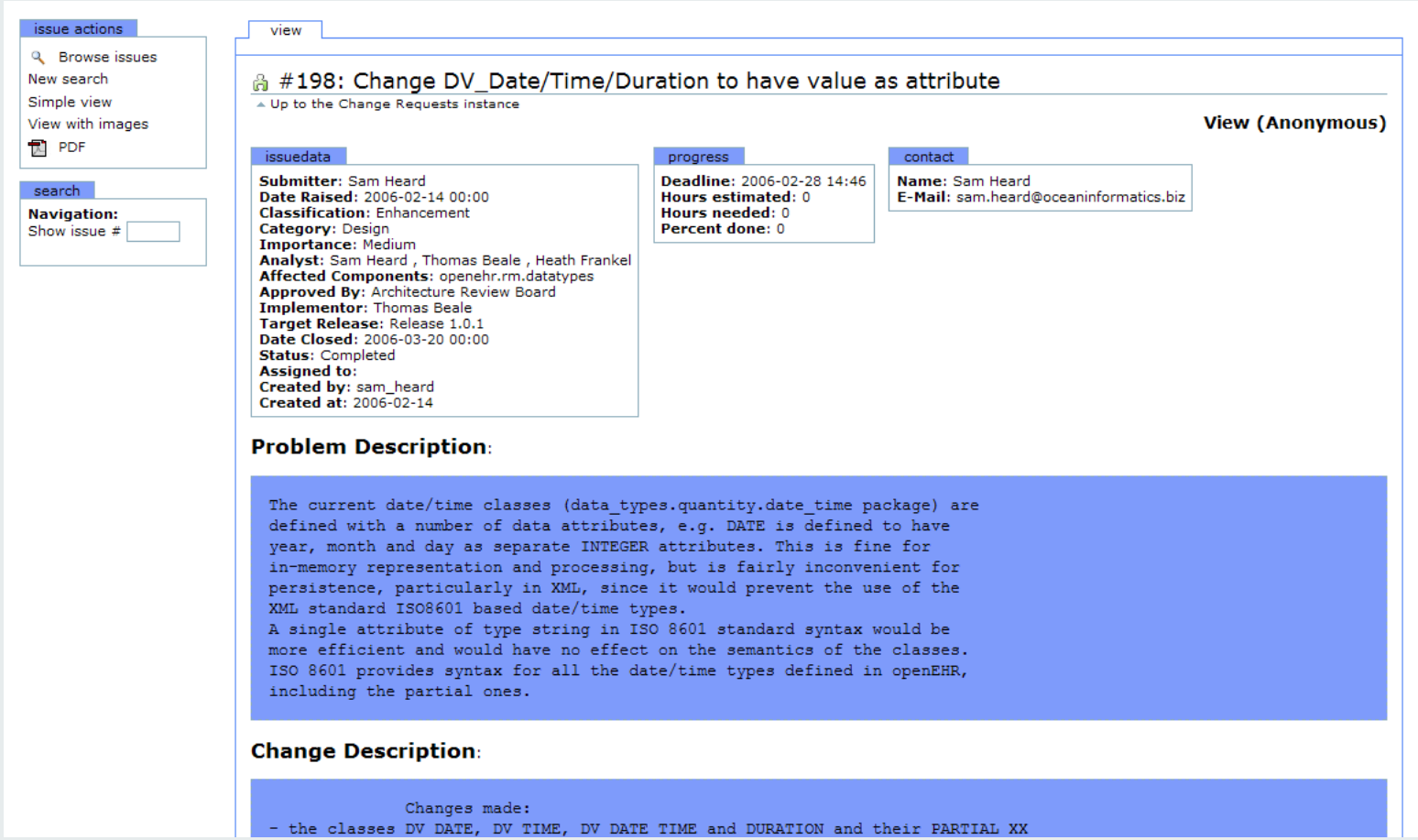


openEHR

Change management



Example: Change request



issue actions

Browse issues
New search
Simple view
View with images
PDF

search

Navigation:
Show issue #

view

#198: Change DV_Date/Time/Duration to have value as attribute

Up to the Change Requests instance

View (Anonymous)

issuedata

Submitter: Sam Heard
Date Raised: 2006-02-14 00:00
Classification: Enhancement
Category: Design
Importance: Medium
Analyst: Sam Heard , Thomas Beale , Heath Frankel
Affected Components: openehr.rm.datatypes
Approved By: Architecture Review Board
Implementor: Thomas Beale
Target Release: Release 1.0.1
Date Closed: 2006-03-20 00:00
Status: Completed
Assigned to:
Created by: sam_heard
Created at: 2006-02-14

progress

Deadline: 2006-02-28 14:46
Hours estimated: 0
Hours needed: 0
Percent done: 0

contact

Name: Sam Heard
E-Mail: sam.heard@oceaninformatics.biz

Problem Description:

```
The current date/time classes (data_types.quantity.date_time package) are
defined with a number of data attributes, e.g. DATE is defined to have
year, month and day as separate INTEGER attributes. This is fine for
in-memory representation and processing, but is fairly inconvenient for
persistence, particularly in XML, since it would prevent the use of the
XML standard ISO8601 based date/time types.
A single attribute of type string in ISO 8601 standard syntax would be
more efficient and would have no effect on the semantics of the classes.
ISO 8601 provides syntax for all the date/time types defined in openEHR,
including the partial ones.
```

Change Description:

```
              Changes made:
- the classes DV_DATE, DV_TIME, DV_DATE_TIME and DURATION and their PARTIAL XX
```

openEHR

Features and benefits

- Enables clinical control of semantic interoperability through archetypes
- Allows evolution of representation of clinical concepts over time
- Dissociates electronic health care records from dependency on particular clinical software applications or particular health care information infrastructures
- ‘Future-proofs’ health records for lifelong care
- Has been shown to provide a more sustainable code base for clinical systems, up to 8x more time-efficient to maintain than traditional database methods

State of play, today

- Comprehensive EHR specification
  - Information model, Archetype model, Communication specification, Service specification
- Growing
  - base of implementation experience and learning, in real-life settings
  - set of tools - .NET, JAVA, Ruby, Python
  - community of developers and users, organised within national/regional associations
- Linkage with clinical research, clinical trials standards and education

Outcomes

*open*EHR is now found…

- in CEN/ISO EN13606-1 and -2
- in around 15 commercial products
- in the CIMI content standardisation initiative
- in the e-health programmes of the UK, Denmark, Sweden, Australia and Brazil, with another 10 or so countries moving towards it
- In national chapters in Japan, New Zealand and Brazil
- in dozens of universities
- in a growing number of enterprise clinical and secondary applications

Need to extend *open*EHR's governance, in order to:

- Broaden input to *open*EHR policy and strategy, through strategic partnership and collaboration
- Strengthen its mission, while enabling it to sustain its focus on clinical implementation
- Widen clinical and health informatics community, government and industry acceptability of what it offers
- Attract financial support
- Promote higher and more active profile and role in e-health programmes

openEHR

Cancer genomics clinical trials, opthalmology, machine learning

Some related new open source and open data initiatives

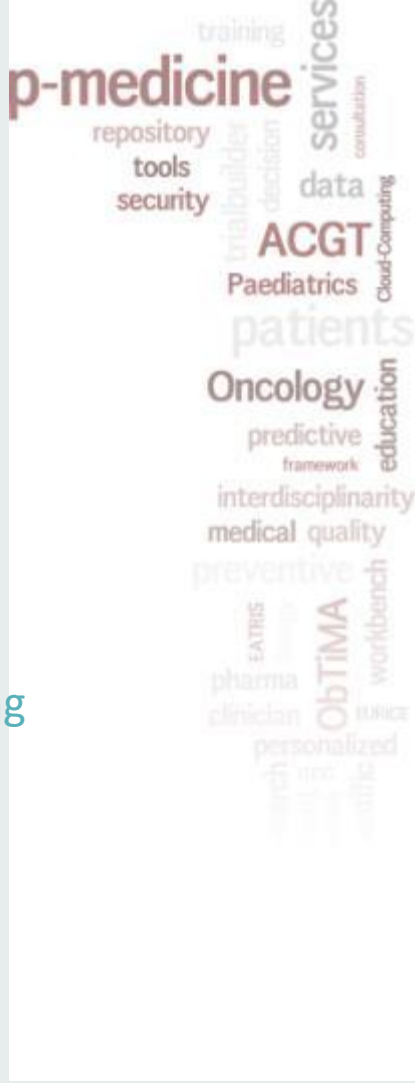
Towards personalized medicine

Clinical champion – Norbert Graf, paediatric oncologist

- **Data integration**
  - Clinical data, imaging data, molecular data, etc.
- **Legal and ethical issues**
- **System biology models**
- **Tools and models**
  - Clinically driven, re-usable, modular, interoperable
  - Evaluated and user friendly
  - Validated and standardized for reuse
  - Certified
- **Logistics**
  - IT infrastructure handling vast amounts of data
  - Access to high performance computing
  - Availability of data in due time
- **Sustainability**

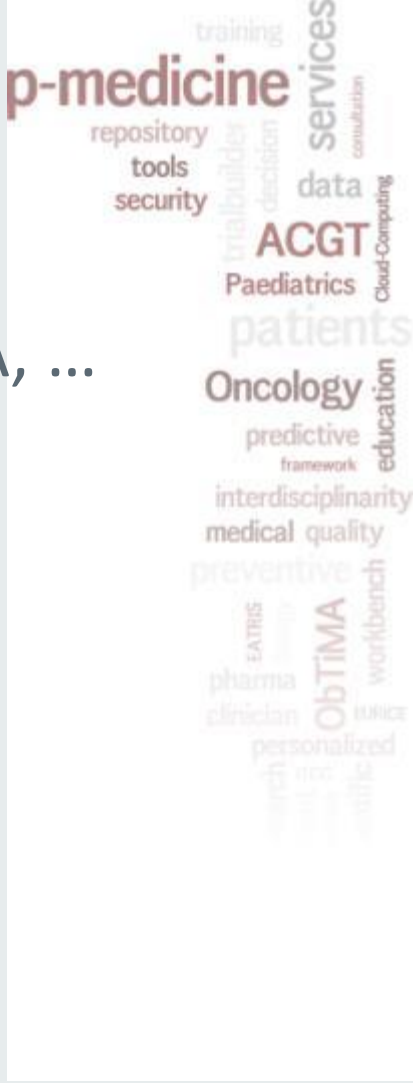
Why?

- The conduct of clinical trials in Europe is characterized by
  - Redundant paperwork
  - Liability tangle
  - Complicated legal and ethical regulations causing an unending bureaucracy
  - Lack of easy to use open-source data management systems
- Translational Research needs an infrastructure and more funding
  - The gap between clinical research and basic research is increasing
- p-medicine solving many of the above mentioned items needs:
  - Maintenance and
  - Sustainability
- More patients have to be enrolled in clinico-genomic trials
- Patients have to play a more active role in clinical trials
- Not all patients do receive the best available treatment
  - Wrong treatment harms patients and increases health costs unnecessarily
- Information overload covers relevant and reliable information
- Curricula of Medical Schools have to adapt to the need of IT possibilities to achieve the goal of a personalized and better medicine in future



Collaborations

- SIOP, ENCCA, GPOH, BBMRI, ECRIN, EURECA, …
- US Food and Drug Administration (FDA)
  - Biovista's Clinical Outcome Search Space™
    - Predictions of adverse events
      - Verification with foreign academic community
      - Usage in the design of future clinical trials
- European Medicines Agency (EMA)
  - Biomarker Qualification procedure
    - Guidance document for qualification of Biomarker
    - Advice and input from
      - Innovation Task Force
      - Pharmacogenomics Working Group



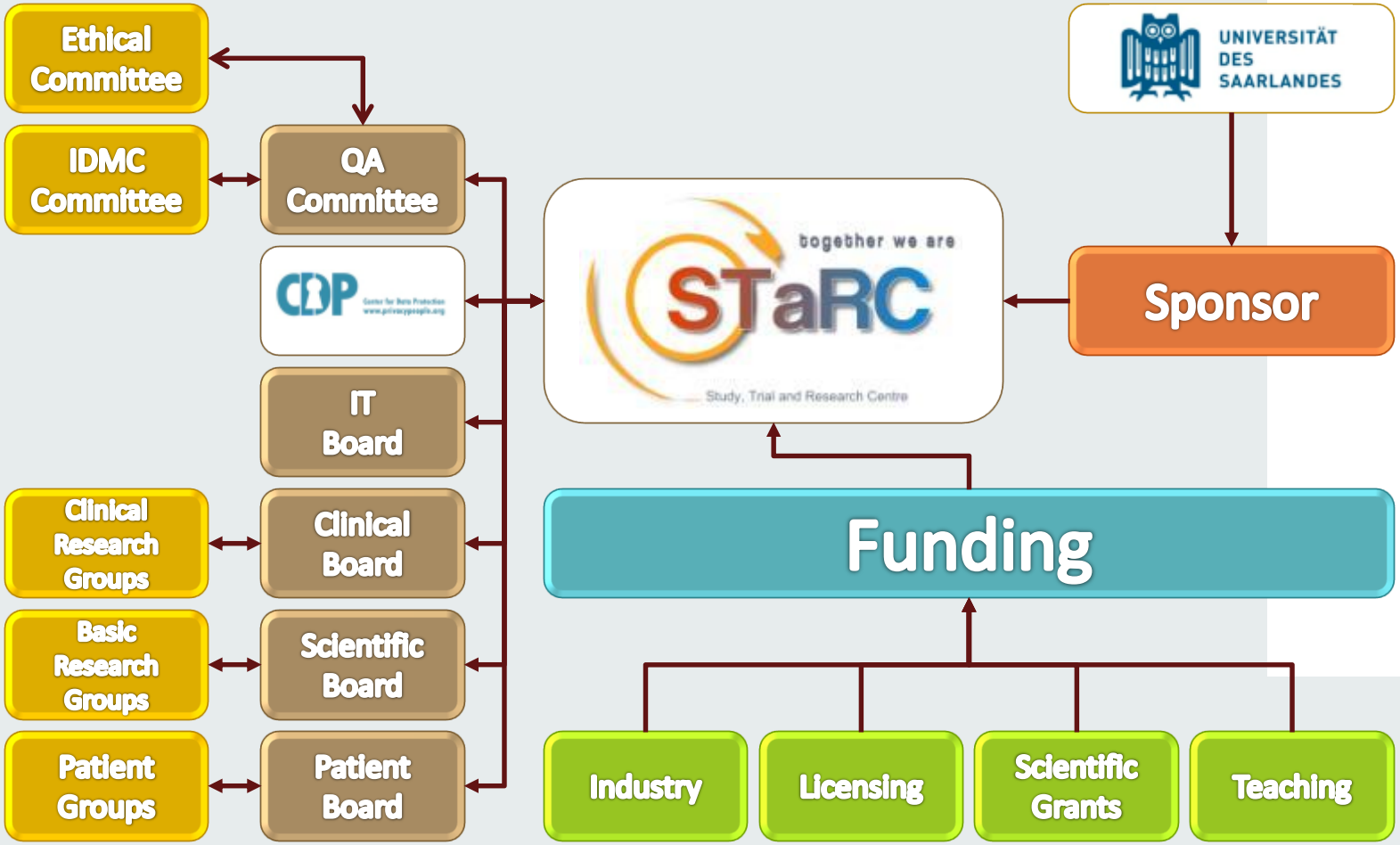
General aspects

- Three cancer domains
  - Acute lymphoblastc leukemia
  - Breast cancer
  - Nephroblastoma
- Scenario based
  - 52 use cases are defined
- Legal and ethical framework
  - Informed consent
  - Anonymization/pseudonymization
  - Contracts
- Open source, retro- and prospective data
  - Clinical, DICOM, molecular, …

Sustainability

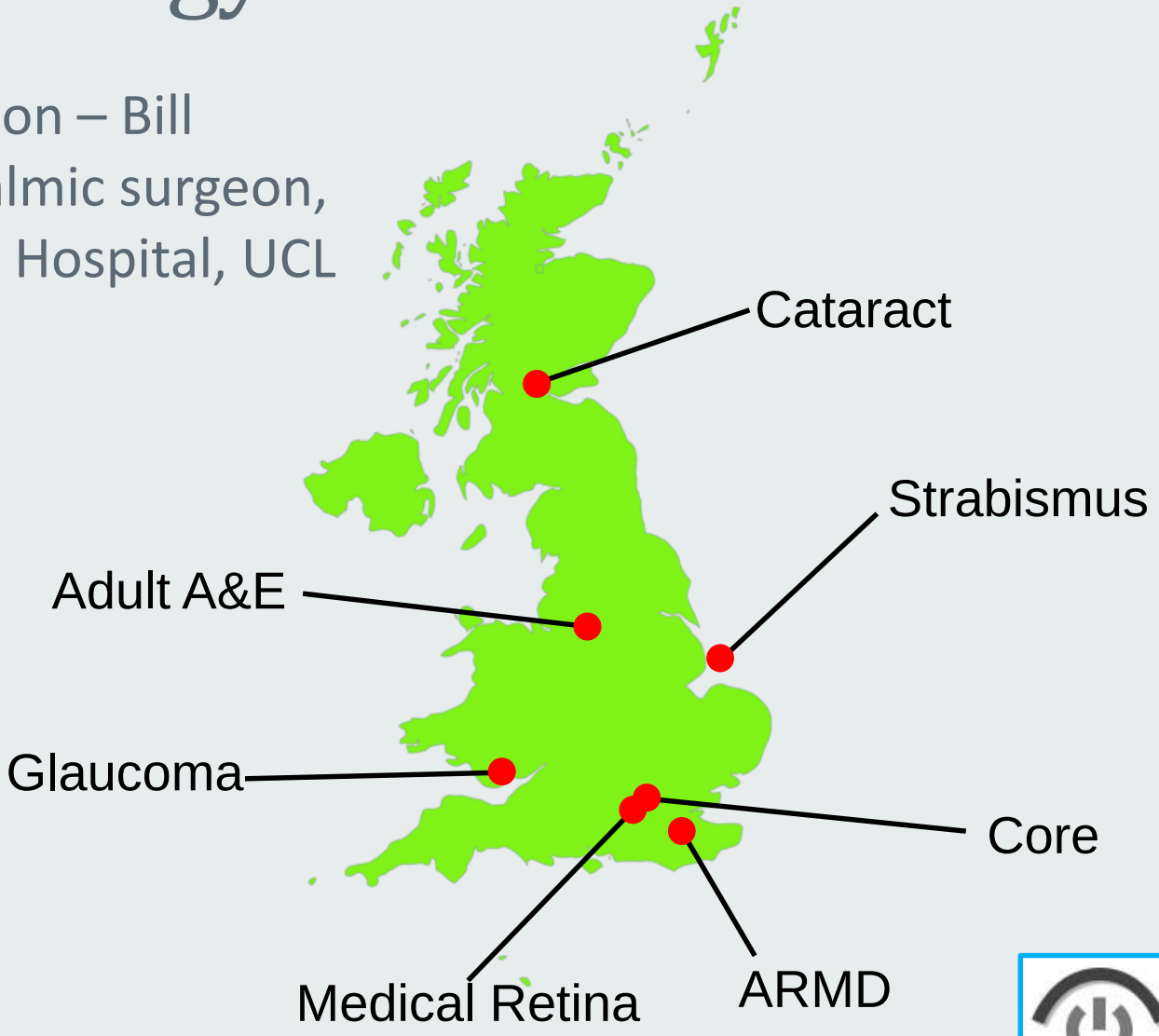
- Business goals
  - Discover knowledge
  - Explore hypothesis
  - Personalize treatment
  - Empower patients
  - Share data
  - Share knowledge

Sustainability



OpenEyes Collaboration for Opthalmology Records

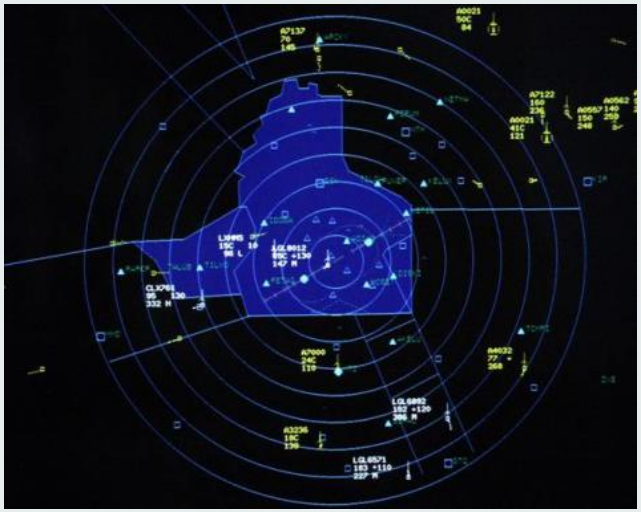
Clinical champion – Bill Aylward, opthalmic surgeon, Moorfields Eye Hospital, UCL Partners



What will OpenEyes do?

1) Get data into electronic form

2) Integration




MOORFIELDS EYE HOSPITAL
CONFIDENT

Albert Hall - 2000101

user: John Saunders firm: Garway-Heath Firm service: Glaucoma Service

Find patient | Summary | Clinical | Spare | Diagnoses | Contacts | Home | Logout

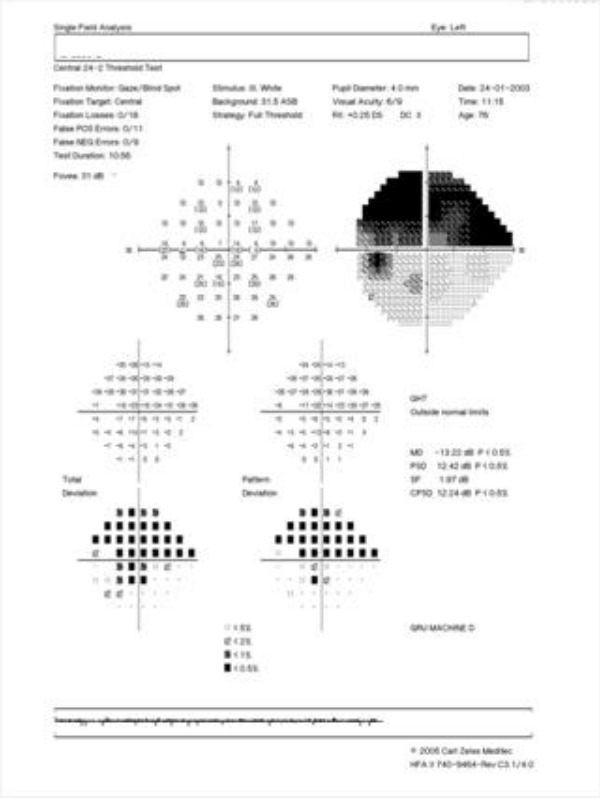
- Vitreoretinal
- Glaucoma
  - 08/11/2010
  - 08/11/2010

Record successfully saved

Date: 8th November 2010 User: John Saunders Event: Visual field

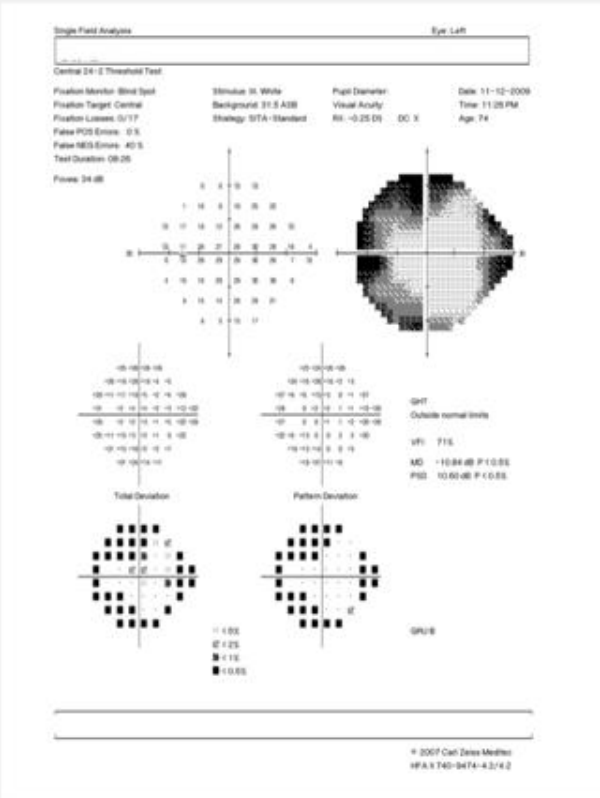
Right Eye:

Pattern: 10-2 Strategy: SITA Standard



Left Eye:

Pattern: 10-2 Strategy: SITA Standard



Timeline

Feb 2010	Project initiated
Nov 2010	Pilot (Paediatric A&E)
Jan 2012	V0.9 (Booking, WL management)
Jun 2012	V1.0 (Cataract/glaucoma)
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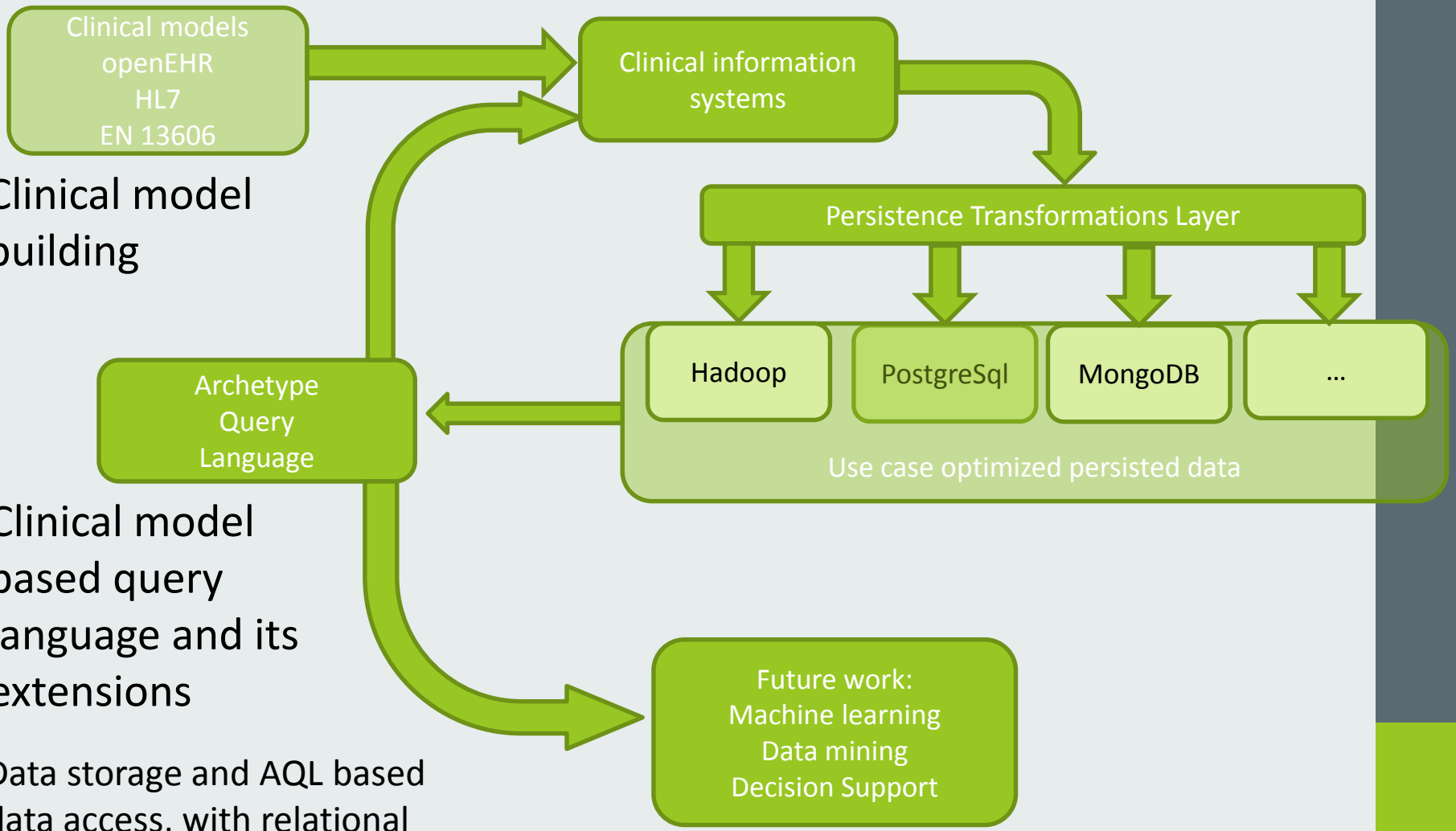
Dec 2013	All subspecialties covered

Clinical data management for machine learning: Opereffa framework

- Data mining tools and frameworks are usable mostly for statisticians, computer scientists
- They are expensive. More expensive if you want to scale
- Open-source frameworks help with the cost, but they are still tools for the few, and don't mean much to clinicians
- openEHR has been helping clinicians take control, to deliver efficient clinical information systems
- Can it also help them improve CDS/mathematical modelling/machine learning?
- Opereffa attempts to find out

UCL CHARING SYSTEMS

Opereffa Architecture



Clinical model building

Clinical model based query language and its extensions

Data storage and AQL based data access, with relational databases, are already being published open-source

UCL

CHARING SYSTEMS

Opereffa framework: plans for future

- Proven, open source persistence stacks aligned along the scale axis: PostgreSql, MongoDB, Hadoop
- High performance open source parallel processing frameworks for scaling up: Akka, Hadoop
- Tooling to eliminate complicated technology & infrastructure management process: Eclipse framework
- Number 1 domain to learn from: finance.
- Bring all these technologies together with a strongly model driven approach, for outcomes that are portable to other domains.

UCL CHARING SYSTEMS

Case for greater use of open-source frameworks

- Promote effective and efficient developer communities
  - pioneers traditionally have had to build whole local infrastructures
  - many wheels still being reinvented, unnecessarily
- Pool costs of development and maintenance of essential infrastructure
- Enable research interface – discipline grows through sharing, review and testing of methods
- Improve procurement – ability to see what's under the bonnet
- Support integration – combat fragmentation

But there must be a business case – government and industry support is needed for the transition to an open-source community

The growing worldwide community of openEHR would welcome your participation in its future development

THANK YOU