

Opportunities for Pre-competitive Data Exchange through Biomedical Networks

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- Nothing to disclose

Biomedicine: “fallen and it can’t get up”

- Impending “*Pharmageddon*”*: Declining R&D Productivity with Rising Costs
- Healthcare ecosystem is broken
- Poor understanding of the underlying biological complexity – current dominance of reductionist paradigm
- Vertically integrated development model (FIPCo) vs networked model (FIPNet) that dominates other sectors
- Exponential fragmentation of health information

need to embrace biomedicine as *SYSTEM*

* from M. King Jolly, Pharm.D. Quintiles, Inc. **DIA 2011**

Biomedicine: a Complex Adaptive System

“the whole is more than the sum of the parts”

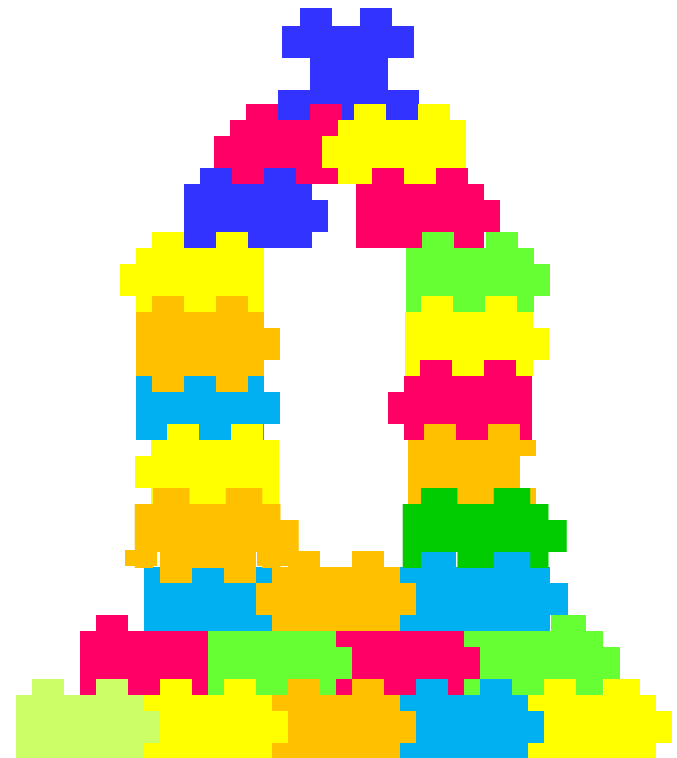
- Diverse stakeholders: multidimensional, interacting “**ecosystem**”
 - Industry, Academe, Government, **NGOs**
 - Physicians, Regulators, Researchers, **Payors, Consumers, Public Health Officials**
 - Biology, Chemistry, Medicine, Business, **Sociology, Anthropology**
- Adaptive behaviors (dynamic as opposed to static)
- Emergent properties (or unintended consequences)
- Interdependencies
 - Resources
 - **Information**

Strategies for “Managing” Complexity

- **Networking**
 - **Differentiated functions** connected through well-defined **interfaces** – e.g.
 - Biologic processes
 - Manufacturing
- **Layering**
 - **Abstracted combinations of functions** into hierarchical/multidimensional strata which connect through well defined **interfaces** –e.g.
 - Quantum physics – Newtonian physics
 - Biologic complexity : cell, organism, society
 - Organizational hierarchies

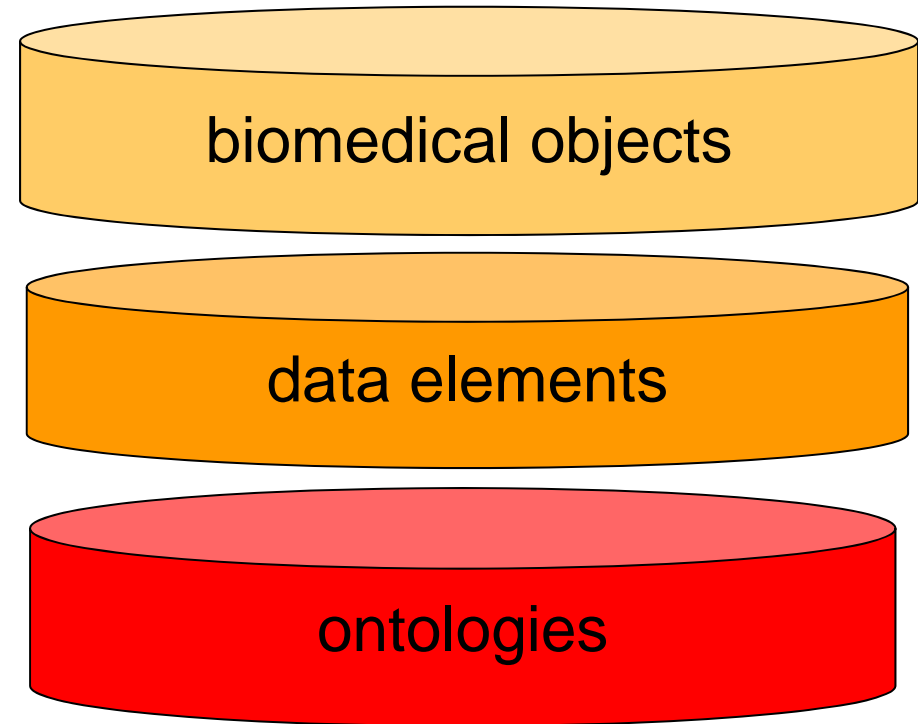
Applying CAS Principles to Facilitate Information Flow

- Define ***modules*** that address specific needs
- Connect ***through “well-defined electronic interfaces”***
- ***Semantic Interoperability***
 - Defined ***syntax***
 - Defined ***semantics***

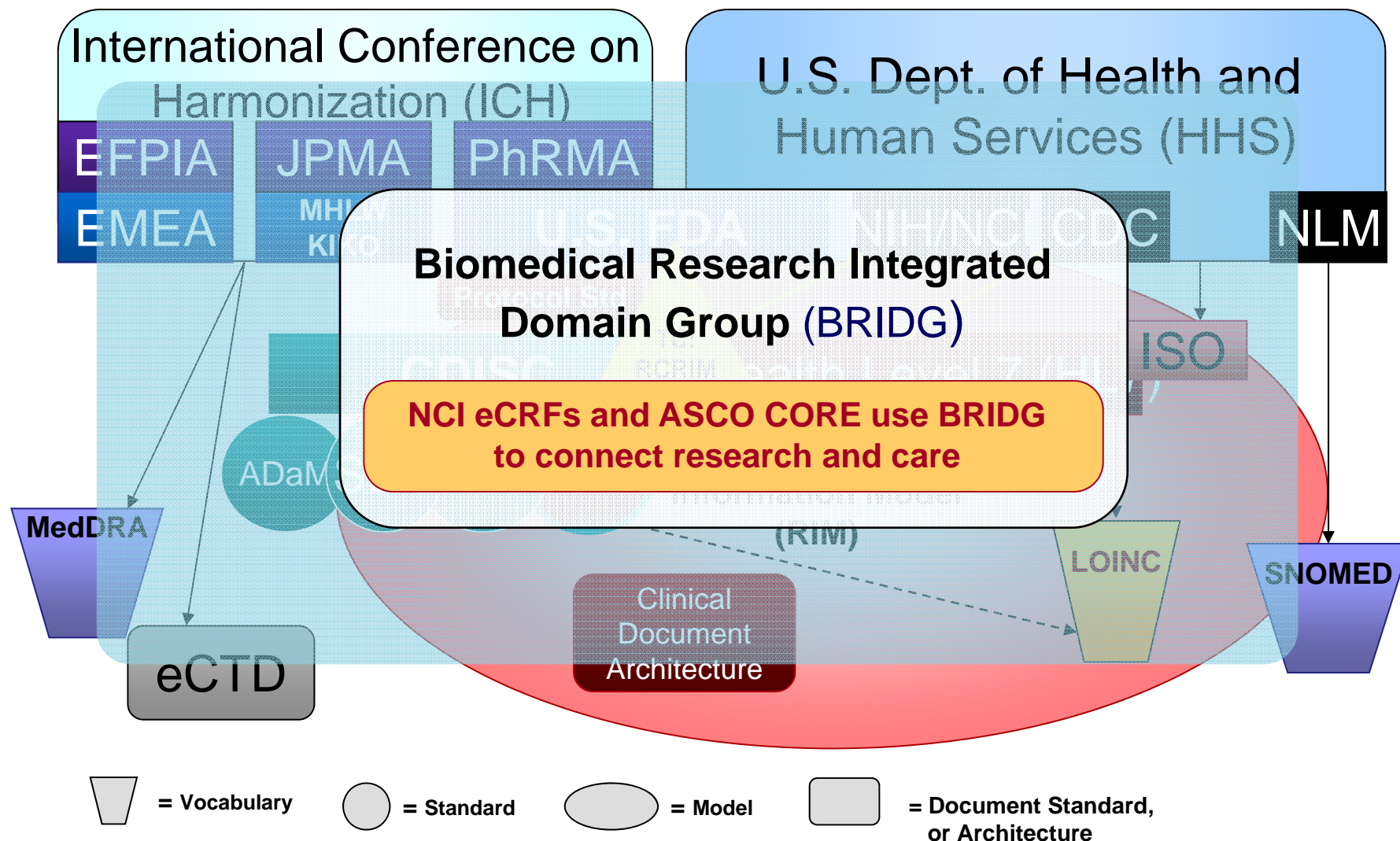


Interoperability through Metadata-based “Knowledge Stack”

- Componentized knowledge representation
- Permits information to be “pivoted”
- Based on international standards



clinical information representation



Complicating Considerations

- **Nature of Data**
 - “Data Validity”: Garbage In- Garbage Out
 - Human Subjects Protections
 - Intellectual Property
- **Technical**
 - Secure access
 - Volume/Magnitude
 - Need for integration
 - Diverse Data
 - Multiple Source
 - Need for choreography
- **One size does not fit all**
 - Nature of the data to be accessed
 - The question one wants to answer

Continuum of need mediates the need for adding layers of complexity

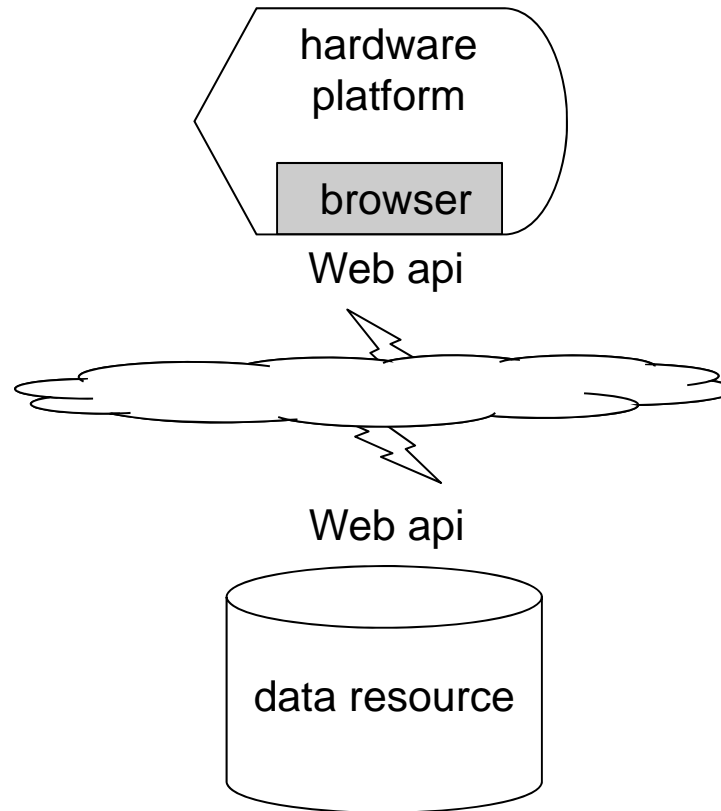
Strategies for Addressing Complexity

- **Diversity of APIs** that support paradigms within given communities (expose multiple “flavors” where possible)
- Add **modules** to address issues **ONLY** when **necessary**
- **Federate Access**: Data control remains local
- **Escalating** introduction of **standards**-based metadata
- **Analytics go to the data**/co-reside with the data
- **Virtual Communities** where access to individual level data is needed

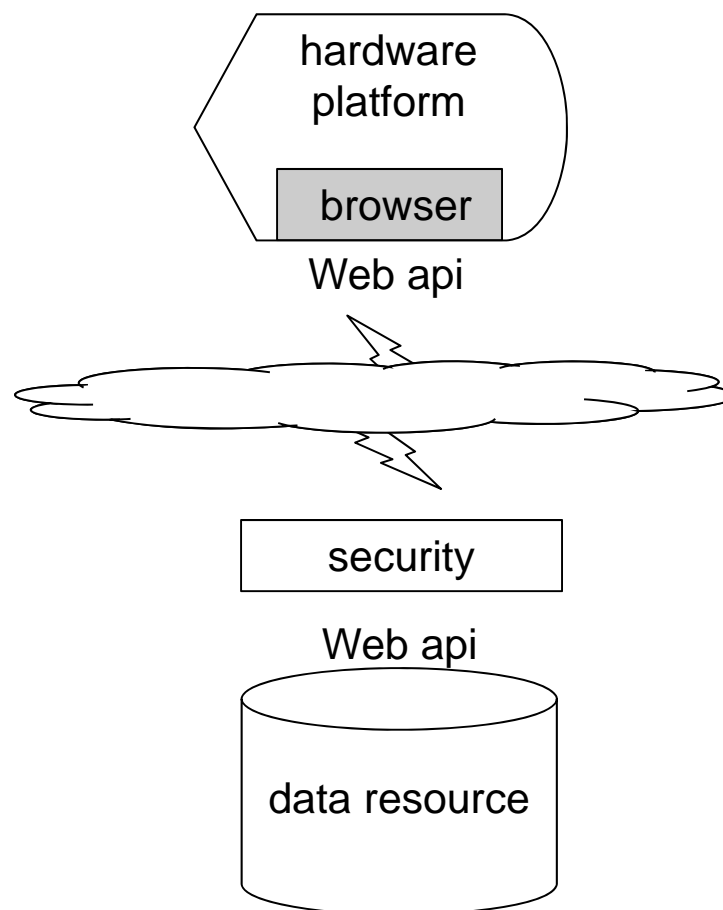
Open Source Framework: Modular/Layered Complexity

- **caCORE SDK (syntactic interoperability)**
 - Model driven resource generator
 - creates Java, web (SOAP), REST, Grid APIs
- **caGrid Introduce**
 - Service definition and “publishing”
- **caGrid Grouper (security)**
 - Defines virtual community access
- **caCORE Semantic services (semantic interoperability)**
 - Vocabularies/Ontologies
 - Data Elements Respository
 - Information Models
- **Adapters**
 - caAdapter
 - caXchange – enterprise service bus
 - iHub/Mirth-Connect – semantic service bus

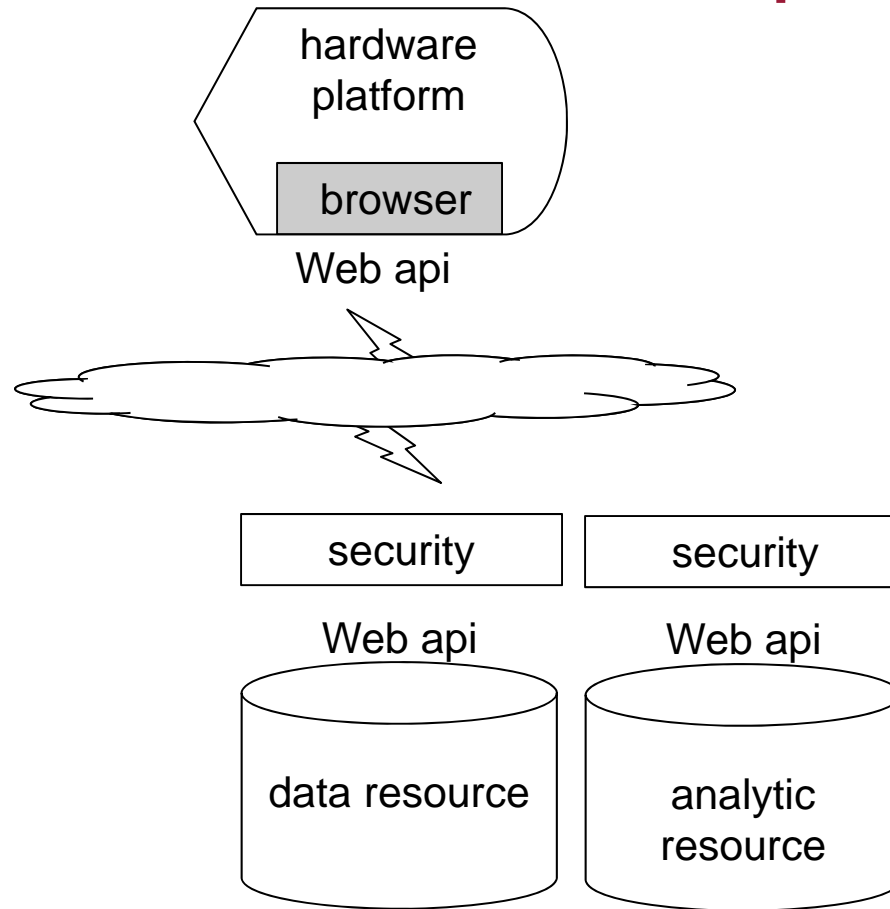
Escalating complexity facilitating Biomedical Research Data Liquidity



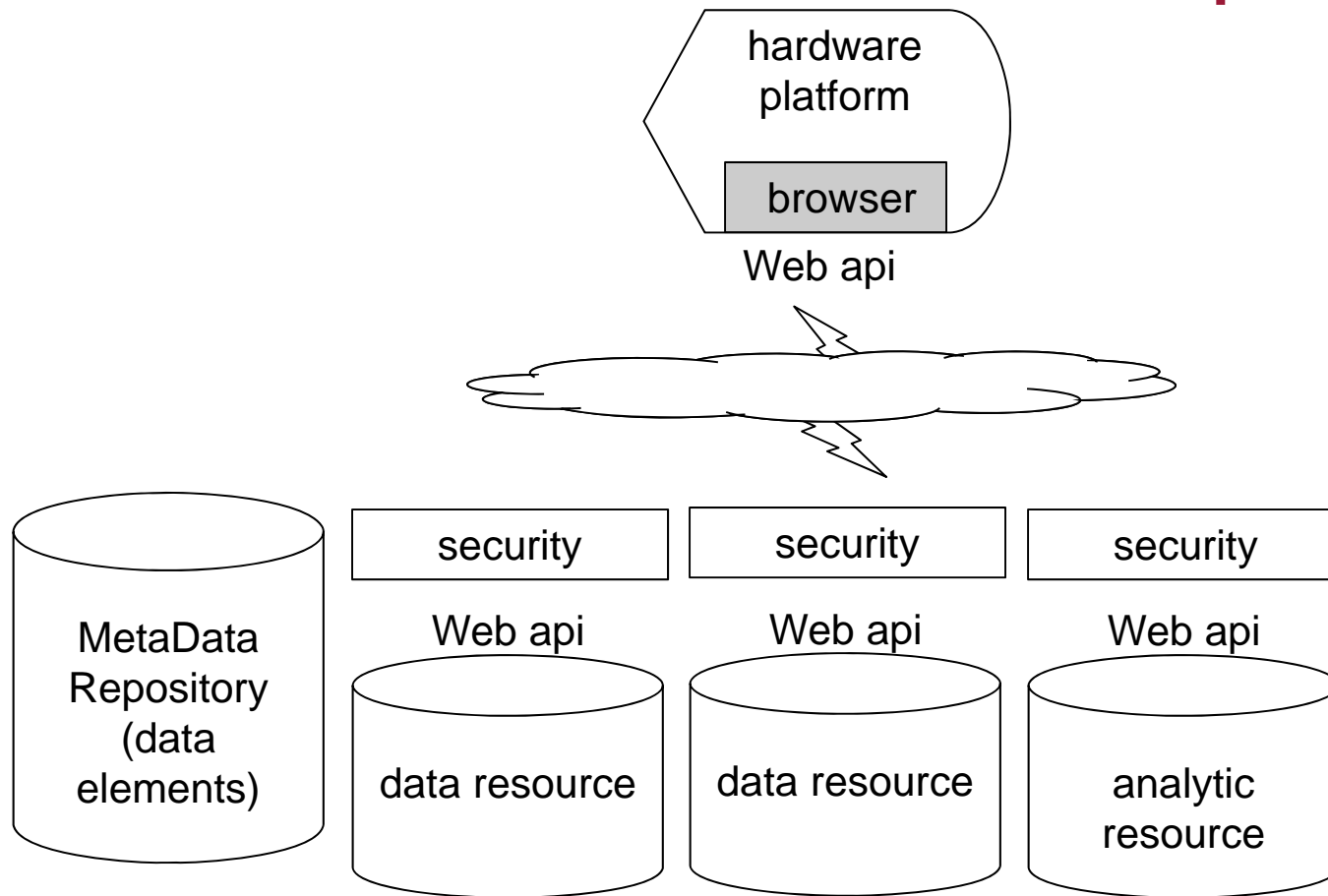
Escalating complexity facilitating Biomedical Research Data Liquidity



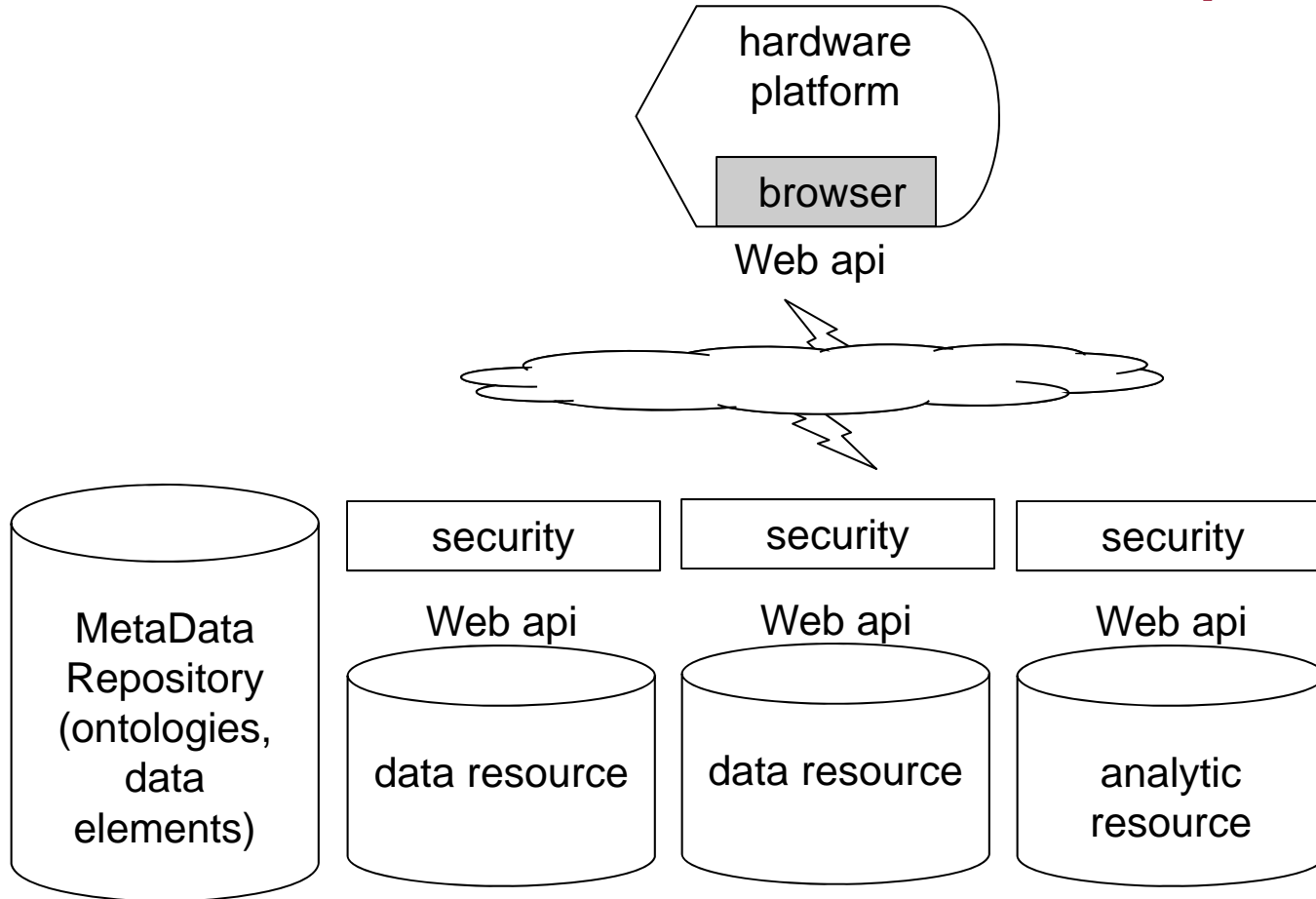
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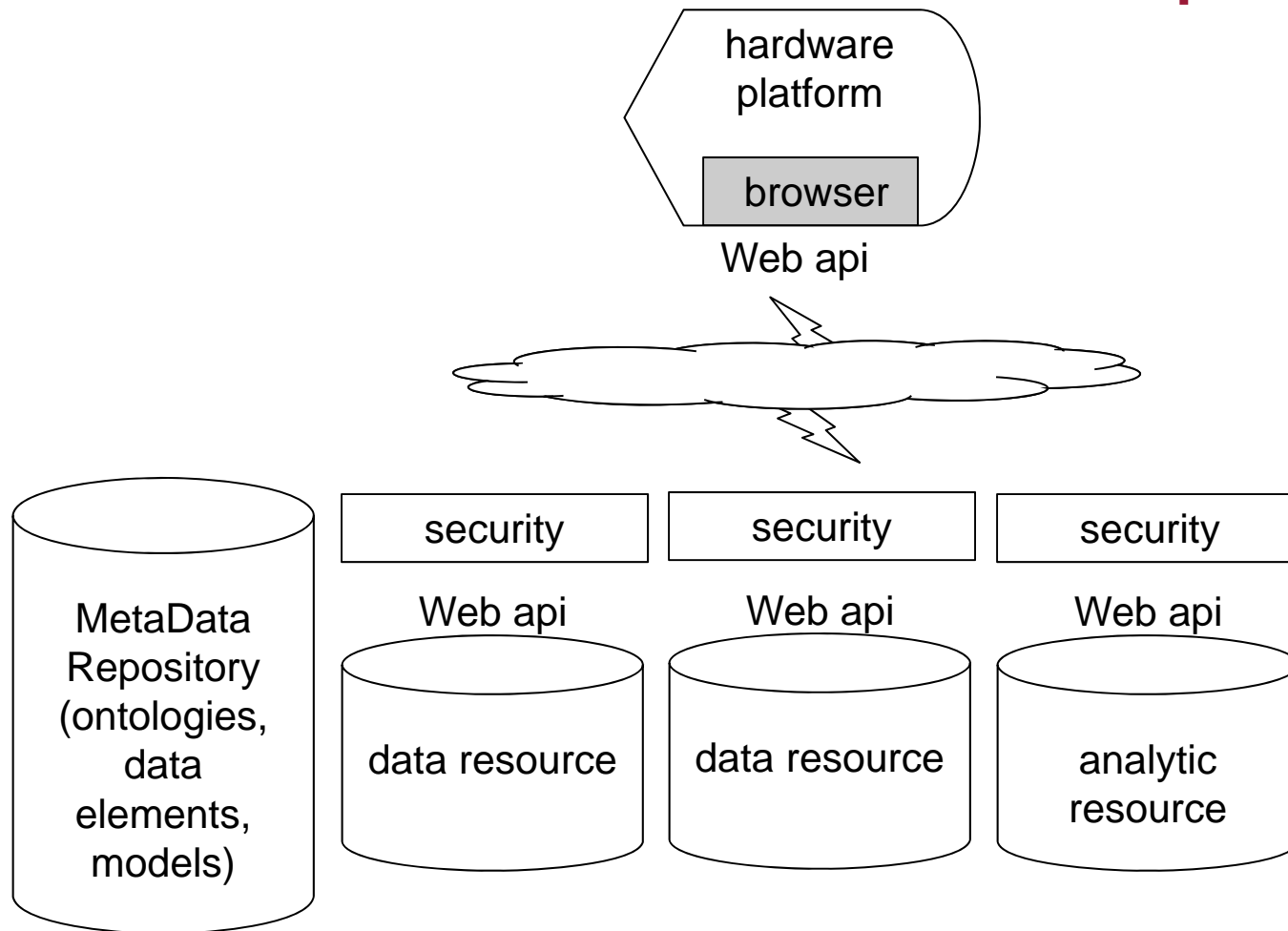
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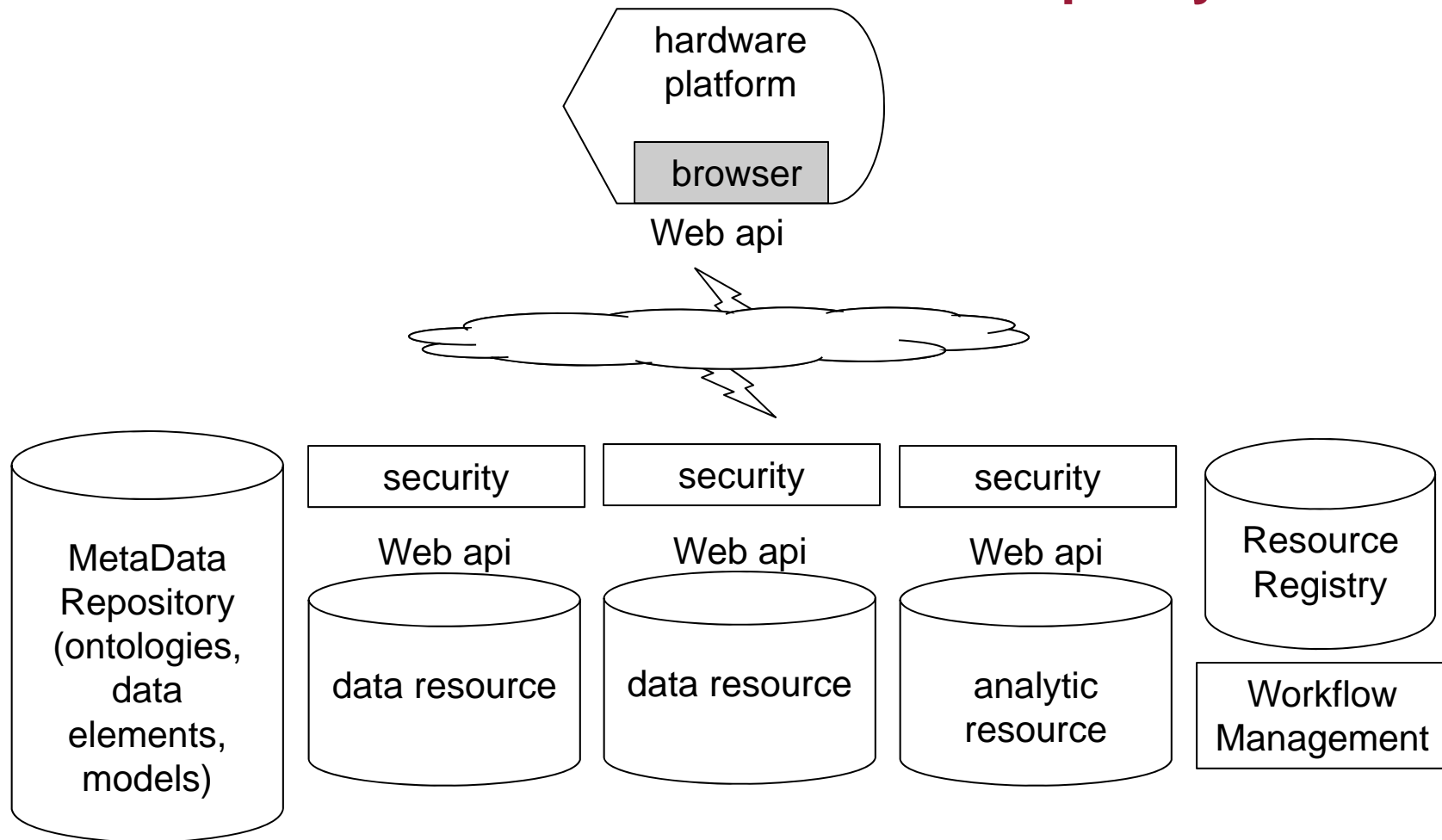
Escalating complexity facilitating Biomedical Research Data Liquidity



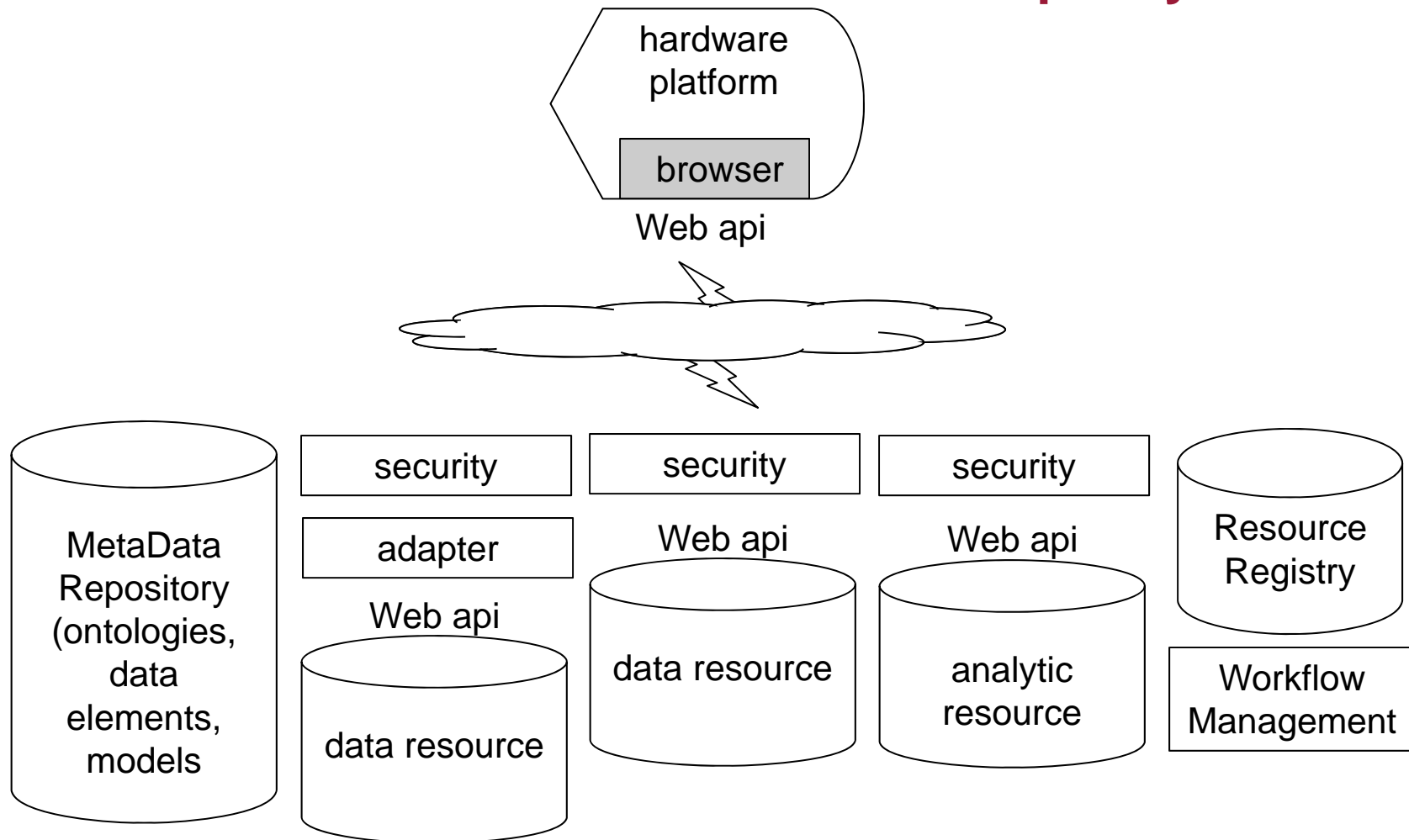
Escalating complexity facilitating Biomedical Research Data Liquidity



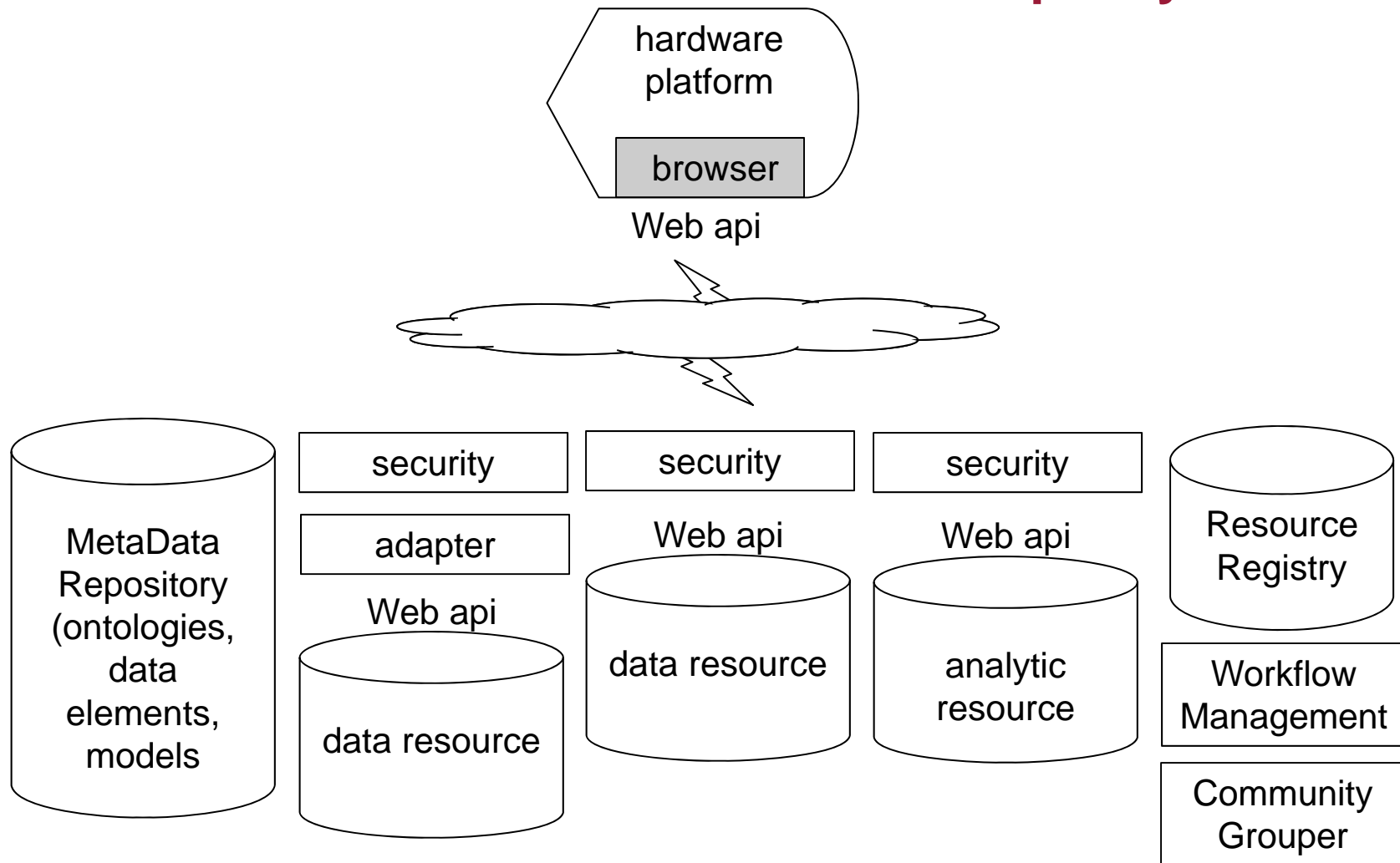
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Escalating complexity facilitating Biomedical Research Data Liquidity



Escalating complexity facilitating Biomedical Research Data Liquidity



1st Generation Global Exchange Network: caBIG[®]

- **Portfolio of electronically-accessible resources**
 - Clinical research: 10,000's of clinical records
 - *In vivo* images: > 4.5 million images
 - Population: > Registries with >17% of U.S. population
 - Molecular signatures: > 45,000 characterizations
 - Biospecimens: >2 million specimens
- **Example Organizational Application**
 - Aga Khan University, Pakistan
 - VU Medical Center DeCoDe, The Netherlands
 - UCSF I-SPY2 Trial, USA

Aga Khan University Clinical Trials



Patient visits the Physician

Cancer Central Clinical Participant Registry (C3PR)

Eligibility is verified and patient is registered to a study

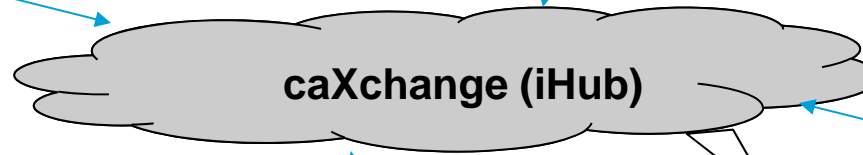
Patient Study Calendar (PSC)

Tracks the patient schedule throughout the study

Lab Viewer

Lab Name	Result	Unit	Reference Range	Comments
Complete Blood Count	12.5	g/dL	12.0 - 16.0	
Hemoglobin	15.2	g/dL	13.5 - 16.5	
Hematocrit	45.8	%	38.0 - 48.0	
Mean Corpuscular Volume	100.0	fL	84.0 - 101.0	
Red Blood Cell Count	4.5	mill/cmm	4.0 - 5.5	
White Blood Cell Count	10.0	thous/cmm	4.0 - 11.0	
Platelet Count	250	thous/cmm	150 - 400	

Identifies labs, loads them into the CDMS and AE system



Clinical Data Management System (OpenClinica)

Clinical data is captured

Cancer Adverse Event Reporting System (caAERS)

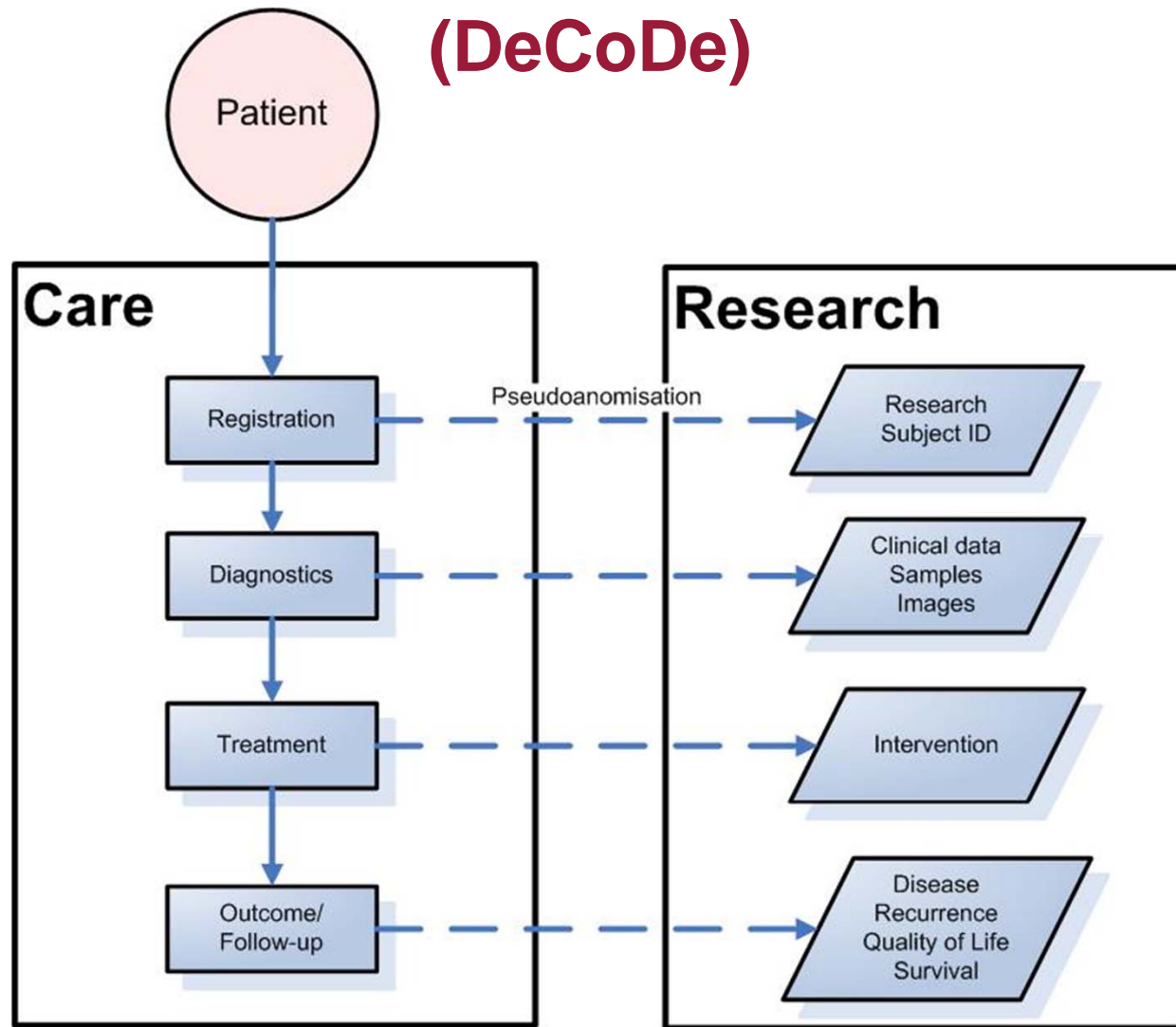
Identifies and tracks adverse events

(api's)

Clinical Trials Database (CTODS)

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VUMC Decrease Colorectal cancer Death (DeCoDe)



From:
Gerrit Meijer
VUMC

VUMC Decrease Colorectal cancer Death (DeCoDe)



Clinical Annotations



Imaging

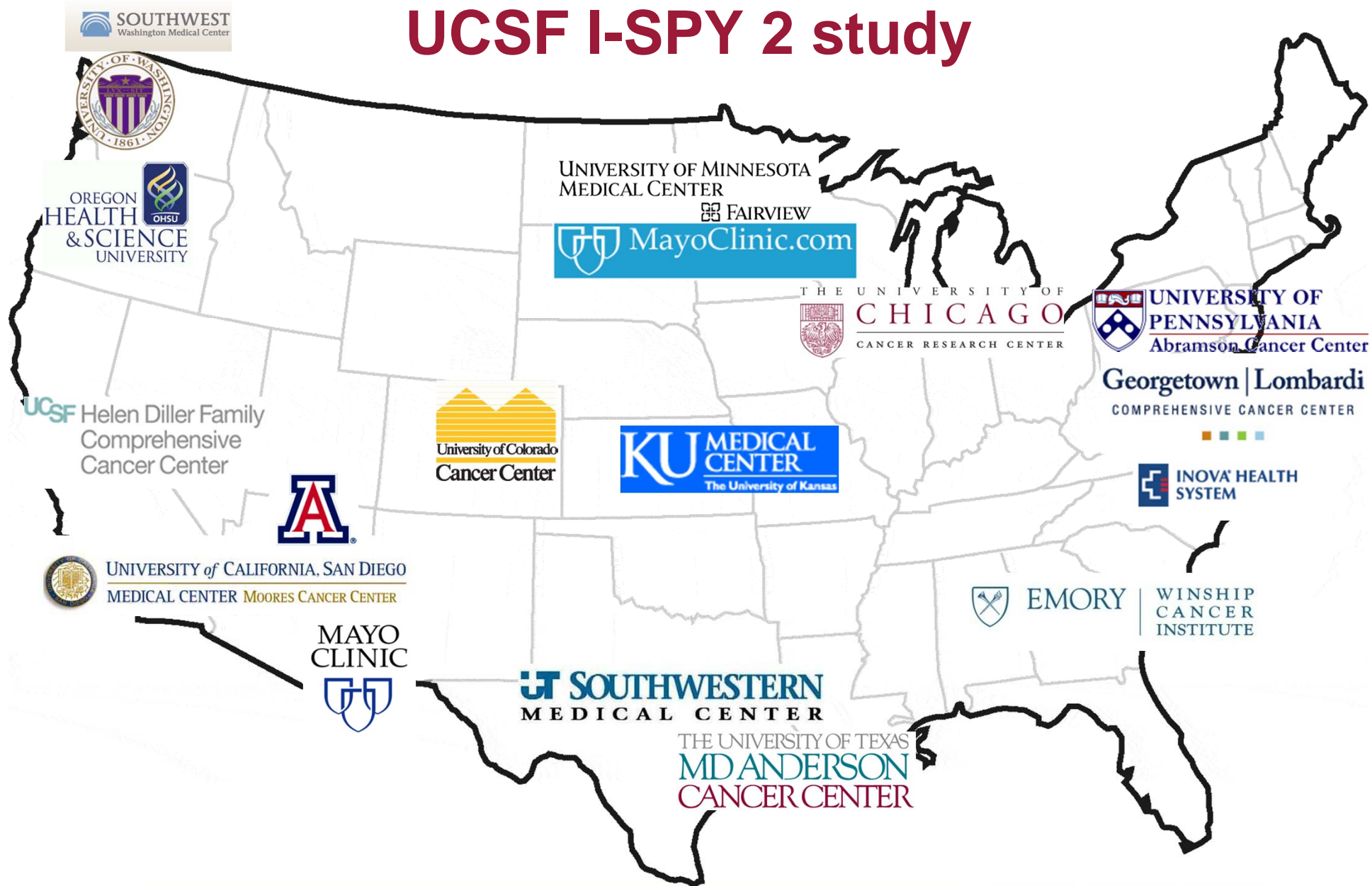


Experimental Data



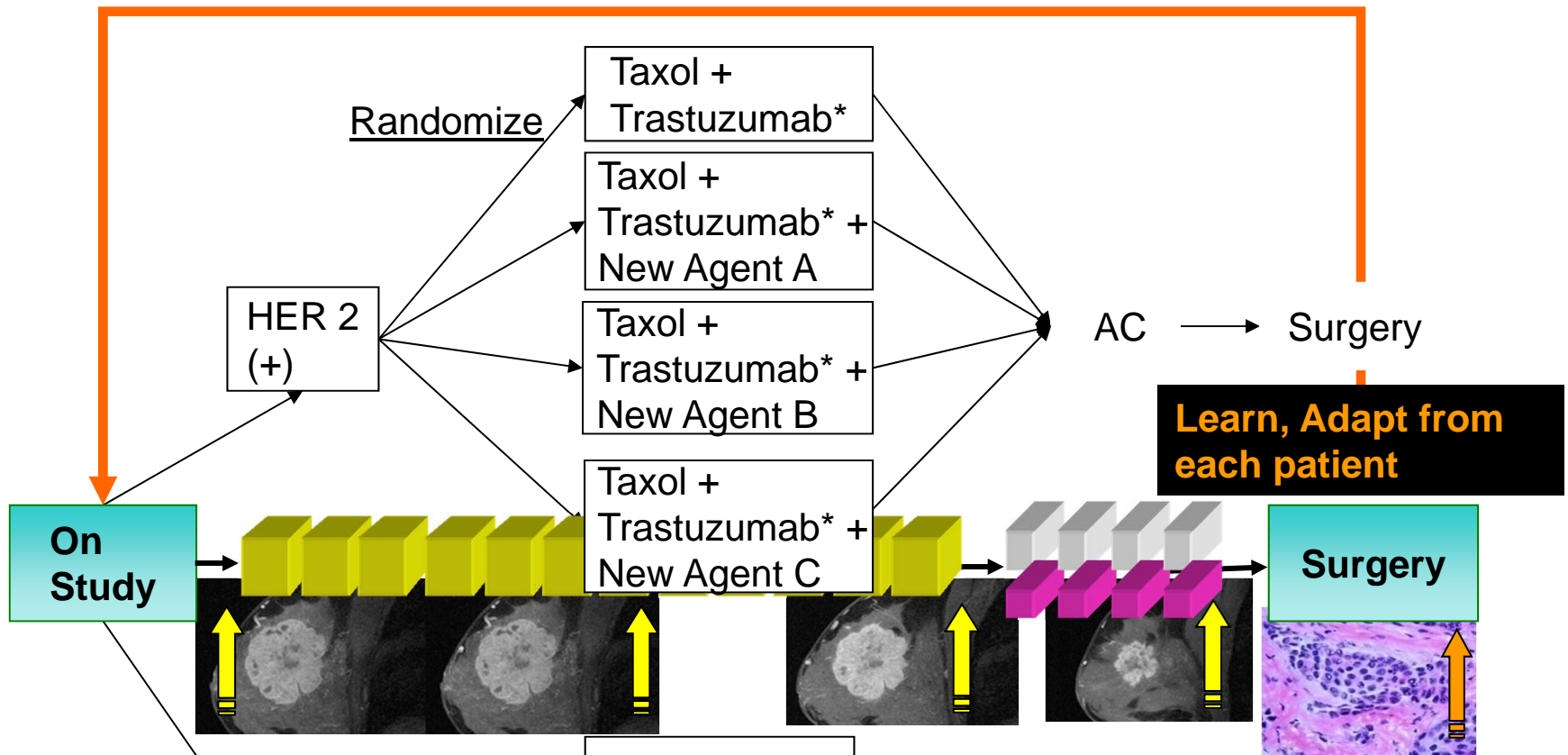
Biobanking

UCSF I-SPY 2 study



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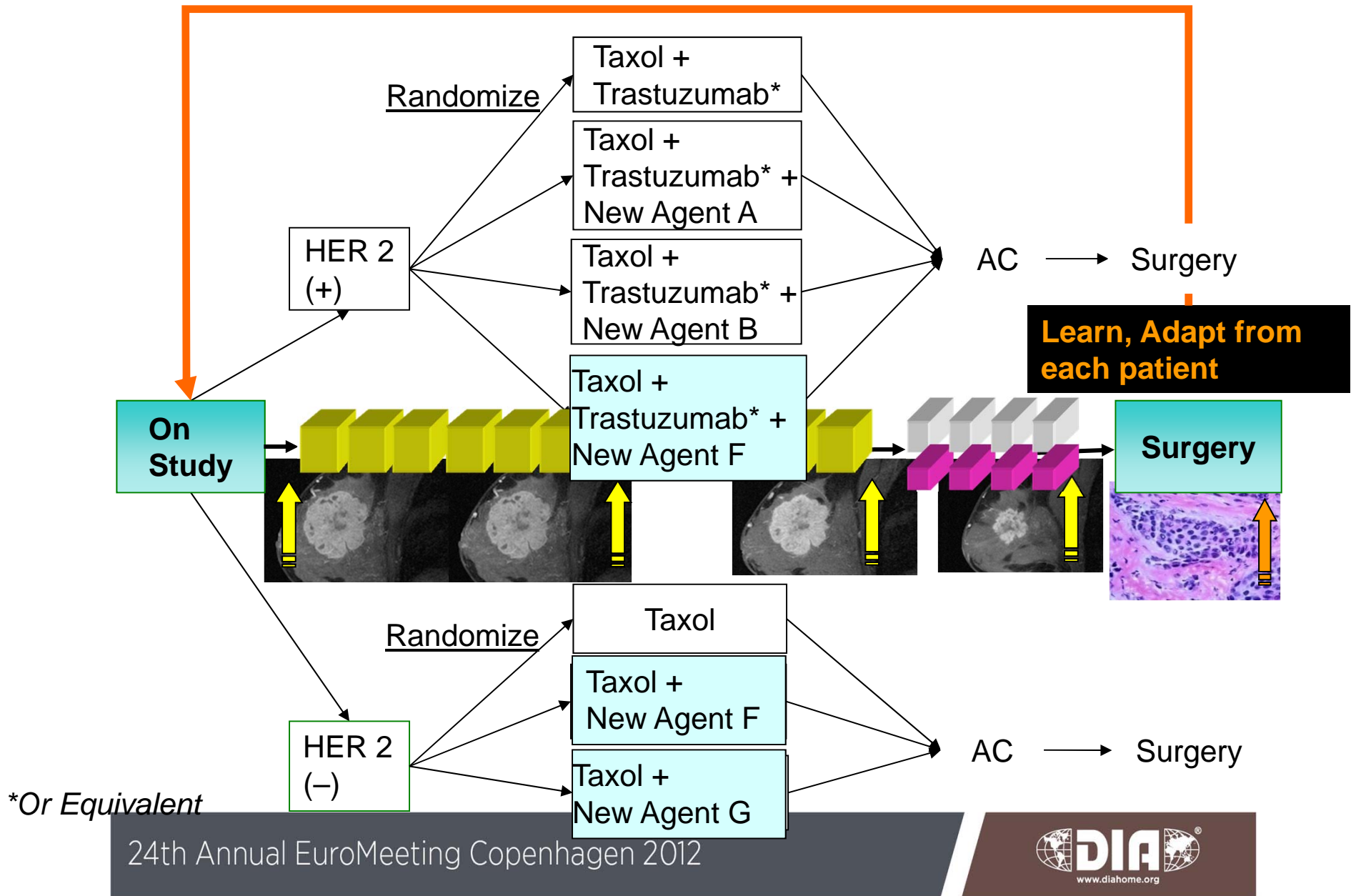
I-SPY Adaptive Trial: Introduce several new agents for a given profile



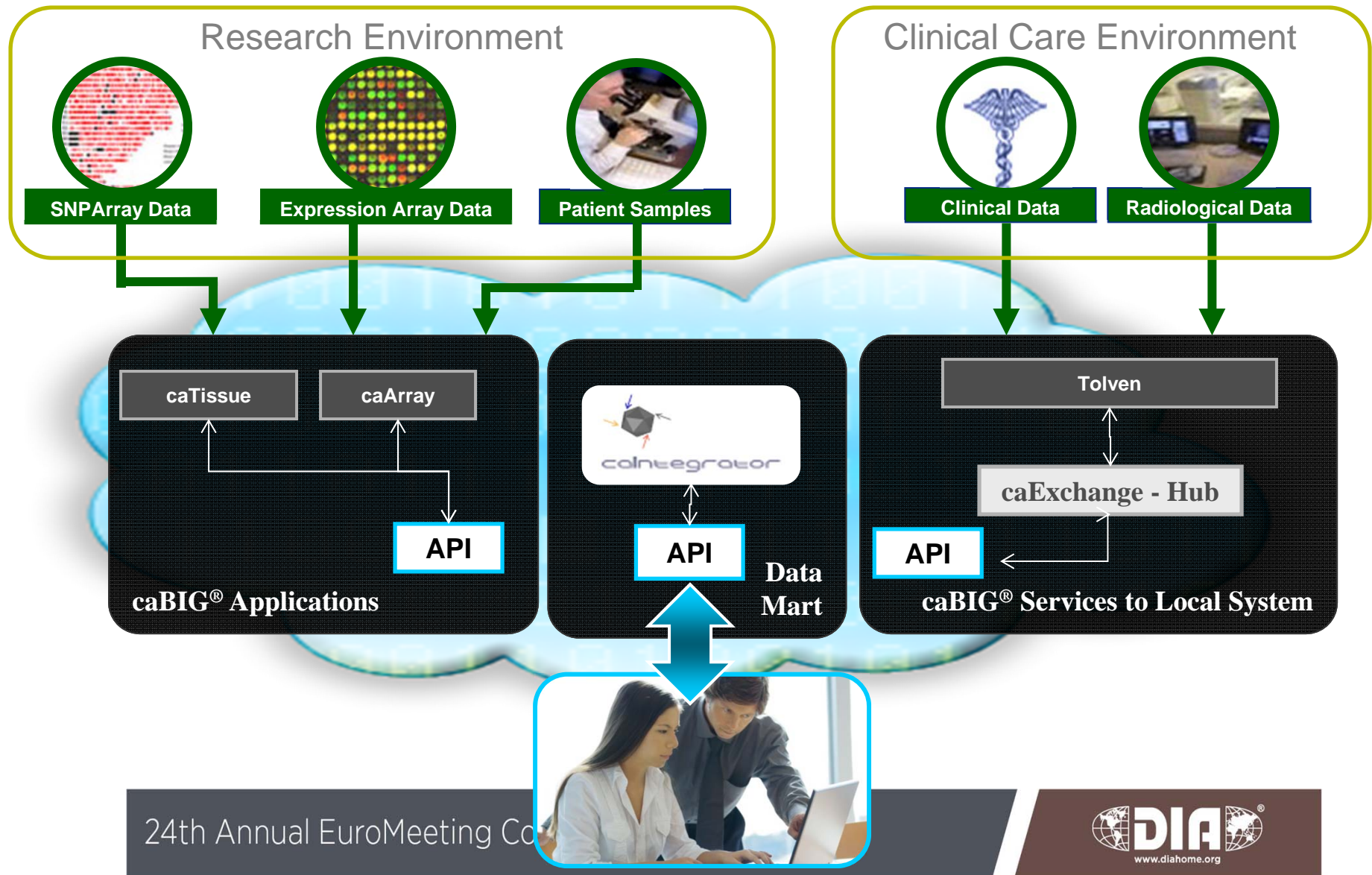
**Or Equivalent*

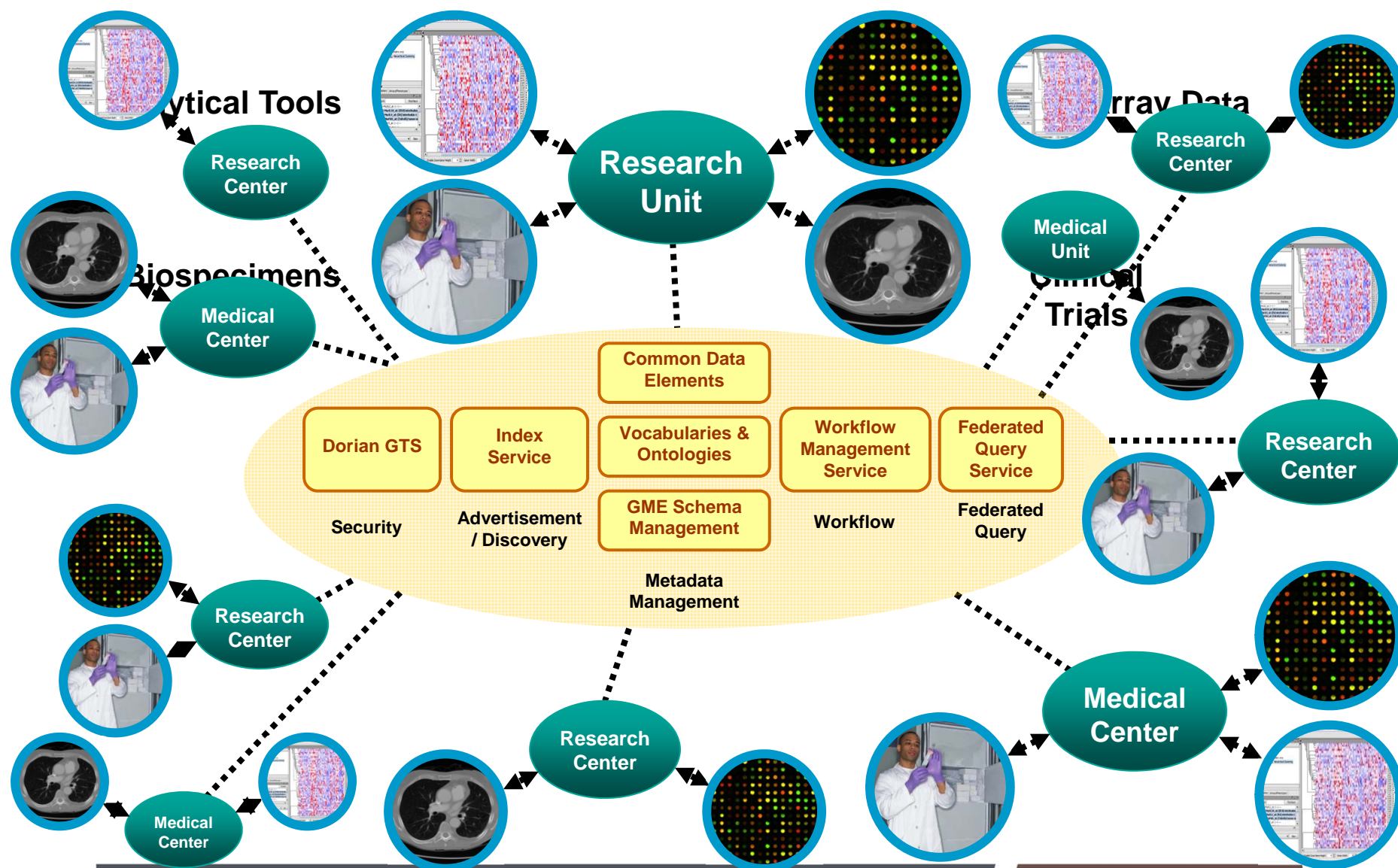
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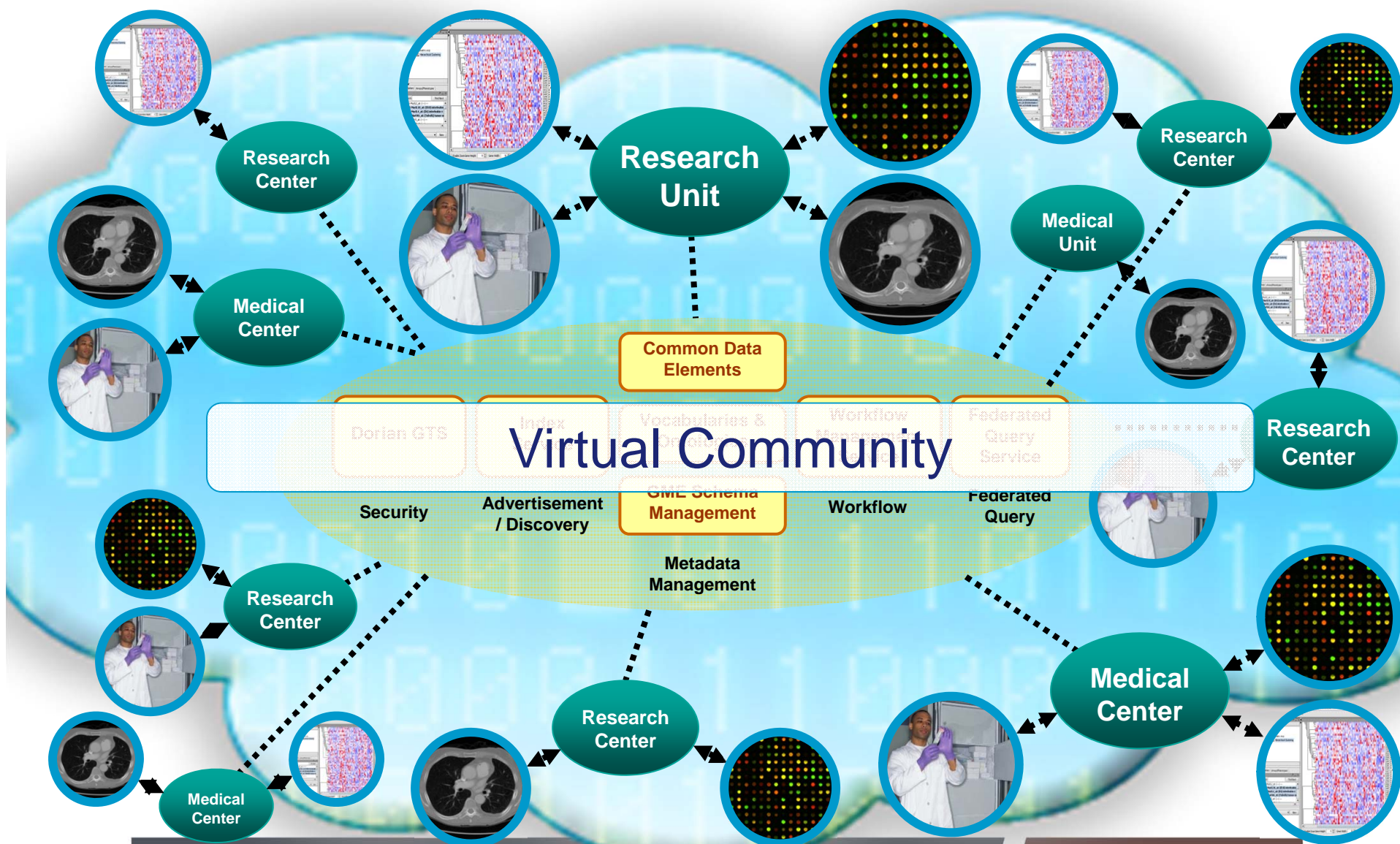
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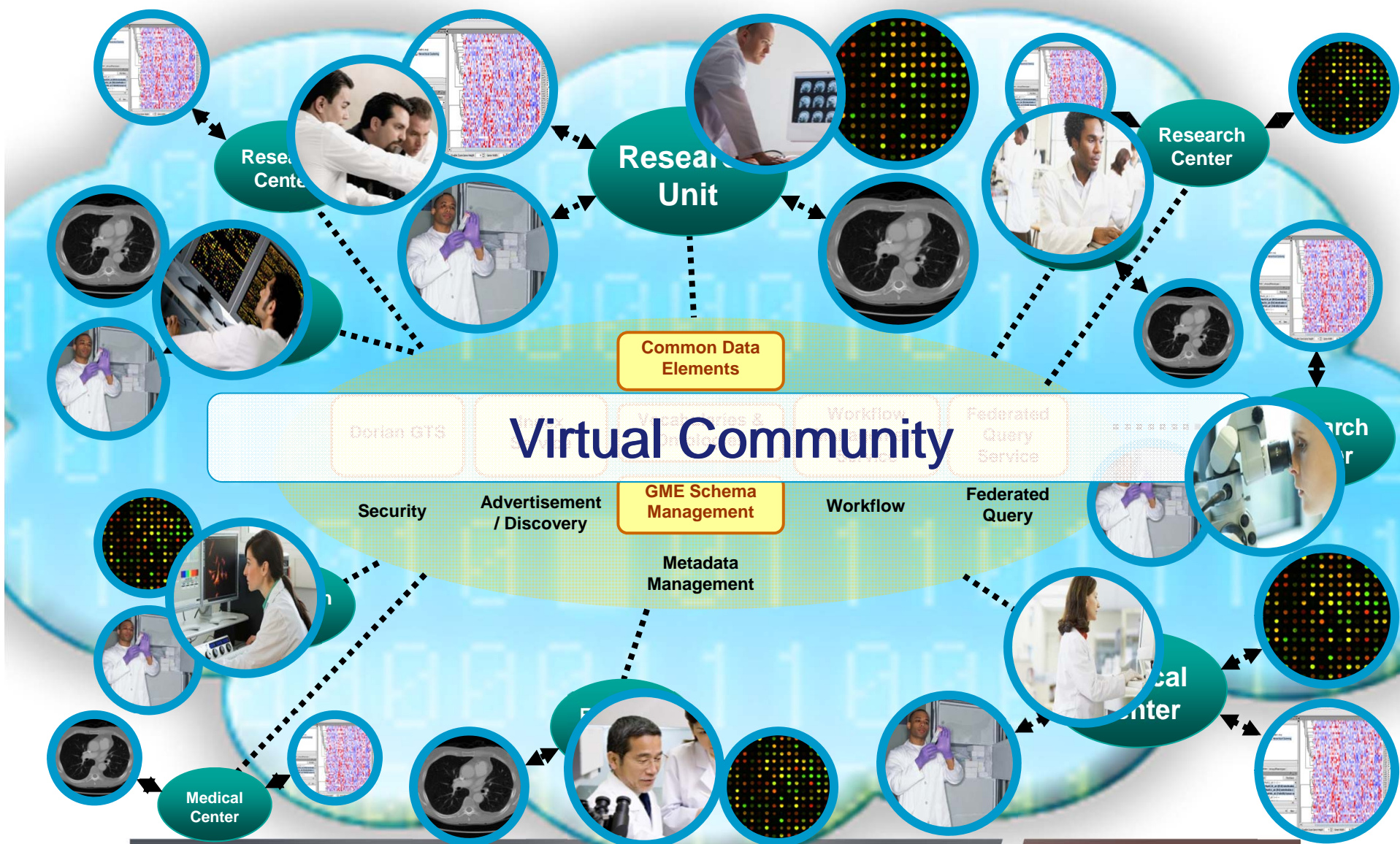


I-SPY TRIAL IT Infrastructure









Toward a Sustainable Effort?

INSTITUTE OF MEDICINE
OF THE NATIONAL ACADEMIES

Advising the nation • Improving health

Achieving Data Liquidity in the Cancer Community: Proposal for a Coalition of All Stakeholders

Marcia A. Kean, Feinstein Kean Healthcare; Amy P. Abernethy, Duke University School of Medicine; Adam M. Clark, MedTran Health Strategies; William S. Dalton, Moffitt Cancer Center & Research Institute; Brad Pollock, University of Texas Health Sciences Center; Lawrence N. Shulman, Dana-Farber Cancer Institute; Sharon B. Murphy, Institute of Medicine¹

National Cancer Policy Forum: “Informatics Needs and Challenges in Cancer Research”
February 28, 2012

Summary

- Approaching **Biomedicine as a Complex Adaptive System** may help address some of the challenges it currently faces
- **Information**, and as such Information Technology can serve as the glue to **connect the Ecosystem**
- It is **technically feasible** to create and deploy technology to exchange information within and between members of the ecosystem
- A **multi-stakeholder, multidimensional community** will be necessary to create a sustainable ecosystem