

Personalized Medicine Utilizing Ontologies in support of linking Devices to the Intelligent EHR

By

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Mayo Clinic, College of Medicine



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Key Guiding Principle

“The best interest of the patient is the only interest to be considered.”

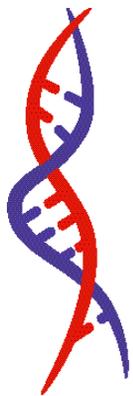
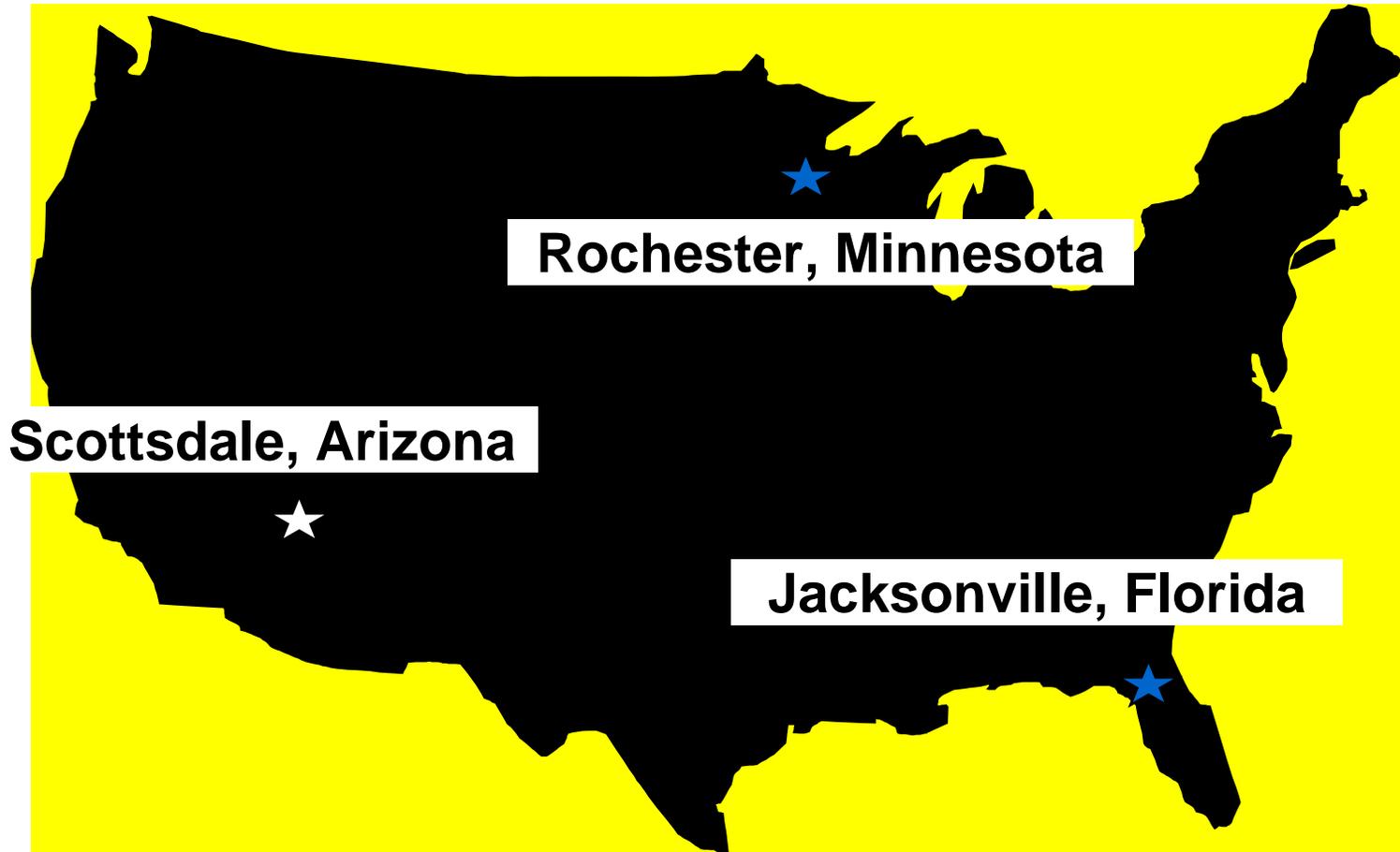
William J. Mayo, M.D.



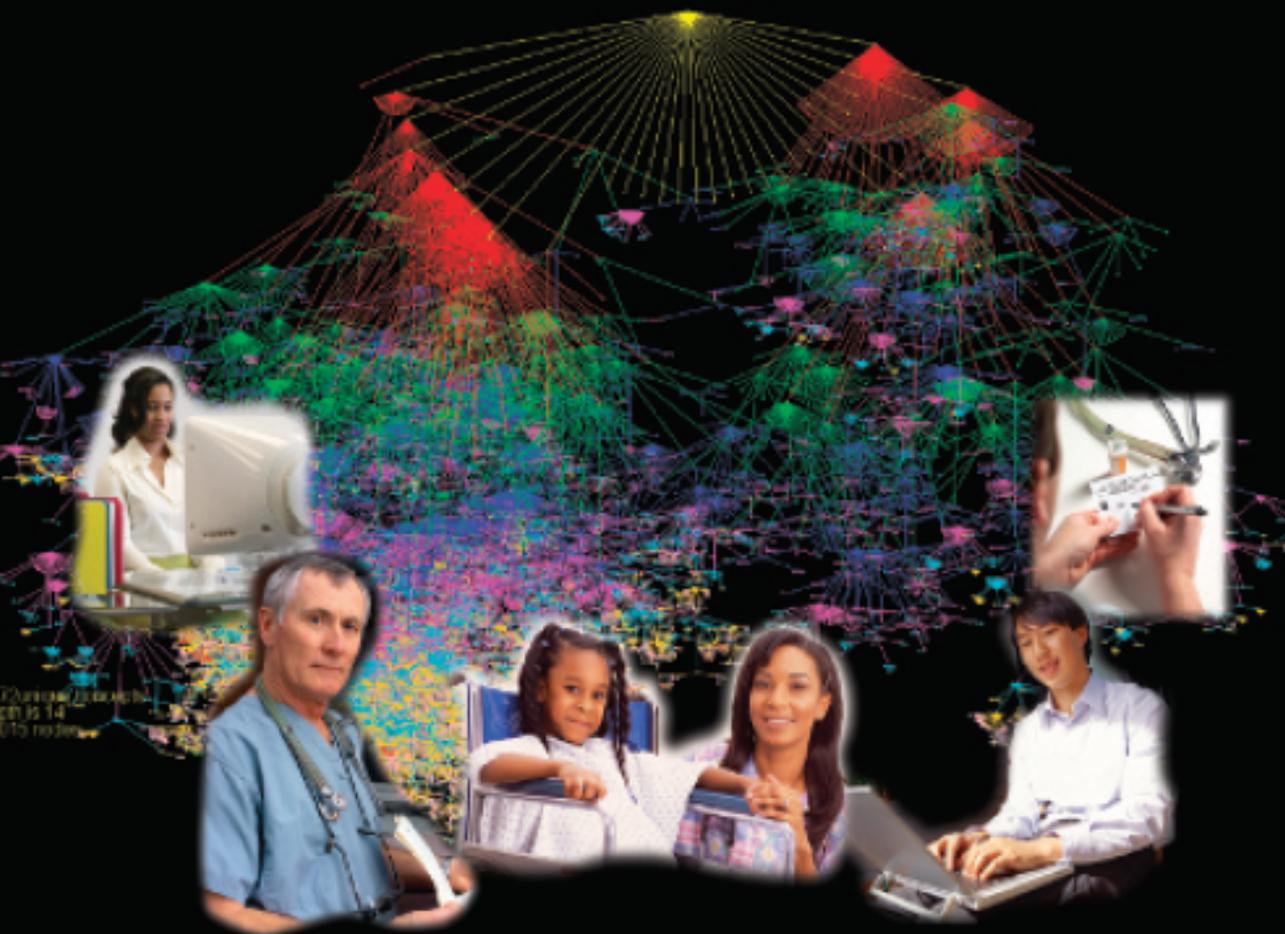
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Mayo Clinic practice sites



Intelligent Electronic Health Record (iEHR)



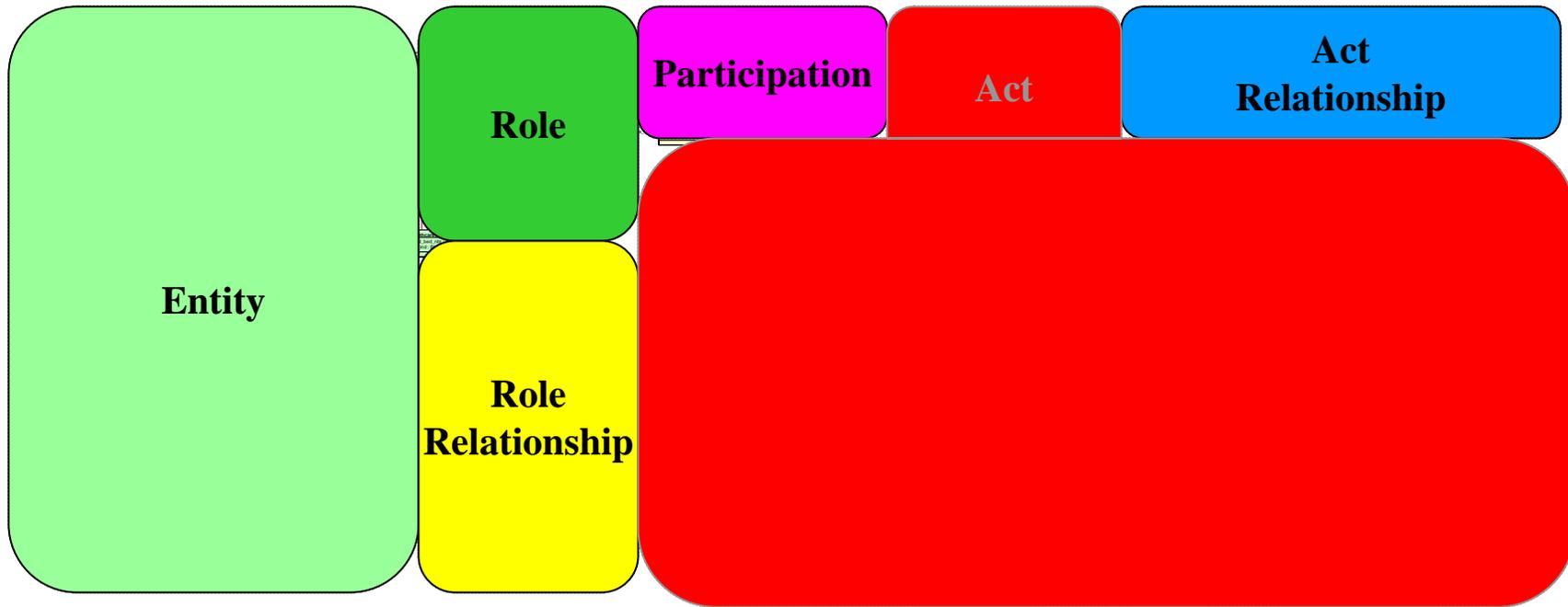
Personalized Medicine in the 21st Century

- Individualized care includes....
 - Your longitudinal data acquired from home devices (BP, Wts, BS, FEV1, cardiac rhythm, etc.)
 - Your personal health data
 - Problems
 - Medications (and Medication History) \ Allergies
 - Your genomic and proteomic data
 - Family history
 - Sequence Data
 - Probes and Markers
 - Microarray Data
 - Mass Spec Data
 - Your personal care preferences



Level One Ontology

HEALTH LEVEL 7
REFERENCE INFORMATION MODEL
RIM_0100



Level Three Ontology

- Fully Encoded Health Record
- Consistent with the Level One and Two Ontologies for Health
- Compositional Expressions are assigned Automagically
- Information is gathered through the usual documentation of patient care.
- Example.....



Overall Goal

Data



Information



Knowledge



INTELLIGENCE

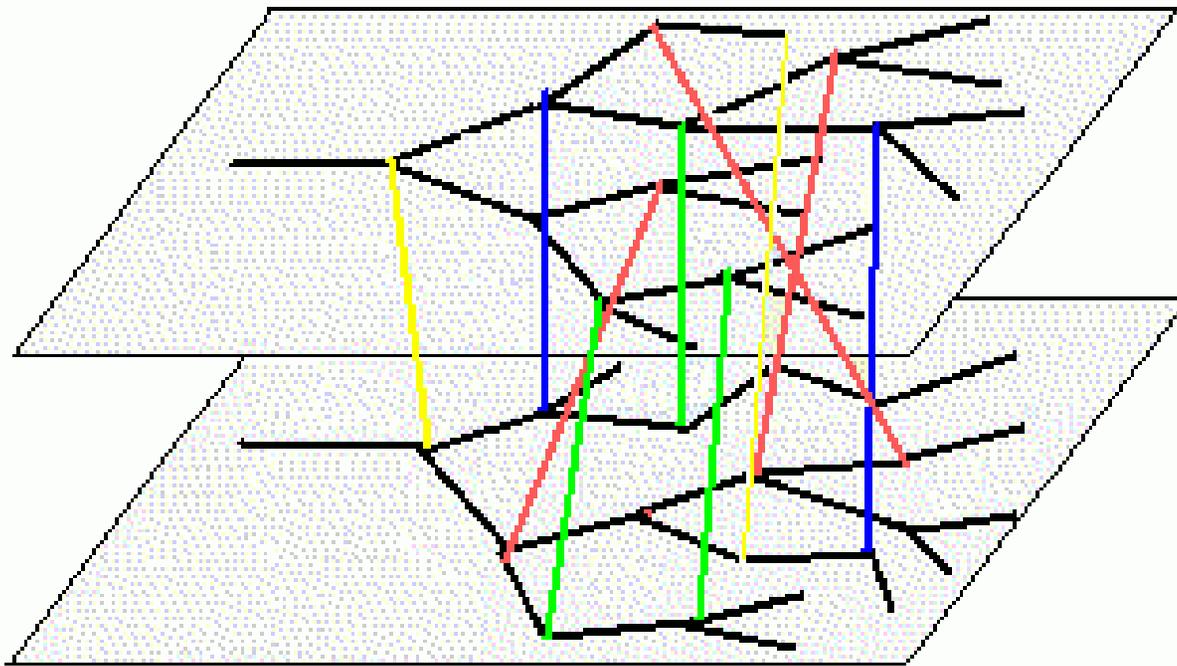


Clinical Outcomes



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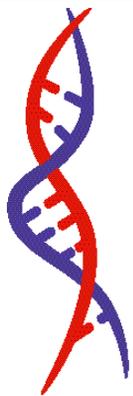
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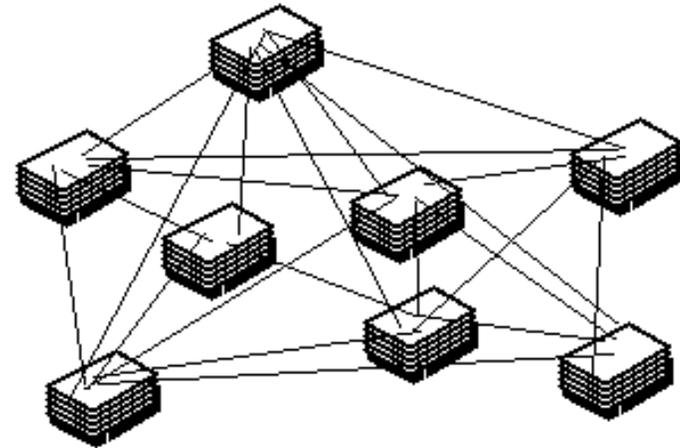
Case One

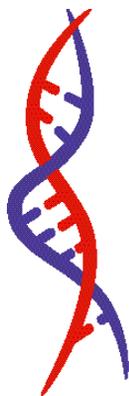
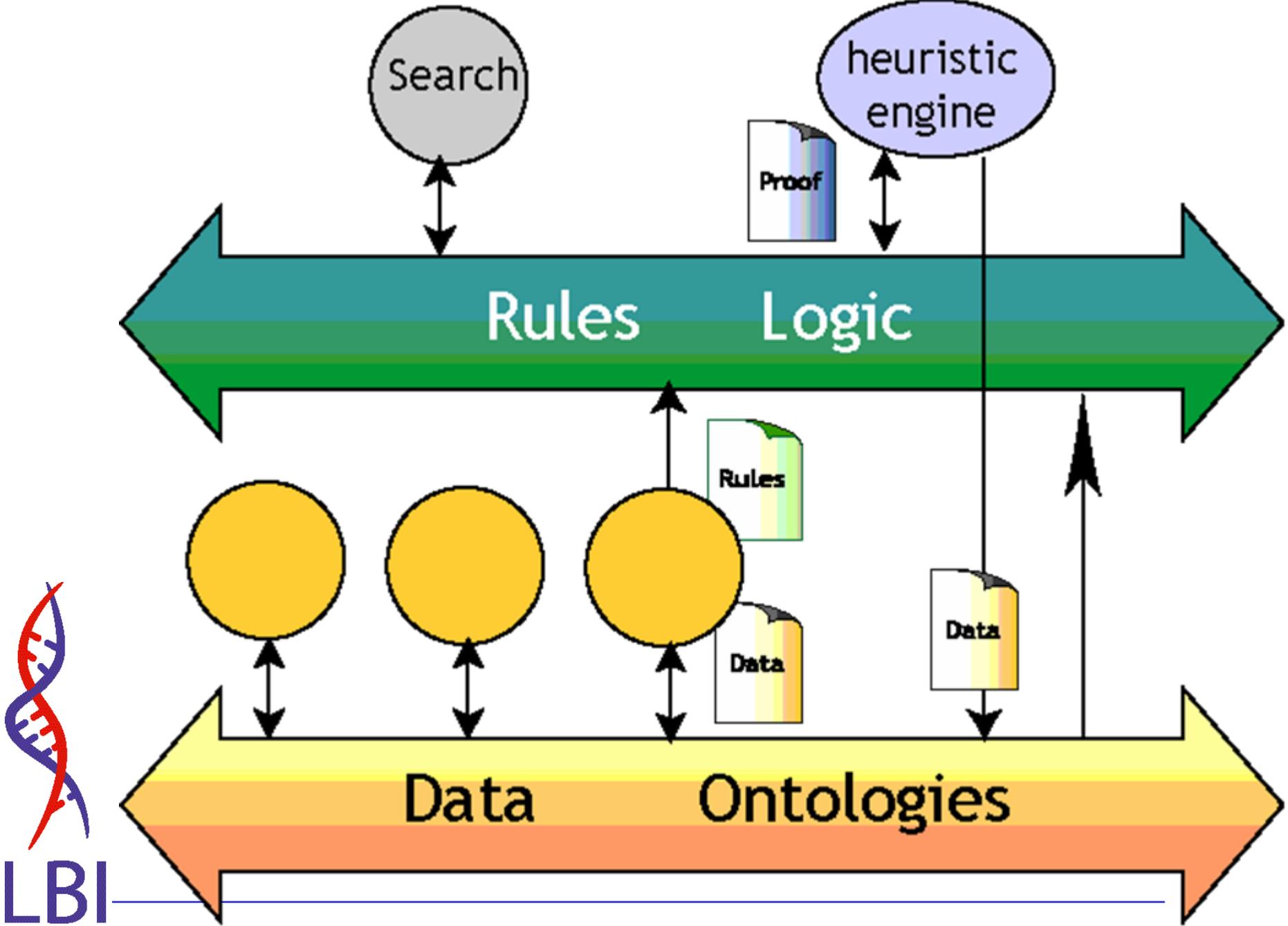
Case Two

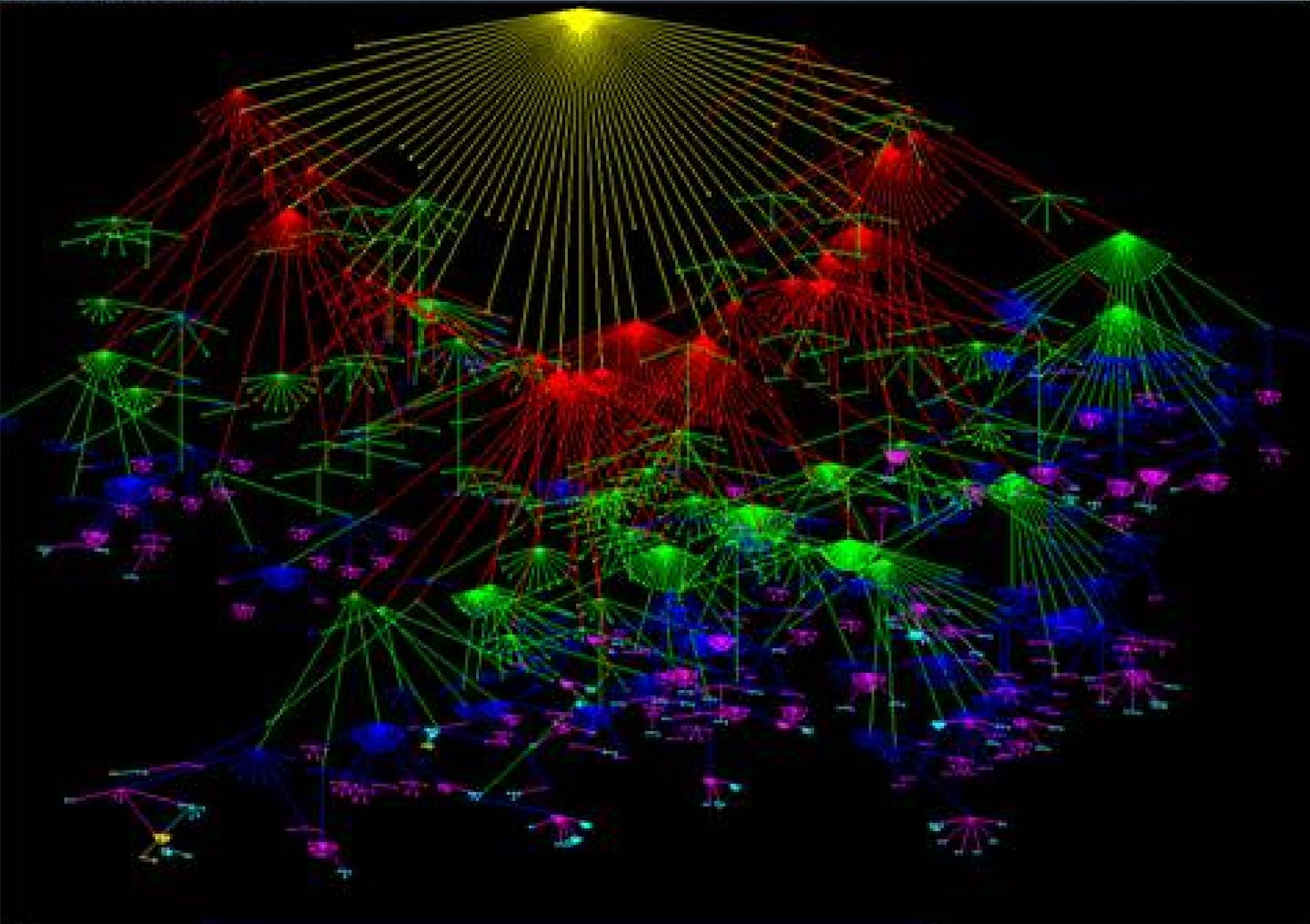
Semantic Network

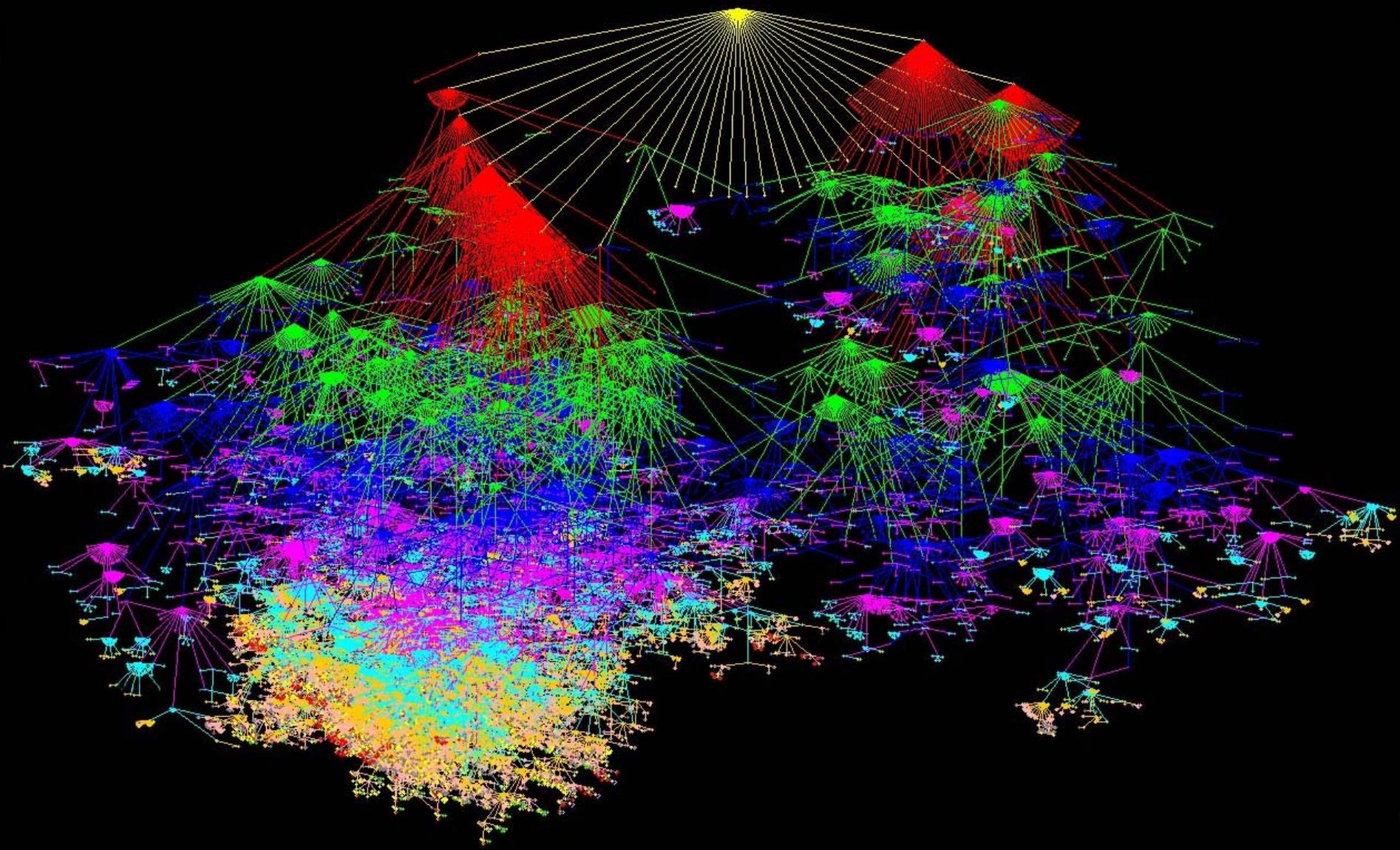


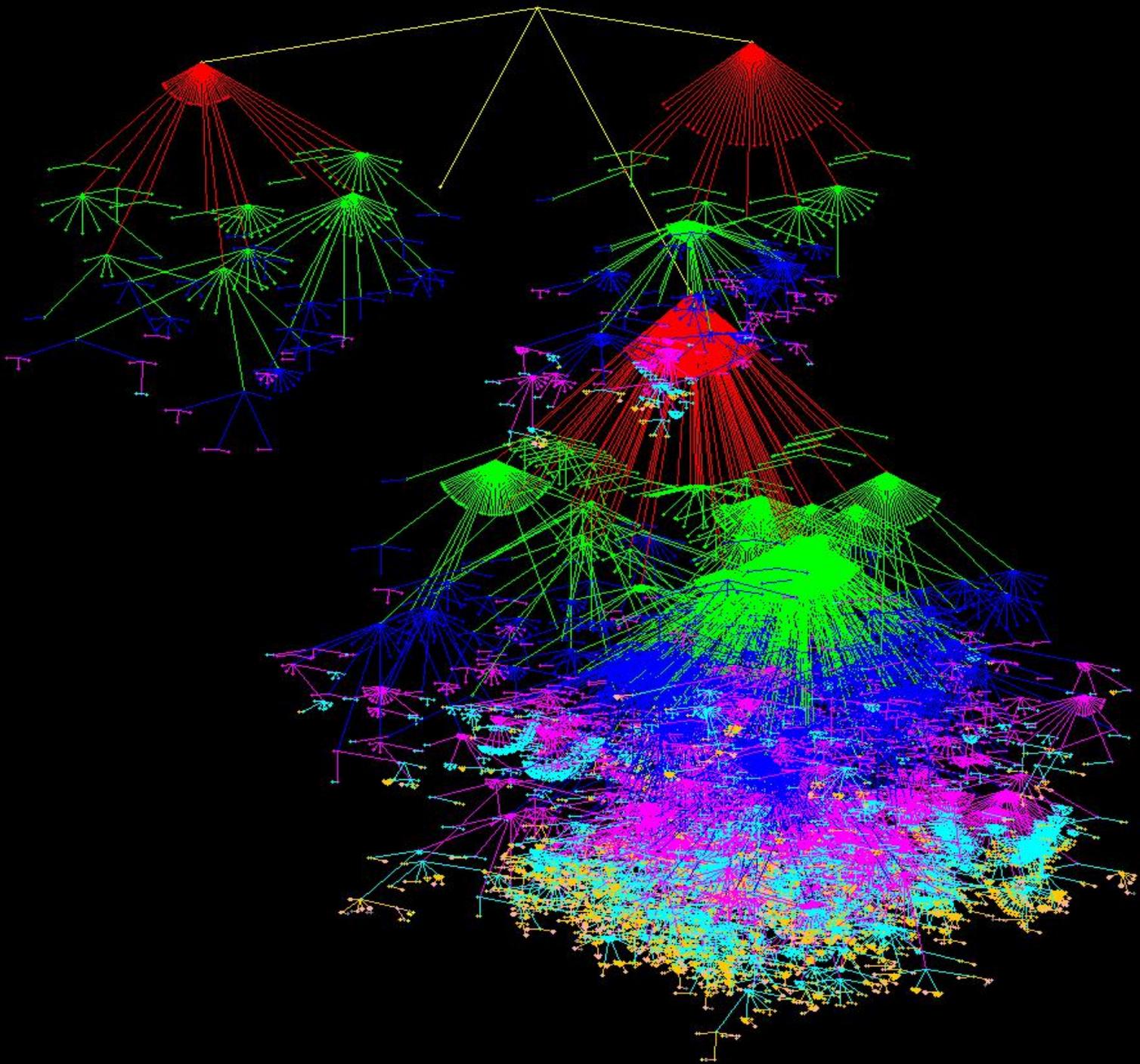
**Multi-Center Data
Sharing and
Interchange**

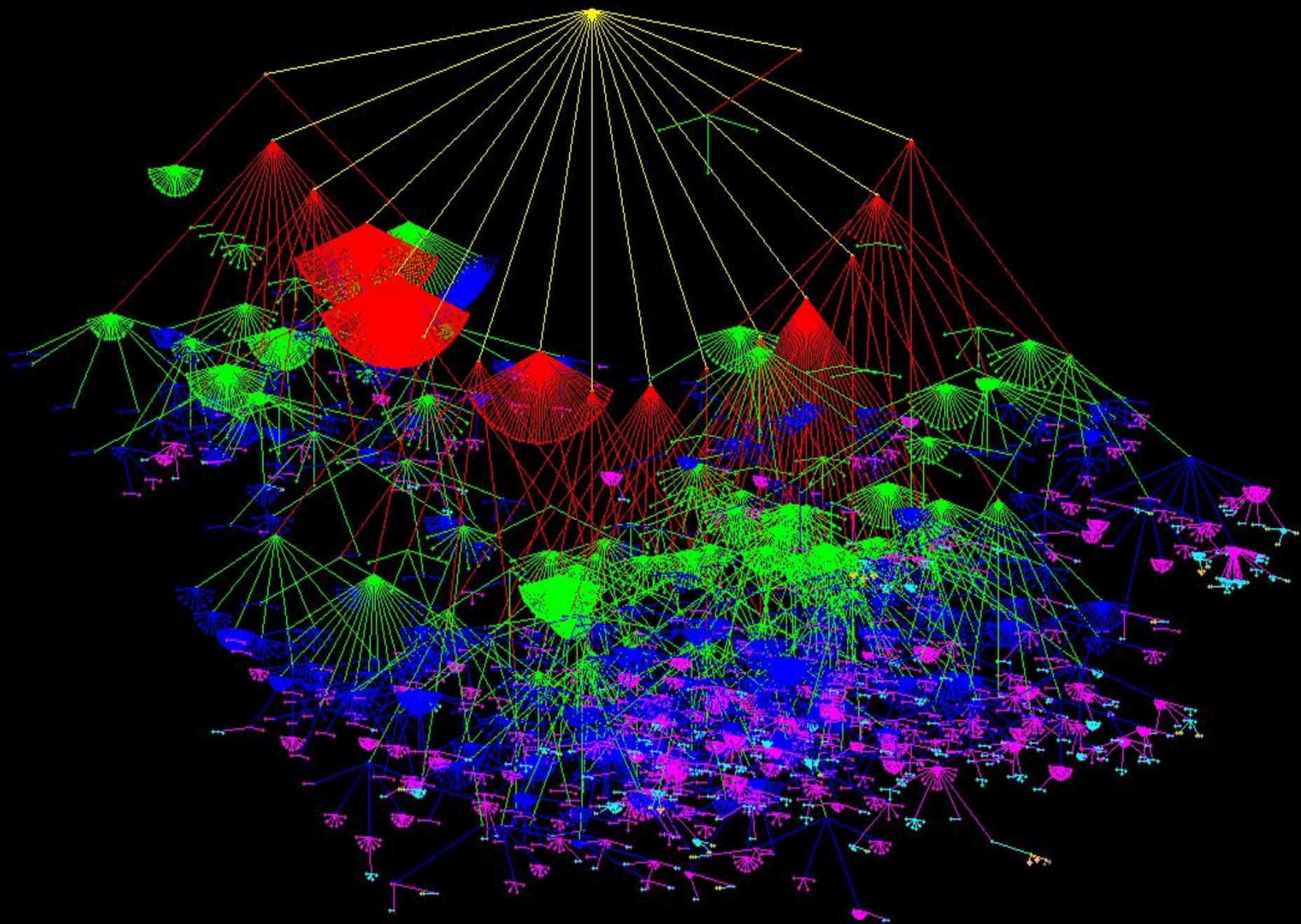


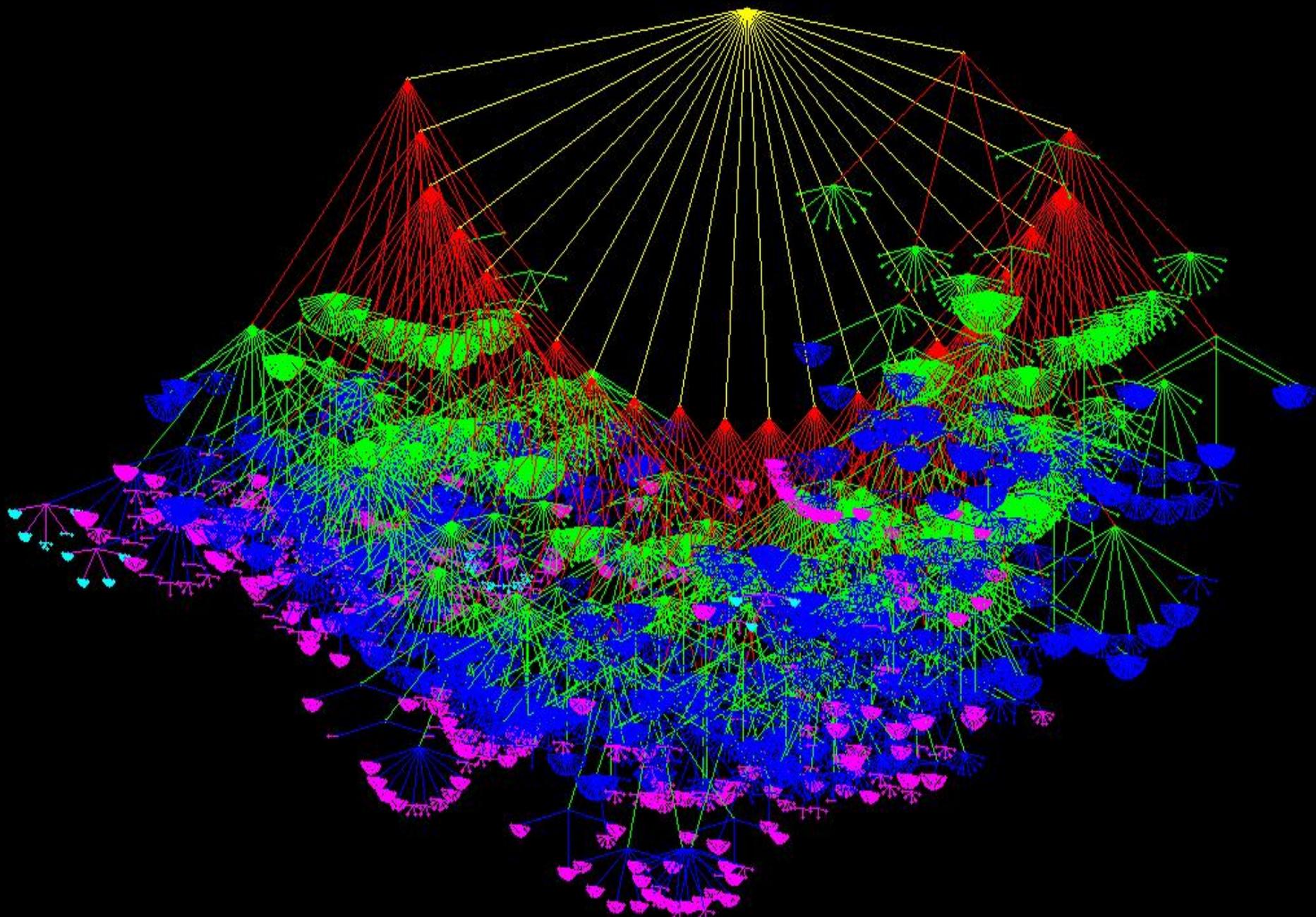


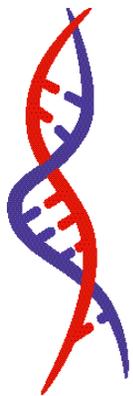






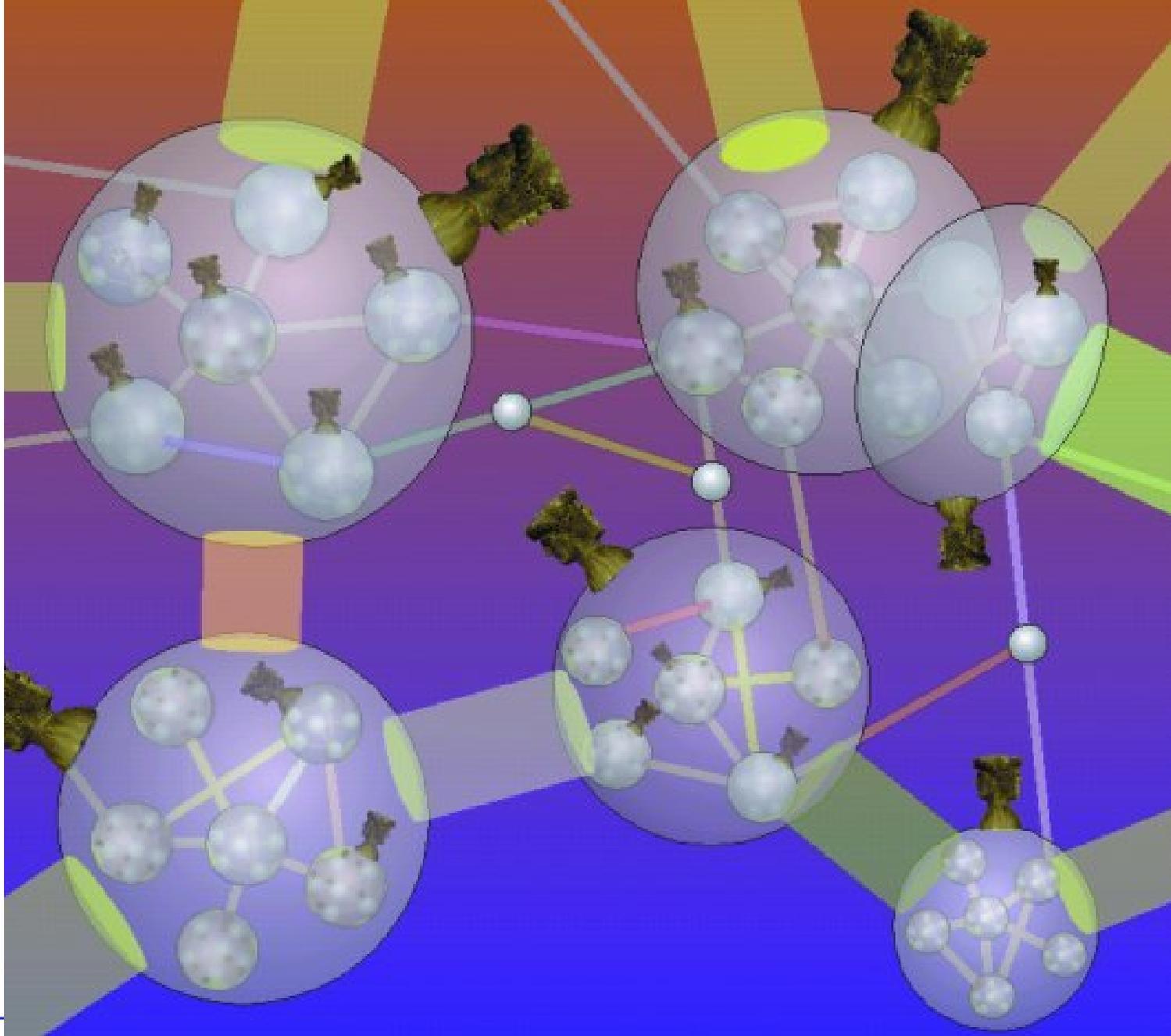






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Intelligent Agents

Rationale for the Use of Human Factors Engineering

- So What?
- Who Cares?
- What is in it for you?



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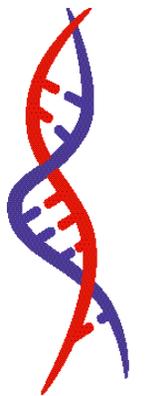
So What?

- IBM – “2/3 of all healthcare dollars spent on IT are spent on Systems which are never used or are used for less than three months.”
- Patient Safety can be compromised by poorly designed systems
 - Has led to deaths
 - Is a source of unnecessary liability



Who Cares?

- Administration
 - Limiting Costs (Mayo saved 1.5M, day 1)
- Physicians
 - Limiting Errors
 - Increased Efficiency
- Patients
 - Greater Safety



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What is in it for you?

- Greater Reliability
- Greater Acceptance
- Lower Cost of Implementation
- Lower Cost for Training
- Increased Patient Safety
- Improved Clinical Reputation of your Organization



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Reasons for Hard-to-Use Products

- Development Emphasis was on the Machine or System, Rather than the User
- Target Audience is a Moving Target
- Lack of Design Verification (Science vs. “Common Sense”)
- Development Teams are not well Integrated
- Skills necessary for the interface Design are Different than those necessary for the Technical Implementation of Systems!

User-Centered Design

- Requires an early focus on users and tasks
- Requires empiric measurement of product usage
- Requires iterative design cycles
 - Design
 - Testing
 - Modification
 - Re-Design

Human Factors Analysis

- **Contextual Inquiry**
 - Understanding End-User Needs
- **Competitive Usability Evaluations**
 - Expose Gaps in Existing Systems
- **Low-Fidelity Prototyping**
 - Rapid turnaround of Identified Program Changes
- **Modified Focus Groups**
 - Understand Relevant Work Flow and Processes

Usability Studies

- Developers and Evaluators
- Observe without Intervention
- Feel the Users Pain
- Come to Grips with Imperfection
- Resist the Impulse to Blame the User
- Resist the Impulse to Blame Yourself
- Acceptance
- Progress



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Realities of Human Factors Engineering

~Jakob Nielsen

- **Your Best Guess Is Not Good Enough**
 - It is impossible to design an optimal user interface just by giving it your best try.
 - Users will make unexpected misinterpretations of the interface and perform tasks differently than you expect.



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The User is Always Right

- **Accept the need to make modifications to fit the users' needs and expectations.**
- **If users have problems with the software, it is not their fault.**



The User is Not Always Right

- **Caution:** But it does not follow that the most usable interfaces can be designed just by asking users what they would like. Users may not understand how changes/enhancements could be beneficial.



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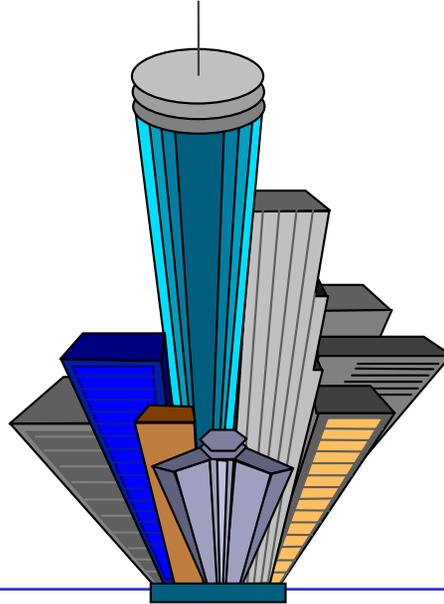
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Designers Are Not Users

- **Designers have a great deal of computer experience**
- **Designers have an inherent enthusiasm about computer applications**
- **Designers know the conceptual foundation for the design of the interface**
- ***“Knowing about a system is a one way street. One cannot go back to knowing nothing.”***

Vice Presidents Are Not Typical Users

- **Company executives typically have very different characteristics than the user population.**



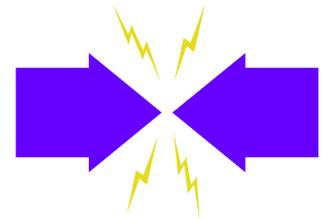
Usability Engineering is a Process

- **The Usability Engineering process is well refined and the activities needed to arrive at a good result are fairly constant**
- ***However*, each project is different and will have different objectives.**



Why GUI Design Fails

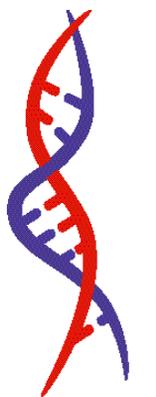
- **Engineers / Designers**
 - Design to their work patterns, not user work patterns
 - Design to their metaphor, not user perceptions
 - Want the application to control user tasks
 - Assume all users will be “Trained”
 - Plan that users will refer to documentation
 - Provide all features at the top levels
 - Are unaware of consistency issues or standards



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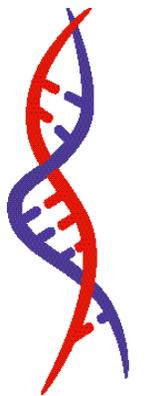
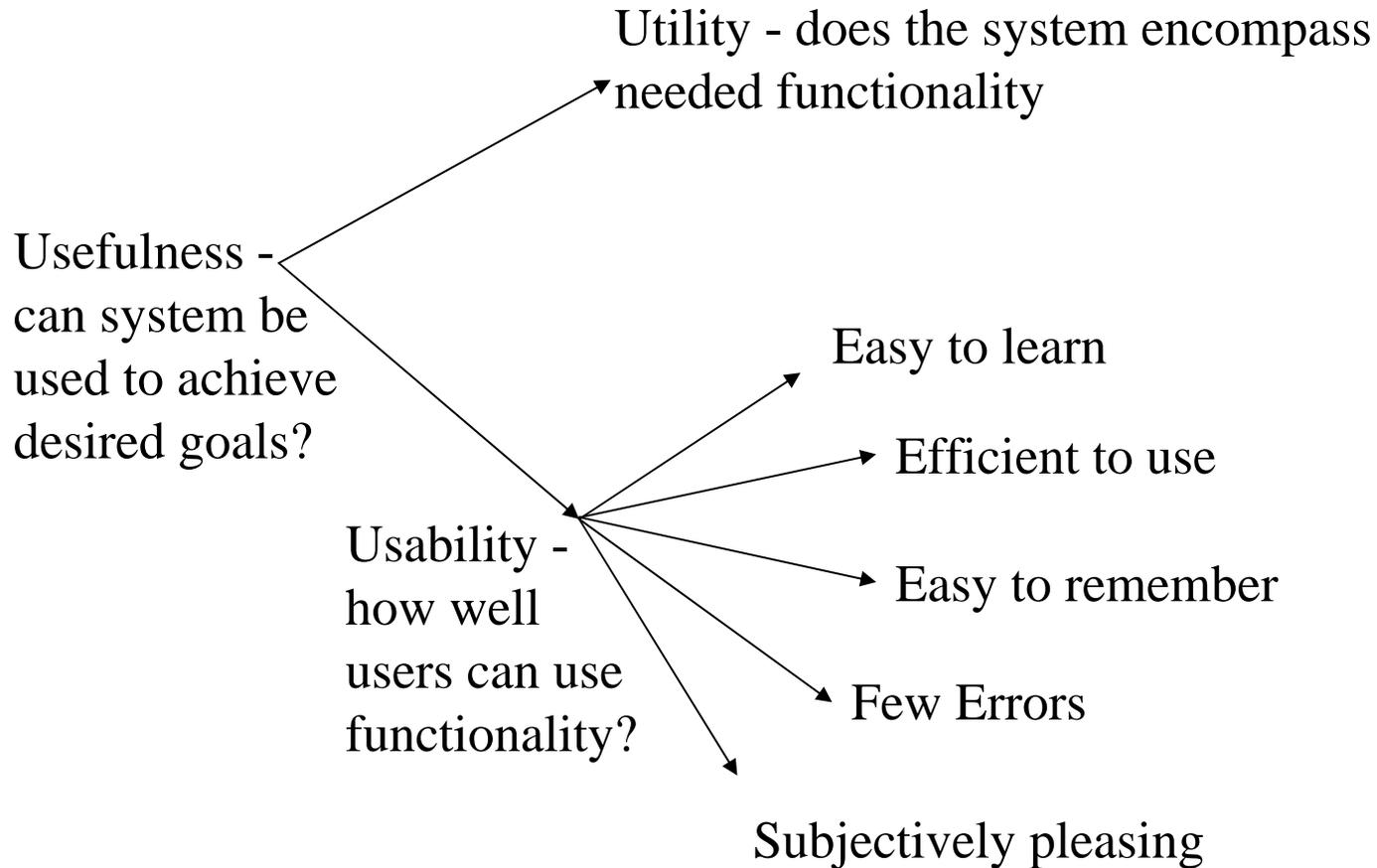
Bird Flu



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Usefulness: What Does This Mean?

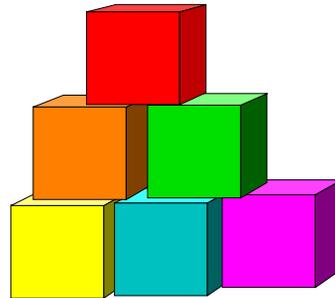


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What is a Usability Study?

- **A usability study is a replicable study of consumer/product or consumer/process interactions conducted in a controlled, simulated environment.**



Essential Components



- **To accomplish a valid study, we follow a specific protocol and have multiple participants interact with the same situations (scenarios).**
- **It is important to observe several participants interacting with the software in order to identify trends and prioritize issues. The goal is to improve the process or product, not to train the participants.**



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What can be studied?

- **Products or Processes**
- **True classical experiments with large sample sizes and complex test designs**
- **Informal, less complex studies designed for rapid processing of results**

Note: Each type of study has different objectives, as well as different time and resource requirements.



What can be learned?

- **Features/Functions that work**
- **Features/Functions that need improvement**
- **User/Consumer work patterns and mental models**
- **User/Consumer expectations and desires**
- **Prioritize areas for improvement - *unique advantage***



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Objectives Addressed Through the Study Design

- **Will the application make users' jobs easier/ Will it make users more productive?**
- **Is the system responsive/ fast enough?**
- **Is the complexity of the application appropriate for the defined/ intended user group(s)?**
- **What On-line Help functions are needed?**
- **What type(s) / degree of training is needed?**



Limitations of Usability Testing

- Testing is always an artificial situation
- Test Results do not Prove that a Product Works
- Participants are rarely truly representative of their target Population
- Testing is not Always the Best Technique (To Test or Not to Test?)
 - vs. Expert Evaluation
 - Focus Groups

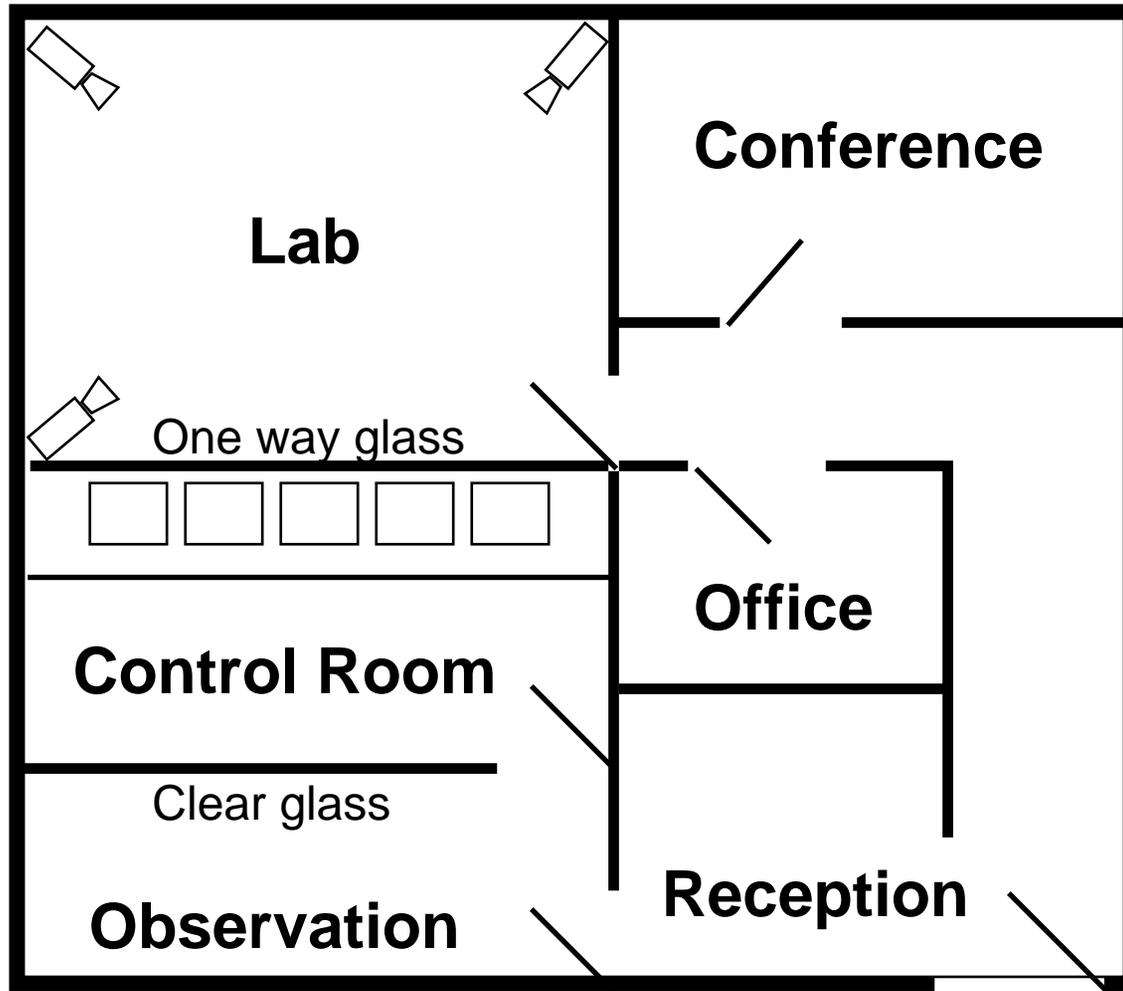


~~When Usability Study~~

- When Studying Complex Processes without option to Study Components Separately
- Lab Environment is Vastly different than User Environment
- Lab Space will not accommodate the Test
- When feedback will not be Utilized
- Subjects can not be found (Typical Users)



Usability Lab



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Usability Lab

In Use

038









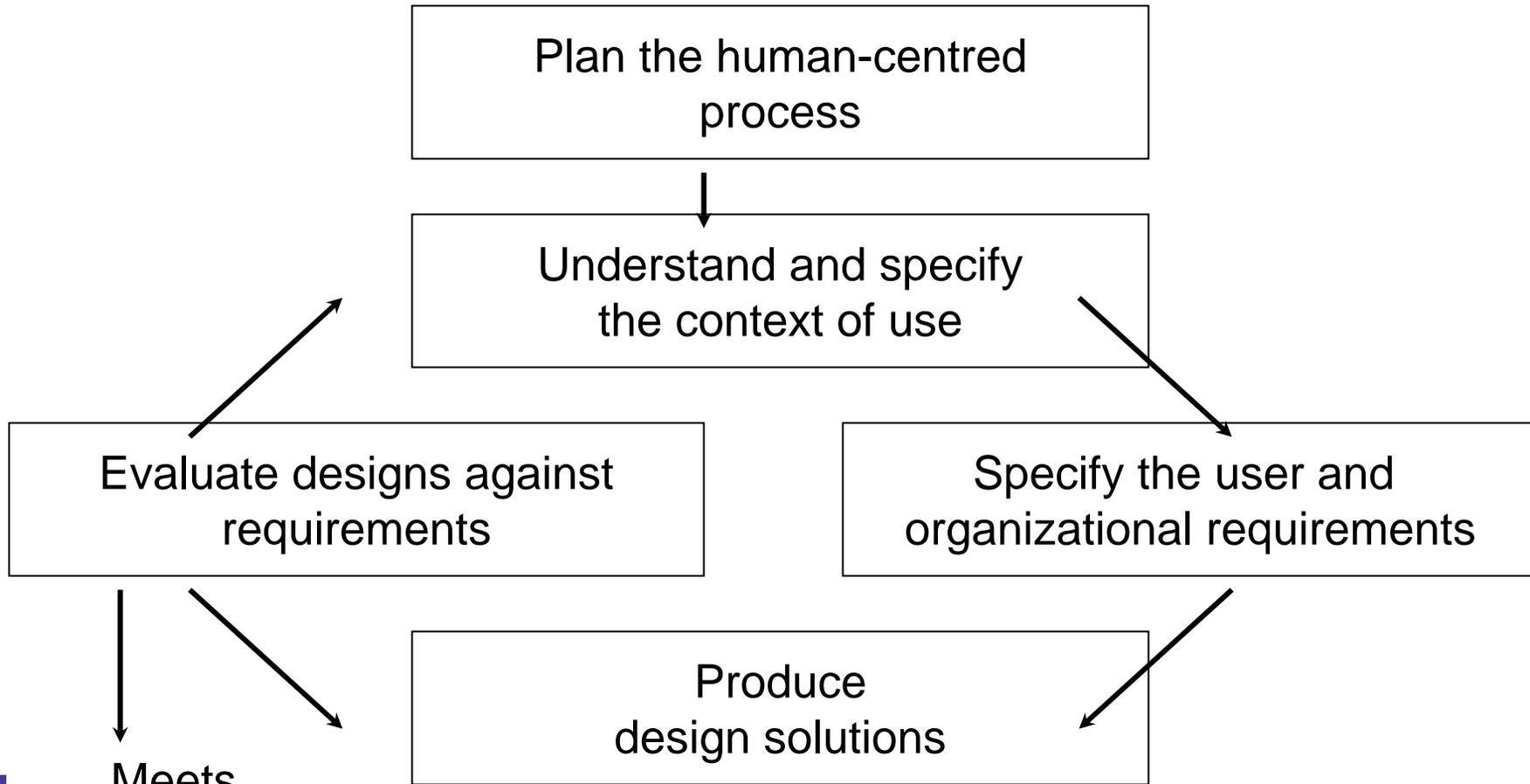


- * Dr. Howard
- * Dr. Fine
- * Dr. Howard
- ✓ Dr. F. Stein
- ✓ Dr. McCoy

- * Did no
navigat
- * Had tr
- * Wanted



Human-centred design development cycle (ISO 13407)



ISO 13407 & ISO/IEC 12207

		ISO/IEC-12207 primary lifecycle				
		Acquisit. & supply	Development			Operatio n & mainten.
			Require. anal.	Architect . Design	Qualific. testing	
ISO 13407	Context of use			N/A	N/A	N/A
	User & org. requir.			N/A	N/A	N/A
	Design solutions				N/A	N/A
	Evaluate					



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Conclusions

- Usability Studies
 - Useful Mechanisms for Objective Evaluation
 - Designed to Answer Specific Questions
 - Designed to Discover Questions to Answer



Quote: Peter Drucker – Harvard University

- “The Best Way to Predict the Future,
- Is to Create It.”



Health Information Technology Standards Panel

By

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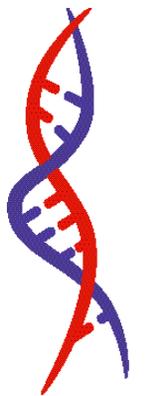
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HITSP

- *Context and process overview*
- Technical Committees
 - Consumer Empowerment
 - Biosurveillance
 - Electronic Health Record

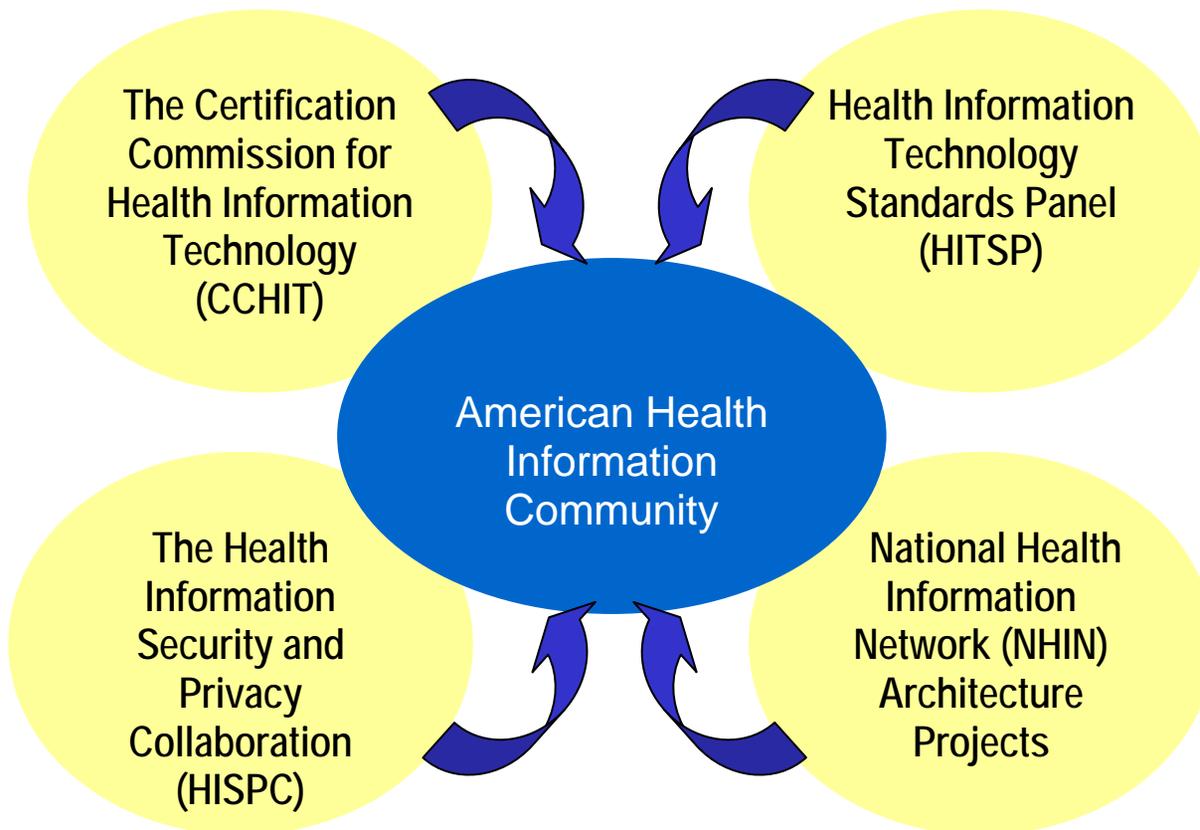


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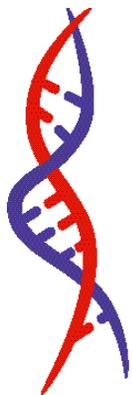
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The Community is the hub that drives opportunities for increasing nation wide health information interoperability



- CCHIT focuses on developing a mechanism for certification of health care IT products
- HITSP brings together all relevant stakeholders to identify appropriate IT standards
- HISPC addresses variations in business policy and state law that affect privacy and security
- NHIN is focused on interoperability pilots



HITSP was formed to prototype a process used to harmonize industry-wide HIT standards . . .

- HITSP formed under the sponsorship of the American National Standards Institute (ANSI), coordinator of the U.S. voluntary standardization system
- The Healthcare Information and Management Systems Society (HIMSS), the Advanced Technology Institute (ATI) and Booz Allen Hamilton serve as strategic partners with ANSI in this initiative
- Brings together a wide range of stakeholders into a formal “panel” to identify, select, and harmonize standards for communicating data throughout the healthcare spectrum
- Formation of the Panel was endorsed by a number of industry groups and has the oversight and backing of ONCHIT
- John D. Halamka, MD, MS, CIO of the Harvard School of Medicine chairs the Panel
- A total of 155 organizations participate in HITSP representing consumer, SDO, non-SDOs, and government interests
- Non SDO make up 67% of the panel and include clinicians, providers, safety net providers, vendors, purchasers, payers, public health professionals, and researchers



. . . The process is repeatable and fully integrated with CCHIT and AHIC

1. For each AHIC Use Case, HITSP Technical Committees identify candidate standards which are harmonized into a final list of standards
 - ▶ They also identify overlaps and highlight gaps. Gaps are forwarded to Standards Development Organizations for their guidance as to emerging candidate standards or new standards requirements.
 2. The final standards chosen by the Technical Committees are discussed and ratified by the HITSP panel.
 3. These standards are available for public comment and feedback.
 4. Technical Committees work with SDOs and other groups to produce detailed specifications, an unambiguous “cookbook”, for the implementation of chosen standards. HITSP provides a convening and facilitation function for this activity.
 5. HITSP work products are delivered to AHIC for their endorsement.
 6. CCHIT will include functional criteria for interoperability based on HITSP specifications in its certification work
-

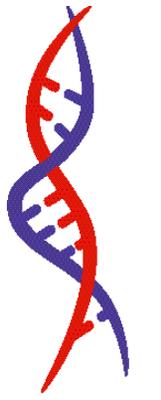
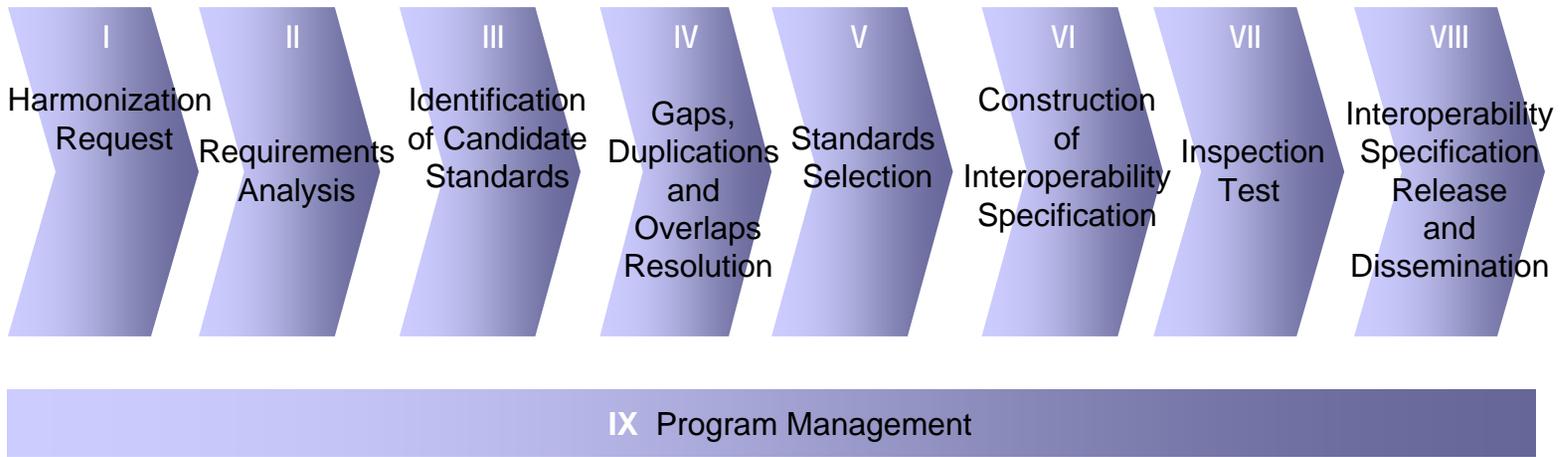


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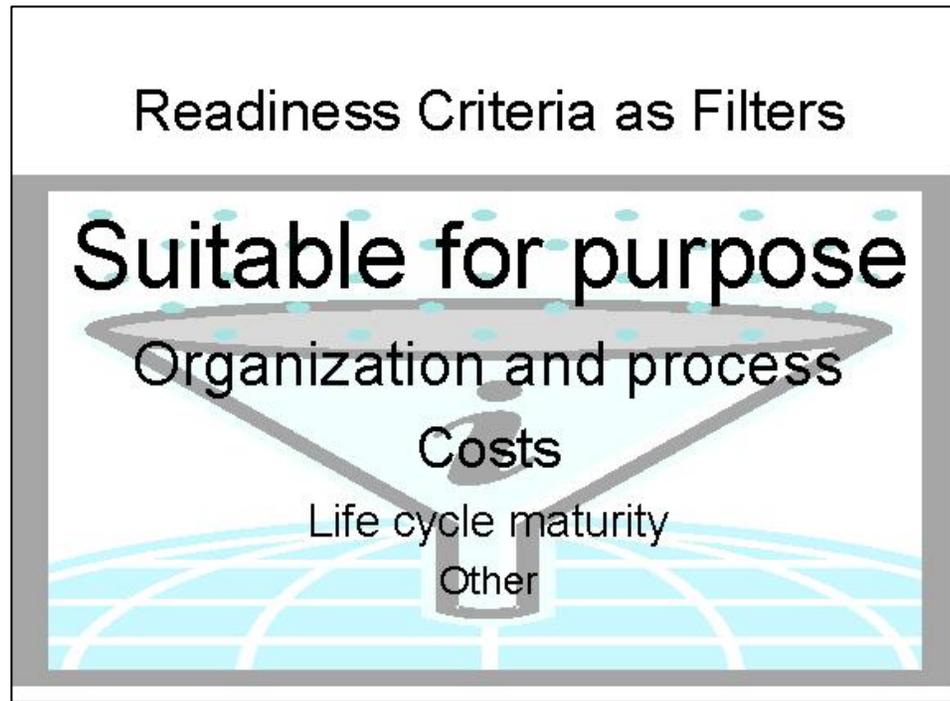
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The HITSP process results in creation of an Interoperability Specification used to promote nationwide interoperable health information exchange

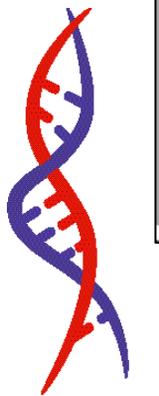
Harmonization Process Steps



Tier 1 Standards Readiness Criteria



- The standards required to support each major Use Case event were organized within an agreed upon standards taxonomy
- The standards selected for inclusion in the pool were examined using ‘HITSP approved’ Tier 1 and Tier 2 Harmonization Readiness Criteria



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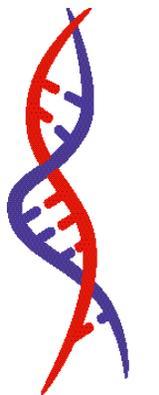
Tier 2 Standards Readiness Criteria

- Suitability
 - The standard is named at a proper level of specificity and meets technical and business criteria of use case
- Compatibility
 - The standard shares common context, information exchange structures, content or data elements, security and processes with other HITSP harmonized standards or adopted frameworks as appropriate
- Preferred Standards Characteristics
 - Approved standards, widely used, readily available, technology neutral, supporting uniformity, demonstrating flexibility and international usage are preferred
- Standards Development Organization and Process
 - Meet selected criteria including balance, transparency, developer due process, stewardship and others.
- Total Costs and Ease of Implementation
 - Deferred to future work

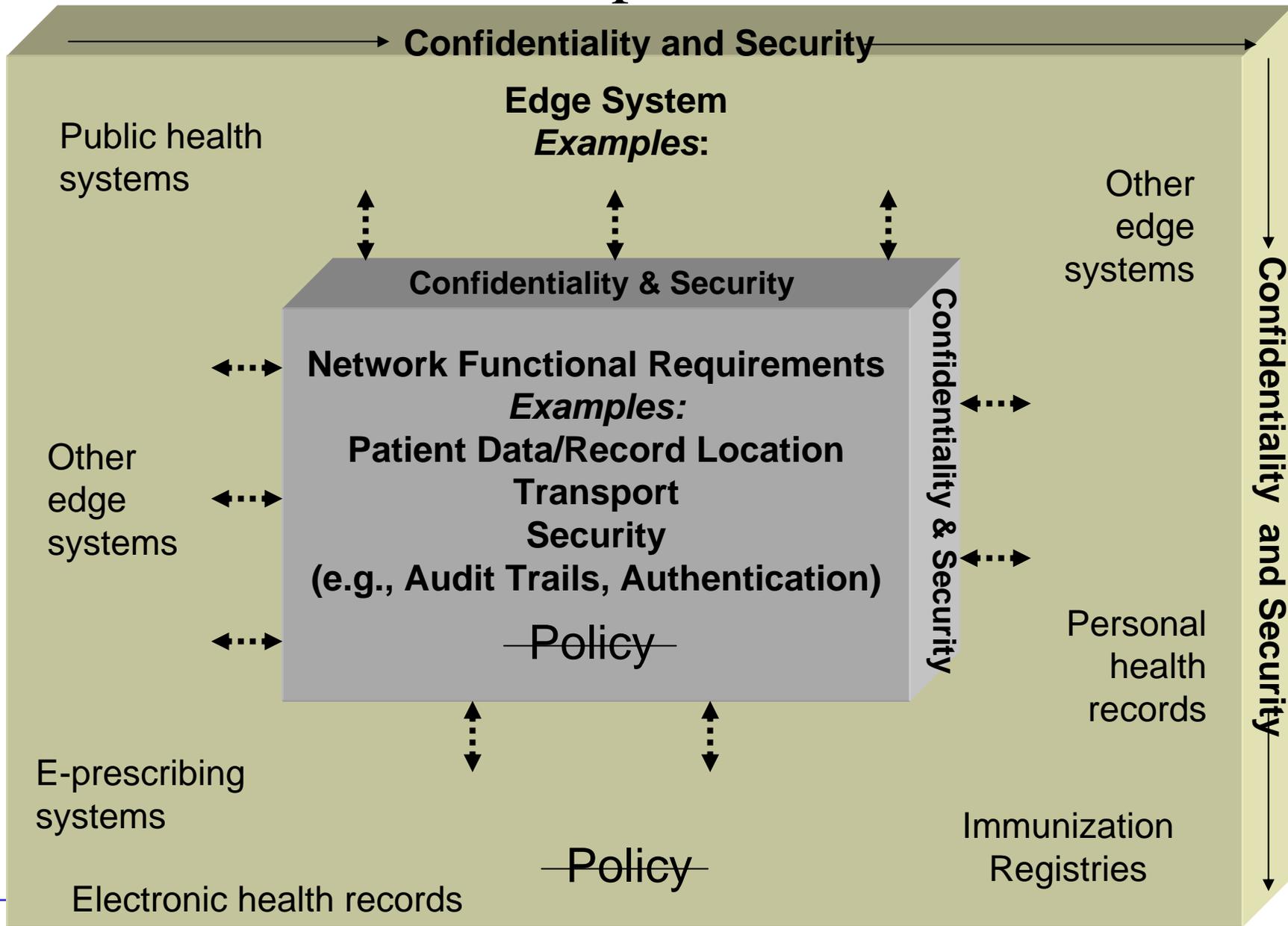


Progress to date:

- In June of 2006, HITSP reduced 570 candidate standards to 90 appropriate standards for secure exchange of medication, lab, allergy and demographic data
- In September 29, 2006, HITSP delivered interoperability specifications which will enable vendors, hospitals and government to create software components for clinical data exchange
- Beyond 2006, HITSP will develop harmonized standards and unambiguous implementation guides which provide precise instructions for data sharing for all future requests for harmonization
- Also, it will standardize the interoperability specifications for technology products, while permitting differentiation and competitive advantage in the marketplace. HITSP hopes to empower patients and care providers with Devices including Electronic Health Records (EHR) that facilitate easy access to health data that is longitudinal, accurate, private and secure.
- HITSP is a key component of the Health and Human Services vision to create an interoperable healthcare system, and we look forward to our work products empowering patients, providers and government stakeholders in 2006 and beyond



Discussion Template of NHIN



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Proposed Nationwide Health Information Network

Functional Categories

- Audit and logging
- Authentication
- Authorization
- Confidentiality
- Credentialing
- Data access and update
- Data content
- Data filtering
- Data mapping/translation
- Data quality/data integrity

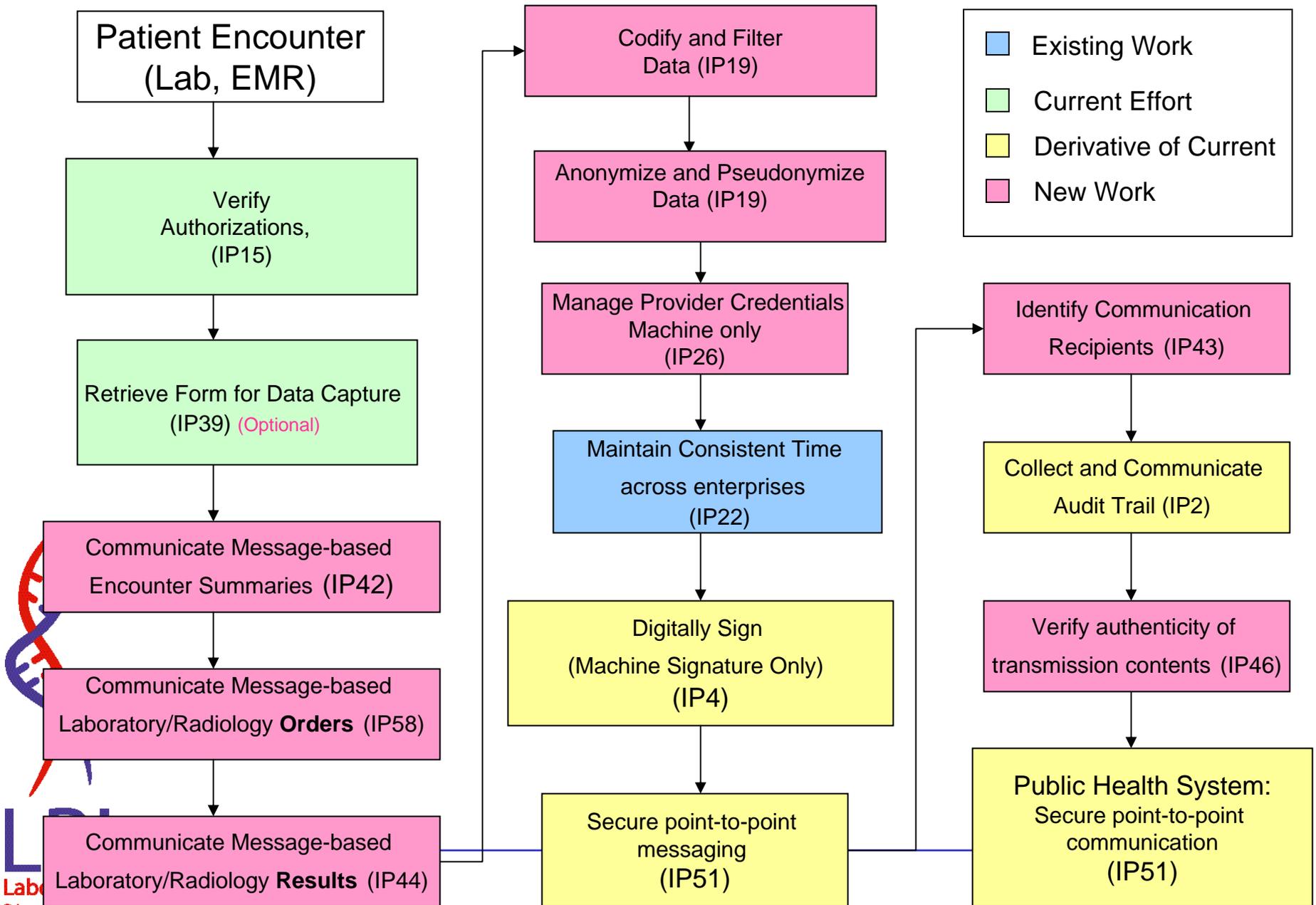
- Data rendering
- Data retrieval (pull)
- Data routing
- Data source
- Data transmission (push)
- Data usage
- Identity/information correlation
- Persistent data storage
- Record location
- Transient data



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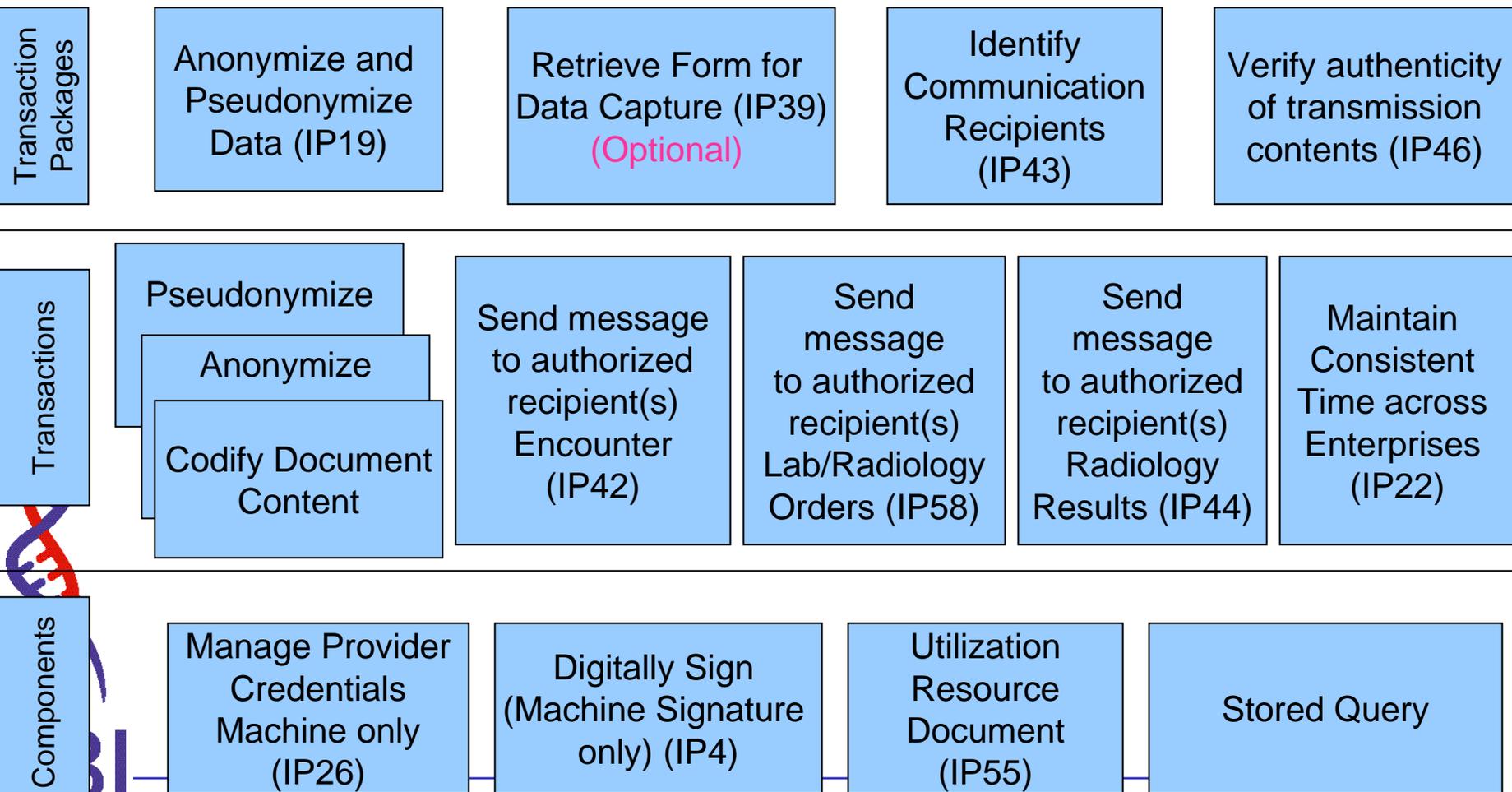
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Surveillance Message-Based Data Submission Functional Flow



BIO Construct Framework - Draft

BIO - Constructs



NHII Framework for Strategic Action

- Inform clinical practice
- Interconnect clinicians
- Personalize care
- Improve population health



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*We need better mechanisms by which we can
provide personalized care for our patients!*

Conclusions: Personalized Medicine Utilizing Ontologies in Support of the iEHR

- **Personalized Medicine** requires a detailed understanding of the relationship between:
 - Complex phenotypes and genotypes
- Longitudinal data capture from Medical Devices
- Safe and Effective Use of Prescription Medications
- Phenomics – An important Bioinformatics resource
- Interoperability can facilitate communication between home health devices and the intelligent electronic health record
- **Biomedical Informatics** => *One Discipline with Many areas of specialization including BioInformatics and Clinical Informatics*

