HL-7 at the Epicenter

Standards, Interoperability and the Need to Become Involved

Prepared For

The PRISM Forum

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The healthcare market has several characteristics that make it very attractive from an informatics perspective ...

Enormous Market	• $1.4 trillion (U.S.) < $3.5 trillion worldwide • Growing at GDP + 4.0%
Inefficiency	• Labor-intensive business processes • Historical underinvestment in technology
Information Intensity	• Mountains of patient information and medical knowledge to manage
Fragmented Customer Base	• Tremendous need for connectivity, knowledge sharing, and transaction processing across multiple organizations
Biological Complexity	• Need for sophisticated data management, analysis and modeling tools

… the healthcare market also presents several unique challenges related to informatics

Challenges	Implications
Patient Privacy and Data Security	• Extreme sensitivity to maintaining privacy and anonymity
Central Role of Physicians	• Technology solutions must consider needs of physicians and provide incentives to encourage adoption
Government Regulation	• Requirement for customized solutions to address industry specific needs such as reimbursement, FDA product approval, etc. • Technology solutions must be compliant with government standards (e.g. HIPAA)
Technology Hurdles	• "Last mile issues" • Bandwidth bottlenecks • Integration of legacy systems
Multiple, Disconnected, Publicly Funded Initiatives	• Local issues and political imperatives • Single payer vs. multi-payer conflicts • Aggressive funding (NHIS, NHS Singapore, etc.)

The nature of information targets in healthcare are either "structural" or "procedural"

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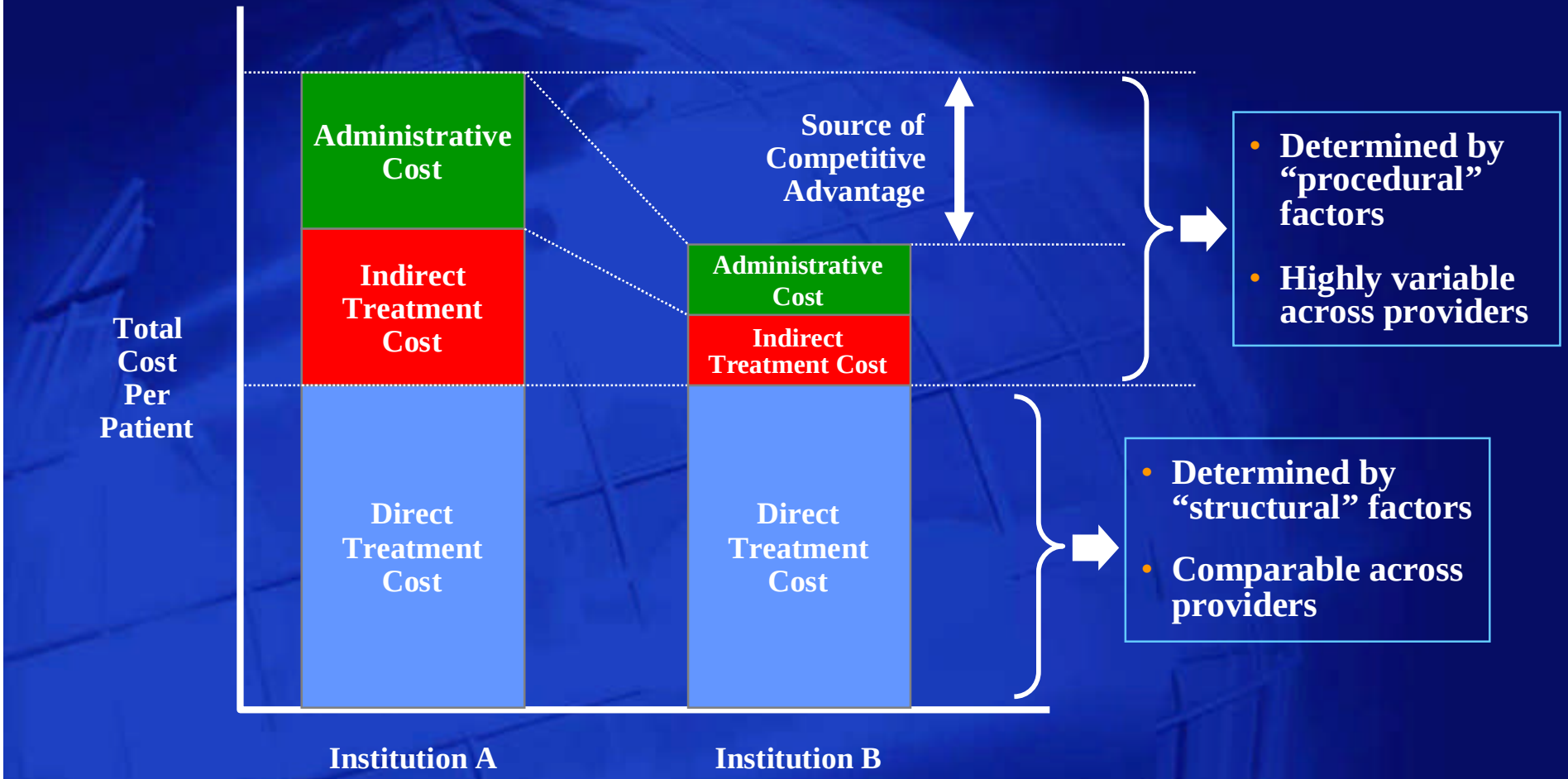
Since all healthcare providers have to bear the cost of structural changes, differentiation and competitive advantage are determined by procedural competencies, with significant impact on health information deployment



"E-health" providers have seized upon transitioning informational needs and increasingly focus on internet-enabled solutions …

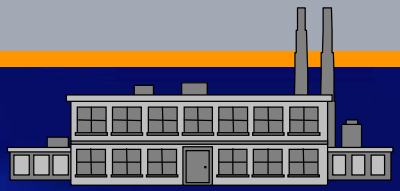
	Content	Connectivity	E-Commerce
Products/ Services	• Medical information resources	• Communications and knowledge sharing	• On-line marketplaces • Claims processing
Revenue Model	Subscription or Advertising	→	Transactions

… with obvious impact on "how, where and why" systems are accessed, used and deployed

Information Exchange Patterns – Present …

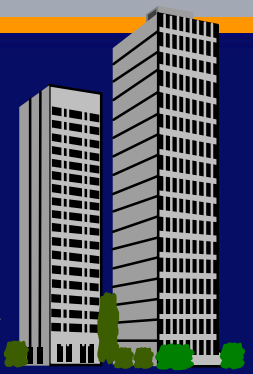
Hospitals

Laboratories

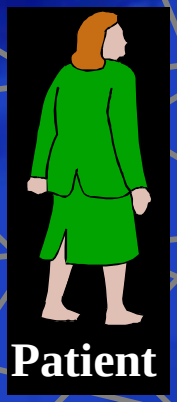


Employer

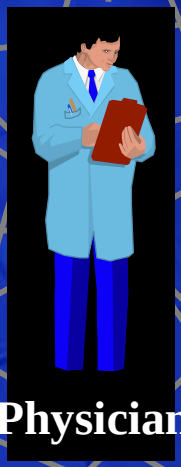
Insurance Company



Specialist



Patient

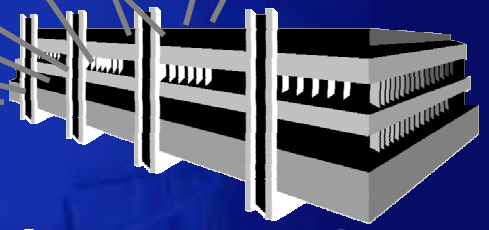


Physician

Credit Card Company

Bank

Pharmacy



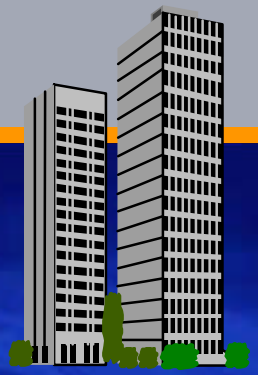
Other Insurance Company and Government

… poor quality of information, generally non-interoperable

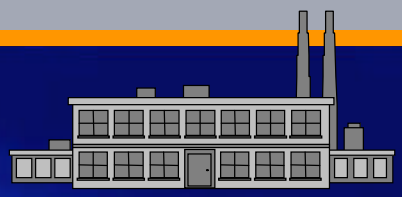
Information Exchange Patterns – Future …

Hospitals

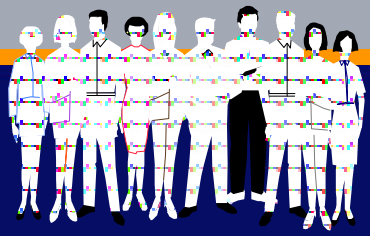
Laboratories



Insurance Carrier



Employer



Members

Pharmacy

Ubiquitous Connectivity

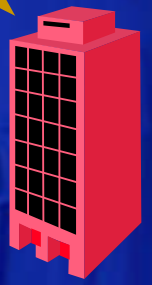
Bank

Specialist

Medical Library

Pharmaceutical Company

Government



Third Party Administrators

Credit Card Company

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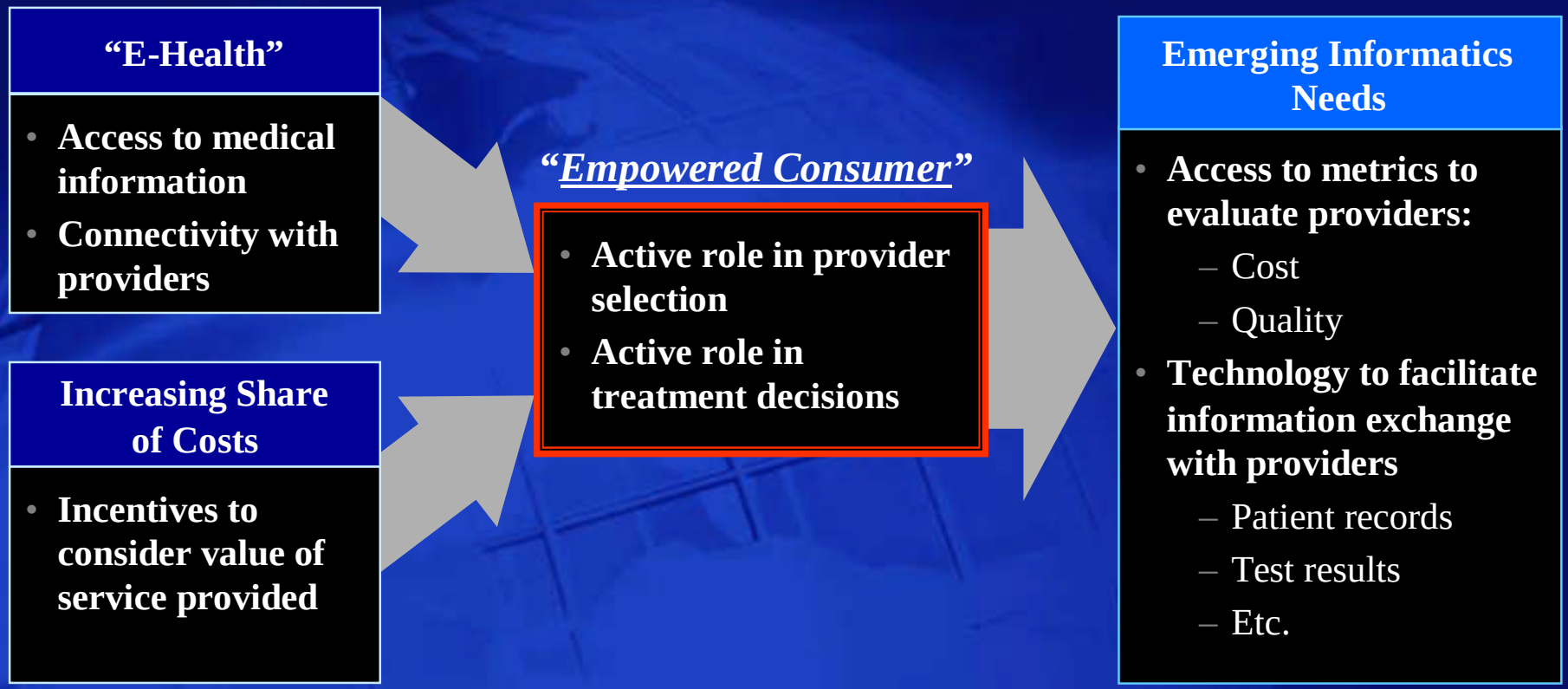
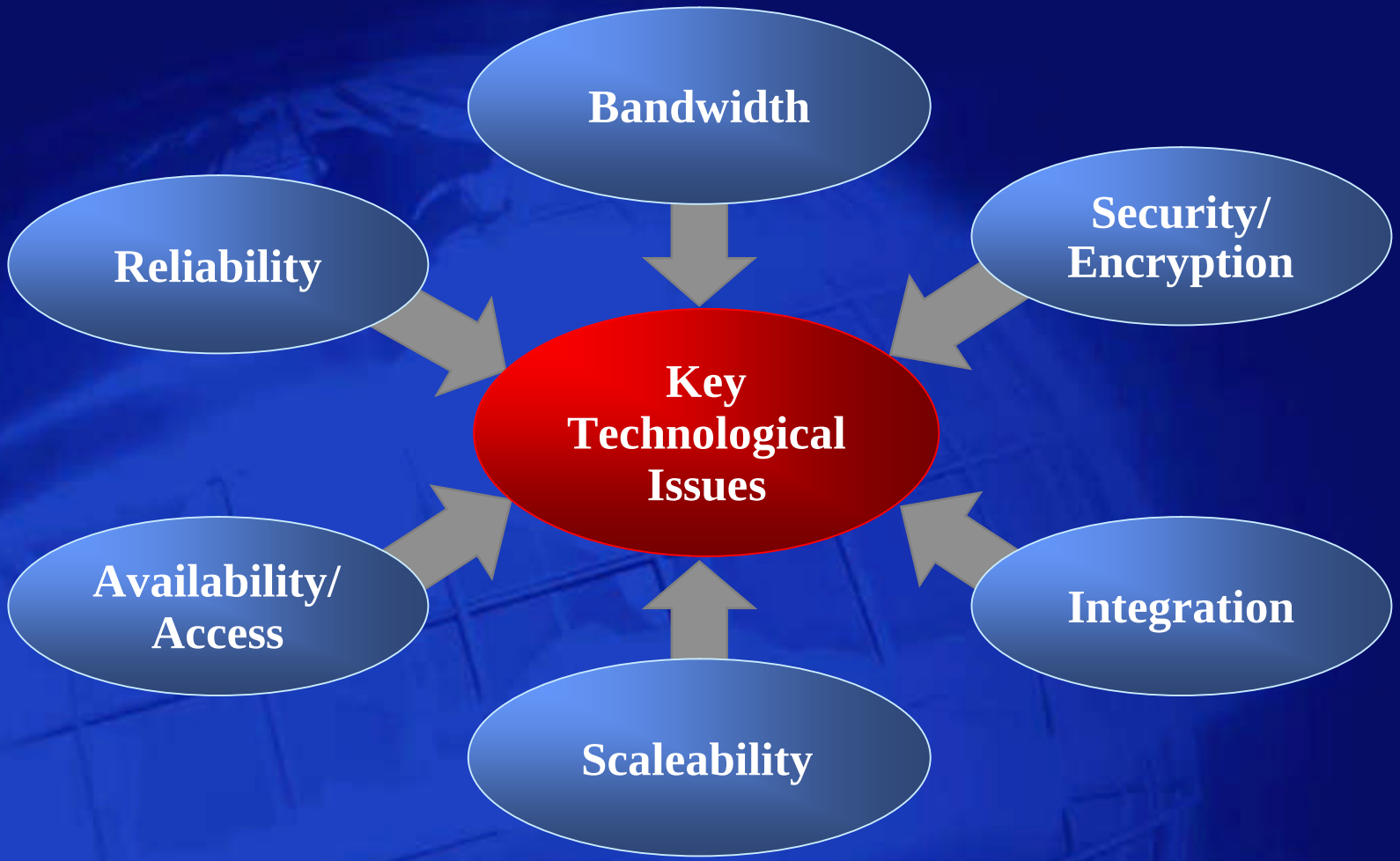
… high "value" information that is uniformly interoperable

The twin forces of "e-health" and payor initiatives to increase patient share of healthcare costs will increasingly drive patients to move beyond their traditional role as "passive" recipients of care …



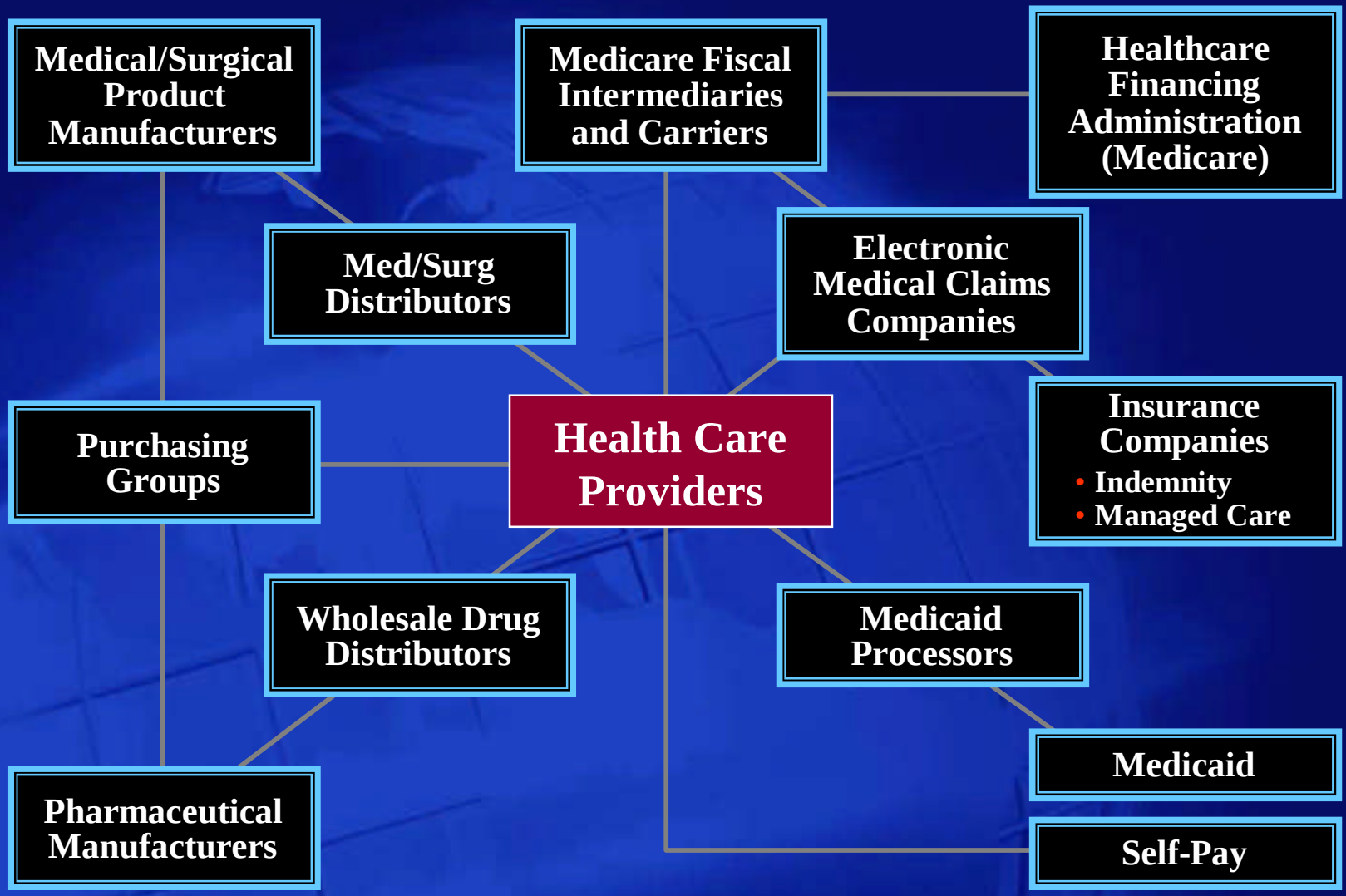
… with very significant impact on the need for open access and interoperability

Health informatics is no longer an island - the critical information technology issues in healthcare are increasingly those confronted and resolved by industry in general …



… Unique, however is the seminal need for standards and interoperability by all constituents

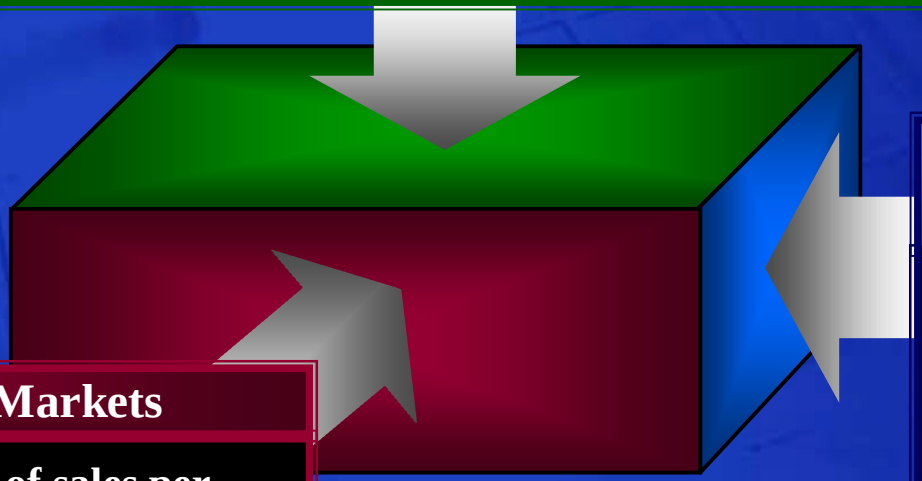
Integration issues are obviously challenging in healthcare, given the need to interface with existing legacy systems, the inherent divergence of the participants, and the reality implicit to changing "practices" to successful deployment



The Pharmaceutical industry is increasingly driven to participate in eHealth

Price Controls

- **Most western European countries as well as Canada and Australia have a price control mechanism built into their national health care systems**
- **While there are no government price controls in the U.S., pressure is mounting**
  - Self-imposed pricing restraint due to threat of regulation



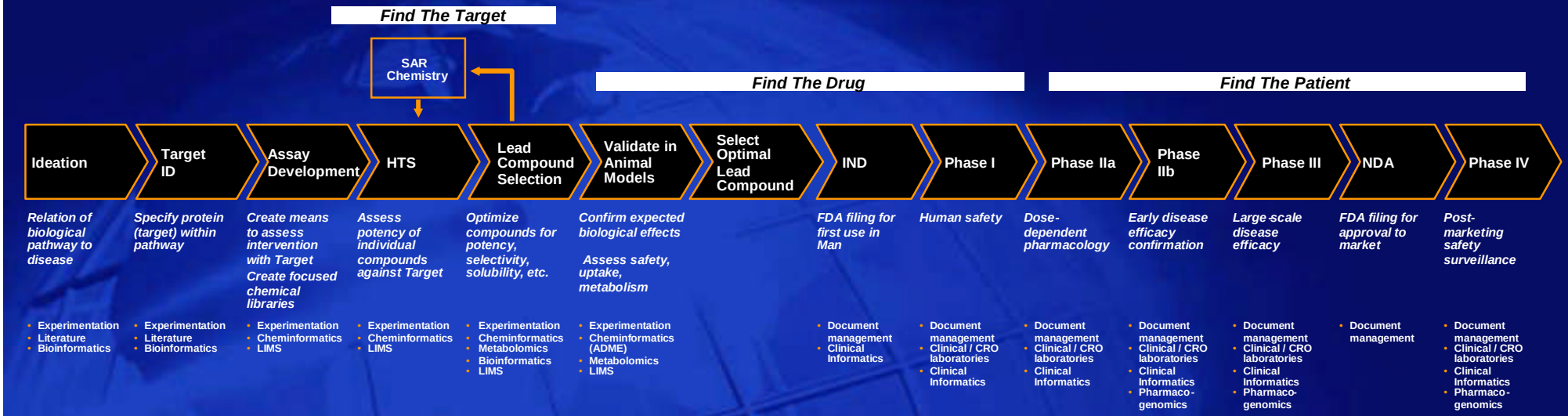
Narrower Markets

- **Potential volume of sales per compound may get significantly smaller**
  - "Micromarkets" resulting from genetic profiling

Increasing Competitive Intensity

- **Product life-cycles are shortening**
  - Shorter windows of exclusivity
  - Aggressive generic competitors challenging patent extension strategies

The drug development process is driven by the need for actionable and accurate data and information to support product selection, development and deployment …



… real-time clinical data is at the heart of an improved discovery/development process

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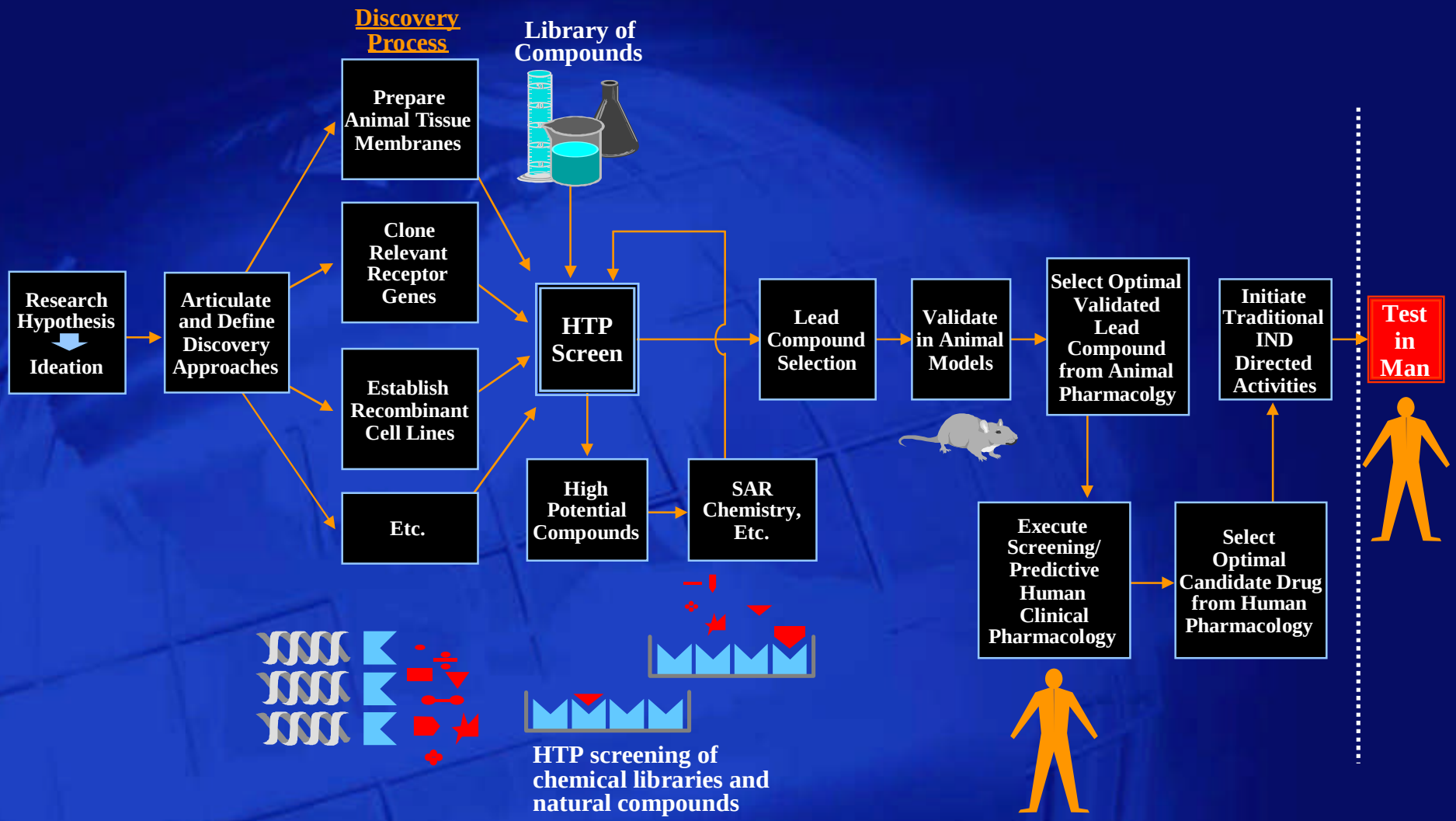
This reality can be impacted by the earlier and more defined introduction of human clinical pharmacology in the drug development process - man as a tool of discovery as well as approval …



… this also demands eHR deployment and interoperability

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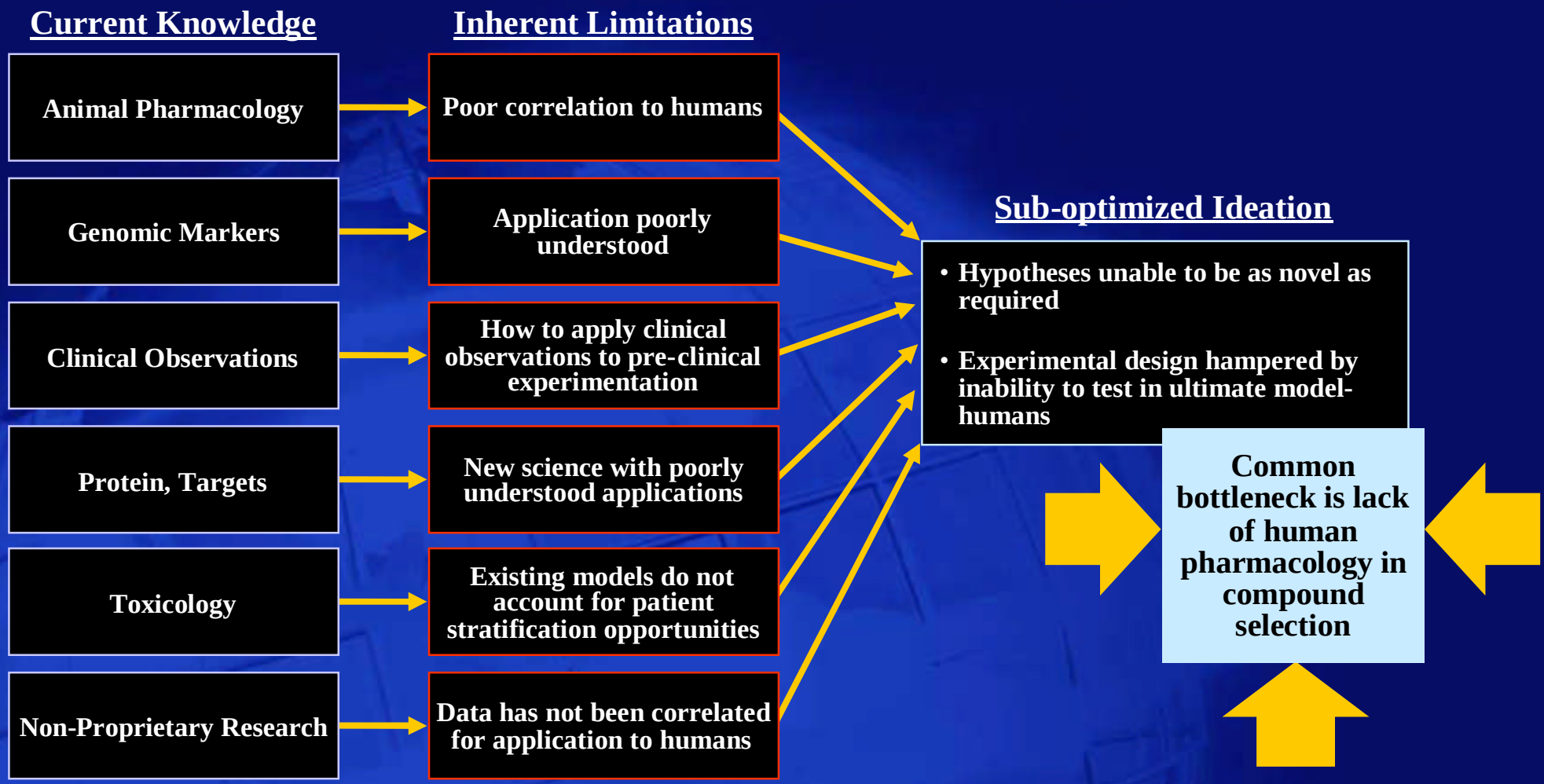
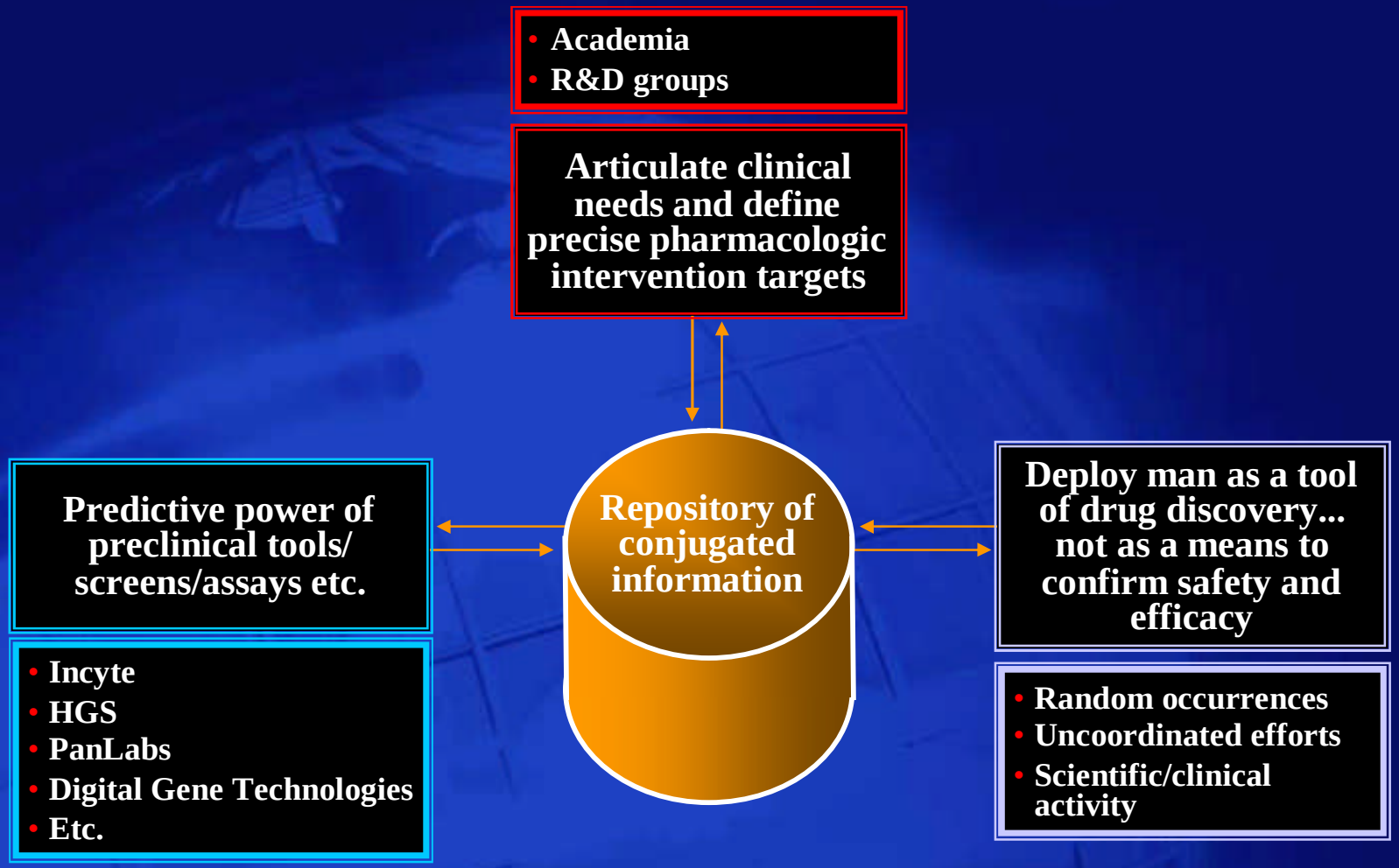
The application of experimental medicine for lead compound selection is of critical importance to improving productivity …



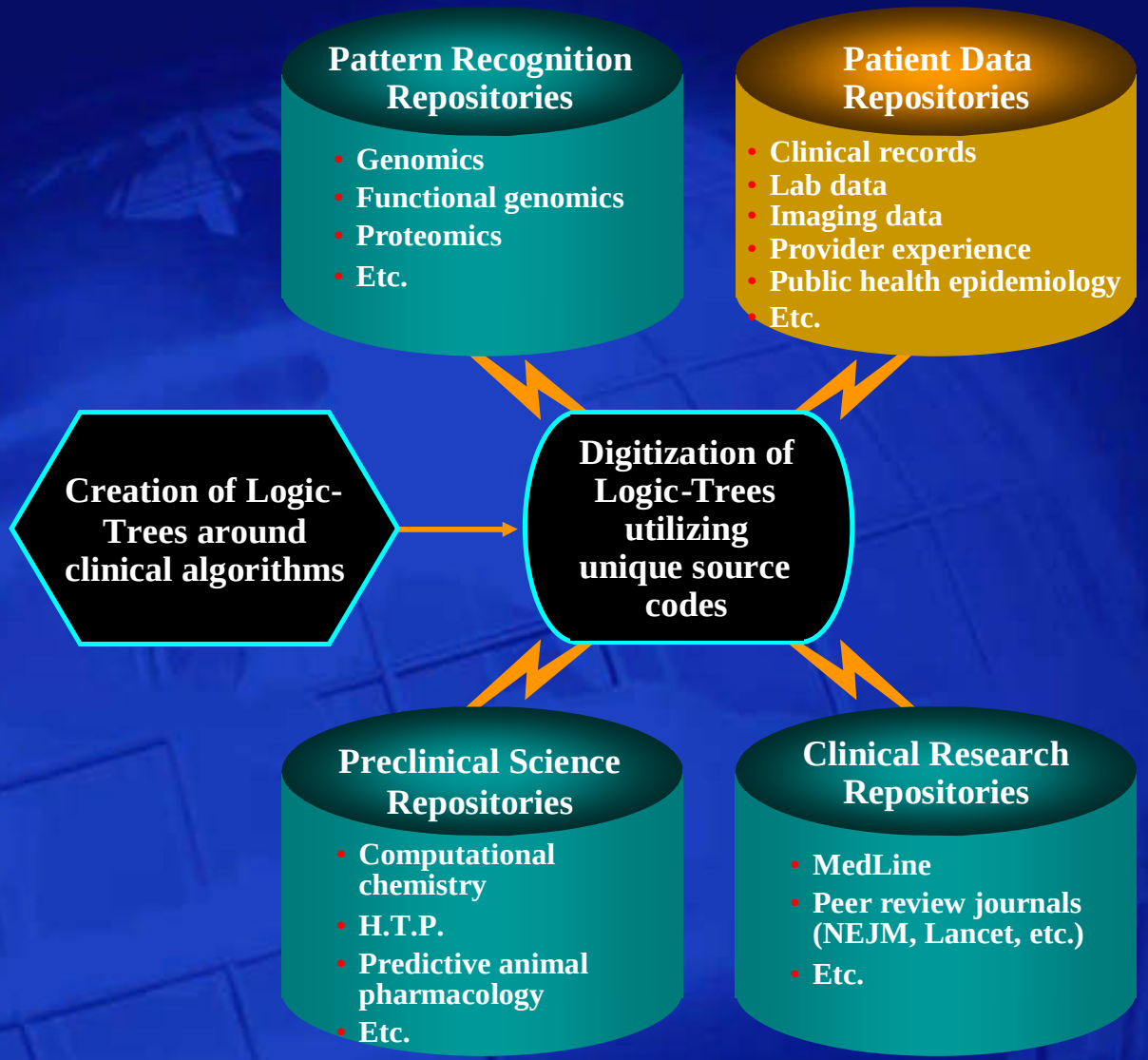
… it is hampered by deficiencies in existing knowledge management capabilities and access to defined patient populations

The linking of preclinical science and information tools to human pharmacological outcome remains a substantial impedence to continued improvement in efficiency of drug discovery and development …



… it will be impacted only by the human experience and will be defining of future success. It demands a deployed eHR network, uniformly adopted standards and interoperability

The provision of premier codified (digitized) human clinical pharmacology information, relationally linked to all available preclinical data/information (scientific and informational) is a gating requirement to alter the probability and speed in the drug discovery and development process



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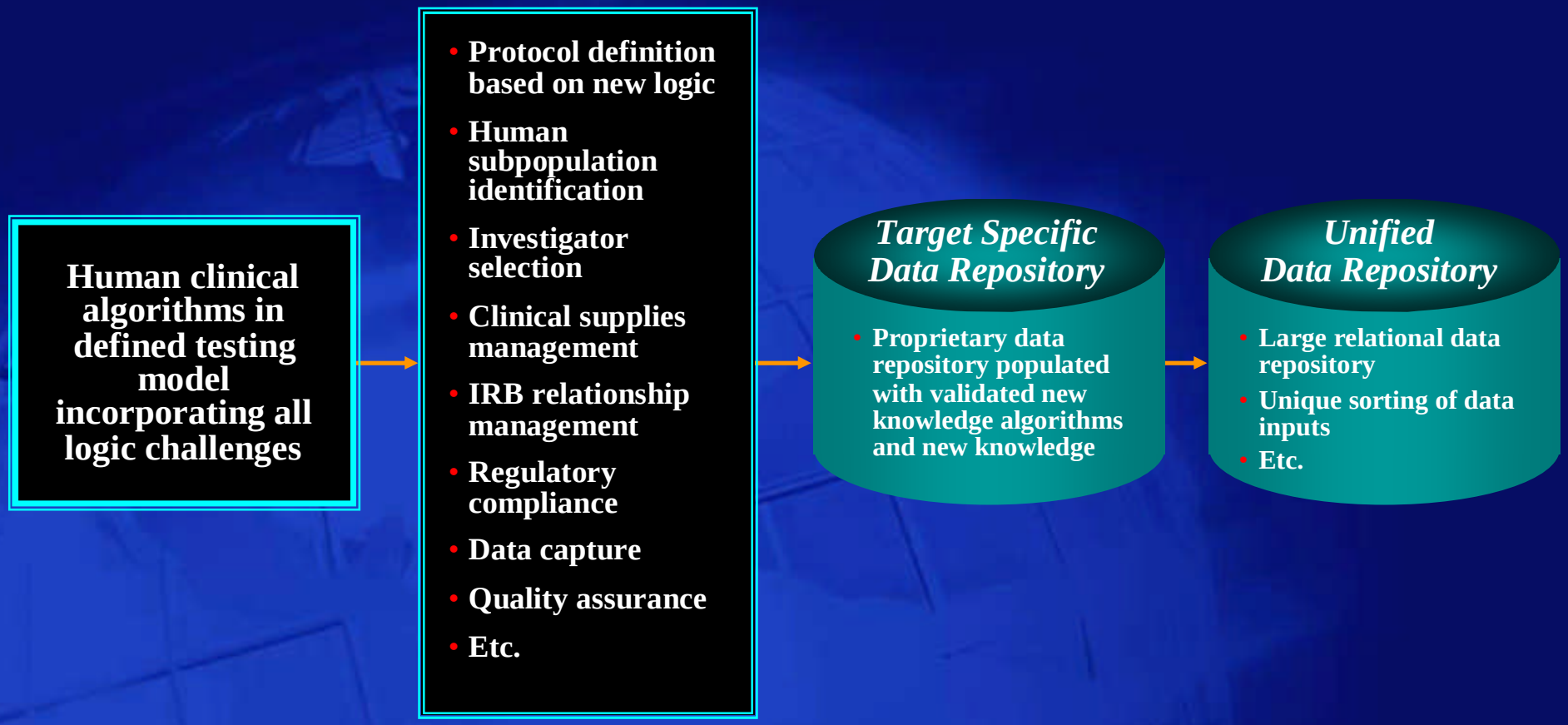
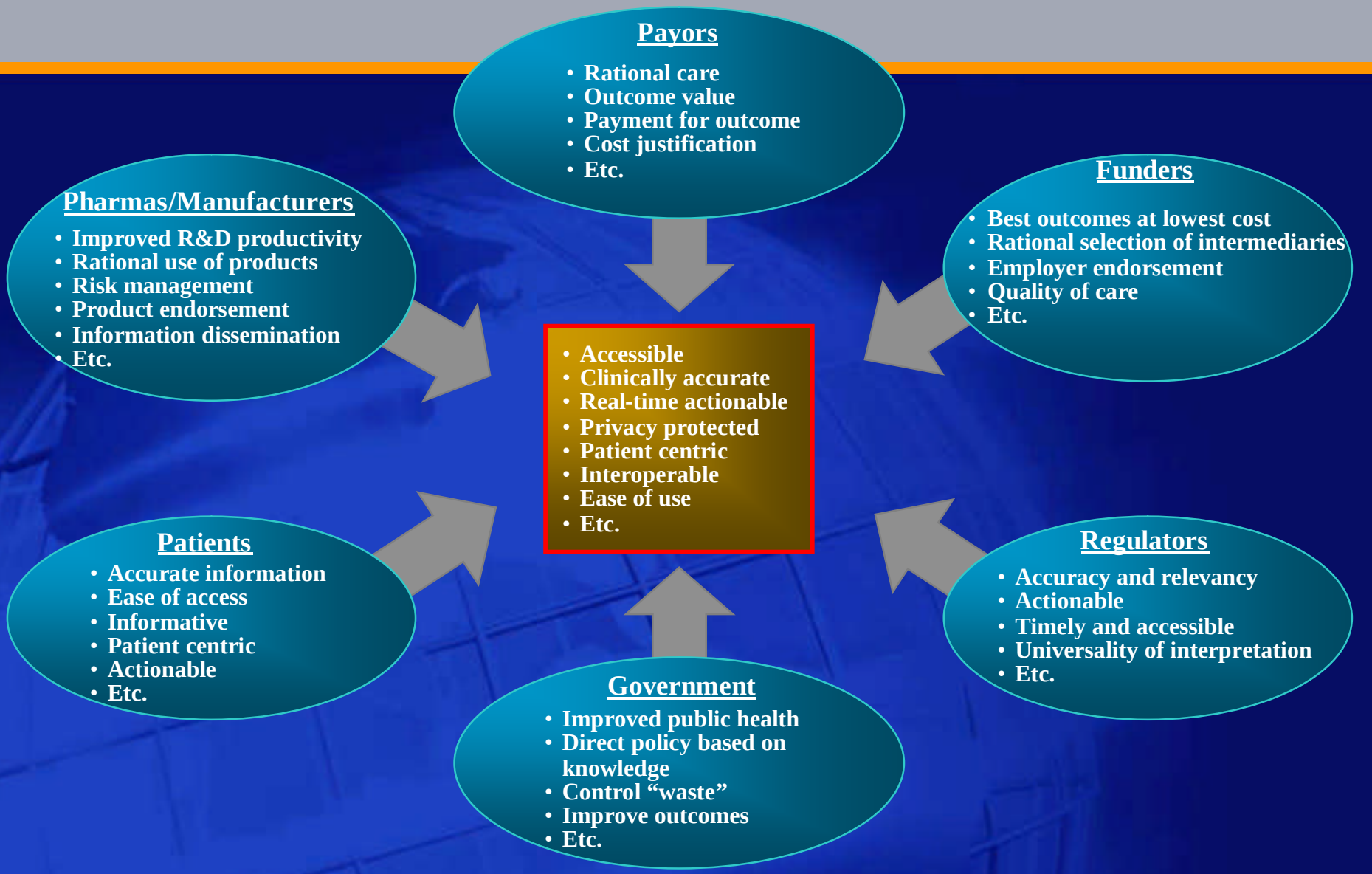
Human clinical pharmacology/outcome algorithms will materially alter lead compound selection through clinical sites …



… it is the "holy grail" of drug development. It requires her deployment, standards and interoperability

There is an increasing alignment of interests of all major stakeholders in healthcare …



… all are enabled by real-time, accurate, accessible, interoperative, actionable and clinically relevant information!

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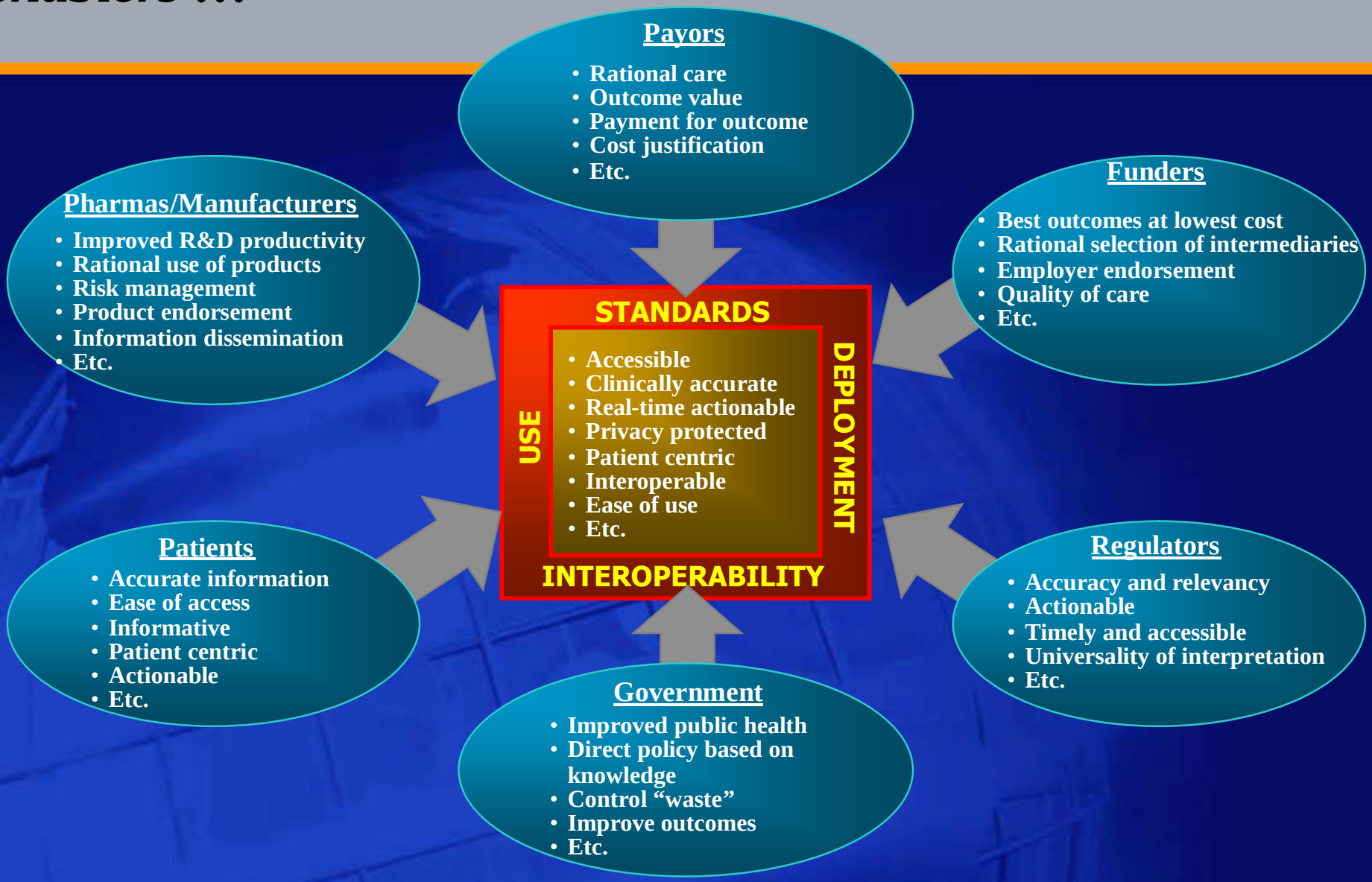
Interoperability and effective standards are critical enablers …



… HL-7 is committed to this goal!

The HL-7 Mission Statement defines a lofty goal …

"HL-7 is an international community of healthcare subject matter experts and information scientists collaborating to create standards for the exchange, management and integration of electronic healthcare information. HL-7 promotes the use of such standards within and among healthcare organizations to increase the effectiveness and efficiency of healthcare delivery for the benefit of all"

HL-7 State of the Union Address – Sept. 2005

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… HL-7's mission implies more than creating standard messages, documents, services/API's, etc.

To expedite this goal, HL-7 has set a primary (and growing) focus on standards collaboration and systems harmonization. It has set in place three clear imperatives

Promote and enable standards groups working together with the goal of making the information content of their standards shareable without loss of computable meaning between/among their messages/services documents and other "interoperable forms"

Creating the appropriate changes to each/all standards to achieve this goal

Promoting a formal methodology and a common reference information model

An effective reference information model must have the two critical attributes …

- **Sufficient granularity to be able to represent all the information represented by any standard**
- **A formal method to support the extensibility that will be required to represent all the information represented by any standard**

HL-7 will contribute to reference information by effecting two important contributions

- **The HL-7 RIM and the HL-7 HDF include a reference information model with the requisite granularity and extensibility**
- **HL-7 possesses the extensibility needed to accommodate new domains of information without changing the existing information domains**

- **Sufficient granularity to be able to represent all the information represented by any standard**
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An effective collaboration must execute and perform seamlessly to the goal of ubiquitous utility, it must …

- **Be among the standards produced by a single SDO and between standards produced by different SDOs**
- **Must allow and enable the user community to decide which existing or new standards they wish to use, and in which contexts, without the concern that information created in one context will be un-usable in another**
- **Not be a "rip and replace" effort but a "collaborate and harmonize" effort**

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- **HL-7 possesses the extensibility needed to accommodate new domains of information without changing the existing information domains**

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HL-7 has set critical imperatives that will help enable it's mission

- **Develop coherent, extendible standards that permit structured, encoded health care information of the type required to support patient care, to be exchanged between computer applications while preserving meaning**
- **Develop a formal methodology to support the creation of HL-7 standards from the HL-7 Reference Information Model (RIM)**
- **Educate the healthcare industry, policy makers, and the general public concerning the benefits of healthcare information standardization generally and HL-7 standards specifically**
- **Promote the use of HL-7 standards world-wide through the creation of HL-7 International Affiliate organizations, which participate in developing HL-7 standards and which localize HL-7 standards as required**
- **Stimulate, encourage and facilitate domain experts from healthcare industry stakeholder organizations to participate in HL-7 to develop healthcare information standards in their area of expertise**
- **Collaborate with other standards development organizations and national and international sanctioning bodies (e.g. ANSI and ISO), in both the healthcare and information infrastructure domains to promote the use of supportive and compatible standards**
- **Collaborate with healthcare information technology users to ensure that HL-7 standards meet real-world requirements, and that appropriate standards development efforts are initiated by HL-7 to meet emergent requirements**

HL-7 is already involved in widely disparate projects that are focused on interoperabilities and harmonization

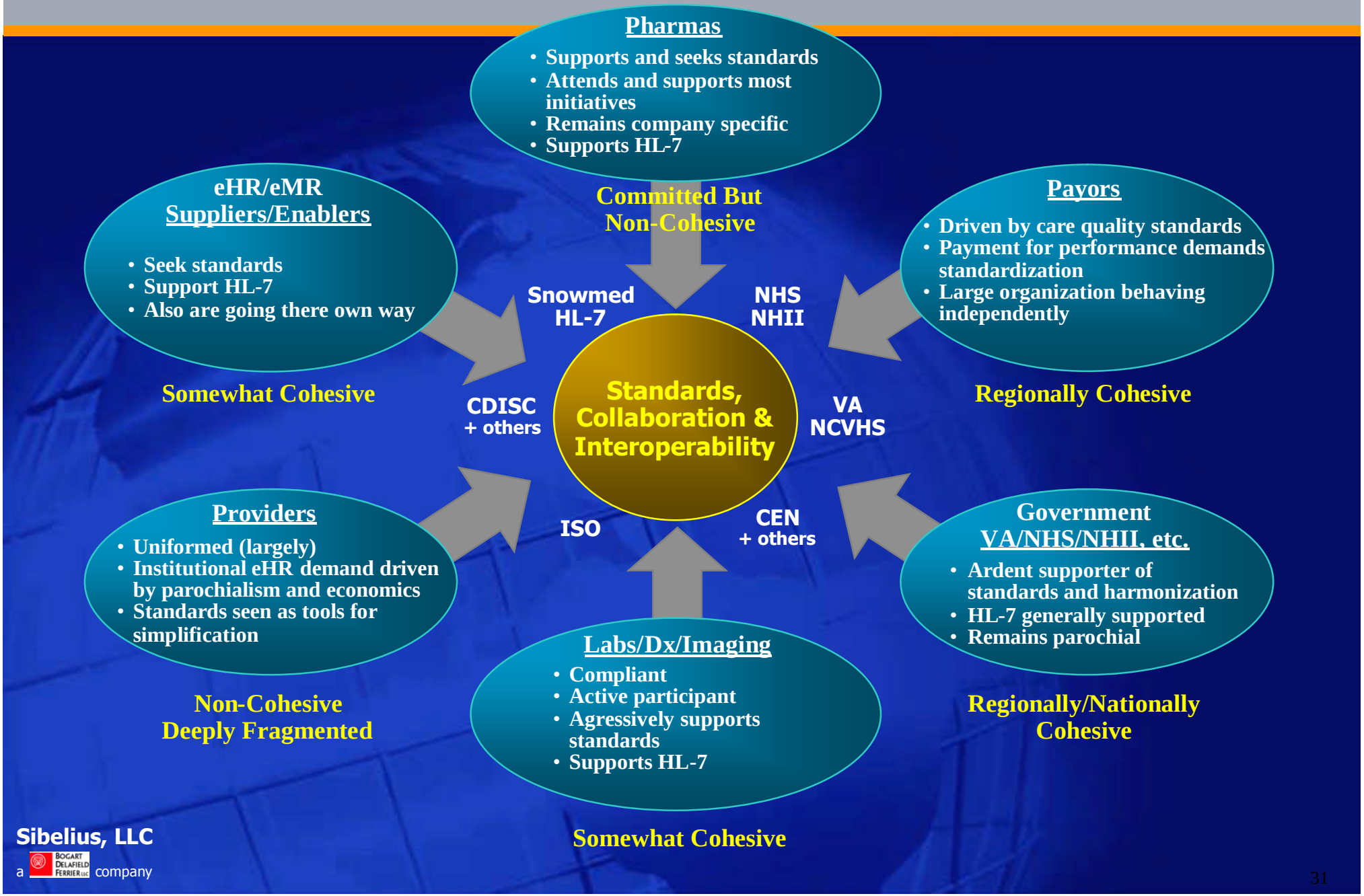
- **Health information domain projects focused on**
  - Patient care structured documents
  - Common model for clinical statements (LAB, Rx, Dx, etc.)
    - Early version is already integrated, with updates following
- **Terminfo Project**
  - Binding of standard vocabularies to version-3 models; focused on clinical statements
  - HL-7/Snomed collaboration at many levels
- **Templates Project**
  - Defining technical aspects to define template artifacts – incorporating these in HL-7 methodologies
  - Work on print and computerized versions from multiple professional societies (HL-7 + CEN TC 251 joint project)
  - Opens EHR and CEN TC 251 collaboration
- **Allergies Project**
  - Common information model to present allergies in patient care, implementation, patient safety, pharmacy, etc. (TCs and SIGs)
- **Infrastructure Projects**

Infrastructure Projects

- **V2.x Tooling**
- **MWB new version is available, plus a new tool in development**
- **A new version of Message Maker that automatically generates test messages for HL7 V2 conformance profiles**
- **New multi-phase project proposal (Jiva Medical, Eclipse healthcare forum) for complete suite of open source HL-7 tools**
- **HL-7 open source licensing approach for tools development**
- **V3 tooling: new projects:**
  - Architecture - UML component model of requirements with documentation, UML interface definitions with documentation, set of test cases for component interfaces
  - GForge - configuration for HL-7 tooling requirements
  - Update the UML HL-7 profile
  - Model Interchange Format (MIF) completion - including support for conformance profiles, templates, dynamic model, free-standing documents, and vocabulary constraints
  - Enhancements to v3 publishing tools
  - HDF Phase III: planned
- **Dynamic Model: planned**
- **Conformance registries (co-developed with NIST) for v2 and v3 (in process)**
- **v2-v3 mapping project – still in "project formation stage"**
- **Registry Patterns project – An effort jointly undertaken with contributions from HL-7 Canada and HL-7 Netherlands who are likely to be early adopters**

AND MUCH MORE

Domain guidance and leadership is critical to the success of HL-7's mission. It is sought by HL-7



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