



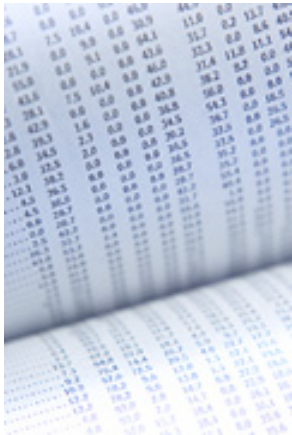
## Information Transparency to Drive Knowledge-Based Drug Development

Alan S. Louie, Ph.D., Research Director  
Health Industry Insights

PPM Philadelphia 2008, September 15, 2008

# Life Science R&D is in Transition

**Beyond good work and continuous innovation, sustainable and productive life science R&D will require an agile, effective IT infrastructure.**

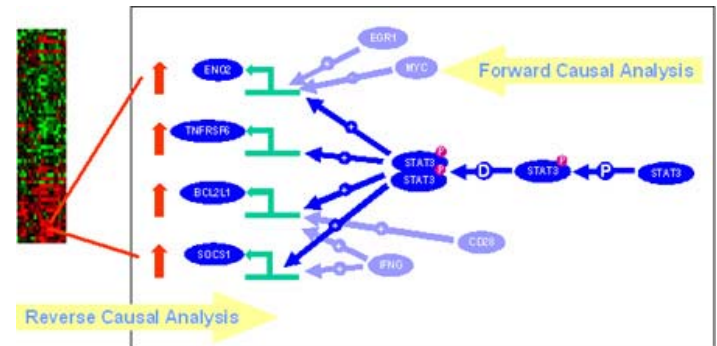


Effective management and exploitation of massive amounts of data

Creation and management of knowledge



Automated and transparent information connectivity



Source: Genstruct, 2007.

# New Approaches to Pharma Information Management Are Being Put In Place

## Traditional IT Infrastructure is under siege

- Globalization and increased M&A are driving distributed solutions
  - The industry is moving from multiple groups to multiple divisions and multiple companies
- Cost containment pressure is driving the push for increased efficiency options
  - Complete hosted solutions are becoming viable
- IT technologies are mature and enabling
  - Web based solutions are becoming powerful enablers
- Intellectual property concerns are waning
  - While non-core competencies are transitioning first, expect all of pharma R&D to become global

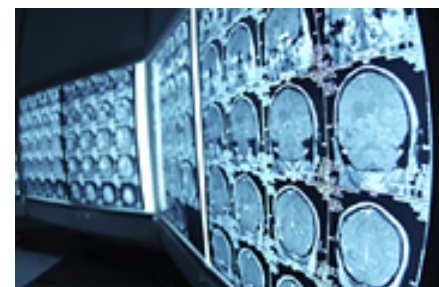
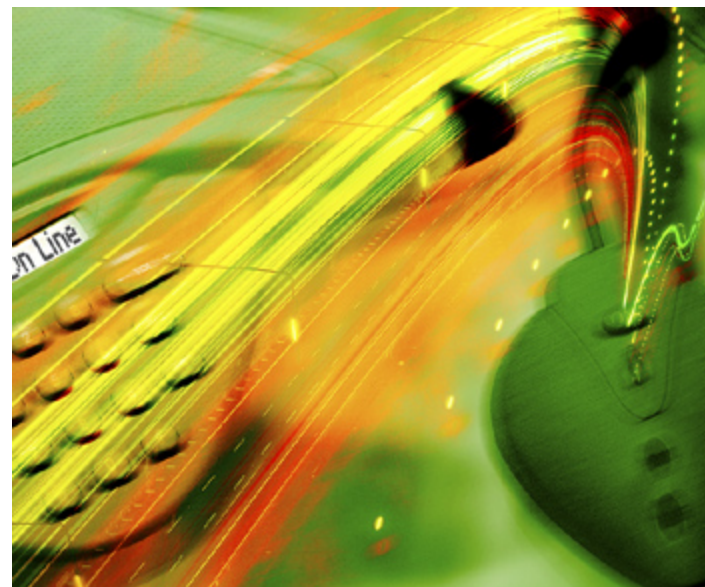


# The Use of Information in the Life Sciences Is Changing

**Research in the life sciences today will be increasingly driven by timely use of information to make strategic decisions.**

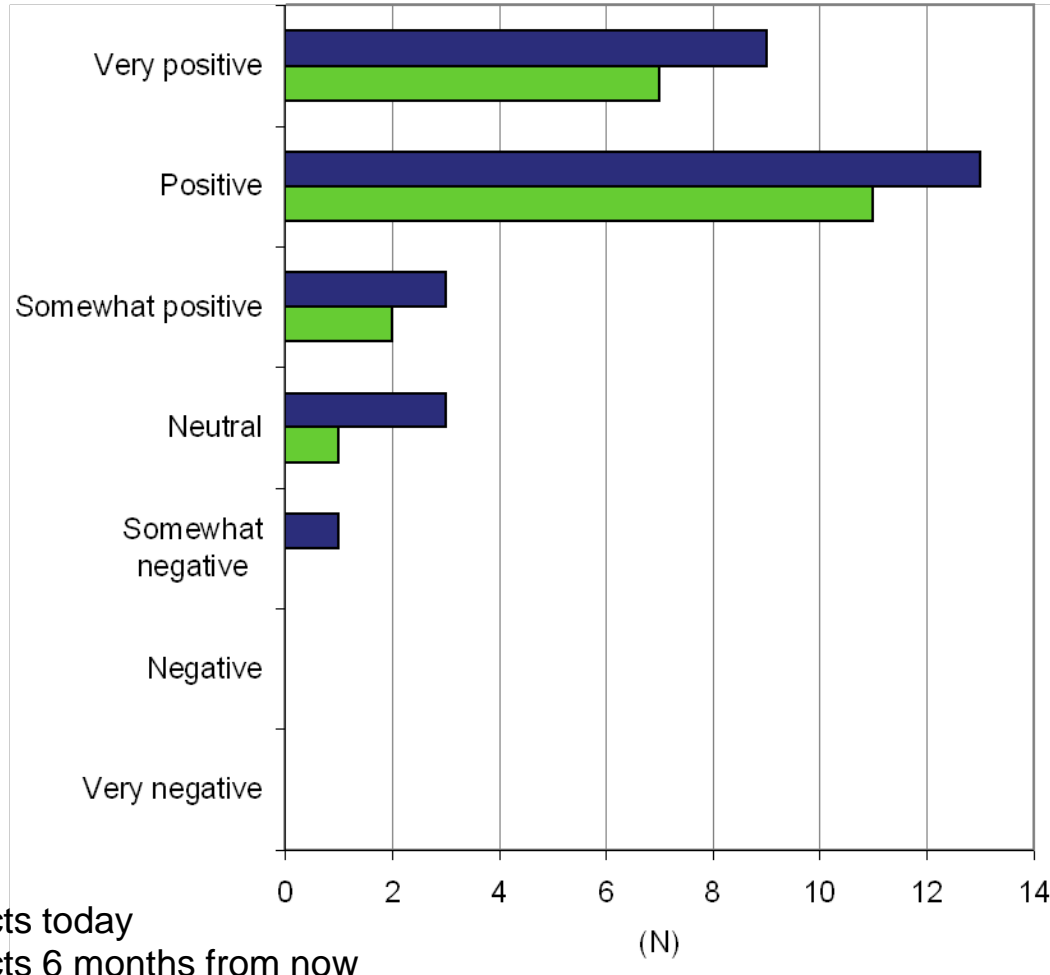
**This requires changes in the way that pharmaceutical R&D is done.**

- Real time knowledge sharing
  - Standardized data repositories
- Data stewards
  - Single instances of the truth
- Siloed research is becoming a thing of the past
  - eNotebook data accessible to everyone
  - Research programs are increasingly under comparative microscopes for progress and milestones



# Business Prospects

*What is your outlook on the business prospects for your organization today and 6 months from now?*



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■ Business prospects today  
■ Business prospects 6 months from now

Source: Health Industry Insights, 2008

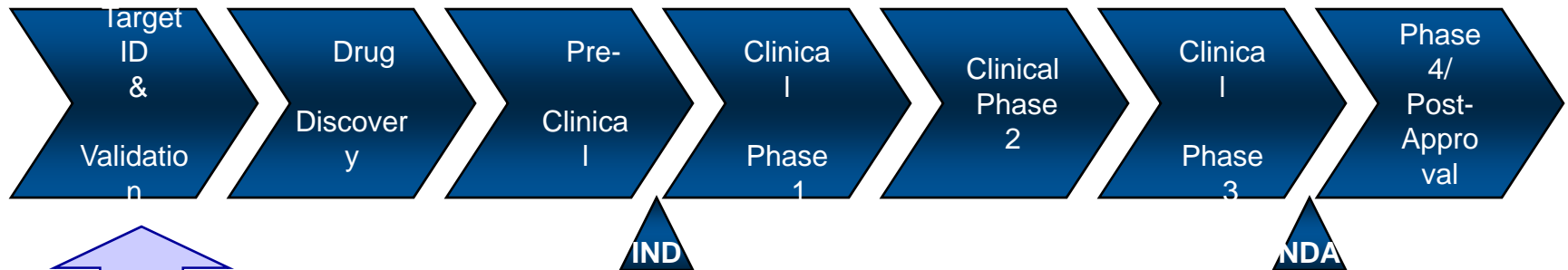
# A Health Industry Insights Definition of Information Transparency

**Information Transparency** in the health industry is the situation where the user accessing a resource (such as an application program or data) leverages supporting data, information and/or knowledge without being aware of the need beforehand. Effective implementation of information transparency solutions institutionalize available knowledge from across the organization to enhance daily project and/or strategic decision making.

Information transparency solutions should be “alive”, enabling continuous updating as new data, information, and knowledge is accumulated.

# Information Transparency Across the Value Chain

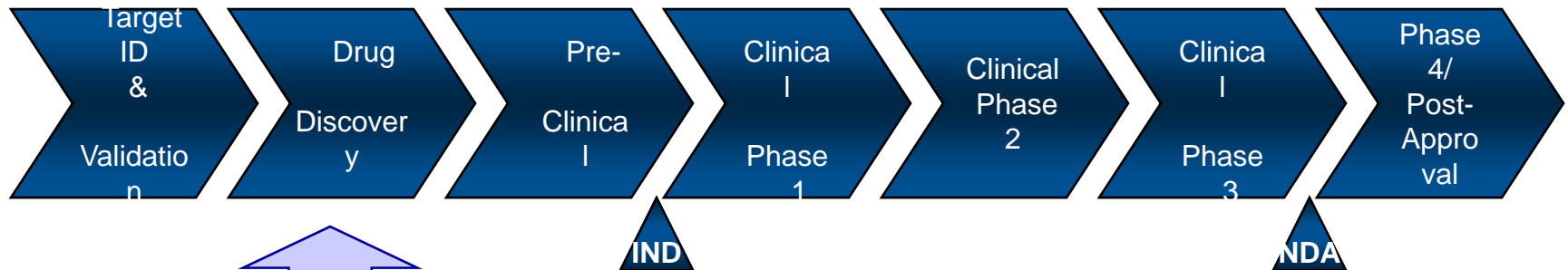
In early research...



- Automated correlation of chemical compound libraries
- Active moiety alerts for potential adverse events
- Predictive modeling of disease model systems
- ...

# Information Transparency Across the Value Chain

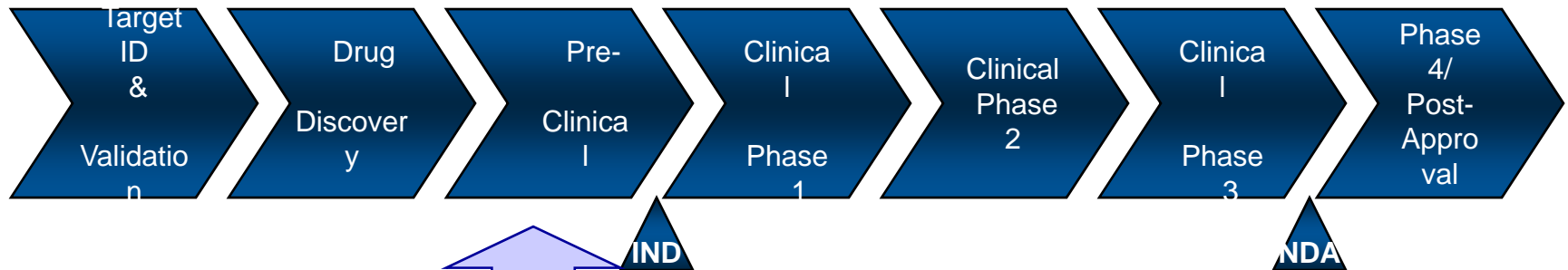
## In drug discovery...



- Predictive modeling of molecular interactions
- Systematic management of data from high throughput test systems, automation
- Capture of research plans and results into eNotebooks
- Systems biology
- Google for biology
- ...

# Information Transparency Across the Value Chain

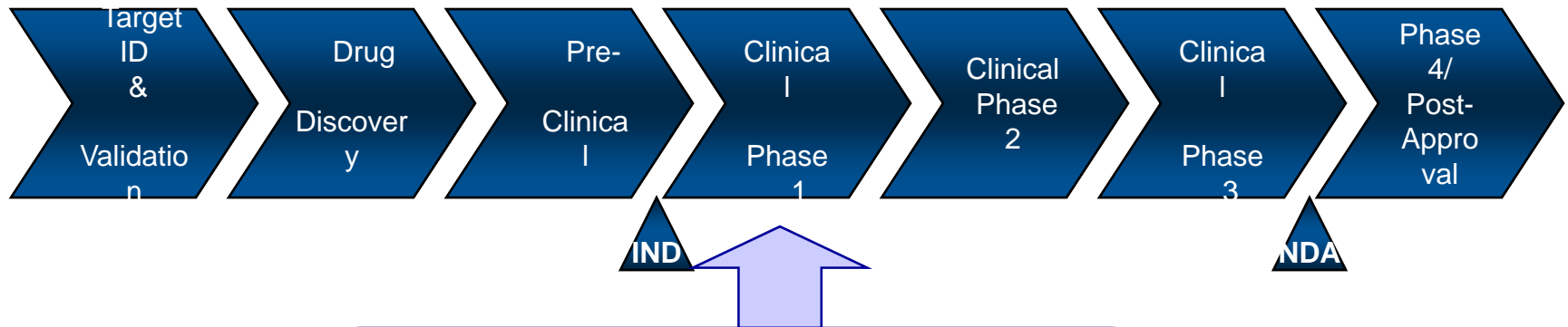
## During pre-clinical research...



- Knowledge intensive animal and human model systems to predict drug outcomes
- Animal imaging analytics to rapidly identify and characterize drug interactions
- ...

# Information Transparency Across the Value Chain

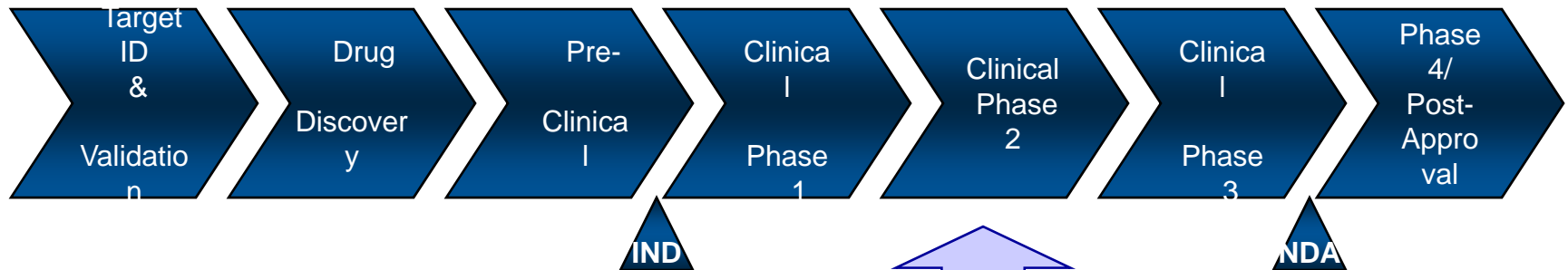
## During Phase I clinical trials...



- EDC and CDMS
- Transparent meta-data management
- Knowledge intensive animal and human model systems to predict drug outcomes
- Genetic analytics to identify and support genetic factors impacting drug activity
- Human imaging analytics to rapidly identify drug interactions
- ...

# Information Transparency Across the Value Chain

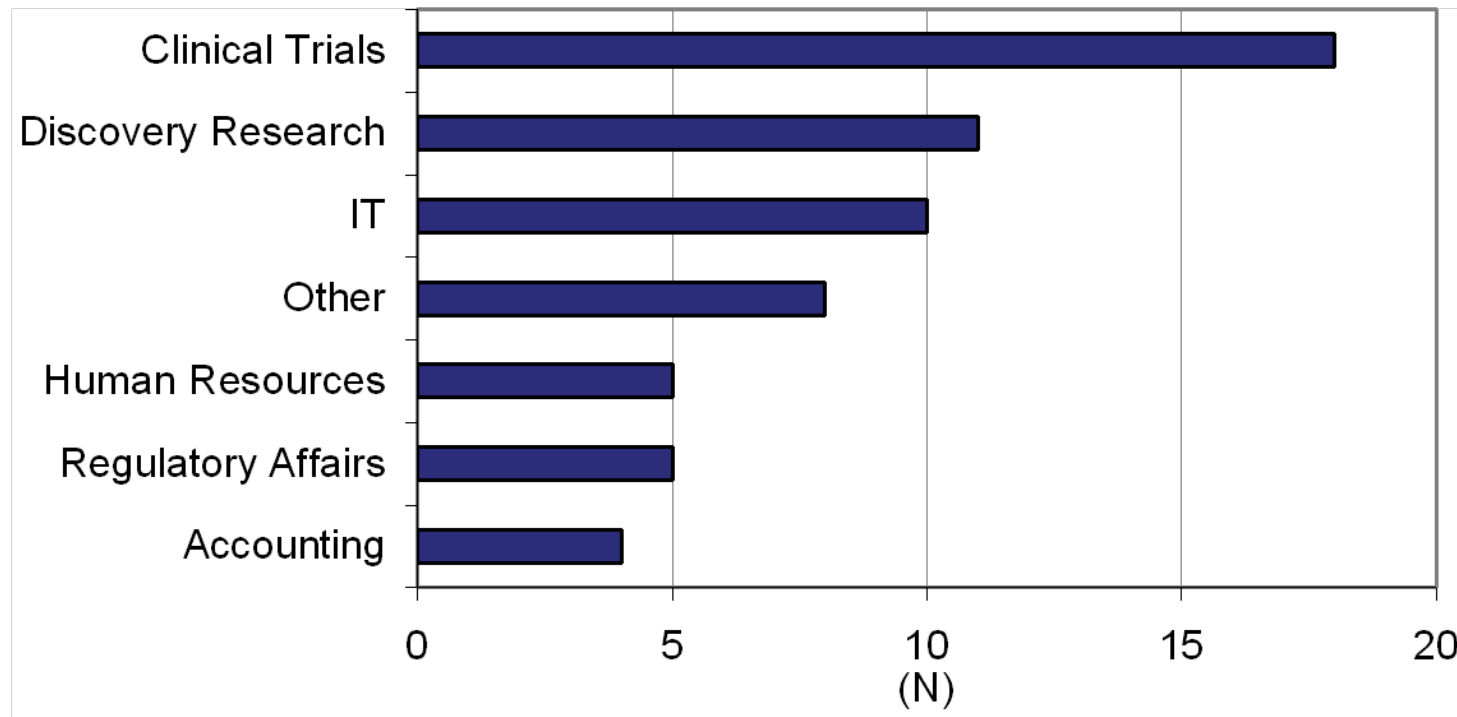
## During Phase II clinical trials...



- EDC, CDMS and CTMS
- Multi-site automated data integration, including globalization
- Adaptive clinical trial methodologies
- Automated adverse event signal detection
- Complex clinical data integration from multiple sources
- ...

# Outsourcing Trends within Organizations

*What areas of your organization are you currently outsourcing (both in part or entirely) to an external vendor?*

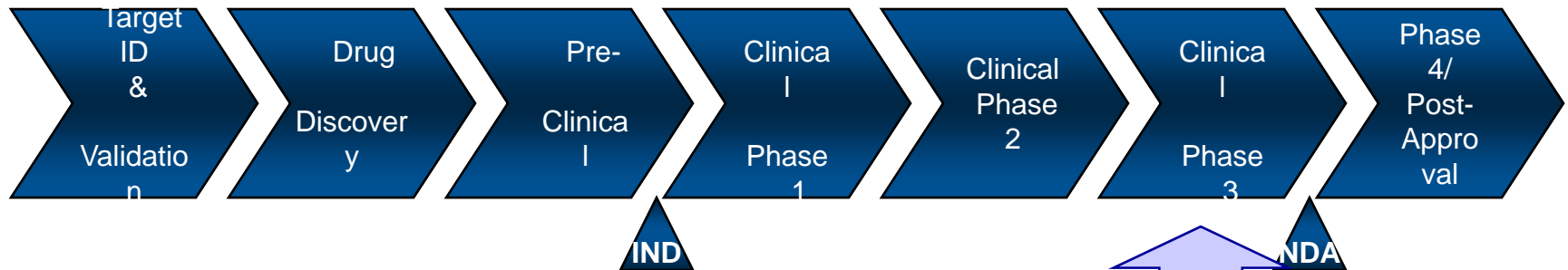


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Source: Health Industry Insights, 2008

# Information Transparency Across the Value Chain

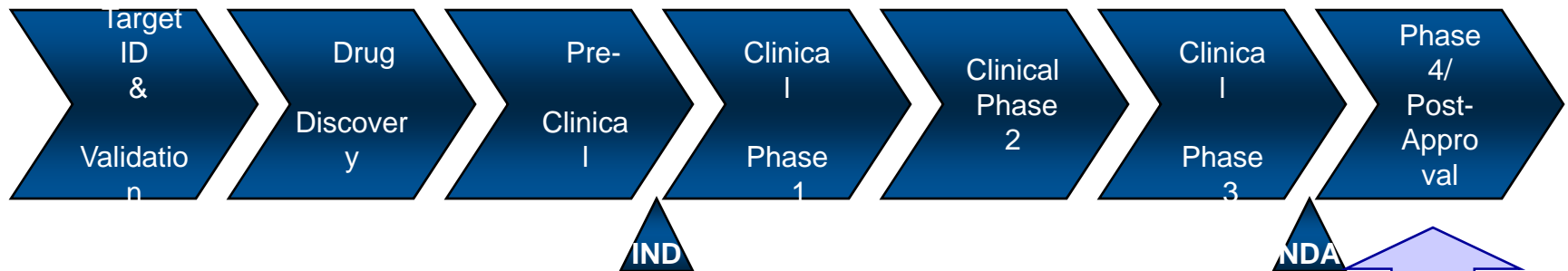
## During Phase III clinical trials...



- Global automated data integration
- Adaptive clinical trial methodologies
- Automated adverse event signal detection
- Electronic data lifecycle management
- Large scale information management, including EDC, CDMS and CTMS
- Complex clinical data integration from multiple sources
- ...

# Information Transparency Across the Value Chain

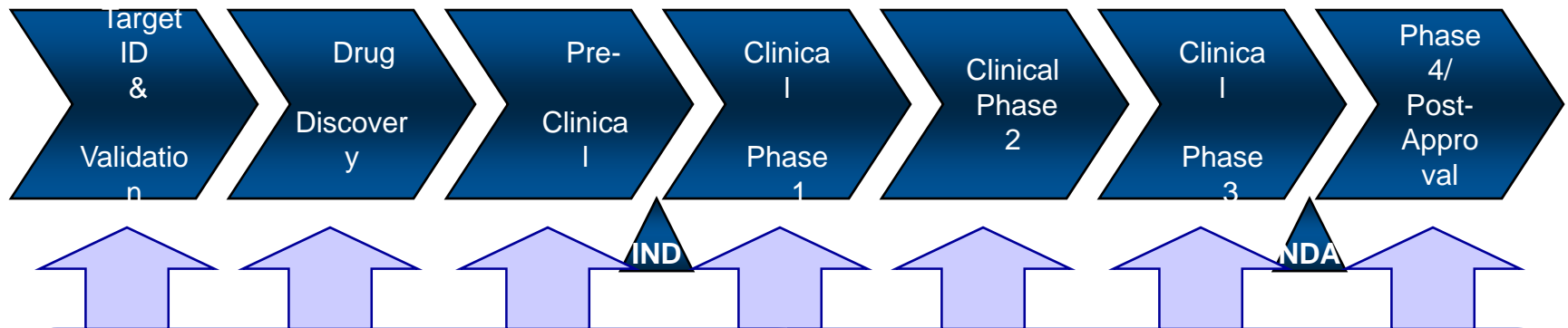
During Phase IV clinical trials and post-approval...



- Automation of FDA mandated reporting
- Pipelining of patient response data back into R&D
- Automated adverse event signal detection
- ...

# Information Transparency Across the Value Chain

And in some cases, all across the development path...



- Consolidated view of diverse data across multiple data warehouses
- Related literature patent review and alerts
- Cross organizational information trackers to alert to possible related efficacy and adverse event data from discovery through to post-approval insights
- Active data mining to track real-time project progress
- Functional business intelligence (BI)
- Translational research initiatives
- ...

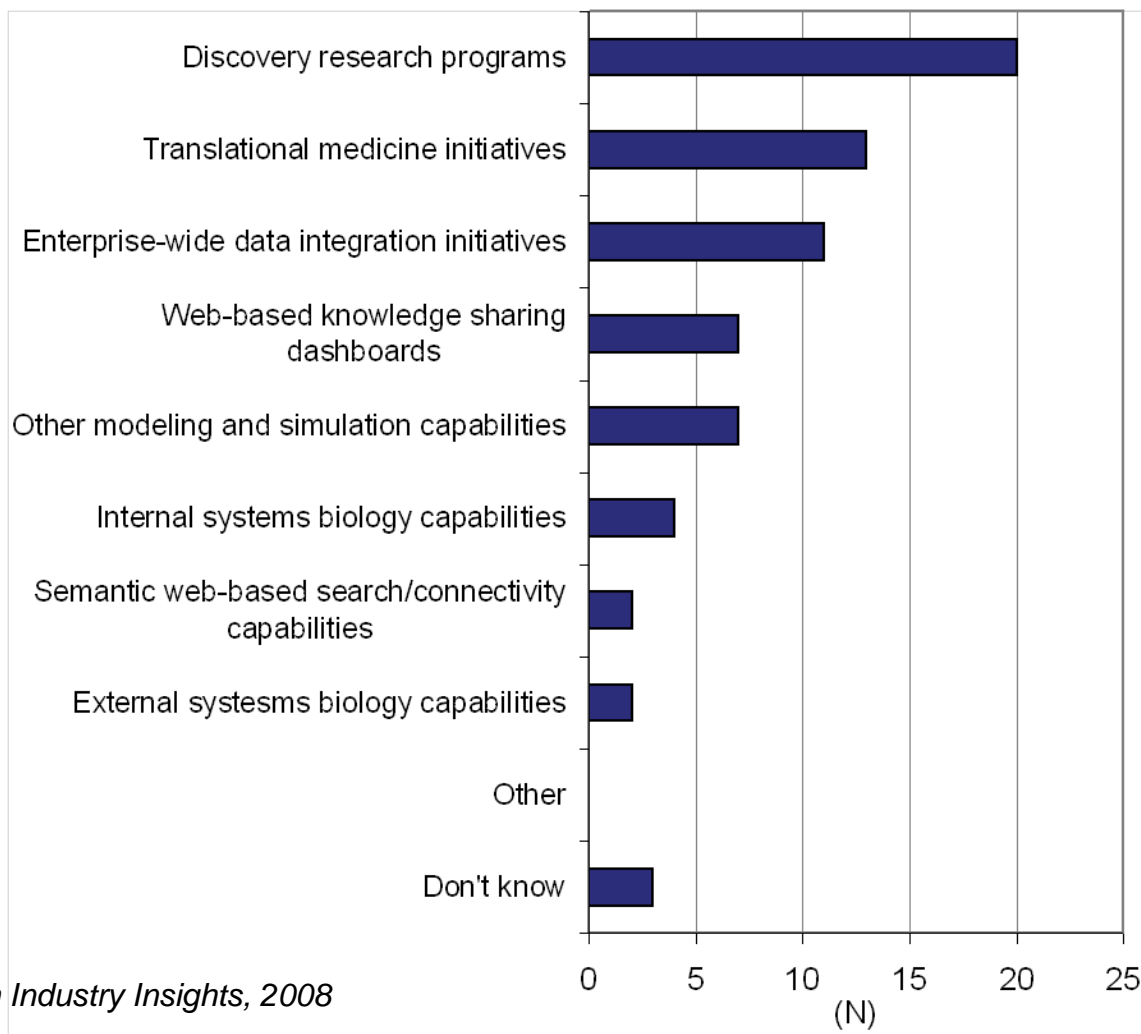
# Information Management: Organization-wide

With the right tools, it becomes possible to look across the organization from a strategic perspective.



# Knowledge-based Drug Development

*What knowledge-based drug development initiatives are present at your organization?*



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# Life Science Pain Points

## Pharma-centric

- Impending loss of the blockbuster model
- Belt tightening to increase efficiency
- Transitioning non-core activities to low cost solutions
- Increasing requirements for drug safety

## Cross-industry needs

- The need to increase the efficiency of the industry
- The shift towards increased information transparency



# A Health Industry Definition of BI

**Business intelligence (BI)** in the health industry seeks to exploit mature systems and analytics to measure and optimize organizational productivity and effectiveness. Effective BI solutions institutionalize the capture and consolidation of data and subsequently enable analysis and report generation to support management decision making.

A simple definition for BI in the health industry would be systems and solutions that improve organizational decision making through regular access to detailed quantitative organizational data.

# IDC Estimates for BI Investment in the Health Industry

Based on HII/IDC data, BI is a growing area of investment in the health industry.

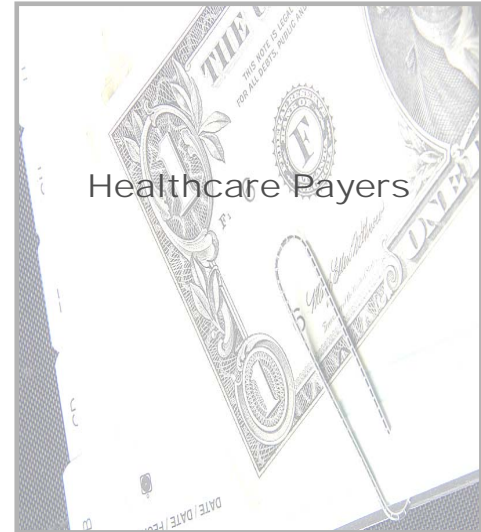
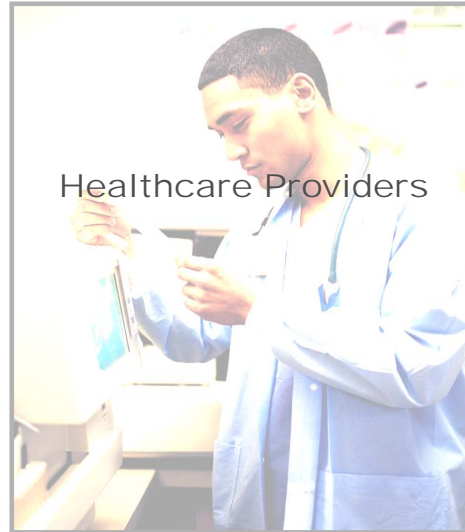
**TABLE 1**

HII/IDC Estimated US BI Software and Services Spending  
(in millions) in the Health Industry

Industry Segment	2007	2008	2009	2010
Life Sciences	\$168.7	\$188.4	\$211.7	\$241.3
Healthcare Providers	348.6	389.3	437.4	498.6
Healthcare Payers	267.4	300.0	336.5	380.0
<b>Totals</b>	<b>784.6</b>	<b>877.7</b>	<b>985.6</b>	<b>1,120.0</b>

Source: Health Industry Insights, 2007

# BI Solutions in the Health Industry



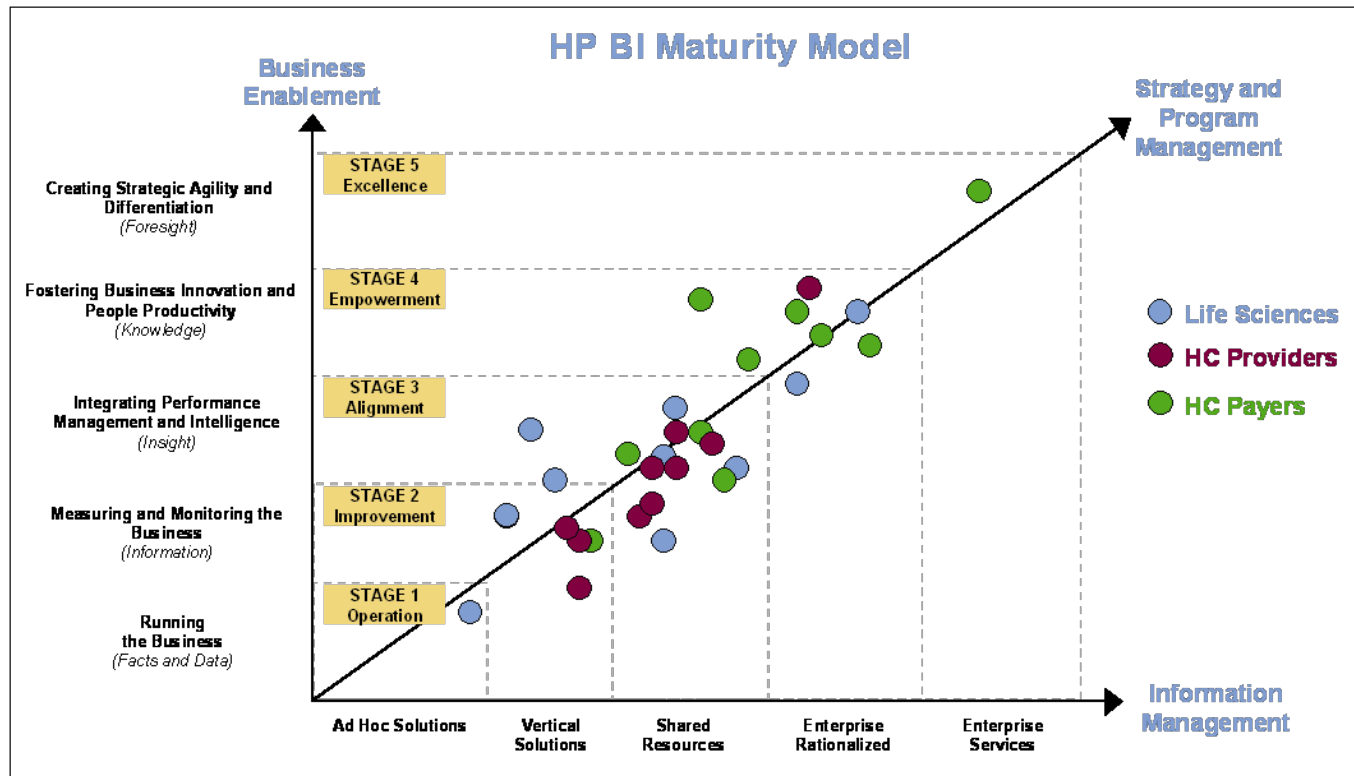
Improve Operational Excellence

Improve Research/Clinical Performance

Cost Savings

# Maturity of BI Users in the Health Industry

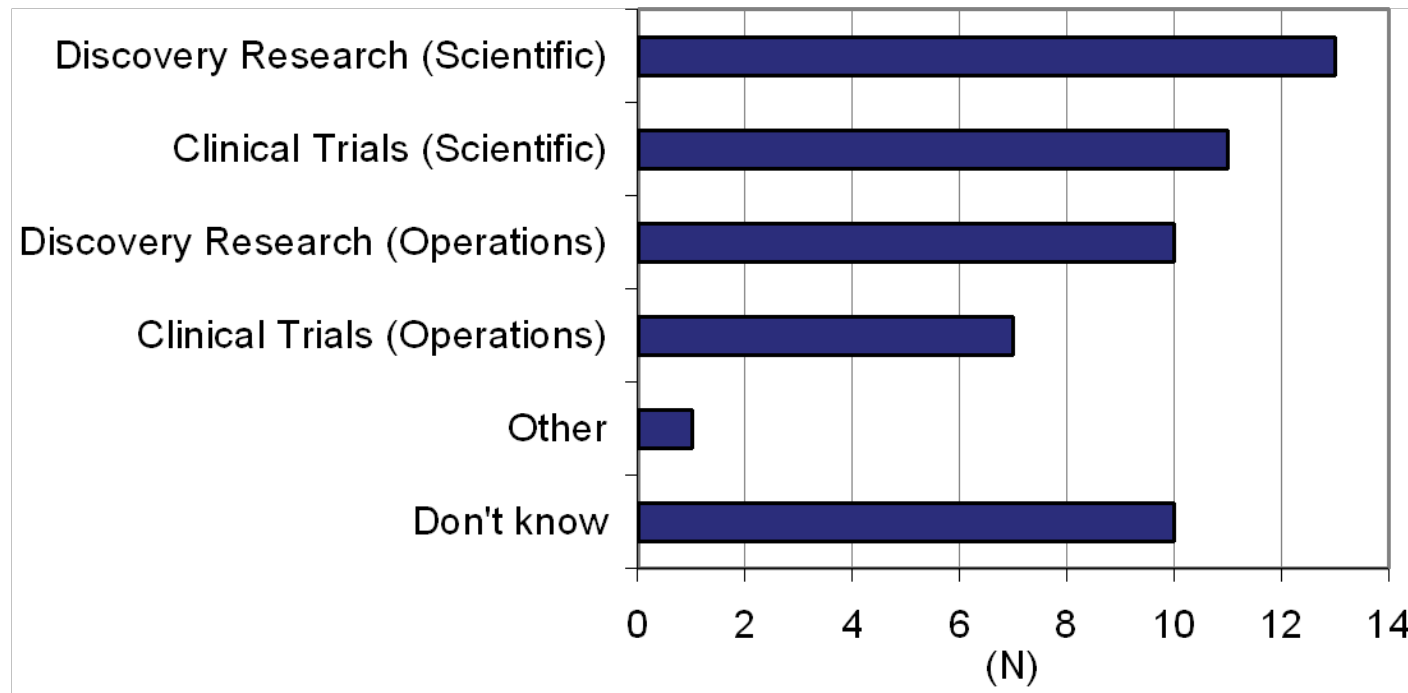
Based on our discussions with users in the industry, we found varying levels of maturity for the use of BI within the different industry segments.



Model Source: HP Information Management Group, 2007.

# BI in the Life Sciences Industry

*What areas of your organization are investigating or have in place business intelligence (BI) tools?*



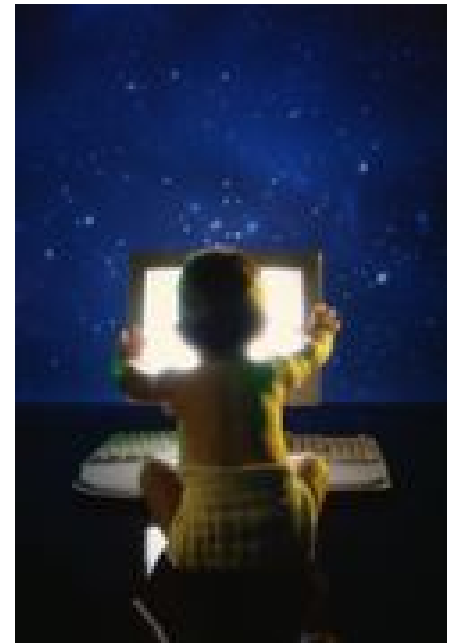
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# Future Outlook for BI in the Life Sciences

**Business intelligence will be a key contributor to the future of the life sciences industry as it begins to shift from the current blockbuster business paradigm.**

**Effective adoption of BI requires a change in current practices and thinking, including:**

- Applying BI to both research and operations
- Creating a mindset around data creation, ownership, and accessibility
- Investment in data integration initiatives to connect disparate information sources
- Increasing web-based reporting tools and technologies
- Thinking across organizational boundaries

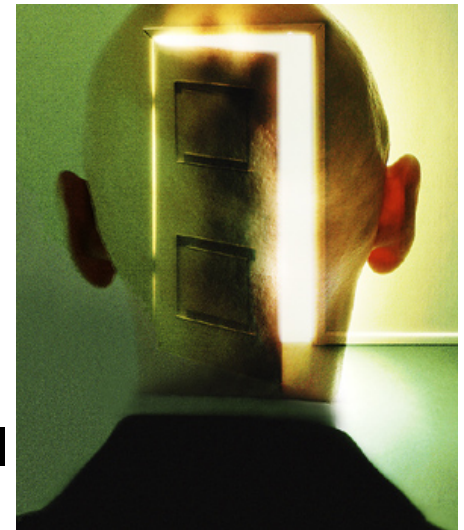


# HII Essential Guidance - Life Sciences

**Information Transparency will be key to sustainability in the life science industry.**

**Our research suggests several core concepts, including:**

- The solution will require much more than consolidated data warehouses and packaged software
- Underlying connectivity between data stores, based on standards or semantics or TBD, will be critical to effective information exploitation
- Organizational change will be key to success
- The future lies across boundaries (both geographical and organizational)
- Near and long term opportunities for success are available to drive and support adoption



# Questions

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