



**Food and Drug Administration Part 15
Public Hearing on**

**Electronic Submission of Regulatory Information and
Creating an Electronic Platform for Enhanced
Information Management**

[Docket No. 2006N-0464]

December 18, 2006

CRIX Community Perspective

- The CRIX Community is pleased to have the opportunity to provide a cross-community perspective on the topics of electronic submissions and Third Party information exchanges
- Today you will hear input from various representatives of the CRIX Community including:

Stakeholder Group	Perspective	Presenter
CRIX International	CRIX Community at large	Debra Bremer, VP Development & Medical Informatics, Pfizer
Industry	Large biopharmaceutical	Diana McKenzie, Exec Director Information Systems, Amgen
Industry	Small biopharmaceutical	Sue Dubman, VP IT & Informatics, Theravance, Inc.
Research Community	Academic research & cooperative groups	J. Robert Beck, M.D, VP/CIO Fox Chase Cancer Center
Patients	Patient interests	Diane Paul, Patient Advocate
Liaison Technologies	External industry perspective on exchanges	Bob Renner, CEO, Liaison Technologies
Booz Allen Hamilton	Service provider perspective	Mark Adams, Sr Associate, Booz Allen-Hamilton

Bio-Pharmaceutical Industry

Amgen
AstraZeneca
Bristol Meyers Squibb
Genzyme
Johnson&Johnson
Merck
Millenium Pharmaceuticals
Novartis
Pfizer
Sanofi-Aventis
Theravance

Government Research Sponsors

NCI - Cancer Therapeutic Evaluation Program
NCI - Center for Cancer Research
NCI - Division of Cancer Prevention
NIH Division for Allergy and Infectious Disease

Government Advisors

FDA - Division of Scientific Investigations
FDA - Office of the CIO
FDA - Regulatory and Data Standards
NCI - Center for Bioinformatics

Cancer Centers & Cooperative Groups

City of Hope
Duke University
Eastern Cooperative Group
Johns Hopkins University
Mayo Clinic
Memorial Sloan Kettering
University of Chicago

Industry Service Providers & Support Groups

Booz Allen Hamilton
First Clinical Research
Intel
International Business Machines - IBM
Patient Advocates

Standards & Trade Organizations

BIO
CDISC
PhRMA
SAFE

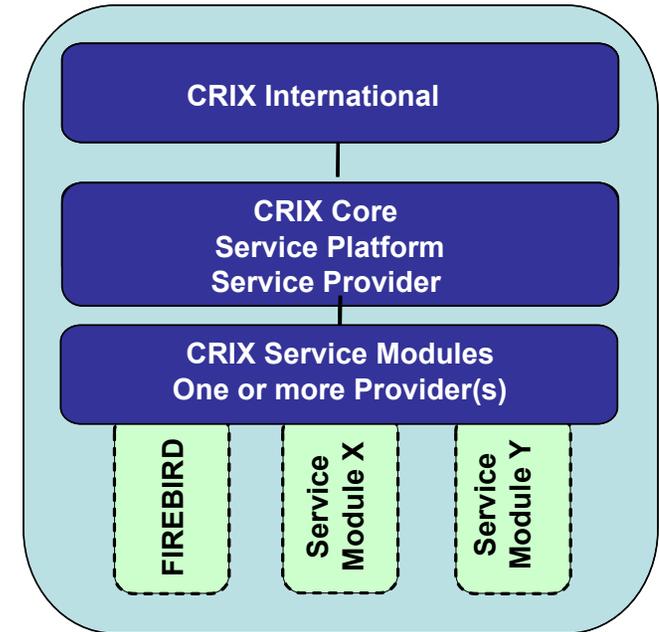
Industry (2003-2004)
SEBIX

**2005 - Clinical Research
Information Exchange (CRIX)**

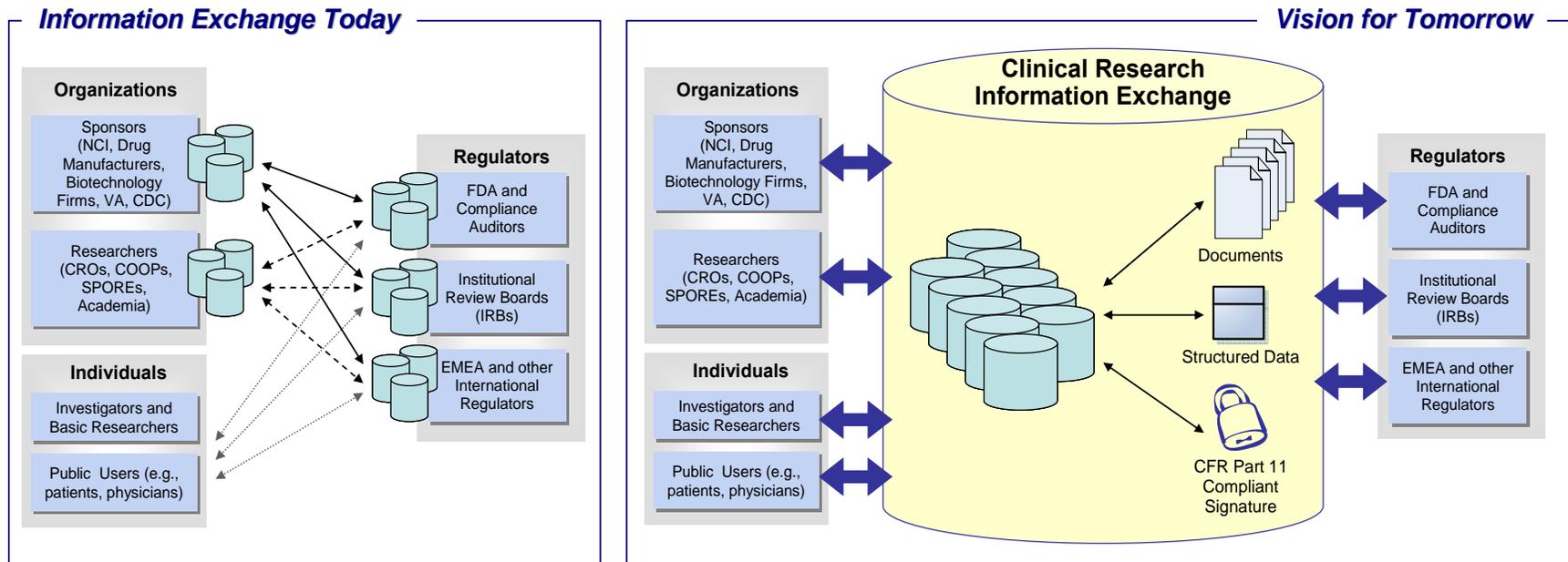
US Gov't (2004)
FDA/NCI IOTF

- **Convergence of initiatives**
- **Technical and environmental lessons learned**
- **NCI stewardship with industry support and participation**
- **NCI / FDA Memorandum of Understanding**
- **Multiple stages of technical and operational testing of initial application completed**

- **What is CRIX?**
 - A public-private, not-for-profit community initiative
 - A secure, shared technology infrastructure
 - An exchange including applications and tools
- **Core Elements**
 - Secure, standards-based information exchange platform
 - Information Governance framework
 - Authoritative source registries for commonly referenced information
 - User support services (user support, implementation support, etc)
 - Paper to electronic migration support
 - Standards compliant user credentialing
 - 21 CFR Part 11 compliant e-signatures



- Escalating R&D costs combined with fewer new therapies require a focus on efficiency



The services offered through an exchange will ...

- **Speed processes** related to regulatory data exchange
- **Result in cost savings** due to improved workflow and business processes
- **Enable efficiencies and new insights** due to faster and increased access to information.

The Clinical Research Information Exchange will deliver value to its users in the form of:

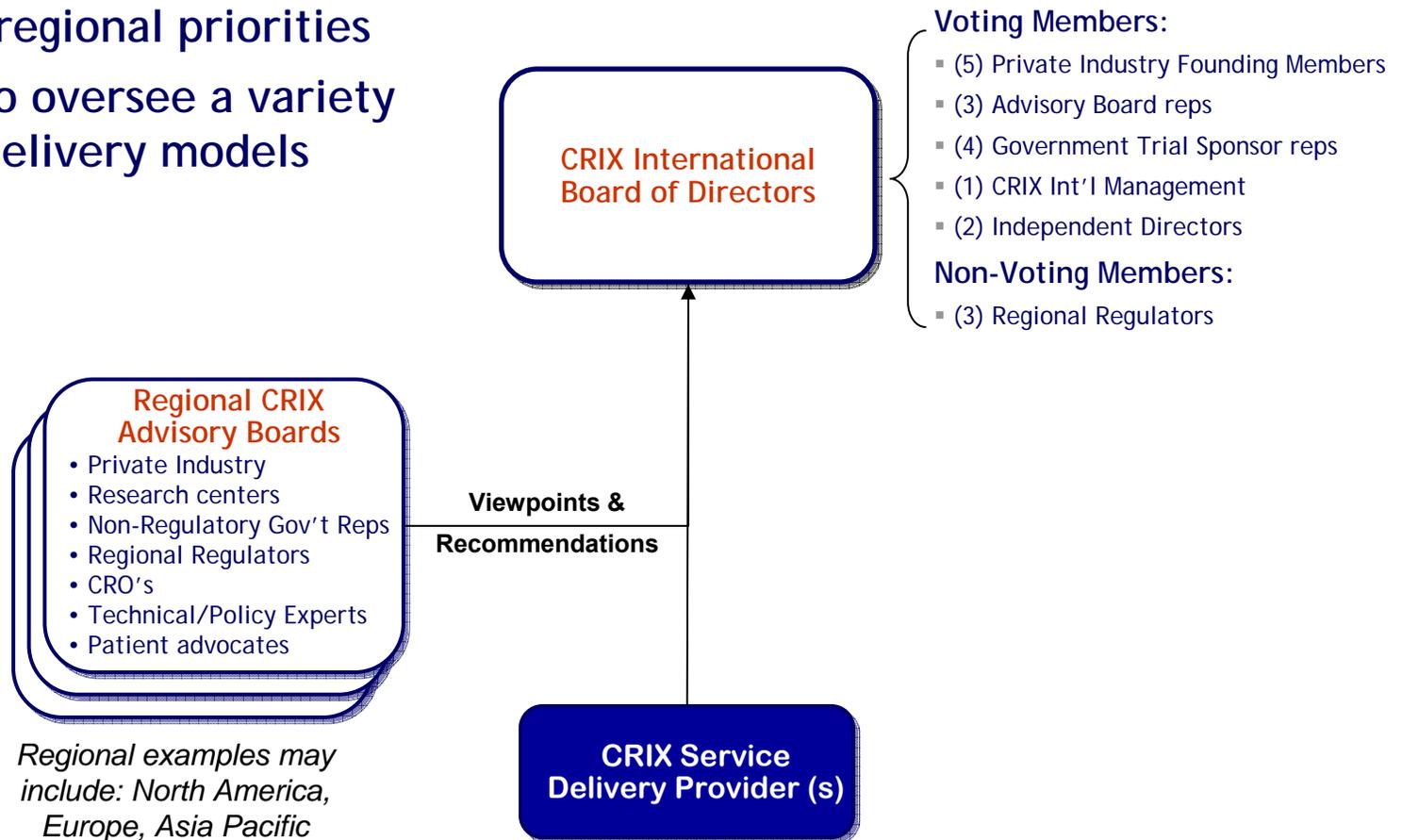
- Workflow efficiencies, lower process, resource, and operational costs
- Reduced infrastructure development expenses
- Faster submission notification and delivery time (days to minutes)
- Accelerated achievement of FDA Critical Path initiative and NIH Roadmap goals

- **The CRIX Community formed CRIX International in early December 2006**

- **CRIX International, a not-for-profit association**
 - Ensures public-private partnership goals are met
 - All stakeholder groups able to participate in system governance
 - Outreach and alignment underway with other existing groups- e.g., Google Foundation, CDISC, etc.

- **CRIX International responsibilities**
 - Establish the product and service strategies, pricing framework, standards, and service management guidelines
 - Responsible for vendor selection and oversight
 - Formalize an implementation and deployment plan for CRIX and Firebird

- Ensures representation of broad stakeholder interests
- Establishes regional priorities
- Flexibility to oversee a variety of Service Delivery models



- **The 1st CRIX Service offering**

- **A web-based global investigator registry for:**
 - Investigator Registry of commonly referenced information
 - Allows investigators to register online with sponsoring organizations
 - Provides a secure central repository to maintain and manage a profile containing the essential documents and forms for clinical trials

- **FIREBIRD is in pilot today**
 - Led by NCI with participation from the FDA and Industry
 - Industry Participants: Amgen, Genzyme, Merck, Novartis, Pfizer, Quintiles, Sanofi-Aventis
 - Production launch in 2007

- FIREBIRD will provide cost savings and improved business processes for investigator registrations

- For industry:
 - 67% reduction in costs
 - Enables accelerated regulatory package completion

- For government:
 - NCI projects a 32% reduction in costs
 - Positive impact to investigators and site/study coordinators
 - Pan-NIH extensibility
 - FDA has the potential for significant annual cost savings
 - Elimination of data entry costs
 - Consolidation and elimination of infrastructure

- **Future service modules will leverage and extend the base infrastructure established for FIREBIRD**
- **Several possible next services for CRIX are being explored:**
 - Connecting Patients to Trials
 - Janus
 - Structured Product Labeling
 - Safety Data Workflow
 - Standardized Protocol Initiation and Structure

- CRIX International formed in early December, 2006
- Formalize public and private participation in CRIX International
- Outreach and alignment with other groups - e.g., Google Foundation, CDISC, etc.
- RFP/Vendor selection for Core Platform and FIREBIRD
- FIREBIRD Production availability 4Q, 2007

- **The CRIX Community is in place and represents a diverse set of stakeholders aligned to common goals:**
 - Lowering drug development costs
 - Speeding new therapies to patients
- **An exchange platform is essential to this mission**
- **CRIX Community has a working exchange service in pilot**
- **CRIX International can provide the trust and independence required to effectively oversee the development and implementation of new business processes and technologies**

Thank You

Questions?

CRIX Community Perspective

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- Significant unmet medical need; Patients wait far too long to get access to new therapies
- An estimated \$49.3 billion was invested in biopharmaceutical R&D in 2004¹
- 40% of the R&D spend can be attributed to paper handling and process transaction costs.
- Average cost to bring a drug to market > \$900 million²
- Estimated that drug companies stand to lose between \$600,000 and \$8 million each day clinical trials are delayed³
- In 2003, 94% of U.S. clinical trials were running at a delay, with 72% of these delayed by over a month⁴

¹ Pharmaceutical Industry Profile 2005 - From Laboratory to Patient: Pathways to Biopharmaceutical Innovation, PhRMA

² PAREXEL's Pharmaceutical R&D Statistical Sourcebook 2004/2005. PAREXEL International Corp., 1995, p. 83

³ Cutting Edge Information Inc., ibid

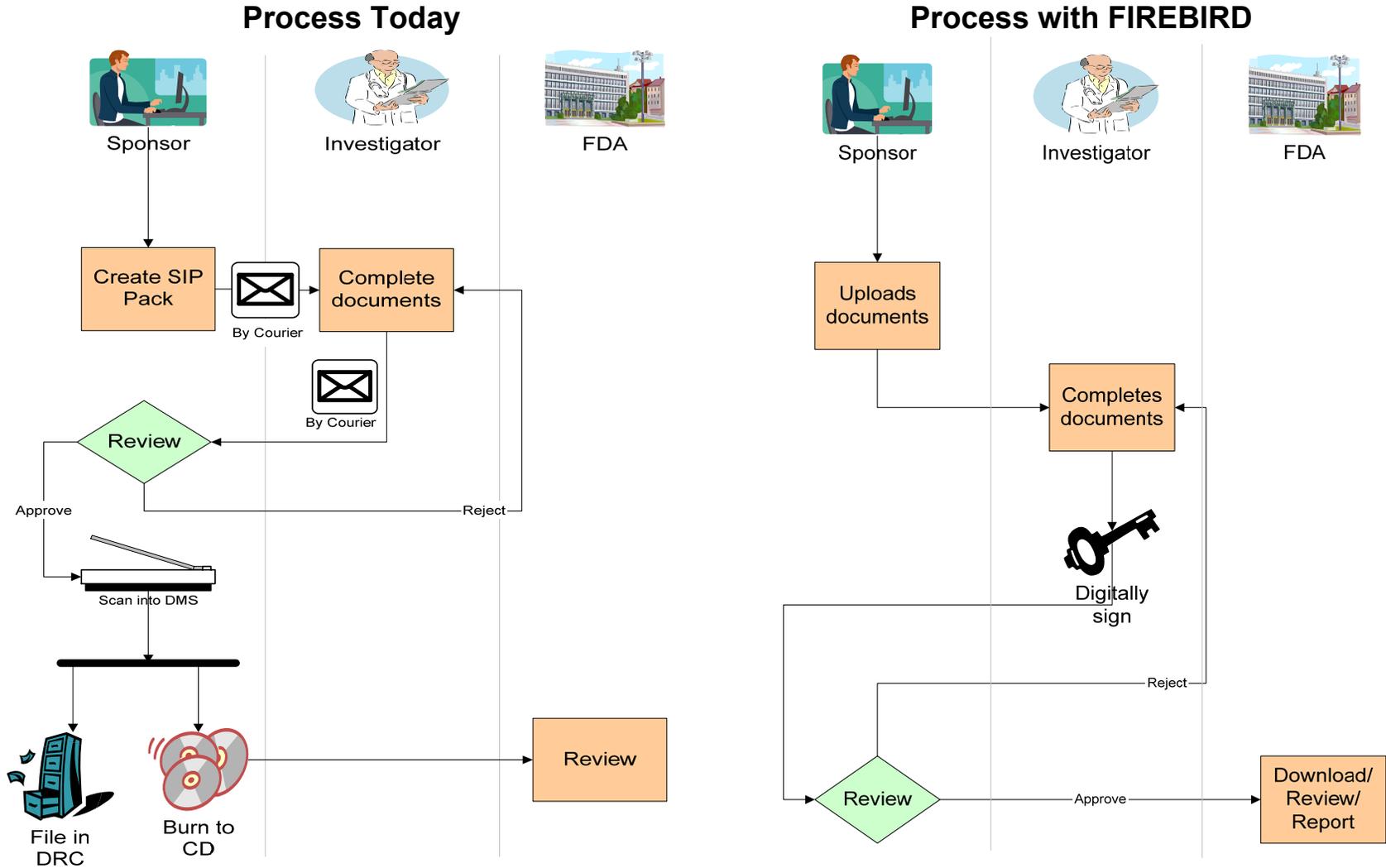
⁴ Site Strategies to Improve Recruitment Advertising Effectiveness", CenterWatch, Article 334, Volume 10, Issue 10, October 2003

- E-Submissions today for Amgen
 - Safety reports
 - eCTD

- Dual systems required to support e-submissions and a paper-based information supply chain

- Shared exchange creates:
 - Supply chain costs are lower
 - Happier business partners

An Illustration: FIREBIRD for Study Initiation



What is the value of FIREBIRD to Amgen?

- CRIX through the FIREBIRD service has the potential to:
 - Reduce the costs (up-front investment and operating) associated with site initiation and regulatory filings*
 - Speed the process of completing regulatory submissions*
 - Improve the ability of regulatory agencies to review information quickly and easily

Cost Model 1 – Non CRO Managed Studies Only

	<u>Site Selection</u>	<u>Approve Shipment</u>	<u>Scan and File</u>	<u>Updates</u>	<u>Total Cost</u>
TODAY	\$376k	\$60k	\$79k	\$128k	\$644k
1572 Only	\$256k	\$34k	\$0k	\$32k	\$322k (\$322k)
Complete SIP	\$118k	\$28k	\$0k	\$32k	\$178k (\$466k)

- * The value that Amgen derives from this will depend on the ability to integrate the whole SIP business process, not just the 1572 portion

Everybody Wins

Feature	Benefit	P.I.	FDA	Amgen	CRO
Centralized profile information	Eliminates need to reenter data	●			
Central database of investigators	Streamlines 1572 registration		●	●	●
Standardized 1572 registration process	Reduces set up time for study sites. Reduces effort to review 1572 docs	●	●	●	●
Replace wet signatures with e-signatures	Reduce cost of submitting and storing paper originals	●	●	●	●
Wizard driven data entry	Reduces time to create SIP Packets Improves data quality	●		●	●

- **Community based perspective from the outset**
 - Inclusive approach to ensure key stakeholder alignment
 - No single vendor or stakeholder group dominating the outcome

- **Shared infrastructure yields lower costs**
 - Lower infrastructure investment (\$1-2 million for a standalone SIP)
 - Lower operational costs (50-60% improvement)

- **Community alignment yields lower costs and lower risks**
 - Higher acceptance/usage rates
 - Faster adoption and implementation
 - Lower conversion costs

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Some Facts: Drugs in Development by Disease (2004)

Category	Total Drugs in Development	Biotech Companies Involved	% of Total Drugs Biotech Developed
Cancer	704	486	69% of products
Children	200	93	47% of products
Neurological Disorders	176	125	71% of products
Heart Disease and Stroke	122	88	72% of products
Women	358	204	57% of products
Older Americans	295	176	57% of products
<i>Sources: PhRMA; BIO</i>			

Strategic focus for small bio-pharma companies should be on science vs. technology infrastructure

Top 10 Barriers to Electronic Submissions for Small Bio-pharma

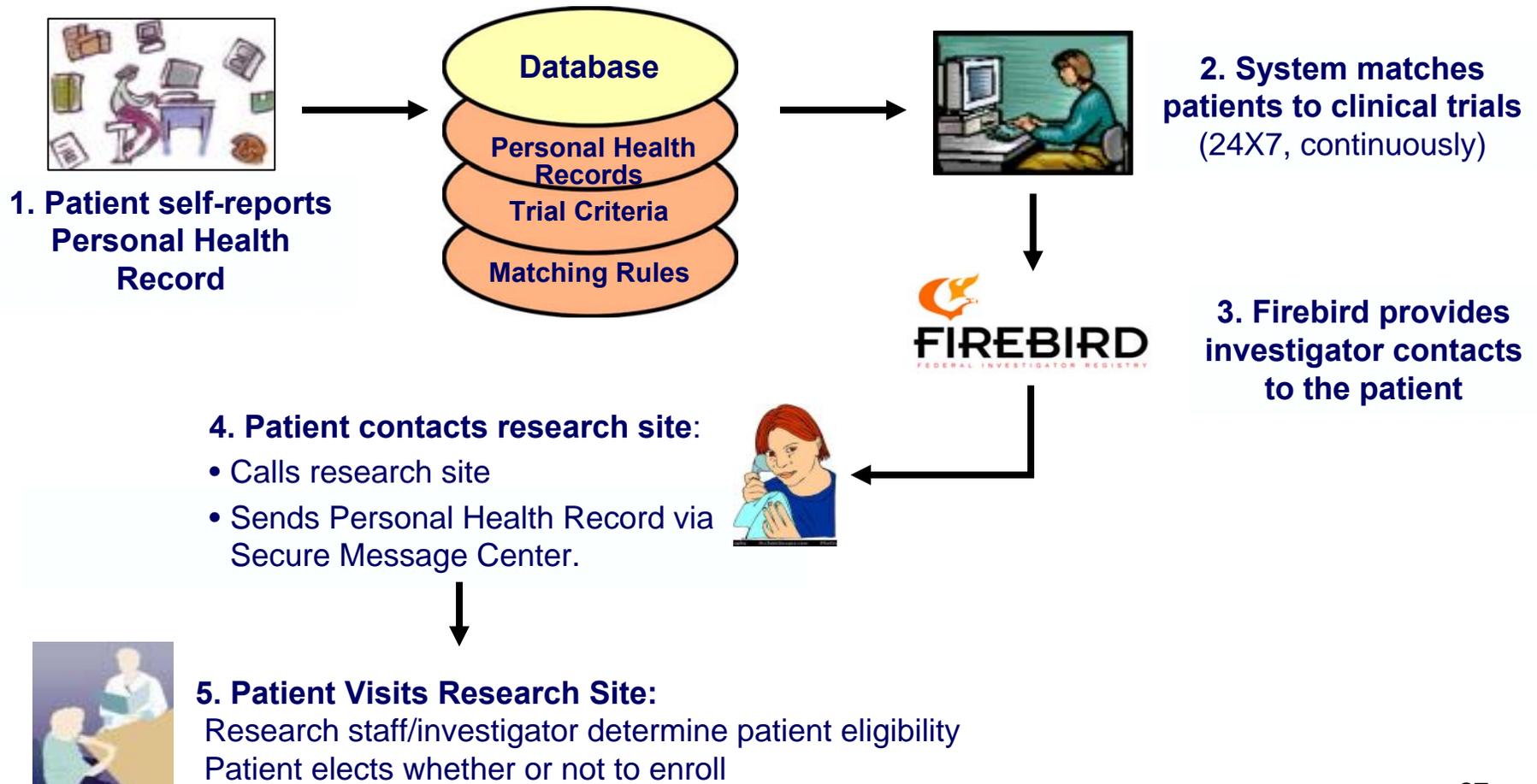
1. Cost-effectiveness for a small number of submissions
2. It's not required (yet)
3. Steep learning curve
4. New, special tools required
 - Tools available to help today are expensive, putting small biopharma at competitive disadvantage
 - Small biopharma have little voice into the service roadmap
5. Need to validate compliance with standards specs
6. Clarity around the "rules" for validating data
7. Changes to standards over time: what version of the standard will FDA accept when you are ready to file?
8. Standards must take into account huge differences in project type, personnel, complexity, etc.
9. Overlaps and inconsistencies across standards
10. "Lowest common denominator" often emerges as a compromise in developing any standard

Top 10 Reasons for Small Bio-pharma to Use Electronic Submissions

1. Focused and supported by FDA
2. Cost savings and scale efficiency in the long-term
3. Greater ease of doing business with partners
4. Standards facilitate exchange of information between two or more parties with common interests
5. Standards increase efficiency of exchange
6. Standards make interactions/decisions easier/faster/cheaper
7. Standards facilitate communication and usability
8. Useful if you want to build a clinical data warehouse for all your clinical trials (Janus model)
9. FDA requirement might stimulate tool development from vendors
10. Potential gains in interoperability among clinical information systems in the future

Example 1: Leveraging Firebird to...

- Empower patients to identify experimental therapies where traditional therapies are not effective
- Accelerate clinical trial recruitment



Why is Accelerating Clinical Trial Recruitment Important?

- 30-40% of trial costs tied directly to patient recruitment
 - Estimated cost of \$1.8-2.4 billion
 - Out of US \$5.9 billion spent annually on clinical trials
- > 80% of clinical trials have major recruitment delays
- Only 1 in 20 recruited patients become enrolled subjects
- Clinical trial costs have risen 55% since 1999

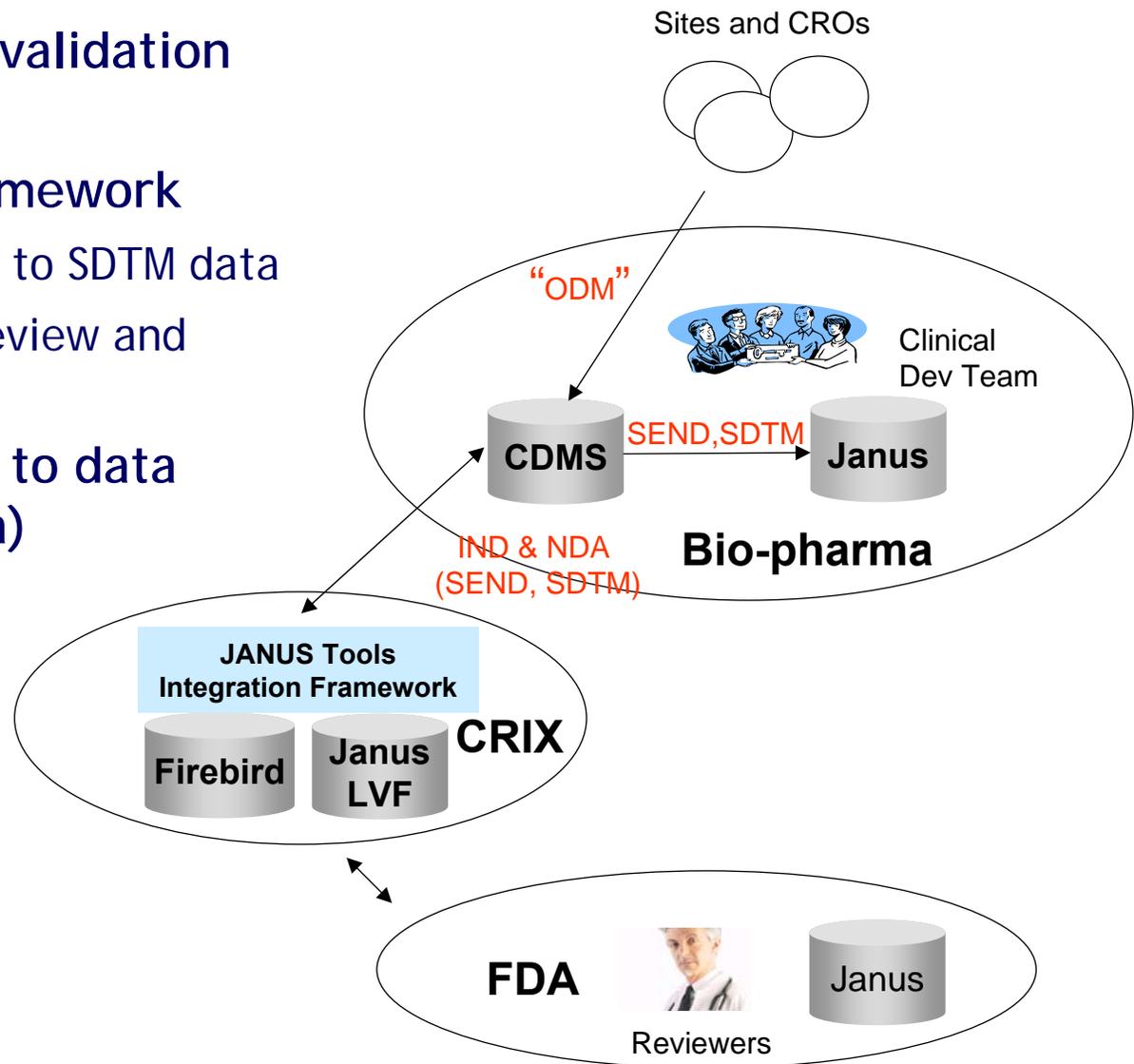
For large pharma → Big expense

For small bio-pharma → Such delays can put you out of business

For patients → Many innovative new treatments may not get to market

Example 2: Potential tools to Support SDTM Submission

- SDTM Load and data validation services
- Tools integration framework
 - Standardized access to SDTM data
 - Common tools for review and analysis
- Bi-directional access to data (FDA and bio-pharma)
- Standards-based data warehouse for all clinical trials

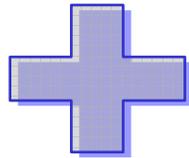


It can be done!

The RECIPE



Defined and accepted data standards



A shared environment in which to
implement the standards

A critical element for small bio-pharma companies

How does CRIX address barriers and help achieve benefits for small bio-pharma?

- **CRIX provides a voice for small bio-pharma**

- **CRIX reduces infrastructure burden**
 - Shared infrastructure is more cost effective
 - Shared implementation tools lower cost of conversion into a fully electronic business and regulatory process
 - Agreement/use of common standards reduces costs

- **Potential to bring new treatments to market quicker by leveraging CRIX capabilities**
 - The Registries underlying FIREBIRD provide for authoritative source information that allows biopharma to move more quickly to trial
 - Investigator recruitment
 - Investigator registration
 - Firebird provides a valuable infrastructure leverage point for connecting patients to trials

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- 150 protocols, each with its own forms, procedures, addresses, etc.
- Investigator-initiated protocols, quite challenging to export beyond single institution due to lack of standardization
- “Every time I work with a new sponsor, it costs me money.”
- Fox Chase Partners: 20+ institutions in region that could function as single collective entity with improved automation and standardization of protocol management, investigator data

Cost Savings

- Reduce paper shipment, reconciliation & storage costs
- Single electronic master repository for investigator regulatory documentation for the entire institution and its partners
- Minimizing the number of documents the coordinator or investigator must manage (initiate, update, etc.)

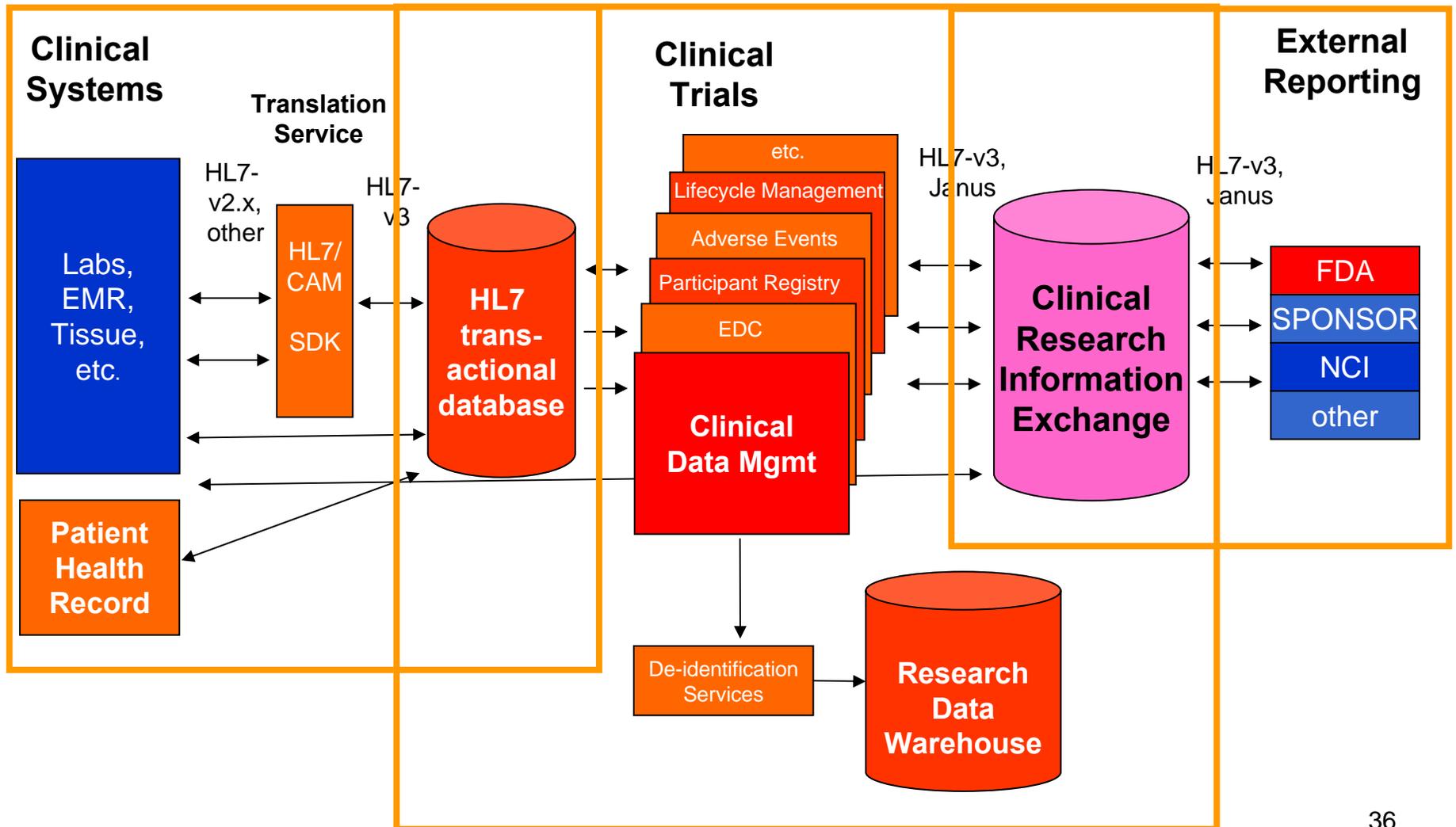
Standardization

- One industry portal available for use between all sponsors and all sites
- Standardization across sponsors of technical management of regulatory documentation
- Non-standard forms will be standardized (i.e. CV, FDF) across sponsors
- Establish SAFE credentials that can be used for other systems

Improved Cycle Time

- Reuse of frequently used information leading to reduction in the number of errors
- Accelerated regulatory document package completion, shorten the time required to initiate a new study
- Reduce redundant sponsor requests and data entry for routine contact information; enter and maintain once for all sponsors

- **Allows more protocols, sponsors without increasing staff resources**
- **Minimizes paper and paper-handling costs**
- **Simplified and lower-cost compliance environment**
 - Enhances patient safety
 - Facilitates investigator compliance
- **Offers potential to leverage other information management and informatics investments**
 - Electronic Health Record
 - Clinical Data Warehouse



Thank You

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- Patient's experience
- Goal: Speed the development and the approval processes for new therapies
- Challenge: "Silos" = Real and sometimes artificial Barriers
- Overcome Barriers through an open, trusted, community-based approach

How the CRIX Initiative Helps

- **The CRIX initiative will enable the standardization and electronic transfer of data. This will service patients in a number of ways:**
 - More treatment choices, fewer delays in trial start
 - Timely openings will improve accrual rates
 - Lower development process costs allows for more investment in new therapies and the potential to control escalating drug costs
 - Standards based trial data yields more meaningful treatment information for doctors once treatments are approved

- **Another way the CRIX initiative could help is to establish ways for patients to find appropriate trials across both the private and public arenas.**
 - Matching patients to trials will be a big step forward for patients and doctors

- **Patient advocates work on many levels of research and treatment development.**
 - The CRIX initiative includes patient advocates in all areas of its governance structure to assure that the patient concerns will be heard and met by the initiative.

Thank You

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CRIX Community Perspective

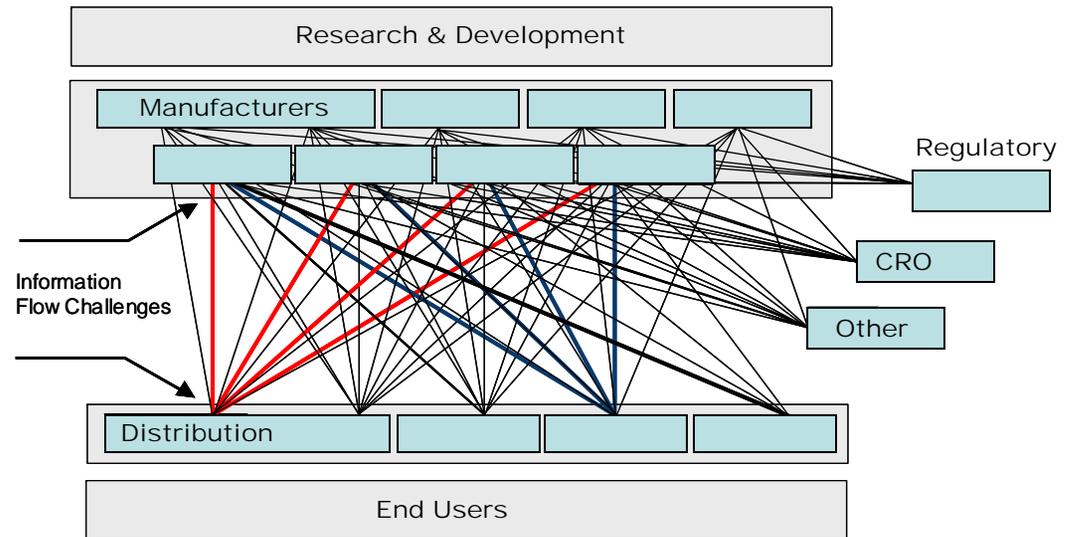
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- A six year old, US based technology services company focused on servicing vertical markets (the forest and paper and pharmaceutical industries)
- Formed to create a set of shared services and to promote and facilitate the use of common industry standards (e.g., papiNet, CDISC, etc.)
 - Funded by Global 1000 companies (fifteen in the forest and paper industry)
 - Change agent for standards within the paper industry
- **Solutions and Services**
 - Electronic Messaging Network (over 3.1 million messages processed per month with over 3,100 connected companies)
 - Complete Integration & Data Management Outsourcing Services
 - Consulting, Implementation, and Support Services

Point-to-Point Architecture:

- Low cost for simple implementations
- Limited Scalability
- Complex as connections grow

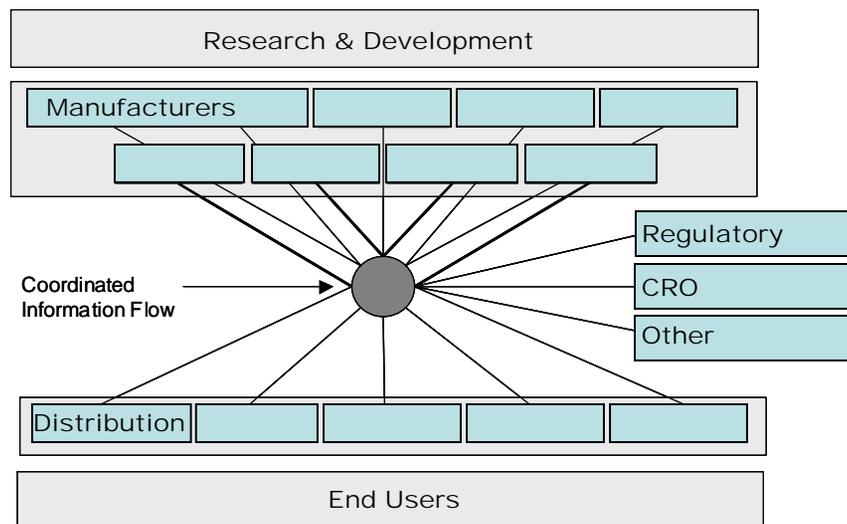
“Enterprise Software” from an Industry perspective

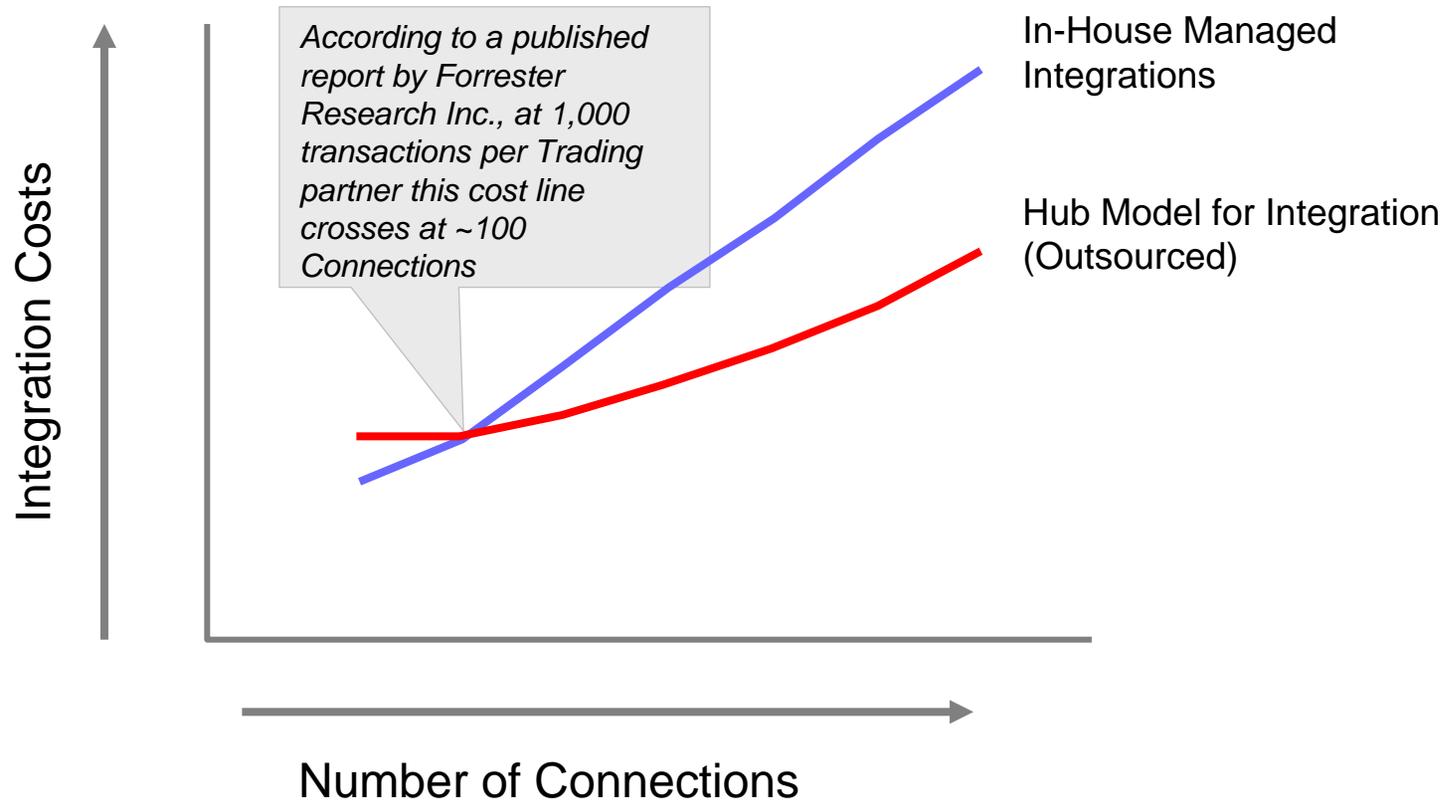


Value-Added Hub and Spoke Architecture:

- Requires initial planning
- Lowest cost as the model scales
- Maximum standards leverage

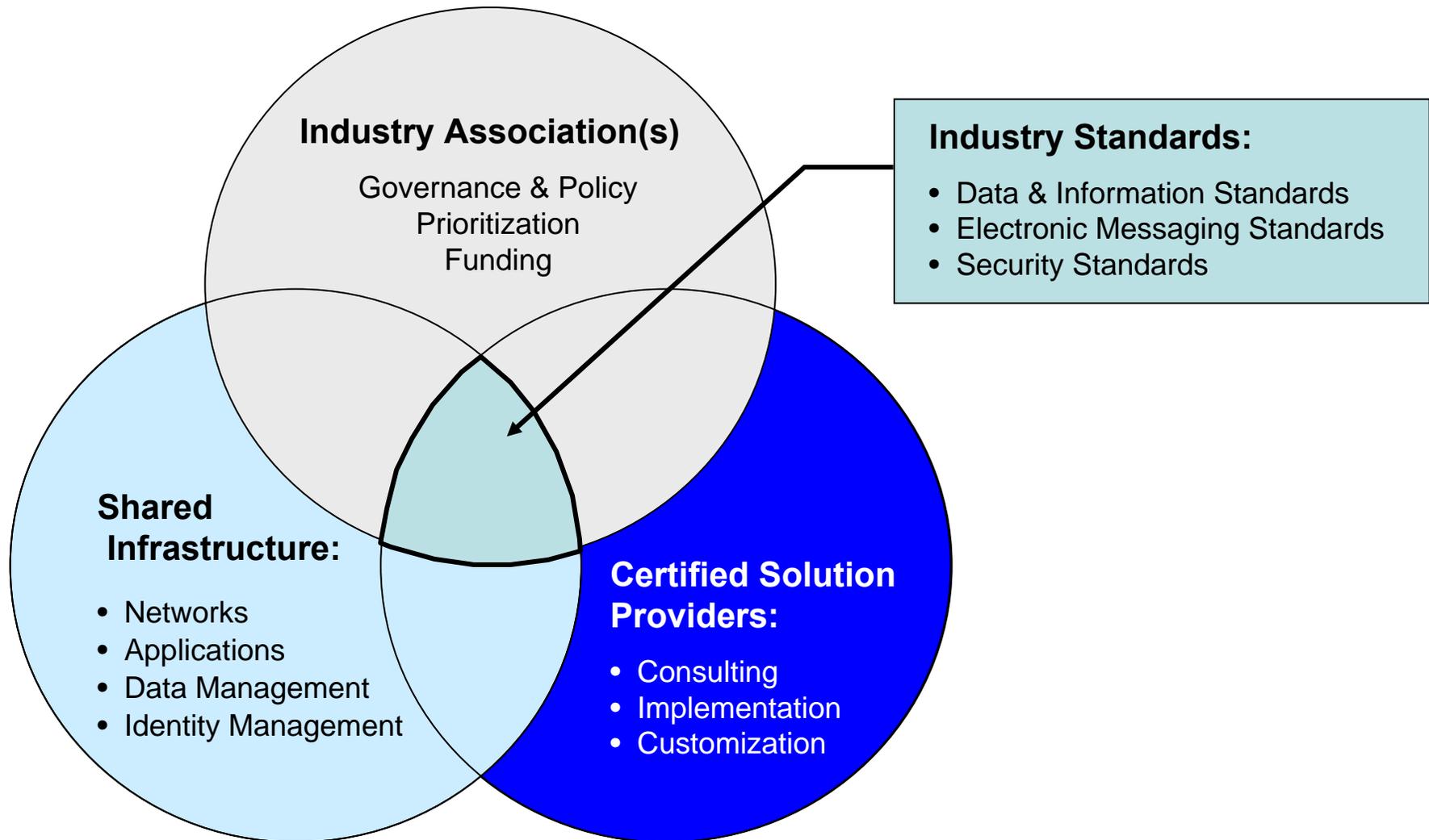
“Value-Added hub” from an industry perspective





***Scale economics is the basic financial justification for all industry Hubs
– but cost savings is not the whole story***

Industry Governance & Standards Bodies	Industry Exchange Infrastructure	Industries Served
OTA <small>(various standards)</small>	Sita & Equant	Airline and Transportation Industry
ACORD	IVANS	Insurance Industry
AIAG <small>(various standards)</small>	ANX <small>(acquired by SAIC)</small>	Automotive Industry
AIAG <small>(OAGIS)</small>	Covisint <small>(acquired by Compuware Corp.)</small>	Automotive Industry
Uniform Code Council (UCC)	Transora <small>*Merged with UCCNet now not for profit</small>	Retail and Consumer Package Goods Industry
CIDX	Elemica	Chemical Industry
papiNet	Liaison Technologies	Paper and Forest Industry
RosettaNet	e2Open	Supply chain hub for high tech (extending to other industries)



- Most flexible and efficient model for collaboration with common partners and compliance with regulatory authorities
- The only way to effectively administer industry information standards throughout the entire product life cycle and across many industry participants.
- Can be leveraged by individual companies beyond compliance to gain further competitive advantage or efficiencies

By definition, the same results can not be achieved with in-house, company specific solutions for external business processes

- **Gain initial sponsorship/leadership from a few important players**
 - Be inclusive across the value chain quickly (example; not just manufacturers)
 - Actively market each success and build momentum
- **Identify specific opportunities and focus there first**
 - Avoid areas of competitive advantage with implications of intellectual property
 - Clearly identify leverage points for industry solutions
- **Employ the proper (sustainable) business model to deliver on the vision**
 - Not for Profit consortia model works best for Consensus and Compliance
 - For Profit model works best for Execution and Service Delivery

*These challenges take time to solve
(companies can not simply throw money at the problem and fix it over night)*

The Liaison logo features the word "LIAISON" in white, uppercase letters on a blue rectangular background. The letter "I" is replaced by a vertical bar, and a semi-circle of yellow dots is positioned above the letters "A", "I", and "S".

L I A I S O N

Questions?

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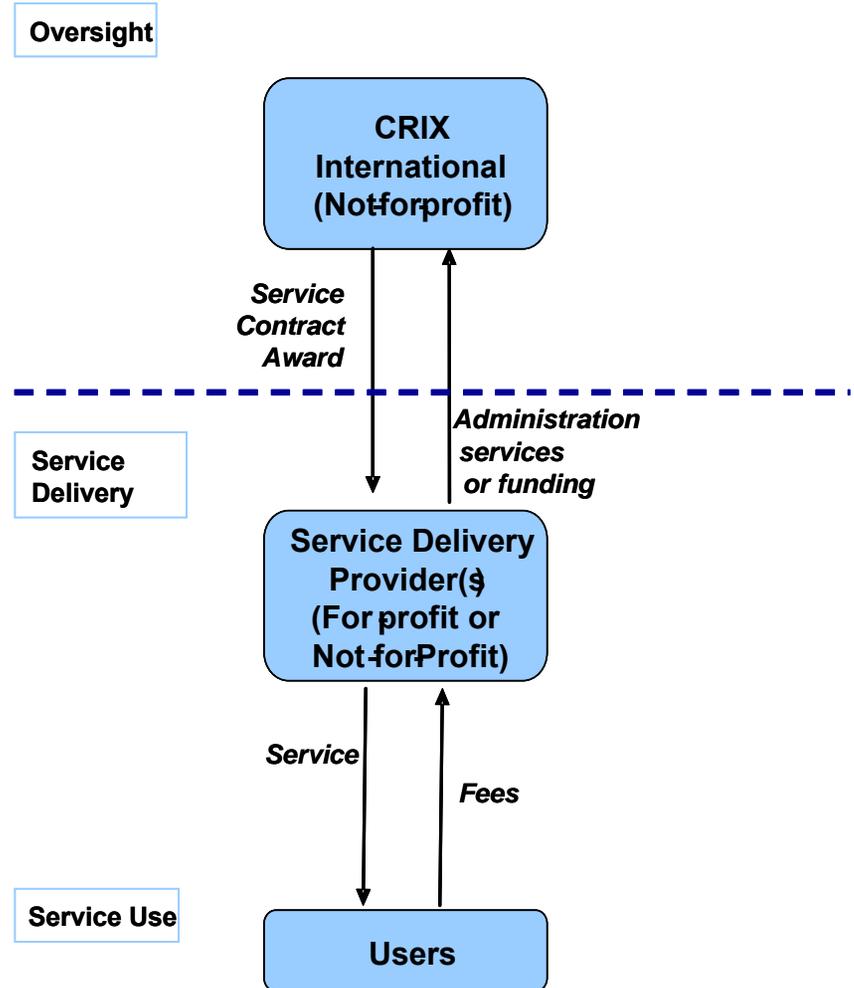
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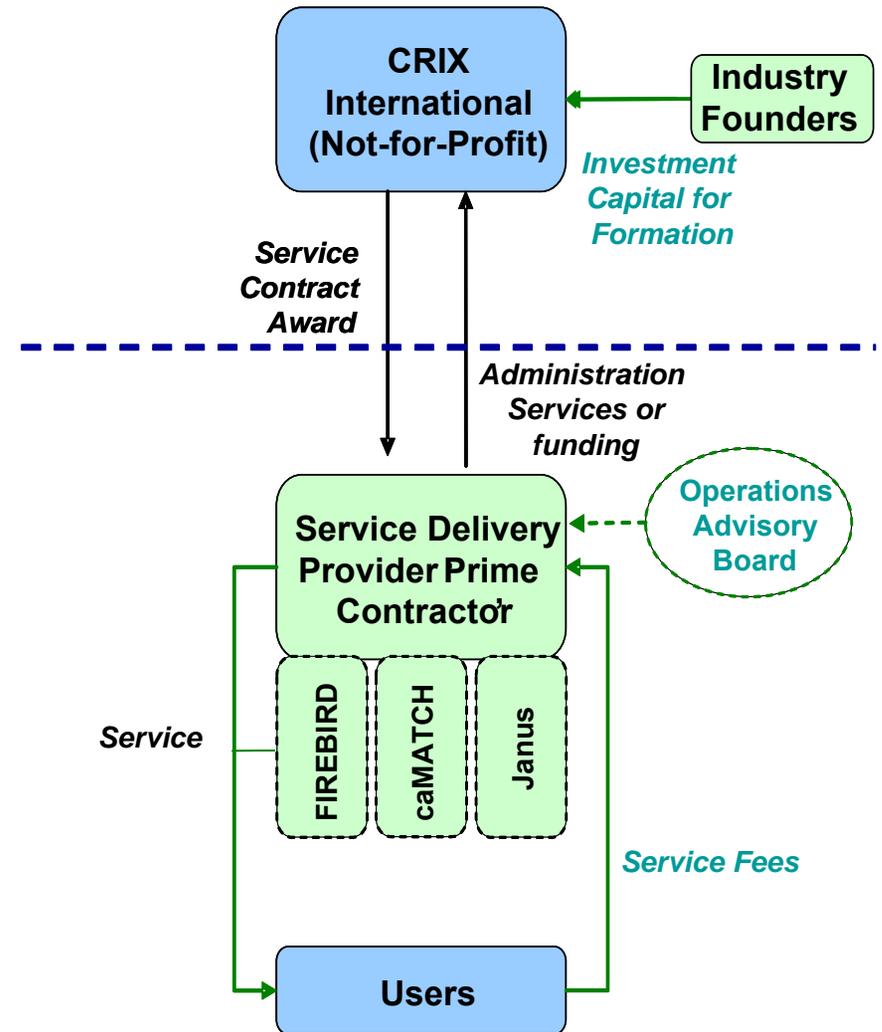
- What are your general viewpoints on a third party entity or entities providing services related to such an electronic platform?
- What is the proposed business model that outlines the relationship between the third party entity, service provider, government and larger community?
- How will this model ensure fair competition and open access?

- CRIX International will select one or more Service Delivery Providers
- CRIX Service Delivery Provider(s) Responsibilities
 - Build, deploy and operate Exchange components
 - Regulatory compliant development and production operations
 - Contract with users for service delivery



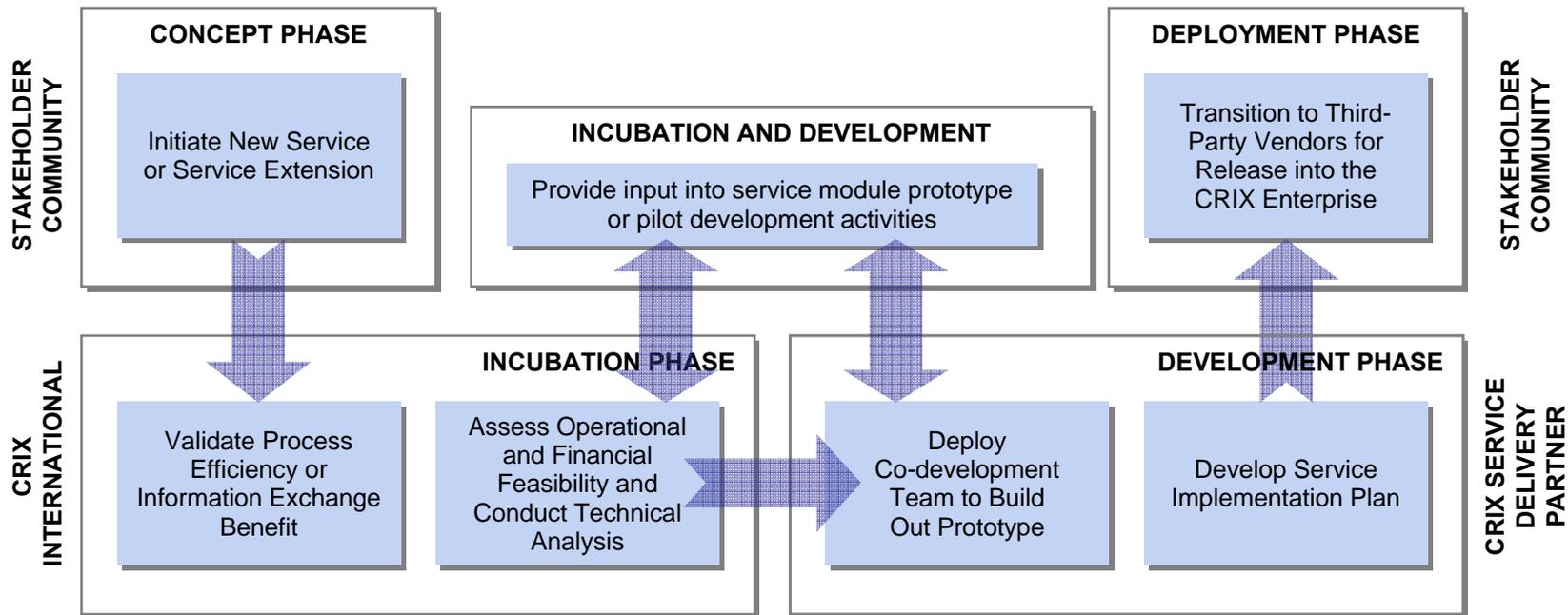
Service Provider Structure

- “Prime Contractor” approach for shared service elements
- Service module operation may be sub-contracted to specialty vendors
- Affords efficiencies and cost advantages for the community
- Fosters faster delivery and greater control of the development process



- **Service Fees for module usage to be established by CRIX International**
 - Provide revenue stream for service module operations and maintenance expenses
 - Annual pricing tiered based on customers' "ability to pay"
 - Once the CRIX exchange reaches self-sustaining operations, fees can be/will be reduced
- **Commercial award approach for prime contractor and specialized service module providers**
 - Award processes based on fair, open, and objective criteria

Development Approach for Future Service Modules



- Community provides inputs on new services
- Development and incubation can be conducted inside or external to CRIX International
- Formal business case developed, vetted and accepted by CRIX International - includes business analysis of the technical and financial feasibility of new service modules
- Acceptable modules are transitioned into the CRIX Service Delivery infrastructure

- Third party oversight ensures vendor neutrality and cost efficiency.
- Single service delivery provider reduces contractual complexities and mitigates risks associated with coordinating with multiple vendors.
- Approach promotes open dialogue and involvement that is inclusive of CRIX community of stakeholders, ensuring their interests are met.
- Investment review, incubation and development oversight ensures service module selection is technically and fiscally sound.

Thank You

Questions?