

**FDA Part 15 Hearing  
CRIX Community Testimony  
December 18, 2006**

**Speaker #1: Debra Bremer, Pfizer**

Good afternoon. My name is Debra Bremer. I am the Vice President of Development and Medical Informatics at Pfizer. Thank you for providing this opportunity to speak with you today about clinical information exchange and electronic submissions.

***Slide 1 – CRIX: Clinical Research Information Exchange***

Today, I am presenting on behalf of the CRIX Community. CRIX (which stands for the Clinical Research Information eXchange) is a secure, shared-technology, standards-based service platform. We are developing this exchange to deliver value added services to the biopharmaceutical industry and for use in information exchange between research organizations, our business partners and regulatory authorities. CRIX can potentially deliver similar services to support other regulated products. We, as a community, formed CRIX International as a not-for-profit entity just this month with the vision of a public-private partnership in mind. An entity such as this is essential for the initial and on-going success of a clinical research collaborative environment. The board of CRIX International will be composed of representatives from the public and private sectors, and CRIX International will govern and oversee the operations of the services. While we have taken the initial steps to form an entity that embraces a public-private partnership in its very structure, if desirable, it could readily be merged into an existing strategically aligned non-profit organization. For more specifics on the role of CRIX International I would refer you to the CRIX Executive Summary document submitted to the public record for this Hearing.

We believe CRIX services will deliver to users workflow efficiencies; lower operational costs; reduced infrastructure development expenses; and faster drug development times. CRIX can also contribute to accelerated achievement of the goals of the FDA Critical Path and NIH Roadmap initiatives; for example, a shared public/private infrastructure

provides a platform for streamlining clinical trials and potentially assisting with adverse event data mining. In later testimony you will hear examples of how CRIX can streamline clinical trials.

### *Slide 2 – The CRIX Community*

The CRIX Community encompasses a broad range of stakeholders. Represented within our community are hospital groups, patient advocates, government agencies, academic research centers, trade and standards-setting organizations, and industry service providers. The CRIX Community is constantly growing, and our **goal** is that it will embrace all organizations involved in, supporting or overseeing clinical research.

### *Slide 3 - History*

CRIX is a collaborative shared technology exchange, so it is fitting that it grew out of two previous collaborations. Both of the preceding collaborations were looking to enhance and accelerate the process of developing diagnostics and therapeutics.

In 2003 FDA and NCI initiated the Interagency Oncology Task Force – the IOTF – to streamline the development of cancer drugs. In 2004 the IOTF focus expanded to include a shared technology information exchange. At around the same time the PhRMA trade association was engaged in an effort called SEBIX, exploring how to save time and money through the development of a shared infrastructure and means of information exchange.

In 2005 NCI launched CRIX as an initiative to demonstrate the value of a shared infrastructure, leveraging the momentum of the IOTF and drawing on lessons learned from the SEBIX experience. Development then began on the first service module for CRIX – the Federal Investigator Registry for Biomedical Informatics Registry Data, which is why we call it FIREBIRD. To date FIREBIRD has been developed under NCI's Center for Bioinformatics with knowledge, technical expertise and resources contributed by the broader CRIX Community. Going forward we propose FIREBIRD, as well as

future service offerings, be developed and overseen by the formal public/private partnership represented by CRIX International.

#### ***Slide 4 – Poised for Success***

The CRIX Community is active and thriving with broad stakeholder group representation. The Community holds the shared goals of lowering drug development costs and speeding new therapies to patients. We believe an information exchange, such as CRIX, is essential to achieving those goals, and we believe that CRIX has the financial backing, organizational sponsorship and the right governance and operation structure to make it succeed. We have demonstrated that an exchange can work through the FIREBIRD pilot, and we propose to release the production version of FIREBIRD in 2007.

With the governance structure that we are putting in place through CRIX International we are confident that CRIX will continue to grow its services within clinical research and could be extended to support other regulated products. CRIX will continue to grow its community, and deliver value to community members and patients.

#### ***Slide 5 Community Perspective***

Members from the stakeholder community will provide their perspectives on the challenges of drug research and development in the current environment and the value of a third party information exchange in addressing those challenges. They will also provide information which supports CRIX as an ideal model for regulatory information exchange and collaboration.

Six speakers will give their insights on CRIX, each bringing a different perspective on the need for, benefits of, and governance structure of CRIX. We will hear the viewpoints of representatives from large and small bio-pharmaceutical companies, academia, the patient advocacy community, a provider of exchanges in an external industry sector, as well as a service vendor.

Thank you.

I will now hand over to Diana MacKenzie from Amgen, who will provide the large biopharmaceutical company perspective on CRIX

**Speaker #2: Diana McKenzie, Amgen**

Good afternoon. I would also like to thank you for this opportunity to speak to the value we believe the CRIX initiative offers to the broader clinical research community.

My name is Diana McKenzie and I am here today, representing Amgen. Amgen is a leading human therapeutics company that serves the needs of millions of patients worldwide. We strive to be an entrepreneurial, science-driven enterprise dedicated to helping people fight serious illness and we believe that by aligning with the CRIX initiative, we demonstrate our commitment to this aspiration.

***Slide 6 – Industry Challenges***

I believe we are all familiar with the challenges we face in addressing both the costs and complexity of research and development in the biopharmaceutical industry. In addition to these, Amgen has experienced significant and positive growth over the course of the past several years. In light of both these industry challenges and our own growth, we are required to find ways to improve business processes and our supporting IT infrastructure so that our increased scale does not slow progress with developing important therapies. These improvements will help us to reduce the costs of clinical research in an effort to maximize both our investment in identifying new therapies and patient access to them.

***Slide 7 – An Illustration: FIREBIRD for Study Initiation***

FIREBIRD serves as an excellent example of the type of improvement that not only addresses challenges for the broader clinical research community but also has value for Amgen internally. We expect that with a successful deployment of FIREBIRD we can reduce the cycle time associated with capturing the 1572 and CV during investigator site initiation, a common industry process, from 8 weeks to mere hours. In addition, we

believe that these reductions in cycle time also lead to higher quality information and improved ease of review for our regulatory colleagues. Lastly, we recognize that for our investigator community, we demonstrate our commitment to easing the administrative burden for them with participating in clinical trials thus allowing them to focus on the patient.

### ***Slide 8 – Value of FIREBIRD to Amgen***

Our internal business case for FIREBIRD, while conservative, demonstrates the proposed reduction in clinical trial costs at Amgen for both the current phase, which is limited to the 1572 and investigator CV, and future phases where we expect to see greater return when expanded to encompass the entire Site Initiation Packet. We have not incorporated additional CRIX capabilities, such as patient recruitment matching, into our business case; however, believe that these capabilities will only increase the value of CRIX to the research community.

### ***Slide 9 – Everybody Wins***

In summary, we believe that CRIX is an effort, one of many being pursued in the era of Health Information Technology Deployment, which benefits all stakeholders. I have had the privilege of working in this industry for 20 years and I have learned a great deal about what it takes to successfully deliver IT-enabled solutions within R&D. I have been actively engaged in discussions to advance the exchange concept since 2003. It is because of the diverse CRIX community represented here today, the quantifiable business case we have developed and our collective desire to ensure all stakeholders benefit in some way, that we believe the CRIX initiative can successfully help us to address the challenges of speeding new therapies to patients and reducing the costs of research to maximize their access to those therapies. Thank you.

### ***Slide 10 – CRIX Community Perspective***

I will now hand over to Sue Dubman from Theravance, who will provide the small biopharmaceutical company perspective on CRIX

### **Speaker #3: Sue Dubman, Theravance**

I would like to thank the FDA for the opportunity to speak today.

My name is Sue Dubman. I was one of the originators of CRIX when I worked at the National Cancer Institute and have been a supporter of the need for CRIX from its early beginnings in 2004. Currently I am the Vice President of Information Technology and Informatics at Theravance, Inc., one of approximately 900, mostly small to medium-sized bio-pharmaceutical companies in the San Francisco Bay Area.

#### ***Slide 11 – Some Facts: Drugs in Development by Disease***

Small to medium-sized bio-pharmaceutical companies, like Theravance, play a critical role in new drug development. According to statistics compiled by the PhRMA and BIO trade associations, as much as 70% of new drugs in major disease categories are being developed by biotechs and many, if not most of these, are being developed by small to medium-sized companies. As such, any capabilities that allow a small bio-pharmaceutical company and its many partners (CROs, large bio-pharmaceutical companies, academic research institutes and others) to improve their ability to bring safe, effective drugs to market sooner and for less expense are a win-win for everyone, but especially patients.

#### ***Slide 12 – How does CRIX address barriers...***

Talking with many other small to medium-sized bio-pharmaceutical companies and having just submitted our first NDA electronically to the FDA, I believe that the CRIX initiative has the potential to not only streamline electronic transfer of data to the FDA but also to improve the processes for collaboration with industry partners in the future.

1. CRIX can provide cost savings and scale efficiency if CRIX supports use and adoption of common standards for regulatory submissions by all stakeholders (industry, government and academia). Today, we find inconsistencies and overlap among the various standards and the interpretation and use of these standards by multiple parties. CRIX, with its vision of a shared infrastructure and tools used by

- all, has the potential to address these issues, thereby increasing the efficiency of exchange and making interactions and decisions easier, faster and cheaper.
2. CRIX, because it is standards-based, can also potentially make it easier and more cost effective to collaborate with our many partners. Standards, by their very nature, facilitate the exchange of information between two parties with common interests. However, today, there is a steep learning curve and cost to adopt standards. If the shared CRIX infrastructure can provide capabilities to create and use data in standard formats and make validation of compliance with standards easier, CRIX will have a favorable impact on the cost and time it takes to bring new treatments to market.
  3. The CRIX community has the potential to ensure that standards address the needs of all stakeholders involved in the creation and development of new treatments. In any community standards effort, not just CRIX, there is a danger in the “lowest common denominator” emerging as a common standard. The CRIX community needs to make sure that standards take into account differences in project type, personnel, complexity and other factors. This can be ensured by having all stakeholders at the CRIX table, government, industry, academia, the standards community and patient advocates.

### ***Slide 13 – Potential Future Capability...***

CRIX also provides potential gains in interoperability of clinical systems in the future. For example, FIREBIRD, the CRIX Clinical Investigator Registry for regulatory submissions, potentially provides authoritative investigator, site and protocol information for connecting patients to trials. This is critically important as recruitment of patients to clinical trials is a HUGE problem. According to market research, upwards of 40% of clinical trial costs out of nearly \$6 billion spent annually on clinical trials is tied directly to patient recruitment and greater than 80% of clinical trials have major recruitment delays. Also, these costs are not going away. With the growing complexity of research and targeted therapeutics for increasingly narrow populations, with the needs for larger,

more diverse patient populations for longer durations to ensure drug safety and with the requirements to enforce HIPAA-compliant environments with a diverse and complex set of rules of engagement between clinicians, investigators and patients, the delays associated with patient recruitment are likely get to worse *unless we find a new way*. For large pharmaceutical companies, patient recruitment difficulties are a big expense, resulting in fewer development projects and slowness in bringing new drugs to market. For small to medium-sized bio-pharmaceutical companies, significant patient recruitment delays and the associated additional cost can put a company out of business. For patients, this means that many innovative new treatments may never get to market.

### ***Slide 14 – It can be done!***

We need to find better, more cost effective ways to do drug development. CRIX addresses one piece of the overall problem. With the CRIX initiative, we have the potential to stay focused on the science, the medicine and most importantly, the patient, rather than the information technology infrastructure. This is critical to all of us, because some day all of us, our family, our friends and our colleagues, will be patients. When that happens, we will need and want the best possible, most cost effective and safe treatments. As my mentor at the NCI, Dr. Ken Beutow, always says, the question is not “why now?” but “why not sooner?”

### ***Slide 15 – CRIX Community Perspective***

I will now hand over to Robert Beck from Fox Chase Cancer Center, who will provide the Research Center perspective on CRIX.

Thank you again for allowing me the opportunity to speak with you today.

***Speaker #4: J. Robert Beck, Fox Chase Cancer Center***

I also would like to thank the FDA for the opportunity to speak today.

My name is Bob Beck. I serve as the vice president for information services and the deputy director of the population sciences division at Fox Chase Cancer Center in Philadelphia. I am familiar with the CRIX initiative through activities in the Strategic Planning Workspace of the cancer Biomedical Informatics Grid, or caBIG™. I am speaking as an individual, although attempting to represent the academic health research community. We believe that the Clinical Research Information Exchange offers an unparalleled opportunity to strengthen the academic clinical research community.

### ***Slide 16 – Problems in Clinical Research Management...***

Managing clinical research at an academic cancer center has logistical, regulatory, and management challenges. At Fox Chase we handle over 150 active protocols, from individual investigator-initiated projects, to industry-sponsored trials, to large NCI cooperative group trials. Each protocol has its own forms, procedures, addresses, rules and regulations. Investigator-initiated protocols are particularly difficult. Although the sine qua non of clinical research at an NCI-designated cancer center, they are quite challenging to export beyond the single institution where they are developed, due to lack of standardization across institutions and protocols.

Sponsored trials, while offering some limited standardization within a corporation's offerings, generate their own problems. As one colleague comments, "Every time I work with a new sponsor, it costs me money." That's because new sponsors mean new forms, new organization of trial data, and other inefficiencies that standardization could address.

We recently celebrated the 20<sup>th</sup> anniversary of Fox Chase Partners, a consortium of over 20 institutions in Pennsylvania, New Jersey and Delaware. Our partners participate in clinical research, add many patients to clinical trials, and form the substance of a Community Clinical Oncology Program, or CCOP. However, the problems of clinical trial management are multiplied 20-fold when extending them to this community. This group could function as single collective entity with improved automation and standardization of protocol management and investigator data.

### ***Slide 17 – FIREBIRD: Benefits for Academic Sites and Investigators***

CRIX and the FIREBIRD initiative offer several positive features for busy academic clinical research organizations. **Cost Savings** can be achieved by reducing paper shipment, reconciliation and storage costs; by creating a single electronic master repository for investigator regulatory documentation for the entire institution and its partners; and by minimizing the number of documents the coordinator or investigator must manage. **Increased Standardization** can arise through the establishment of a single industry portal available for use between all sponsors and all sites. This would particularly help our CCOP. Standardization across sponsors of technical management of regulatory documentation would be a plus, as would the standardization of idiosyncratically designed forms. Establishing SAFE credentials that can be used for other systems would represent a further important step. Also, **Improved Cycle Time** is of import not only to industry, but to busy academicians. Reuse of frequently used information, leading to reduction in the number of errors, is part of FIREBIRD's appeal. Also, accelerated regulatory document package completion will shorten the time required to initiate a new study, whether initiated by an individual investigator, a cooperative group or an industrial sponsor. Most attractive to us is the reduction of redundant sponsor requests and data entry for routine contact information. We of course want to enter and maintain our static data once for all sponsors. When changes then occur, updates through a central portal would provide accurate information to all our sponsors simultaneously.

### ***Slide 18 – Other Benefits of Automated Clinical Research Data Management***

Automation of the clinical research enterprise at the federal level allows more protocols and sponsors at the academic site without increasing staff resources. FIREBIRD and CRIX promise to minimize paper and paper-handling costs, and thus to simplify the entire compliance environment. This in turn could enhance patient safety even as it facilitates investigator compliance with appropriate, but burdensome regulation. Most exciting is the potential of these systems to leverage other information management and informatics investments, such as the Electronic Health Record. Fox Chase Cancer Center as part of its participation in caBIG is developing a Clinical Data Warehouse that can

take results of translational and clinical research directly into consensus records populated by the Electronic Health Record. This project can be rapidly accelerated with the sort of standardization offered through the Clinical Research Information Exchange.

***Slide 19 – Clinical Research IT Infrastructure***

This project can be rapidly accelerated with the sort of standardization offered through the Clinical Research Information Exchange, which will leverage institutional electronic record systems and clinical research technologies for the benefit of all participants.

***Slide 20 – CRIX Community Perspective***

I will now hand over to Diane Paul, a Patient Advocate, who will provide the Patient perspective on CRIX

Again thank you for allowing me the opportunity to speak with you today.

***Speaker #5: Diane Paul, Patient Advocate***

***Slide 21 – Patient Advocate Perspective***

I would like to thank the FDA for the opportunity to speak today.

My name is Diane Paul and I am a 13 year survivor of advanced ovarian cancer. While I belong to a number of different advocacy organizations, I am speaking to you today as an individual. I have been a member of the CRIX Steering Committee for a year and a half.

Over the last 13 years I have witnessed, first hand, the roadblocks that exist in bringing treatments to patients. Time after time, I have seen patients willing and able to enroll in clinical trials, who have to go back on standard treatments because of delays in the opening of trials. I have seen patients waiting for new drug approvals die, before those drugs get to the marketplace. When treatments do receive approval, they are often no longer of interest to patients because newer, less toxic methodologies are emerging.

Prior to January of 2000, I was employed in the Information Technology Department at the Fashion Institute of Technology in NYC as a systems analyst. When I first came to FIT in 1979, there were many problems with admitting and enrolling students in a timely fashion. The different silos of information which the admissions, financial aid and registrar's offices maintained, caused similar problems to what I see as issues in the drug development and approval process. The first step in solving these problems was to get representatives from each area to work together towards a common purpose. Communication between the FDA, the research community and the pharmaceutical industry, is the first step in breaking down barriers which hamper them all. The CRIX initiative provides the framework for communication so areas of agreement can be documented and real problems can be defined and solutions explored. With this type of framework all three entities can work together for the public good.

### ***Slide 22 – How the CRIX Initiative Helps***

The CRIX initiative will enable the standardization and electronic transfer of data. This will speed both the development and the approval process. It will service patients in a number of ways:

1. Treatment choices often must be made in a relatively short period of time, in order to best serve the patient. Patients often are unable to enroll in trials, when they and their doctors deem it appropriate, because of the delay in opening the trials.
2. Timely openings will improve accrual rates. This will have a ripple effect on the time it takes to complete the trial and get information about efficacy and toxicities to regulatory agencies and hopefully increase the speed with which treatments are available for the public.
3. Costing savings resulting from standardization and electronic transfers of data should allow for more investment in new therapies as well as savings in treatment costs for the public.

4. Better standardized information from trials should provide more meaningful treatment information for doctors treating patients in the clinic, following the completion of trials and treatment approvals.

Currently cancer patients and their doctors need to search various data bases in order to find trials which are open and available. One way the CRIX initiative should help is to establish ways for patients to find appropriate trials across both the private and public arenas. Matching patients to trials across the health continuum will be a big step towards improving accrual times for trials and the ability to search the public and private sector at the same time, will allow better information for patients and their doctors to determine what trial choices exist and what is the best choice for the patient.

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. I volunteer my time to the CRIX Steering Committee because I believe it is of utmost importance that we change the current system to better service patients. I feel the CRIX initiative will help to do that.

### ***Slide 23 – CRIX Community Perspective***

I will now hand over to Dan Ruggles of Liaison Technologies, who will provide a perspective on how other industries have dealt with the establishment of exchanges.

Again thank you for allowing me the opportunity to speak with you today.

### ***Speaker #6: Dan Ruggles, Liaison Technologies***

My name is Dan Ruggles from Liaison Technologies, speaking on behalf of Bob Renner, our CEO, who could not make the meeting today. I would like to thank the FDA for the opportunity to speak today and to share our experiences in setting up and operating a Consortia Exchange.

Liaison Technologies (formerly known as ForestExpress) was founded in June of 2000 and is headquartered in the US, with operations in Europe. We are a private, for-profit company. We act as a Shared Infrastructure Provider for an exchange, which I will define later in this discussion.

Liaison has been funded by Global 1000 companies, with the clear intent to foster and promote standards with our implementation of an exchange.

Today we operate a production set of systems that process about 3.1 million messages per month with over 3,100 connected companies.

### ***Slide 24 – Consortia Models by Industry***

The two typical architectures in a consortia exchange are either point-to-point or hub-and-spoke. The point-to-point model involves a series of direct connections between two unique end points. Most industries have deployed the hub-and-spoke model for their exchange.

As can be seen by the table, these exchanges have gained significant momentum and business model validation over time and involve the active participation of competitors to work together to help drive down their own respective costs and improve cycle times.

Common themes of these consortium exchanges are:

- Industry leader participation and commitment (actively leading and visible high profile companies)
- Clear separation between the standards bodies (generally not for profit) and operating the exchange (generally for follows a profit model)

Significant investment is required (nearly all successful exchanges report investments between \$100 - \$250 million – mostly in startup costs) before reaching substantial benefit for the members. (\*Note: ForestExpress raised \$100 million and Transora raised \$250 million. Covisint, Elemica, and Quadrem were well within this bracketed range.

### ***Slide 25 – Consortia Functions***

There are usually three functioning parts in a consortium exchange. The initial driving force is the top one, the Industry Association(s) which sets and promotes standards, governance, and coordinates funding. They frequently act as the:

- Voice of the Industry
- Marketing Champion
- Low financial investment but significant in terms of time from senior industry leadership resources.

On the lower left is the Shared Infrastructure (Exchange Operator): Standards Implementation

- Execution and Management of Shared Platform and Shared Services (referred to as the Service Provider in previous and subsequent CRIX presentations today

Lastly, there are the Certified Solution Partners: This is a typical leverage model of using economics to speed the adoption of the Standards and in some cases Adaptation of the Standards over time, based on real-world experience.

Our experience has shown that validation and enforcement activities for industry standards can ONLY be maintained through a shared services model. Without the Consortia Exchange, Certified Solution Providers and individual companies will deviate from the standard to accommodate their needs. The Consortia Exchange acts as a control point to localize exceptions.

Companies' use of the exchange can provide advantage, in terms of cost economies, quicker to market by taking advantage of services, etc.

However, by definition these core services and infrastructure will not provide competitive advantage to any of the individual members.

### ***Slide 26 – Key Learning's***

From our experiences and observations of other exchanges and as a service provider,

- Getting started required strong industry leadership and commitment.

- This model required a long-term view. The economic benefits may not likely be reached for 5-7 years (although break-even operations may come within 2-3 years, if carefully managed).
- Consortium Exchange is a proven model, as exemplified by other industries
- The three key stake holders groups all have a role to play (Industry Association, Shared Infrastructure Provider (Exchange Operator), and Certified Partners
- Lastly, long-term commitment by all stakeholders for success

### ***Slide 27 – CRIX Community Perspective***

I will now hand over to the Community's last speaker Mark Adams from Booz Allen Hamilton, who will provide a service provider's perspective on the CRIX initiative.

Again thank you for allowing me the opportunity to speak with you today.

***Speaker #7: Mark Adams, Booz Allen Hamilton***

### ***Slide 28 – Questions Addressed***

Thank you for the opportunity to speak to the panel to provide a service provider perspective. My name is Mark Adams, and I work for Booz Allen Hamilton, a management consulting company here in the Washington, DC area. I would like to address these questions in my remarks.

### ***Slide 29 – CRIX Service Delivery***

The CRIX Service Delivery Provider(s) will be responsible for the construction, deployment and operation of the tools and components of the CRIX service. The providers will also ensure that the development and service provisions meet compliance requirements outlined for them.

The provision of these services is provided to the community of users via contracts, which would provide the platform for Service Level Agreements (SLA), et al.

CRIX international would select one or more Service Delivery Providers to deliver the services to the CRIX community, and would contract with those Service Delivery Providers, providing structure, scope and governance for their activities. The Service Delivery Providers must be independent from CRIX International, but can be either a for-profit or not-for-profit organization.

### ***Slide 30 – Service Provider Structure***

One of the key recommendations from industry is to select a single Prime Contractor to act as the Service Delivery Provider. The Service Delivery Provider would then subcontract with the entities providing specific subcomponents which comprise the CRIX services. The Service Delivery Provider can then subcontract with specialty vendors to provide the key project activities. Thus, each subcomponent can be supplied by “best of breed” groups, without burdening the CRIX community with the need to identify and contract individually with all of them.

This includes software development, deployment, hosting, support services, *et al...* Industry regards a prime contractor as the most efficient way to provide the CRIX collection of service modules. This also ensures that the interactions between those providing the specific services to the community are consistent and flexible, and also allows new services and/or service providers to be added to the processes without disrupting or adding complexity to the users of CRIX services. Additionally, consistency and synergy can be realized by providing shared help desk, software support and other shared services for all of the tools and capabilities provided to the CRIX community.

In this simplified contracting and funding approach, all the users of CRIX services would execute a single contract with the Prime Contractor for all desired modules, which additionally provides a single channel for the collection of service fees.

A single point of contact also provides a mechanism for a single, well-defined issue escalation and dispute resolution mechanism, and allows for flexibility in resolving such issues quickly and effectively.

### ***Slide 31 – Service Provider Structure – cont'd***

The funding model for CRIX International would depend on a set of initial contributions from industry founders. These contributions would provide the foundation on which the initial organization would be formed, and then service fees for module usage would provide an ongoing revenue stream to support module operations, support and maintenance activities. These Service Fees would be set by CRIX International, and would be based on levels of usage, and the organization's ability to pay. A CRIX users "ability to pay" would be measured by firms' global annual sales, where firms with higher sales are expected to pay more for services. The annual fees for founders and non-founders would be set in relation to projected market share in order to minimize the capital investment requirements, and achieve self-sustaining cash flow by the third full year of operations. This will ensure that the services provided by CRIX International are available to all organizations, regardless of their size and stature. As the CRIX organization reaches a self-sustaining level, the fees can be reduced or excess funds may be directed towards the development of new services.

The process for selecting commercial suppliers for the prime contractor and subcontractor roles would be done via a standard competitive award process, which will ensure a fair, open and objective review and selection of vendors in all of the roles. This ensures maximum fairness in the process, and the best value to the users of CRIX services.

### ***Slide 32 – Development Approach for Future Service Modules***

Through the proposed process, the community is involved in all the phases of new module development, both that carried out internally or externally to the CRIX International. From a governance perspective, once the Prime Contractor is in place, industry recommends establishing an advisory board to ensure that explicit implementation meets the needs of customers as well as CRIX International. This would provide management oversight and leadership connecting the community with the CRIX activities. To facilitate this, it is proposed that CRIX International will oversee the selection of service modules in an inclusive manner that ensures appropriate business analysis, incubation and development. This provides a mechanism for a successful, cost effective deployment that meets the customer's needs and adheres to regulatory requirements.

### ***Slide 33 – Summary***

In Summary, the proposed structure yields several advantages:

- 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.

### ***Slide 34 – Thank you***

Again thank you for allowing me the opportunity to speak with you today. My colleagues and I would be pleased to field any questions the panel might have concerning our presentation this afternoon.