

# Secure Digital Identities for Authentication & Signing in an Electronic Healthcare Community

John Hendrix; Program Director

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HIMSS 2009



# Overview

- **Challenges to Secure Transactions in an Electronic Environment**
- **How SAFE-BioPharma Overcomes These Hurdles**
- **Use Cases and Example Healthcare Pilots**
- **Introduction to SAFE-BioPharma Association**
- **Summary**

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# Challenges to Secure Transactions in an Electronic Environment

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# Business Drivers in an Electronic Healthcare World

- **Business Process Improvement**
  - Reduce Costs while Improving Quality of Care
- **Trust/Identity Management Drivers**
  - Identity Management
    - Trust people's identities, how do I know who is on the other end of a transaction?
    - Establish risk based methods to confirm and authenticate identity
  - Digitally sign documents
    - Eliminate wet signatures
  - Eliminate multiple user IDs & passwords
- **Interoperability with Business Partners and Regulators**
  - Standards based – Interoperate regardless of technology or vendor
- **Regulatory Requirements**
- **Legal Drivers**

# Core Issues Associated with Simply Going Electronic

- Conducting business electronically requires Trust in the identity of the parties involved and the integrity of the documents or communications utilized.
- **The Electronic Business Problems Defined:**
  - How do I know I am dealing with a particular Doctor or Patient?
  - How do I verify a patient has consented to allow access to their records?
  - How do I verify that items signed by a signatory are from them and have not been altered?
  - How can I make it easy for a user to get a certificate that offers interoperability, legal and regulatory acceptance, and is non-reputiable?
  - How can I make it easy to manage a user's certificate?

# Organizational Identity Management Issues

- **Scalability**
  - Different risk factors may require different levels of certificate
    - Differing methods of identity verification provide the ability to support multiple identity assurance levels – while still providing the same level of trust
- **Flexibility**
  - Two assurance levels, based on the identity verification process, and four certificate types
    - Basic Assurance Software, Medium Assurance Software, Medium Assurance Hardware, Roaming Digital ID (Medium Assurance Software)
  - As the level rises, so does the ability to strongly assert the identity
- **Collaborative Development and Partnering Opportunities**
  - Access to partner systems
  - Hidden costs of user name and password management
- **Move to Electronic Health Records and Increased Need for Access Across Organizations**
  - Current hybrid systems do not support

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# How SAFE-BioPharma Overcomes These Hurdles

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# The SAFE-BioPharma Standard

The SAFE-BioPharma Standard is the Only Complete Set of Managed Business and Technical Policies, Procedures and Agreements for Digital Signing and Authentication in the Global BioPharma and Healthcare Communities to Foster Interoperability, Regulatory, and Legal Compliance

## Business

- Operating Policies
- Contracts
- Processes

- *Agree to Accept digitally signed transactions*
- *Agree to limited liability caps*
- *Agree to dispute resolution*
- *Agree to identity assurance*
- *Agree to self-audit & meet SAFE-BioPharma requirements*

## Technical & Identity

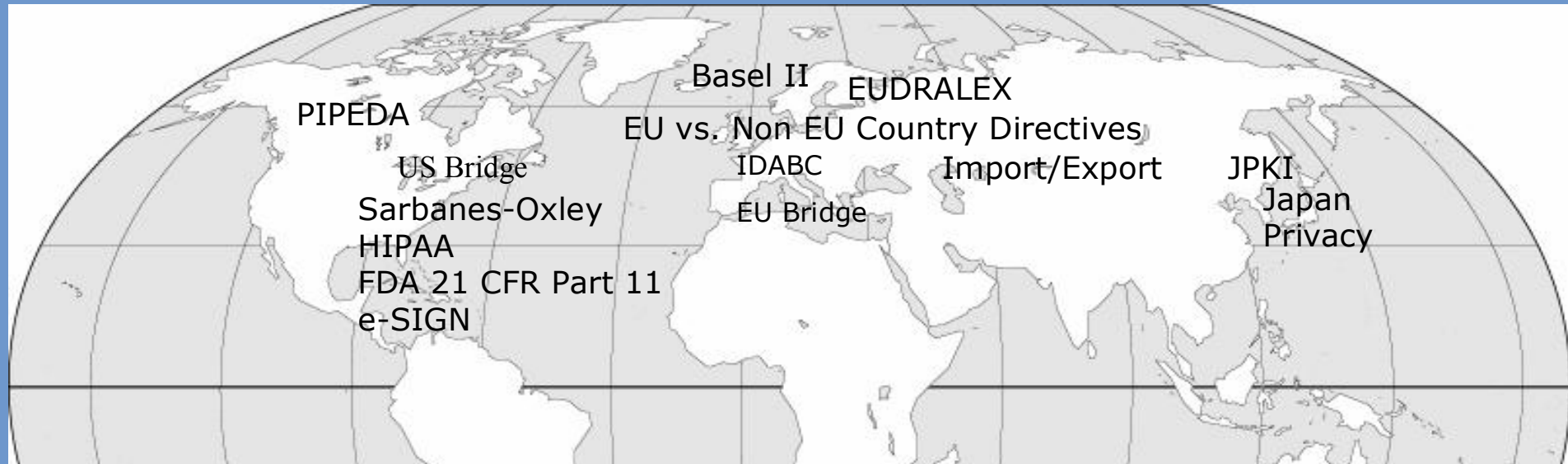
- Certificate Policy (PKI)
- Specifications
- Guidelines

- *Identity verification*
- *Identity life cycle management*
- *Comply with referenced standards*
- *Follow security, audit & control requirements*
- *Certification*

# What are SAFE-BioPharma Compliant Certificates?

- Based on Public Key Infrastructure (PKI) Technology using Public and Private Keys
- An Arrangement that Binds Public and Private Keys with Respective User Identities by Means of a Certificate Authority (CA).
- Validity Conditions and Other Attributes are Made Unforgeable in Public Key Certificates Issued by the CA.
- Can be Used to Authenticate to Systems and/or Digitally Sign Data/Documents
- Validation of the Digital Certification Enables the Parties in a Dialogue to Establish Confidentiality, Message Integrity, and User Authentication Without Having to Exchange any Secret Information in Advance, or Even any Prior Contact

# Regulatory Requirements



- ▶ Policy alignment and consistency is essential
- ▶ Regulations all have an impact on your identity management strategy
- ▶ Conflicting regulations increase risks and costs especially depending on geography

**Control Frameworks:  
EAL, ETSI, ISO, NIST**

# Member Public Key Infrastructure Options

- **Internal infrastructure**
  - Cross certified with SAFE Bridge
  - BMS, J&J – soon others
- **Outsourced infrastructure**
  - Cross-certified with SAFE Bridge:
    - Chosen Security
    - Citibank
    - IdenTrust
    - Trans Sped
    - Verizon Business/Cybertrust
- **SAFE tiered services infrastructure (member-funded)**
  - External partners
  - Regulatory uses
  - Healthcare providers
  - Members

# Options for Flexible Use

- **Two levels of trust:**
  - Basic Assurance for authentication
  - Medium Assurance for trusted identity uniquely linked to authentication, digital signature and EU-qualified
- **Three digital signing technologies:**
  - Software
  - Hardware (zero footprint now undergoing FIPS certification)
  - Roaming
- **Three identity-proofing options**
  - Antecedent – enterprise and on-line
  - Trusted agent
  - Notary – including office/home notary services

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# Introduction to SAFE-BioPharma Association

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# Who is SAFE-BioPharma?

- SAFE-BioPharma is a Strategic Initiative of the Global Biopharmaceutical and Healthcare industries to Facilitate Transformation to Fully Electronic
- SAFE-BioPharma is a member-governed, not-for-profit enterprise
  - SAFE-BioPharma Standard
  - Legal and Contractual Framework
  - Bridge Trust infrastructure
  - SAFE-BioPharma Identity Credentials used for:
    - Digital Signatures
    - Authentication
  - SAFE-BioPharma-enabled Products
- SAFE-BioPharma-BioPharma Association

- |                        |                     |                     |
|------------------------|---------------------|---------------------|
| •Amgen                 | •GlaxoSmithKline*   | •Pfizer*            |
| •Abbott                | •J&J*               | •Premier Purchasing |
| •AstraZeneca*          | •Merck*             | •Roche              |
| •Bristol Myers Squibb* | •Natl. Notary Assn. | •Sanofi Aventis*    |
| •Eli Lilly             | •Organon*           |                     |

\*Denotes Board Member

# What is SAFE-BioPharma?

Standards Body	Shared Services Association	Healthcare Industry Association
<ul style="list-style-type: none"> <li>▶ <b>Standard Development &amp; Maintenance</b></li> <li>▶ <b>Certification standards &amp; administration:</b> Members Vendors, Issuers</li> <li>▶ <b>Alignment to HL7, CDISC, ICH</b></li> <li>▶ <b>Standards Working Groups</b> <ul style="list-style-type: none"> <li>–Technical</li> <li>–Business/Implementation Support</li> <li>–Global Regulatory</li> <li>–SAFE-BioPharma EU Advisory Council</li> </ul> </li> <li>▶ <b>Regulatory relationships:</b> <ul style="list-style-type: none"> <li>–FDA; EMEA</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>▶ <b>Vendor partner program</b></li> <li>▶ <b>Operation of a “bridge” connecting to other trusted communities, eg US Gov.</b></li> <li>▶ <b>Cross-cert with FBCA</b></li> <li>▶ <b>Collaborative projects/audit</b></li> <li>▶ <b>Provides multi-tiered identity certificates</b></li> <li>▶ <b>Driving/Incubating Innovation</b> <ul style="list-style-type: none"> <li>–Credentials Issuance Model &amp; Pricing</li> <li>–Investigator directory</li> <li>–Application certification</li> <li>–Web-based signing and registration authority</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>▶ <b>Stakeholder outreach</b></li> <li>▶ <b>Education &amp; advocacy</b></li> <li>▶ <b>Policy engagement</b></li> <li>▶ <b>Member engagement and information exchange:</b> <ul style="list-style-type: none"> <li>–Implementation tools</li> </ul> </li> <li>▶ <b>Industry awareness &amp; engagement</b></li> <li>▶ <b>Public-private approach: NCI Firebird pilot</b></li> <li>▶ <b>Media: local, national, trade, international</b></li> </ul>

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# Use Cases and Example Healthcare Pilots

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Premier, Inc



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# Premier Pilot

- **Company profile**
  - Largest Group Purchasing Organization (GPO) in U.S.
  - Owned by non-profit hospitals
  - Serves 2,000 U.S. hospitals and 53,000-plus other healthcare sites
  - Buys from ~700 suppliers
  - <http://www.premierinc.com/>
- **Scope:**
  - Eliminate overnight shipping, fax and related workflows for contract origination and amendments
  - Provide SAFE-BioPharma credentials to Premier Sourcing/Procurement employees and their supplier colleagues for signing new and amended supplier contracts
  - eContracting process ~700 companies and thousands of contracts and/or amendments

# Milestones

- **Open**
  - Phase 2 communications plan
  - Execute phase 2 with 6 supplier companies
  - SAFE-BioPharma - Full Member
  - Production implementation rollout
- **Timeline**
  - 11/9: meeting with sr. executives re: to-be process
  - 11/10-12/19: phase 2 including suppliers
  - Q408: complete Member Agreement
  - Q109 Production rollout

# CDC-MedNet



# Federated Identity Management

## Purpose

- Accelerate and simplify the Disease Investigation process
- Build a scalable framework aligned with the National Health Information Network (NHIN) architecture and structures
- Establish a cross-jurisdictional, credential compatible with the Federal Architecture and Federal PKI Policy Authority (FPKIPA)

## Efficiency

- Disease investigator can access state systems and query for meta data and request a CDA or CCD document back electronically.
- Reduction of phone calls, faxes and emails needed for routine investigation workflow.
- Overall time to track and close investigations should decrease.
  - *Will be validated by ROI analysis in Pilot Phase.*

## Cost

- Overall reduced cost due to increased efficiency of investigation workflow
- Reduced maintenance cost of security sub systems.
  - *Certificates not maintained by state investigator or CDC.*
  - *Federal Identity (Federal Bridge Model) provider issues the certificates.*

# Pilot Charter

- **Focus: Enhance disease investigations**
- **Phase 1**
  - SAFE-BioPharma/MedNet/MN public health and HIE
  - State level disease investigation tools, e.g. NEDSS
  - Cross-jurisdictional access with SAFE-BioPharma certificates, public health and HIE doctors
  - Integrate access portal with NHIN services
  - Target launch – January 2009
- **Phase 2**
  - CDC, federal credentials added
  - CCID linked to state public health pilot
  - Local jurisdictions provide controlled, timed access to HIE-based CCDs

# Overview



# Summary

## SAFE-BioPharma meets Requirements for ubiquitous IT adoption

- **An Identity Management Trust Infrastructure**
  - Mitigate risk – Secure infrastructure that ensures privacy & confidentiality
- **Business process improvement for both industry and regulators**
  - Reduce cost
  - Increase productivity
  - Reduce cycle times
- **Globally accepted standards**
- **Develop Global Regulatory compliance strategy**
- **Vendor/technology neutral – interoperable**
- **Legally enforceable**
- **Collaborate with Healthcare and Pharmaceutical Communities**

## For More Information on Our Organization

- ✓ **Come visit us during the show; or leave us a business card with your questions**
  - ***We will get you the answers you need to achieve the most out of your electronic initiative!***
- ✓ **Visit us on the web at: <http://safe-biopharma.org/>**
- ✓ **Or feel free to contact any of us below at anytime:**

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