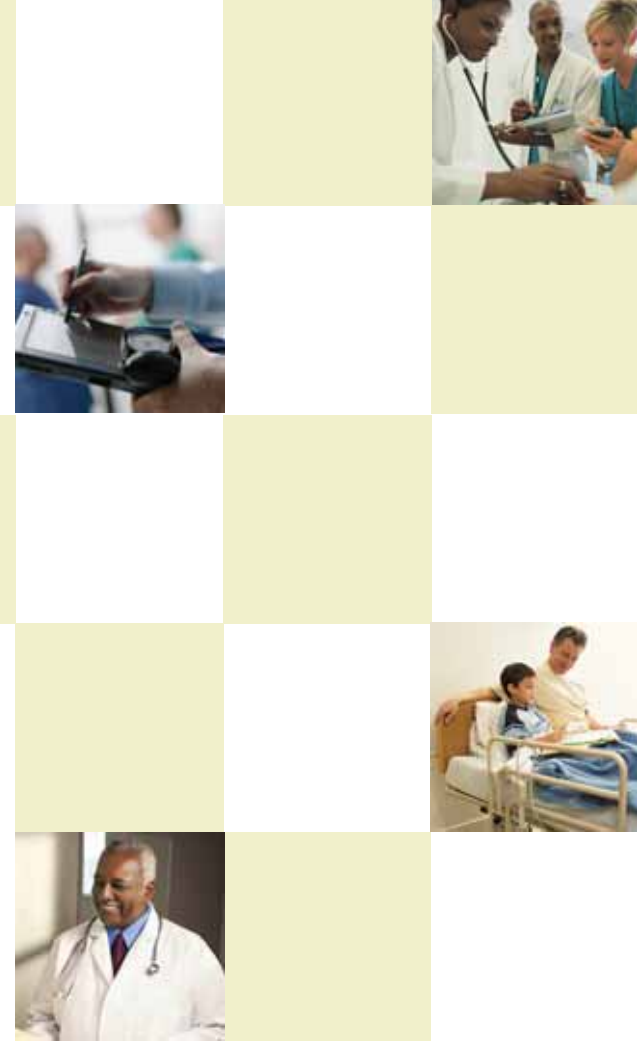




**SAFE-BioPharma Association**  
*Signatures And Authentication For Everyone*



## SAFE Introduction and Overview

# What is the SAFE-BioPharma Association?



- ▶ A health industry sponsored association
- ▶ Focused on supporting the health industry's migration from paper to electronic transactions
- ▶ Built on:
  - Common operating policies
  - Digital signature & signed e-record standard (including infrastructure & practices)
  - Legal & liability risk management framework
- ▶ To provide:
  - Increased business & process efficiency
  - Legally enforceable & regulatory compliant identity credentials
  - Globally acceptable digital signatures on electronic record transactions
  - Ease of interoperation between community members

# SAFE-BioPharma Association



Technical Standards Body	Shared Services Company	Healthcare Industry Association
<ul style="list-style-type: none"> <li>▶ Standard Development &amp; Maintenance</li> <li>▶ Certification standards &amp; administration: Members; Products; Issuers</li> <li>▶ Alignment to HL7, CDISC, IHE, ICH, EAP</li> <li>▶ Standards Working Groups</li> <li>▶ Regulatory relationships:                             <ul style="list-style-type: none"> <li>–FDA; EMEA</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>▶ Vendor partner program</li> <li>▶ Operation of bridge</li> <li>▶ Cross-cert of FBCA</li> </ul> <p><b>Driving/Incubating Innovation:</b></p> <ul style="list-style-type: none"> <li>▶ Credentials Issuance Model &amp; Pricing for Investigators</li> <li>▶ Directory of Users</li> <li>▶ Member Implementation support and tool development</li> <li>▶ Vendor audits</li> <li>▶ Tech Devel: USSI, Profiler, Remote</li> <li>▶ NCI Firebird</li> </ul>	<ul style="list-style-type: none"> <li>▶ Stakeholder outreach</li> <li>▶ Education &amp; advocacy                             <ul style="list-style-type: none"> <li>–eHI</li> <li>–Digital ID and Signature WG</li> </ul> </li> <li>▶ Policy engagement                             <ul style="list-style-type: none"> <li>–Congress &amp; leg.</li> <li>–HHS, NCI</li> <li>–EFPIA, PhRMA, BIO, ACRO, etc.</li> </ul> </li> <li>▶ Industry awareness &amp; engagement</li> <li>▶ Media: local, national, trade, international</li> </ul>

# SAFE-BioPharma – the Association



- ▶ Not for profit entity:
  - Issued digital signature standard in 2004 under PhRMA
  - Created industry association in 2005
  - Not about financial return to SAFE; return delivered to members through the use of the system
  - Ensure open access to all within the broad healthcare industry
- ▶ Provides:
  - Delivery & maintenance of common global standard
  - Standard services
  - Leverage for application enablement and certification
  - Member support
- ▶ Seeks to minimize financial impact to participants
  - Shared-services
  - Shared-liability
  - Mutual problem solving
  - Shared costs via annual participation fees and fees-for-services

Founded in May 2005 by:



**SAFE is the only global standard  
for the healthcare community  
that enables trusted, secure, legally enforceable paperless business and  
clinical transactions.**



# What's Wrong With a Signature on Paper?



- ▶ Signatures & signed content can be fabricated or modified
  - Possible to create a fabricated copy as good as, or better than, original
  - Possible to undetectably remove key items from medical record
- ▶ Growing expense
  - Signed record management, retrieval & storage
  - Transport of signed originals
- ▶ Physical signing process can be onerous
  - e.g., Physician signature on each and every page of each case report form associated with a clinical trial/study
- ▶ Hard to recall distributed copies needing correction
  - Physical central repository not practical
- ▶ Government electronic health record initiatives
  - e.g., National Health Information Network (NHIN)

# Financial Impact in Today's Environment - Biopharmaceuticals



- ▶ Industry spends > \$1 billion per year on independent identity credentialing models
  - Over 200,000 clinical investigators sites
  - 1,500 contract research organizations
  - 1,000 university medical centers
  - 1,000 medical labs
  - Approximately ~700,000 individual users
  - All use independent proprietary credentials for remote access to information systems
  
- ▶ Approximately 40% of annual R&D costs attributed to paper based business processes (\$9 Billion in US alone)

# Financial Impact in Today's Environment – Health Care



- ▶ New England Journal of Medicine, 2004, et al.
  - Paperwork = 31% of all health costs / \$500 billion in 2004
    - Emergency Department: 1 hr. care / 1 hr. of paperwork
    - Surgery & Inpatient Acute Care: 1 hr. care / 36 min. paperwork
    - Skilled Nursing Care: 1 hr. care / 30 min. of paperwork
    - Home Health Care: 1 hr. care / 48 min. of paperwork
  
- ▶ Without a legally enforceable and interoperable identity and digital signature and signed electronic records solution, industry cannot eliminate or reduce these expense bases

***There is a clear business case for electronic signatures & records***

# The Vision. . .



- ▶ What would the world be like if we could conduct
  - business electronically with the same certainty of paper?
  
- ▶ What would our business processes be like if we could
  - Eliminate wet signatures?
  - Digitally sign documents the same way we do paper?
  - Trust people’s identities without ever meeting them?
  - Eliminate multiple passwords, passcards?
  - Interoperate regardless of technology or vendor?
  
- ▶ How much faster? How much more productive?
  
- ▶ How much more accurate?
  
- ▶ How much faster and safer could industry deliver medicines to patients?

# So What's Hinderering the Industry?



## ▶ Regulatory Concerns

- Good clinical, lab, safety, and manufacturing practices; global digital signature requirements; privacy protection; data quality

## ▶ Legal Concerns

- Global operations; legal liabilities; regional acceptance; intellectual property protection

## ▶ Trust Concerns

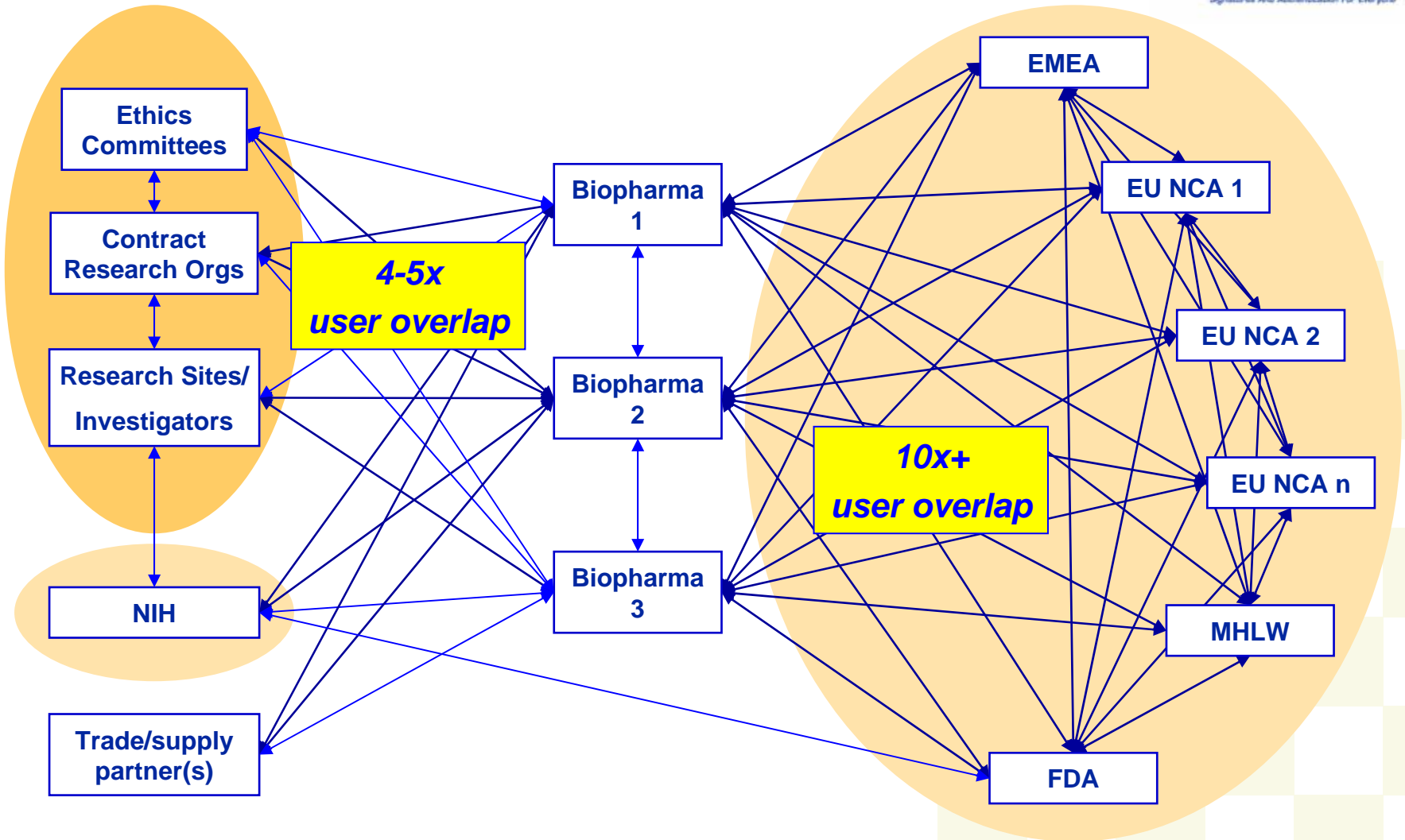
- Digital identity; consistency across trading partners; data integrity

## ▶ Infrastructure Concerns

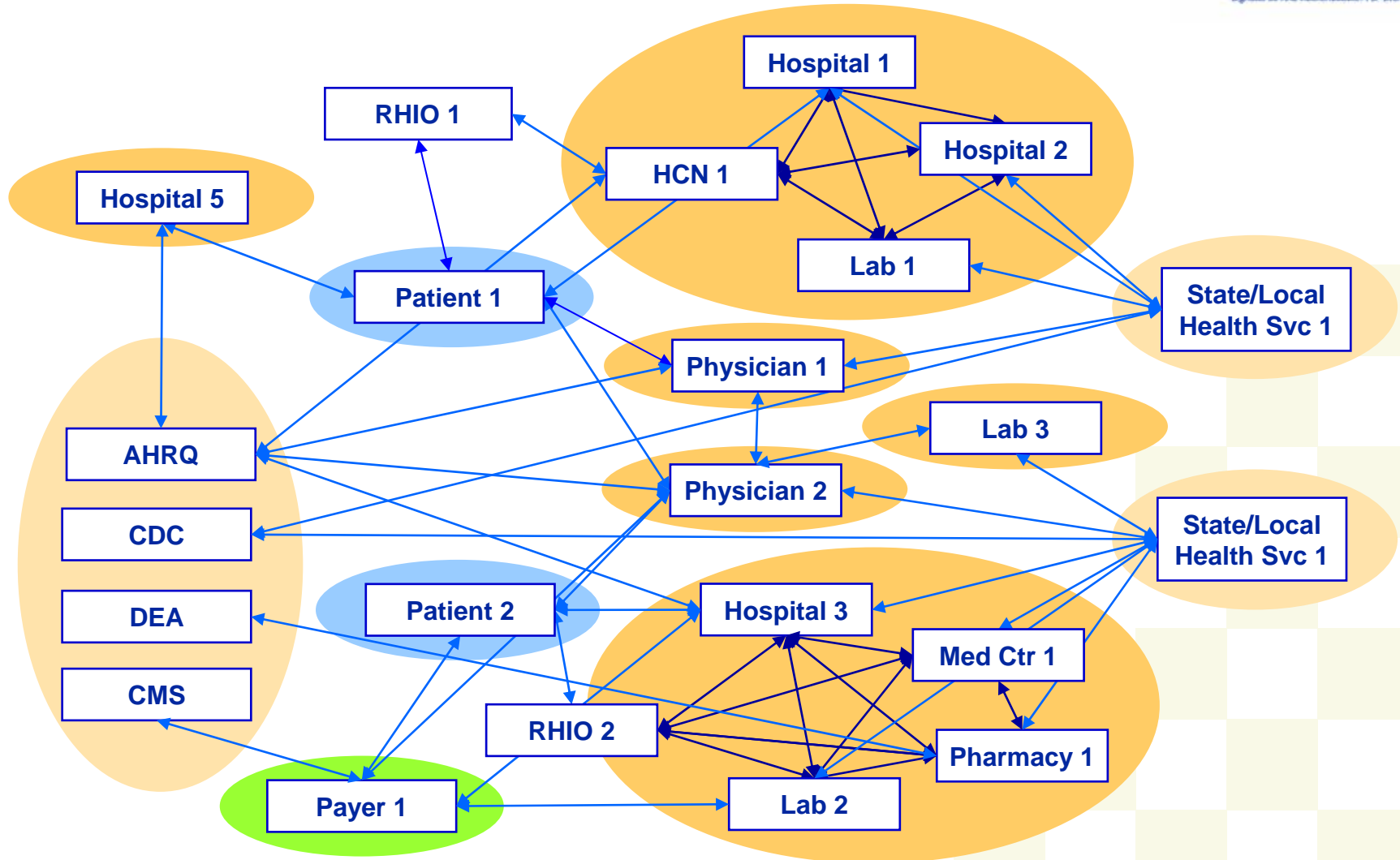
- Reuse of current investments; vendor support; interoperability with trading partners; multiple overlapping standards

***Basic recognition 1: Each business should not have to re-solve the problem independently***

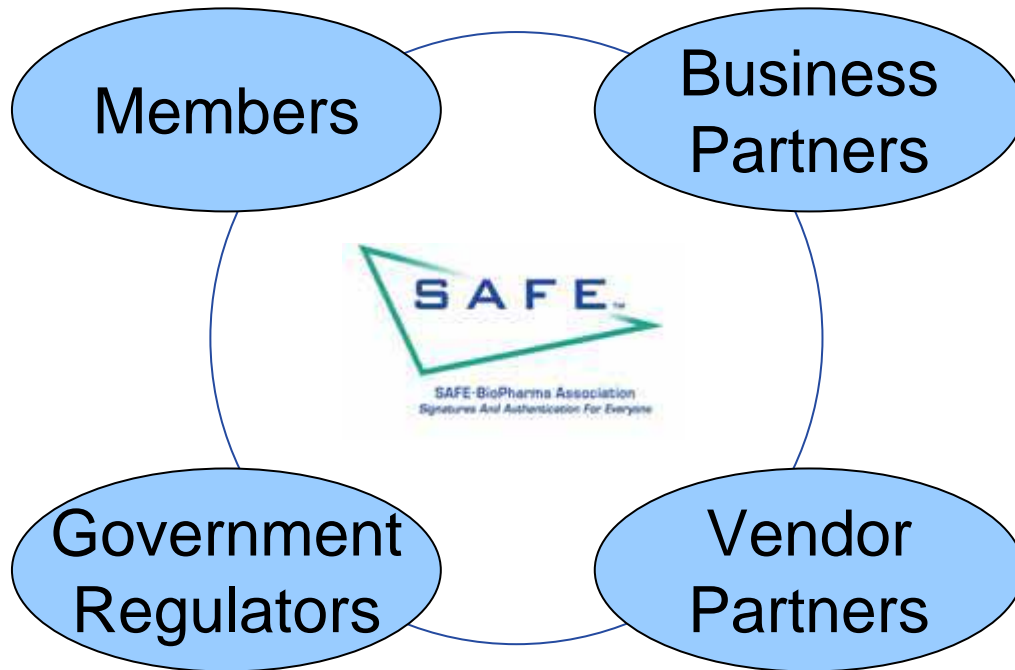
# The Global Identity Challenge - Biopharmaceuticals



# The Global Identity Challenge - Healthcare



**Basic recognition 2: Managing the problem requires cooperation**



***SAFE community  
represents over \$400B in  
annual revenues !***

- Small management & support team
- SAFE Central Services:
  - ✓ Product Certification
  - ✓ Workshops
  - ✓ Working Groups
  - ✓ Universal SAFE Signing Interface (pilot mode)
  - ✓ Identity Credentialing
- SAFE Bridge operational
  - ✓ Four Issuers currently cross certified
- Over 60,000 active SAFE identity credentials deployed

# The SAFE Community Participants



## BioPharma Members

- Abbott Labs
- AstraZeneca – Founder
- Bristol-Myers Squibb – Founder
- GlaxoSmithKline – Founder
- Genzyme
- INC Research
- Johnson & Johnson – Founder
- Merck – Founder
- Nektar
- Organon
- Pfizer – Founder
- Procter & Gamble – Founder
- Roche
- Sanofi-Aventis – Founder

## Government Agencies

- National Cancer Institute
- Food & Drug Administration
- European Medicines Evaluation Agency
- Irish Medicines Board
- Medicines Evaluation Board – Netherlands
- EOF: Greece
- Veterinary Medicines Directorate: United Kingdom

## Research Sites & IRB's

- Memorial Sloan Kettering
- Mayo Clinic
- City of Hope National Medical Center
- Women & Infants Hospital of Rhode Island
- H Lee Moffitt Cancer Center
- Sidney Kimmel Cancer Institute
- Shulman & Associates
- Western IRB

## Association Partners

- Pharmaceutical Research & Manufacturers Association
- European Federation of Pharmaceutical

# SAFE Participation Drivers



## Members

Merck, Johnson & Johnson, Abbott Labs, AstraZeneca, Sanofi-Aventis, Bristol Myers-Squibb, Pfizer, Roche, Organon, Genzyme, GlaxoSmithKline, P&G

### Drivers

- Shared cost model, and experience
- Cost avoidance
- Interoperability at scale
- Broad application
- Risk management infrastructure

## Business Partners

Labs, Investigators, CROs, Bio-Techs, Manufacturing Supply Chain, Sales

### Drivers

- Simplified end user experience, standard interoperability requirements
- Community of practice
- Improved and lower cost partner interactions
- Operational value added services

## Government, Regulatory Agencies, Associations (EU, USA, ASIA PAC)

PhRMA (sponsor), EFPIA (sponsor), FDA, EMEA

### Drivers

- Standard Compliance
- Cost Avoidance
- Less Paper
- Interoperability at scale
- Broad application

## Vendor Partners

Issuers, Applications providers, Systems Integrators

### Drivers

- Access to a channel
- Customer driven product enhancements
- Leadership advantage
- New business opportunities



# The SAFE Standard



## ▶ Business

- Operating Policies
- Agreements (Member, Issuer)
- Processes



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

## ▶ Technical

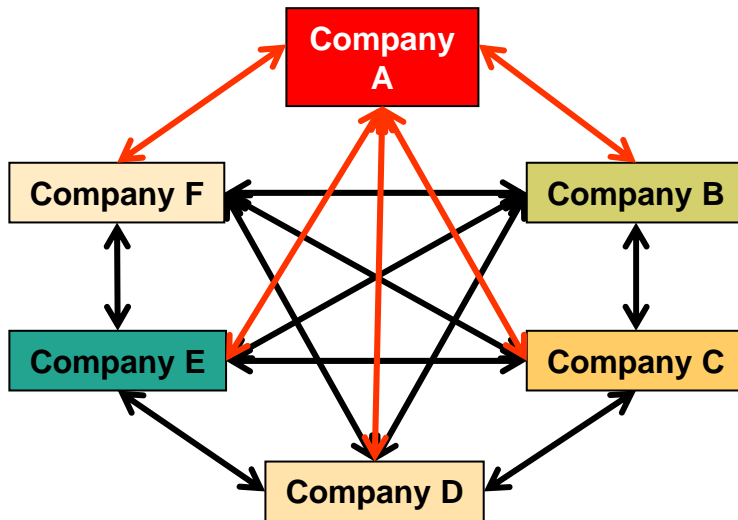
- Certificate Policy
- Specifications
- Guidelines & Guidance



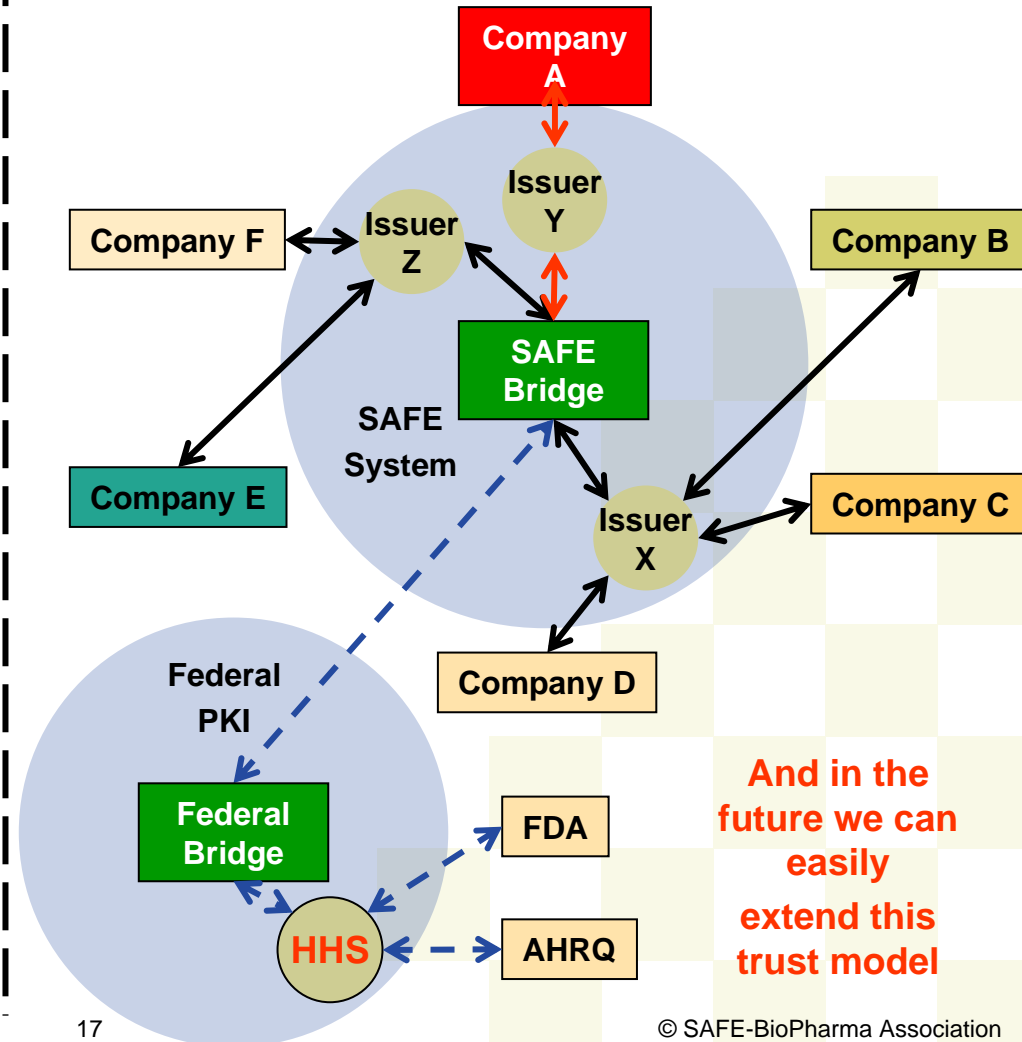
- ***Manage identity life cycle***
- ***Comply with referenced standards***
- ***Follow security, audit & control requirements***

# How the SAFE Simplifies Trust Relationships

Prior to today establishing trust meant individual agreements

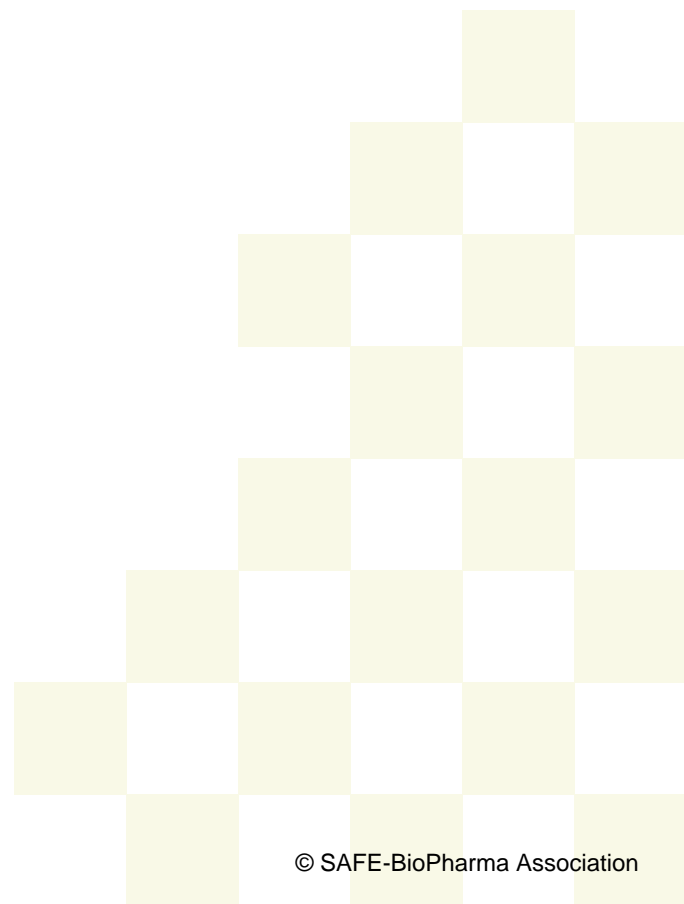


As of today we can bridge trust and reduce complexity

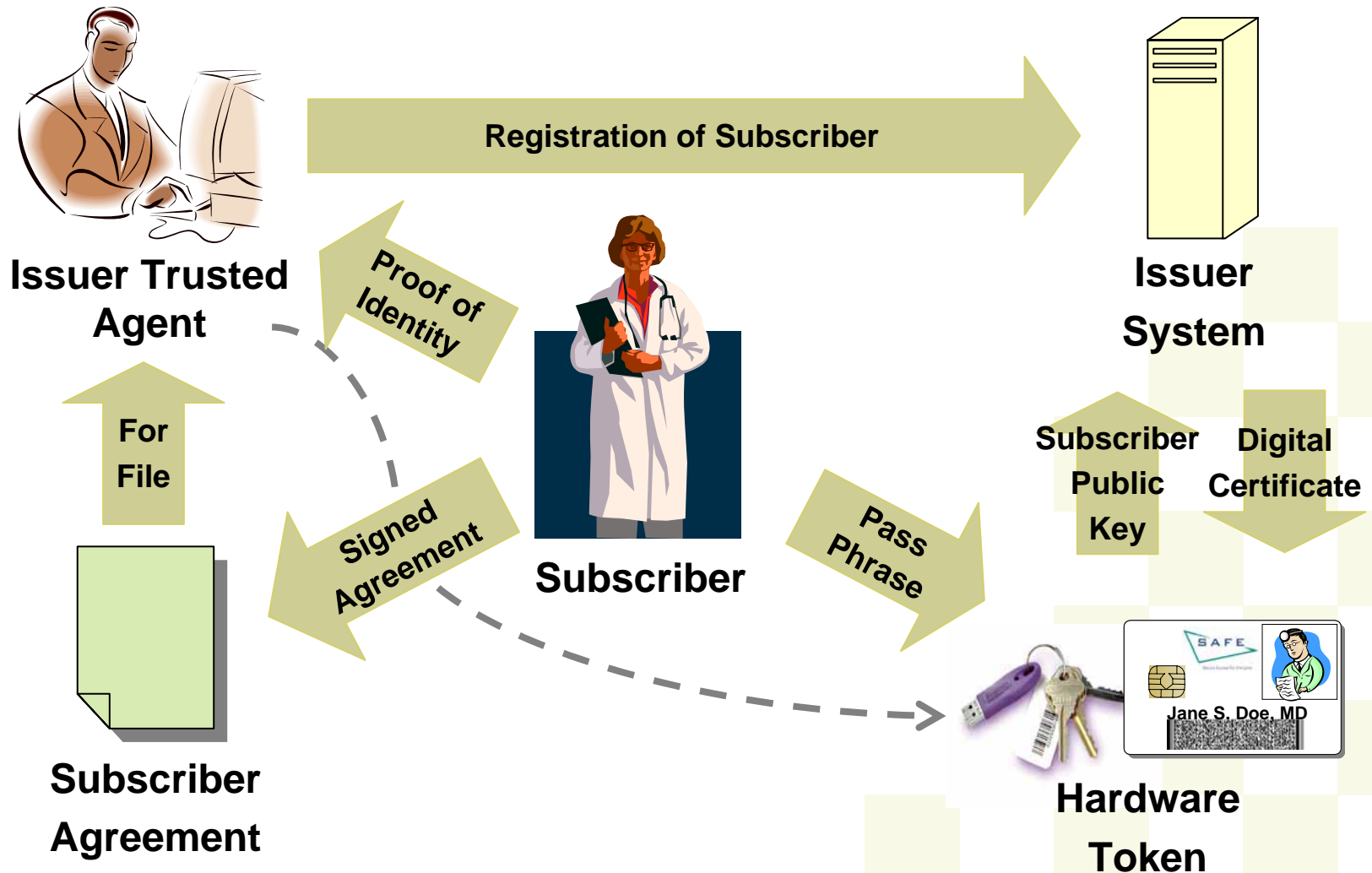


And in the future we can easily extend this trust model

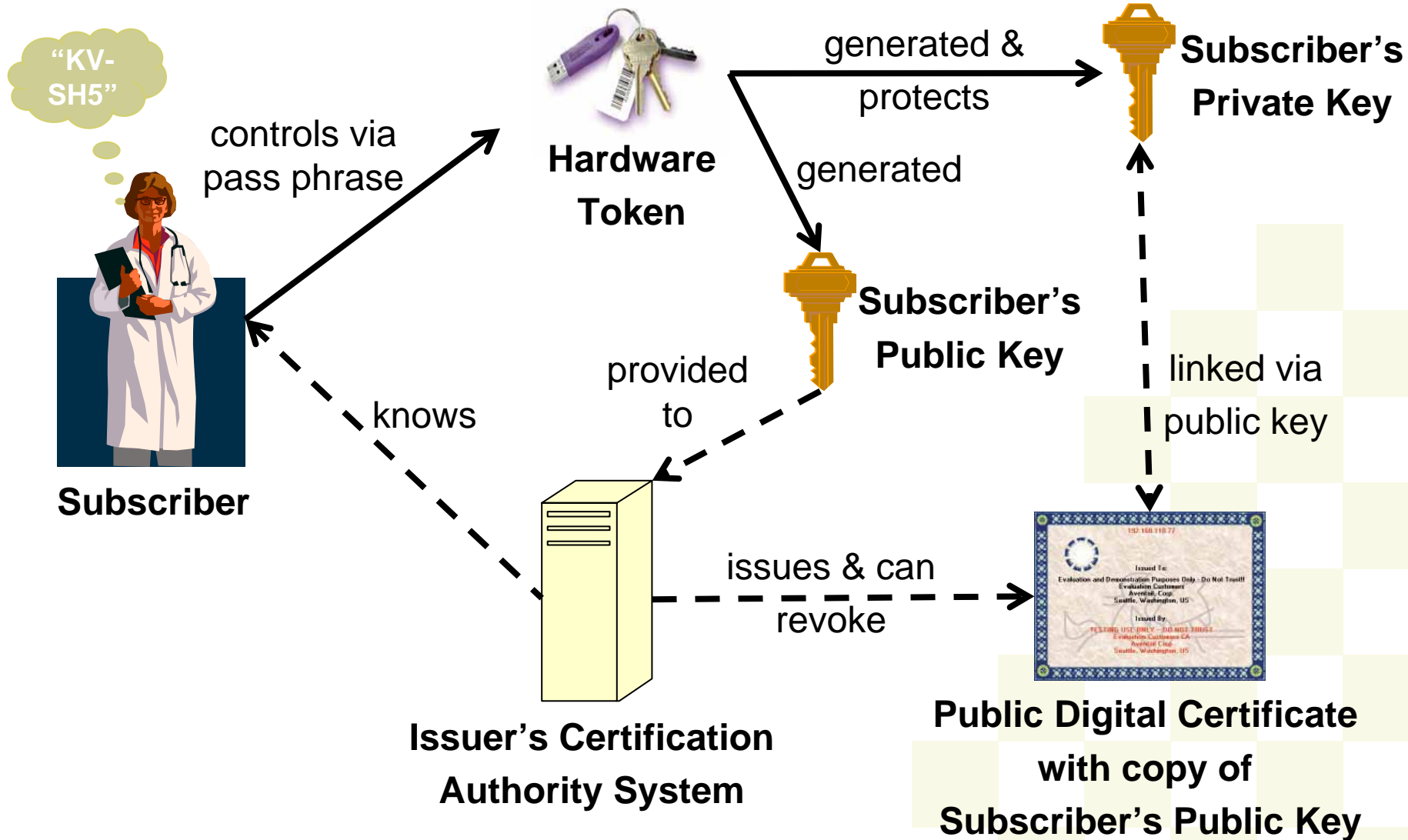
# Using SAFE



# Issuing SAFE Credentials



# Binding of Subscriber & Subscriber's Private Key



# Signing with a SAFE Credential



The screenshot shows a Microsoft Internet Explorer browser window displaying the USSI (Universal Safe Signing Interface) application. The address bar shows the URL <https://www.safesign.org/uss/sp>. The browser's address bar and search bar are visible. The main content area of the browser shows the USSI interface, which includes a sidebar with navigation options like "Profile", "My Signature Book", and "Upload Document". The main content area displays a document titled "Please Sign 157217.pdf" and a certificate dropdown menu set to "George.S.Rathbun". Below the certificate, there is a "Signature Field" labeled "SIGNATURE OF INVESTIGATOR", a "Reason" field with the text "I attest to the accuracy and integrity of this document.", and a "Comment" field with the text "Dear Doctor , Please sign". At the bottom of the interface, there are four buttons: "REVIEW DOC", "SIGN DOC", "CANCEL", and "REJECT". The SAFE logo is visible in the bottom right corner of the interface.

## Signer:

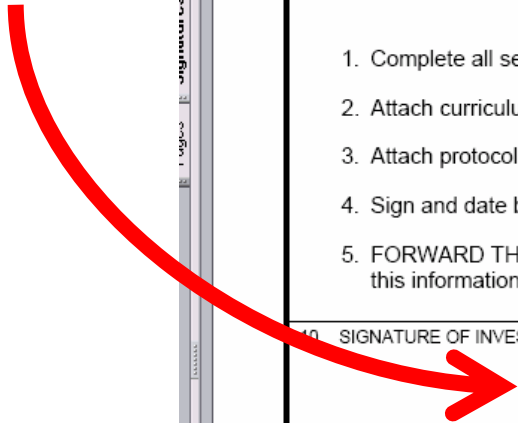
1. Selects document to sign
2. Acknowledges SAFE signature rules
3. Provides reason for signing (if needed)
4. Inserts hardware token
5. Enters pass phrase to complete signing operation

# Validating a SAFE Signature



SAFE-BioPharma Association  
Signatures And Authentications For Electronic

Just Click  
On it ...



Internet Explorer

Address: https://www.safesign.org/ussis/sp/downloads/Please\_Sign\_157216.pdf?ID=2220&RSTR=q99p0ujl6ssvl2j&MODE=SIGNED&TEST=test.pdf

INSTRUCTIONS FOR COMPLETING FORM FDA 1572  
STATEMENT OF INVESTIGATOR:

1. Complete all sections. Attach a separate page if additional space is needed.
2. Attach curriculum vitae or other statement of qualifications as described in Section 2.
3. Attach protocol outline as described in Section 8.
4. Sign and date below.
5. FORWARD THE COMPLETED FORM AND ATTACHMENTS TO THE SPONSOR. The sponsor will incorporate this information along with other technical data into an Investigational New Drug Application (IND).

10. SIGNATURE OF INVESTIGATOR	 Mark A Nelson For Demonstration Purposes Only	11. DATE
-------------------------------	--	----------

(WARNING: A willfully false statement is a criminal offense. U.S.C. Title 18, Sec. 1001.)

Food and Drug Administration  
CDER (HFD-94)  
12229 Wilkins Avenue  
Rockville, MD 20852

Please DO NOT RETURN this application to this address.

11:21 AM

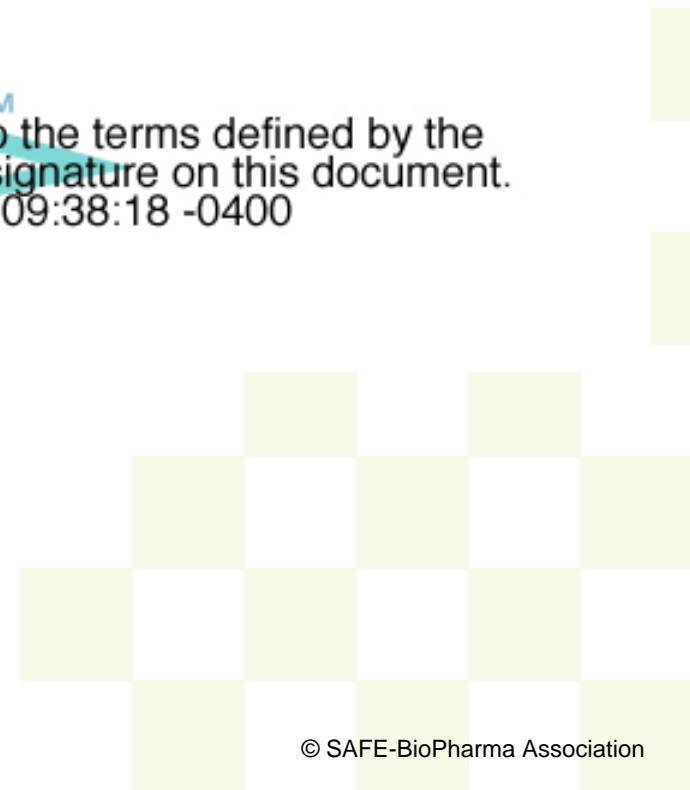
**Validation: Confirms Integrity  
of Signed Document & Validity  
of Signer's Digital Certificate**



Dr. Robert Hill

SAFE

Dr. Robert Hill™  
Reason: I agree to the terms defined by the  
placement of my signature on this document.  
Date: 2006-06-15 09:38:18 -0400





**SAFE-BioPharma Association**  
*Signatures And Authentication For Everyone*

## SAFE and Regulators

# SAFE Compliance Working Group



- ▶ SAFE Member reps with QA/Compliance/Regulatory backgrounds
- ▶ FDA
  - CDER/Division of Scientific Investigations
  - Part 11 Council
  - CIO
  - CBER
- ▶ Jointly-developed SAFE/FDA Auditor Familiarization Program
- ▶ Products
  - Inspection Techniques Manual for Auditors
  - Auditor Familiarization Training Materials
  - Regulatory Compliance Matrix
  - Functional Validation Scenarios & Validation Checklists
  - Internal SOP Matrix

The FDA's goal is to eliminate paper from application receipt and review processes. A completely paperless application process must be supported by implementation of legally binding electronic signatures.

SAFE provides that solution.

## ▶ Participants

- SAFE Evaluation Team: EMEA, GSK, Organon, Pfizer



## ▶ Deliverables

- Technical
- Functional validation audit scenarios and validation checklists
- Compliance matrix
- EMEA legal statement on acceptability
- EMEA statement acknowledging auditability

## ▶ SAFE EU Advisory Council

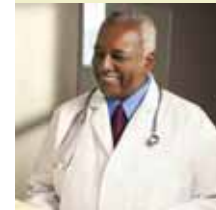
- EU and Member State regulations
- EU implementations

**The SAFE Evaluation Team (EMEA, EFPIA, Companies) determined that SAFE meets EU Electronic Signature Directive requirements.**



**SAFE-BioPharma Association**  
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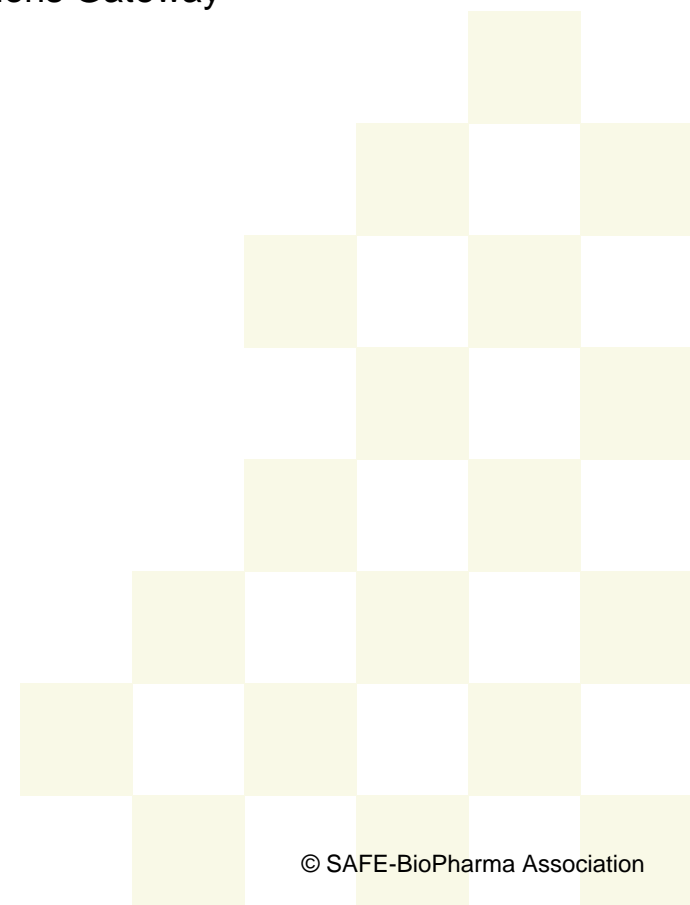
## SAFE Implementations



# SAFE Member Implementations



- ▶ **Pfizer:**
  - eLab Notebooks
  - Regulatory submissions
  
- ▶ **AstraZeneca:**
  - Regulatory submissions through FDA's Electronic Submissions Gateway
  
- ▶ **Merck:**
  - Product sampling
  
- ▶ **J&J:**
  - All J&J digital signatures are SAFE signatures
  
- ▶ **P&G:**
  - Enterprise digital signature solution



# SAFE-NCI Firebird Operational Pilot



## ▶ Firebird – Federal Investigator Registry for Bioinformatics Registry Data

- Investigator profile management
- 1572 info & related workflows
- Standardized templates
- Legally-enforceable digital signatures (SAFE)
- Electronic upload of documents
- Integration with existing regulatory and sponsor data bases

## ▶ 1572 business case for large pharma

- Average of 1,500 1572s/year @\$487.78
- With Firebird, costs drop to \$327.90 or savings of \$159.90/form
- Average large pharma annual savings of \$491,825
- Reduced costs of preparation, handling, mailing, storage, copying, printing, paper.

## ▶ Future applications:

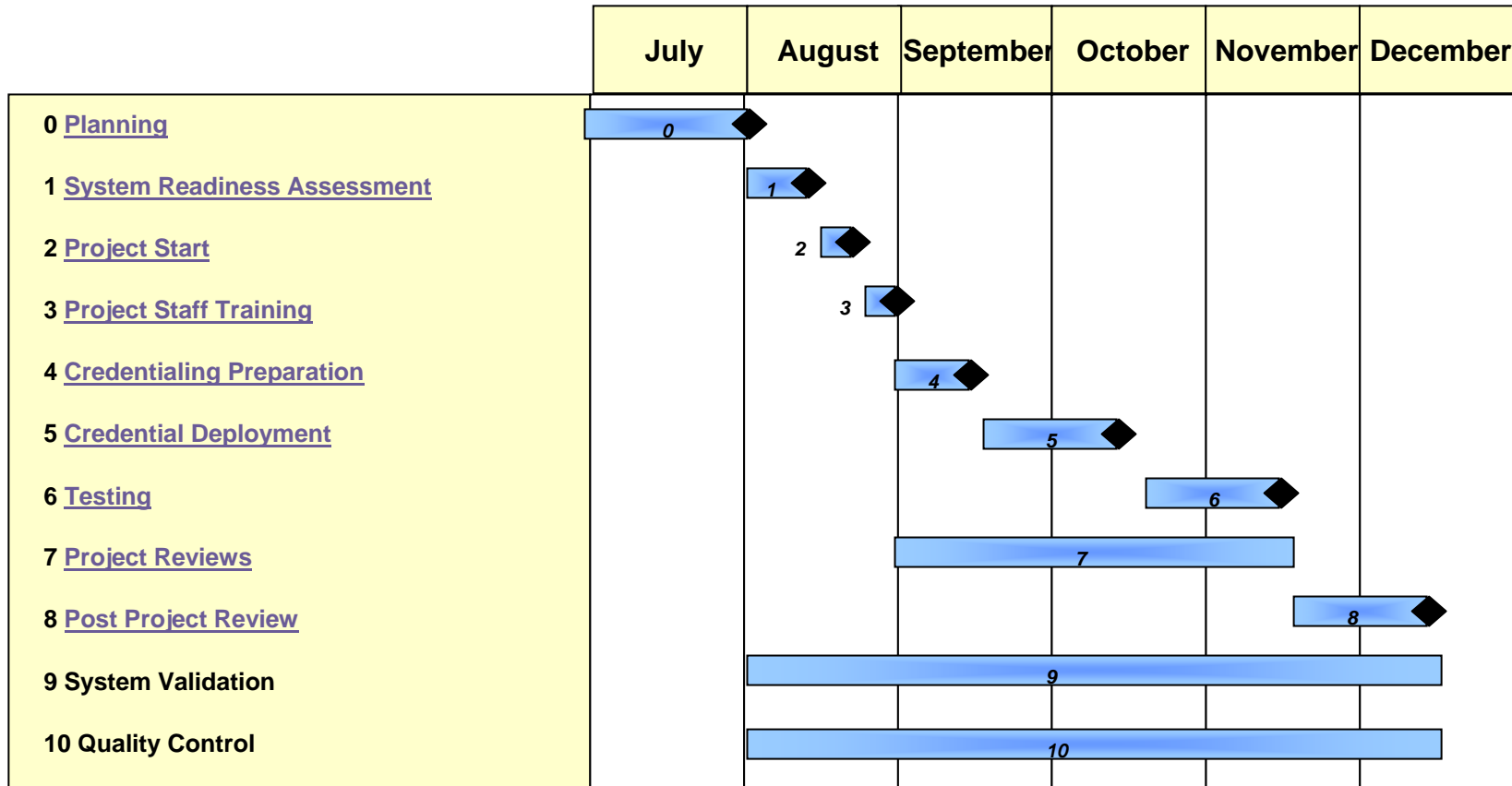
- Secure document exchange for SSI process (e.g., IRB/IEC approval/favorable opinion, signed protocol and amendments)
- On-line data capture of pre-clinical trial essential documents and formats relevant to SSI process

# SAFE-NCI Firebird Pilot Overview



- ▶ **Overview:** SAFE is the identity management and authentication and digital signature application for Firebird
- ▶ **Objectives:**
  - To successfully deliver production credentials to ~100 Firebird investigators;
  - To test, refine and assess the SAFE credentials issuance process; and
  - To develop and test training, communications, and support tools.
- ▶ **Scope:** Production process and credentials to ~100 investigators:
  - Participants: NCI, CTEP, DCP, Terapin Systems (NCICB) CTIS, AstraZeneca, Genzyme, Pfizer, Merck, Sanofi-Aventis, Amgen <final list pending>
  - SAFE member participants perform Trusted Agent and Requestor functions in the credential issuance and activation processes
  - Investigator selection: Combination of member- and NCI- identified investigators.

# Project Phases/Timelines



# SAFE and eHealth, SDOs



## ▶ Objectives:

- Increase awareness of SAFE to healthcare community
- Participate in standards development
- Provide framework to foster/evolve industry standard

## ▶ SAFE - E-Health Partnership:

- US: e-HI Identity Management and Dig Sig Working Group
- EU Forum
- White papers – e.g., risk management, legal

# The SAFE Vendor Community



## SAFE Premier Partners

- ✓ Adobe
- ✓ Aladdin
- ✓ Arcot
- ✓ Bearing Point
- ✓ CoreStreet
- ✓ Cybertrust
- ✓ Hitachi
- ✓ IBM
- ✓ IDBS
- ✓ Northrop Grumman
- ✓ Strategic Identity Group

## SAFE Premier Partners

- ✓ Algorithmic Research (ARX)
- ✓ DataLabs
- ✓ Open Text

**is the only global standard for healthcare community interoperability that enables trusted, secure, legally enforceable, paperless healthcare regulatory and business transactions**



# Becoming a SAFE Member

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<http://www.safe-biopharma.org>

[Mollie@SAFE-BioPharma.org](mailto:Mollie@SAFE-BioPharma.org)

