

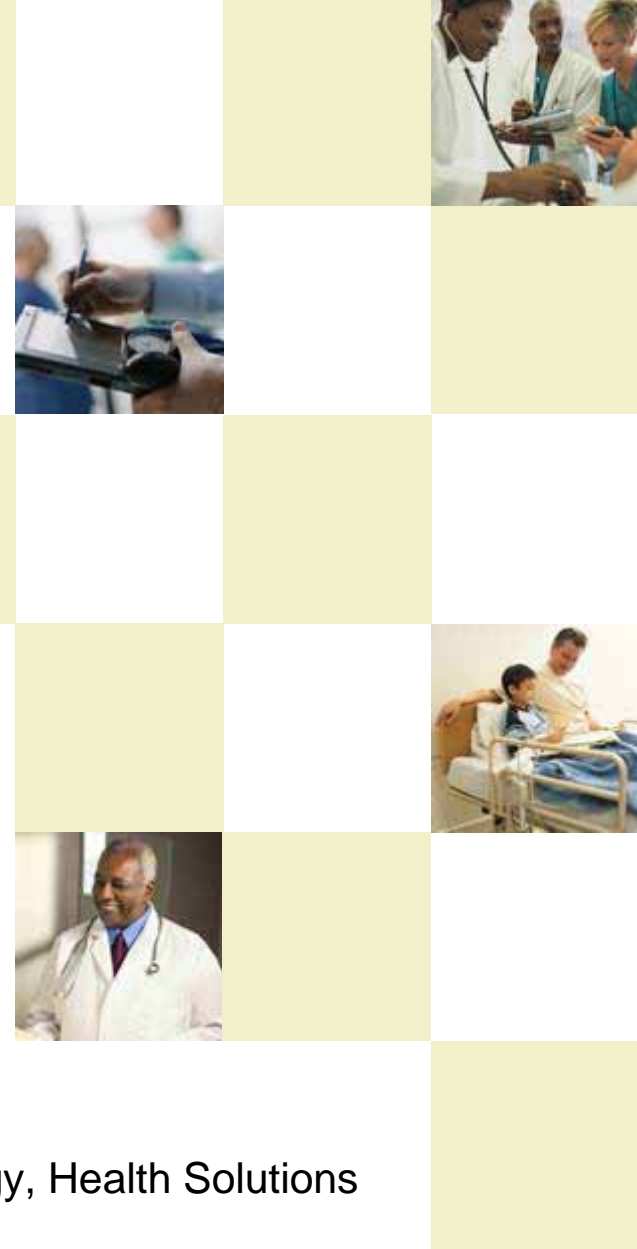


SAFE-BioPharma Association
Signatures And Authentication For Everyone

SAFE-BioPharma Association

A Cooperative Model for Technology Enablement of Health-Related Communities

by: Terry Zagar Northrop Grumman Information Technology, Health Solutions
SAFE-BioPharma Core Team



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 – 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

SAFE-BioPharma Association

The Business Case for a Cooperative Model In Health-Related Communities

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

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

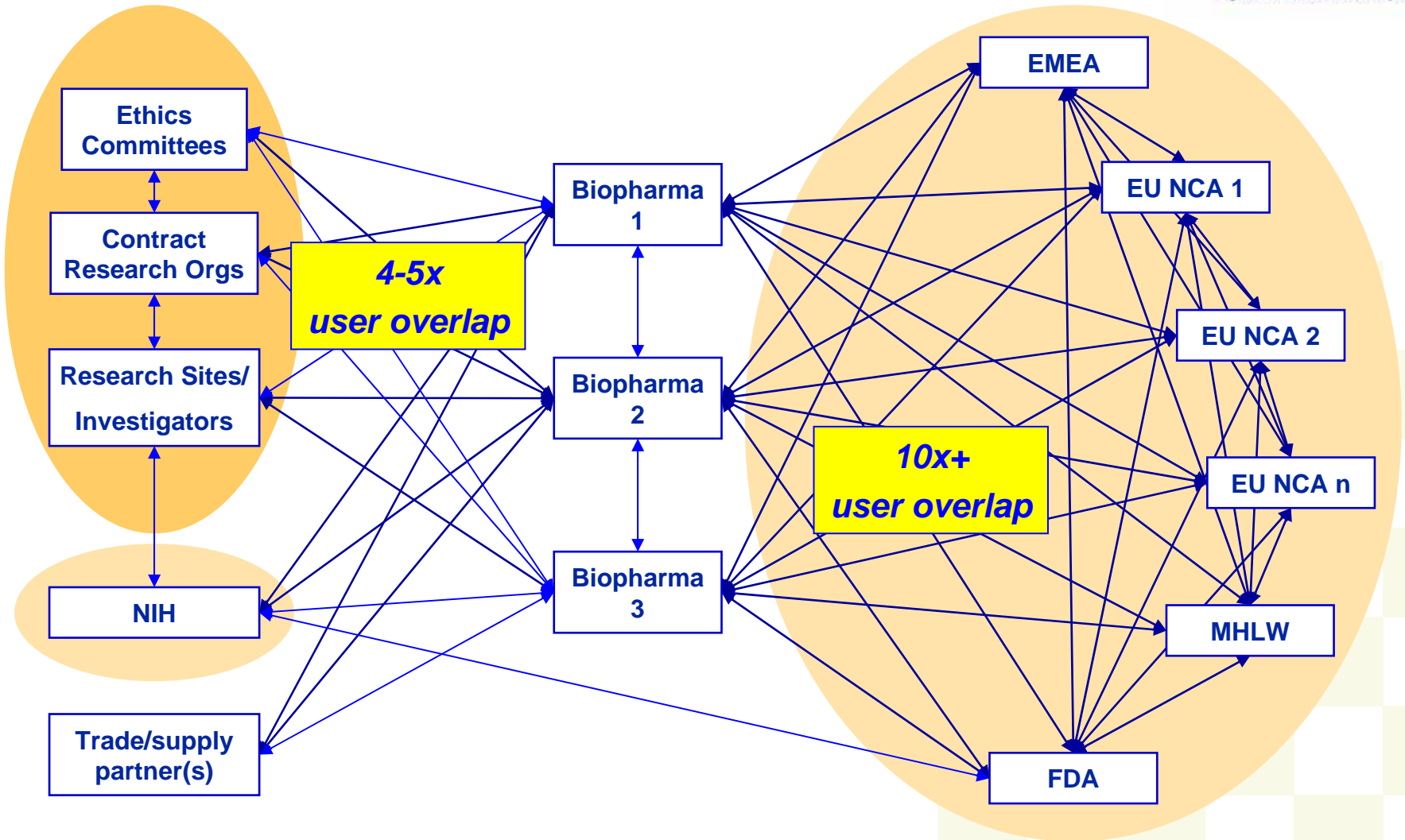
- Digital identity; consistency across trading partners; data integrity

▶ Infrastructure Concerns

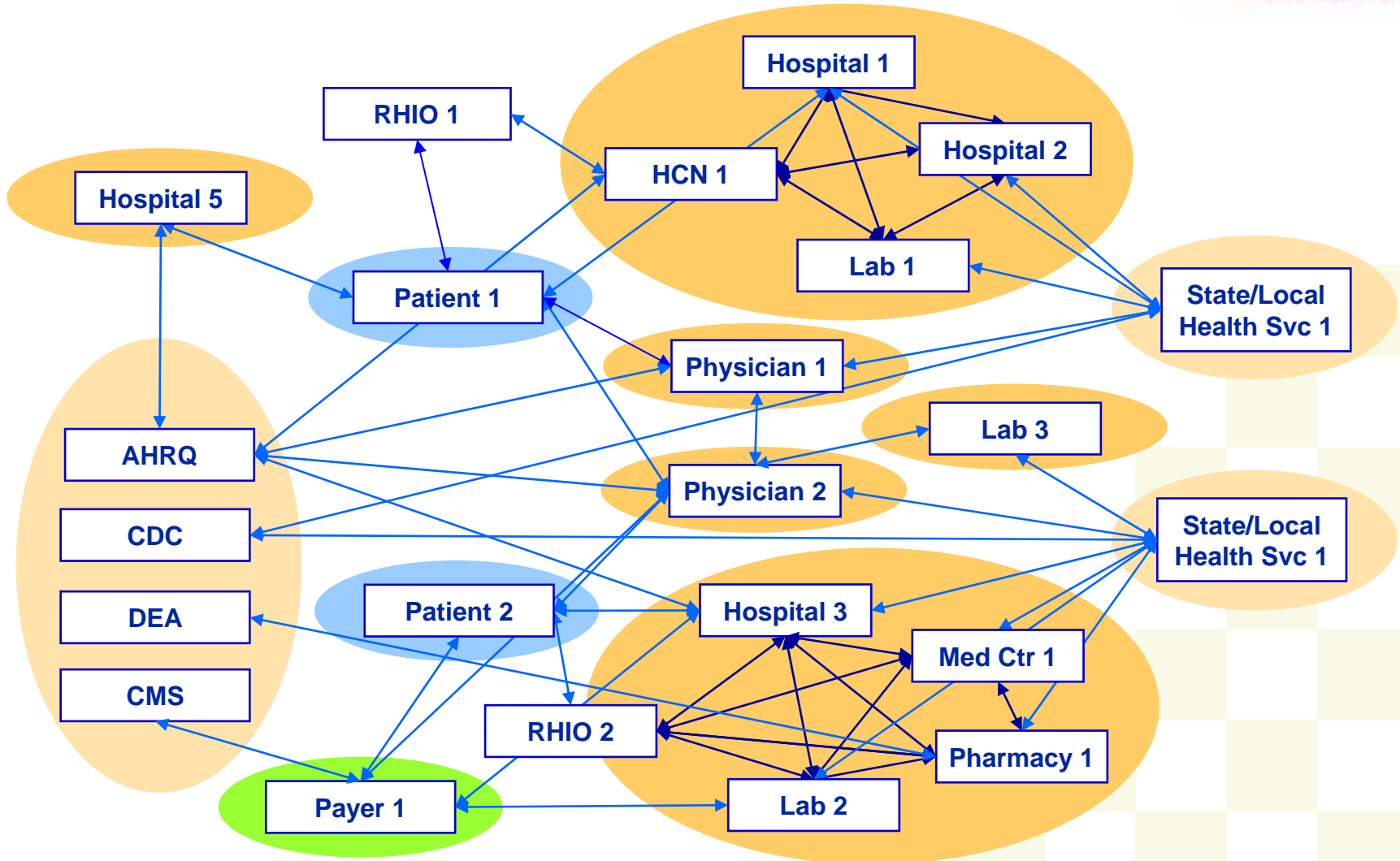
- Reuse of current investments; vendor support; interoperability with trading partners; multiple overlapping standards

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-BioPharma Association Participating Companies

Biopharma Companies

Abbott Labs
Amgen
AstraZeneca – *Founder*
Bristol-Myers Squibb – *Founder*
GlaxoSmithKline – *Founder*
INC Research
Johnson & Johnson – *Founder*
Merck – *Founder*
Pfizer – *Founder*
Procter & Gamble – *Founder*
Sanofi-Aventis – *Founder*
TAP Pharmaceuticals

Governments

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

Association Sponsors

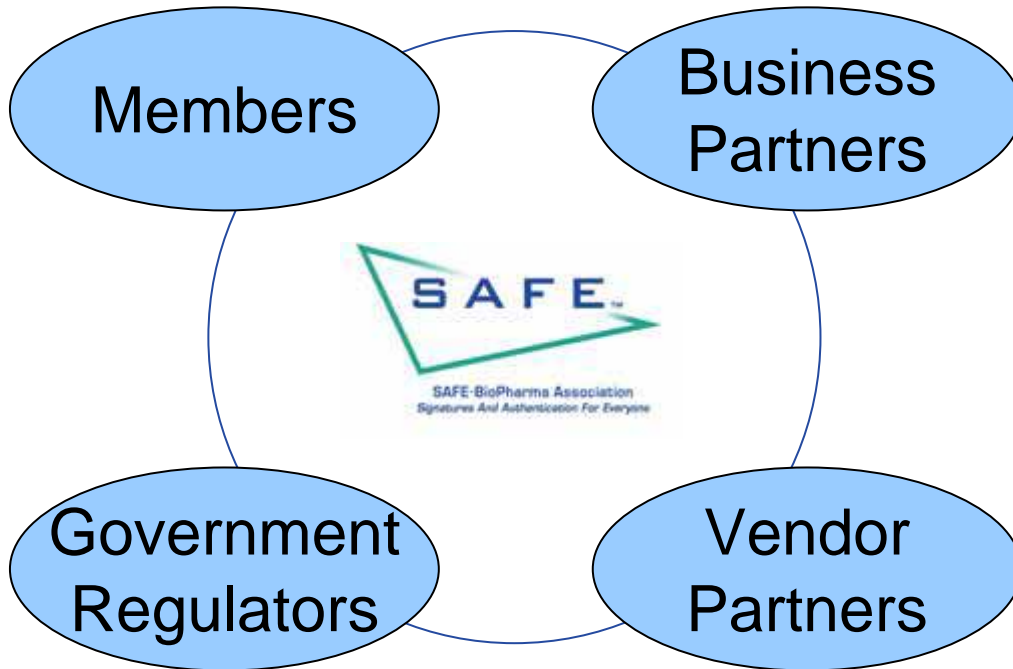
Pharmaceutical Research & Manufacturers Association
European Federation of Pharmaceutical Industries & Associations
International Federation for Animal Health

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

Health industry partnership to address regulatory, legal, trust, & infrastructure concerns

SAFE Today



***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 (May 2006)
- SAFE Bridge operational
 - ✓ Two Issuers currently cross certified
 - ✓ Third in progress
- Over 60,000 active SAFE identity credentials deployed

SAFE Participation Drivers



Members

Merck, Johnson & Johnson, Abbott Labs, AstraZeneca, Sanofi-Aventis, Bristol Myers-Squibb, Pfizer, GlaxoSmithKline, Procter & Gamble

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***

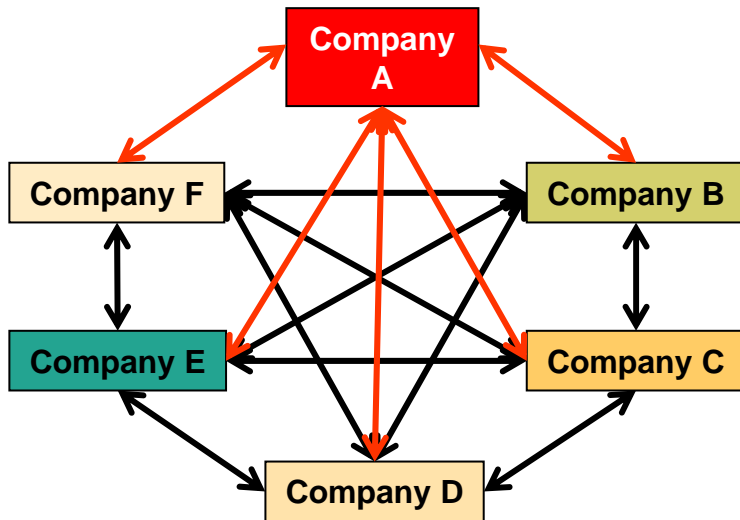
▶ Technical

- Certificate Policy
- Specifications
- Guidelines & Guidance

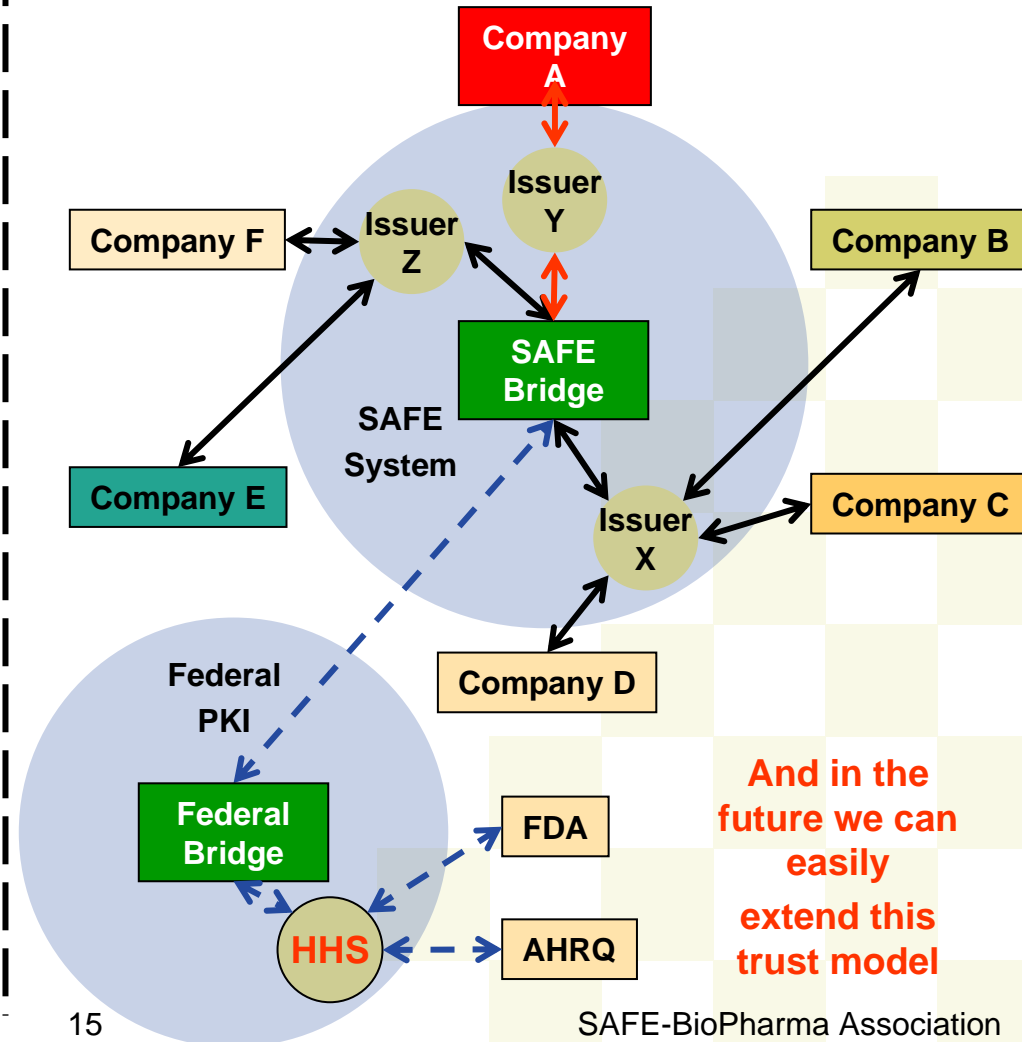
- ***Manage identity life cycle***
- ***Comply with referenced standards***
- ***Follow security, audit & control requirements***

How the SAFE Simplifies Trust Relationships

Prior to today establishing trust meant individual agreements



As of today we can bridge trust and reduce complexity



SAFE Directions



▶ Expanding Membership

- Shared service model → more members = lower cost to each member
- Enhances ubiquity of digital credential approach
- Broaden beyond biopharmaceutical companies to all healthcare & related entities

▶ Expanding new business process opportunities

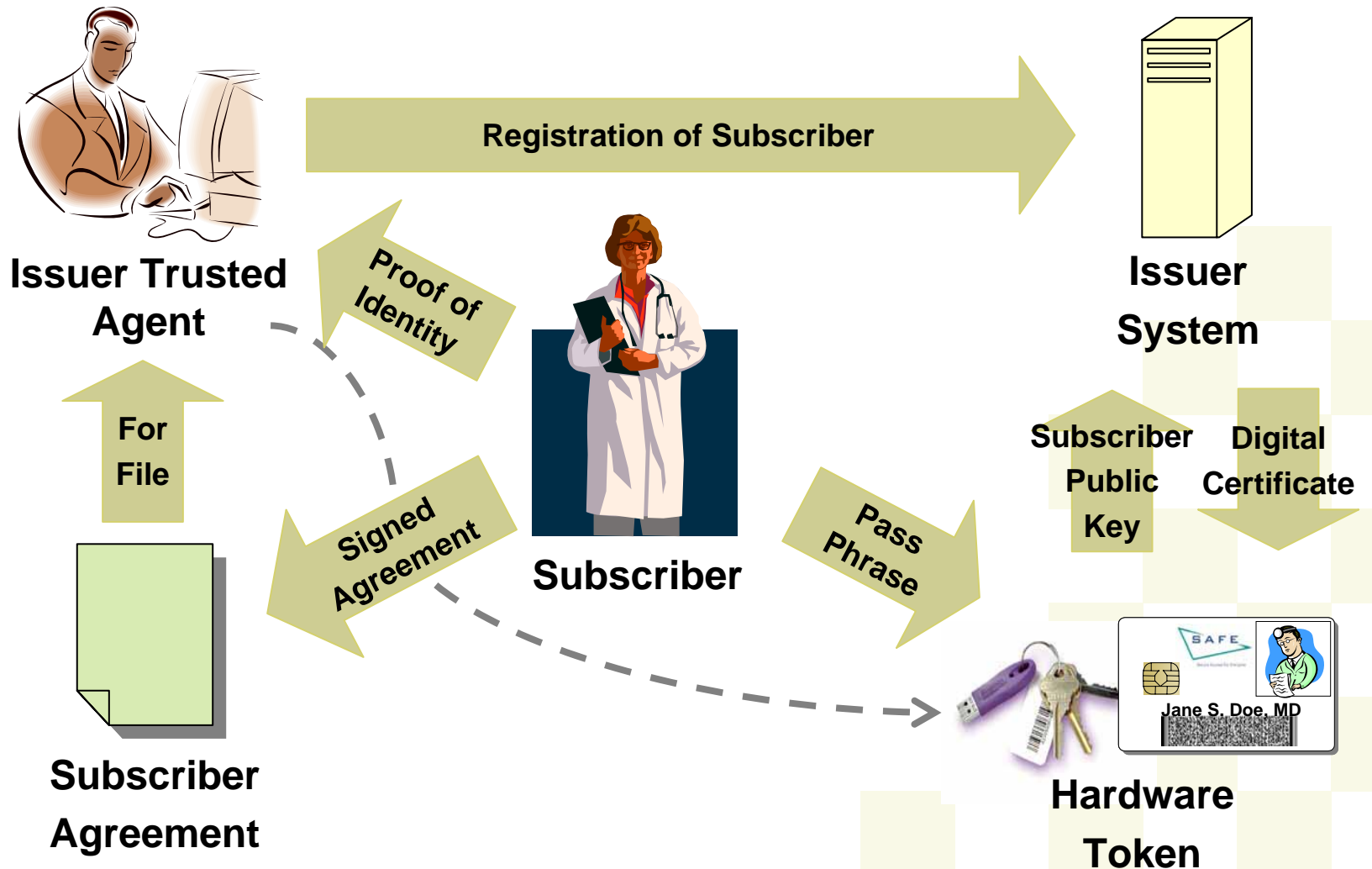
- Move beyond clinical trials & investigators to other areas common across health industry
- Linkage to evolving e-Health and e-HR initiatives

▶ Applications

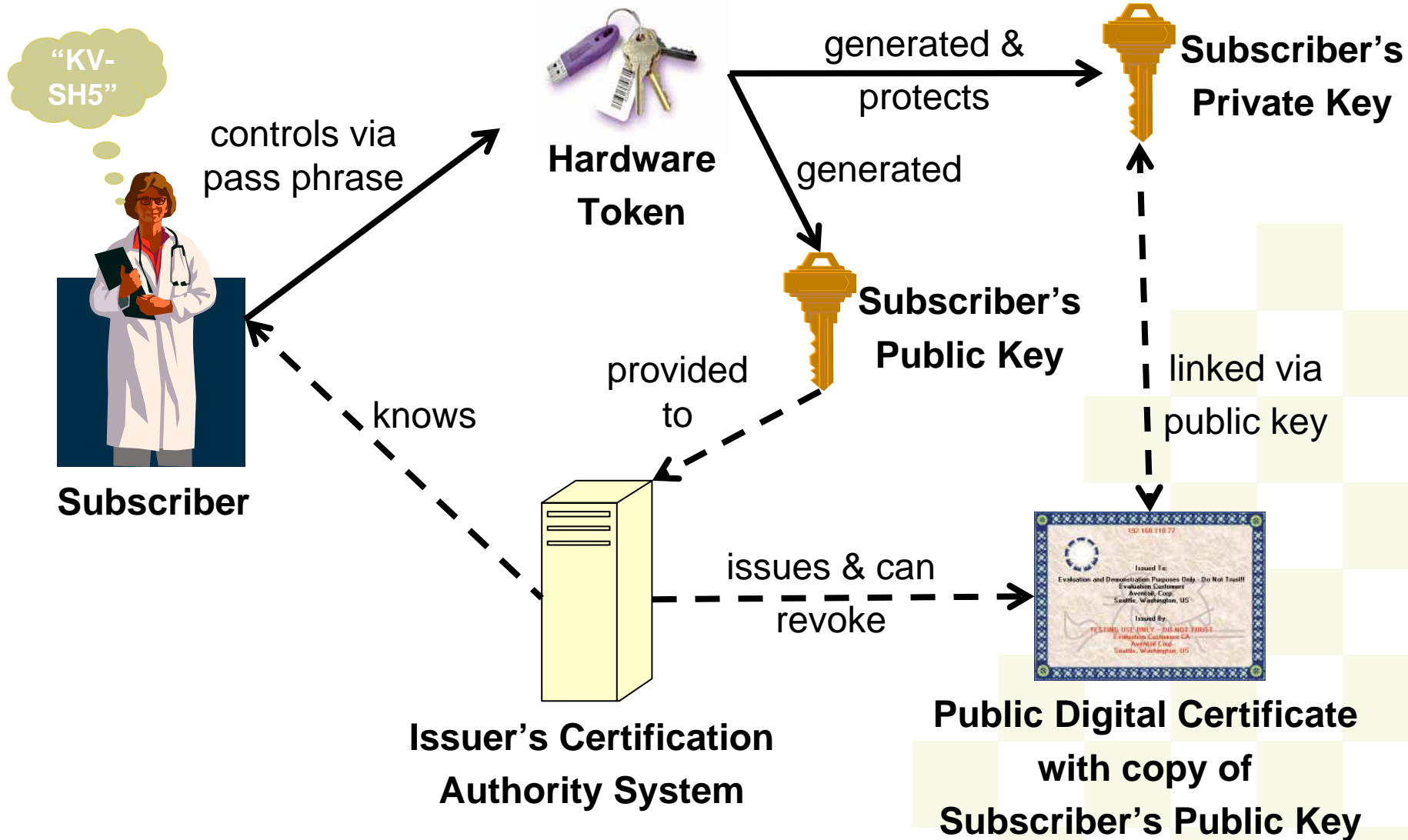
- Identification of common applications
- Leverage with application vendors
- Member companies free to work on their own applications

Using SAFE

Issuing SAFE Credentials



Binding of Subscriber & Subscriber's Private Key



Signing with a SAFE Credential



SAFE BioPharma Association
Signatures And Authentication For Everyone

You are viewing: Ashley Evans's Application

USSI - Universal Safe Signing Interface - Microsoft Internet Explorer

Address: <https://www.safesign.org/ussii/sp>

SAFE

USSI INTERFACE

Document Please Sign 157217.pdf

Certificate [\(Details\)](#) George.S.Rathbun

Signature Field SIGNATURE OF INVESTIGATOR

Reason I attest to the accuracy and integrity of this document.

Comment Dear Doctor ,
Please sign

REVIEW DOC SIGN DOC CANCEL REJECT

SAFE

Internet

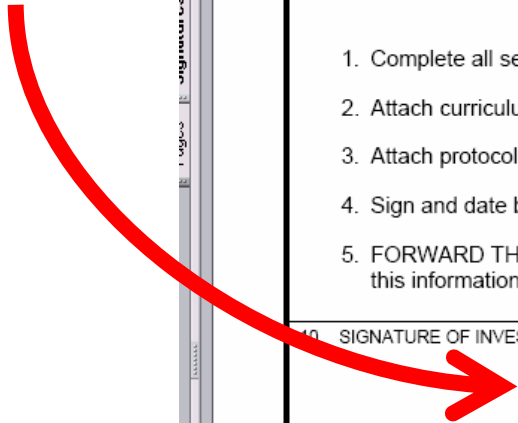
Signer:

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



Just Click
On it ...




Internet Explorer SHARING

Address: https://www.safesign.org/ussi/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).

SIGNATURE OF INVESTIGATOR	 Mark A Nelson For Demonstration Purposes Only	11. DATE
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(WARNING: A willfully false statement is a criminal offense. U.S.C. Title 18, Sec. 1001.)

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of Signed Document & Validity
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Questions?