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)
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


- 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 Hindering 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 resolve the problem independently
The Global Identity Challenge - Biopharmaceuticals

- Ethics Committees
- Contract Research Orgs
- Research Sites/Investigators
- NIH
- Trade/supply partner(s)

Biopharma 1
- 4-5x user overlap

Biopharma 2

Biopharma 3

EMEA
- EU NCA 1
- EU NCA 2
- EU NCA n
- MHLW
- FDA

10x+ user overlap
Basic recognition 2: Managing the problem requires cooperation
SAFE-BioPharma Association
Participating Companies

<table>
<thead>
<tr>
<th>Biopharma Companies</th>
<th>Governments</th>
<th>Research Sites &amp; IRB's</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abbott Labs</td>
<td>National Cancer Institute</td>
<td>Memorial Sloan Kettering</td>
</tr>
<tr>
<td>Amgen</td>
<td>Food and Drug Administration</td>
<td>Mayo Clinic</td>
</tr>
<tr>
<td>AstraZeneca – Founder</td>
<td>European Medicines Evaluation Agency</td>
<td>City of Hope National Medical Center</td>
</tr>
<tr>
<td>Bristol-Myers Squibb – Founder</td>
<td>Irish Medicines Board</td>
<td>Women &amp; Infants Hospital of Rhode Island</td>
</tr>
<tr>
<td>GlaxoSmithKline – Founder</td>
<td>Medicines Evaluation Board: Netherlands</td>
<td>H Lee Moffitt Cancer Center</td>
</tr>
<tr>
<td>INC Research</td>
<td>EOF: Greece</td>
<td>Sidney Kimmel Cancer Institute</td>
</tr>
<tr>
<td>Johnson &amp; Johnson – Founder</td>
<td>Veterinary Medicines Directorate: United Kingdom</td>
<td>Shulman &amp; Associates</td>
</tr>
<tr>
<td>Merck – Founder</td>
<td></td>
<td>Western IRB</td>
</tr>
<tr>
<td>Pfizer – Founder</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Procter &amp; Gamble – Founder</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sanofi-Aventis – Founder</td>
<td></td>
<td></td>
</tr>
<tr>
<td>TAP Pharmaceuticals</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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

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

- 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 community represents over $400B in annual revenues!
## 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

### 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

### 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

### Vendor Partners
- Issuers, Applications providers, Systems Integrators

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

---

April 26, 2006
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
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.
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

Issuer Trusted Agent

Registration of Subscriber

Proof of Identity

Subscriber Agreement

For File

Signed Agreement

Pass Phrase

Subscriber

Issuer System

Digital Certificate

Subscriber Public Key

Hardware Token

John S. Doe, MD
Jane S. Doe, MD

Hardware Token

Digital Certificate

Pass Phrase

Subscriber Agreement
Binding of Subscriber & Subscriber’s Private Key

Subscriber

controls via pass phrase

“KV-SH5”

Subscriber's Private Key

generated & protects

Subscriber’s Public Key

linked via public key

Hardware Token

generated

Subscriber’s Public Key

provided to

Issuer’s Certification Authority System

issues & can revoke

Public Digital Certificate with copy of Subscriber’s Public Key

SAFE-BioPharma Association
Signing with a SAFE Credential

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 ...

Validation: Confirms Integrity of Signed Document & Validity of Signer’s Digital Certificate
Becoming a SAFE Member

Visit:

http://www.safe-biopharma.org
Questions?