The SAFE Standard: Digital Signatures for Achieving Global, Compliant Requirements for Health Care

Terry Zagar
Core Team Member
SAFE-BioPharma Association
The Business Case For SAFE
What’s Wrong With a Signature on Paper?

- Signatures & signed content can be fabricated
  - Possible to recreate a modified copy as good as, or better than, the original

- Growing expense:
  - Signed record management, retrieval & storage
  - Mailing 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
Financial Impact in Today’s Environment - Pharmaceuticals

- Industry spends > $1 billion per year on independent identity credentialing models
  - Over 200,000 clinical investigators sites
  - 1,500 CRO’s
  - 1,000 university medical centers
  - 1,000 medical labs
  - Total amounts to ~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 solution, industry cannot eliminate or reduce either of these expense bases

There is a clear business case for electronic signatures & records
So What’s Hindering Us?

- **Regulatory Concerns**
  - Good clinical, lab, safety, and manufacturing practices; global digital signature requirements; privacy protection

- **Legal Concerns**
  - Global operations; legal liabilities; regional acceptance

- **Trust Concerns**
  - Digital identity; consistency across trading partners

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

*Basic recognition: One business alone cannot address these*
The Global Identity Challenge

If tackled independently → recipe for management nightmare
SAFE-BioPharma Association

Participating Companies

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

➢ Provide a digital signature standard & associated operating rules
  – Built on existing standards
  – minimize reinvention

➢ Delivers unique electronic identity credentials
  – Legally enforceable
  – Regulatory compliant
  – Acceptable across the global biopharmaceutical environment

➢ Provides shared services in support of health industry electronic transactions
  – Business-to-Business
  – Business to Regulator
SAFE & Bio-Pharmaceutical Community Timeline

MAY 2003
SAFE → strategic PhRMA initiative

DEC 2003
Seed investment → 12 bio-pharmaceuticals

JUN 2003
SAFE Standard v1.0

DEC 2004
SAFE-BioPharma → 8 bio-pharmaceuticals

SEP 2005
SAFE Bridge & SAFE Standard v2.0
SAFE-BioPharma – the Association

Not for profit entity:
- Created by biopharmaceutical industry
- Not about financial return via the SAFE entity; 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 and service offerings
- Outsourcing of credential providers
- Trust Bridge
- Leverage for application enablement and certification
- Member support

Seeks to minimize financial impact to “owners/system members”
- “Shared-service” model
- Revenue stream from Member fees
SAFE – a Community Framework

**Member**
- **Full**
  - For-Profit Entities
  - Not-For-Profit Entities
  - Government Orgs
- **Associate**
  - Medical Practitioners
  - Other Entities/Individuals designated by SAFE

**SAFE-BioPharma**
- **SAFE Standard**
  - Business/Legal
  - Governance
  - Specifications
- **Services**
  - SAFE Bridge CA
  - Directory
  - Issuer Services for Medical Practitioners/Others

**Issuer**
- **Services**
  - Certification Authority
  - Credentials for Members
  - Identity Proofing

**Agreement**
Using SAFE
SAFE Business Scope

- Common digital signature use & acceptance agreement → execute once
  - Continuing accreditation & audit of Members / Issuers
  - Capped liability limits on SAFE digital signature use
  - Dispute resolution process & framework for SAFE stakeholders

- Independent certification of SAFE-enabled applications

- Commitment to SAFE digital signature standard → updates driven by SAFE community
SAFE Technical Scope

- Issuance of a unique SAFE identity credential & its binding to a specific individual
- Provide business-to-business trust across different infrastructure implementations via the SAFE Bridge
- Digitally sign an electronic record or object
- Validate one or more digital signatures on an electronic record or object, and confirm integrity of the electronic record or object
- Present & display a SAFE signature on a document
Issuing SAFE Credentials

Issuer Trusted Agent

Registration of Subscriber

For File

Issuer System

Proof of Identity

Subscriber

Signed Agreement

Pass Phrase

Subscriber Agreement

Signed Agreement

Pass Phrase

Hardware Token

Digital Certificate

Subscriber Public Key

Jane S. Doe, MD

SAFE-BioPharma Association
SAFE Bridge

- Ensures trust across heterogeneous Issuer systems
- Ensures transactional interoperability among these “bridged” systems
- Reduces cost & extends flexibility for SAFE Members by promoting availability of competitive external supply sources or ability to utilize internal solutions
- Reduces application complexity by minimizing need to cross-certify with multiple Issuers for credential validation support
SAFE Signature Block – Visual Representations

Valid Signature

Jane Doe

Reason: Affirm information on Form 1472
DN: CN=Jane Doe, C=US, O=Miracle Cure Pharma, OU=000000000177
Date: 2005.10.19 20:33:07 – 4’00’

Invalid Signature

Jane Doe

Reason: Affirm information on Form 1472
DN: CN=Jane Doe, C=US, O=Miracle Cure Pharma, OU=000000000177
Date: 2005.10.19 20:33:07 – 4’00’

Complete Validation Report Can Be Viewed & Saved for Audit Purposes
SAFE in Operation
Strategic Approach to Build Critical Mass for SAFE

Centers of Gravity
SAFE is focusing its resources and efforts around a small number of Centers of Gravity (Programs) to ensure early stage successes that are self-sustaining and leverageable by others with or without follow-on support from SAFE.

SAFE will Influence these Centers of Gravity in order to stimulate demand pull that is aligned to value delivery on a sustained and accelerating basis.
Pfizer & SAFE

**Situation:**
- Pfizer manages identity credentials for over 200,000 employees and contractors
- It spends an estimated $10 million per year for password resets
- Every digital signature utilized for regulatory and non-regulatory transactions eliminates the costs of approximately $125 dollars required per wet signature

**Approach:**
- Replace the multiple ID architectures that were in place with a common internal identity management framework
- Leverage SAFE to uniquely align identity credentials with secure information exchange
- Pfizer chose a unified identity model that links multiple credentials onto one cryptographic hardware device (Smart Card). The unique ID badge provided a consistent user experience for access control and digital signing.

**Results & Benefits:**
- Pfizer has deployed a unique ID platform across their infrastructure
- Elimination of costly paper-based business processes and creation of universal identity badges
- Full-scale systems reengineering & identity management solution that impacted all Pfizer employees & contractors
- Pfizer employees and contractors being able to have their identity authenticated at remote Pfizer locations without having to travel to visitor's station for additional screening

**Challenges**
- Adopting an identity management strategy, and linking multiple identity credentials to one token
- Keeping up with demand for identity badges once employees realized the convenience of using a single ID badge.
Leveraging SAFE Membership
SAFE Participation & Drivers

**Sponsors**
Merck, Johnson & Johnson, Abbott Labs, AstraZeneca, Sanofi-Aventis, Bristol Myers-Squibb, Covance, 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

**Vendors**
Issuers, Applications providers, Systems Integrators

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

- SAFE Working Groups → opportunity to share solutions & lessons learned

- Best Practice guides for Members (under development):
  - SAFE / 21 CFR Part 11 Implementation Guidance Checklist
  - Credential provisioning and applications support guideline

- Vendor programs:
  - Application & infrastructure product SAFE-enablement workshops
  - Applications certification program
  - Issuer accreditation program

- While SAFE does not provide its members with hardware or software directly, SAFE has a standard user desktop hardware & software bundle for investigators. This ensures:
  - Consistent end-user experience
  - Ensures application accessibility for key apps – Adobe, web browser

- Bundle can be readily obtained by Members through SAFE Issuers
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/healthcare related entities

➤ Expanding new business process opportunities
  – Move beyond clinical trials and investigators to other areas common across our industry
  – Linkage to evolving e-Health and e-HR initiatives

➤ Applications
  – Identification of common applications
  – Ability to approach application vendors as an industry versus individual companies
  – Does not take away individual company ability to work on their own applications
Becoming a SAFE Member

Visit:

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