SAFE™

Signatures and Authentication For Everyone

Realizing the National Health IT Strategy Through the Adoption of a Standardized Digital Identity Solution

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SAFE-BioPharma Association

Agenda

- Why do we need a healthcare industry identity assurance standard?
- Limitations of current proprietary approaches
- How SAFE's global digital identity delivers unique and authenticated digital signatures across multiple healthcare transactions

The Impetus for SAFE……

- **Revolution in life sciences and medical technology:**
  - Changing the way we live
  - Expensive, complex, geography, many players
- **Need to improve safety, quality, development times:**
  - Paper costs: 40% of R&D costs; 33% all healthcare costs
  - Increasingly complex industry
  - Wall Street imperative: reduce cost structure
- **Need to improve efficiencies, reduce costs;**
  - Shift to eClinical
  - eRegulatory processes
  - eHealthcare, e.g., UK, France, US

There is a pressing need to better allocate healthcare resources to deliver more new medicines and services to patients, faster and safely.

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 – 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 solution, industry cannot eliminate or reduce either of these expense bases**

There is a clear business case for electronic signatures & records

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)**

The Vision. . .

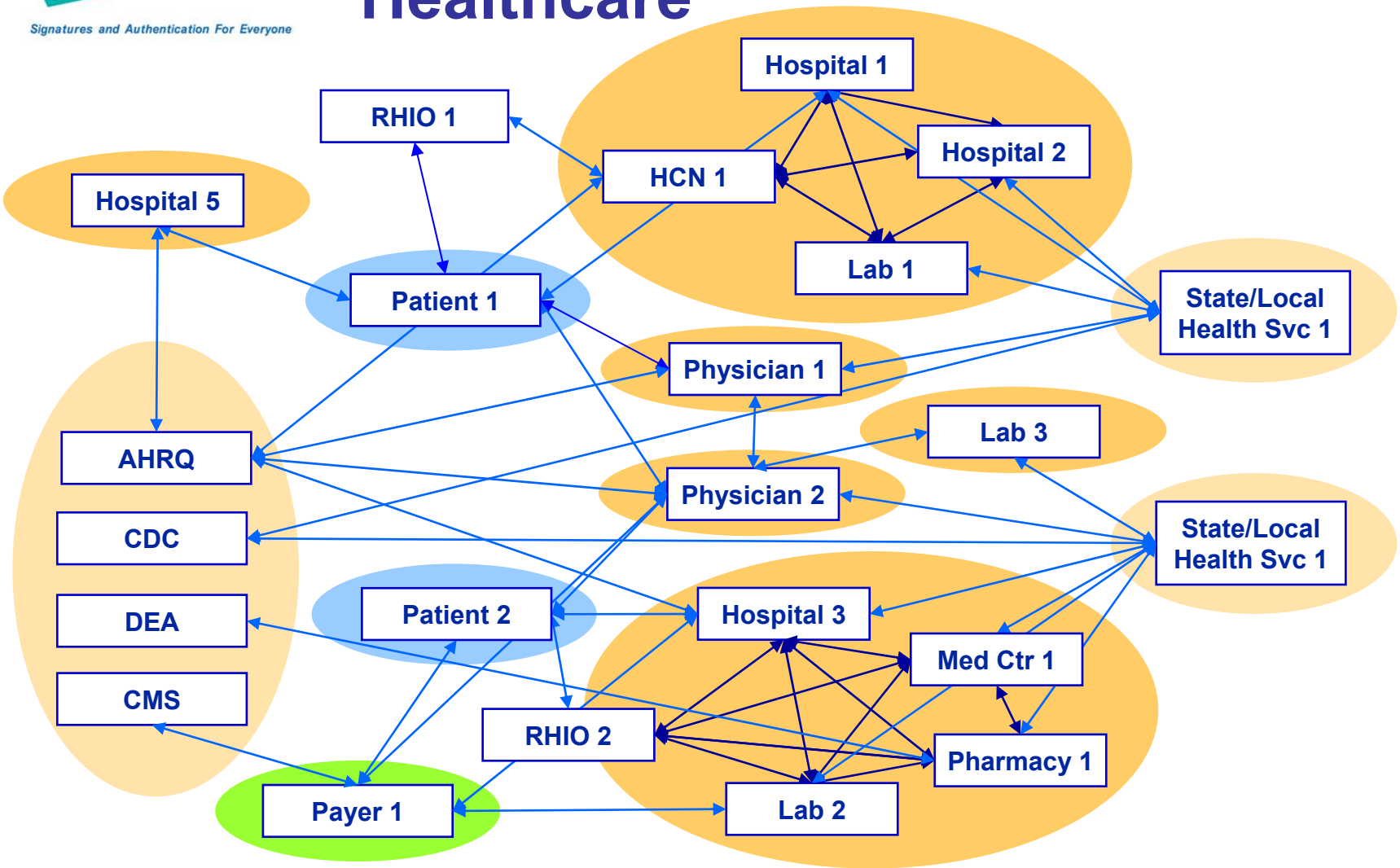
- **What would the world be like if we could conduct**
  - business electronically with the same certainty of paper?
- **What would our business processes be like if we could**
  - Eliminate wet signatures?
  - Digitally sign documents the same way we do paper?
  - Trust people's identities without ever 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 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

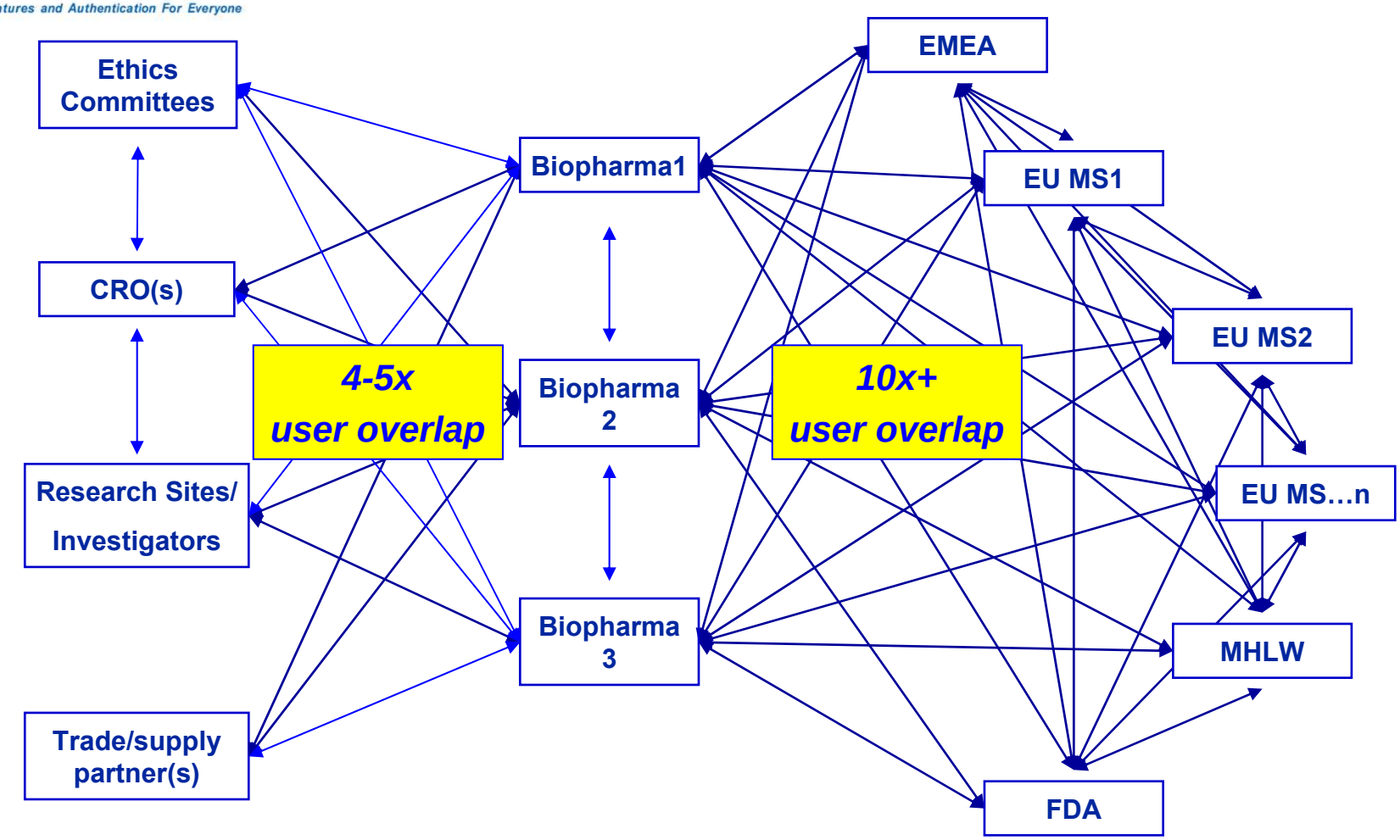
One organization alone cannot address these

The Global Identity Challenge - Healthcare



Managing the problem requires cooperation

The Global Identity Challenge -- BioPharma



If tackled independently → recipe for management nightmare

SAFE™

Signatures and Authentication For Everyone

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.

sanofi aventis
Because health matters

AstraZeneca
INTERNATIONAL

Bristol-Myers Squibb Company

gsk GlaxoSmithKline

P&G

Pfizer

MERCK

Johnson & Johnson

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

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***

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

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

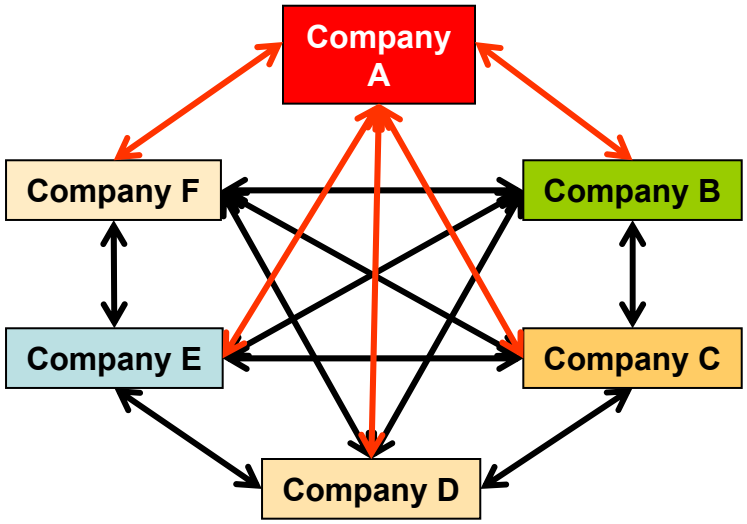
Drivers

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

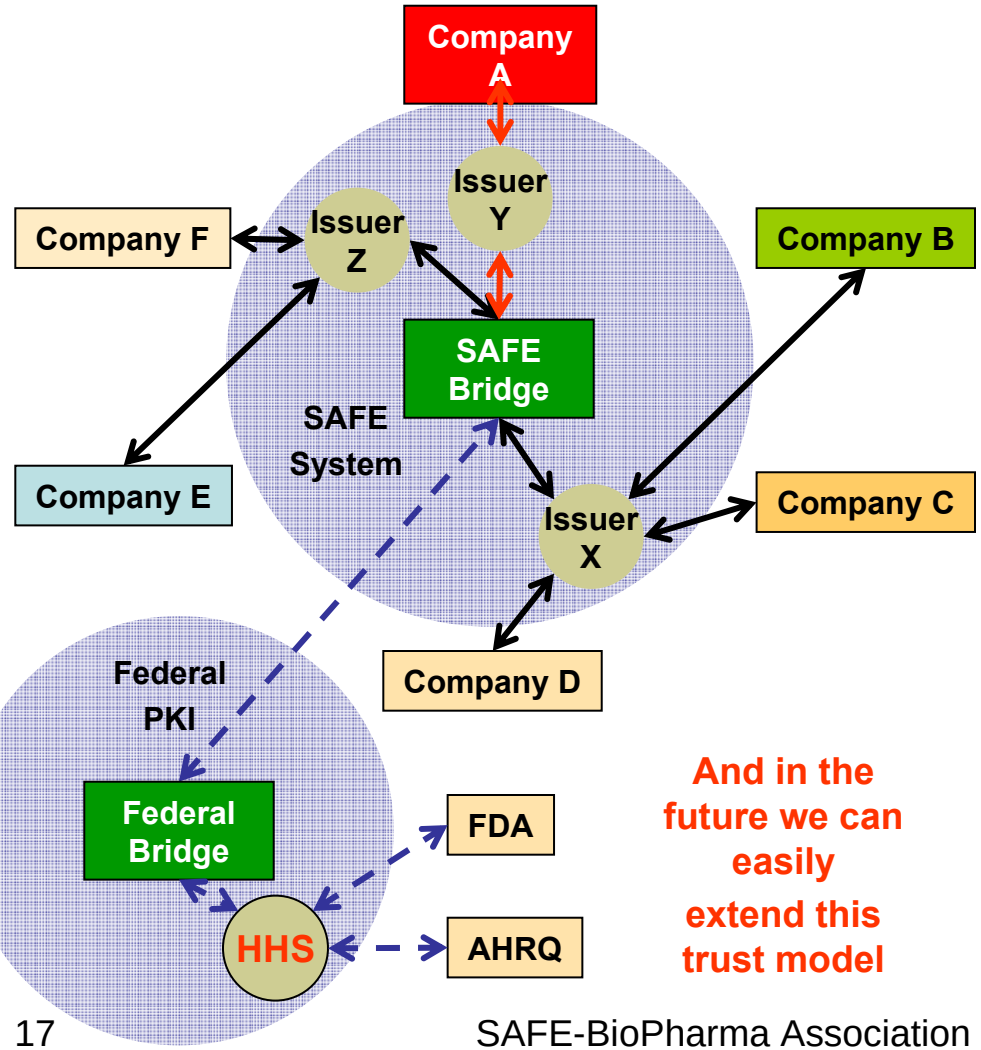
SAFE Simplifies Trust Relationships

Signatures and Authentication For Everyone

Prior to today establishing trust meant individual agreements



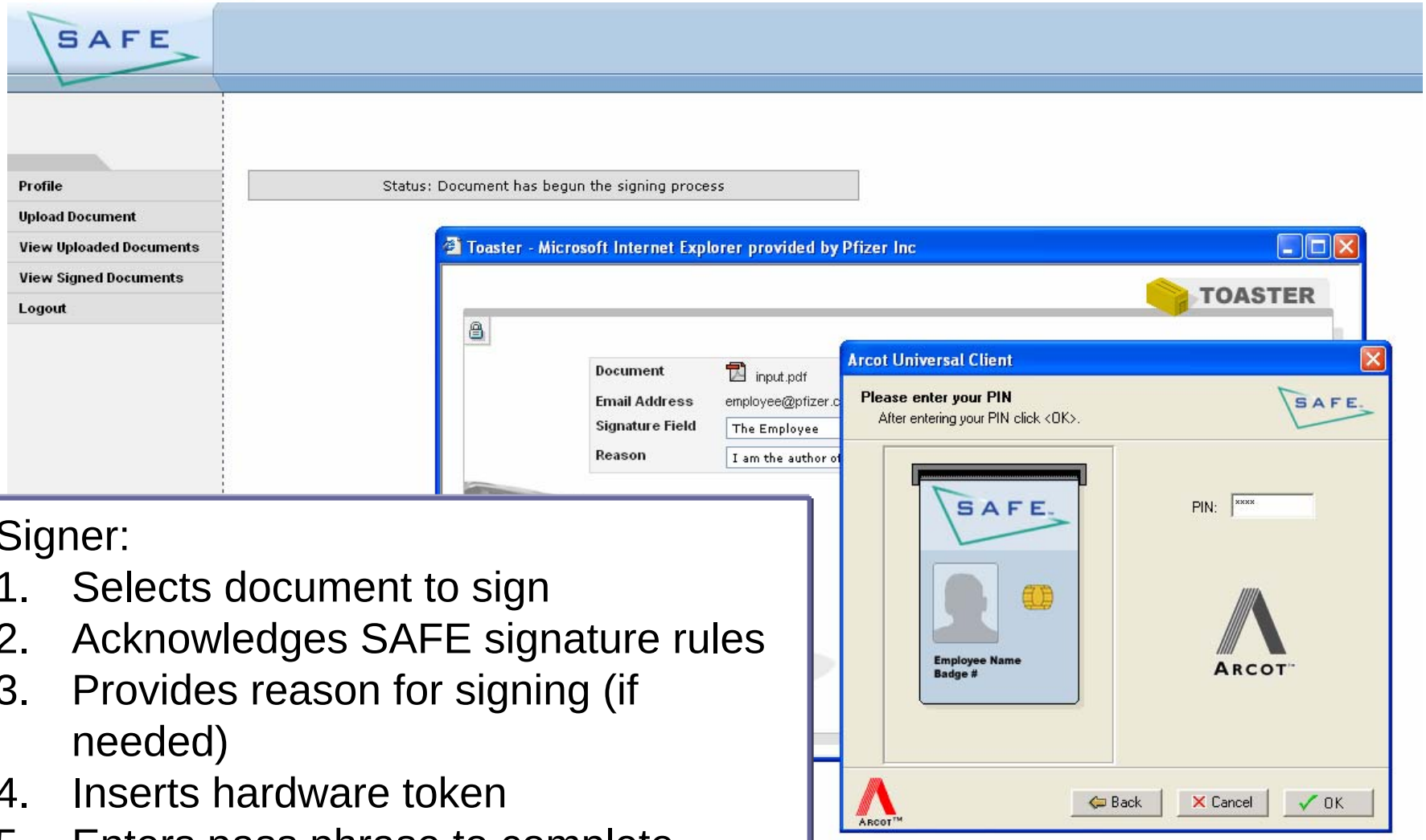
As of today we can bridge trust and reduce complexity



And in the future we can easily extend this trust model

Using SAFE

Signing with a SAFE Credential

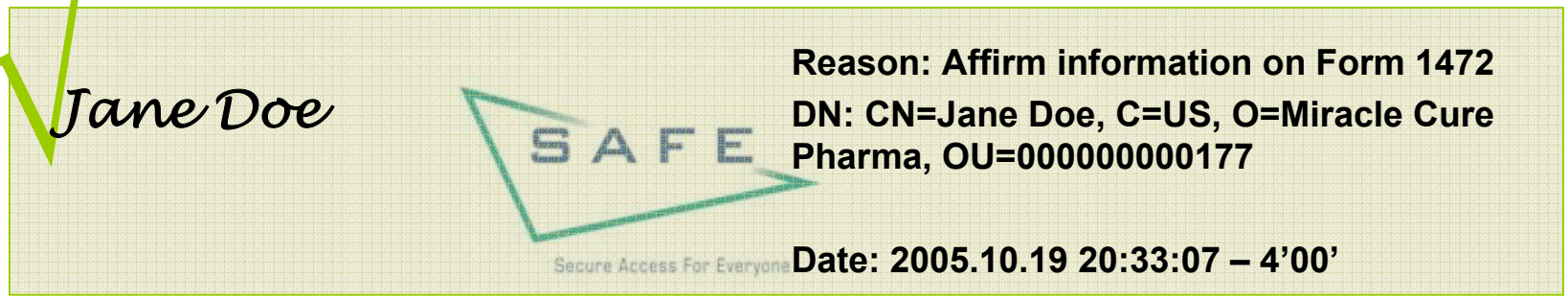


Signer:

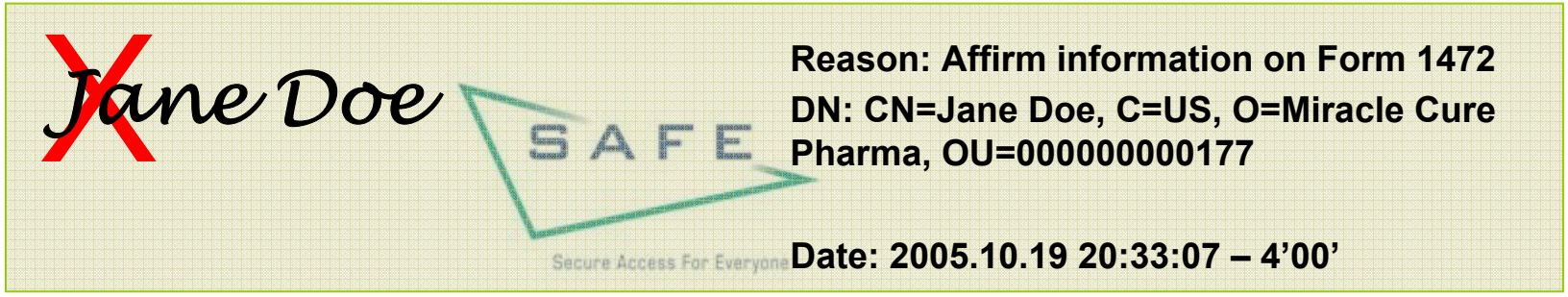
1. Selects document to sign
2. Acknowledges SAFE signature rules
3. Provides reason for signing (if needed)
4. Inserts hardware token
5. Enters pass phrase to complete signing operation

SAFE Signature Block – Visual Representations

Valid Signature



Invalid Signature



Complete Validation Report Can Be Viewed & Saved for Audit Purposes

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.

SAFE EMEA Pilot

- **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 Member Implementations

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

SAFE-NCI Firebird Pilot

- **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, AstraZeneca, Genzyme, Pfizer, Merck, Sanofi-Aventis, Amgen
  - SAFE member participants perform Trusted Agent and Requestor functions in the credential issuance and activation processes
  - NCI-FDA Memo of Understanding
- **Timeline:** Pilot completion by mid-December 2006

SAFE

is the only global standard for healthcare community

interoperability that enables trusted, secure, legally enforceable,

paperless healthcare regulatory and business transactions

Imagine a Future……

- Patient visits physician
- Registered with the swipe of a card
- Physician enters info on integrated point of care device, orders tests, prescribes, enrolls patient in clinical trial – all electronically
- Lab tests submitted and reported electronically
- Medicines are manufactured in batch and sent via electronic order
- Claims submitted and paid and records kept electronically
- Clinical trial data managed, signed and submitted electronically
- Patient carries personal health record……

Questions?

For further information, contact

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