

# SAFE Digital Identity and Digital Signature Standard

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SAFE-BioPharma Association



# 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 and shift resources to priorities – delivering medicines and therapies for unmet medical needs.

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

# 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 Hinderling 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
- Risks:
  - Need to ensure controls and risk level of existing processes are at least matched in new electronic processes
  - Need to understand new threats/risks associated with new processes not possible or part of existing paper processes

***One organization alone cannot address these***

# SAFE-BioPharma Association

- SAFE project initiated in November 2003
- SAFE-BioPharma Association incorporated May 2005
  - AstraZeneca - BMS
  - GSK - J&J
  - Merck - Pfizer
  - P&G - Sanofi-Aventis
- SAFE is a member-governed, not-for-profit enterprise that:
  - Manages and promotes the SAFE standard
  - Provides a legal and contractual framework
  - Provides technical infrastructure to bridge different credentialing systems
  - Provides SAFE identity credentials, directly and through vendors
  - Supports vendors who supply SAFE-enabled products
  - Facilitates Member implementations

# The SAFE Standard

- **Business**

- Operating Policies
- Agreements
- 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*
- *Certification*

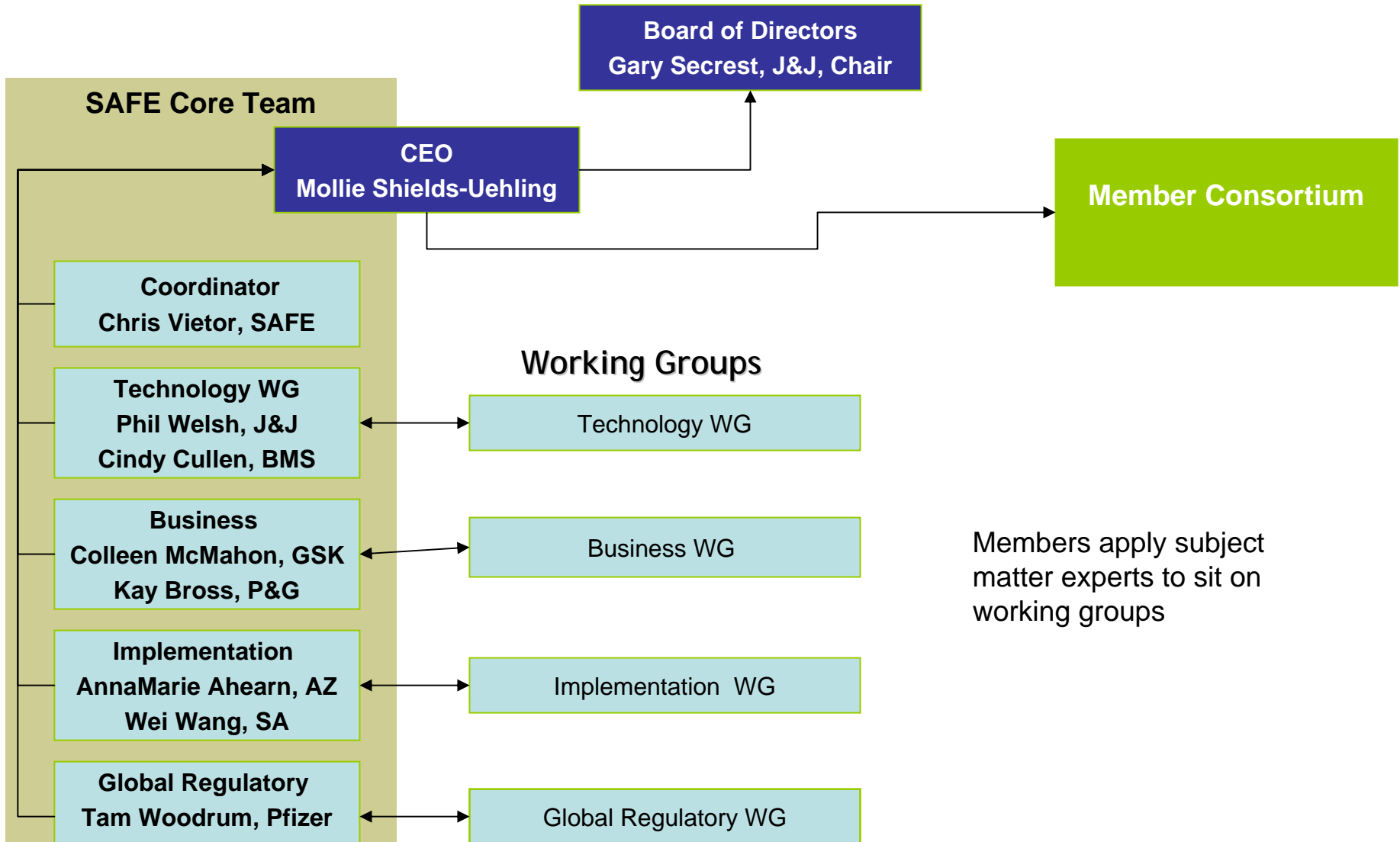
# The Elegance of the SAFE Standard

- Addresses industry's regulatory concerns
- Provides strong legal framework
- Mitigates risk
- Take global approach
- Provides interoperability
- Technology and vendor neutral
- High trust assurance
- Consistency – one standard; one network
- Leads change
- Contribution and collaboration with healthcare community

# SAFE-BioPharma Association

Standards Body	Shared Services Company	Healthcare Industry Association
<ul style="list-style-type: none"> <li>•Standard Development &amp; Maintenance</li> <li>•SDO recognition</li> <li>•Certification standards &amp; administration: Members Products, Issuers</li> <li>•Alignment to HL7, CDISC, IHE, ICH, EAP</li> <li>•Standards Working Groups               <ul style="list-style-type: none"> <li>–Technical</li> <li>–Business</li> <li>–Implementation</li> <li>–Global Regulatory</li> </ul> </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 with FBCA</li> <li>•Collaborative projects/audit</li> </ul> <p style="text-align: center;"><b>Driving/Incubating Innovation</b></p> <ul style="list-style-type: none"> <li>•Credentials Issuance Model &amp; Pricing for Investigators</li> <li>•Investigator directory</li> <li>•Vendor audits</li> <li>•Tech Devel: USSI, RACCA</li> </ul>	<ul style="list-style-type: none"> <li>•Stakeholder outreach</li> <li>•Education &amp; advocacy</li> <li>•Policy engagement</li> <li>•Member engagement and information exchange:               <ul style="list-style-type: none"> <li>–Implementation tools</li> </ul> </li> <li>•Industry awareness &amp; engagement</li> <li>•Public-private approach: NCI Firebird pilot</li> <li>•Media: local, national, trade, international</li> </ul>

# SAFE: A Member-Driven Standards Association



# **SAFE and the FDA: Compliance Working Group**

- SAFE Member reps with QA/Compliance/Reg backgrounds
- FDA key offices engaged since inception
- Jointly-developed SAFE/FDA Auditor Familiarization Program
- FDA statement on SAFE

**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.**

# FDA CDER Statement

“The FDA does not endorse any particular electronic signature solution. The Agency has, however, worked with the biopharmaceutical community over the past two and one-half years to help ensure that the Signatures and Authentication for Everyone (SAFE) Standard: 1) complies with appropriate guidance, especially as related to 21CFR11; and (2) when used as the basis for implementation of a digital signature capability, the SAFE standard facilitates user compliance with 21CFR11.”

Informal response to question posed by SAFE-BioPharma.

# SAFE EMEA Pilot

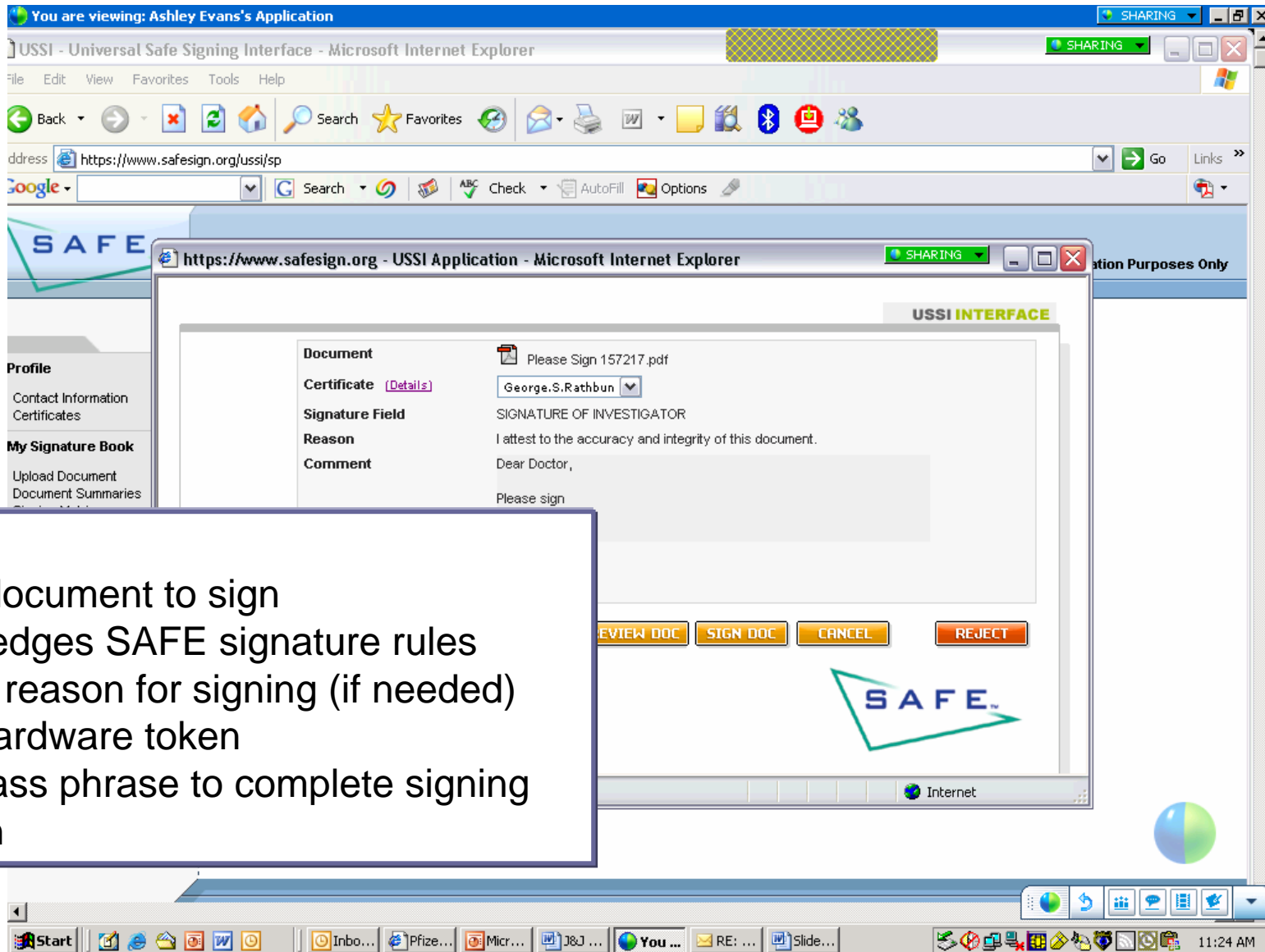


- Participants
  - SAFE Evaluation Team: EMEA, GSK, Organon, Pfizer
- Deliverables
  - Technical
  - Functional validation audit scenarios and validation checklists
  - Compliance matrix
  - EMEA legal statement on acceptability
  - EMEA statement acknowledging auditability
- SAFE EU Advisory Council
  - EU and Member State regulations
  - EU implementations

**The SAFE Evaluation Team (EMEA, EFPIA, Companies) determined that SAFE meets EU Electronic Signature and Clinical Trials Directives' requirements.**

# Using SAFE

# Signing with a SAFE Credential



**Profile**

- Contact Information
- Certificates

**My Signature Book**

- Upload Document
- Document Summaries

**USSI INTERFACE**

<b>Document</b>	Please Sign 157217.pdf
<b>Certificate</b> <a href="#">(Details)</a>	George.S.Rathbun
<b>Signature Field</b>	SIGNATURE OF INVESTIGATOR
<b>Reason</b>	I attest to the accuracy and integrity of this document.
<b>Comment</b>	Dear Doctor , Please sign

[VIEW DOC](#) [SIGN DOC](#) [CANCEL](#) [REJECT](#)

SAFE

Internet

11:24 AM

## 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



Dr. Robert Hill

SAFE

Dr. Robert Hill <sup>TM</sup>

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-NCI Firebird Operational Pilot

- 1572 Investigator statement:
  - Most voluminous/redundant FDA submission (220,000-240,000/yr)
  - Investigator CV, financial statement, trial protocols, IRB
- Firebird: average annual savings of switch from paper to electronic:
  - Large pharma: \$491,825
  - Mid-sized pharma: \$323,000
  - Small pharma: \$158,825
- **Firebird – Federal Investigator Registry for Bioinformatics Registry Data**
  - Electronic investigator profile management
  - 1572 templates & related workflows
  - For electronic submission and review by the FDA
  - Governed by NCI-FDA MOU
- NCI, AstraZeneca, Genzyme, Pfizer, Merck, Sanofi-Aventis, Amgen
- **SAFE is the identity authentication and digital signature** application
- Pilot completion: **February 2007**

# SAFE Member Implementations

- AstraZeneca:
  - Electronic Submissions Gateway: 356h's and eCTD
- GSK:
  - eCTD submissions
- Merck
  - Product sampling for physicians
- J&J:
  - All J&J digital signatures are SAFE signatures
  - Electronic Master File
- Pfizer:
  - eLab Notebooks
  - Regulatory submissions
- P&G:
  - Enterprise digital signature solution
  - eLab Notebooks
  - ePurchasing
  - eHR – forms
  - ePatent Filings
- BMS:
  - External partner authentication
- NCI and Amgen, Pfizer, Merck, SanofiAventis, and Genzyme – **1572s**

# SAFE Vendor Community

## SAFE Premier Partners

- ✓ Adobe
- ✓ Aladdin
- ✓ Arcot
- ✓ Bearing Point
- ✓ CoreStreet
- ✓ Cybertrust
- ✓ Hitachi
- ✓ IBM
- ✓ IDBS
- ✓ Northrop Grumman
- ✓ SAIC

## SAFE Partners

- ✓ ARX
- ✓ DataLabs
- ✓ IntraLinks
- ✓ Solabs
- ✓ Open Text

## SAFE Issuers

- ✓ Citibank
- ✓ Cybertrust
- ✓ IdenTrust
- ✓ J&J

# 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.....

# The SAFE Standard

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

**Single identity; consistent signing experience; auditable; globally recognized;  
single standard for vendor enablement; network of networks.**

# Questions?

For more information, contact:

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