



Signatures and Authentication For Everyone

Building Trust: SAFE Digital Identity and Signature Standard

Mollie Shields Uehling
SAFE-BioPharma Association

14th National HIPAA Summit

SAFE-BioPharma Association





Agenda

- ▶ Why we need a healthcare industry identity assurance standard.
- ▶ Limitations of current proprietary approaches.
- ▶ What is SAFE.
- ▶ How it works.
- ▶ How it facilitates meeting HIPAA requirements.
- ▶ How SAFE is being used.



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.



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

- ▶ **Approximately 40% of annual R&D costs attributed to paper based business processes (\$9 Billion in US alone)**

- ▶ **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



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**
 - Use 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 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, both directly and through vendors
 - Supports vendors who supply SAFE-enabled products.

- ▶ **SAFE project initiated in November 2003**

- ▶ **SAFE-BioPharma Association incorporated May 2005**
 - AstraZeneca
 - GSK
 - Merck
 - P&G
 - BMS
 - J&J
 - Pfizer
 - Sanofi-Aventis



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***
- ***Certification***



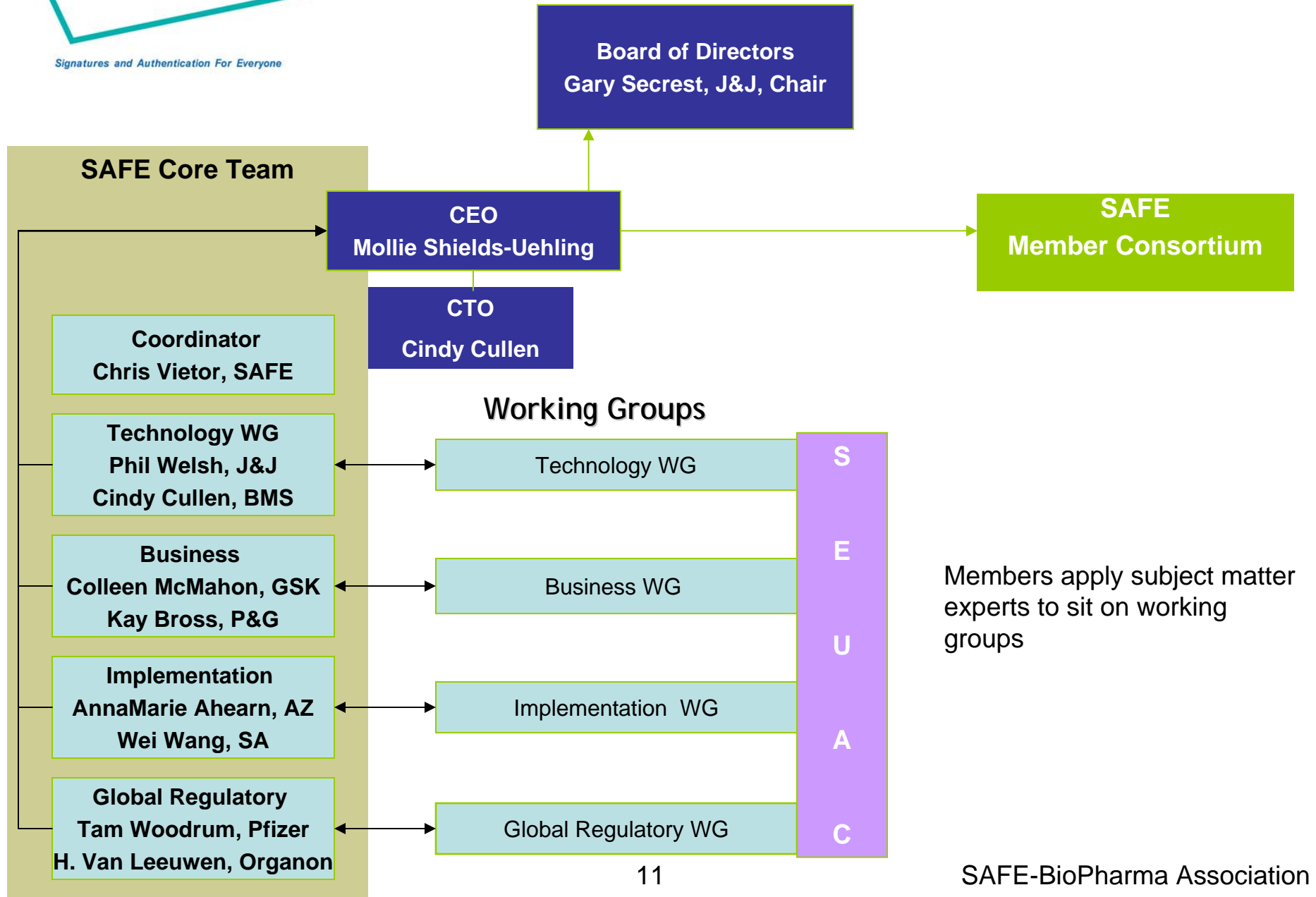
SAFE-BioPharma Association Today

Signatures and Authentication For Everyone

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



A Member-Driven Standards Association





Using SAFE



Dr. Robert Hill

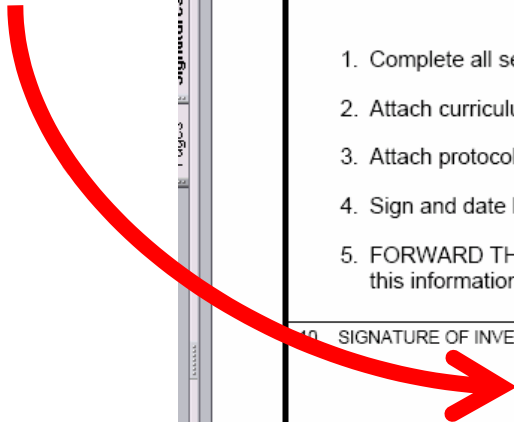
SAFE

Dr. Robert Hill TM
Reason: I agree to the terms defined by the
placement of my signature on this document.
Date: 2006-06-15 09:38:18 -0400



Validating a SAFE Signature

Just Click
On it ...




**Validation: Confirms Integrity
of Signed Document & Validity
of Signer's Digital Certificate**

You are viewing: Ashley Evans's Application

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).

10. SIGNATURE OF INVESTIGATOR	 Mark A Nelson For Demonstration Purposes Only	Mark A Nelson CN=Mark A Nelson, OU=Pfizer, DC=Cybertrust, DC=com Date: Date: 2006-03-21 11:20:41 -0500 Reason: I attest to the accuracy and integrity of this document.	11. DATE
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(WARNING: A willfully false statement is a criminal offense. U.S.C. Title 18, Sec. 1001.)

Food and Drug Administration
CDER (HFD-94)
12229 Wilkins Avenue
Rockville, MD 20852

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

Please DO NOT RETURN this application to this address.

FORM FDA 1572 (4/03) PREVIOUS EDITION IS OBSOLETE



SAFE Member Implementations

- ▶ **Pfizer:**
 - eLab Notebooks
 - Regulatory submissions
- ▶ **AstraZeneca:**
 - 150+ regulatory submissions via FDA's ESG: 2252, 1571, 356h and eCTD
- ▶ **GSK:**
 - eCTD submissions
- ▶ **Merck**
 - Product sampling for physicians
- ▶ **J&J:**
 - All J&J digital signatures are SAFE signatures
 - Electronic Master File
 - Regulatory submissions
- ▶ **P&G:**
 - Enterprise digital signature
 - 4,500 eLab Notebooks
 - ePurchasing
 - eHR – forms
 - ePatent Filings
- ▶ **BMS:**
 - External partner authentication
- ▶ **NCI, Amgen, Pfizer, Merck, Sanofi-Aventis, and Genzyme – Firebird -- 1572s**



SAFE-NCI Firebird Operational Pilot

- ▶ **1572 Investigator statement:**
 - Most voluminous and redundant submission to FDA (220,000-240,000/year)
- ▶ **Business case for pharma:**
 - 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
 - For electronic submission and review by the FDA
 - Governed by NCI-FDA MOU
- ▶ **Participants: NCI, AstraZeneca, Genzyme, Pfizer, Merck, Sanofi-Aventis, Amgen**
- ▶ **SAFE is the identity authentication and digital signature application**
- ▶ **Pilot Completed: February 2007**
- ▶ **Firebird production: Fall 2007**



Signatures and Authentication For Everyone

SAFE Vendor Community

SAFE Partners

- ✓ Adobe
- ✓ Aladdin
- ✓ Arcot
- ✓ ARX
- ✓ Bearing Point
- ✓ CoreStreet
- ✓ DataLabs
- ✓ Hitachi
- ✓ IBM
- ✓ IDBS
- ✓ IntraLinks
- ✓ Microsoft
- ✓ Northrop Grumman

SAFE Partners

- ✓ nCipher
- ✓ Open Text
- ✓ SAIC
- ✓ Solabs
- ✓ SupplyScape
- ✓ SureScripts

SAFE Issuers

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



SAFE and the FDA

- ▶ **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**
- ▶ **Next steps:**
 - April 20th SAFE-FDA Auditor/Compliance Workshop
 - Training audit of SAFE-signed submission

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.”



Electronic Submissions Gateway: FDA Slide

► Important process information

- No paper required for gateway submissions
- Accepted signature methods by FDA, at this time, for required FDA forms (e.g., 1571, 356h) and documents
 - Scanned signatures
 - Digital signatures
 - Flatten digital signatures, must include;
 - » the printed name of the signer
 - » the date and time when the signature was executed
 - » the reason for signature

<p>10. SIGNATURE OF INVESTIGATOR</p> <p style="font-size: 1.2em; font-weight: bold;">Geroge.S.Rathbun</p> <p style="font-size: 0.8em;">For Demonstration Purposes Only</p> <p style="font-size: 0.7em; color: red;">1 Facsimile of Original Digital Signature</p> <div style="font-size: 0.7em; border: 1px solid black; padding: 2px;"> Geroge.S.Rathbun CN=Geroge.S.Rathbun,OU=Test Use Only,DC=SafeSign,DC=org Date: Date: 2006-04-20 15:48:08 -0400 Reason: I attest to the accuracy and integrity of this document. </div>	<p>11. DATE</p>	
(WARNING: A willfully false statement is a criminal offense. U.S.C. Title 18, Sec. 1001.)		
<p>Public reporting burden for this collection of information is estimated to average 100 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:</p>		
<p>Food and Drug Administration CBER (HFM-99) 1401 Rockville Pike Rockville, MD 20852-1448</p>	<p>Food and Drug Administration CDER (HFD-94) 12229 Wilkins Avenue Rockville, MD 20852</p>	<p>"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."</p>
<p>Please DO NOT RETURN this application to this address.</p>		



SAFE EMEA Pilot



▶ Participants

- SAFE Evaluation Team: EMEA, GSK, Organon, Pfizer

▶ SAFE EU Advisory Council

- EU and Member State regulations
- EU implementations

▶ Next Steps

- eCTD submission by SAFE member
- Auditor workshop – EMEA and Member State Regulators

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



Signatures and Authentication For Everyone

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.....**



SAFE

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



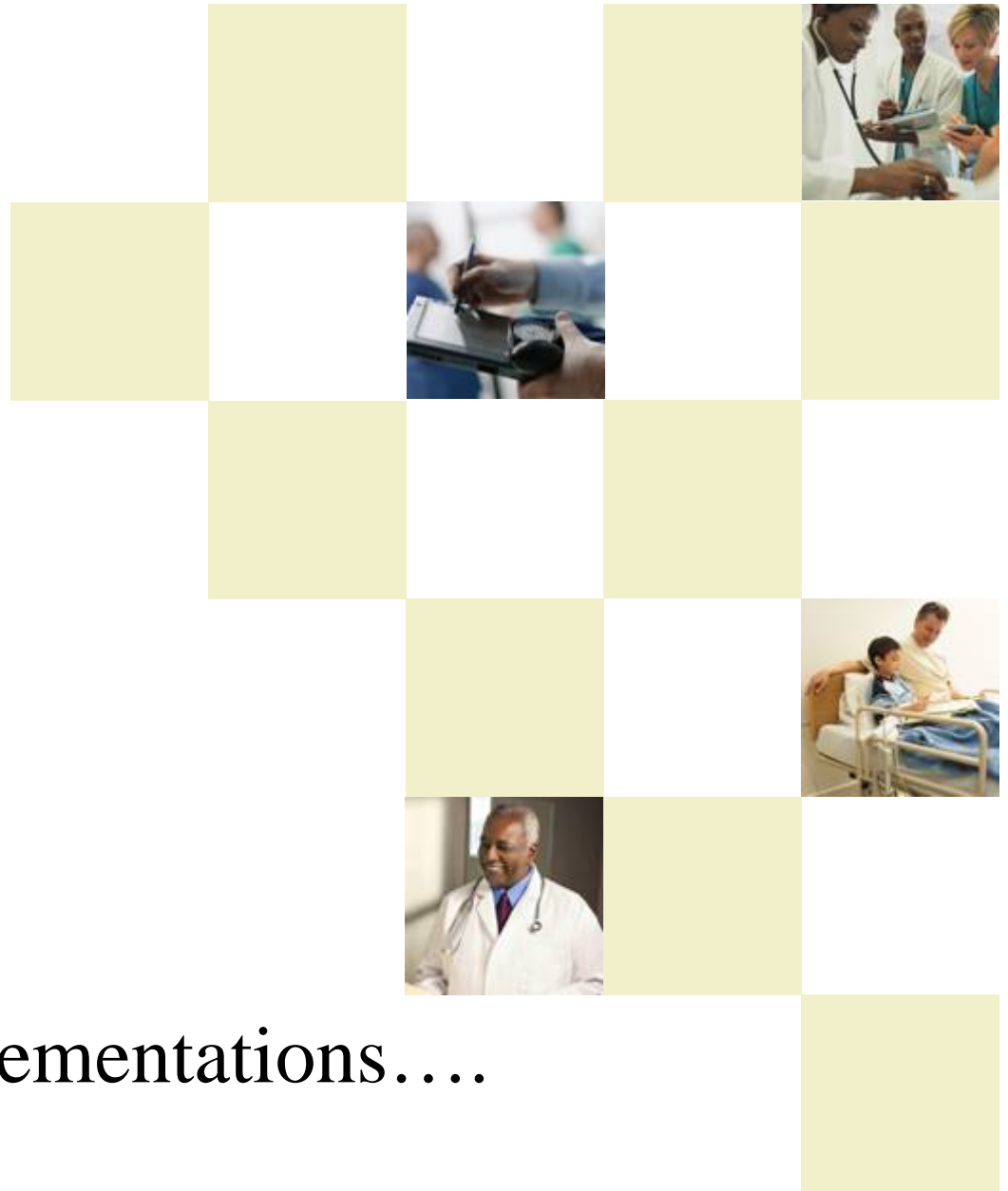


Questions?

Mollie.Shields.Uehling@SAFE-BioPharma.org



Signatures and Authentication For Everyone



A Tale of two Implementations....

Colleen McMahon

GlaxoSmithKline

SAFE-BioPharma Association



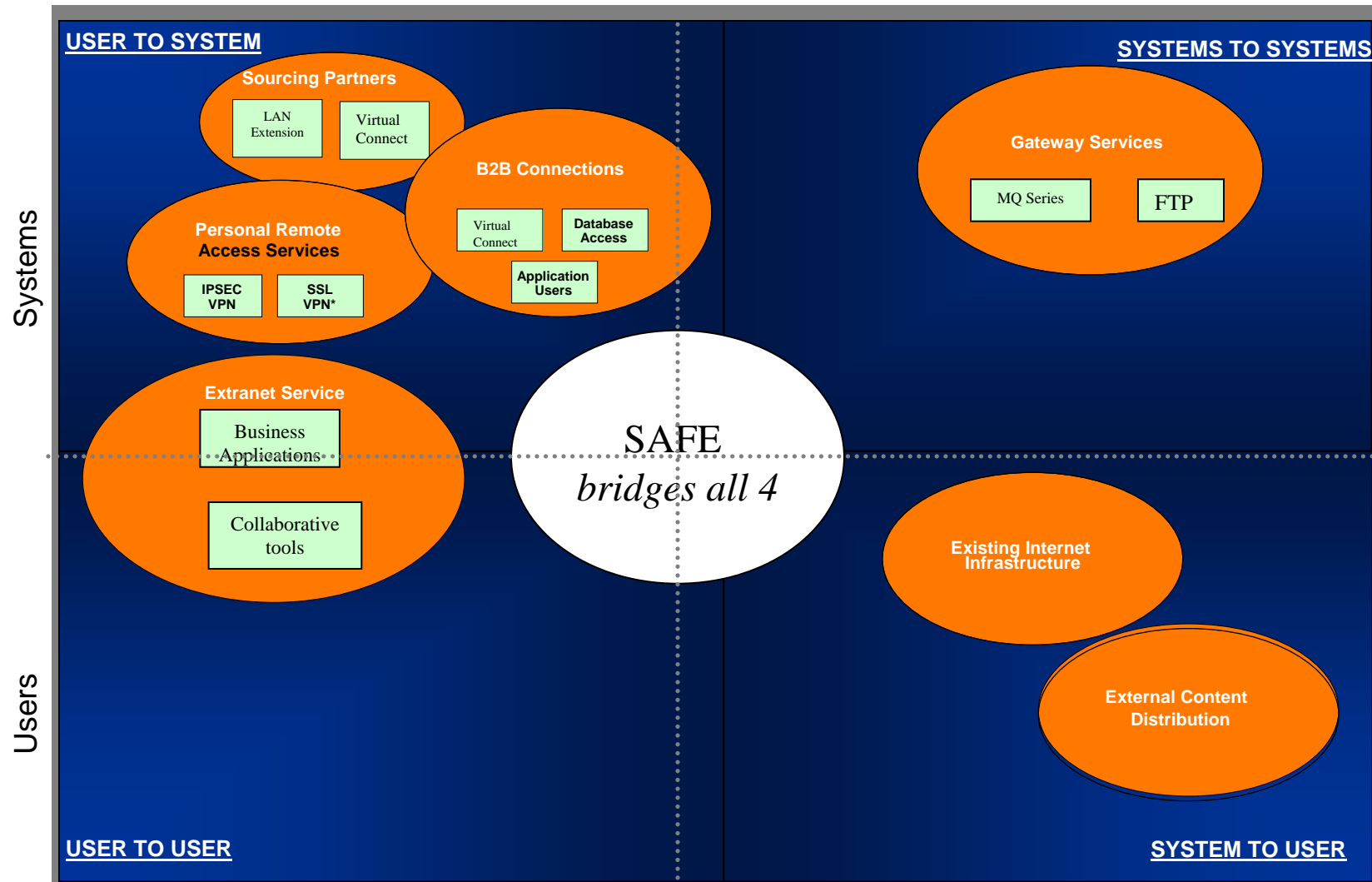
Reasons Pharmas Are Implementing SAFE

- ▶ **Paperless/Paper 'light'**
- ▶ **Globalization**
- ▶ **Virtualization**
- ▶ **Global Sourcing**
- ▶ **Legally enforceable**
- ▶ **Regulatory and Governmental mandate premonitions**
- ▶ **Consumer pressure for lower cost medicines**
- ▶ **Interoperability**



Simplification

Signatures and Authentication For Everyone





Benefits

▶ **Pharma Mission**

- Paperwork elimination - transaction cost avoidance (~20% per trial)
 - Pure electronic records
 - Automation capability of archiving function
- Increased Productivity
 - Reduction in cycle times end to end
 - Improved compliance rates



Benefits

► Usability

- Interoperability
 - Single credential for all Pharma interactions
 - Single 'experience' for signing
- Portability
 - Credential can be taken with the user anywhere
- Scalability
 - Number of applications does not impact credential issuance or maintenance



Benefits

▶ **Regulatory Compliance**

- Eliminates Ambiguity
- Electronic Submissions
 - Digital signatures and strong authentication enable electronic submissions
 - Regulatory acceptance of SAFE signed submissions
- Auditability
 - Check-list approach to audit requirements
 - Ability to trace transaction to a clear certificate holder
 - Access/Audit trails easier to maintain



Benefits

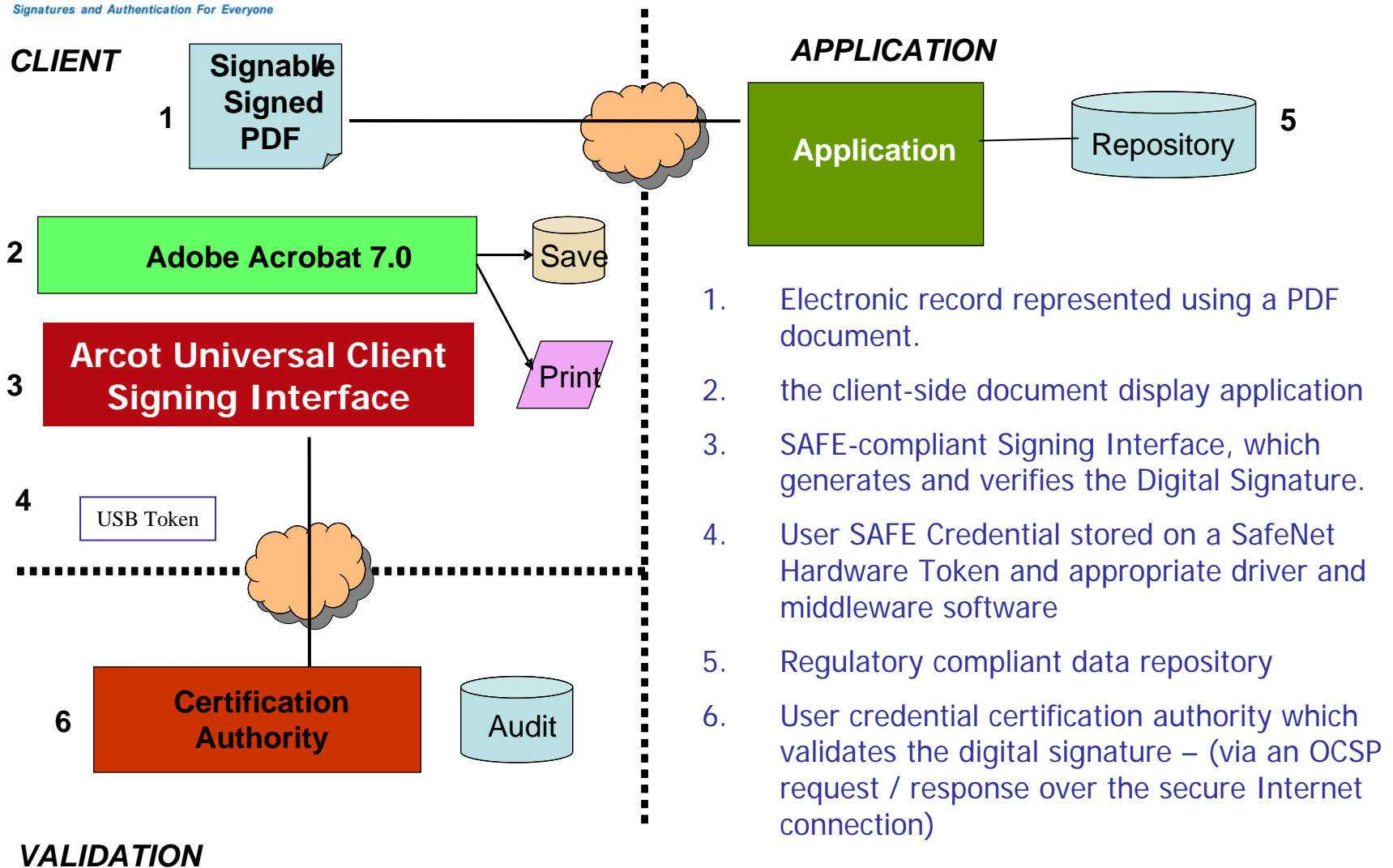
▶ **Legal Compliance**

- Improve intellectual property protection capabilities
 - Ability to demonstrate intent, origination, and origin of transactions
 - Data and time stamping of content by trusted third-party time
- Non-repudiation of signatures
- ‘Closed System Approach’
 - Each Pharma bound to a single rule set



Signatures and Authentication For Everyone

Basic Architecture





Tale 1: FDA Submissions

- ▶ **Scope**
 - Signing a 1572 and submitting it to the FDA via the Electronic Submissions Gateway (ESG) (Sept 2006)
 - 356h - submit it via the Electronic Submission Gateway
- ▶ **Timing**
 - April – September 2006
- ▶ **Key Success Factors**
 - Limited number of users
 - Small focused team
 - Small Scope
- ▶ **External Environment**
 - Leveraged Electronic Submission Gateway (ESG)



Signatures and Authentication For Everyone

Tale 1: FDA Submissions

- ▶ **Policy Considerations**
 - Leveraged SAFE Templates for Policies and Procedures
 - “live” digital signature vs. flattened file
- ▶ **Validation Requirements**
 - System Validation including off-the-shelf solutions
 - Vendor Audit – Arcot
- ▶ **Infrastructure implications:**
 - Firewall configurations to allow Arcot Traffic via Port 80
- ▶ **Software Used for Implementation**
 - Adobe Acrobat 7 Pro
 - SafeNet token drivers
 - SafeNet Middleware (policy)
 - Arcot Universal Client



Tale 1: FDA Submissions

▶ **Support**

- Help Desk for business support
- SAFE area-specific support

▶ **Benefits**

- SAFE Improved cost and time efficiencies for both sponsor and agency – NO PAPER
- More efficient transfer of our electronic submissions
- Facilitates earlier access to the submission by the review division
- Reduced effort to process and archive
- Efficiencies related to electronic processing and transfer of forms to signatories
- First movement towards a digital identity
- Reputation Impact
- Leveraging investment in SAFE



Tale 2: eLNB

- ▶ **Key Goal:**
 - SAFE digital signature used to sign laboratory research, experiments and procedures
 - 4500 **Scientists and technicians.**
- ▶ **Timing**
 - Currently in Beta – Production in June 2007
- ▶ **Policy Considerations**
 - Intellectual Property Protection
 - GLP
- ▶ **Software Used for Implementation**
 - Adobe Acrobat with SAFE signature plug-in
 - USSI



Tale 2: eLNB

► **Deployment**

- Support for external partner signatures
- Support one-off signatures
- Imbed support of signing into application
- Leverage time-stamping and data integrity

► **Benefits:**

- Total electronic environment
 - Does not need paper backup in support of a wet signature.
- IP Legal (intellectual property)
 - SAFE digital signatures are the equivalent of wet signatures.
- Significant decrease in cycle time savings from experiment completed to 'signed and approved'



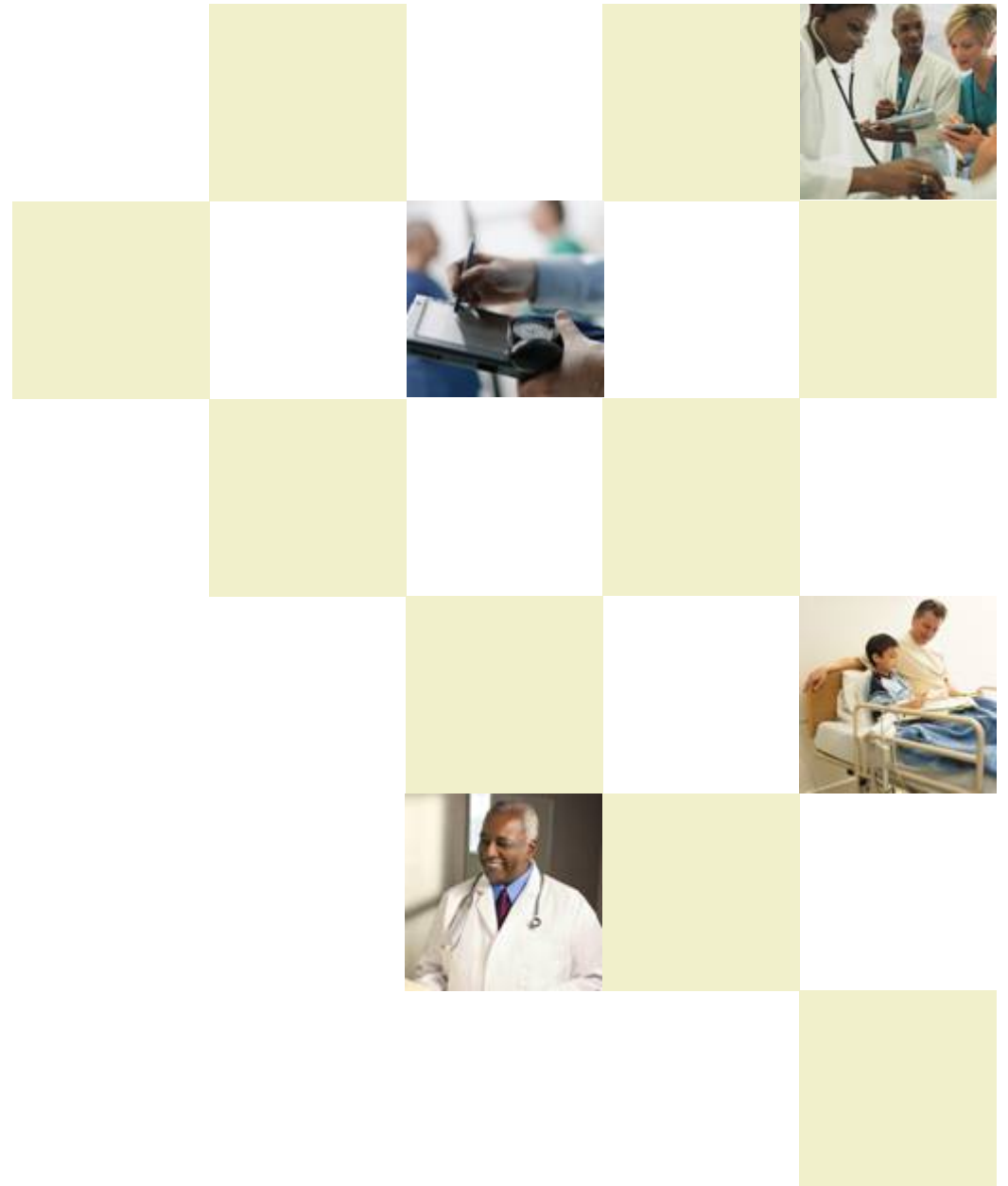
Other Implementations

- ▶ **Several eCTDs**
- ▶ **Filing in Europe (EMEA)**
- ▶ **eSampling**
- ▶ **Firebird/NCI**



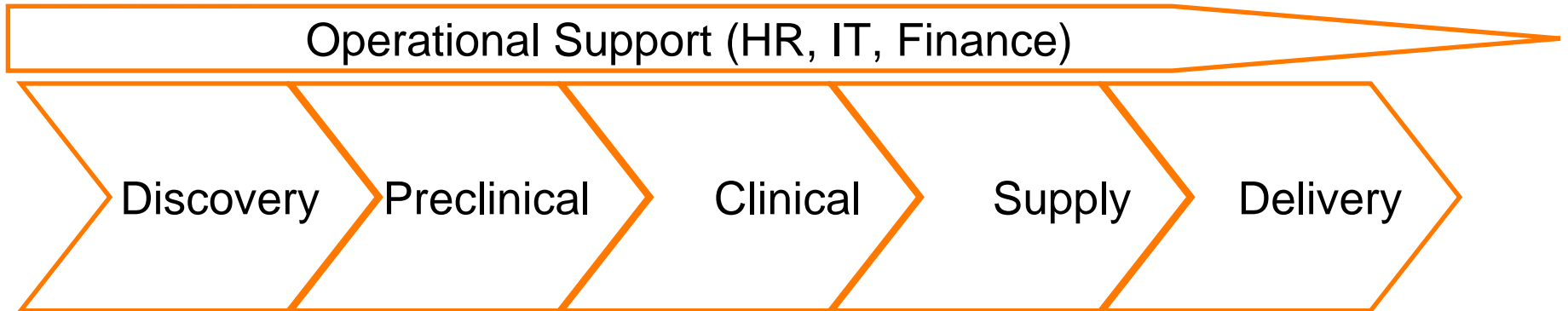
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Back-up





Signature Landscape



eLab Notebooks (IP Protection)	Electronic Data Capture
eLabeling	eArchiving
Grant Management	Code Signing
Site Study Initiation Packages (1572)	Contracts/Grant Signatures
Electronic Submissions (eCTD)	SOP approvals
Quality Documentation Approvals	Expense Reporting
Adverse Event and Safety Reporting	Human Resources (payroll, benefits)
Informed Consent Forms	Software Licensing Agreements
ePrescribing	Patient Compliance
eSampling	Investigator/Patient Portals
eDetailing	Key Opinion Leader (KOL) Management
Vaccines Ordering	Financial Reporting
Press Releases/PR approvals	39 Patents and Grants



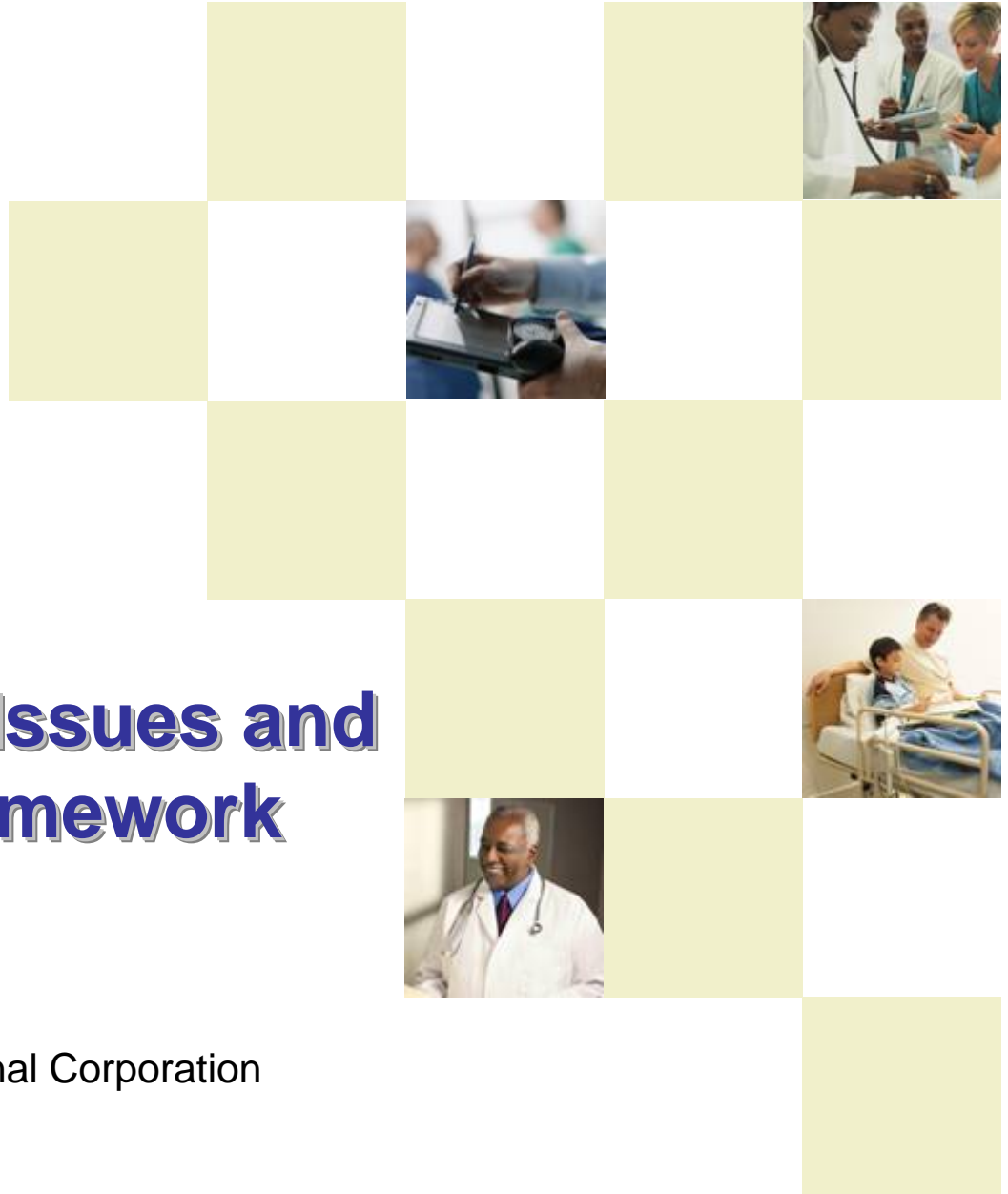
Signatures and Authentication For Everyone

Building Trust: Legal Issues and the SAFE Legal Framework

Paul Donfried

Science Applications International Corporation

14th National HIPAA Summit



Legal Challenges



- ▶ Proof of Compliance with Laws and Regulations
- ▶ Corporate policies
- ▶ Information Protection Management Guidelines
- ▶ Reporting Requirements
- ▶ Discovery and Production



- ▶ Corporate Truth Vs. Working Record
- ▶ Record Retention Requirements
- ▶ How long do you Keep
- ▶ When to Decommission
- ▶ How to Protect Against Fraudulent Elimination
- ▶ Business Continuity

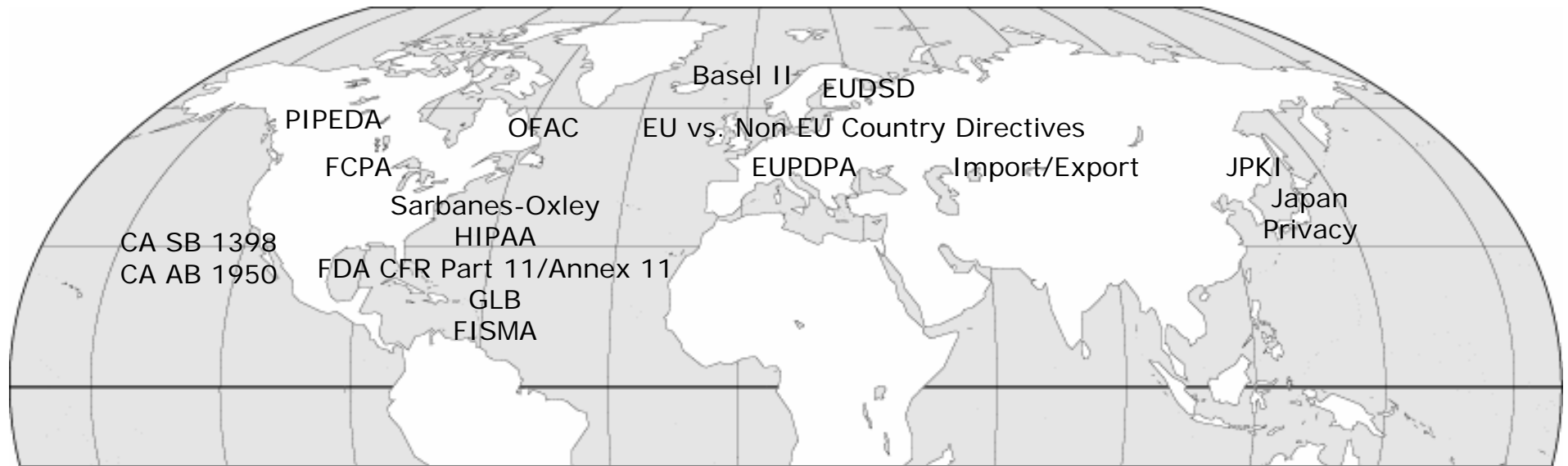


- ▶ Privacy and Security
- ▶ IP Protection
- ▶ User Controls and Desktop Controls
- ▶ Data Breach Management
- ▶ Separation of Duties



- ▶ Electronic Original vs. electronic Copy, vs. Flattened
- ▶ Business Record Management
- ▶ Paper as original
- ▶ Indexing paper for reuse
- ▶ Rights Management
- ▶ Serialized and Watermarked

Regulatory Challenges



- ▶ Regulations all have an impact on your identity management strategy
- ▶ Conflicting regulations increase risks and costs especially depending on geography
- ▶ Policy alignment and consistency is essential

**Control Frameworks:
COBIT ISO 17799 NIST**



Legal Issues with Electronic Records

- ▶ **Discovery**
- ▶ **Admissibility**
- ▶ **Performance (enforceability)**

- ▶ **Liabilities associated with Electronic Records**
 - Privacy & Confidentiality
 - Authentication compromise
 - Integrity compromise
 - Unintended loss or destruction
 - Inability to expunge

I&AM is not technology!

I&AM services should be designed to ensure that all business transactions contain and convey the appropriate evidence relative to:

Who is allowed in?



Identity Management

Who and what is performing the transaction?

The transactional record must support and be compliant with applicable Global legal and regulatory requirements

What can they Access/Do



Access Management

What was accessed what happened?

Evidence



Binding/Acceptance

**When did the transaction occur
How was the user bound to the transaction**



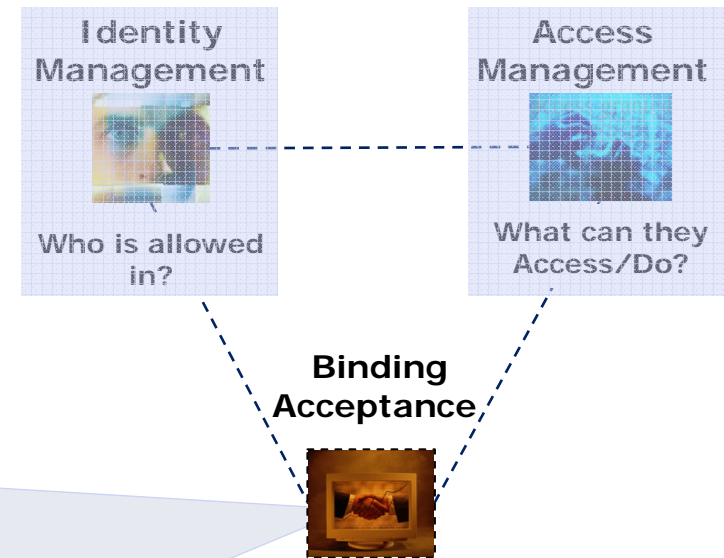
Strength of Evidence

A digital signature is a specialized type of electronic signature

Digital Signature	Data associated with a Record as a result of processing the Record using PKI, which data can be used to determine: (1) whether the data was created using the Private Key that corresponds to the Public Key in the signing Entity's Digital Certificate; and (2) whether the message has been altered since the Digital Signature was associated with the Record.
eSig, eSignature, Electronic Signature	An electronic sound, symbol, or process, attached to or logically associated with a contract or other Record and executed or adopted by a person with the intent to sign the Record.

Records Management

Evidence: What bound the transaction	
Taxonomy	Policy Components
<ul style="list-style-type: none"> ➤ eRecords ➤ Transactions ➤ Audit Records ➤ eSignatures 	<ul style="list-style-type: none"> ➤ Documents ➤ Archive ➤ Audit Logs
<ul style="list-style-type: none"> ➤ eRecords Lifecycle Management ➤ eRecords BCP ➤ Record Retention and Elimination ➤ Audit Records and Logging ➤ Ownership and Custodianship 	
Risk Framework	Procedures
<ul style="list-style-type: none"> ➤ Reg /Legal Statutory Requirements ➤ Deletion, Tampering Detection ➤ Logical and Physical Controls ➤ Media Stability / Transformation ➤ Format Stability / Transformation ➤ Cryptographic Stability / Transformation 	<ul style="list-style-type: none"> ➤ Create, Read, Update, Delete ➤ Logging ➤ Archive ➤ Back-up and Replication ➤ Controls Implementation Guidelines

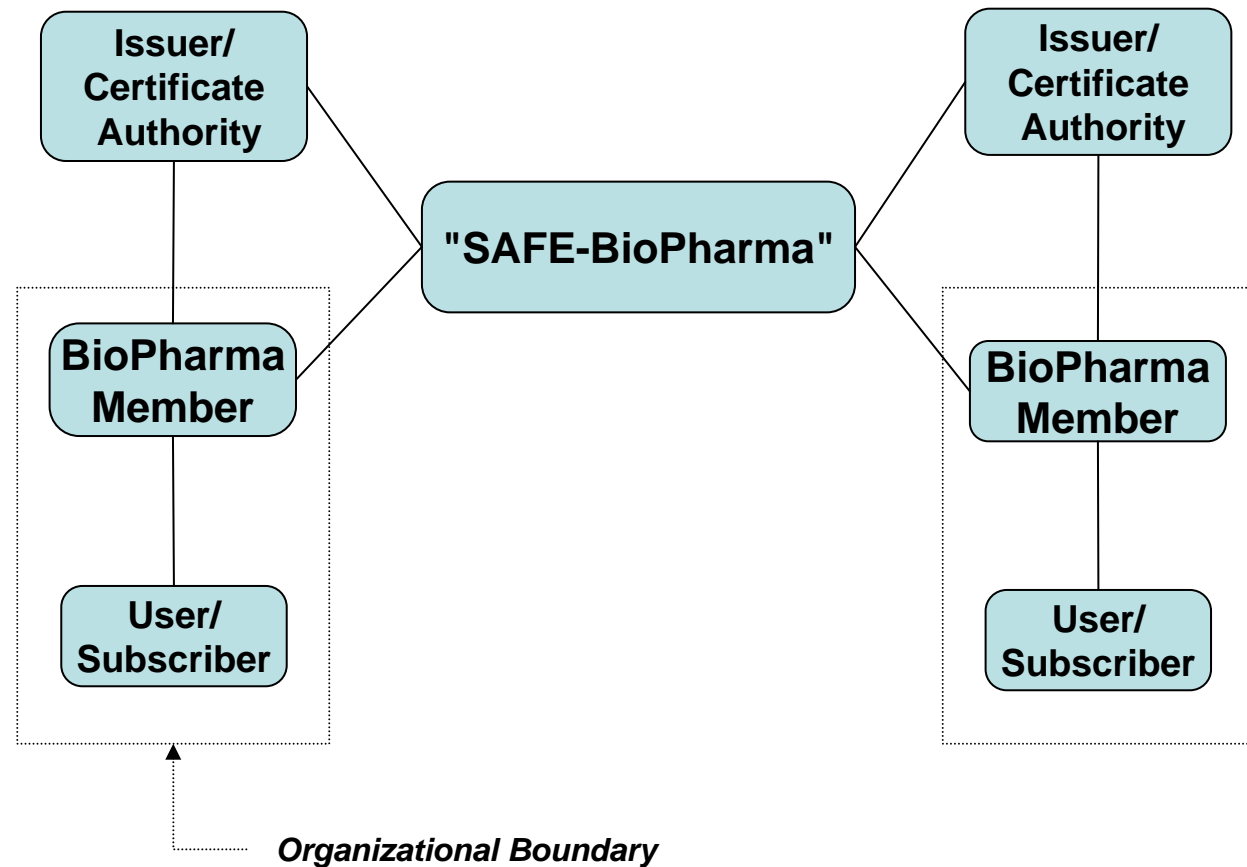




SAFE Stakeholders – Legal Relationship

Stakeholders

- "SAFE-BioPharma"
- BioPharma Members
- Issuers/ CA's
- Users/ Subscribers

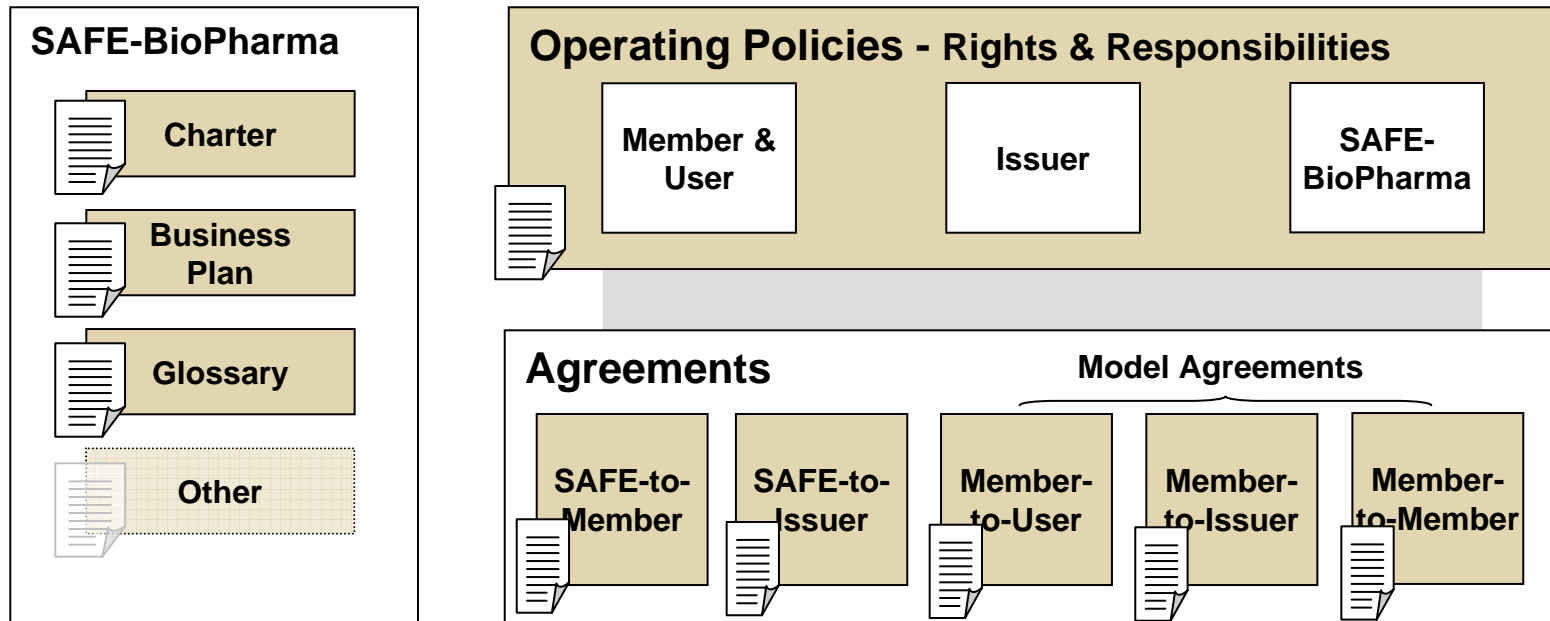




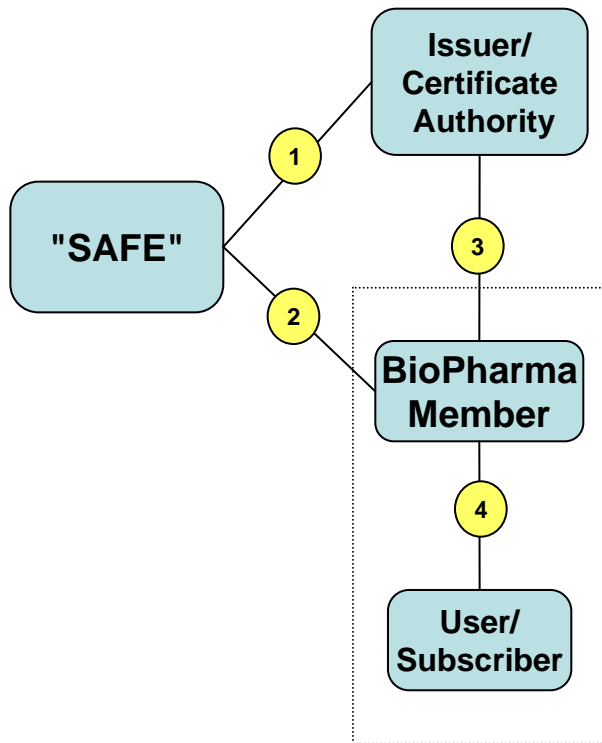
SAFE Business Policies: Common Legal Rights & Responsibilities

Business Policies

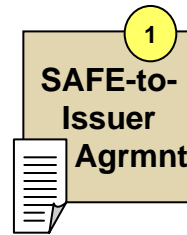
- Policies provide an overview of SAFE, define the business requirements for "SAFE Association", Members, Issuers, and Users, and define the minimum legal terms and conditions for respective SAFE agreements



SAFE Agreements: Establish Global Legal Framework for Enforceability & Risk Management



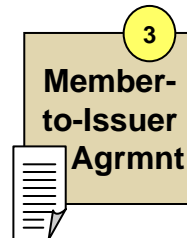
- Closed contractual system
- Defined rights & responsibilities
- International arbitration for dispute resolution



- *Liability Limits*
- *Dispute Resolution*
- *Accreditation Responsibilities*
- *E-Signature enforcement provisions*



- *Liability Limits*
- *Dispute Resolution*
- *Accreditation Responsibilities*
- *E-Signature enforcement provisions*



- *Service Levels*
- *Notifications*
- *E-signature enforcement provisions*
- *Dispute resolution*
- *Liability allocation*



- *Scope of use*
- *Protection requirements*
- *E-signature use and verification requirements*



Questions?

Paul.A.Donfried@SAIC.com