



SAFE-BioPharma Association
Signatures And Authentication For Everyone

Building Trust

21 CFR Part 11 and How the SAFE Standard Enables Legally Enforceable Digital Signatures & Identity Management

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Today's Meeting



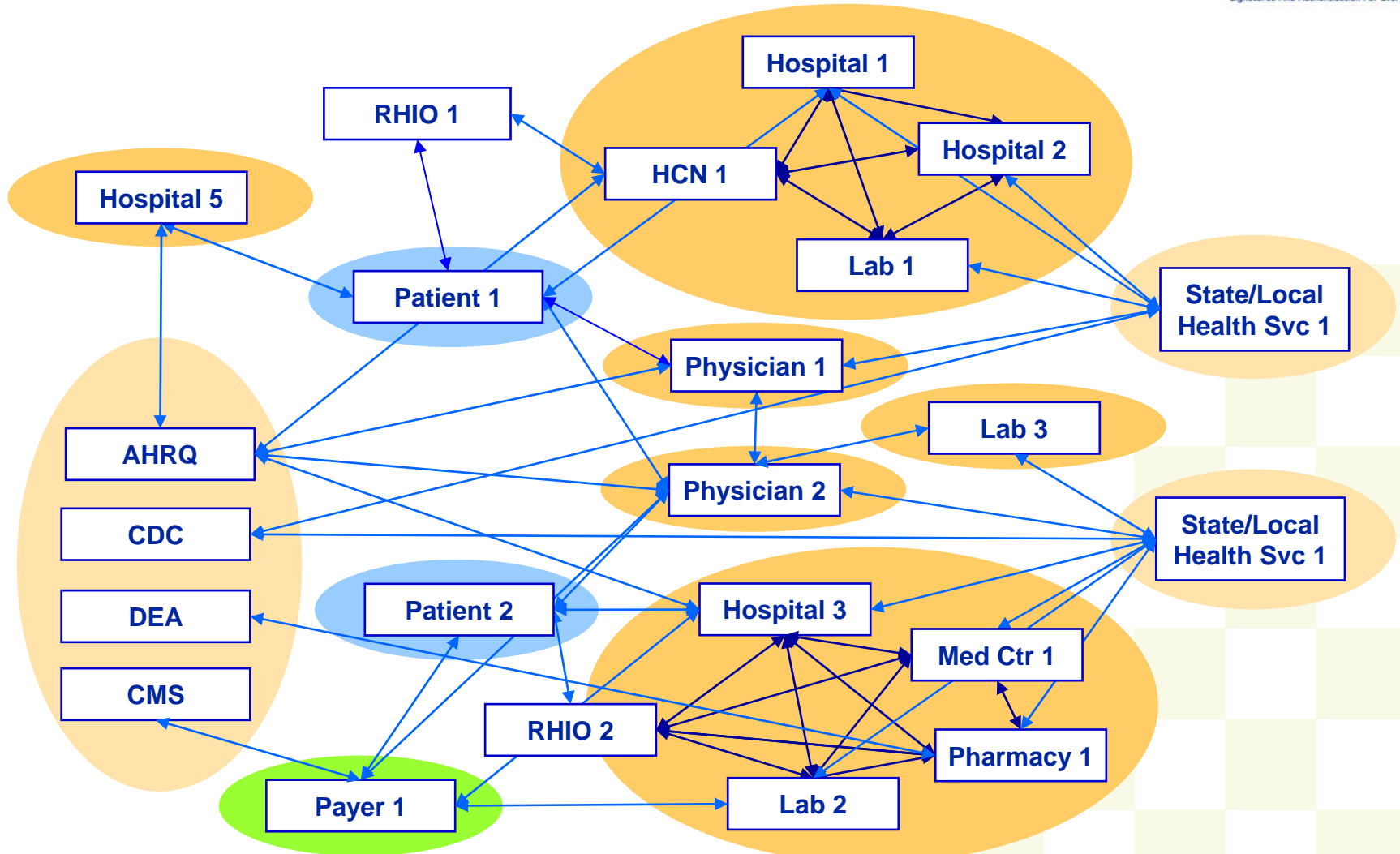
- ▶ The complex challenges we face
 - Business model
 - Legal
 - Regulatory

- ▶ How the SAFE standard unravels the complexity
 - Obstacles
 - Solutions

- ▶ State of Compliance
 - US
 - EU



The Global Identity Challenge - Healthcare



Managing the problem requires cooperation

Financial Impact in Today's Environment – Health Care



▶ New England Journal of Medicine, 2004, et.al.

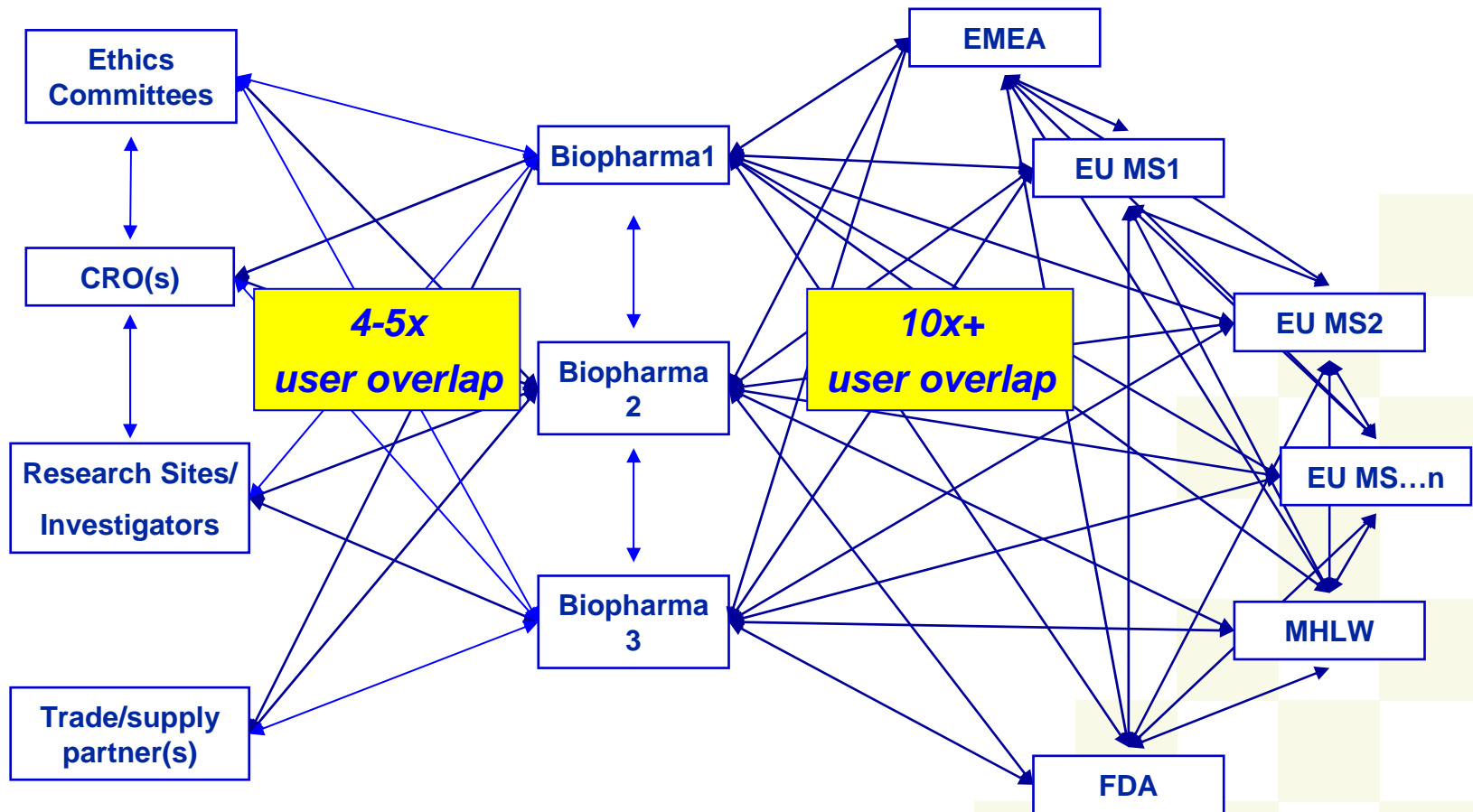
– Paperwork = 31% of all health costs / \$500 billion in 2004

- 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

The Global Identity Challenge - BioPharma



If tackled independently → recipe for management nightmare

Financial Impact in Today's Environment - BioPharma



- ▶ 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 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 is SAFE?



- ▶ 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

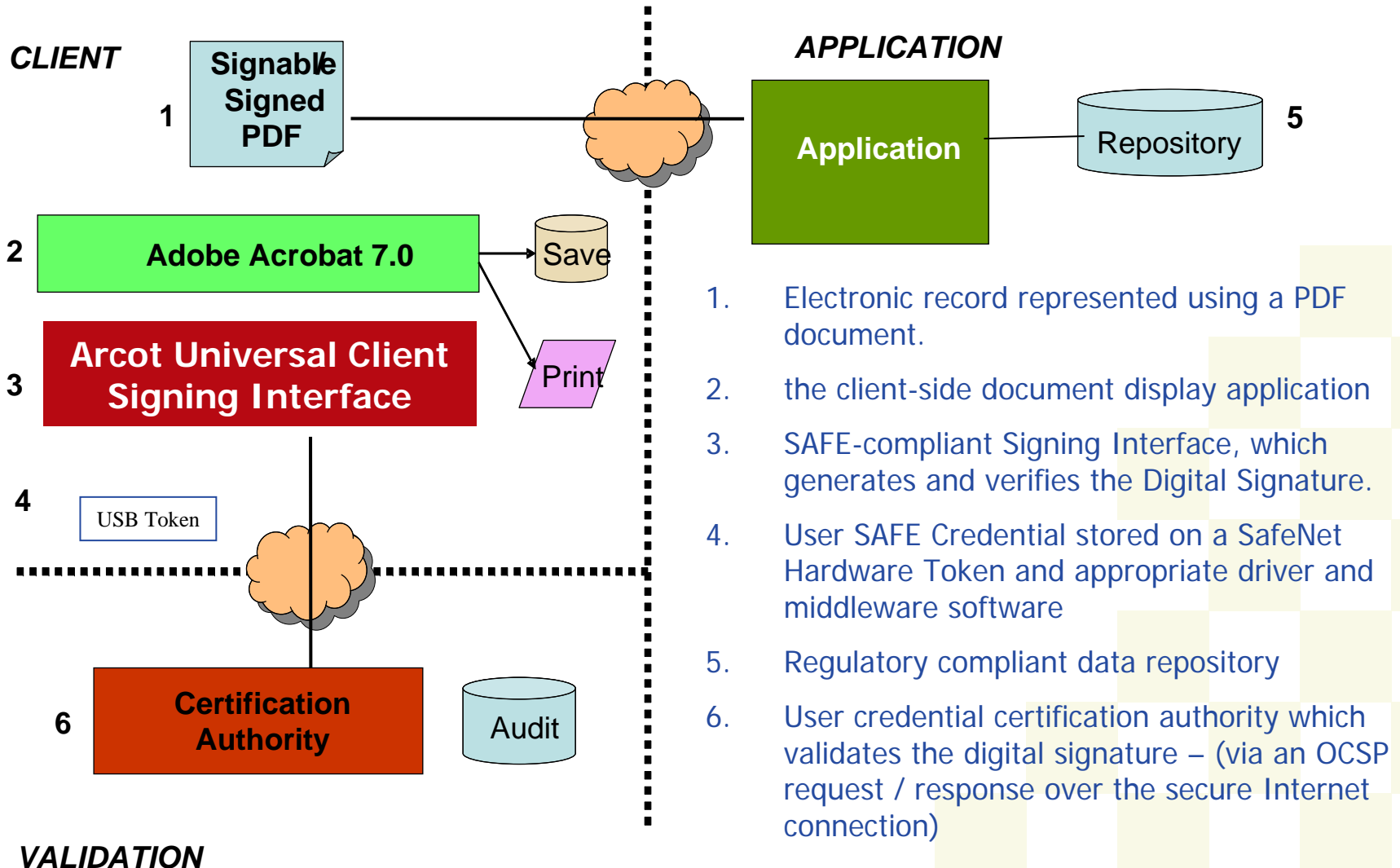
- ▶ SAFE-BioPharma Association incorporated May 2005
 - AstraZeneca
 - GSK
 - Merck
 - P&G
 - BMS
 - J&J
 - Pfizer
 - Sanofi-Aventis

What is SAFE?



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 <div style="background-color: #d9c88f; padding: 5px; text-align: center;">Driving/Incubating Innovation</div> <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

What is SAFE?



Obstacles – 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

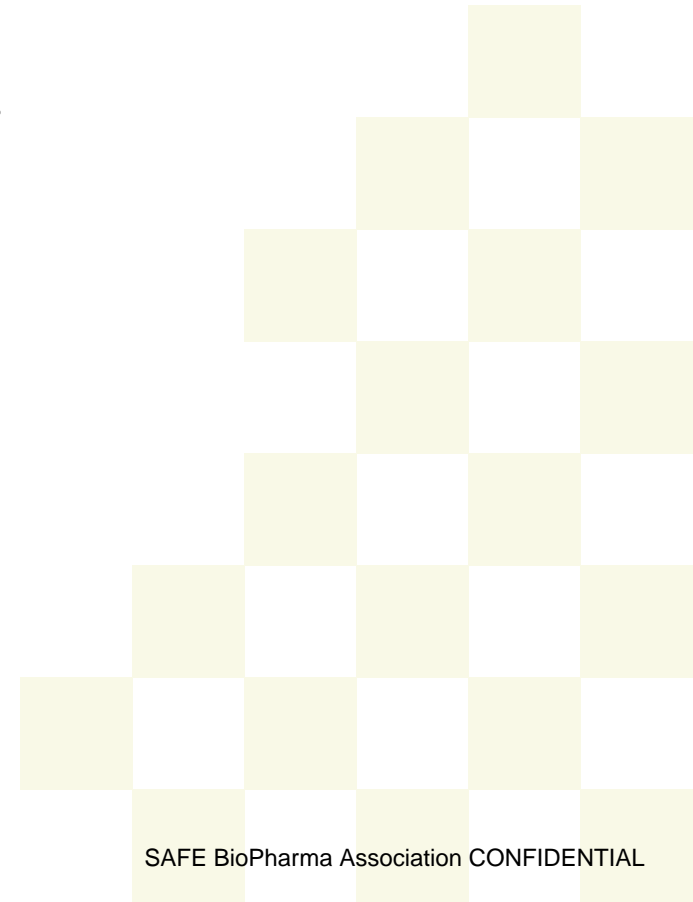


- ▶ Electronic Original vs. electronic Copy, vs. Flattened
- ▶ Business Record Management
- ▶ Paper as original
- ▶ Indexing paper for reuse
- ▶ Rights Management
- ▶ Serialized and Watermarked

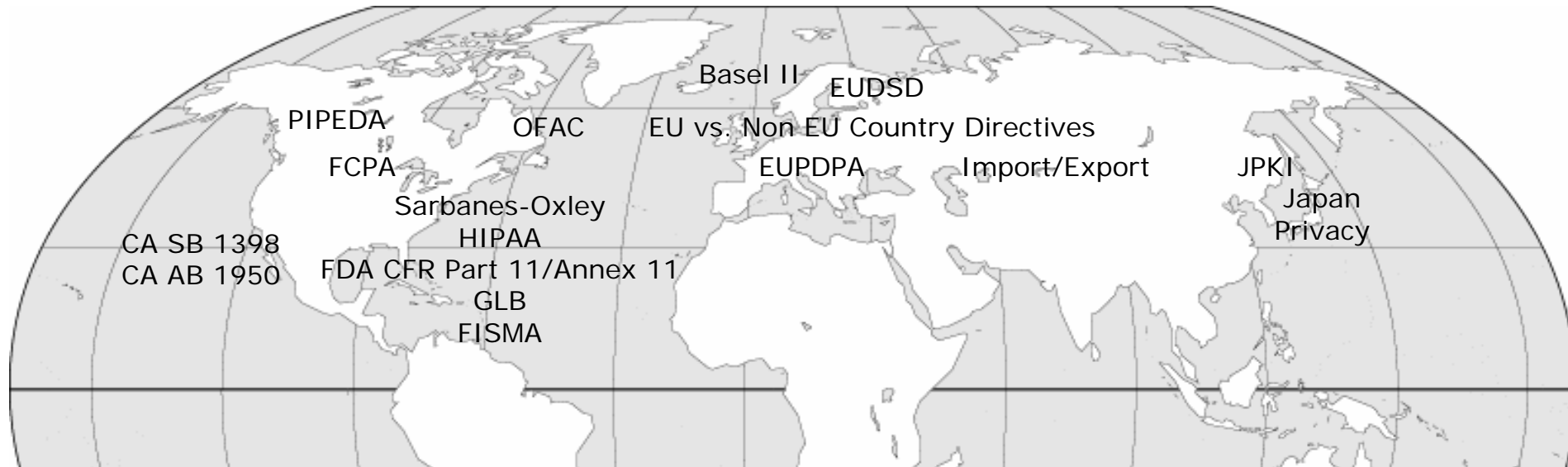
Obstacles – Legal Challenges

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

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



Obstacles – 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**

Solution – SAFE Standard



▶ Business

- Operating Policies
- Agreements (Member, Issuer)
- Processes

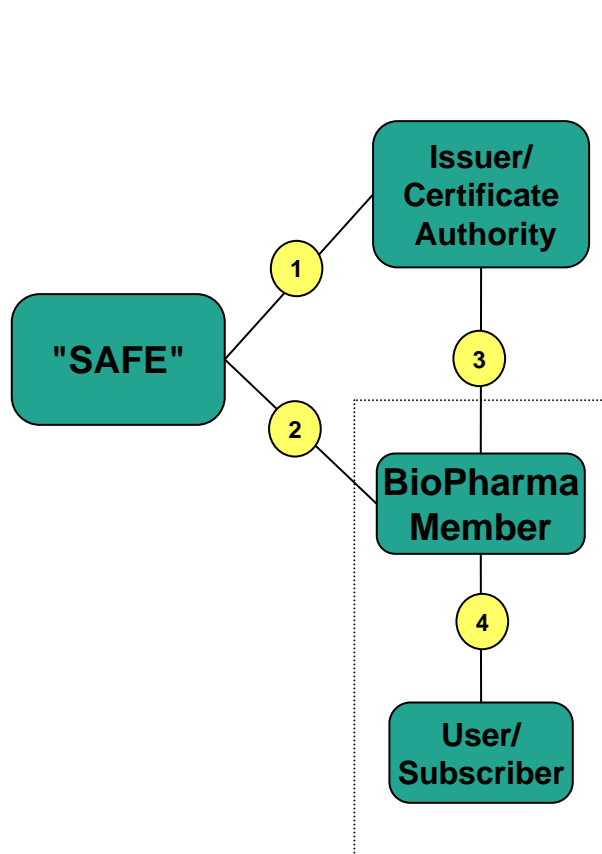
- ***Accept digitally signed transactions***
- ***Agree to limited liability caps***
- ***Agree to dispute resolution process***
- ***Agree to self-audit & meet SAFE requirements***

▶ Technical

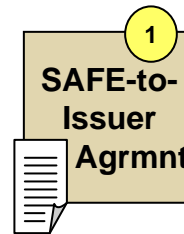
- Certificate Policy
- Specifications
- Guidelines & Guidance

- ***Manage identity life cycle***
- ***Comply with referenced standards***
- ***Follow security, audit & control requirements***
- ***Certification***

Solution - SAFE Global Legal Framework for Enforceability & Risk Management



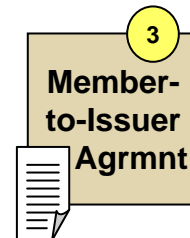
- Closed contractual system
- Defined rights & responsibilities
- International arbitration for dispute resolution



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



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



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

Solution - Identity and Access Management

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

Evidence



Binding/Acceptance

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

What can they Access/Do



Access Management

What was accessed what happened?

Solution - Strength of Evidence

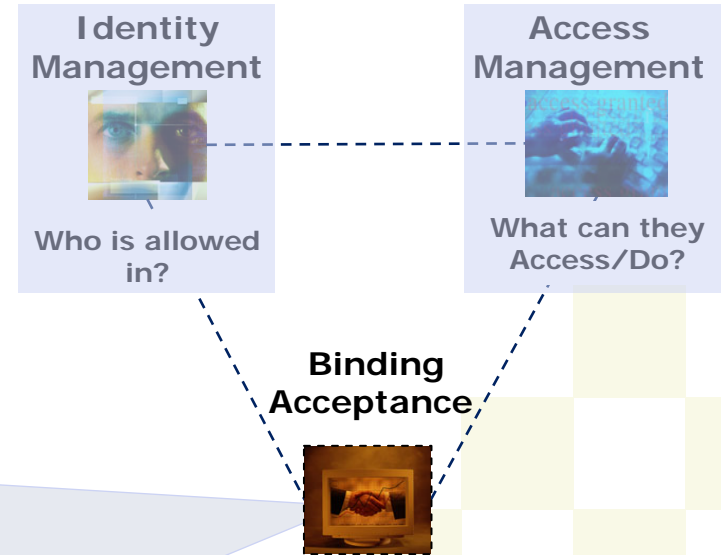


A digital signature is a specialized type of electronic signature

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.

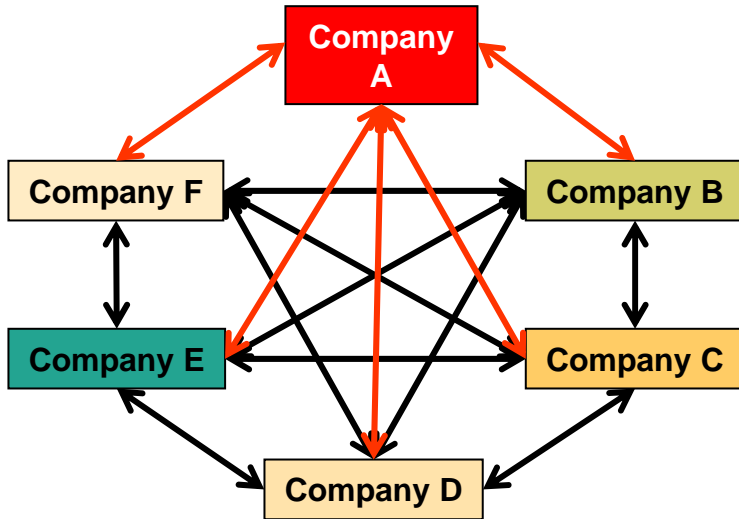
Solution – Records Management

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 ➤ Original, Copy, Flattened 	
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

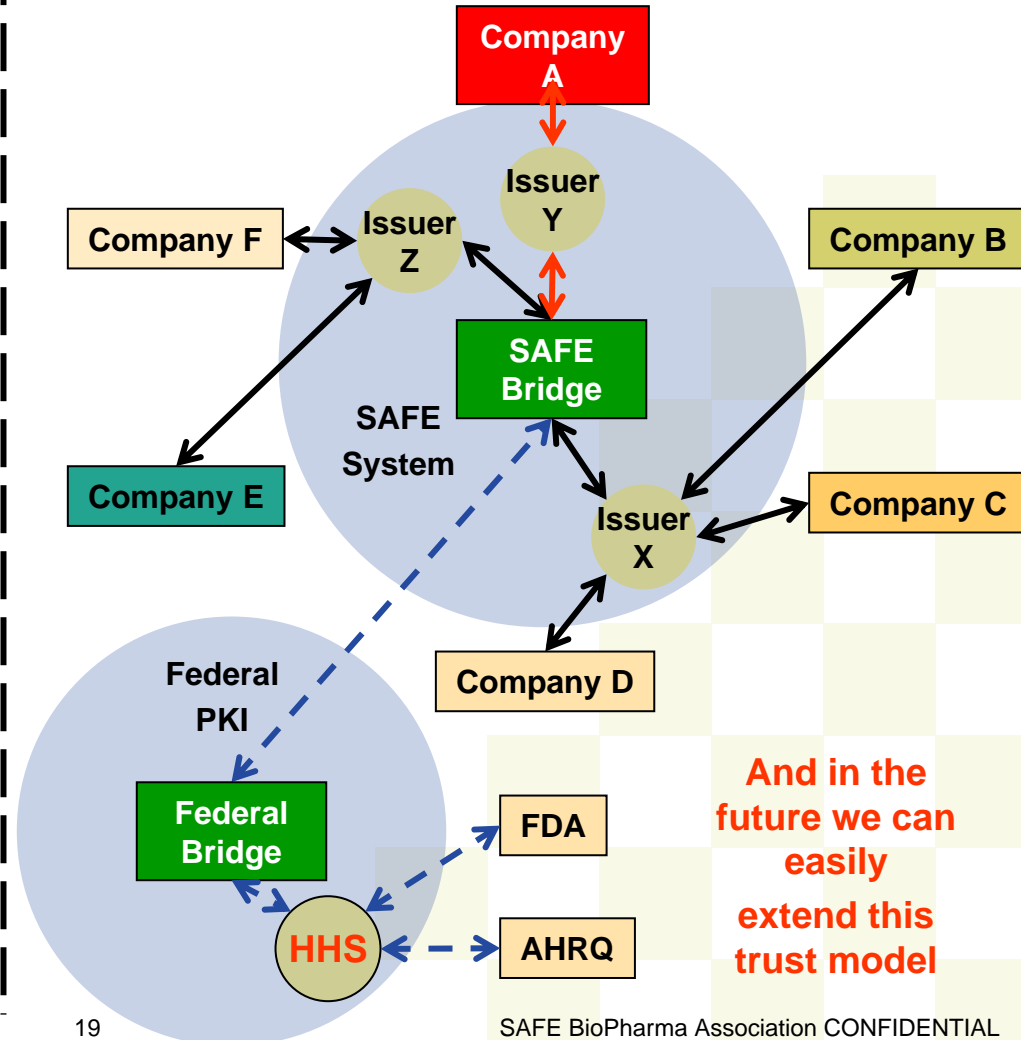


Result – Simplifying Trust

Prior to today establishing trust meant individual agreements



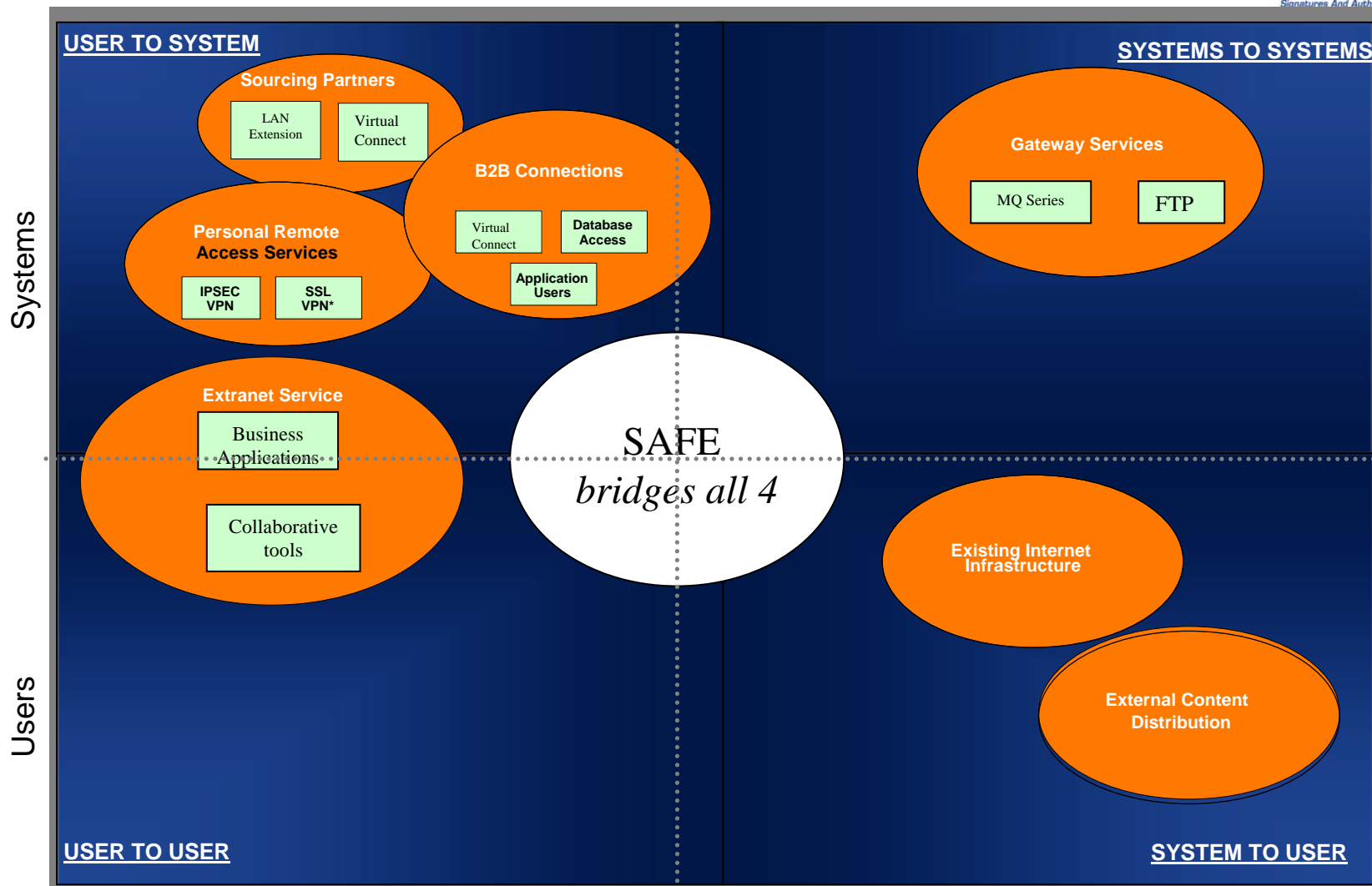
As of today we can bridge trust and reduce complexity



Result – Simplifying Trust



SAFE-BioPharma Association
Signatures And Authentication For Everyone



Third Party Users

Third Party Systems

State of Compliance – Regulator Requirements



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

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.

“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.”

State of Compliance – Regulator Requirements



SAFE and EMEA – PILOT COMPLETE

▶ 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.

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 Initiatives Underway



Pilot

Production

Industry Initiatives

EMEA Secure Document Exchange

Clinical Research Information Exchange Firebird

Samples Portal

FDA Gateway

Company Initiatives

eLab Notebooks (4)

Site Study Initiation (4)

Samples (1)

Technical POC's (4)

eLab Notebooks (1)

Site Study Initiation (3)

FDA Gateway Submission (3)

Enterprise Based

External 3rd Party

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.....

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





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Questions

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