



Identity Management & Digital Signatures in the BioPharmaceutical Industry

John Hendrix; Program Director
CTST 2009



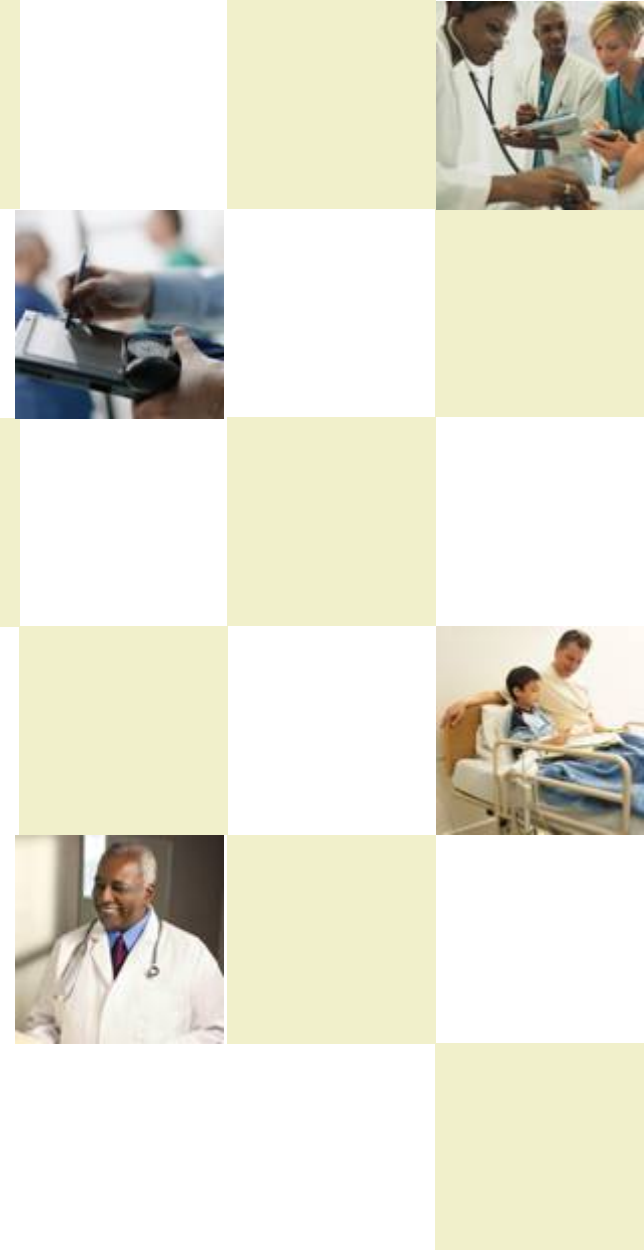
Overview

- ▶ **Conducting Business in the Electronic World**
- ▶ **Regulatory & Legal Issues**
- ▶ **Introduction to SAFE-BioPharma Association**
- ▶ **How SAFE-BioPharma Members Overcome these Hurdles**
- ▶ **Summary**



Conducting Business in the Electronic World

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Business Trends in the Biopharmaceutical Community

▶ 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 must be reduced : 40% of R&D costs; 33% all healthcare costs
- Must look for ways to speed processes

▶ 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.

Business Drivers in the Electronic World

▶ **Business Process Improvement**

- Standards based – Interoperate regardless of technology or vendor
- Identity Management
 - Trust people's identities, how do I know who is on the other end of a transaction
 - Establish risk based methods to confirm and authenticate identity
- Digitally sign documents
 - Eliminate wet signatures
- Eliminate multiple user IDs & passwords

▶ **Regulatory Requirements**

- How is the eCTD implemented?

▶ **Legal Drivers**

- Patent Protection

▶ **Trust/Identity Management Drivers**

- How do I know...

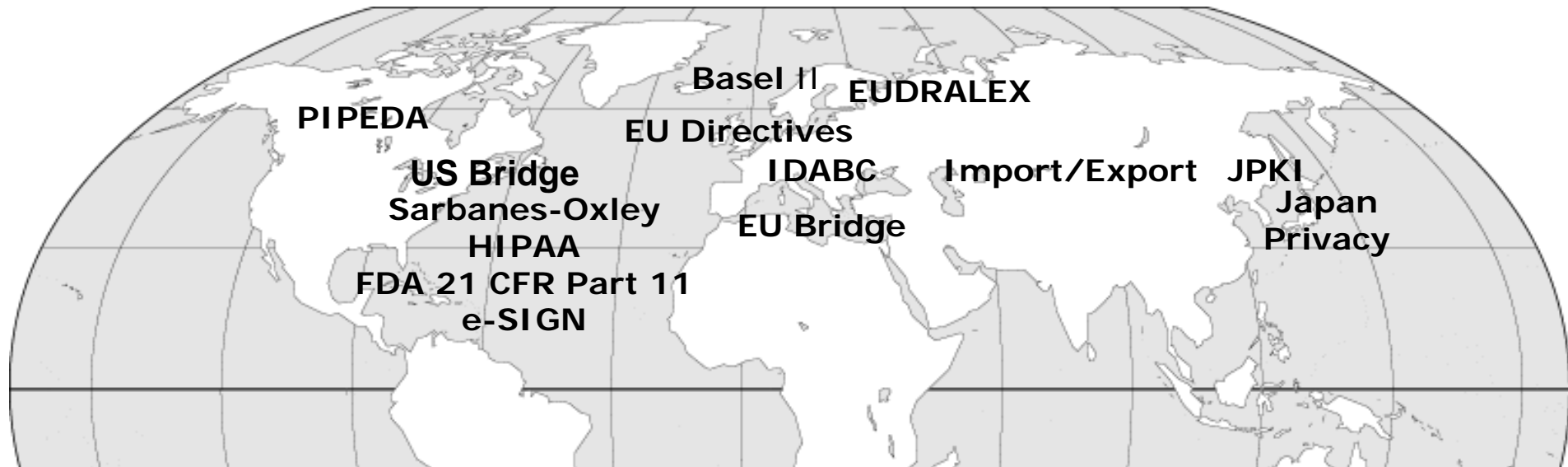
▶ **Interoperability with Business Partners and Regulators**



Regulatory and Legal Issues

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Regulatory Requirements



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

Control Frameworks:
EAL, ETSI, ISO, NIST

E-sig & D-sig Definitions

► What is an Electronic Signature?

- Data in electronic form which is attached to or logically associated with other electronic data and which serve as a method of authentication.
- An electronic sound, symbol, or process, attached to or logically associated with a record and executed or adopted by a person with the intent to sign the record.

► What is a Digital Signature?

- A specific type of Electronic Signature.
 - The Signature is based upon cryptographic methods of originator authentication, computed by using a set of rules and a set of parameters such that the identity of the signer and the integrity of the data can be verified.
- Only specific digital signatures, generated under the requirements of the EU Directive will qualify as an “advanced electronic signature” in the EU
- Only “advanced electronic signature” are legal equivalent of handwritten signatures

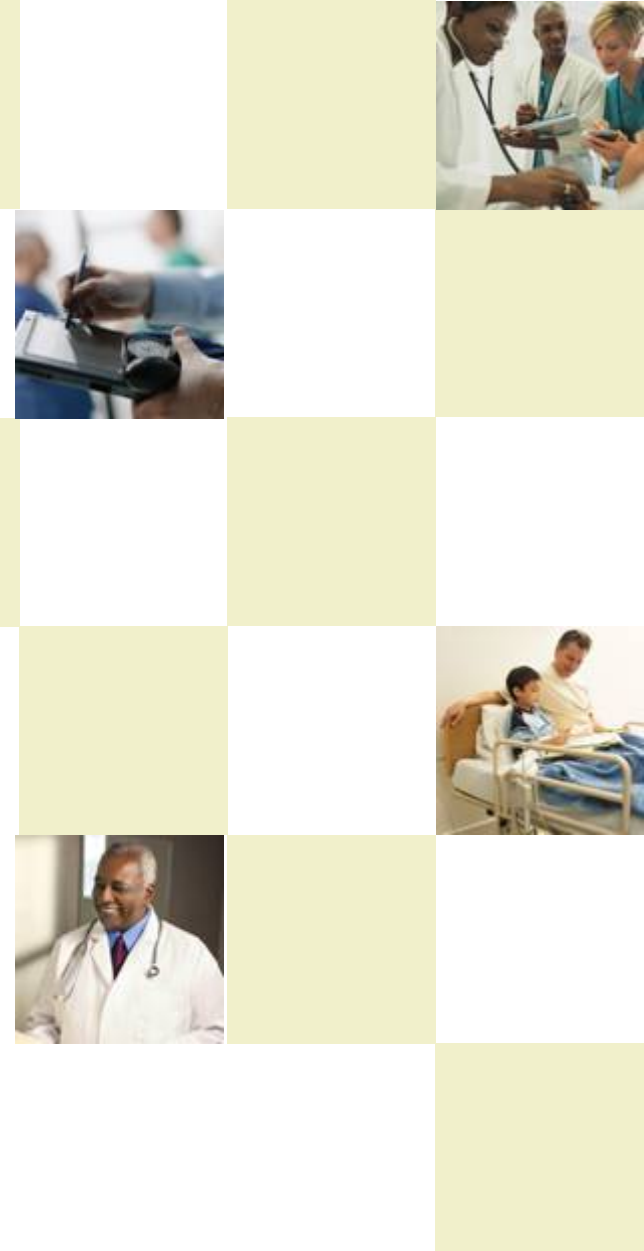
A Comparison of Electronic and Digital Signature Features for the US and EU

Feature	Electronic Signatures	Digital Signatures
Tight binding to the individual through face to face or other strong identity verification	No	Yes
Legally enforceable	Maybe	Yes
Supports strong non-repudiation	No	Yes
Maintains persistence, can be verified after certificate expires	No	Yes
Legal equivalent of hand written signature	Yes	Yes
Scalable	Yes	Yes
Tight binding to document signed (prevent “forgery”)	No	Yes
Detect document tampering	No	Yes



Introduction to SAFE-BioPharma Association

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Who is SAFE-BioPharma?

- ▶ SAFE-BioPharma is a strategic initiative of the global biopharmaceutical industry to facilitate transformation to fully electronic
- ▶ SAFE-BioPharma is a member-governed, not-for-profit enterprise
 - SAFE-BioPharma standard
 - Legal and contractual framework
 - Bridge Trust infrastructure
 - SAFE-BioPharma identity credentials
 - Digital Signatures
 - Authentication
 - Multi-factor
 - SAFE-BioPharma-enabled products
- ▶ SAFE-BioPharma-BioPharma Association
 - **Amgen**
 - **BMS**
 - **Genzyme**
 - **Merck**
 - **Pfizer**
 - **Roche**
 - **AstraZeneca**
 - **GSK**
 - **J&J**
 - **Organon**
 - **P&G**
 - **Sanofi-Aventis**
 - **Premier**
 - **Abbott**
 - **Lilly**
 - **MedNet World**
 - **Novartis**

The SAFE-BioPharma Standard

The SAFE-BioPharma Standard is the Only Complete Set of Managed Business and Technical Policies, Procedures and Agreements for Digital Signing and Authentication in the Global BioPharma and Healthcare Communities to Foster *Interoperability, Regulatory, and Legal Compliance*

Business

- Operating Policies
- Contracts
- Processes

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

Technical & Identity

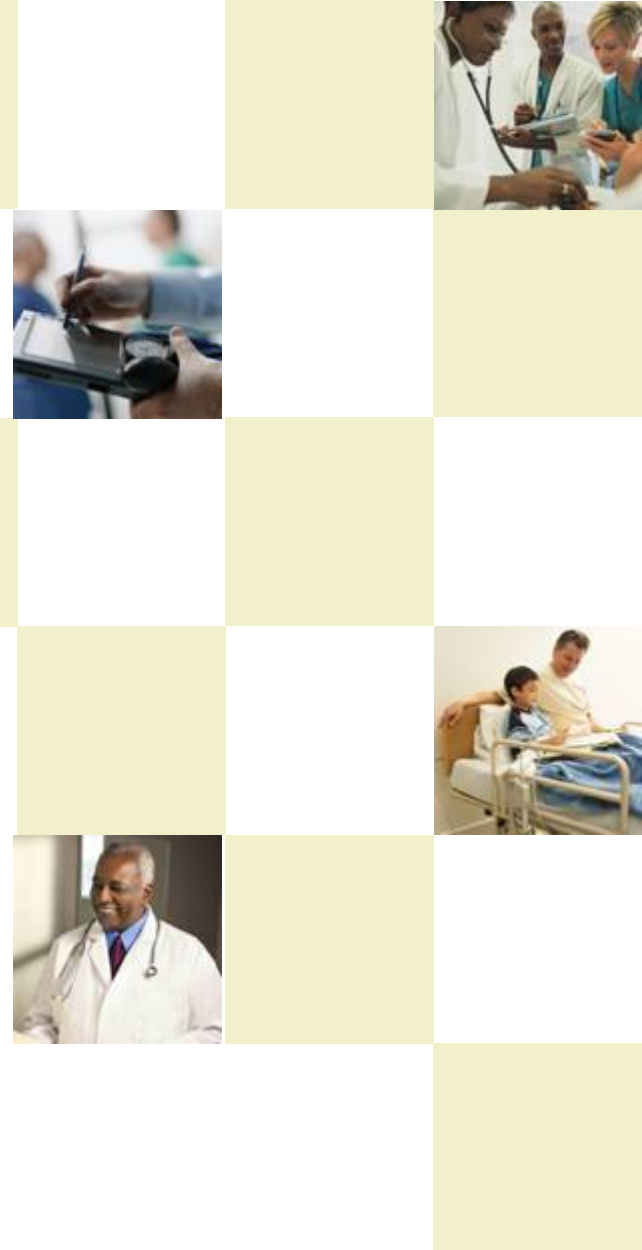
- Certificate Policy (PKI)
- Specifications
- Guidelines

- *Identity verification*
- *Identity life cycle management*
- *Comply with referenced standards*
- *Follow security, audit & control requirements*
- *Certification*

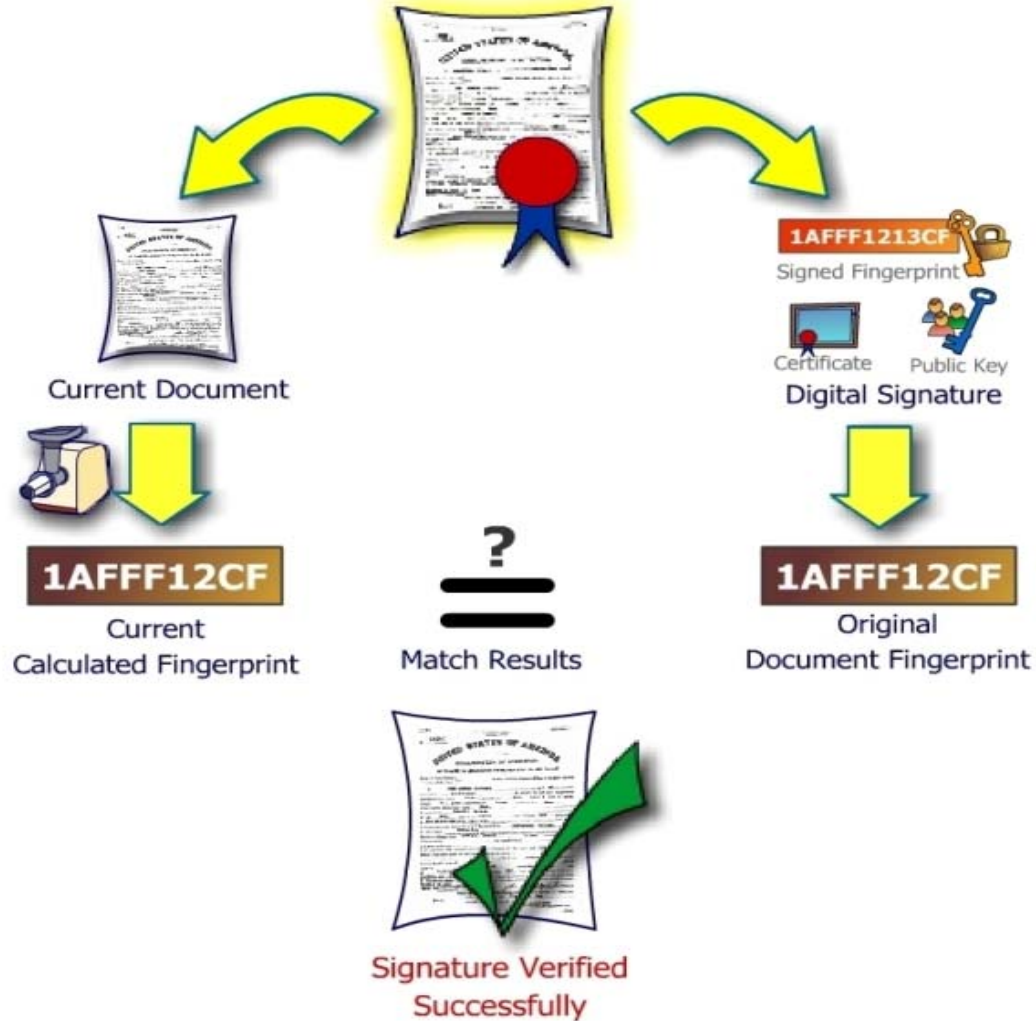


How SAFE-BioPharma Members Overcome These Hurdles

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The SAFE-BioPharma Digital Certificate

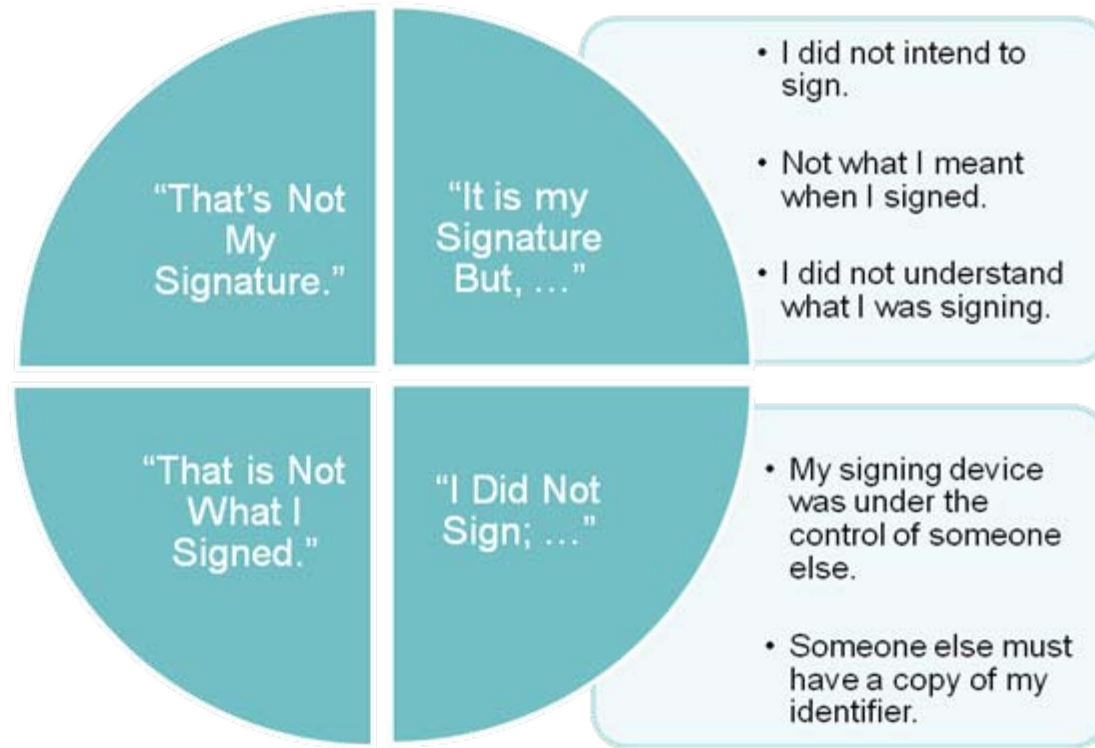




SAFE-BioPharma Association
Signatures and Authentication for Everyone

SAFE-BioPharma Compliant Digital Signatures...

Help Members Overcome the Simple Electronic Signature Shortfalls such as...



...While Enabling 1) Trust and Communication Among Members and All Stakeholders, 2) Platform/Program and Process Interoperability, 3) Regulatory and Legal Compliance, and 4) Risk Mitigation

Organizational Identity Management Issues

➤ Scalability

- Different risk factors may require different levels of certificate
 - Differing methods of identity verification provide the ability to support multiple identity assurance levels

➤ Flexibility

- Two assurance levels, based on the identity verification process, and four certificate types
 - Basic Assurance Software, Medium Assurance Software, Medium Assurance Hardware, Roaming Digital ID (Medium Assurance Software)
- As the level rises, so does the ability to strongly assert the identity

➤ Collaborative development and partnering opportunities

- Access to partner systems
- User name and password management

➤ Requirements for electronic submissions and electronic records

- Agencies establish e-submission guidance and regulations

➤ Current hybrid systems do not support

- Most built around scanned signatures to PDF but still require paper retention



Options for Flexible Use

▶ **Two levels of trust:**

- Basic Assurance for authentication
- Medium Assurance for trusted identity uniquely linked to authentication, digital signature and EU-qualified

▶ **Three digital signing technologies:**

- Software
- Hardware (zero footprint now undergoing FIPS certification)
- Roaming

▶ **Three identity-proofing options**

- Antecedent – enterprise and on-line
- Trusted agent
- Notary – including office/home notary services



Member Public Key Infrastructure Options

▶ Internal infrastructure

- Cross certified with SAFE Bridge
- BMS, J&J – soon others

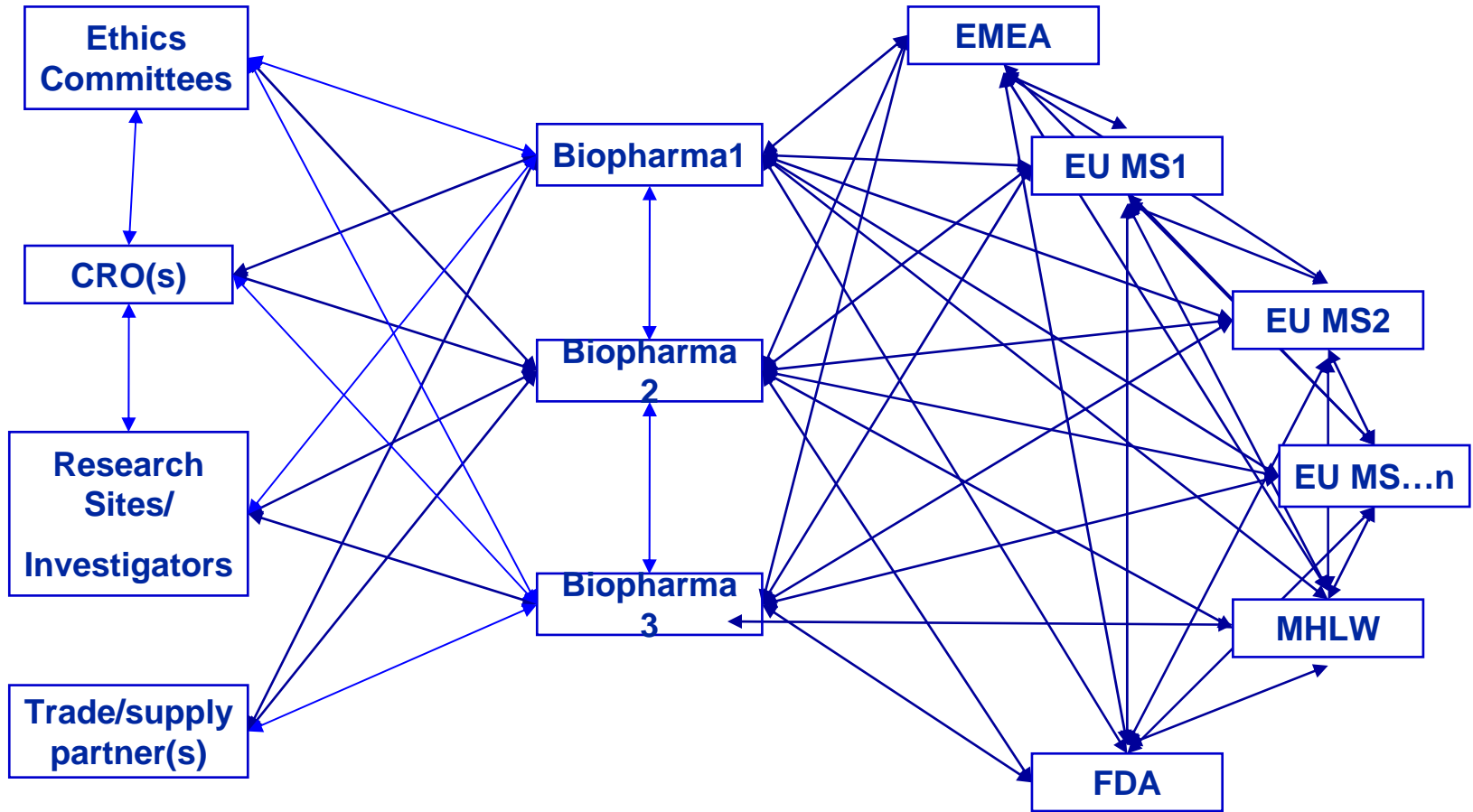
▶ Outsourced infrastructure

- Cross-certified with SAFE Bridge:
 - Chosen Security
 - Citibank
 - IdenTrust
 - Trans Sped
 - Verizon Business/Cybertrust

▶ SAFE tiered services infrastructure (member-funded)

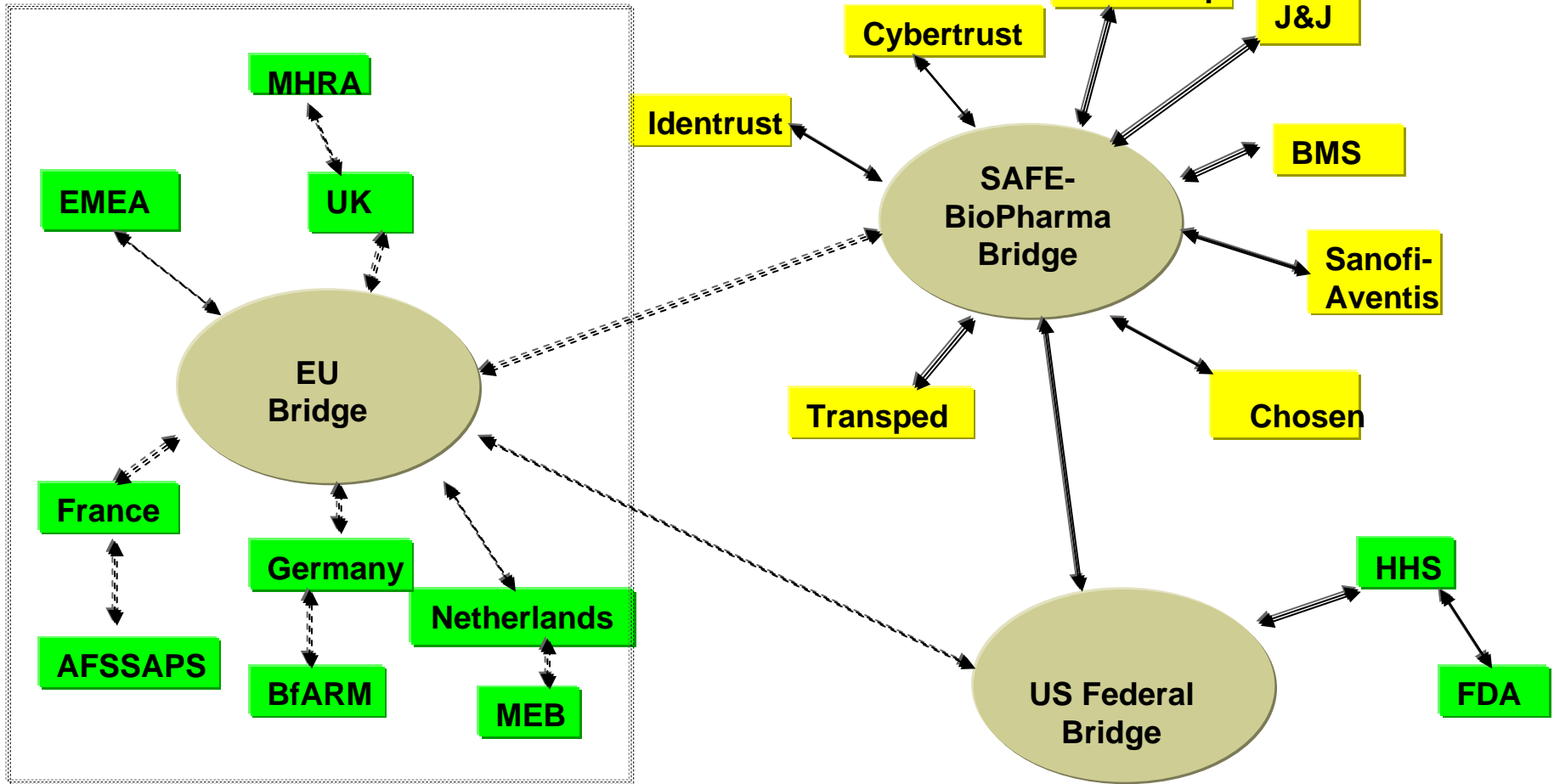
- External partners
- Regulatory uses
- Healthcare providers
- Members

The Global BioPharma eBusiness Challenge



If tackled independently → recipe for management nightmare

Simplifying Trust





SAFE-BioPharma Pilots & Implementations

Organization	Pilots and Implementations
Abbott	ELN
Amgen	ELN, Clinical Research Info Exchange (CRIX)
AstraZeneca	ELN, eSubmissions (US); Investigator Portal; Global infrastructure
BMS	ELNs; Promotional material review (EU); eSubmissions; alliances
CDC-MedNet-SAFE-BioPharma	Cross-jurisdictional public health-disease surveillance
EMA	EudraVigilance; eCTDs, regulatory submissions
GSK	eSubmissions, R&D docs; Global infrastructure
J&J	90,000+ employees; eSubs; External partners; Records
Eli Lilly	eSubmissions
Merck	ELN
National Notary Association	Digital Notary Signature
Pfizer	ELNs; eSubmissions; contracts/SOWs; investigator portal
P&G	ELNs; contracts; HR
Premier	Supplier and member contracts
Sanofi-Aventis	ELNs, eSubmissions; Finance and Purchasing

Summary

SAFE-BioPharma meets Requirements for ubiquitous IT adoption

- ▶ **An Identity Management Trust Infrastructure**
 - Mitigate risk – Secure infrastructure that ensures privacy & confidentiality
- ▶ **Business process improvement for both industry and regulators**
 - Reduce cost
 - Increase productivity
 - Reduce cycle times
- ▶ **Mandated globally accepted standards**
- ▶ **Develop Global Regulatory compliance strategy**
- ▶ **Vendor/technology neutral – interoperable**
- ▶ **Legally enforceable**
- ▶ **Collaborate with Healthcare industry**