



# Identity Management & Digital Signatures in the BioPharmaceutical Industry

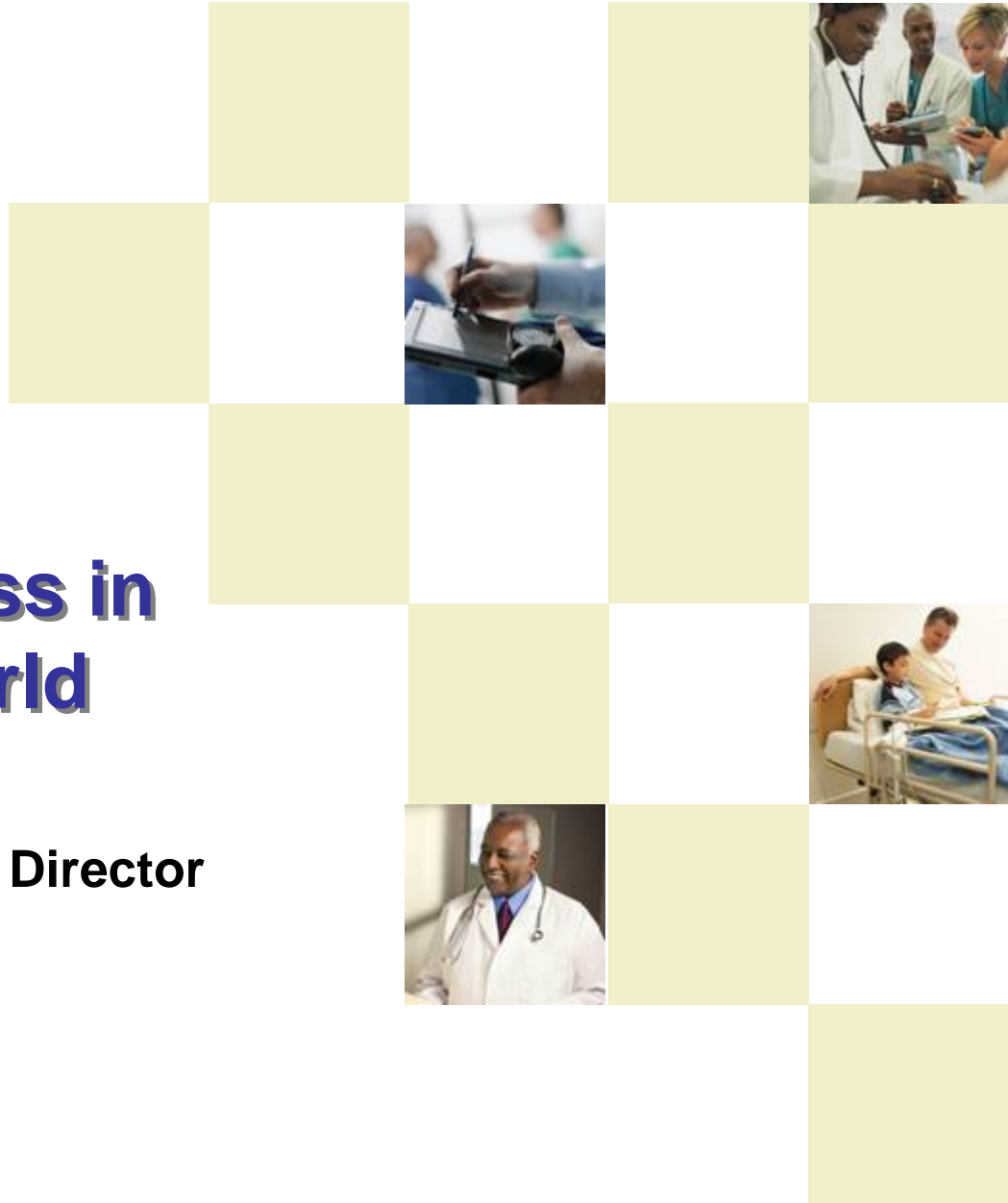
**John Hendrix; Program Director**

**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?

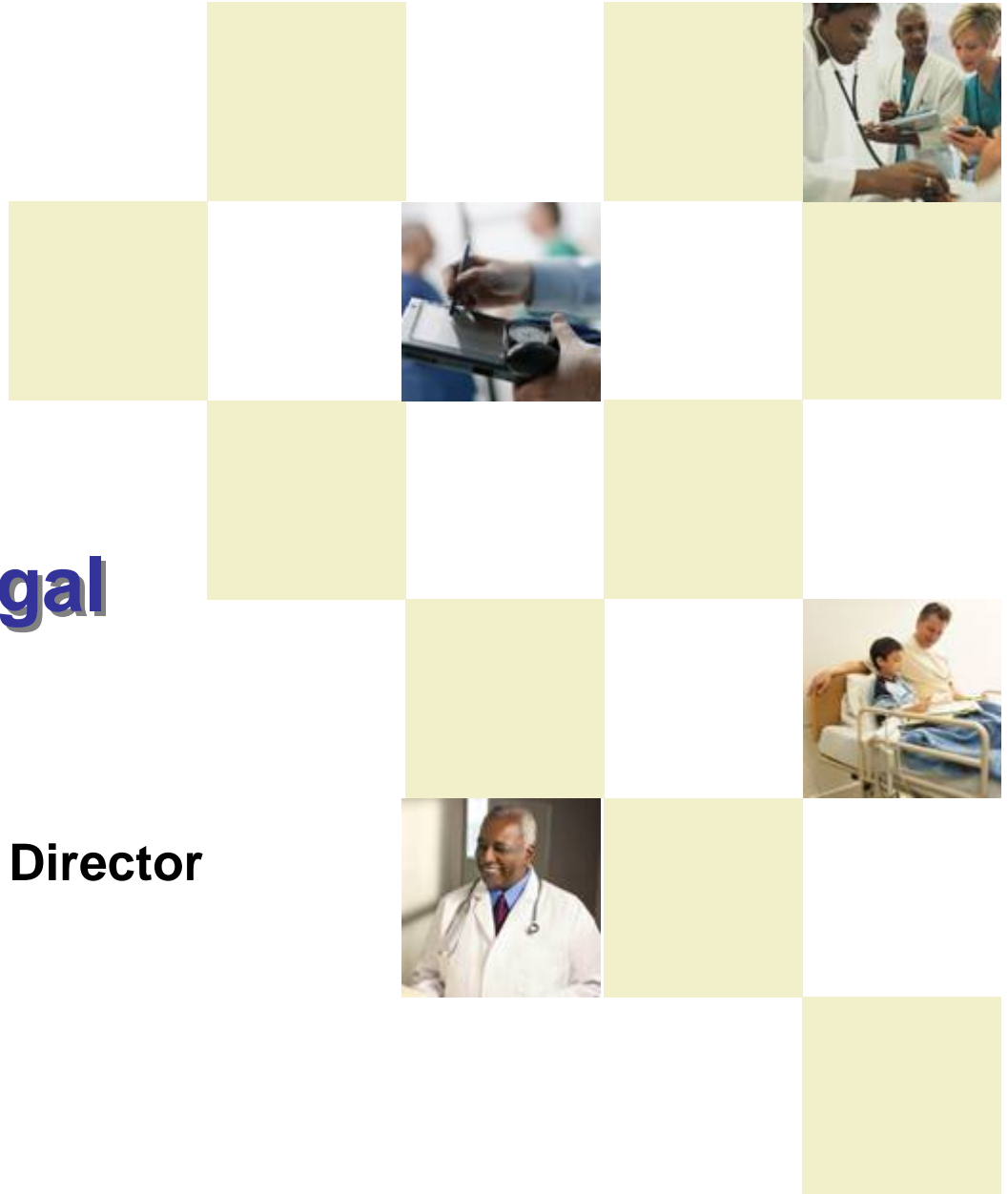
## ▶ **Legal Drivers**

- Patent Protection

## ▶ **Trust/Identity Management Drivers**

- How do I know...

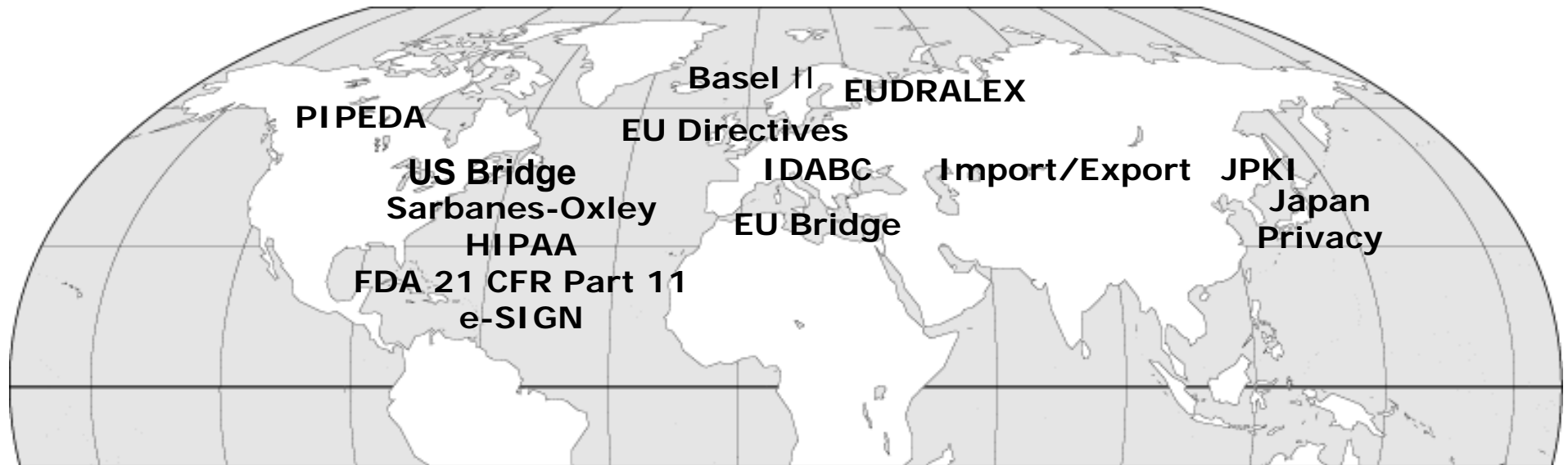
## ▶ **Interoperability with Business Partners and Regulators**



# 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.

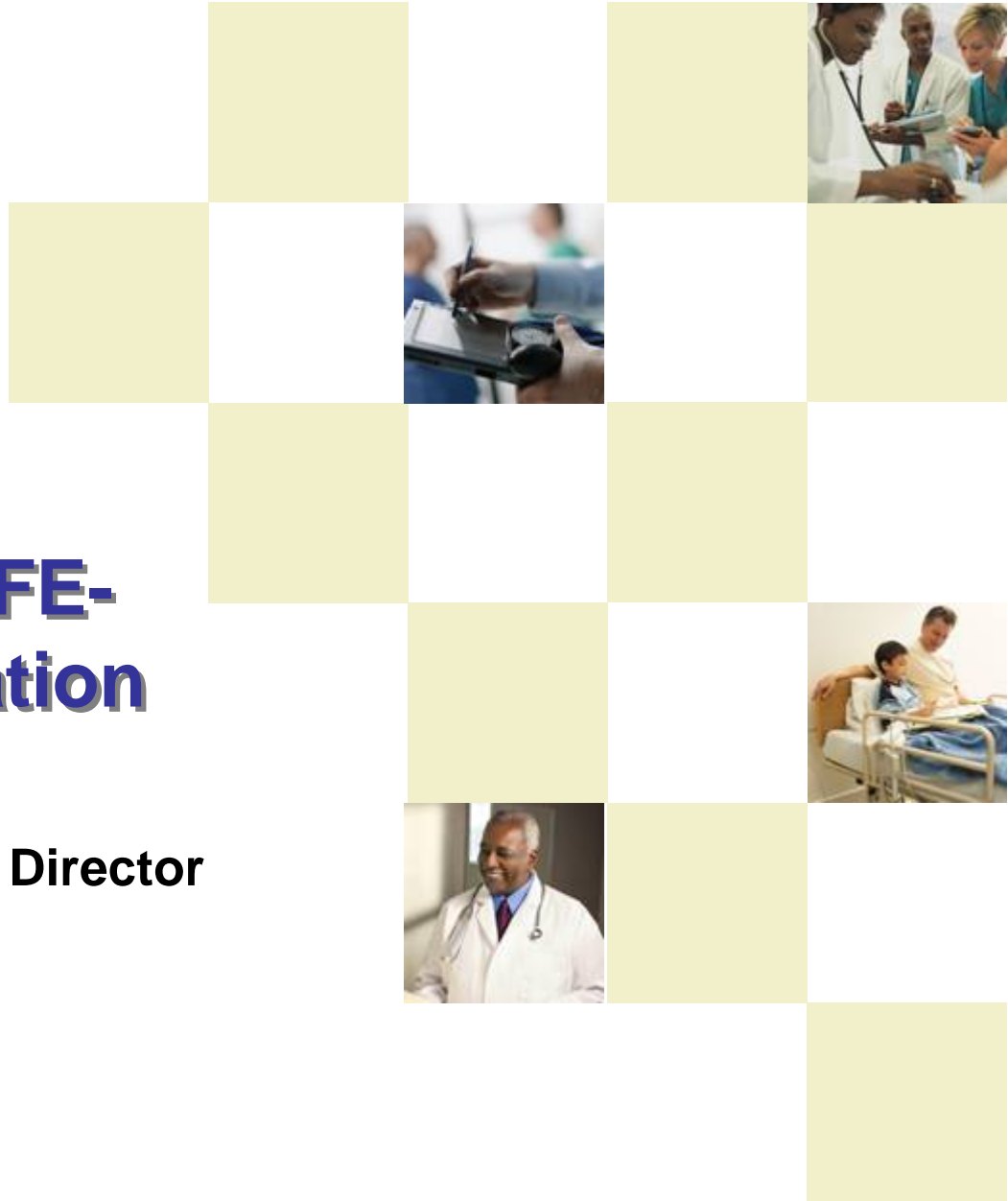
## ► What is a Digital Signature?

- 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

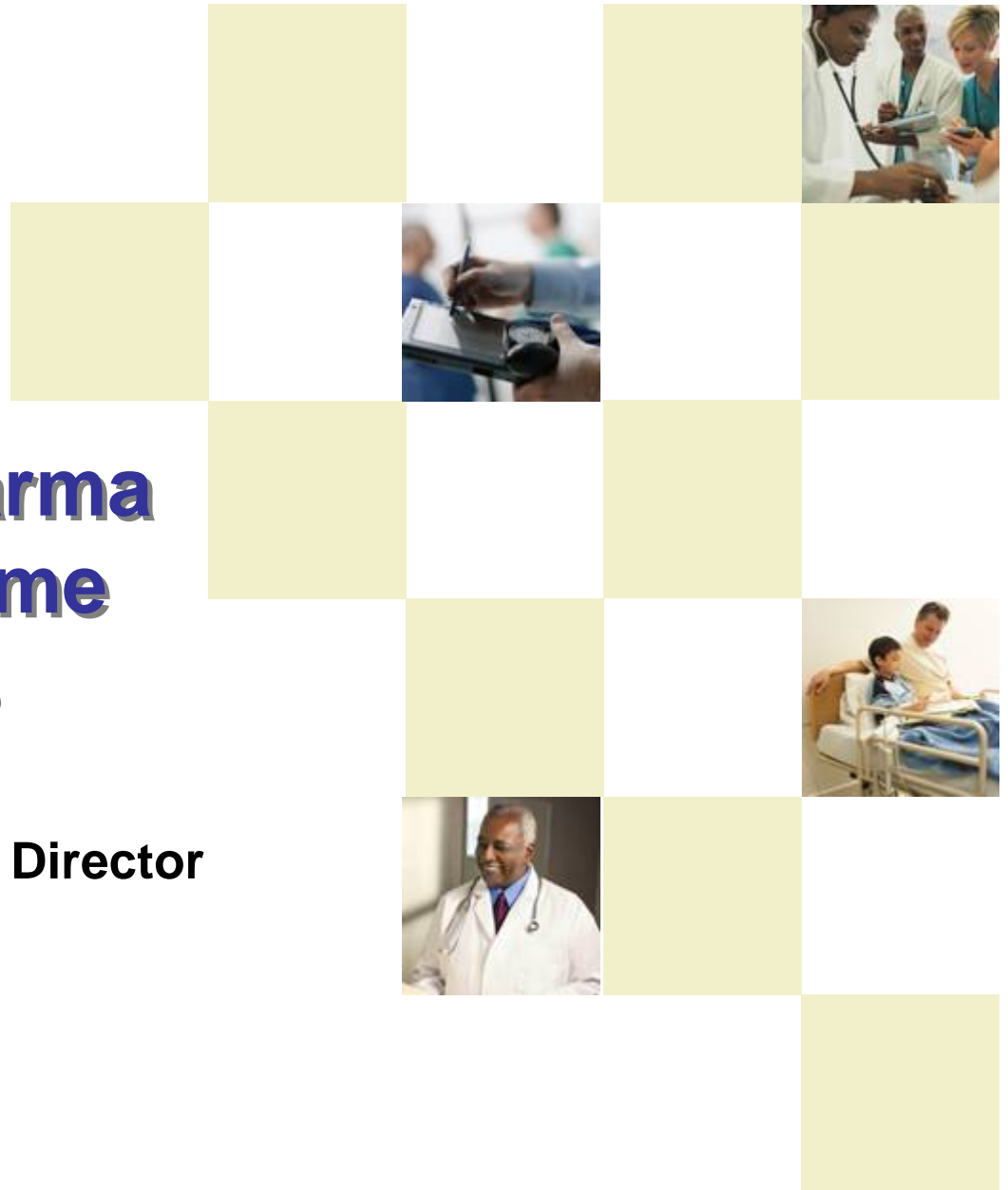
- Certificate Policy (PKI)
- Specifications
- Guidelines

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

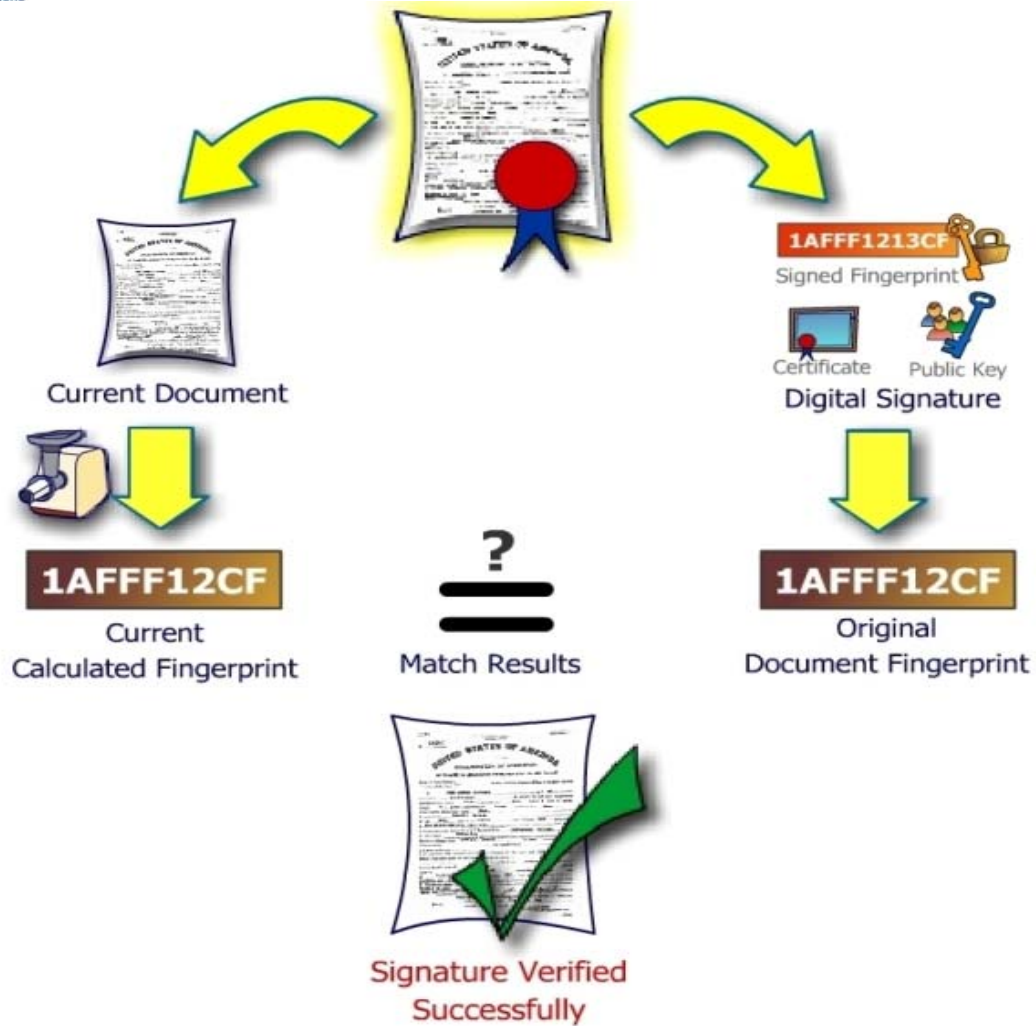


# How SAFE-BioPharma Members Overcome These Hurdles

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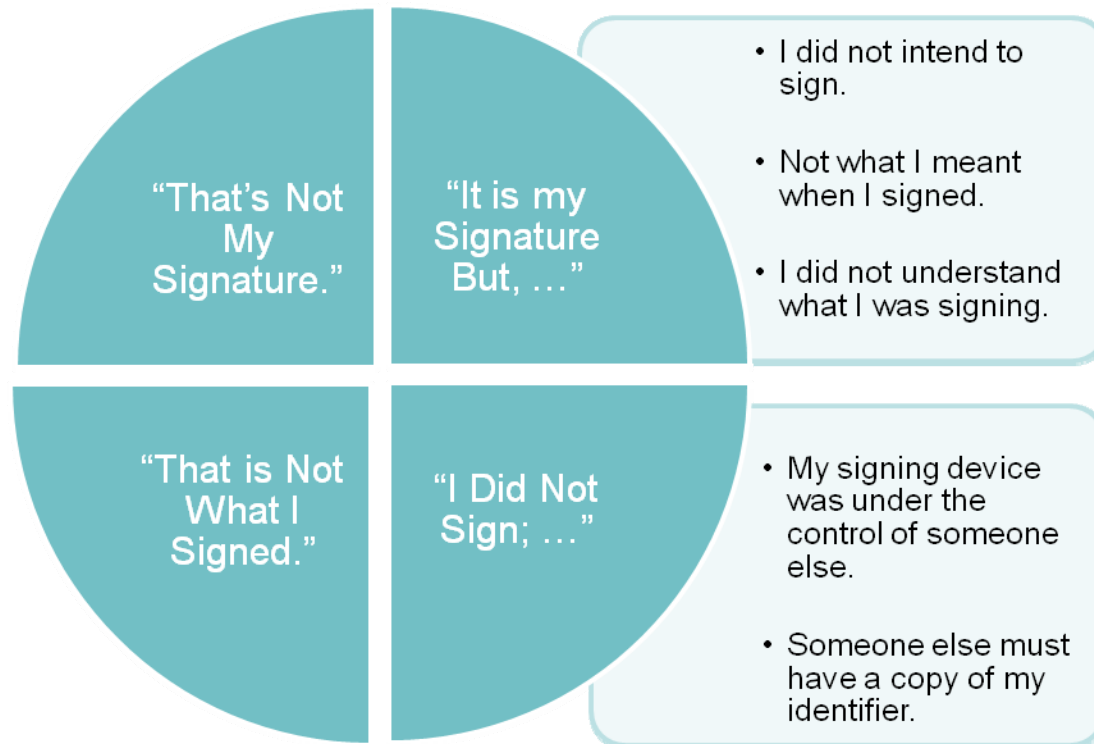
# The SAFE-BioPharma Digital Certificate





# SAFE-BioPharma 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

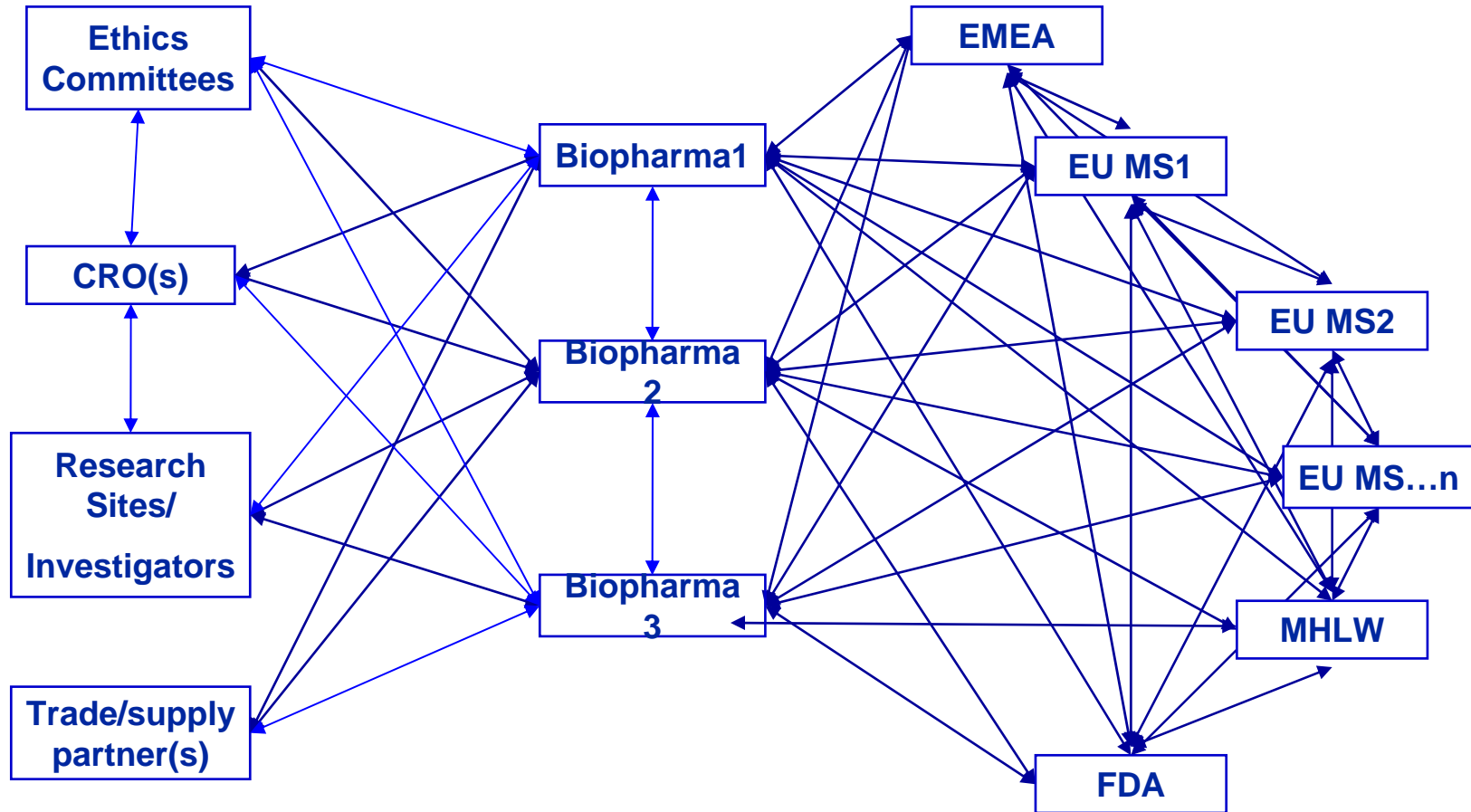
- Cross-certified with SAFE Bridge:
  - Chosen Security
  - Citibank
  - IdenTrust
  - Trans Sped
  - Verizon Business/Cybertrust

## ▶ SAFE tiered services infrastructure (member-funded)

- External partners
- Regulatory uses
- Healthcare providers
- Members

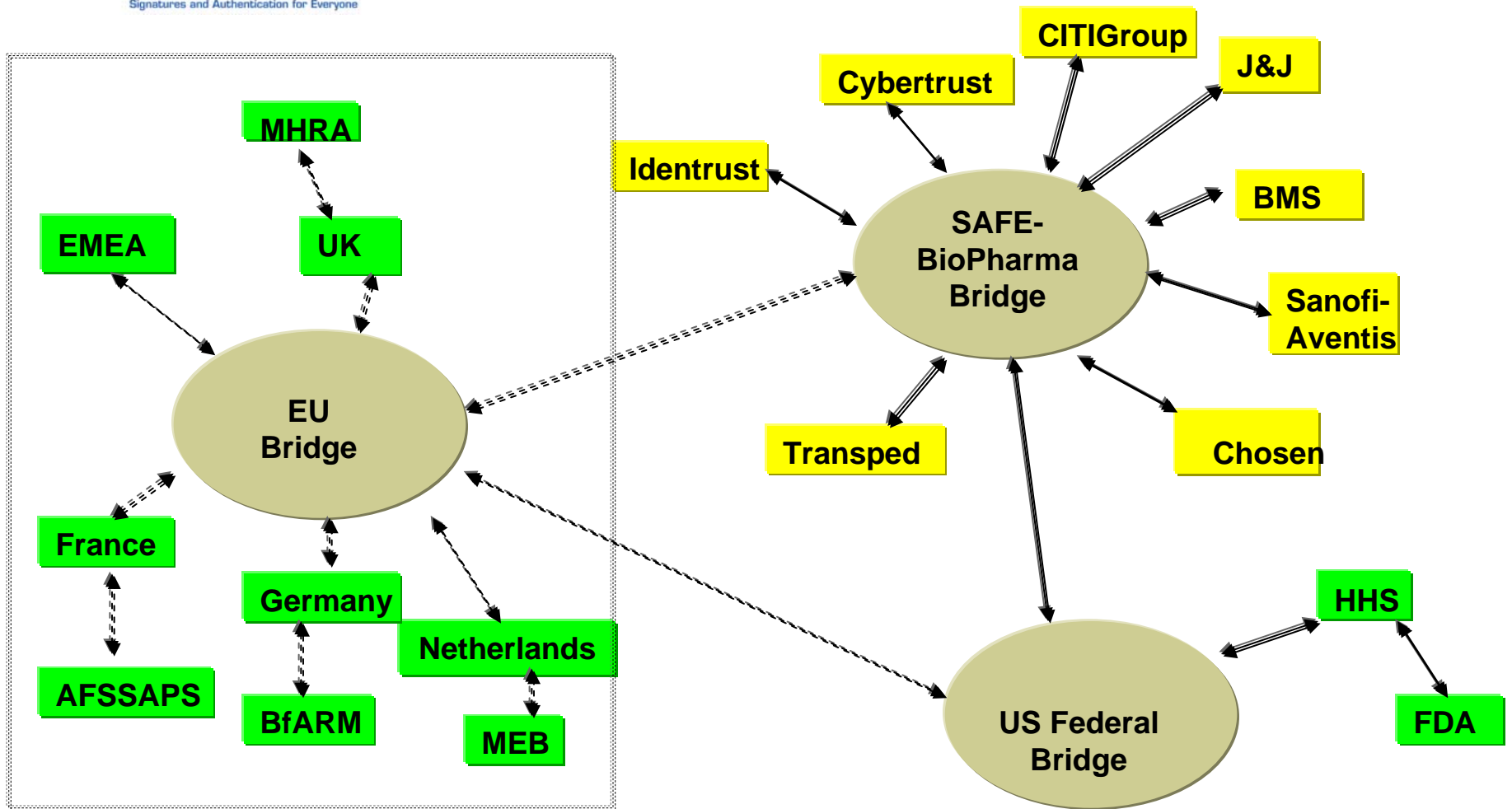


# The Global BioPharma eBusiness Challenge



***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**