



Signatures and Authentication For Everyone

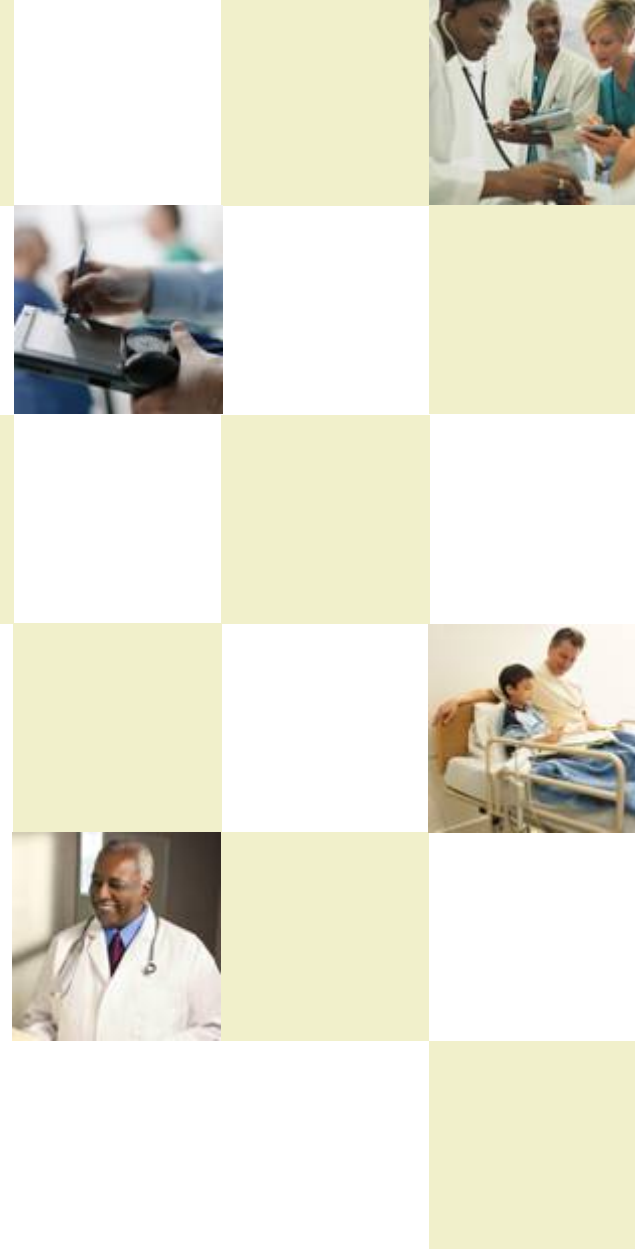
SAFE-BioPharma Association: FDA IT Strategy

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Agenda

- **Introduction to SAFE Bio-Pharma Association**
- **Business Paradigm**
- **Process Improvement**
- **Industry wants/needs**
- **Legal & Regulatory Implication**
- **Strategic Directions for Industry**
- **Questions?**



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SAFE Bio-Pharma Association

- ▶ SAFE is a strategic initiative of the global biopharmaceutical industry to facilitate transformation to fully electronic
- ▶ SAFE is a member-governed, not-for-profit enterprise
 - SAFE standard
 - Legal and contractual framework
 - Bridge Trust infrastructure
 - SAFE identity credentials
 - Digital Signatures
 - Authentication
 - Multi-factor
 - SAFE-enabled products
- ▶ SAFE Bio-Pharma Association

- | | |
|-----------|------------------|
| • Amgen | - AstraZeneca |
| • BMS | - GSK |
| • Genzyme | - J&J |
| • Merck | - Organon |
| • Pfizer | - P&G |
| • Roche | - Sanofi-Aventis |

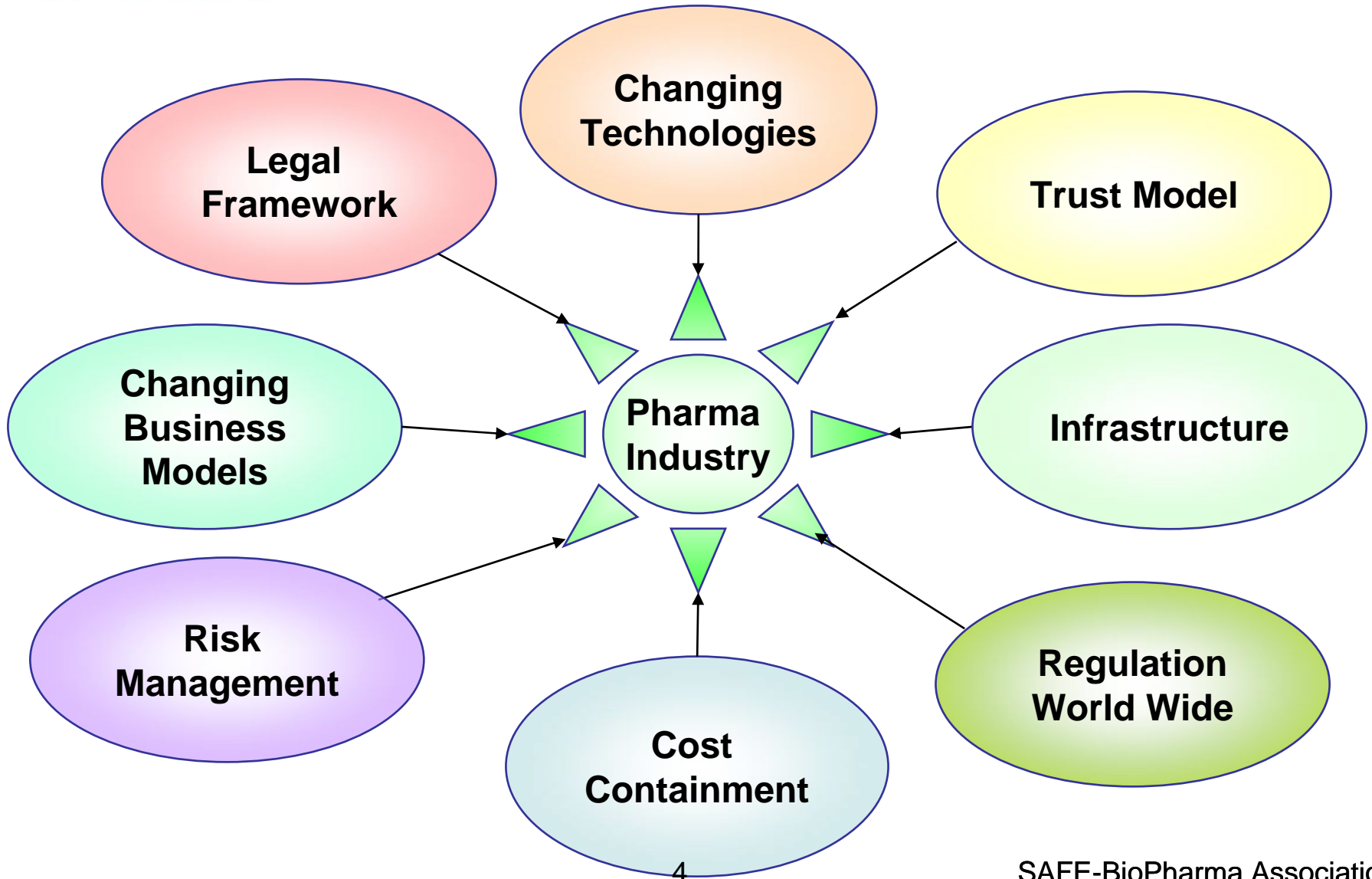
SAFE Founders





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Business Paradigm





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Pain Points

- ▶ **Global Regulatory Challenges**
- ▶ **Trust/Identity Management Challenges**
- ▶ **Interoperable**
- ▶ **Legally enforceable**
- ▶ **Mitigate risk – Security, privacy, confidentiality, cost, etc. ...**
- ▶ **Business process improvement**
 - Reduce cost
 - Increase productivity
 - Reduce cycle times



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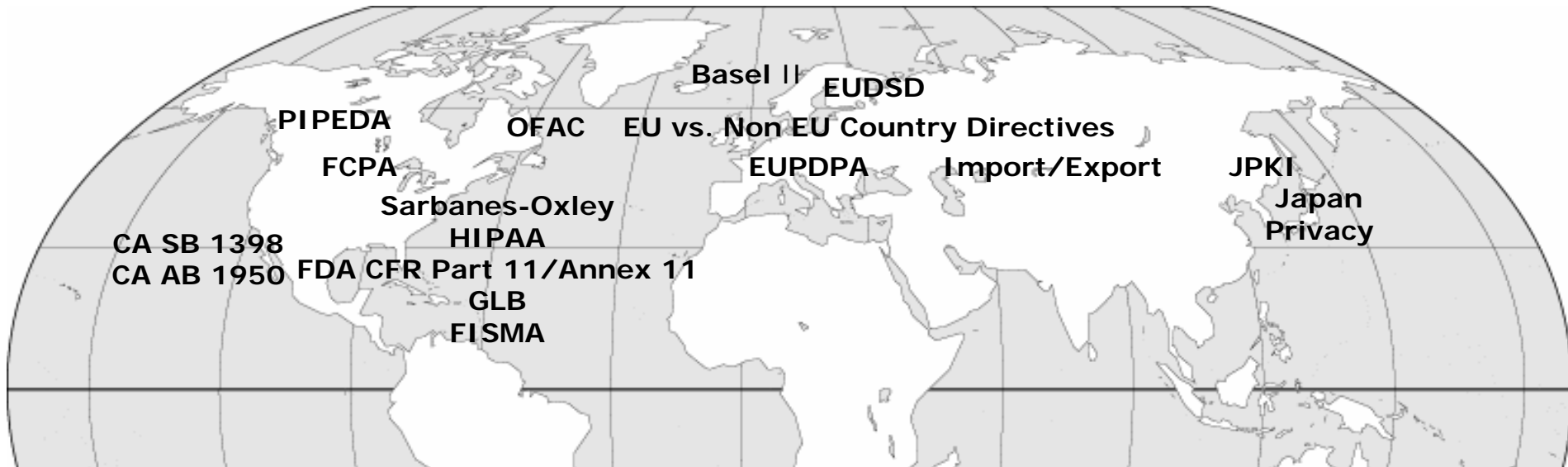
Process Improvement

- ▶ **High cost due to paper**
- ▶ **\$1 Billion/yr on Identity Management**
 - 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
- ▶ **Streamlining Processes**
 - Moving paper to electronic business processes
 - Eliminating re-entry of data
 - Minimize need for signatures
 - Approval/authorization is sufficient
 - Authentication standardization
 - Work Right Initiatives
 - Six Sigma/Lean



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Regulatory Challenges



- ▶ 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:
COBIT ISO 17799 NIST



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SAFE Member Implementations

▶ Pfizer:

- eLab Notebooks
- Regulatory submissions

▶ AstraZeneca:

- Regulatory submissions via FDA's ESG: 2252, 1571, 356h and eCTD

▶ GSK:

- eCTD submissions

▶ BMS:

- External partner authentication
- e Lab Notebooks

▶ J&J:

- Cross-certified with SAFE Bridge; digital signatures are SAFE signatures
- Regulatory submissions
- External Partner Authentication

▶ P&G:

- 4,500 eLab Notebooks
- ePurchasing
- eHR – forms
- ePatent Filings
- eManufacturing

▶ Organon-Merck: alliance

▶ Amgen:

- Clinical research -- investigators

▶ NCI, Amgen, Pfizer, Merck, Sanofi-Aventis, and Genzyme – Firebird -- 1572s

▶ Pfizer, BMS, P&G, CRIX, SanofiAventis – cross-certifying with SAFE



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The SAFE Vision...

- ▶ **Business Process Improvement:**
 - Standards based – Interoperate regardless of technology or vendor
 - Identity Management
 - Trust people's identities
 - Digitally sign documents – Eliminate wet signatures
 - Eliminate multiple userIDs & passwords

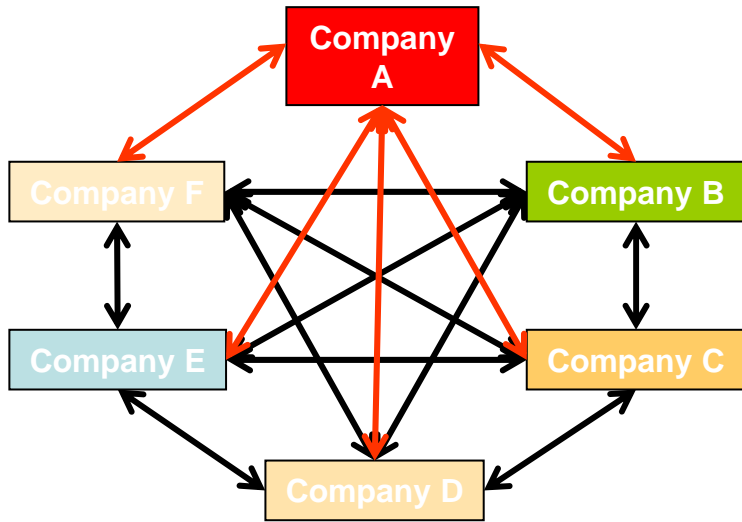
- ▶ **Business Process that are:**
 - Faster; Secure
 - More productive
 - More accurate

- ▶ **Delivery of medicines would be faster and safer**

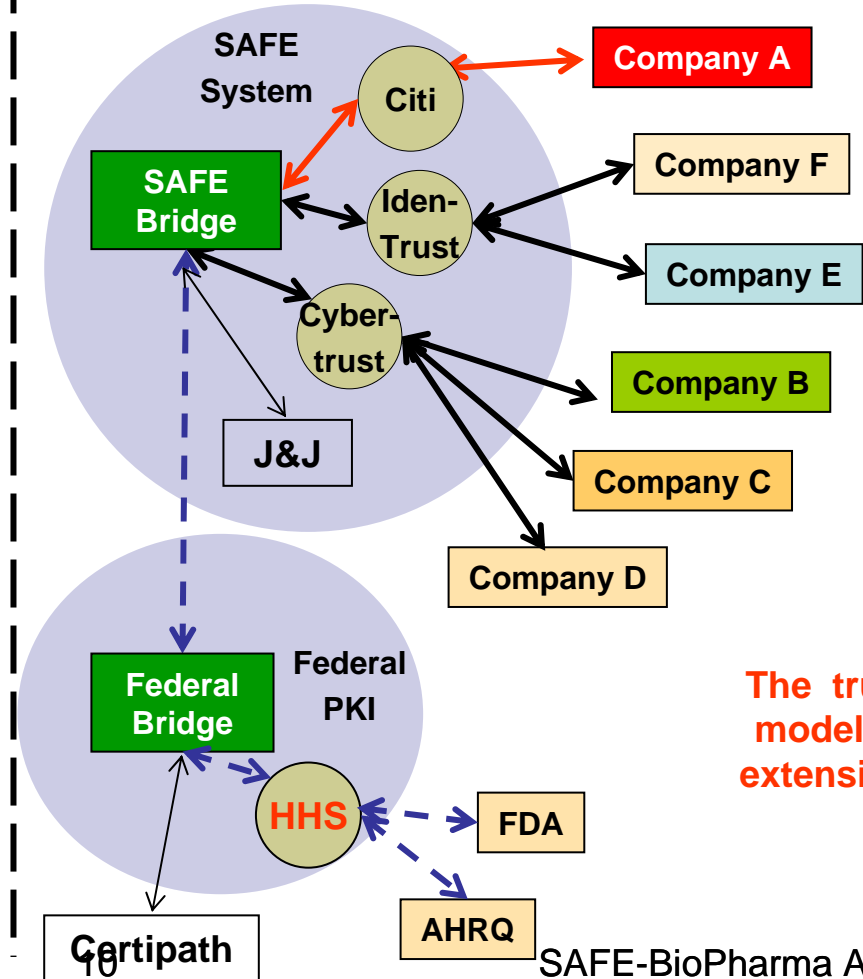


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Simplifying Trust



Bridges trust and reduces complexity



The trust model is extensible



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Recommendations Regarding Electronic Submissions

- ▶ **Promulgate specific regulatory requirements for digital signatures and/or recognize standards meeting those requirements:**
 - Amend 21CFR Part 11 to require implementation of a digital signature standard;
 - Map identity and authentication requirements to Federal Common Policy and requirements of Federal Bridge Certification Authority;
 - Require identity assurance at medium assurance level;
 - Require multi-factor authentication.

- ▶ **FDA requirements or standards recognition will:**
 - Provide an interoperable standard to replace existing profusion of signatures/identities;
 - Provide high trust assurance, non-repudiation, security, record integrity, and legal enforceability; and
 - Provide ability for FDA to generate standard audit methodology.



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Recommendations Regarding Electronic Submissions

- ▶ **Provide incentives for electronic submissions such as:**
 - FDA commitment to faster review cycles for fully electronic submissions;
 - Preferential review to electronic submissions over paper submissions (when all other factors are equal);
 - Publish future dates by which:
 - Paper submissions will no longer be accepted;
 - Hybrid submissions will no longer be accepted; and
 - All submissions must be fully electronic.

- ▶ **Such incentives will:**
 - Provide clear timeline for electronic implementation; and
 - Send clear message of importance/priority Agency places on electronic receipt and review;
 - Provide an orderly transition.



Summary

Requirements for ubiquitous IT adoption

- ▶ **Business process improvement**
 - Reduce cost
 - Increase productivity
 - Reduce cycle times
- ▶ **Mandated globally accepted standards**
- ▶ **Develop Global Regulatory compliance strategy**
- ▶ **Collaborate with Healthcare industry**
- ▶ **Vendor/technology neutral – interoperable**
- ▶ **Designed to support legally enforceability**
- ▶ **A Trust Infrastructure – Identity management infrastructure**
- ▶ **Mitigate risk – Secure infrastructure that ensures privacy & confidentiality**



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Questions?

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