



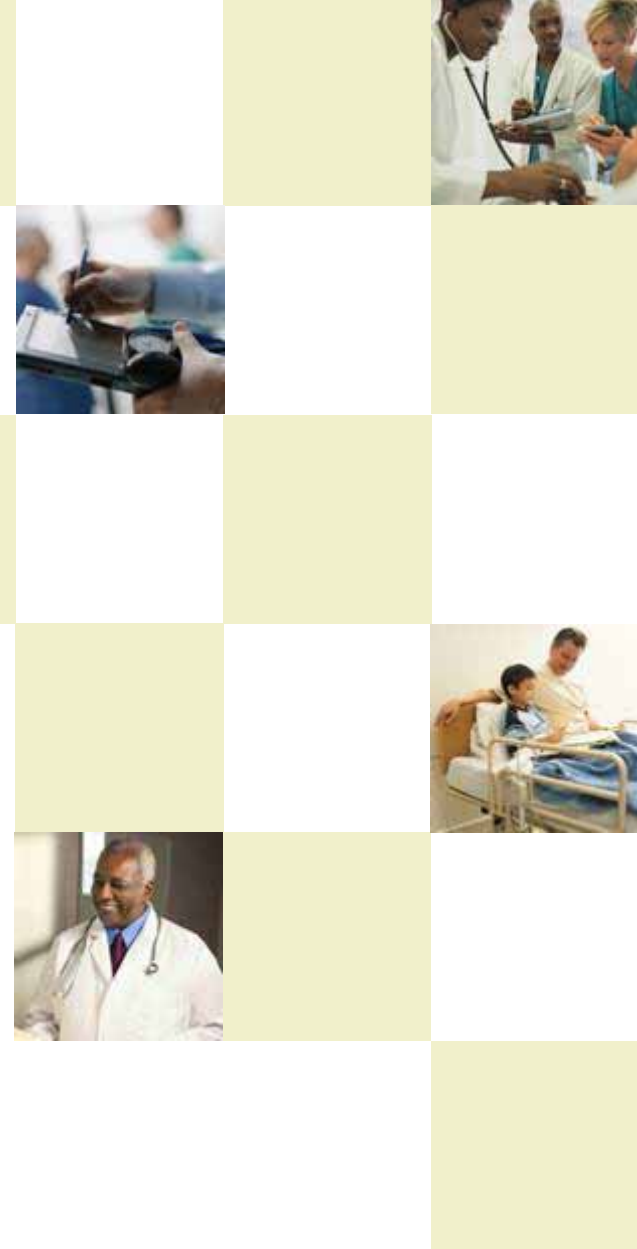
Signatures and Authentication For Everyone

The SAFE Standard: Digital Signatures for Achieving Global, Compliant Requirements for Health Care

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The Business Case For SAFE



What's Wrong With a Signature on Paper?

- ▶ **Signatures & signed content can be fabricated**
 - Possible to recreate a modified copy as good as, or better than, the original
- ▶ **Growing expense:**
 - Signed record management, retrieval & storage
 - Mailing of signed originals
- ▶ **Physical signing process can be onerous**
 - e.g., Physician signature on each and every page of each case report form associated with a clinical trial/study
- ▶ **Hard to recall distributed copies needing correction**
 - Physical central repository not practical



Financial Impact in Today's Environment - Pharmaceuticals

- ▶ **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

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



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



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

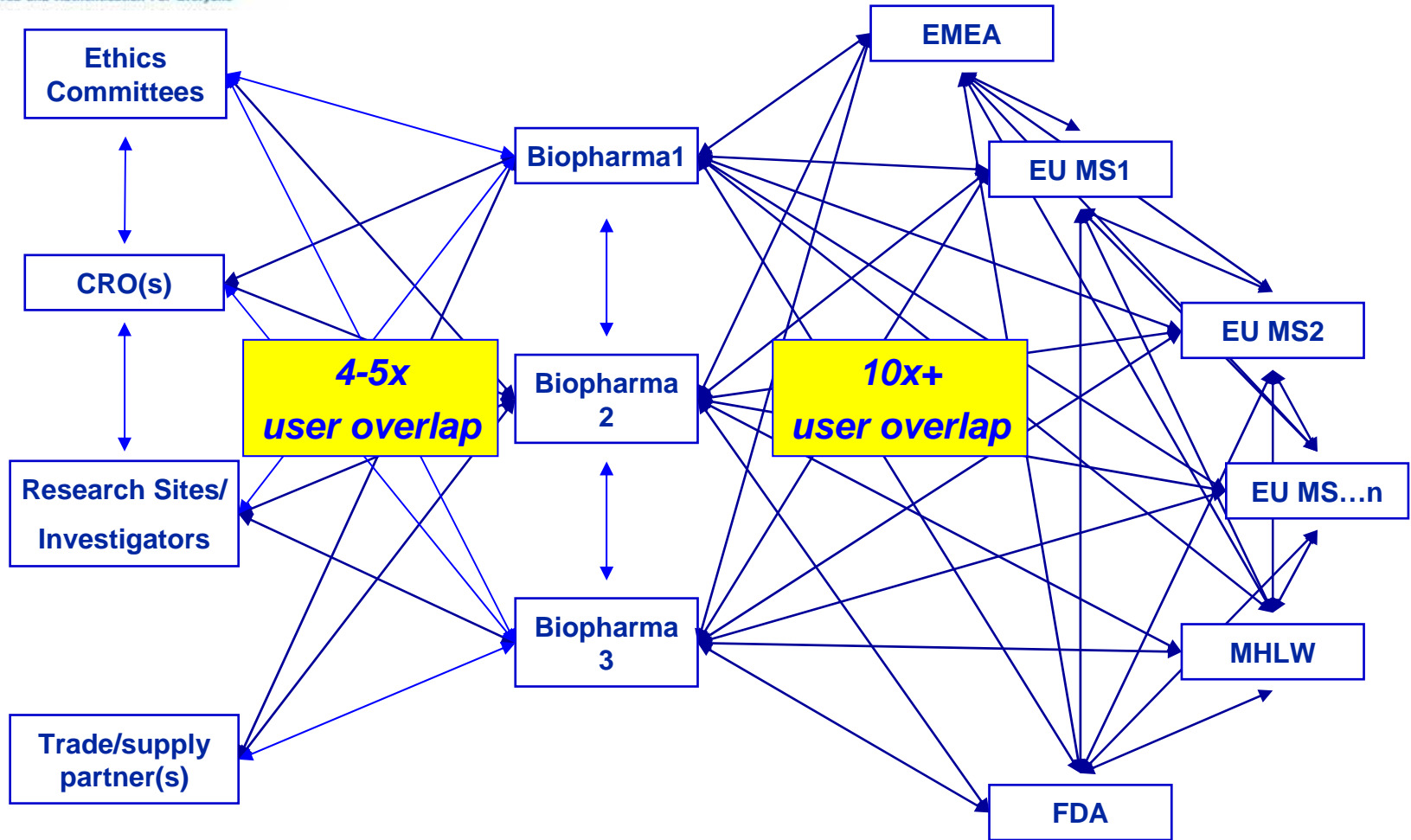
- Reuse of current investments; vendor support; interoperability with trading partners; multiple overlapping standards

Basic recognition: One business alone cannot address these



Signatures and Authentication For Everyone

The Global Identity Challenge



If tackled independently → recipe for management nightmare



Enter SAFE ...

SAFE-BioPharma Association

Participating Companies

Biopharma Companies

Abbott Labs
Amgen
AstraZeneca – *Founder*
Bristol-Myers Squibb – *Founder*
GlaxoSmithKline – *Founder*
INC Research
Johnson & Johnson – *Founder*
Merck – *Founder*
Pfizer – *Founder*
Procter & Gamble – *Founder*
Sanofi-Aventis – *Founder*
TAP Pharmaceuticals

Governments

National Cancer Institute
Food and Drug Administration
European Medicines Evaluation Agency
Irish Medicines Board
Medicines Evaluation Board: Netherlands
EOF: Greece
Veterinary Medicines Directorate: United Kingdom

Association Sponsors

Pharmaceutical Research & Manufacturers Association
European Federation of Pharmaceutical Industries & Associations
International Federation for Animal Health

Research Sites & IRB's

Memorial Sloan Kettering
Mayo Clinic
City of Hope National Medical Center
Women & Infants Hospital of Rhode Island
H Lee Moffitt Cancer Center
Sidney Kimmel Cancer Institute
Shulman & Associates
Western IRB

Health industry partnership to address regulatory, legal, trust, & infrastructure concerns



SAFE Overview

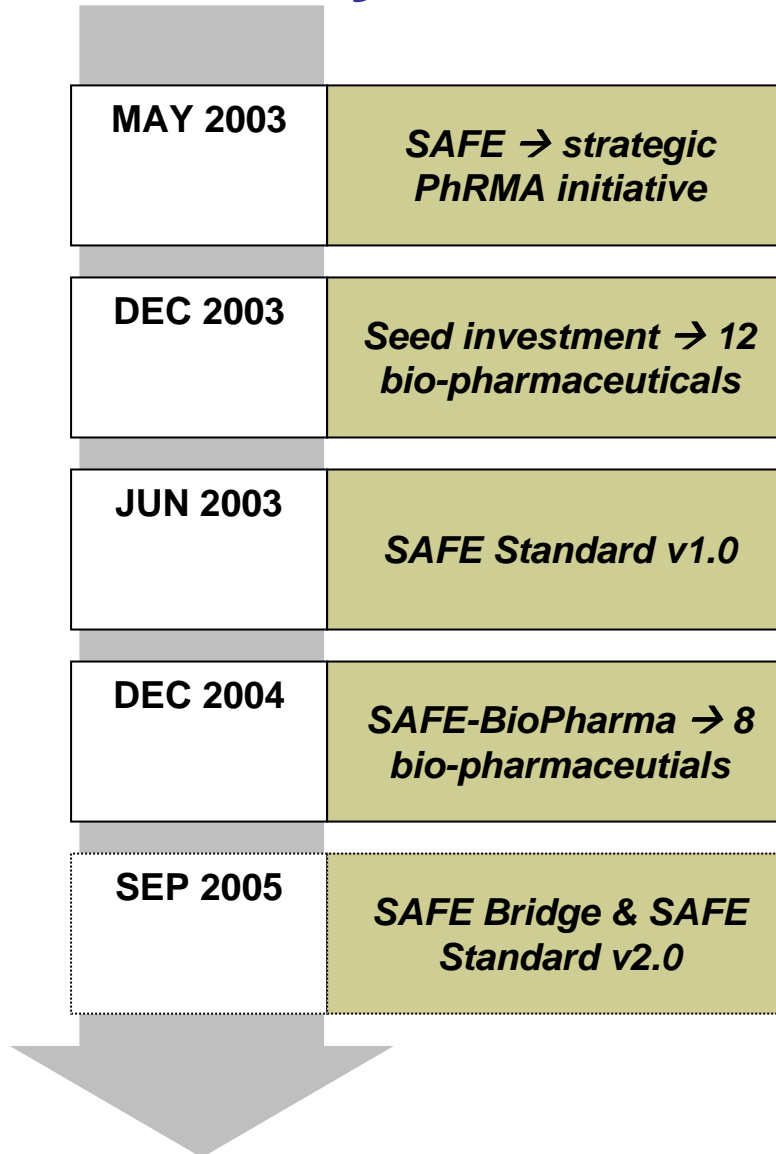


SAFE Mission

- ▶ **Provide a digital signature standard & associated operating rules**
 - Built on existing standards
 - minimize reinvention
- ▶ **Delivers unique electronic identity credentials**
 - Legally enforceable
 - Regulatory compliant
 - Acceptable across the global biopharmaceutical environment
- ▶ **Provides shared services in support of health industry electronic transactions**
 - Business-to-Business
 - Business to Regulator



SAFE & Bio-Pharmaceutical Community Timeline





SAFE-BioPharma – the Association

▶ **Not for profit entity:**

- Created by biopharmaceutical industry
- Not about financial return via the SAFE entity; return delivered to members through the use of the system
- Ensure open access to all within the broad healthcare industry

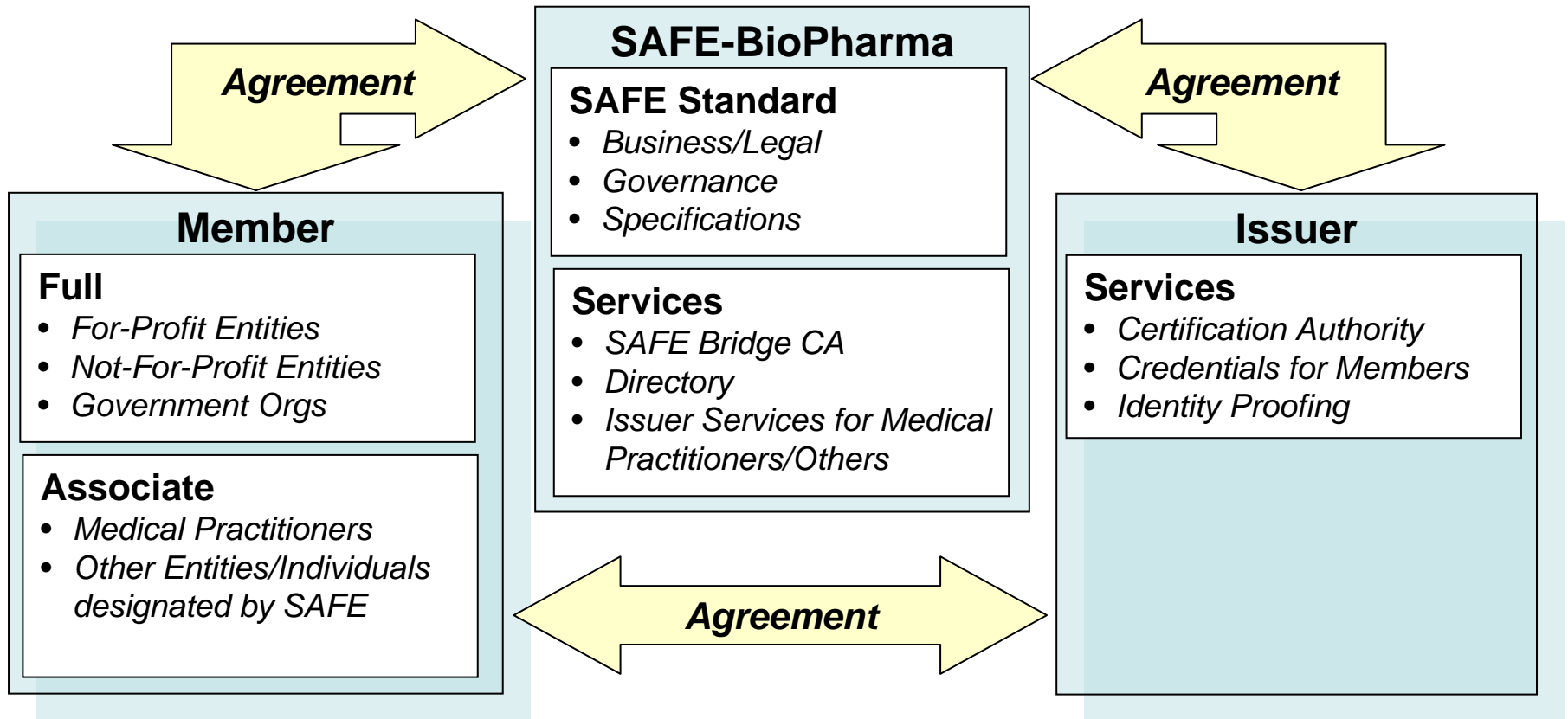
▶ **Provides:**

- Delivery & maintenance of common global standard and service offerings
- Outsourcing of credential providers
- Trust Bridge
- Leverage for application enablement and certification
- Member support

▶ **Seeks to minimize financial impact to “owners/system members”**

- “Shared-service” model
- Revenue stream from Member fees

SAFE – a Community Framework





Using SAFE



SAFE Business Scope

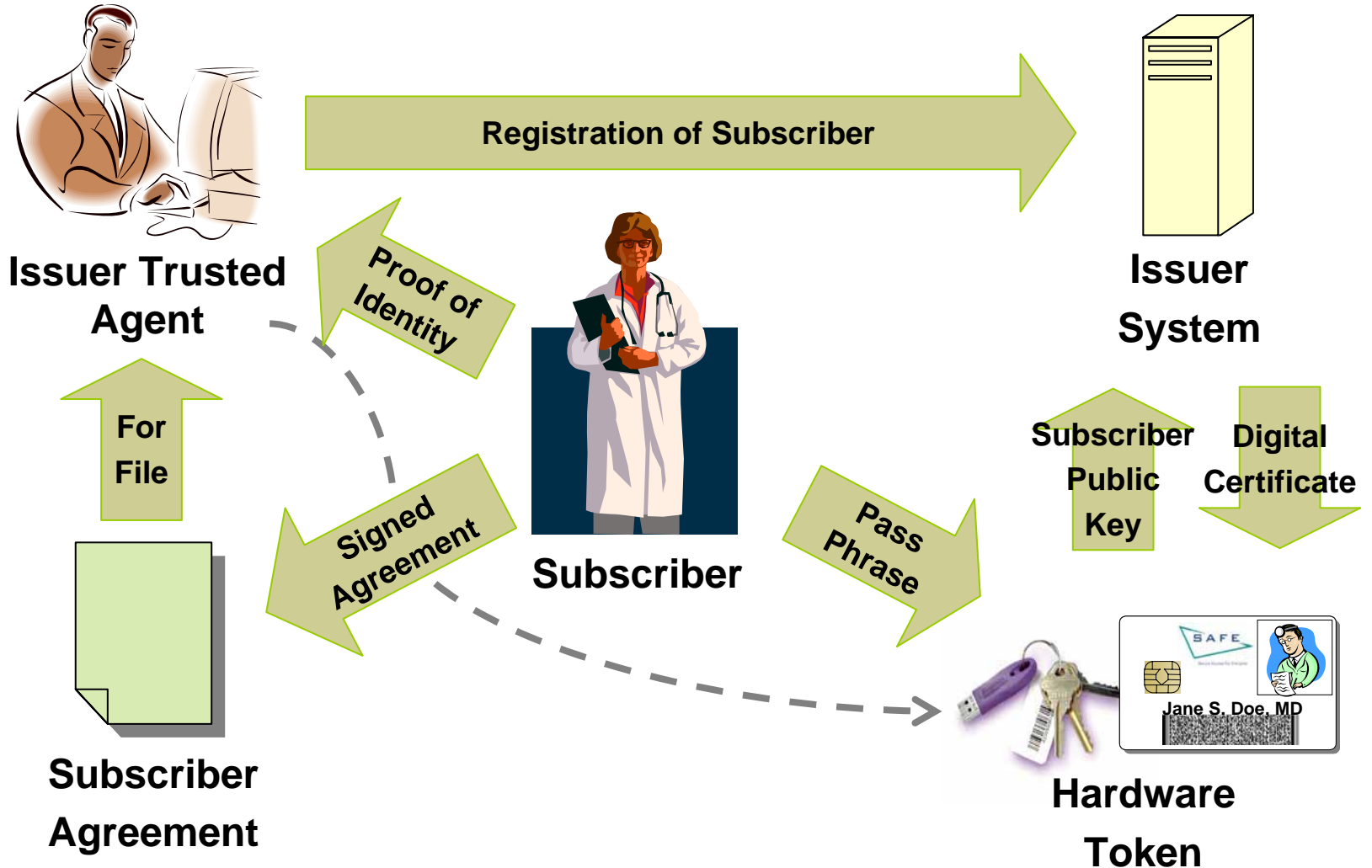
- ▶ **Common digital signature use & acceptance agreement → execute once**
 - Continuing accreditation & audit of Members / Issuers
 - Capped liability limits on SAFE digital signature use
 - Dispute resolution process & framework for SAFE stakeholders
- ▶ **Independent certification of SAFE-enabled applications**
- ▶ **Commitment to SAFE digital signature standard → updates driven by SAFE community**



SAFE Technical Scope

- **Issuance of a unique SAFE identity credential & its binding to a specific individual**
- **Provide business-to-business trust across different infrastructure implementations via the SAFE Bridge**
- **Digitally sign an electronic record or object**
- **Validate one or more digital signatures on an electronic record or object, and confirm integrity of the electronic record or object**
- **Present & display a SAFE signature on a document**

Issuing SAFE Credentials

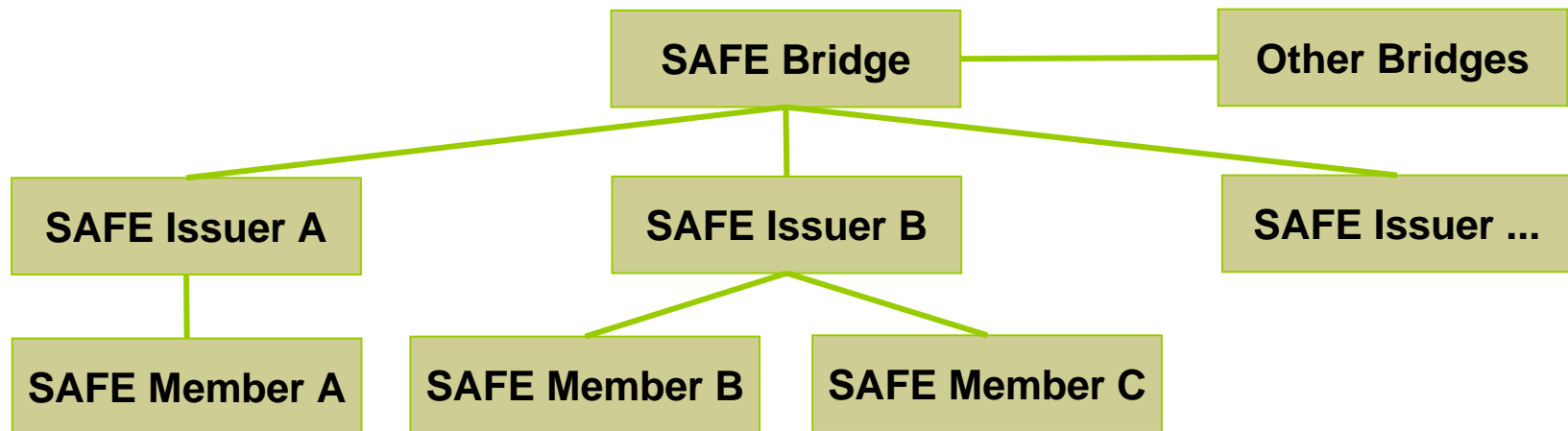




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SAFE Bridge


- ▶ Ensures trust across heterogeneous Issuer systems
- ▶ Ensures transactional interoperability among these “bridged” systems
- ▶ Reduces cost & extends flexibility for SAFE Members by promoting availability of competitive external supply sources or ability to utilize internal solutions
- ▶ Reduces application complexity by minimizing need to cross-certify with multiple Issuers for credential validation support






SAFE Signature Block – Visual Representations

Valid Signature


 *Jane Doe*



Secure Access For Everyone

Reason: Affirm information on Form 1472
DN: CN=Jane Doe, C=US, O=Miracle Cure
Pharma, OU=000000000177

Date: 2005.10.19 20:33:07 – 4'00'

Invalid Signature

 *Jane Doe*


Secure Access For Everyone

Reason: Affirm information on Form 1472
DN: CN=Jane Doe, C=US, O=Miracle Cure
Pharma, OU=000000000177

Date: 2005.10.19 20:33:07 – 4'00'

Complete Validation Report Can Be Viewed & Saved for Audit Purposes



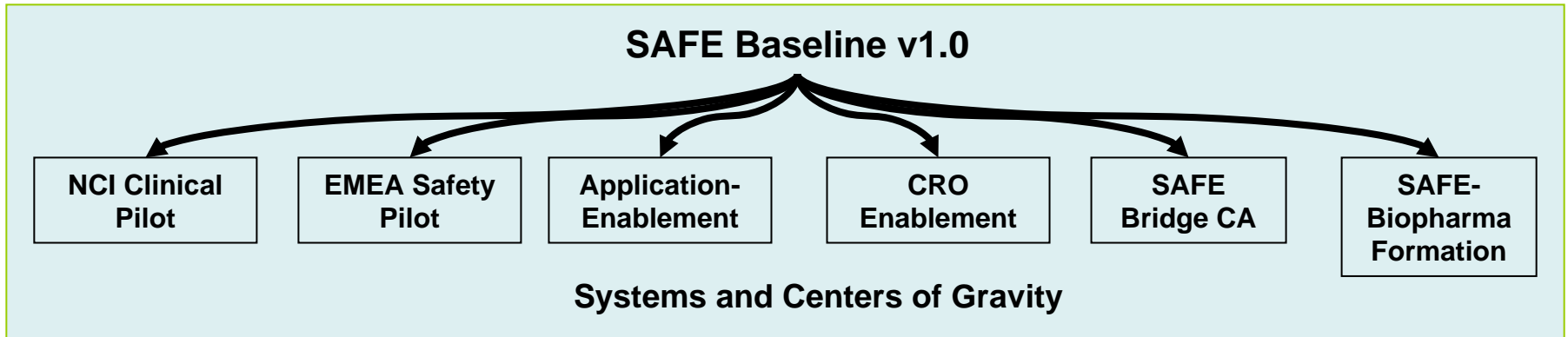
SAFE in Operation



Strategic Approach to Build Critical Mass for SAFE

Centers of Gravity

SAFE is focusing its resources and efforts around a **small number** of Centers of Gravity (Programs) to ensure **early stage successes** that are **self-sustaining and leverageable** by others with or without follow-on support from SAFE



INVESTIGATORS

REGULATORS

SPONSORS

CROs

ISSUERS

STANDARD MANAGEMENT

SAFE will Influence these Centers of Gravity in order to stimulate demand pull that is aligned to value delivery on a sustained and accelerating basis



Pfizer & SAFE

► **Situation:**

- Pfizer manages identity credentials for over 200,000 employees and contractors
- It spends an estimated \$10 million per year for password resets
- Every digital signature utilized for regulatory and non-regulatory transactions eliminates the costs of approximately \$125 dollars required per wet signature

► **Approach:**

- Replace the multiple ID architectures that were in place with a common internal identity management framework
- Leverage SAFE to uniquely align identity credentials with secure information exchange
- Pfizer chose a unified identity model that links multiple credentials onto one cryptographic hardware device (Smart Card). The unique ID badge provided a consistent user experience for access control and digital signing.

► **Results & Benefits:**

- Pfizer has deployed a unique ID platform across their infrastructure
- Elimination of costly paper-based business processes and creation of universal identity badges
- Full-scale systems reengineering & identity management solution that impacted all Pfizer employees & contractors
- Pfizer employees and contractors being able to have their identity authenticated at remote Pfizer locations without having to travel to visitor's station for additional screening

► **Challenges**

- Adopting an identity management strategy, and linking multiple identity credentials to one token
- Keeping up with demand for identity badges once employees realized the convenience of using a single ID badge.



Leveraging SAFE Membership



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SAFE Participation & Drivers

Sponsors

Merck, Johnson & Johnson, Abbott Labs, AstraZeneca, Sanofi-Aventis, Bristol Myers-Squibb, Covance, Pfizer, GlaxoSmithKline, Procter & Gamble

Drivers

- Shared cost model, and experience
- Cost avoidance
- Interoperability at scale
- Broad application
- Risk management infrastructure

Government, Regulatory Agencies, Associations (EU, USA, ASIA PAC)

PhRMA (sponsor), EFPIA (sponsor), FDA, EMEA

Drivers

- Standard Compliance
- Cost Avoidance
- Less Paper
- Interoperability at scale
- Broad application

Business Partners

Labs, Investigators, CROs, Bio-Techs, Manufacturing Supply Chain, Sales

Drivers

- Simplified end user experience, standard interoperability requirements
- Community of practice
- Improved and lower cost partner interactions
- Operational value added services

Vendors

Issuers, Applications providers, Systems Integrators

Drivers

- Access to a channel
- Customer driven product enhancements
- Leadership advantage
- New business opportunities



Signatures and Authentication For Everyone



Participation Benefits

- ▶ **SAFE Working Groups** → opportunity to share solutions & lessons learned
- ▶ **Best Practice guides for Members (under development):**
 - SAFE / 21 CFR Part 11 Implementation Guidance Checklist
 - Credential provisioning and applications support guideline
- ▶ **Vendor programs:**
 - Application & infrastructure product SAFE-enablement workshops
 - Applications certification program
 - Issuer accreditation program
- ▶ **While SAFE does not provide its members with hardware or software directly, SAFE has a standard user desktop hardware & software bundle for investigators. This ensures:**
 - Consistent end-user experience
 - Ensures application accessibility for key apps – Adobe, web browser
- ▶ **Bundle can be readily obtained by Members through SAFE Issuers**



SAFE Directions

▶ **Expanding Membership**

- Shared service model – more members = lower cost to each member
- Enhances ubiquity of digital credential approach
- Broaden beyond biopharmaceutical companies to all healthcare/healthcare related entities

▶ **Expanding new business process opportunities**

- Move beyond clinical trials and investigators to other areas common across our industry
- Linkage to evolving e-Health and e-HR initiatives

▶ **Applications**

- Identification of common applications
- Ability to approach application vendors as an industry versus individual companies
- Does not take away individual company ability to work on their own applications



Becoming a SAFE Member

Visit:

<http://www.safe-biopharma.org>



Questions?