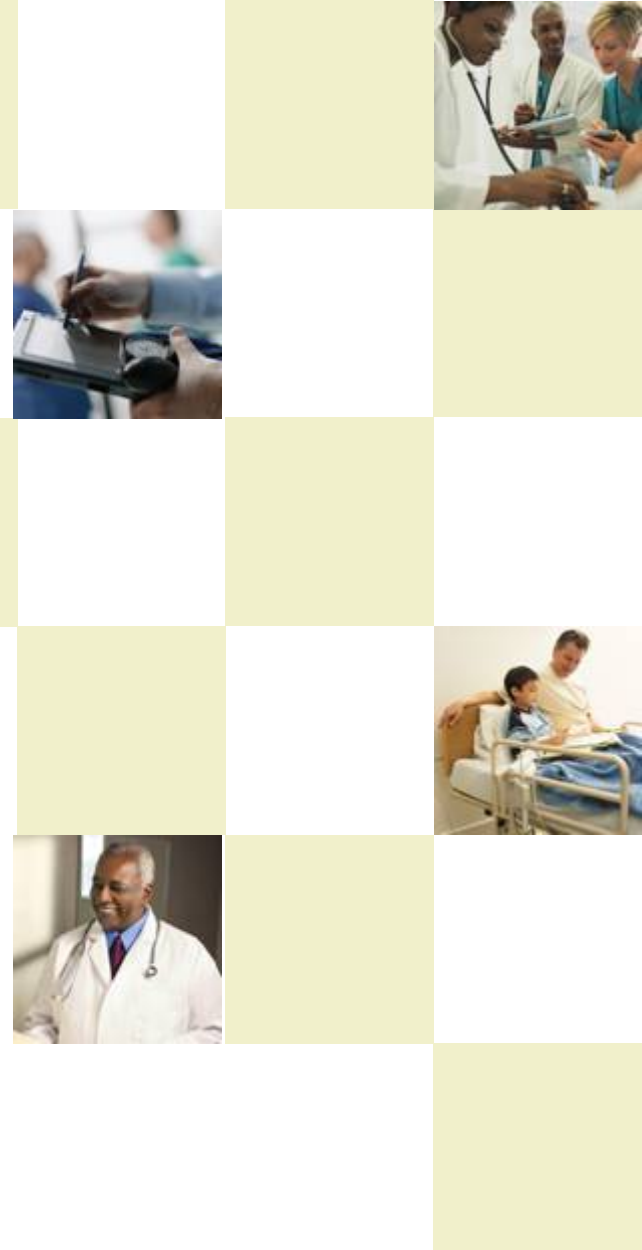




CTST The Americas, 2008

Orlando, Florida

Chris Vietor, Program Director
SAFE-BioPharma Association





WHAT IS SAFE-BIOPHARMA?

- ▶ **Signatures and Authentication for Everyone (SAFE)**
- ▶ **Strategic industry initiative started in Nov 2003 by PhRMA & EFPIA**
- ▶ **SAFE-BioPharma Association incorporated May 2005**
 - Fall 2005, standard approved.
 - 2006-2007, Pilots and early adopters.
- ▶ **A member-governed, not-for-profit collaborative industry enterprise:**
 - Amgen, AstraZeneca*, BMS*, Genzyme, GSK*, J&J*, Merck*, Organon, Pfizer*, P&G*, Roche, Sanofi-Aventis*

MISSION & VISION STATEMENTS

Mission Statement for

SAFE-BioPharma Association / SAFE-BioPharma™ Digital Standard

Our mission is to be the digital identity and signature standard for the global biopharmaceutical and healthcare communities.

SAFE-BioPharma Vision Statement

Our vision is for the SAFE-BioPharma™ standard to be a catalyst in the transformation of the biopharmaceutical and healthcare communities to a fully electronic business environment by 2012.



WHY SAFE-BIOPHARMA?

- One digital identity per user
- Facilitates inter-organizational, global collaboration
- Facilitates interoperability
- Vendor/ technology neutral standard
- Choice of digital identity formats
- Heightens security
- Improves productivity & reduces cycle time
- Manage digital identities effectively
- Digitally sign electronic documents with ease
- Mitigates legal, regulatory and other business risk
- Save on paper & additional resources

WHO SHOULD YOU TRUST?



"On the Internet, nobody knows you're a dog."



THE SAFE-BIOPHARMA STANDARD

▶ Business

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

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

▶ Technical (PKI)

- Certificate Policy
- Specifications
- Guidelines & Guidance

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



GLOBAL REGULATORY ALIGNMENT



In the United States

- SAFE Member advocates w/ QA, Compliance, Regulatory backgrounds
- FDA key offices engaged since inception
- FDA Auditor Familiarization Program
- FDA informal statement on SAFE

In Europe

- SAFE-EMA Pilot
- SAFE EU Advisory Council
- EMA proposal to use SAFE as access solution to EudraVigilance data base (~3,000 users)
- Legal equivalent of handwritten signature
 - meets EU “Qualified Electronic Signature” requirements

DIGITAL IDENTITY PROVISIONING OPTIONS

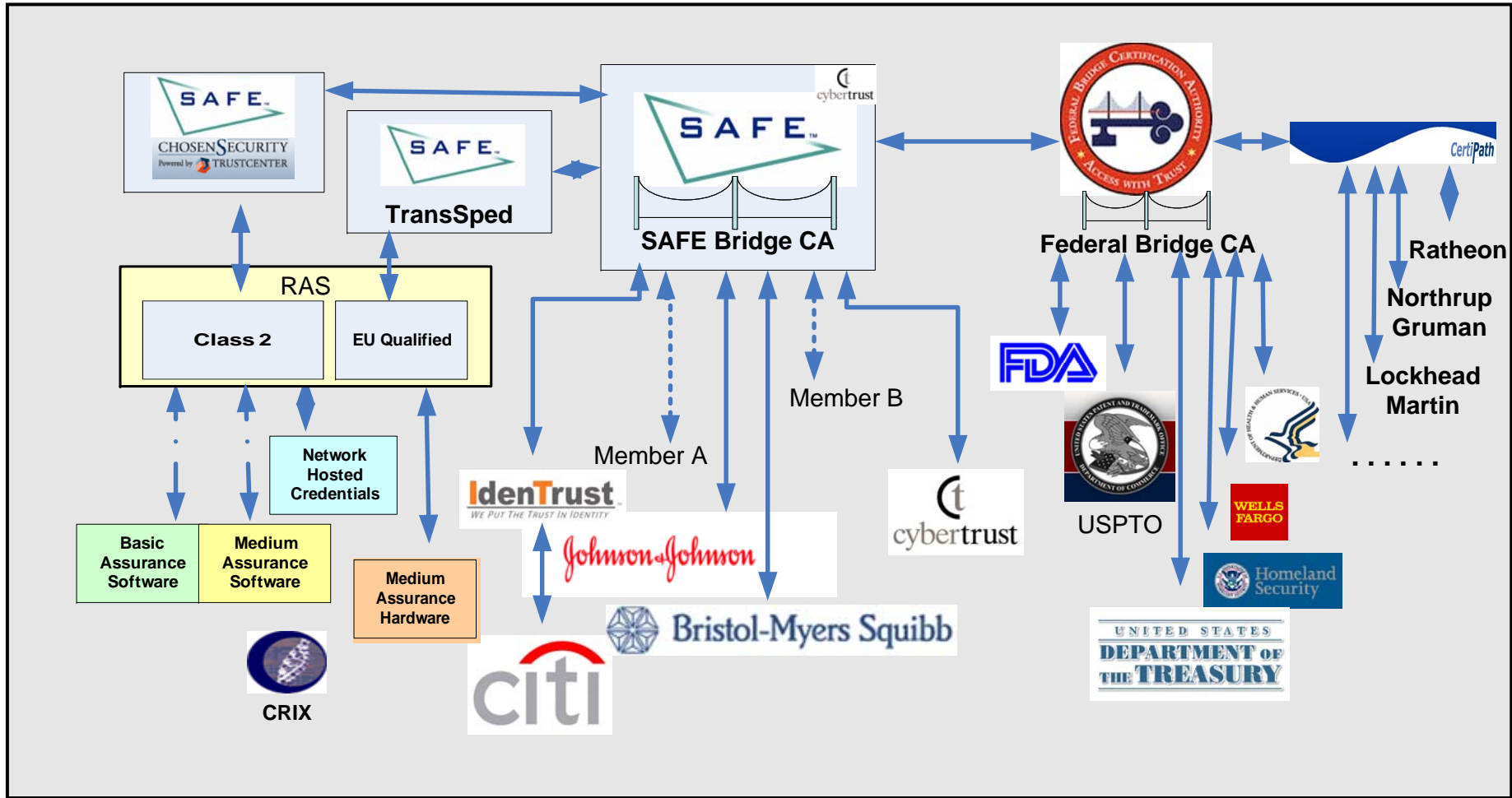
▶ **Internal infrastructure**

- PKI cross certified with SAFE
- J&J, BMS

▶ **Outsourced infrastructure**

- Cross-certified with SAFE Standard
 - Citigroup-Identrust, Chosen Security, Verizon Business
- Obtain credentials from SAFE
 - AstraZeneca, GSK
- Capable of issuing EU Qualified certificates

HIGH-LEVEL ARCHITECTURE



CURRENT USE APPLICATIONS

- ▶ Electronic Laboratory Notebooks
- ▶ Regulatory Submissions
- ▶ Promotional materials review & approval
- ▶ Contracting
- ▶ HR



SAFE VENDOR PARTNER PROGRAM

1. Access to policies and procedures
2. SAFE sponsored event participation
3. Technology Working Group participation
4. Access to SAFE Product Certification Program
5. Support from SAFE-staff
6. Strategic/co-marketing opportunities



CURRENT SAFE VENDOR PARTNERS

SAFE Vendor Partners

- ✓ Adobe Systems
- ✓ Aladdin Knowledge Systems
- ✓ Arcot
- ✓ Algorithmic Research
- ✓ Gemini Security
- ✓ IBM
- ✓ IDBS
- ✓ Microsoft
- ✓ MXI Security
- ✓ Northrop Grumman
- ✓ nCipher
- ✓ Open Text
- ✓ PA Consulting

SAFE Vendor Partners

- ✓ Paragon Computing Professionals
- ✓ SAIC
- ✓ Tricipher

SAFE Issuers

- ✓ BMS
- ✓ Chosen Security
- ✓ Citibank
- ✓ Cybertrust/Verizon
- ✓ IdenTrust
- ✓ J&J
- ✓ TranSped



PRODUCT CERTIFICATION PROGRAM

What?

- ▶ Program of self-test prove compliance with SAFE standard for
 - Applications
 - Infrastructure components (OCSP responders, tokens, HSM, etc)

Why?

- ▶ To help SAFE Members determine what products comply

How?

- ▶ Become SAFE Vendor Partner
- ▶ Develop & Execute test scripts
 - Resolve anomalies
- ▶ Prepare test report
- ▶ CEO & PAA review & approval



EXCITING RECENT DEVELOPMENTS

- ▶ **New SAFE Registration System**
 - w/ tiered service offerings
- ▶ **Cross-certification with FBCA**
- ▶ **New member applications**
 - ePatent Filings
 - external partner authentication
 - CRIX International
 - intra- and inter-state healthcare provider collaborations
 - SAFE-BioPharma → U.S. Govt. Agencies,



FOR MORE INFORMATION

- ✓ Visit the SAFE-BioPharma website : <http://safe-biopharma.org/>
- ✓ Pfizer's Implementation of SAFE Digital Signatures in ELNs:
http://www.safe-biopharma.org/images/stories/pfizer%20white%20paper_v1.pdf
- ✓ Watch the SAFE introductory video:
<http://www.phillipsvideopost.com/safe>

Chris Vietor
SAFE Program Director
chris.vietor@safe-biopharma.org
617-467-5084 or
781-962-3172



FDA CDER STATEMENT

“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.”