

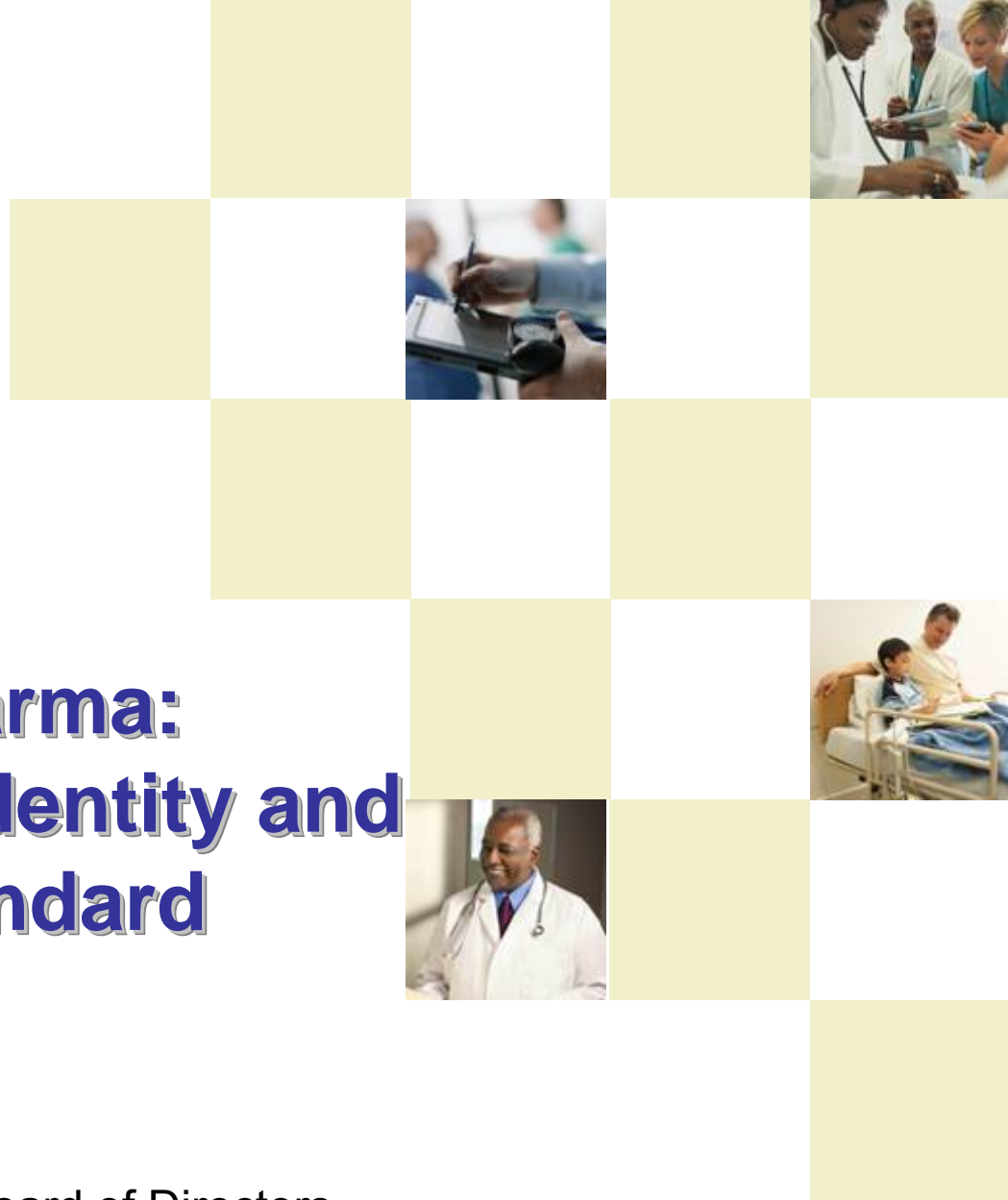


SAFE-BioPharma: Industry's Digital Identity and Signature Standard

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Chairman, SAFE-BioPharma Board of Directors

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SAFE-BioPharma Digital Identity and Signature Standard

- **Strategic industry initiative started 11/03 by PhRMA & EFPIA**
 - Transform biopharma and healthcare communities to fully electronic
 - Interoperable trusted identity and non-repudiable digital signature
 - Risk Mitigation
 - FDA and EMEA alignment
 - Technology and vendor neutrality
 - Global
 - Interoperability
- ▶ **SAFE-BioPharma Association incorporated May 2005**
 - Fall 2005, standard approved
 - 2006-2007, pilots and early adopters
 - 2007-2008, expansion of standard; increased implementations
- ▶ **Member-governed, non-profit collaborative industry org.:**
 - Amgen, AstraZeneca*, BMS*, Genzyme, GSK*, J&J*, Merck*, National Notary Association, Organon, Pfizer*, P&G*, Roche, Sanofi-Aventis*

The SAFE-BioPharma Standard

▶ **Business**

- Operating Policies
- Contracts
- Processes

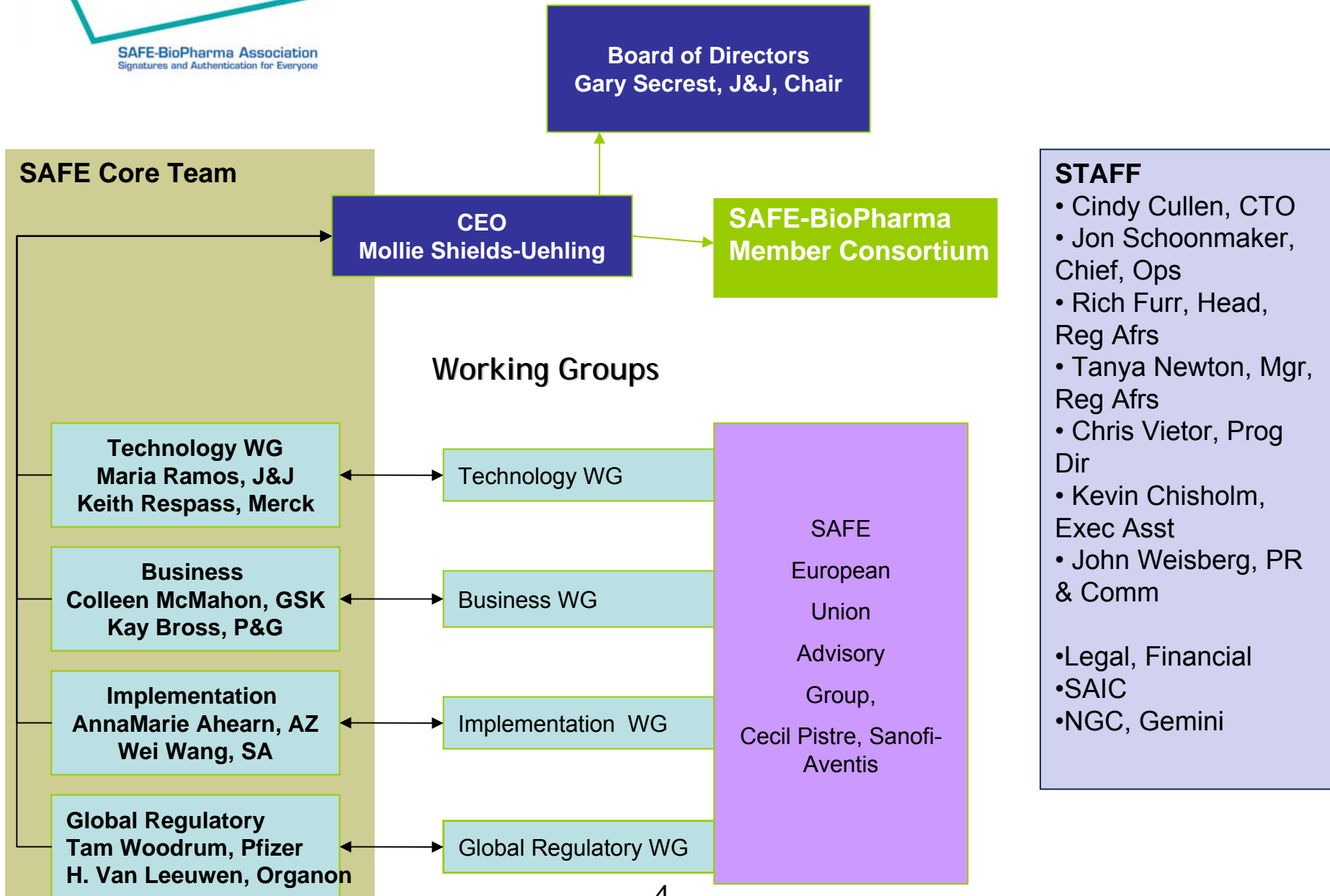
- ***Accept digitally signed transactions***
- ***Agree to limited liability caps***
- ***Agree to dispute resolution***
- ***Agree to identity assurance***
- ***Agree to self-audit & meet SAFE requirements***

▶ **Technical & Identity**

- Certificate Policy (PKI)
- Specifications
- Guidelines

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

A Non-Profit, Member-Driven Standards Association



SAFE-BioPharma Association – Non-Profit Standard Association

Standards	Standards-Related Services	Collaborative Association
<ul style="list-style-type: none"> ▶ Standard Development & Maintenance ▶ Certification: <ul style="list-style-type: none"> - Products - Issuers ▶ Standards engagement: HL7, HITSP, CDISC, IHE, ICH, ETSI ▶ Working Groups <ul style="list-style-type: none"> –Technical –Business –Implementation –Global Regulatory –SAFE EU Advisory Council ▶ Regulatory alignment: <ul style="list-style-type: none"> –FDA; EMEA; NCAs, MHLW 	<ul style="list-style-type: none"> ▶ Operation of SAFE bridge ▶ Cross-cert with FBCA ▶ Vendor partner program – applications ▶ NCI Firebird pilot ▶ Clinical Research Info Exchange (CRIX) ▶ Implementation tools ▶ Provisioning for regulatory submissions <div style="background-color: #FFD700; padding: 5px; text-align: center;">Incubating Innovation</div> <ul style="list-style-type: none"> ▶ Credentials Issuance Model ▶ Registration system (RAS) ▶ Antecedent Data ID Proofing ▶ EU qualified digital identities 	<ul style="list-style-type: none"> ▶ Stakeholder outreach ▶ Education & advocacy ▶ Policy engagement ▶ Industry awareness & engagement ▶ Information/Best Practices Forum ▶ Media: local, national, trade, international



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
 - TransSped
 - Verizon Business/Cybertrust

- ▶ **SAFE tiered services infrastructure (member-subsidized)**
 - External partners
 - Regulatory uses
 - Healthcare providers
 - Members

Options for Flexible Use

- ▶ **Two levels of trust:**
 - Basic Assurance for authentication
 - Medium Assurance for trusted identity uniquely linked to digital signature -- and EU-qualified

- ▶ **Three digital signing technologies:**
 - Software
 - Hardware
 - Roaming

- ▶ **Three identity-proofing options**
 - Antecedent – bulk upload and on-line
 - Trusted agent
 - Notary – including office/home notary services



Antecedent Data Sources

- ▶ **US only at present – international sources being identified**
- ▶ **Authoritative Antecedent Data sources:**
 - DEA Licenses
 - Medical Professional Licenses
 - Physicians & Surgeons
 - Osteopaths
 - Physician Assistants
 - Nursing
 - Pharmacists
 - Among others
 - State Motor Vehicle Records
 - DMV
 - Registrations
 - Property Records

3rd Party Antecedent Process

SAFE-BioPharma™

SAFE-BioPharma Association
Signatures and Authentication for Everyone

▶ ID Vetting Successful:

- Applicant Passes 3rd Party Antecedent identity proofing
- Moved to RA queue for processing and Certificate Issuance steps.
- It's a matter of minutes end-to-end.

The screenshot shows a web browser window titled "SAFE Registration Authority System". The page content includes the SAFE logo and the heading "SAFE User Profile Administration: Identity Verification". Below the heading, it says "Please answer the following questions". There are four sets of radio button options arranged in a 2x2 grid:

- Question 1:** "In what county do you currently live?" with options: Bristol, Barnstable, Berkshire, Middlesex, None of the above.
- Question 2:** "Which of the following streets have you PREVIOUSLY OR CURRENTLY used as your address?" with options: Cranston, 350th, Ashwood, Old Quiry, None of the above.
- Question 3:** "In what state was your Social Security Number issued?" with options: CO, IL, AL, MA, None of the above.
- Question 4:** "Which of the following is/was your phone number?" with options: 624-4171, 666-1402, 307-9991, 631-8023, None of the above.

▶ ID Vetting Not Successful:

- Unable to verify identity via 3rd Party Antecedent
- Process reverts to Notary Process with two service options:
 - User locates notary
 - RAS/NNA will have a local notary contact the Applicant directly

The screenshot shows a form for scheduling a notary appointment. It includes the following fields and options:

- I would like to:***
 - Schedule my own Notary appointment
 - Please have a licensed Notary in my area contact me to schedule an appointment
- Your Email Address:** demo.cp1@kernworld.org
- Your Phone Number:** 777 - 666 - 5555
- Alternate Phone Number?:** [Empty input field]
- I prefer to be contacted by:***
 - Phone
 - Email
- The best time to contact me is: ***
 - Anytime (9 AM - 9 PM)
 - Business hours- Morning (9 AM-Noon)
 - Business hours- Afternoon (Noon-5 PM)
 - After business hours- (5 PM-9 PM)
- Please enter any additional information that will help expedite scheduling a Notary appointment:** [Empty text area]

SAFE-BioPharma and Regulators

- ▶ **FDA engagement since inception**
 - Familiarization program
 - Received 1,000s of SAFE-BioPharma signed submissions
 - HSPD-12 credentials

- ▶ **EMA engagement since inception**
 - Evaluation, pilots, electronic submission guidance
 - Proposal to EFPIA to use SAFE-BioPharma as access solution to EudraVigilance data base (~3,000 users)

- ▶ **Next Steps with Regulators**
 - Eudra Vigilance – EFPIA-EMA meeting late August
 - Simultaneous FDA/EMA eCTD submission by member
 - EMA & Member State Regulators – SAFE-BioPharma Familiarization
 - Pilot within Scientific Division of EMA
 - EMA Digital Signature Work Program (2009)



SAFE-BioPharma Pilots & Implementations

Company	Implementation
Amgen	CRIX; ELN exploration
AstraZeneca	eSubmissions (US)
BMS	ELNs; Promotional material review (EU); alliances
CRIX*	Digital signature
GSK	eSubmissions, R&D docs
J&J	eSubmissions; external partners
Health Info Exchange*	eHealth records; ordering diagnostics; public health reporting
National Notary Association	Digital Notary Signature
Pfizer	Chemistry & Bio Lab Notebooks; eSubs; SOWs; contracts
P&G	ELNs; contracts; HR; patents
Group Purchasing Org*	Supplier and member contracts
Sanofi-Aventis	eSubmissions; ELNs

***Membership in-process.**



The Infrastructure and the Network Are Now In-Place

- ▶ **Expanded Communities of Trust -- 4 Bridges**
 - Federal Bridge CA -- DHHS, CDC, CMS, DOD, VA, DHS, Treasury, Justice, DEA, EPA
 - Other communities – Certipath (Defense & Aerospace), Education Bridge
- ▶ **Expanded Work and Recognition by SDOs --**
 - SAFE-BioPharma-CDISC and HL7 collaboration – pilot demo at HIMSS 2009
 - SAFE-BioPharma-Adobe collaboration around ETSI (for ICH) for PDF v1.7
- ▶ **Expanded Use Cases –**
 - CRIX
 - HIEs
 - Group Purchasing Organizations
 - Federation
 - EU qualified signatures
 - ▶ **Regulatory recognition in US and EU**
- ▶ **Facilitating Ease of Use:**
 - Two levels of trust
 - Expanded signing options ; multiple issuers; multiple certified products and applications
 - Improved I&A: Antecedent and National Notary Association – home/office Identity proofing
 - Member supported digital identity services at competitive prices



Pfizer's Green Signature Book

Published in Internal Newsletter

- ▶ Over 3,500 employees are using My Signature Book with an average of 412 employees being provisioned monthly
- ▶ Over 221,000 documents have been signed at average of 10 pages per document. That's 2,210,000 pieces of paper, 4420 reams, 442 cases, or 4.2 tons of paper.
- ▶ No paper was consumed; no toner used; no printer used; no inter-office envelope, Fax, FedEx, UPS, USPS, or DSL used.
- ▶ No scanning after wet signing or re-indexing the scanned images back into the appropriate repository for safe keeping.
- ▶ No need for multiple people to print multiple signature pages for signature, retrieving, and reconstituting the document for storage.
- ▶ No need to store physical paper either on- or off-site or courier services to transport documents for archiving.



Strategic Value of SAFE-BioPharma

- ▶ **SAFE-BioPharma makes end-to-end eBusiness and eRegulatory processes possible for pharma and healthcare**
 - Legal enforceability
 - Regulatory compliant (US, EU, Japan)
 - Global standard
 - In EU, SAFE-BioPharma digital signature is the legal equivalent of handwritten
 - Mitigates risk
 - Vendor, technology neutral
 - Secure
 - Only one digital identity per investigator or other user
 - Links Federal agencies to pharma and healthcare providers
 - Provides interoperability
 - Improves productivity
 - Reduces cycle time
 - Facilitates collaboration

- ▶ **Enabling technology to transform business and regulatory processes**



- ✓ Please visit the SAFE-BioPharma website : <http://safe-biopharma.org/>
- ✓ Pfizer's Implementation of SAFE-BioPharma Digital Signatures in ELNs: http://www.safe-biopharma.org/images/stories/pfizer%20white%20paper_v1.pdf
- ✓ AstraZeneca's Implementation of SAFE-BioPharma for FDA Submissions: http://www.safe-biopharma.org/images/stories/az_safe_final.pdf
- ✓ Learn more about the SAFE-BioPharma Implementation Toolkit: http://safe-biopharma.org/index.php?option=com_content&task=view&id=254&Itemid=422
- ✓ Watch the SAFE-BioPharma introductory video: <http://www.phillipsvideopost.com/safe>
- ✓ Contact us for more information:

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