SAFE™

Signatures and Authentication For Everyone

HIPAA 12
SAFE: The Key to Identity Management and Digital Signatures

Mollie Shields Uehling

President & CEO

April 11, 2006

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Signatures and Authentication For Everyone

Impetus for SAFE…..

- **Revolution in life sciences and medical technology:**
  - Changing the way we live
  - Expensive
- **Need to improve safety, quality, development time of medicines to patients:**
  - Paper costs: 40% of R&D costs; 33% all healthcare costs
  - Increasingly complex industry
  - Wall Street's imperative: reduce cost structure
- **Need to improve efficiencies, reduce costs, and allocate resources better – eliminate paper costs:**
  - Shift to eClinical
  - eRegulatory processes
  - eHealthcare, e.g., UK, France, US

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The Vision. . .

- **What would the world be like if we could conduct**
  - business electronically with the same certainty of paper?
- **What would our business processes be like if we could**
  - Eliminate wet signatures?
  - Digitally sign documents the same way we do paper?
  - Trust people's identities without ever meeting them?
  - Eliminate multiple passwords, passcards?
  - Interoperate regardless of technology or vendor?
- **How much faster? How much more productive?**
- **How much more accurate? How much more profitable?**

Barriers to Adoption of Digital Signatures/Processes by Bio-Pharma

- Identity Management and Authentication
- Regulatory
- Legal Enforceability
- Risk Management
- Change Management
- Privacy, Security
- Interoperability

Industry Collaboration: Signatures and Authentication for Everyone: May 2005

SAFE is the only global standard for the healthcare community that enables trusted, secure, legally enforceable paperless business and clinical transactions.

What is SAFE?

SAFE enables trusted, secure, legally enforceable paperless business and clinical transactions.

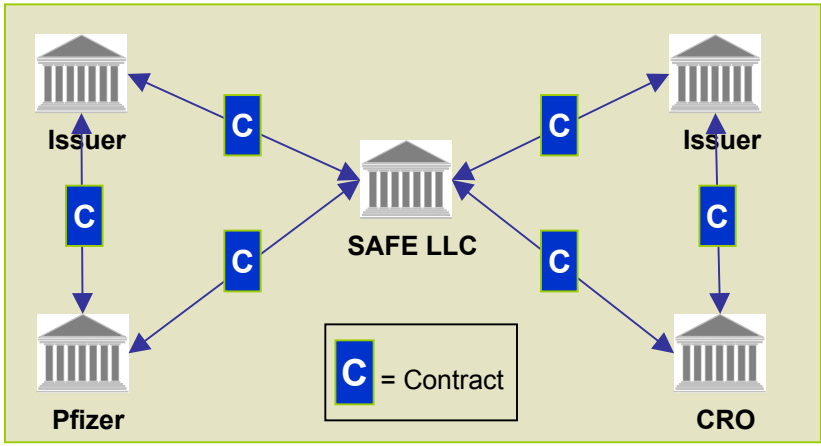
- ***A single common digital credential:***
  - *For ID management*
  - *For digital signatures*
- ***Basis:***
  - *Hardware -- smart card or USB fob*
    - *2-Factor security*
  - *Closed user community*
  - *Bound by contracts*
  - *That manage risk*
  - *That bridge local and regional differences in digital signature laws*
  - *Provide interoperability*

SAFE & Regulatory Requirements

- **Complies with 21CFR11 & other predicate rules**
- **Meets OMB, NIST and EAP Level 4 criteria for eGovernment and e-Authentication**
- **EMEA –** Evaluated SAFE – meets EMEA requirements

SAFE Standard Legal Structure

- Uniform obligations/protections:
  - Safekeeping of credentials
  - Record-keeping
  - Accuracy of registration data
  - Timely revocation
- Global legal enforceability
- Risk Management Approach
  - Arbitration vs. lawsuit
  - Damages capped



Bound by a Closed Contract System

SAFE Features

- **Global Trust network**
  - Face to face ID
  - High assurance that the other end is who they say they are
  - Community of users
- **Signature verified at the time of signing & authentication**
- **SAFE CA Bridge allows interoperability**
- **Certification of products and applications**

The SAFE Community Participants

BioPharma Members

- Abbott Labs
- AstraZeneca – Founder
- Bristol-Myers Squibb – Founder
- GlaxoSmithKline – Founder
- Genzyme
- INC Research
- Johnson & Johnson – Founder
- Merck – Founder
- Nektar
- Organon
- Pfizer – Founder
- Procter & Gamble – Founder
- Sanofi-Aventis – Founder

Government Agencies

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

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

Association Partners

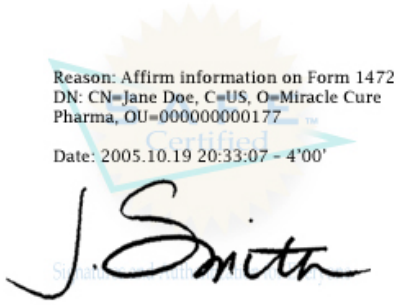
- Pharmaceutical Research & Manufacturers Association
- European Federation of Pharmaceutical

SAFE BioPharma Association

Technical Standards Body	Shared Services Company	Healthcare Industry Association
►Standards Working Groups ►Certification standards & administration ►Standard Development & Maintenance ►Alignment to HL7, CDISC, IHE, ICH, EAP ►Engagement in ONCHIT, AHIC, NHII, PDUFA III, CaBIG	►Issuance of Credentials ►Directory of Users ►Operation of bridge ►Member Implementation ►Member/Product/Issuer certification ►Vendor program ►Tech Devel: Signing Services, Remote ►FDA ►EMEA ►NCI	►Stakeholder outreach ►Education & advocacy –eHI ►Policy engagement –Congress & leg. –HHS, NCI –EFPIA, PhRMA, BIO, ACRO, etc. –FDA, EMEA ►Media: local, national, trade, international ►Working Groups

SAFE Biopharma Association Delivers

SAFE IDENTITY UTILITIES



IDENTITY STANDARD AND GUIDELINES

SAFE Certified

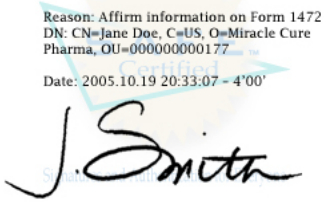
Signatures and Authentication for Everyone

NETWORK AUTHENTICATION SIGNING SERVICES AND UTILITIES

SAFE Identity Standard and Guidelines

- **Value**
  - Creates operating framework for movement to e-business processes
  - Interoperability across all members/users on the network
  - Shared experience improves member implementation success
  - Vendor partner program to deliver off-the-shelf SAFE enabled applications
  - Universal agreement, contractually bound, to abide and comply with rules
  - Risk management scheme
  - Rules are mapped to regulatory requirements to ensure conformance:
    - 21CFRP11, EMEA, SOX, HIPPA
  - Provides legal, regulatory business risk management
- **SAFE Delivers**
  - Policies procedures specifications and guidelines, compliance checklists, legal guidelines
  - Access to SAFE working groups (FDA Compliance, EU Forum, Implementation, Operations technology, e-Health Initiative)
  - SAFE Vendor Partner Program delivers certified applications to the healthcare community

SAFE Identity Utilities



- **Value**
  - Competitive pricing ~$100 per year credential costs
  - Pre-packaged implementation speeds time to production and reduces risk of implementation failure
  - Engineered specifically to meet regulatory requirements
  - Interoperability at scale once the network is in effect
- **SAFE Delivers**
  - USB Identity tokens
    - Use digital certificates (X.509) to access and sign information
  - Universal SAFE Signing Interface web based interface for uploading and signing documents
  - SAFE Registration Authority to register users for credential issuance
  - SAFE call center 24X7 support

SAFE Network Services

- SAFE Signature Book Basic POC Environment
  - 5 pre-production SAFE USB credentials
  - Application integration guide
  - Universal SAFE Signing Interface Code
  - POC end user kit
  - Authentication and document signing service
  - Audit log management
  - Limited diagnosis and implementation support
- **SAFE Signature Book Signing Application Pre-production Pilot**
  - 20–100 pre-production pilot credentials
  - Pilot implementation guideline
  - Universal SAFE Signing Interface Code
  - Infrastructure support
  - Authentication and document signing service
  - Audit log management
  - Diagnosis and implementation support

Visible SAFE Signature Block

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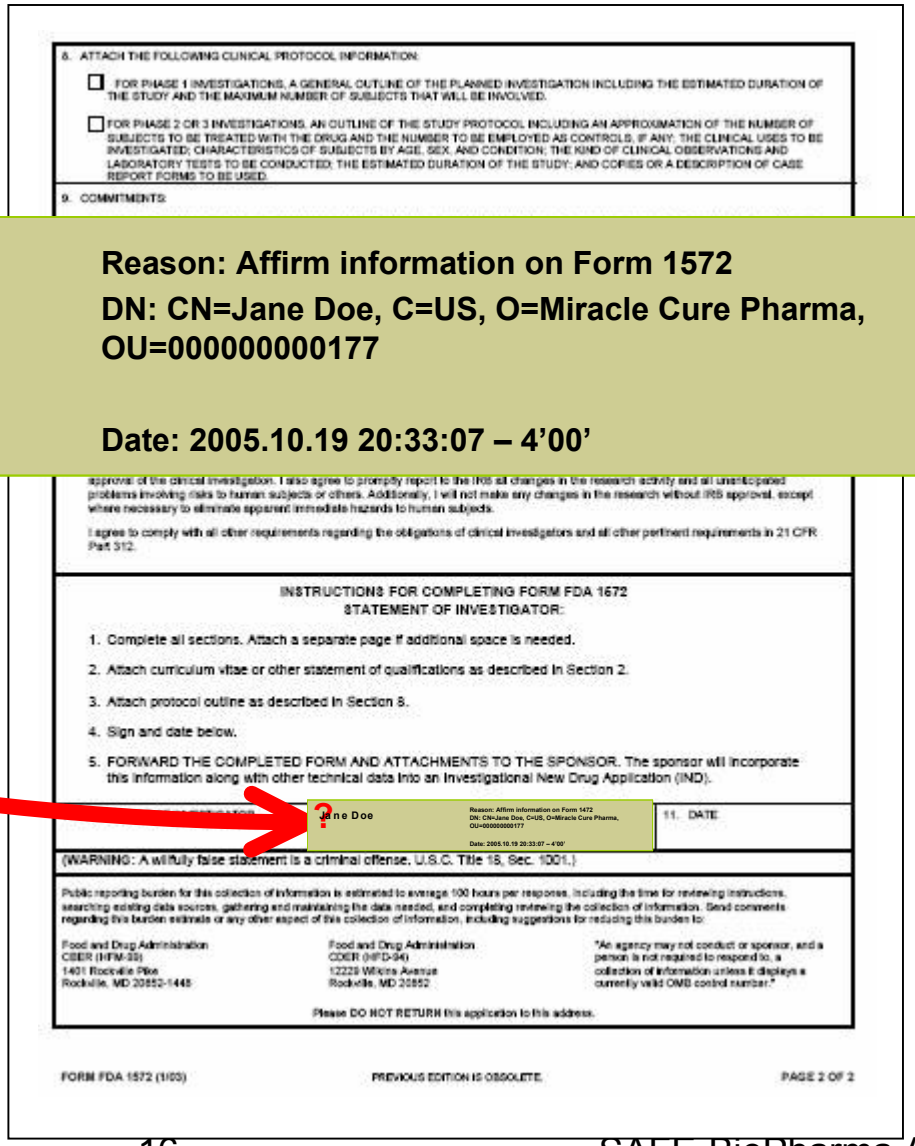
Placement

? Jane Doe

Reason: Affirm information on Form 1572

DN: CN=Jane Doe, C=US, O=Miracle Cure Pharma, OU=000000000177

Date: 2005.10.19 20:33:07 – 4'00'



6. ATTACH THE FOLLOWING CLINICAL PROTOCOL INFORMATION:

☐ FOR PHASE 1 INVESTIGATIONS, A GENERAL OUTLINE OF THE PLANNED INVESTIGATION INCLUDING THE ESTIMATED DURATION OF THE STUDY AND THE MAXIMUM NUMBER OF SUBJECTS THAT WILL BE INVOLVED.

☐ FOR PHASE 2 OR 3 INVESTIGATIONS, AN OUTLINE OF THE STUDY PROTOCOL INCLUDING AN APPROXIMATION OF THE NUMBER OF SUBJECTS TO BE TREATED WITH THE DRUG AND THE NUMBER TO BE EMPLOYED AS CONTROLS, IF ANY; THE CLINICAL USES TO BE INVESTIGATED; CHARACTERISTICS OF SUBJECTS BY AGE, SEX, AND CONDITION; THE KIND OF CLINICAL OBSERVATIONS AND LABORATORY TESTS TO BE CONDUCTED; THE ESTIMATED DURATION OF THE STUDY; AND COPIES OR A DESCRIPTION OF CASE REPORT FORMS TO BE USED.

9. COMMITMENTS:

approval of the clinical investigation. I also agree to promptly report to the IRB all changes in the research activity and all unanticipated problems involving risks to human subjects or others. Additionally, I will not make any changes in the research without IRB approval, except where necessary to eliminate apparent immediate hazards to human subjects.

I agree to comply with all other requirements regarding the obligations of clinical investigators and all other pertinent requirements in 21 CFR Part 312.

INSTRUCTIONS FOR COMPLETING FORM FDA 1572
STATEMENT OF INVESTIGATOR:

1. Complete all sections. Attach a separate page if additional space is needed.
2. Attach curriculum vitae or other statement of qualifications as described in Section 2.
3. Attach protocol outline as described in Section 8.
4. Sign and date below.
5. FORWARD THE COMPLETED FORM AND ATTACHMENTS TO THE SPONSOR. The sponsor will incorporate this information along with other technical data into an Investigational New Drug Application (IND).

? Jane Doe Reason: Affirm information on Form 1572 DN: CN=Jane Doe, C=US, O=Miracle Cure Pharma, OU=000000000177 Date: 2005.10.19 20:33:07 – 4'00'

11. DATE

(WARNING: A willfully false statement is a criminal offense. U.S.C. Title 18, Sec. 1001.)

Public reporting burden for this collection of information is estimated to average 100 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Food and Drug Administration
CBER (HFM-99)
1401 Rockville Pike
Rockville, MD 20852-1448

Food and Drug Administration
CDER (HFD-94)
12229 Wilkins Avenue
Rockville, MD 20852

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

Please DO NOT RETURN this application to this address.

FORM FDA 1572 (1/03) PREVIOUS EDITION IS OBSOLETE. PAGE 2 OF 2

SAFE Signature Block

Non-Validated SAFE Signature

Karl Von Jacobowitz

Name: Karl Von Jacobowitz

Reason: Affirm information on Form 1472

Date: 2005.10.19 20:33:07 – 4'00'

Valid SAFE Signature

Karl Von Jacobowitz

Name: Karl Von Jacobowitz

Reason: Affirm information on Form 1472

Date: 2005.10.19 20:33:07 – 4'00'

Invalid SAFE Signature

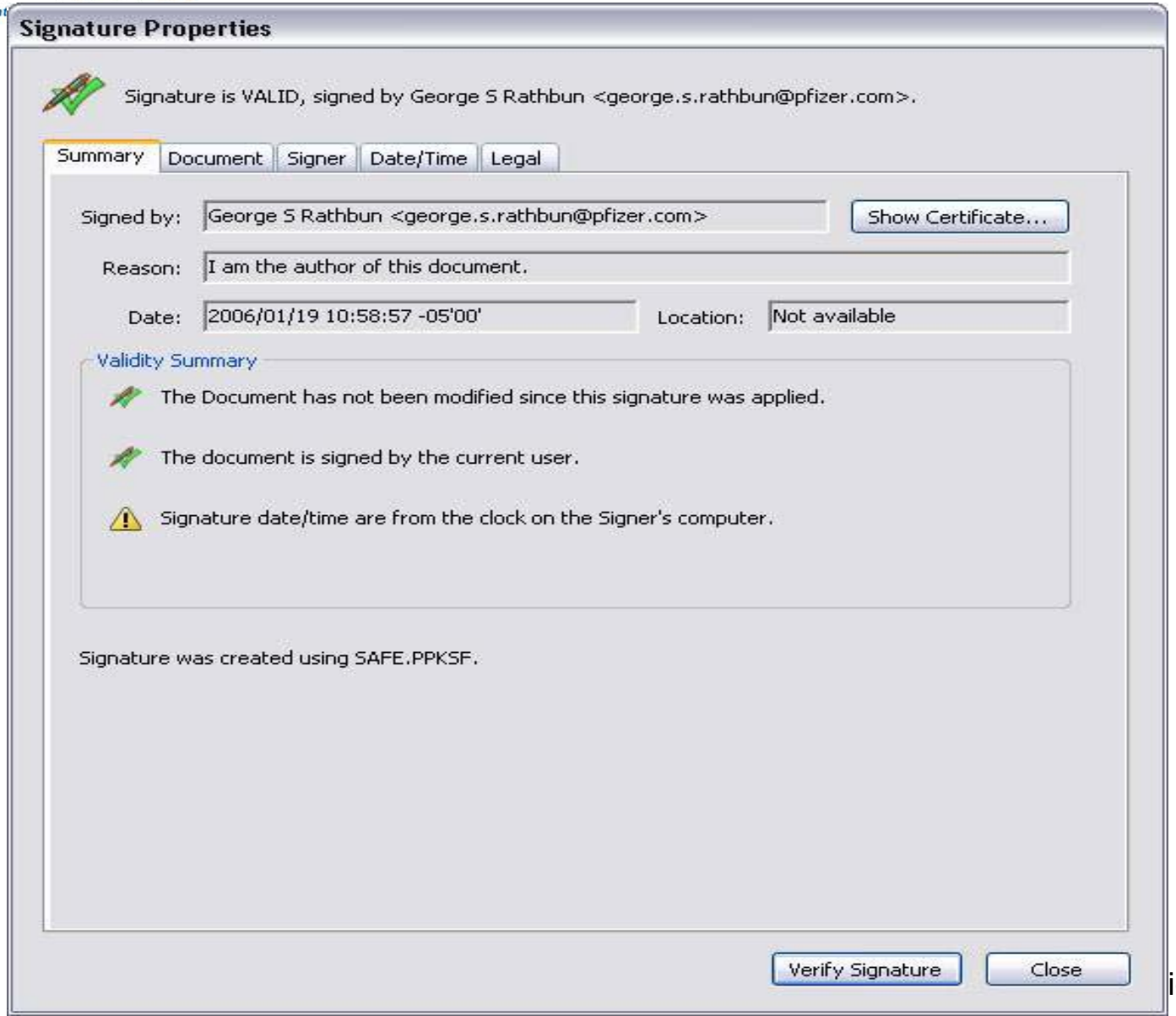
Karl Von Jacobowitz

Name: Karl Von Jacobowitz

Reason: Affirm information on Form 1472

Date: 2005.10.19 20:33:07 – 4'00'

SAFE Signature Validation



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SAFE-FDA

SAFE Compliance Working Group

- **SAFE Member reps with QA/Compliance/Regulatory backgrounds**
- **Works with FDA**
  - CDER/Division of Scientific Investigations
  - Part 11 Council
  - CIO
  - CBER
- **SAFE/FDA Auditor Familiarization Program**
  - Joint effort to develop training for FDA and Member Internal Audit staffs
  - What is SAFE, What is a SAFE Signature, How is it manifested on a record, What should you look for?
- **Products/Schedule**
  - Inspection Techniques Manual for Auditors: Final
  - Auditor Familiarization Training Materials: 2Q06 operational
- **Provides**
  - Regulatory Compliance Matrix
    - How does SAFE comply with Pt 11
  - Functional Validation Scenarios & Validation Checklists
    - Can be used by Members to support system validation
  - Internal SOP Matrix
    - What internal documents does a Member need to develop

SAFE EMEA Pilot

- **Participants**
  - SAFE Evaluation Team: EMEA, GSK, Organon, Pfizer
  - EMEA Manager: Wim Nuyts
- **Pilot has 3 main areas of scope**
  - The technology,
  - EMEA legal opinion
  - Auditability.
  - The Participants will be limited to SET members
- **Key Assumptions**
  - The pilot will interact between the Participants and the EMEA
  - The pilot will utilize the SAFE Profile/USSI proof of concept (POC) signing interface to apply digital signatures to PDF
  - The Participants will digitally sign PDF documents only
  - Email notifications will be sent using SAFEsign.org to confirm approval of documents
  - The pilot will use SAFE test credentials supplied by SAFE

National Cancer Institute

- **Firebird (Federal Investigator Registry for Bioinformatics Research Data):**
  - Investigators register on-line with NCI and other sponsors
  - Clinical trial registration via Form 1572
- **Deployment Scope:**
  - Technical pilot completed
  - Pilot Phase: ~50 investigators and support staff at 8 sites (Q206)
  - Production: 13,500 Principal Investigators; 7,000 research sites to be registered within the next 24 months (end 2006)
- **Pilot Sites:**
  - Memorial Sloan Kettering
  - City of Hope
  - H Lee Moffitt Cancer Center
  - University of Chicago
  - Mayo Clinic
  - Women & Infants Hosp. RI
  - Sidney Kimmel Cancer
  - Stanford University

SAFE Member Projects

- GlaxoSmithKline – EDC, Site Study Initiation
- Merck – Sampling
- Pfizer – Enterprise identity Management, Clinical
- P&G – Digital Signatures
- BMS, AstraZeneca, SanofiAventis, Genzyme

Cross-Certifications: J&J and Cybertrust

- **Johnson & Johnson Services can now offer SAFE digital identity credentials and SAFE authentication and digital signature services across its parent enterprise.**

- **Cybertrust's SAFE customers can now utilize the SAFE digital identity and SAFE digital signatures in a broad range of business-to-business and business-to-regulator transactions utilizing the Internet.**

The SAFE Vendor Community

Signatures and Authentication For Everyone

Premier Partners

- Adobe
- Arcot
- Aladdin
- Bearing Point
- Corestreet
- Cybertrust
- IBM
- Kyberpass

Integration Vendors

- Northrop Grumman
- SAIC
- Ernst & Young
- Teratec
- Accenture
- Churchill & Harriman
- SIG

Infrastructure Vendors

- SafeNet
- Tumbleweed
- Gemplus
- Verisign
- CyberTrust

Applications Vendors

- PhaseFoward
- Relsys
- Liquent
- Microsoft
- Documentum
- Oracle
- OpenText
- Intralinks
- ISI
- Lorenz
- ArborText
- Glemser Technologies
- Scientific Software
- PathData
- Tumbleweed
- FCG

SAFE and eHealth, SDOs

- **Objectives:**
  - Increase awareness of SAFE to healthcare community
  - Participate in standards development
  - Provide framework to foster/evolve industry standard
- **SAFE - E-Health Partnership:**
  - US: e-HI Identity Management and Dig Sig Working Group
  - EU Forum
  - White papers – e.g., risk management, legal

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Imagine a Future……

- Patient visits physician
- Registered with the swipe of a card
- Physician enters info on integrated point of care device, orders tests, prescribes, enrolls patient in clinical trial – all electronically
- Lab tests submitted and reported electronically
- Medicines are manufactured in batch and sent via electronic order
- Claims submitted and paid and records kept electronically
- Clinical trial data managed, signed and submitted electronically
- Patient carries personal health record……

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SAFE

is the only global standard for healthcare community

interoperability that enables trusted, secure, legally enforceable,

paperless healthcare regulatory and business transactions

Becoming a SAFE Member

Visit:

http://www.safe-biopharma.org

Mollie@SAFE-BioPharma.org