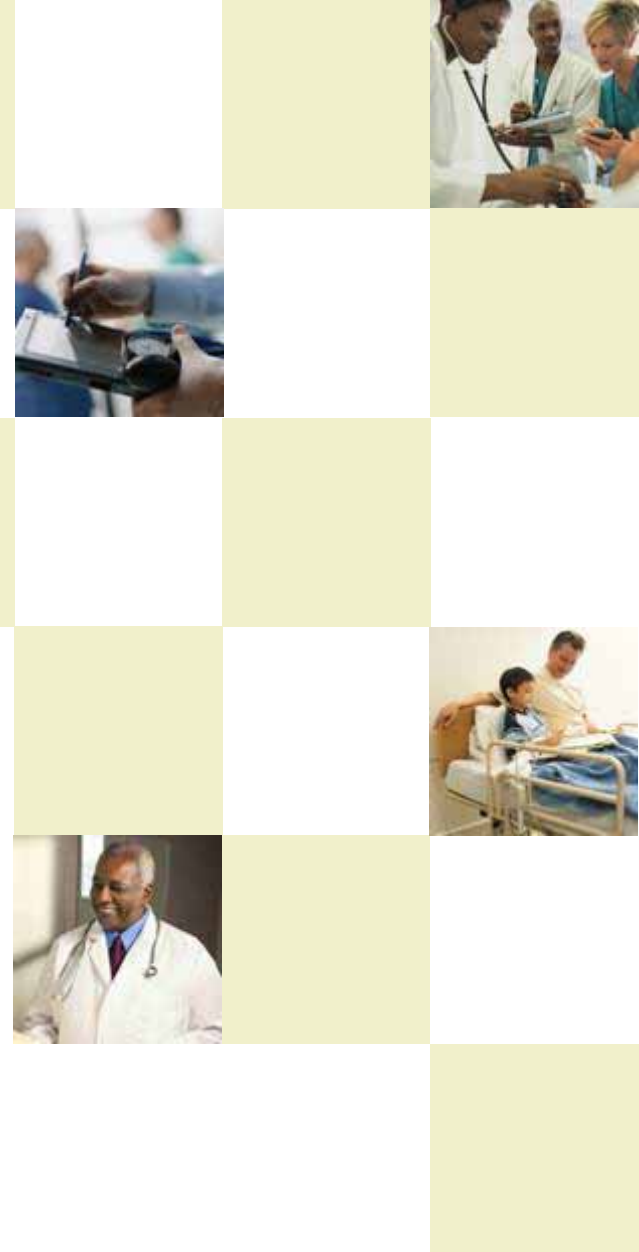




Signatures and Authentication For Everyone

DIA
SAFE Technology Discussion
May 24, 2007

Cindy Cullen
CTO
SAFE Bio-Pharma Association

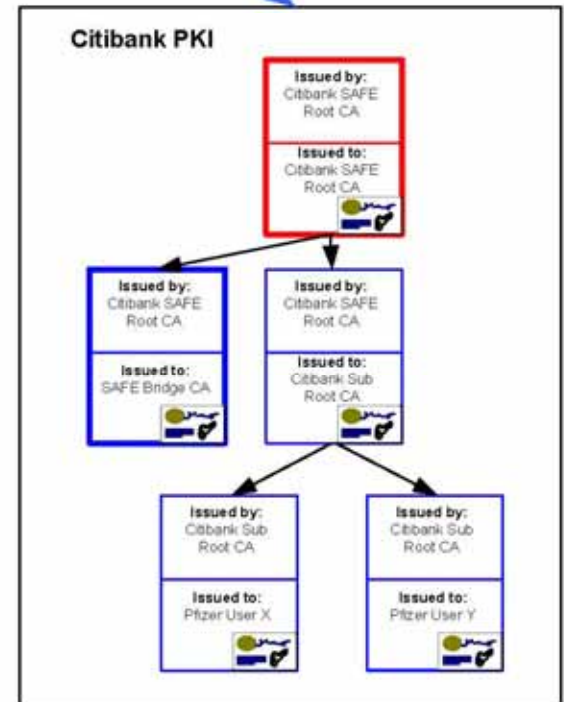
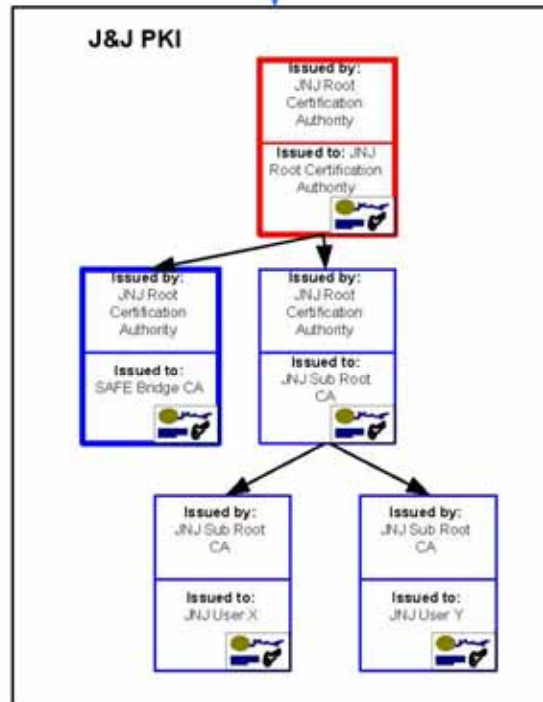
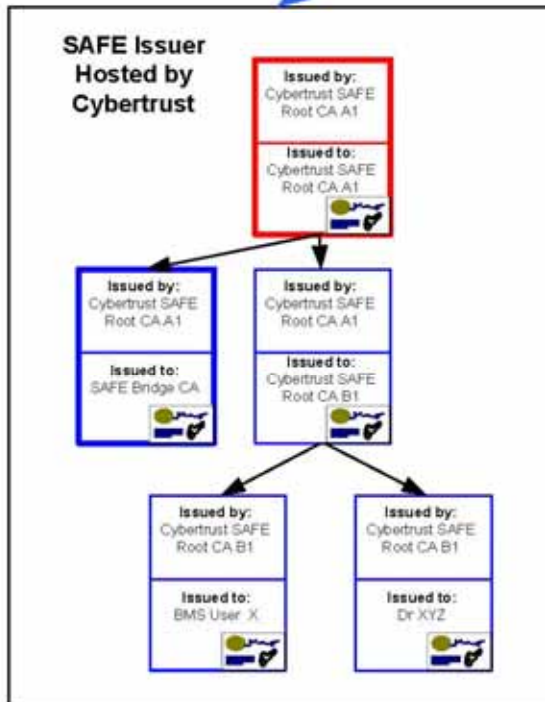
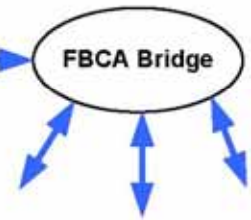
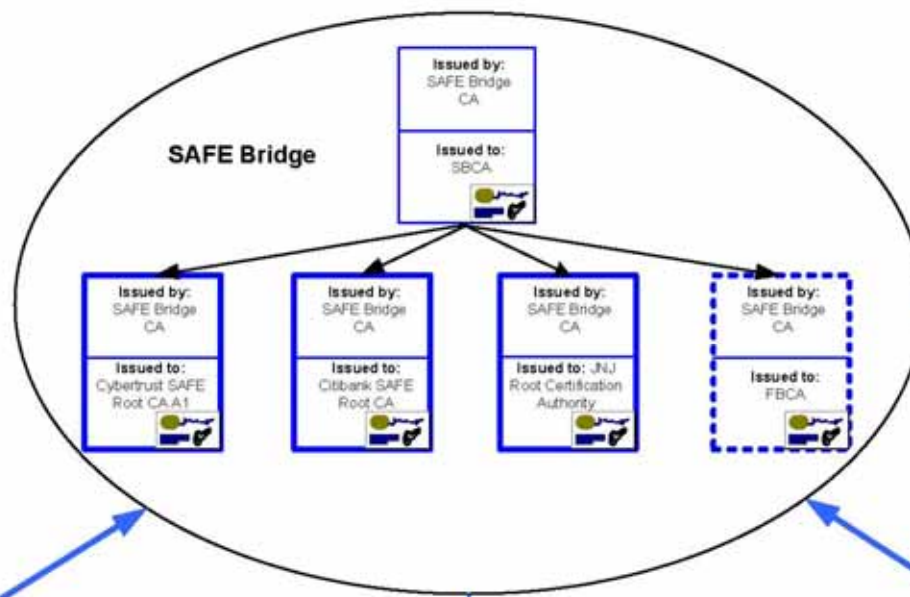
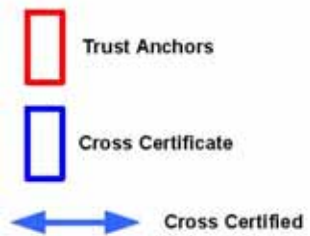




Agenda

- ▶ **SAFE CA Infrastructure**
- ▶ **Cross Bridge Infrastructure**
- ▶ **Certificate Provisioning Process**
- ▶ **TA Certificate Provisioning Process**
- ▶ **SAFE Implementations**
- ▶ **Digital Signatures**
- ▶ **Identity Management**

SAFE PKI Infrastructure





TA Provisioning Process

Signatures and Authentication For Everyone



Employee

Request SAFE Certificate via eSetup (LDAP authentication)

Install software & Access RACCA Site

Set up account & complete steps 1 & 2

Download certificate & sign test document



Manager

Request Approved

Email Invitation and iKey Software

Email Notification

Request Approved

Email Notification



Signatures and Authentication For Everyone

Yes

Yes

Request Approved

Yes



Trusted Agent

Request Approved

Invitation Code

Request Approved



SAFE Member Implementations

▶ **Pfizer:**

- eLab Notebooks
- Regulatory submissions

▶ **AstraZeneca:**

- 150+ regulatory submissions via FDA's ESG: 2252, 1571, 356h and eCTD

▶ **GSK:**

- eCTD submissions

▶ **Merck**

- Product sampling for physicians

▶ **J&J:**

- All J&J digital signatures are SAFE signatures
- Electronic Master File
- Regulatory submissions

▶ **P&G:**

- Enterprise digital signature
- 4,500 eLab Notebooks
- ePurchasing
- eHR – forms
- ePatent Filings

▶ **BMS:**

- External partner authentication - Pilot



SAFE Signature



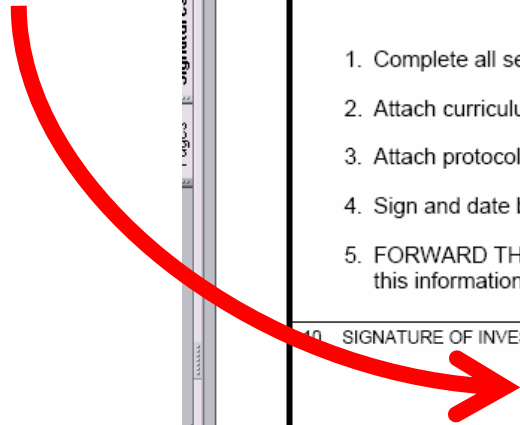
Dr. Robert Hill

SAFE

Dr. Robert Hill TM
Reason: I agree to the terms defined by the
placement of my signature on this document.
Date: 2006-06-15 09:38:18 -0400

Validating a SAFE Signature

**Just Click
On it ...**




You are viewing: Ashley Evans's Application

https://www.safesign.org/ussi/sp/downloads/Please_Sign_157216.pdf?ID=2220&RSTR=q99p...

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).

10. SIGNATURE OF INVESTIGATOR	 Mark A Nelson For Demonstration Purposes Only	11. DATE
(WARNING: A willfully false statement is a criminal offense. U.S.C. Title 18, Sec. 1001.)		

Validation is estimated to average 100 hours per response, including the time for reviewing instructions, maintaining the data needed, and completing reviewing the collection of information. Send comments of this collection of information, including suggestions for reducing this burden to:

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 (4/03) PREVIOUS EDITION IS OBSOLETE

***Validation: Confirms Integrity
of Signed Document & Validity
of Signer's Digital Certificate***



I&AM is not technology!

I&AM services should be designed to ensure that all business transactions contain and convey the appropriate evidence relative to:

Who is allowed in?



Identity Management

Who and what is performing the transaction?

The transactional record must support and be compliant with applicable Global legal and regulatory requirements

What can they Access/Do



Access Management

What was accessed what happened?

Evidence

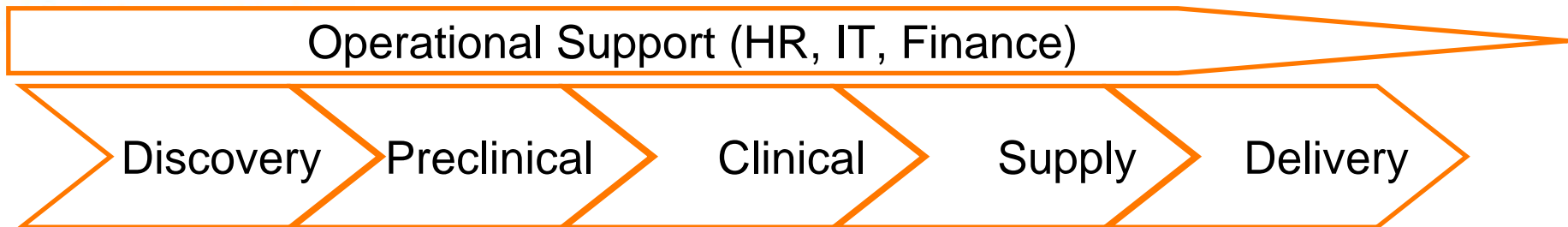


Binding/Acceptance

**When did the transaction occur
How was the user bound to the transaction**



Signature & Identity Management Landscape



eLab Notebooks (IP Protection)	Electronic Data Capture
eLabling	eArchiving
Grant Management	Code Signing
Site Study Initiation Packages (1572)	Contracts/Grant Signatures
Electronic Submissions (eCTD)	SOP approvals
Quality Documentation Approvals	Expense Reporting
Adverse Event and Safety Reporting	Human Resources (payroll, benefits)
Informed Consent Forms	Software Licensing Agreements
ePrescribing	Patient Compliance
eSampling	Investigator/Patient Portals
eDetailing	Key Opinion Leader (KOL) Management
Vaccines Ordering	Financial Reporting
Press Releases/PR approvals	Patents and Grants



Questions?

Cindy.Cullen@Safe-BioPharma.org