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Going Paperless Securely in Clinical Trials: An NCI Pilot Using E-Signatures and the Cloud

SAFE-BioPharma Association
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Conflict of Interest Disclosure

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SAFE-BioPharma Association is a non-profit standards organization dedicated to facilitating the transformation of healthcare and life science business and regulatory processes to fully electronic. It is funded by 30 life science and healthcare companies.



Conflict of Interest Disclosure

<First Name> <Last Name>, <Degree>

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- Other: N/A



Learning Objectives

- Explain to colleagues the fundamentals of starting a clinical trial substituting cloud computing and digital signatures for paper forms
- Recognize the unique role of digital signatures in protecting confidential patient information
- Identify the multiple steps in the NCI/CTEP clinical trial start-up process



The Interoperable SAFE-BioPharma Digital Identity and Signature Standard

- **SAFE-BioPharma Association**
 - A non-profit membership association (est. 2005)
 - Community of interest that manages the Digital Identity and Signature standard
 - Strategic initiative to transform business and regulatory processes to cloud
 - Single identity for use with multiple applications and multiple partners
 - Operate bridge to connect to US Govt and other cyber-communities
 - Standards, profiles, technical specifications
 - Pilot new processes, uses
- **SAFE-BioPharma Digital Identity and Signature Standard**
 - High-level assurance binding identity to a digital signature (NIST)
 - Security and privacy
 - Mitigates risk
 - Provides secure, standardized way to verify and trust identities
 - Vendor and technology neutral
 - Interoperable identity across all US Government agencies and linked cyber-communities
 - Meets FDA, European Medicines Agency, and DEA requirements
 - For authentication and, where needed, digital signing



The SAFE-BioPharma Standard and Regulators

- USFDA and European Medicines Agency (EMA) are on a publicly-announced paths to requiring fully electronic submissions
- FDA helped write SAFE-BioPharma standard
- FDA has accepted 100,000s of SAFE-BioPharma signed submissions
- EMA helped write standard
- EMA recognizes and accepts SAFE-BioPharma signed submissions
- DEA rule on ePrescribing of Controlled Substances recognizes SAFE-BioPharma credentials as compliant
- SAFE-BioPharma now working with Japanese Regulatory Authority



Cloud Collaboration: NCI Clinical Trials Evaluation Program (CTEP) Site Study Initiation

- NCI's Business Problem:
 - NCI world's largest sponsor of cancer clinical trials:
 - Over 800 active trials with great complexity of interactions
 - Over 33,000 patients enrolled at any given time
 - FDA moving to electronic submissions
 - NCI budget constraints
 - Go-green initiatives
 - IT security requirements
 - Paper-based signatures are costly and slow down business
 - Electronic Signature are repudiable; Digital Signatures are non-repudiable



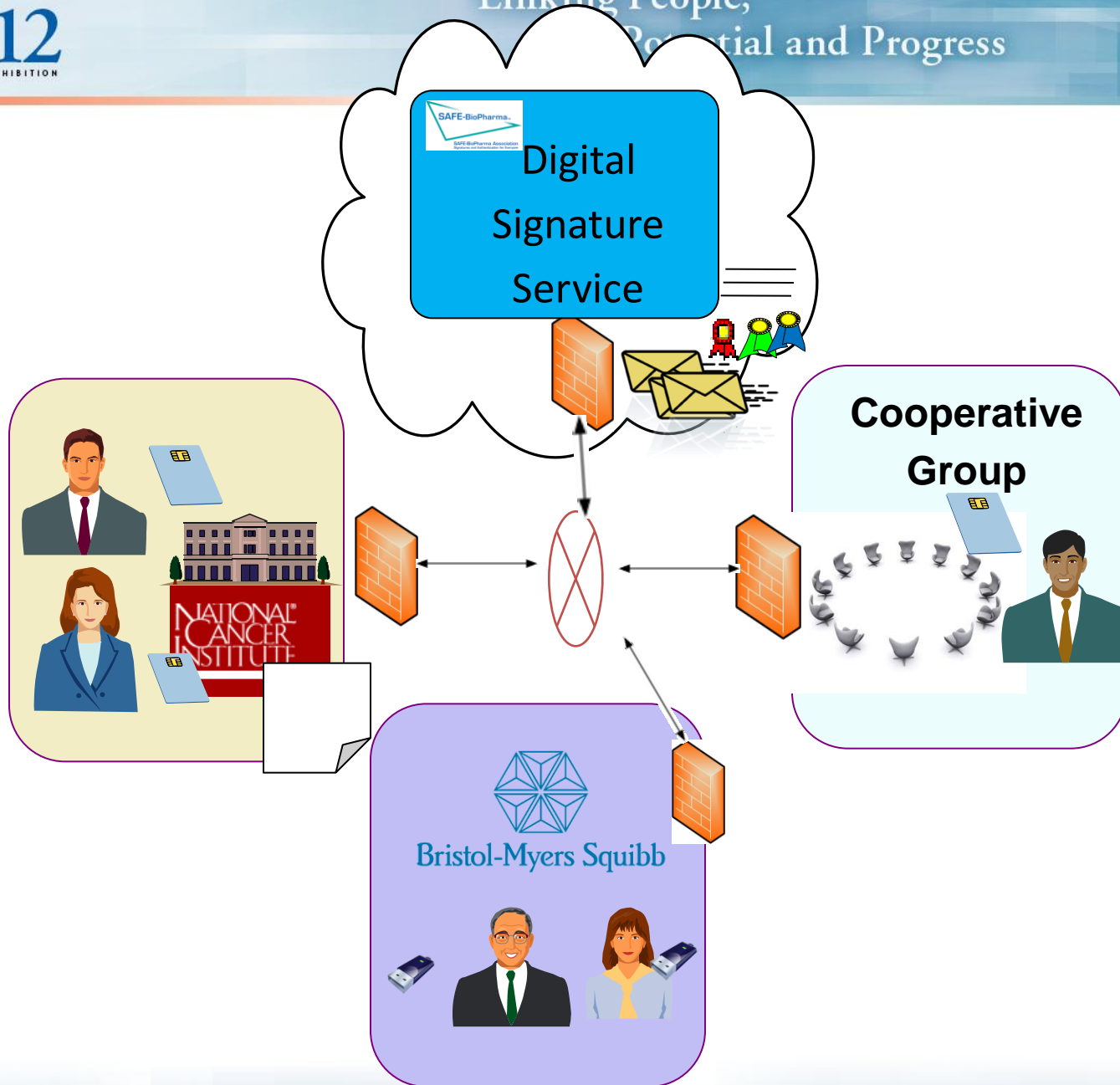
Electronic and Digital Signature Features

Feature	Electronic Signatures	Digital Signatures
Tight binding to the individual through face to face or other strong identity verification	No	Yes
Legally enforceable	Maybe	Yes
Supports strong non-repudiation	No	Yes
Maintains persistence, can be verified after certificate expires	No	Yes
Legal equivalent of hand written signature	Yes	Yes
Scalable	Yes	Yes
Tight binding to document signed (prevent "forgery")	No	Yes
Detect document tampering	No	Yes



NCI-Clinical Trial Site Study Initiation

- **The Pilot Approach:**
 - Using an online digital signature management service to facilitate National Cancer Institute electronic approval of protocols instead of via paper documents.
- **Participants:**
 - NCI Cancer Therapy Evaluation Program Office; Bristol-Myers Squibb; Sanofi-Aventis
- **Business processes:**
 - Uses secure digitally signed documents instead of paper documents.
 - Letters of Intent
 - Clinical Trial Agreements
 - Concept Approvals
 - Protocol Approvals
 - Contracts





Results of NCI's Clinical Trial Study Initiation Project

- Cycle time reduced
- Complexity of paper-based interactions eliminated
- Searchable and auditable
- Uses existing identity credentials – USG and SAFE-BioPharma
- High identity trust assurance for authentication
- Non-repudiable digital signatures
- Research sponsor calculated cost savings of \$500/user/year
- NCI calculated personnel time savings – 2.2 hours per signature

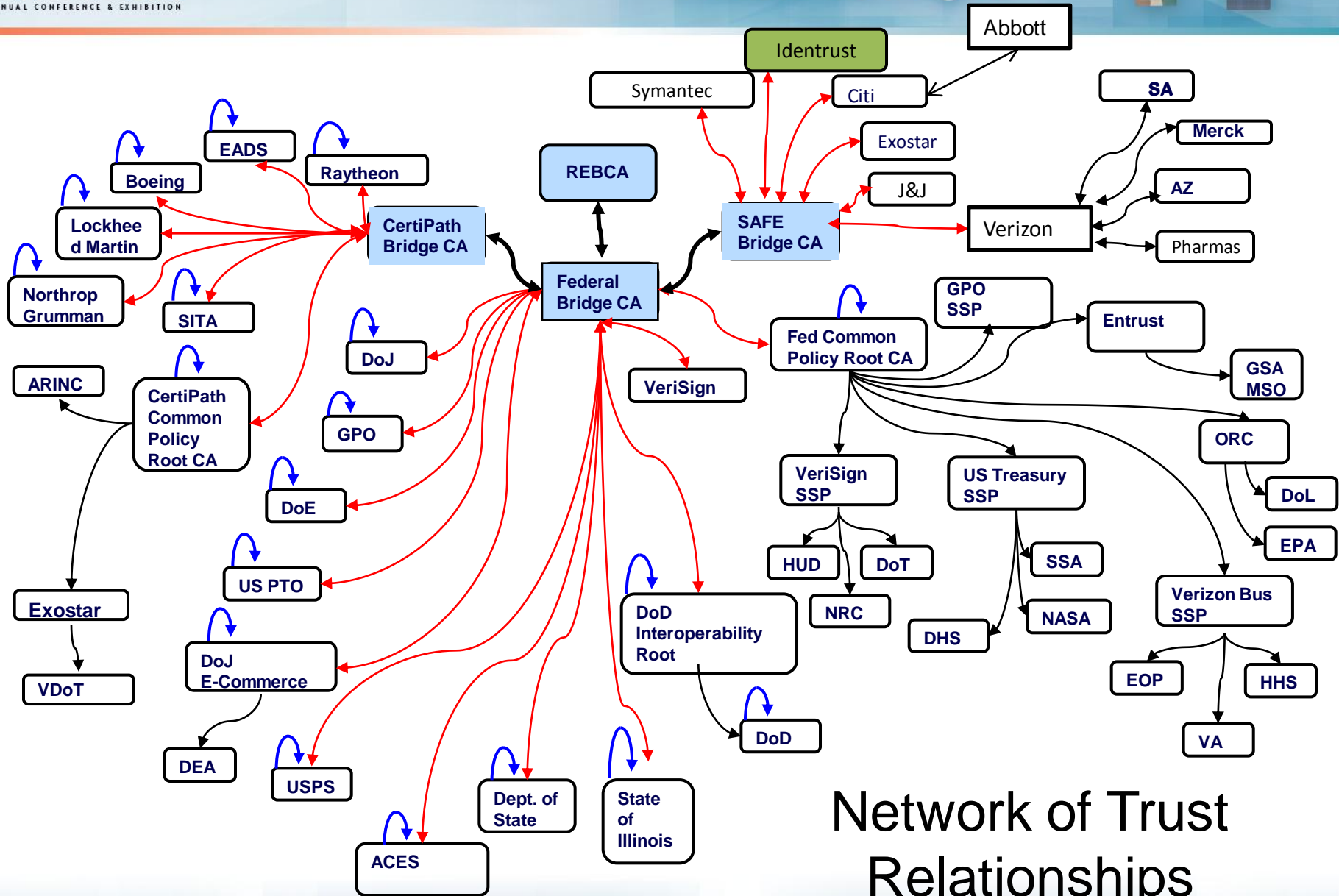
NEXT:

- Moving site study initiation into production
- NCI Conducting additional pilots: eVendor Invoicing Program (eVIP)
- Federation pilot with Merck, others: Adverse Events Reporting



Examples of How SAFE-BioPharma Standard Is Being Used

Use Case	Company
ELNs – basic research	Abbott (including China), BMS, GSK, Pfizer, SA/Aventis Pasteur (vaccines)
Contracts, SOWs	J&J, GSK, Premier, Oxford, MWB Consulting, IPS, Allergy & Asthma Inst.
Physician Signatures	SNAP Diagnostics
ePrescribing (authentication and dig sig)	Allscripts, Omnicare
Purchasing	Premier
Clinical Research	Sanofi-Aventis, BMS, National Cancer Inst., Forest
Research Collaboration	BMS, National Cancer Institute, Sanofi-Aventis
Alliance Management	BMS, GSK
Regulatory Submissions	AZ, BMS, GSK, SA, Eli Lilly, Forest, J&J, Alkermes
Document management system	McDougall Scientific
Legal signatures	Veroha
Paperless business/regulatory environment	Amarin, MWB Consulting, SAFE-BioPharma



Network of Trust Relationships




US On-Line Identity Proofing Process

SAFE Registration Authority System - Microsoft Internet Explorer

File Edit View Favorites Tools Help

Back Forward Stop Home Search Favorites Refresh Print Mail Stop

Address: <https://stg-ras.safe-biopharma.org/prod-sils/questions.php> Go Links

 SAFE Registration Authority System

SAFE User Profile Administration:

Identity Verification

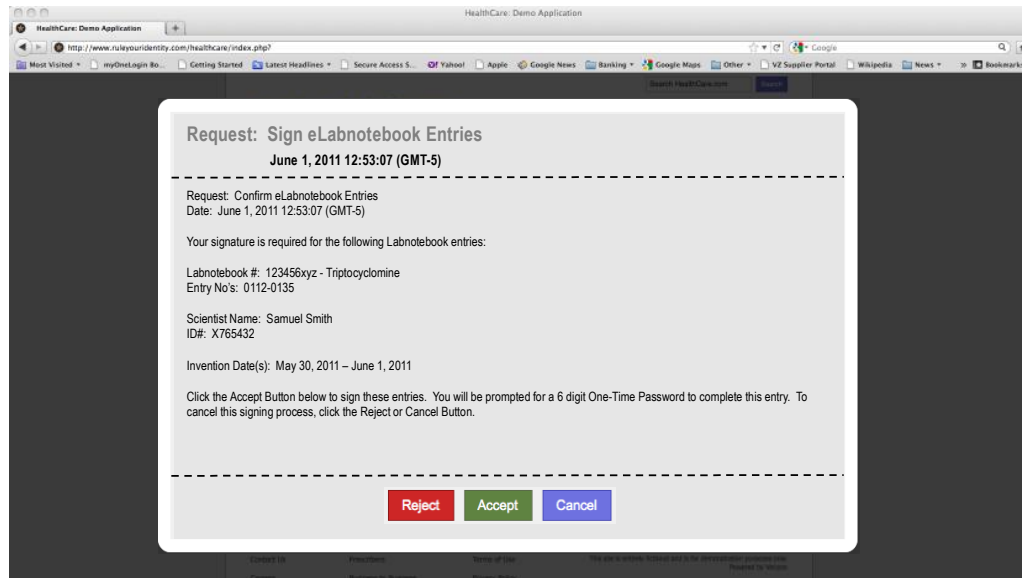
Please answer the following questions

<p>In what county do you currently live?</p> <p><input type="radio"/> Bristol</p> <p><input type="radio"/> Barnstable</p> <p><input type="radio"/> Berkshire</p> <p><input type="radio"/> Middlesex</p> <p><input type="radio"/> None of the above</p>	<p>Which of the following streets have you PREVIOUSLY OR CURRENTLY used as your address?</p> <p><input type="radio"/> Cimarron</p> <p><input type="radio"/> 380th</p> <p><input type="radio"/> Aubinwood</p> <p><input type="radio"/> Old Gurley</p> <p><input type="radio"/> None of the above</p>
<p>In what state was your Social Security Number issued?</p> <p><input type="radio"/> CO</p> <p><input type="radio"/> IL</p> <p><input type="radio"/> AL</p> <p><input type="radio"/> MA</p> <p><input type="radio"/> None of the above</p>	<p>Which of the following is/was your phone number?</p> <p><input type="radio"/> 624-4171</p> <p><input type="radio"/> 555-1402</p> <p><input type="radio"/> 387-9991</p> <p><input type="radio"/> 631-8023</p> <p><input type="radio"/> None of the above</p>

Done Internet



Roaming Credential User Experience: Digital Signing – eLab Notebooks, ePrescriptions, eSamples, etc.





Why Interoperable Digital Identities?

- Strong Identity Trust
- Replace all other forms of electronic identity
- Links user's identity to signed document
- Assure Data Integrity of any Electronic Document
- Creates permanent signature date and time record
- Valid for life of document
- Assures Secure Collaboration
 - Protects against unauthorized access/use on either side of the firewall
 - Protects against hacking and data loss
 - Establishes clear audit trail with every use
 - Simplifies compliance processes
 - Simplifies identity management and eliminates redundant costs
- Trusted by US federal agencies
- Complies with US and EU regulations



Digital Identities and Signatures in Healthcare Collaboration

- 2014: eHRs and ePrescribing requirements
 - Will prescribers be required to use unique credentials for each signing application? For each external partner?
 - How will eHRs be available across the healthcare spectrum while meeting HIPAA requirements? While providing high “usability” to participants?
- The Nationwide Health Information Network (NwHIN):
 - Is a trust framework fundamental/needed for interoperability among healthcare providers comprising the NwHIN?
 - What levels of trust are required?
- When are trusted identities needed for access to healthcare applications/portals?
- When are digital signatures needed?



- ✓ <http://safe-biopharma.org/>
- ✓ <http://www.the4bf.com/>
- ✓ <http://www.safe-biopharma.org/video.htm>

✓ *For more information:*

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