



Trusted Identity of Providers in Cyberspace Hearing Panel Discussion

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- The non-profit SAFE-BioPharma Association was established in 2005 by leading life sciences and healthcare firms to maintain a digital identity and signature standard and set of services to enable the transition of business and regulatory processes to fully electronic.
- The objective of the standard is to:
 - Simplify identity management, standardize trust, speed provisioning of identities and improve security
 - Provide single identity for clinical investigator teams and healthcare professionals that can be used across the life science/healthcare community
 - Replace the multitude of differing, proprietary credentials
- Key provisions of the standard are:
 - Strong identity trust through standardized identity proofing process
 - High-level assurance binding identity to a digital signature
 - Utilizing NIST and Federal government technical standards
 - FBCA cross-certified at medium assurance Commercial Best Practices and
 - FICAM certified as a Trust Framework Provider
 - Contract-based governance, legal and risk mitigation framework
 - Mapped to laws at US state and Federal levels, European Union and Member State levels
 - Strong privacy provisions – HIPAA and EU Safe Harbor
 - Interoperable identities across all USG and linked cyber-communities
 - Meets FDA, European Medicines Agency, and DEA requirements
- Over the past seven years, the SAFE-BioPharma community has conducted a number of pilots with physicians, researchers, prescribers, and other healthcare professionals. These pilots have resulted in significant improvements to the

deployment and use of individual identity credentials. Among these enhancements are:

- A 10-minute on-line identity proofing process meeting FBCA and NIST requirements
- A highly mobile roaming credential (“zero footprint”) that relies on existing devices – iPad, smartphone, home/office phones, existing OTP token – and does not require a special USB fob or smartcard
- These technology and process improvements have been accompanied by a steady decline in the prices of identity credentials, providing affordability for the investment in security, privacy, trust and interoperability they provide.
- Among other uses, the SAFE-BioPharma standard is today being used for:
 - Research collaboration across partners and geographies
 - Purchasing
 - ePrescribing
 - Physician signatures
 - Regulatory signatures and submissions
- Some specific use cases of interest to the ONC-NSTIC community are:
 - Research collaborations between the National Cancer Institute (NCI) and leading research-based pharmaceutical firms. NCI uses its government-issued PIV cards for authentication and digital signing and the pharmaceutical firms use interoperable SAFE-BioPharma credentials for the same purposes. This collaboration has resulted in:
 - One day saved on each official correspondence
 - 3-5 days saved on research material agreements
 - Cost savings of \$10 for every research material agreement
 - 2.2 hours saved for each wet signature replaced by digital
 - ePrescribing – several leading ePrescribing firms are incorporating SAFE-BioPharma compliant credentials in their applications in order to meet DEA requirements for ePrescribing of controlled substances. Omnicare is the first to rollout this new capability to their prescribers.
 - Physicians’ signatures – SNAP Diagnostics’ physicians use SAFE-BioPharma signatures to sign diagnoses and recommend treatments to referring physicians for sleep apnea patients.

- The SAFE-BioPharma community commends the Office of the National Coordinator and the Program Office of the National Strategy for Trusted Identities in Cyberspace for holding this meeting.
- We believe that the FBCA and FICAM standards establish the basis for a nationwide health information network that will provide the trust, security, privacy and interoperability fundamental to protect patients and improve outcomes. We also believe that the healthcare community offers the promise of being the showcase for the NSTIC vision.
- Thank you for the opportunity to present and comment.

For more information, please visit: <http://safe-biopharma.org/>

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