Identity trust in cyberspace

As the industry embraces mobile computing, Mollie Shields-Uehling, president and CEO of the SAFE-BioPharma Association, explains how the association’s digital identities standard establishes the basis for trust in internet transactions.

Smartphones, tablet computers and other mobile devices are being widely used in the biopharmaceutical and healthcare arenas, and are becoming increasingly popular due to their portability, convenience and size.

But, when it comes to accessing or transmitting sensitive and protected information, they share the same issue as their larger, desk-bound PC counterparts. How do you know that the person using the device is who they purport to be?

Fortunately, there is a solution at hand.

SAFE-BioPharma is the digital identity and digital signature standard developed for use in the biopharmaceutical and healthcare industries.

The standard is an industry collaboration and is managed by the SAFE-BioPharma Association, a not-for-profit organisation. Most major global biopharmaceutical companies are members, and groups participating in the standard’s development include the US Food and Drug Administration (FDA) and the European Medicines Agency.

A SAFE-BioPharma digital identity credential identifies the individual at the other end of the internet connection with accuracy and precision. Each individual receiving a SAFE-BioPharma digital identity credential completes a process that closely links it to actual identity. This procedure – most commonly done by answering a short online questionnaire – creates identity linkage between the user and the digital credential. This linkage, when combined with a set of legal agreements, establishes the basis for trust in internet transactions.
The digital credential is used to authenticate the user’s identity and to apply digital signatures to electronic documents. It is accessible from a computer, tablet, smartphone or other device, and can be used anywhere there is an internet connection. This is known as the Zero Footprint Roaming (ZFR) credential.

Organisations using SAFE-BioPharma digital identities are able to manage who has access to sensitive and otherwise confidential electronic information. They also are able to manage access to physical facilities.

This ability to trust cyber-identities is unmatched by any other information security system in common use, and it contributes significantly to our ability to collaborate via the internet.

Additionally, due to a bi-lateral trust agreement with the US Federal Government, a digital identity asserted by SAFE-BioPharma – including the ZFR – will be trusted within the FDA and other agencies, while the identities they assert will be trusted within the SAFE-BioPharma community.

SAFE-BioPharma digital identities can also be used to apply legally binding digital signatures to electronic documents. Because they cryptographically guarantee the integrity of documents to which they are affixed (i.e. any change to a signed document invalidates the signature), digital signatures are the gold standard of electronic signatures. They are widely used to sign electronic laboratory notebooks and are fast becoming the digital signature of choice for signing e-prescriptions.

Due to the protection and convenience they provide, digital signatures – to be distinguished from common electronic signatures – eliminate the use of paper and its associated costs, speed up processes and facilitate audits.

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Pilot study
A global biopharmaceutical firm wanted to determine if tablets could be used to collect and transmit patient data gathered from electronic health records (EHRs) in a hospital setting.

This is a scenario fraught with issues. Many hospitals have internet blackout zones and ban the use of cell phones or other devices that could compromise patient confidentiality.

But it is a scenario that presents opportunities, as well. Patient data can be collected and transferred with startling efficiency and accuracy. Moving from collection of data in EHR form to use of that data offers a lot of promise.

The firm decided to test the use of SAFE-BioPharma digital identities on iPads in a hospital. The study design allowed physicians involved in clinical trials to authenticate identity, which gave them access to the EHRs. It also allowed the physicians to collect patient data, place it in forms via the iPad and apply their digital signatures. Each iPad was provisioned with a digital credential identifying its user, and contained a specialised mobile application to gather and record patient information.

This was done in internet blackout zones, where the data was stored in the iPad for later secure internet transmission to a central clinical trial system.

When patients required prescriptions, the investigator applied a digital signature to the e-prescription and sent it to a central clinical trial system.

The success of this pilot suggests other uses of tablets, smartphones, etc. that have been provisioned with SAFE-BioPharma digital identities. These include:

- **Cloud-based clinical trial document management:** Accessing, signing, and exchanging cloud-located trial documents is facilitated through use of SAFE-BioPharma digital identities. An ongoing study involving US National Cancer Institute oncologists and counterparts at Bristol-Myers Squibb and Sanofi demonstrates significant time and cost savings over use of paper-based systems. Industry researchers are using SAFE-BioPharma digital identities and NCI researchers are using government-issued digital identity credentials. Bilateral trust exists between SAFE-BioPharma identities and those used in US Government agencies.

- **E-prescribing:** Conventional prescribing of controlled substances is paper-intensive, producing multiple printed copies to comply with regulatory, auditing and dispensing requirements. E-prescribing using SAFE-BioPharma digital signatures eliminates paper and allows all form-filling to be done electronically. Use of the ZFR permits authorised medical personnel to log-in through a mobile device and to apply digital signatures to e-prescriptions for controlled and other medications.

- **E-sampling:** Paper forms are eliminated and a fully electronic audit trail automatically established. In addition to the conventional model in which reps deliver samples to the office, one company has experimented with e-sampling, whereby the doctor applies a digital signature to an e-prescription for a sample and transmits it to the pharmacy where the patient is able to have the prescription filled.

Global issue
Identity trust is a major global issue. It is the limiting factor in business-to-business and business-to-government transactions, especially those involving regulated information.

A few years ago, the US Government introduced its National Strategy for Trusted Identities in Cyberspace initiative, while in June the European Commission adopted a proposal for a regulation “on identification and trusted services for electronic transactions in the internal market” to boost user convenience, trust and confidence in the digital world.

SAFE-BioPharma is helping industry stay ahead of the identity trust curve, especially as it embraces mobile computing.