

# Clouds of change

The management of clinical trials is a time-consuming and costly process involving many bodies providing and requiring information at different times. **Mollie Shields-Uehling**, SAFE-BioPharma Association, explains how the cloud computing method employed by the National Cancer Institute can help keep clinical trials on an even keel, heralding the dawn of a new, secure digital future.

**A** new window has opened to the future state of clinical trial management. With it came an invigorating gust of fresh experiences that make it easier and safer to collaborate online with partners, vendors, suppliers and regulatory agencies.

The world's largest sponsor of cancer treatment clinical trials collaborated with two global biopharmaceutical companies to demonstrate how to get a clinical trial off the ground in record time and with less cost by eliminating reliance on paper forms. By using the cloud computing model, they placed the start-up letters, agreements, forms and other documents into the network and equipped researchers with interoperable digital identities so they could securely access, review, sign and exchange them using the internet.

The participants were scientists working for the National Cancer Institute in the US and their counterparts at Bristol-Myers Squibb and sanofi-aventis. They were able to show dramatic time savings for all document flows requiring multiple signatures, they got research underway more quickly and, depending on the specific documents involved, they eliminated hours, weeks and months in the document workflow process.

At the core of the study are interoperable digital identities. The ones used by the NCI researchers were issued by the US Government. Those used by the industry researchers are compliant with the SAFE-BioPharma digital identity and digital signature standard. Even though the researchers only knew each other via cyberspace, they were able to have full trust in their respective identities because SAFE-BioPharma and US Government identities are fully interoperable.

Digital identities are unique because they are closely linked to the holder's actual vetted identity. Without getting into the behind-the-scenes cryptographic technology that creates the close link, it is real and it results in being able to trust another similarly equipped party anywhere in cyberspace. >>



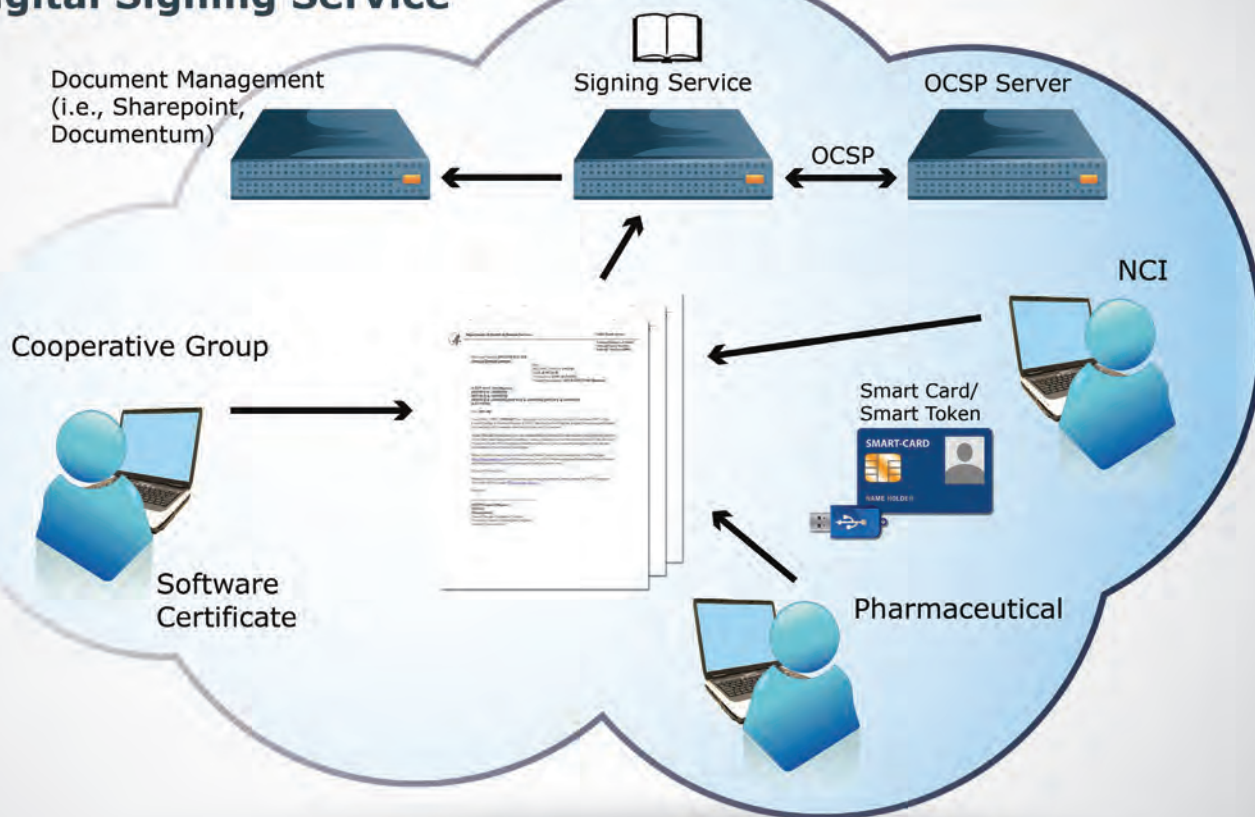
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#### **Mollie Shields-Uehling**

Mollie Shields-Uehling directs the business and strategic activities of the SAFE-BioPharma Association and serves as the primary liaison with members of the growing SAFE-BioPharma community.



## Digital Signing Service



The cloud computing model allowed SAFE-BioPharma to collaborate with two biopharma companies to conduct a clinical trial in record time.

Once that identity vetting process has occurred, the identity credential – a form of software placed in the cloud or installed on a computer, mobile phone, tablet, iPad or other device – can be used to access information and to apply legally binding digital signatures to electronic documents. Every time the credential is used, whether to gain access to a record or to apply a signature, the identity is authenticated. This assures a high level of identity trust – an essential element for the protection of intellectual property and for compliance with regulations across global jurisdictions

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### How does this study apply to the future?

On the one hand, the clinical trial process is expanding geographically, increasingly including sites in China, India and other regions of the developing world. On the other hand, the entire industry has become highly collaborative, requiring a constant flow of confidential information involving researchers, healthcare providers and regulators worldwide. Secure and trusted internet communication is the only practical way to manage these ever-expanding relationships, which is what the coalition of companies and regulatory bodies had in mind when they

developed the SAFE-BioPharma digital identity and signature standard. The result of their efforts is a standard that provides maximum data and identity security for the organisations that use it. They include Pfizer, Bristol-Myers Squibb, Merck, Lilly, GSK, sanofi-aventis, Roche, AstraZeneca and J&J, as well as other smaller companies that are integrating the SAFE-BioPharma standard into their daily business operations.

The standard mitigates the multiple risks inherent in electronic transactions within the biopharmaceutical and healthcare communities. Part of risk management is complying with government regulations: the SAFE-BioPharma digital standard is compliant with US and European regulations.

Interoperability is another important benefit of the SAFE-BioPharma digital identity standard. SAFE-BioPharma identity credentials are trusted by a growing community of pharmaceutical and healthcare organisations, government agencies (for example, the National Institutes of Health, the US FDA and the European Medicines Agency) and companies in other industries. It's like being part of a club where one of the benefits is to be trusted wherever you go. You don't need to wait by the red rope: you and your signature are accepted whenever they are presented to a participating group.

### NCI's pilot study

The needs of the National Cancer Institute, one of the US National Institutes of Health, set the stage for creating a pilot study that successfully demonstrated how interoperable digital identities are

key to accelerating the clinical trial start-up process. The mission of the NCI's Cancer Therapy Evaluation Program (NCI/CTEP) is to improve the lives of cancer patients by finding better ways to treat, control and cure cancer. The programme has over 900 active clinical trials and activates approximately 130 new protocols a year.

**“ The NCI pilot demonstrated that using interoperable digital identities reduces risk, cost and time – those are welcome benefits. ”**

During the protocol lifecycle – from concept to closure – each protocol produces signed and exchanged documents among multiple participants, including cooperative groups – of physicians and/or medical institutions, cancer centres and academic institutions. NCI/CTEP was mandated to more quickly initiate clinical trials to patient accrual, reduce costs, streamline document management while assuring greater document security, and to have environmentally sound procedures. The NCI and industry researchers were provisioned with interoperable digital identity credentials and the electronic documents were placed in the cloud.

Using their digital identity credentials and a SAFE-BioPharma-hosted digital signing service, the researchers were able to access the documents and digitally sign them immediately. Prior to the study, the signature process was delayed by using courier services, faxes and travel.

To pilot the digital signature process, NCI/CTEP selected its randomised phase II and phase III trials conducted through cooperative groups. The protocol process is as follows:

- A cooperative group submits a concept/letter of intent (LoI) for CTEP review and approval.
- After the CTEP review, a signed letter is sent to the cooperative group, along with a consensus review of suggested changes.
- The collaborating pharmaceutical company receives a copy of the LoI or concept and submits a signed drug approval letter. This allows the CTEP to approve the LoI/concept so the group can create and submit a protocol.
- Once the CTEP receives the protocol, a signed acknowledgement letter is sent to the cooperative group.
- Once the protocol is reviewed by CTEP, a signed comment letter is sent back to the cooperative group.
- A revised protocol is then resubmitted (there may be multiple revisions before final protocol approval is granted).
- CTEP approval or disapproval of the revised protocol is sent via a signed letter.
- Amendments to protocols follow the same last few steps for review, revision, and notification of approval or disapproval.

The pilot demonstrated dramatic time savings for all document flows that require multiple signatures from participants working on or off-site. Streamlining the signature workflow allowed research to get underway more quickly. Depending on the

specific documents involved, it eliminated hours in the document workflow process.

- Using paper forms, an average of 10% of the documents are shipped overnight and 10% are shipped by courier service; using digital signing, those costs are eliminated.
- Paper processes are time-consuming and often require physically shipping documents to signatories. Typically it takes 3-5 business days per signature. The pilot demonstrates that each signature can take minutes.
- Lost or misplaced documents were eliminated. Using digital signatures establishes an audit trail of when the email was sent to alert the signatory that the document is available for signature, and when the document was actually signed.
- As well as saving money, time and reducing document loss, the pilot lowers the carbon footprint. Moving to an electronic process eliminates the use of paper and ink and document shipment, and minimises storage and retrieval needs.

### What does it mean for the future?

In order for global collaboration – in general or for clinical trials specifically – to be secure, transactions with external parties need the combined strength of a digital identity and digital signature that is tightly bound to the identity of the signatory.

As the NCI pilot has clearly demonstrated, using interoperable digital identities reduces risk, cost and time, and given the industry's current economic environment, those are welcome benefits. The tools for a secure digital future are available now. Welcome to the future. ■

*A detailed explanation of the process and architecture is described in the white paper 'Research collaboration in the cloud: How NCI and Research Partners are using Interoperable Digital Identities, Digital Signatures and Cloud Computing to Accelerate Drug Development'. For more information, visit: [www.safe-biopharma.org/whitepaperform.htm](http://www.safe-biopharma.org/whitepaperform.htm).*

