



# The Computerworld Honors Program

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## Final Copy of Case Study

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**Organization:**  
BioPharma Association

**Organization URL:**  
[www.SAFE-BioPharma.org](http://www.SAFE-BioPharma.org)

**Project Name:**  
Research Collaboration in the Cloud: How NCI and Research Partners are using Interoperable Digital Identities, Digital Signatures and Cloud Computing to Accelerate Drug Development

**What social/humanitarian issue was the project designed to address? What specific metrics did you use to measure the project's success?**

R&D productivity is one of the major challenges facing the life sciences. Time lost starting or conducting clinical trials results in substantial financial losses and delays delivery of new therapies to patients. The National Cancer Institute has been mandated to more quickly initiate clinical trials to patient accrual, to reduce costs, to streamline document management while assuring greater document security, and to have environmentally sound procedures. Initial success of the project was evaluated in terms of cost savings, time savings, elimination/reduction of document loss, and reduced environmental impact.

**Please describe the technologies used and how those technologies were deployed in an innovative way. Also, please include any technical or other challenges that were overcome for the successful implementation of the project.**

Government (National Cancer Institute's Cancer Therapy Evaluation Program -- NCI/CTEP) and industry (Bristol-Myers Squibb, Sanofi-Aventis) cancer researchers are participating in an ongoing pilot study using interoperable digital identities, digital signatures, and cloud computing aimed at eliminating reliance on paper forms in clinical trials, thus accelerating initiation of a clinical trial while lowering its costs. The researchers were provisioned with interoperable digital identities, a

form of software installed on a computer, cell phone or other device, which establishes a close link with the user's proven identity and allows for the application of digital signatures to electronic documents. Unlike their simple electronic counterparts, digital signatures cryptographically guarantee the integrity of documents to which they are affixed. In the pilot study, the electronic documents were placed in the cloud, where the researchers were able to access and sign them immediately. Prior to the study, the signature process was delayed by use of courier, fax, travel, etc. The digital credentials exist within legally binding and regulatory-compliant cyber-communities known as identity trust hubs. All U.S. federal agencies are served by the Federal Bridge identity trust hub, which provided the NCI researchers with their digital identity credentials. The biopharmaceutical and healthcare communities are served by an identity trust hub known as SAFE-BioPharma, through which the industry (Bristol-Myers Squibb and Sanofi-Aventis) researchers received their credentials. The Federal Bridge and SAFE-BioPharma cross-certified to become interoperable, allowing a digital identity asserted by one to be trusted by the other. The pilot was cited by the White House as a good practice during its introduction of the National Strategy for Trusted Identities in Cyberspace (NSTIC) initiative.

**Please list the specific humanitarian benefits the project has yielded so far.**

The pilot is creating the foundation for delivering new therapies to patients in a timely manner. Clinical trials often are delayed by many months because paper-based processes typically slow the process. The effect is that patients who may benefit from new and developing therapies are unable to participate in these trials, and approval and delivery of therapies is delayed in general. The study showed cost savings through the elimination of paper forms. On average, 10% of documents are shipped overnight and 10% are shipped by courier service. Digital signing eliminated those costs. Time savings also are substantial. Typically, it takes 3 to 5 business days per signature. The pilot demonstrates each signature can take minutes. NCI/CTEP estimates that the year the study was initiated, documents comprising almost 100,000 pages were used to develop and correspond on its clinical trials. While the unit does not track the time involved in scanning, organizing and sending these paper documents to the FDSD, it reports that it is extremely labor intensive and, once digitized, will be greatly simplified. The pilot also demonstrates elimination of lost or misplaced documents. Using digital signatures establishes an audit trail of when the document was uploaded and when the document was actually signed. Besides saving money and time and reducing document loss, the pilot is reducing NCI's carbon footprint. Moving to an electronic process eliminates use of paper and ink, eliminates document shipment, and minimizes storage and retrieval needs.

**Please provide the best example of how the project has benefited a specific individual, enterprise or organization. Feel free to include personal quotes from individuals who have directly benefited from the work.**

The pilot successfully demonstrated the ease with which interoperable digital identities could be deployed and used to access electronic documents and apply digital signatures to them. It eliminated use of paper copies and allowed signed documents to be exchanged rapidly and securely online for business processes initiated by NCI/CTEP's Protocol and Information Office. According to Steven Friedman, MHSA, Chief, Operations and Information Branch, National Cancer Institute's Cancer Therapy Evaluation Program, "During the lifetime of a protocol, a dozen or so signed correspondences may be sent to the site. These same signers travel substantially for CTEP, and the need for a wet signature resulted in additional delays. As more trials are developed seeking to enroll patients located in underserved areas, the ability to penetrate these communities via technology becomes more critical to the success of these trials. By developing and using the digital signing service within CTEP, we can show that information can be readily shared with anyone with a computer and the correct digital identity. So changes to protocols,

especially changes that affect treating of patients enrolled in the trial, can be shared with all trial sites in a faster more secure fashion. This has the potential to improve patient safety and remove barriers from investigators seeking to validate the trial's scientific aims."