

Pilot Study Shows eSignature Lowers Costs and Improves Efficiency in Clinical Trials

A **prospective pilot study** conducted by the American Society of Clinical Oncology compared electronic signatures to ink-and-paper signatures in clinical trials. The data showed **cross-the-board improvements from eSignature: reduced staff time and effort, lower error rate, lower costs and faster document completion time.**

Signature collection has slowed scientific progress

The prospective pilot study was conducted to understand how more efficient signature processes could improve clinical trial efficiency. Clinical trials that rely on cumbersome paper-based signatures run into unnecessary obstacles with patient recruiting and research execution. They also face quality control issues that introduce unnecessary redundancies and errors.

Outdated paper processing is a significant limitation to the success rate of modern trials. Overall, the study cited that paper-based processes result in around 40% of the total costs of bringing a new drug to market. These disjointed, unreliable processes result in fewer completed studies, more errors and a terrible experience for everyone involved.

Why trust eSignature in clinical trials?

A common obstacle for healthcare and life sciences organizations considering electronic signature technology is concern about security and privacy. Before using the technology in a clinical trial, American Society of Clinical Oncology researchers investigated DocuSign eSignature in a pilot study and found that it provided the “high availability, fault tolerance and threat isolation” that healthcare providers need.

The ASCO team explained that eSignature offered simple implementation with flexibility for a range of standard or custom interfaces. They also made note of eSignature’s three-layer logical architecture and ease of integration with other critical applications and system processes.

Electronic signature improves clinical trial workflows

In 6.5 months, three campuses of a single health system combined to realize:

20% reduction

in document preparation time

19% reduction

in total document transaction time

612 hours

of labor savings

\$25,285

cost savings

“We found a strong statistical indication that digital signatures were more efficient... Users found the process convenient and intuitive and preferred to use digital signatures in the future.”

American Society of Clinical Oncology

Experimenting with electronic signature in healthcare research

To test the effect of electronic signatures in clinical trials, ASCO researchers conducted a study on three campuses of a hospital-based health system in California. For 6.5 months, they compared documents completed by a control group using ink-and-paper signatures to a test group that used DocuSign to prepare, route and obtain signatures according to 21 CFR Part 11 regulations.

The results showed that electronic signatures offered significant benefits in document completion time, labor reduction and total cost. Staff time required to prepare documents was measured in minutes and compared between electronic and paper signatures using a Wilcoxon rank sum test. The median time to complete a document with a traditional signature was 7 days, compared to only 3 days for DocuSign users. Within the electronic signature group, nearly two-thirds of all signatures were obtained in less than 2 hours. In a survey of the participants in the study, more than 80% of users described electronic signatures as “very easy,” “very convenient” and “faster than paper signatures.”

Electronic signatures also offered users a range of new benefits including tamperproof audit trails, exportable electronic certificates and unique links to identify signers. By incorporating templates for common document types, the test group could improve document quality by specifying field parameters, incorporating conditional logic and requiring completion of certain fields.

In addition to the efficiency of electronic signatures, participants in the test group also experienced fewer errors related to missing information, incomplete forms, incorrect dates and signatures in the wrong place.

While this particular study primarily focused on single-signature instances, the authors suggest that the savings from electronic signature implementation would increase as usage spread to more complex workflows. With integrations to additional systems and more users learning to use the technology, DocuSign offers the potential for even more efficiency gains.

DocuSign was chosen for this study based on “system security, signature legality, document integrity, implementation ease, costs, flexible electronic signature capture methods, system integration ability and ease of use. The system and securities were validated and 21 CFR part 11 compliance was verified.”

Research Citation: DOI: 10.1200/CCI.20.00027 JCO Clinical Cancer Informatics no. 4 (2020) 854-864. Published online September 24, 2020.

PMID: [32970483](https://pubmed.ncbi.nlm.nih.gov/32970483/)

About DocuSign

DocuSign helps organizations connect and automate how they prepare, sign, act on and manage agreements. As part of the DocuSign Agreement Cloud, DocuSign offers eSignature, the world’s #1 way to sign electronically on practically any device, from almost anywhere, at any time. Today, over a million customers and more than a billion users in over 180 countries use the DocuSign Agreement Cloud to accelerate the process of doing business and simplify people’s lives.

Document characteristics	Electronic (n = 156)		Paper (n = 109)	
	No.	%	No.	%
No. of signatures requested				
1	138	88.5	99	90.8
2	12	7.7	4	3.7
>3	6	3.8	6	5.5
Type of document				
Curriculum vitae	2	1.3	1	0.9
Delegation of authority	15	9.6	12	11.0
Form FDA 1572	10	6.4	17	15.6
Financial disclosure forms	55	35.5	43	39.4
Investigator’s brochure signature page	16	10.3	11	10.1
Note to file	2	1.3	3	2.8
Protocol signature page	12	7.7	14	12.8
Training log	38	24.4	6	5.5
Satellite clinic signature required				
Yes	5	3.2	22	20.2
No	151	96.8	81	74.3
Not reported	0	0	6	5.5
Revisions				
None	134	85.9	77	70.6
1	8	5.1	3	2.8
>1	0	0	0	0
Not reported	11	7.1	29	26.6



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