An Executive Summary

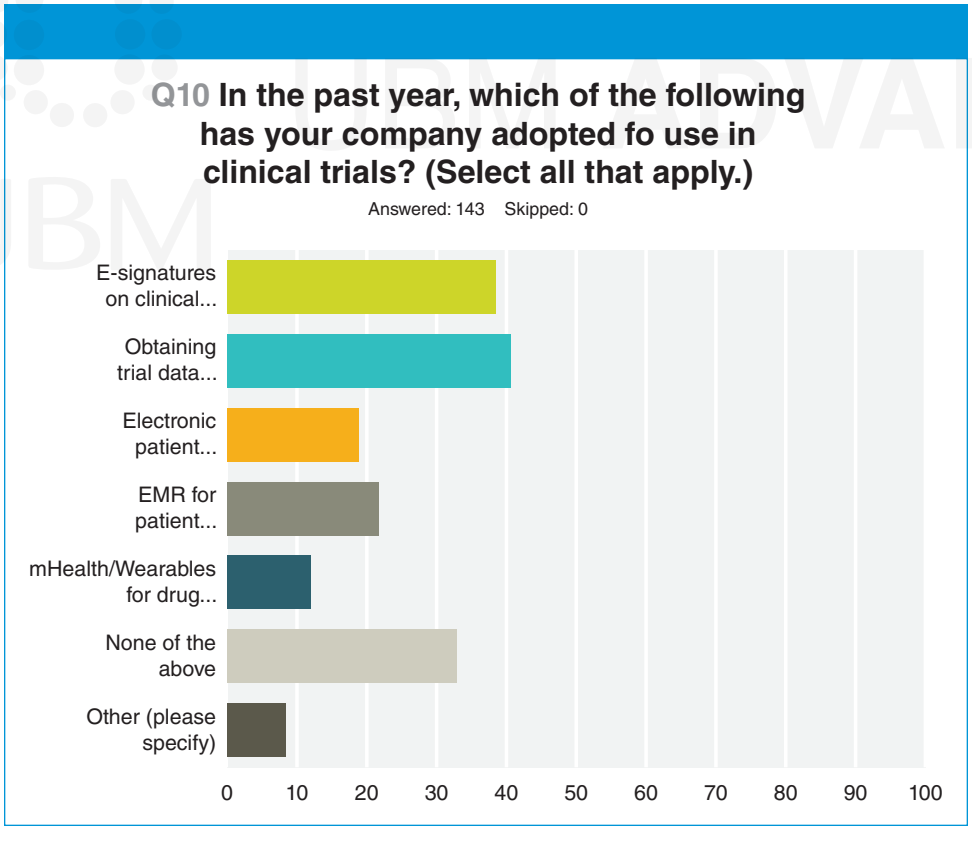
eSignatures and Digital Workflows in Clinical Trials

In clinical trials, the use of eSignatures to improve document workflows such as protocols, informed consent, and investigator brochures, has increased. For all documents that need signed approvals, eSignatures can be implemented to streamline, improve and make the transferring of those documents more efficient.

In a survey we conducted on paperless clinical trials in April 2016, we asked the question "In the past year, which of the following has your company adopted for use in clinical trials?" And 38.4% responded that eSignatures on clinical trial documents had been adopted.

What are the benefits for using eSignatures for improved document workflows in clinical trials? It depends on the process.

Last year, FDA issued its new draft guidance "Use of Electronic Informed Consent in Clinical Investigations". Interestingly, in the background on this Q&A guidance, it specifically states: "To many, the term informed consent is mistakenly viewed as synonymous with obtaining a handwritten signature from the subject or the subject's legally authorized representative (LAR) on a written informed consent form. FDA believes that obtaining a subject's oral or written informed consent is only part of the consent process."



So, number one, this goes to a belief system, that handwritten signatures are the only legal and binding authority in our society. Which is archaic.

And two, the FDA is definitely addressing eSignatures in the informed consent process, as noted in this statement:

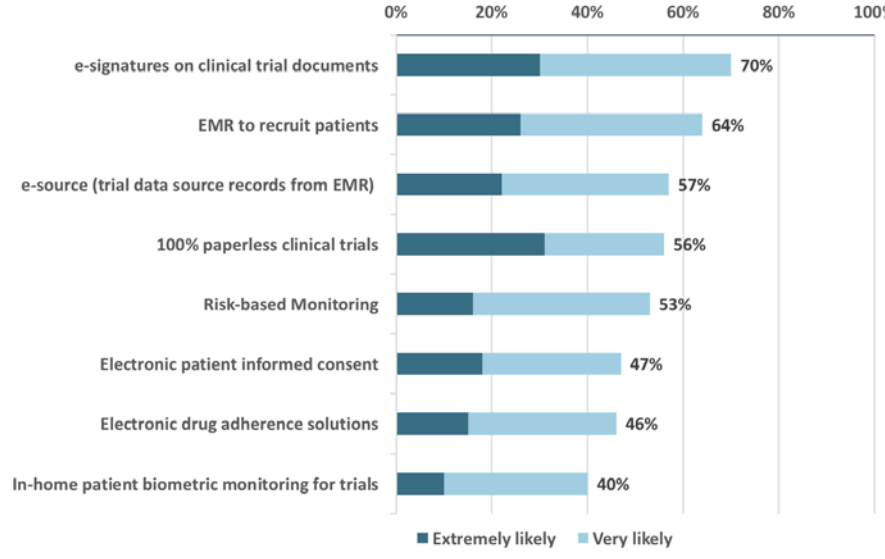
FDA explains: "When written informed consent is required, the use of electronic (including digital) signatures is permitted, provided the electronic signature is in

compliance with applicable FDA regulations. In such cases, the electronic signature is considered by FDA to be trustworthy, reliable, and generally equivalent to handwritten signatures executed on paper (see 21 CFR part 11, subpart A (11.1)(a))."

However, eSignatures are definitely the least "sexy" aspect of electronic informed consent. More articles and attention have been placed upon using interactive electronic media to enhance informed consent. And that is definitely a plus for patients understanding their role in a clinical trial.

But overall, it does point to the fact that eSignatures, while probably the most efficient way to improve process, may not be top of mind for some.

Figure 2: Technology Extremely or Very Likely to Become a Gold Standard within Three Years



Question: In your opinion, how likely is it that following advances in technology will become a gold standard for clinical trials in the next three years? (n=572)

Case Study: Cedars-Sinai Women's Cancer Program

Business Challenge

- Low rate of patient accrual for Research for Her Registry in the Cedars-Sinai Women's Cancer Program
- Implemented a traditional paper-based registry in which face-to-face consenting required at least 15 minutes and the mailed packets consisted of 13 pages
- Staff at the Cedars-Sinai Women's Cancer Program needed a way to recruit women with and without cancer to the research registry, utilizing social marketing to complete consent forms with minimal staff time in a way that would adhere to federal guidelines for electronic signatures

Solution

- Using DocuSign's eSignature capabilities, the Cedars-Sinai Women's Cancer Program was able to move their paper-based process online
- Implementing DocuSign replaced the Cedars-Sinai Women's Cancer Program's multi-step manual registry consent process with an automated one that simplifies participants' consent procedure and saves the staff's time

Results

- Immediate increase in registry enrollment from **5.4** people/month to **26.3** people/month at a much lower cost per enrollment
- **75%** reduction in turnaround time
- **63%** productivity gain
- Up to **$17.16** benefit per document

CEDARS-SINAI

"We won an award for Best Practices in Human Subjects Protection because of DocuSign's help in eliminating paper-based consent forms while adhering to federal requirements and keeping participants safe."

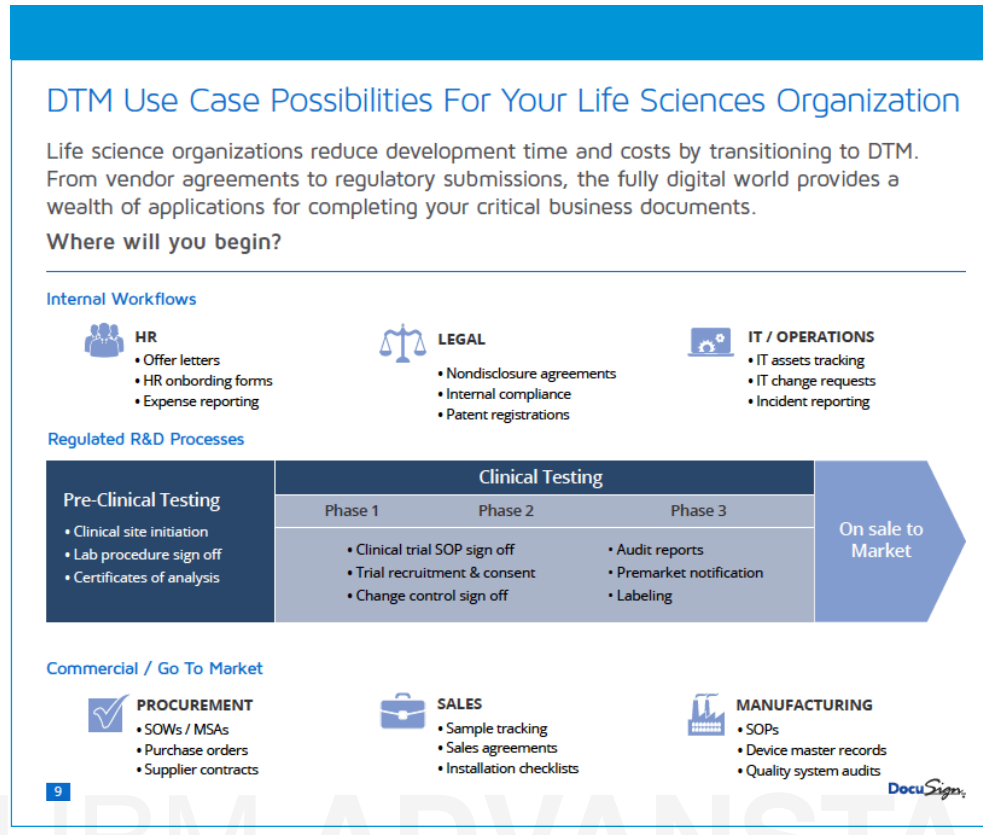
Dr. BJ Rimel
Associate Director of Gynecologic Clinical Trials
Gynecologic Oncologist, Cedars-Sinai Women's Cancer Program

DocuSign

So let's look at some other areas where eSignatures can improve clinical trials processes.

DrugDev, a technology services provider that focuses on solutions that improve the investigator's experience, has surveyed global investigators and has uncovered many of the pain points and solutions that can help there.

In a survey the company revealed late last year, Investigator Views on Future Clinical Trial Technologies, respondents were asked to rate eight different clinical trial technologies/applications across two different scales: its likelihood of becoming the "gold standard" in the next three years, and the likelihood that it will reduce investigators' administrative burden. 70% of investigators responded that it was extremely or very likely that clinical staff use of eSignatures on trial documents would be a gold standard in clinical trials within three years.



In a case study, the Sarah Cannon Research Institute reduced the time it took to get physicians' signatures by 94%. The institute implemented eSignatures to meet the challenge of rising clinical trial costs and ever-burdening paperwork in its 500 clinical trials a year, with 1,000 investigators dispersed globally. This e-signature ability saved SCRI $250,000 in printing and delivery costs in the first year, and the savings in time to get a document signed before took between 19 and 58 days to get a document signed. With eSignatures, it took three to four days.

In this case study, Cedars-Sinai Women's Cancer Program used DocuSign's digital transaction management and eSignature capabilities to move its paper-based trial recruitment process to an automated one that simplified participant consent, and saved staff time. The process allowed a reduction in face-to-face consenting time; staff members could also more quickly identify the women that would be eligible for a clinical trial, thus improving enrollment and recruitment rates. After integrating DocuSign into its consent agreement process, the Cedars-Sinai Women's Cancer Program saw a 75% reduction in turnaround time (TAT) and up to 63% in productivity gain. DocuSign has been able to help Cedars-Sinai increase efficiency and improve the participants' experience. They have also realized up to $17.16 per document savings.

The success around this case study has spurred Cedars-Sinai to expand use of the digital transaction management in consenting patients into gynecologic and breast tissue bank the Gilda Radner Hereditary Cancer Program, and a new Cognitive Function Study. In these new use cases, Cedars-Sinai can expect additional savings and productivity gains. Using DocuSign to automate these additional consent processes, Cedars-Sinai will realize a $46.67 benefit per document and up to a 67% productivity gain.

eSignatures are used in many other industries besides drug development and clinical trials. The figure above illustrates how digital transaction management can be used for the efficiencies and cost savings explored in this article.

eSignatures and DTM most likely aren't going to be found on any innovation keynotes or brightly colored dashboard analytic function. They aren't the eSource of the data to data transfer world. But they are the bread and butter of where approvals and sign-offs in our highly-regulated industry are required. Exploring their use, with FDA's allowance, is an efficient way to expedite processes.

Please visit www.appliedclinicaltrialsonline.com regularly for the latest news and information about clinical trials. Thank you for your time.