

Clinical Trials for Pharmaceutical Companies



USE CASE PROFILE: Pharmaceutical Companies

Challenge: Efficient Regulatory Compliances

Pharmaceutical companies must capture a large number of signatures during the course of clinical trials. Regulations such as FDA 21CFR part 11 govern signature requirements throughout the process, from informed consent, to weekly patient waivers, physician compliance paperwork demonstrating that appropriate protocols have been followed, clinical operations, and electronic lab notebooks. Using paper to gather these signatures is cumbersome and costly, is often fraught with errors, and raises your risk of non-compliance. Pharmaceutical companies are demanding secure and effective alternatives to managing clinical trials using three-ring-binders.

The DocuSign Solution

With DocuSign, patient consent forms, consultancy agreements, weekly waivers, site contracts, and investigator agreements can all be managed online. Participants can fill out required paperwork and sign from any device: PC, laptop, tablets, or even smartphones. Automated reminders help ensure full compliance. Our forms library integrates directly with CRM or contract management systems, allowing your staff easily distribute appropriate forms, and robust workflow capabilities give staff complete control over signer order.

DocuSign provides complete reporting and audit trail capabilities. DocuSign can be easily integrated into your back-end systems, and our partnership with SAFE-BioPharma enables pharmaceutical companies to standardize on one platform for all internal and external document transactions.

DocuSign Key Benefits

Using DocuSign to gather and manage signatures for clinical trials offers many benefits including:

- Reduced compliance risk
- Better visibility using DocuSign's dashboards and on-demand reports to know who has and has not yet signed key documents such as IRB changes/updates
- Ability to easily store documents in the audit file
- Reduced operating costs for mailing, printing, and faxing

Customer Example

A Fortune 500 Pharmaceutical company has been using DocuSign since July 2012 to streamline workflows and compliance of documents flowing through investigator portals. Starting with physicians who provide pharma services for consulting and for clinical trials, the company reduced cycle time from three weeks to three days, negotiated to archived. The business process success has prompted the company to re-examine all physical signatures throughout the business to gain more advantage of automated workflows and electronic signatures.

About DocuSign

DocuSign® is the global standard for electronic signature®. DocuSign accelerates transactions to increase speed to results, reduce costs, and delight customers with the easiest, fastest, most secure global network for sending, signing, tracking, and storing documents in the cloud.



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For European inquiries: free phone +44 203 510 6500 | docuSign.co.uk

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