

Adobe electronic forms for clinical development

Accelerate time to market, protect sensitive information, and help meet regulatory requirements



The extensive process behind producing a safe, effective drug is expensive. Yet, life sciences companies are under increased pressure to build a robust pipeline, while reducing research and development costs. Among the key challenges facing sponsors, investigators, partners, and clinical research organizations (CROs) is how to manage the large volume of electronic and paper documents and forms more efficiently, cost-effectively, and securely. According to statistics published by PhRMA, life sciences companies spend approximately 40% of their R&D budgets managing manual, paper-based processes.

Adobe and its partners offer life sciences companies comprehensive solutions to shorten development cycles. The Adobe electronic forms for clinical development solution is based on the Adobe® Engagement Platform, which helps companies transform paper processes into automated digital workflows. The platform reduces the high costs of research and accelerates revenue by using intelligent forms and documents to streamline the processes involved in bringing a new drug to market.

With Adobe electronic forms in their clinical trials, life sciences companies can:

Reduce time to market

Improve the clinical trials process and shorten product development cycles with automated, intelligent forms.

Track interactions efficiently

Provide an auditable form process history to streamline compliance requirements.

Decrease the costs and risks of distributing confidential information

Apply persistent and dynamic security policies to control how, when, and by whom documents can be accessed.

Protect sensitive data

Use digital signatures to exchange documents electronically with more assurance that the information has not been altered and to verify the author's identity.

Reduce research costs

Use ubiquitous Adobe Reader to quickly collect information and help shorten the costly development cycle.

Streamline paper and electronic processes with intelligent forms and documents

The Adobe Engagement Platform bridges the gap between paper and electronic formats. Life sciences companies can use intelligent documents and forms to incorporate multiple content types—text, audio, video, and images—into a single Adobe PDF document that is accessible online or offline. The document becomes a complete and auditable record. Companies can also insert business logic into these forms and documents to enable automatic calculations and processing. Using XML, organizations can easily integrate captured data into back-end systems, eliminating expensive, manual, and error-prone data entry and extraction.

Throughout the drug development lifecycle, sponsors, investigators, subjects, partners, and CROs can use free Adobe Reader® software to access and update clinical data in various systems. There is no need to purchase additional software or learn new systems.

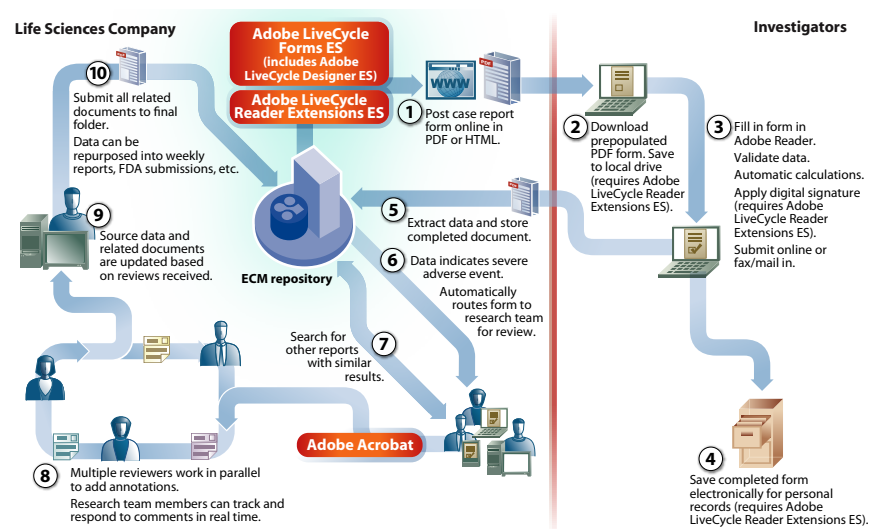
Using Adobe solutions, reviewers involved in a clinical study can more reliably and affordably share memos, reports, and even scanned site case records. By providing document and audit transactions in real time, the Adobe Engagement Platform helps simplify regulatory compliance.

Life sciences companies can further reduce the costs and risks associated with distributing confidential and sensitive information. They can control and manage access to documents inside and outside of their organizations with dynamic security policies. This is particularly important as companies accelerate the transition to digital processes that extend to the broader community of contributing investigators, partners, patients, healthcare providers, and regulatory agencies.

The Adobe electronic forms for clinical development solution provides a trusted environment for distributed collaboration between researchers and investigators, helping sponsors turn information into insights—a clear competitive advantage.

"By deploying the Adobe Intelligent Document Platform, we can conduct clinical trials far more efficiently than before."

Ines Höhne,
International clinical IT coordinator,
Merck KGaA



Adobe electronic clinical forms help shorten costly product development cycles.

Benefits for life sciences companies:

- Reduce cycle time by automating processes
- Respond more rapidly to regulatory requests and updates
- Generate complete and auditable document of record

Benefits for investigators:

- Require no additional hardware/software investment with ubiquitous Adobe Reader
- Protect sensitive information by increasing data control and security
- Provide anytime, anywhere access to forms for completion online or offline using Adobe Reader or Acrobat

Accelerate clinical trials with automated, more secure, intelligent information sharing

Based on the Adobe Engagement Platform, the Adobe electronic forms for clinical development solution helps accelerate development cycles by enabling life sciences companies to:

- Streamline data completion and submission with intelligent forms and documents
 - Allow investigators to electronically access and complete Adobe PDF forms from clinical trial web portals for printing and mailing.
 - Prepopulate clinical forms from core systems.
 - Use Adobe Acrobat® software to dynamically generate, assemble, and deliver personalized documents over a variety of electronic channels, including the web, e-mail, fax, and wireless devices.
- Shorten data collection cycles and improve data accuracy with Adobe LiveCycle® Enterprise Suite software
 - Allow users to complete Adobe PDF forms online or offline, and then reconnect to the web to submit XML data directly into systems and enable more secure information exchange and collaboration across network boundaries.
 - Enable automated, real-time data capture, which reduces costs, errors, and time compared with manual data entry.
 - Use Adobe LiveCycle Barcoded Forms ES software to automate the capture of fill-and-print paper form data; 2D bar code on the form encodes user-supplied data, and the company simply scans the 2D bar code to extract and pass the data into its core systems.
 - Deploy Adobe LiveCycle Forms ES and Adobe LiveCycle Process Management ES software to automate document-based processes, monitor business activity, and generate audit trails using predefined organizational rules and roles.
- Provide more secure online transactions and support for the SAFE standard
 - Apply digital signatures to Adobe PDF files.
 - Use Adobe LiveCycle Reader Extensions ES software to give individuals the ability to sign SAFE-enabled Adobe PDF files with Acrobat or Reader.

"The agency believes that electronic submissions technologies and the accompanying process changes will improve the efficiency of our interaction with industry."

Doreen Hepburn,
Director of Information Management, MHRA

- Deploy Adobe LiveCycle Digital Signatures ES software to validate signatures and the integrity of documents.
- Use Adobe LiveCycle Rights Management ES software to better control documents inside and outside of the firewall by dynamically creating security policies that easily restrict access to Adobe PDF files and prevent others from altering or printing a document.

Gain a competitive advantage using the Adobe Engagement Platform for life sciences applications. For more information about Adobe electronic forms for clinical development, call 800-861-9428, or e-mail solutions@adobe.com.

For more information

For more details about Adobe life sciences solutions, visit www.adobe.com/lifesciences.



Adobe Systems Incorporated
345 Park Avenue
San Jose, CA 95110-2704
USA
www.adobe.com

Adobe, the Adobe logo, Acrobat, LiveCycle, and Reader are either registered trademarks or trademarks of Adobe Systems Incorporated in the United States and/or other countries. All other trademarks are the property of their respective owners.

© 2007 Adobe Systems Incorporated. All rights reserved. Printed in the USA.
95009271 5/07