Adobe® electronic submissions solutions for life sciences

Streamline submission creation, assembly, and delivery

DELAYS ARE COSTLY

Submission delays can significantly impact patient care, company profit, and the competitive advantage of being first to market. Estimates indicate that a single day of delay in the drug development cycle could cost a company approximately $1.3 million in lost prescription sales for an average drug. For new blockbuster drugs, this cost might be up to 10 times the average.

Drug Information Journal, Vol. 34, pp. 725–736, 2000

Complex manual processes cost time and money

In the time-consuming and costly battle to gain market share, faster time to market equals competitive advantage for life sciences companies. Efficiencies in the drug development cycle impact the bottom line. To succeed, companies must streamline the collaborative processes of creating, assembling, and delivering accurate, approvable electronic submissions. Adobe solutions help simplify the submission process, enabling life sciences companies to achieve earlier filing dates, greater accuracy and quality of data, and ultimately, faster time to market.

Adobe provides a trusted environment for electronic submissions

As a trusted enterprise partner, Adobe helps life sciences sponsors streamline both paper-based and electronic elements of the submissions process—including document creation, collaboration, assembly, review, and approval. At the same time, it enables you to secure the movement of information to and from contributors, across business processes, and between sponsors and regulatory agencies worldwide. As a result, your organization can speed its delivery of more accurate and secure information for compliant e-CTD submissions.

With Adobe solutions, life sciences companies complete the submissions process more accurately and quickly, by:

- Combining multiple documents collected from sponsors, clinical research organizations (CROs), and study participants into a single, searchable PDF file—the FDA-required format for electronic submissions—for easy reference and archiving
- Capturing text, 3D images, and audio and/or video submission information into Adobe PDF format that can be shared without requiring reviewers to own the native applications
- Enabling a collaborative round-trip process for accelerated review, approval, and mark-up of critical submission components, including study reports, summaries, expert reports, data analysis plans, and product labels
- Providing access and policy controls to meet regulatory requirements for patient protection and audit control, and protecting valuable research and development intellectual property

The Adobe LiveCycle™ solution speeds drug development cycles

Adobe products make it easy for sponsors to create a secure, efficient, collaborative environment for contributors. They help you create and assemble submission components using Adobe LiveCycle software and build scalable and repeatable workflow processes that extend outside of the company network, so employees can interact more securely and effectively with CROs, joint ventures, outside experts, and other groups critical to the process of creating a submission. Organizations can then use Adobe Acrobat® to digitally sign submissions according to regulatory requirements.

Adobe®

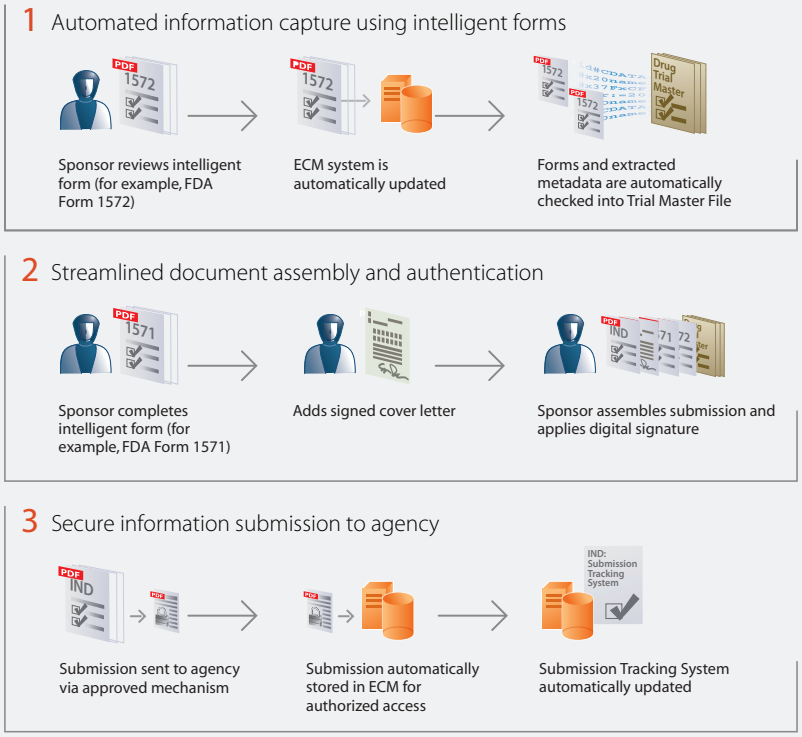
ADOBE ACROBAT AND ADOBE LIVECYCLE PRODUCT FAMILIES

Adobe solutions for electronic submissions are based on the Adobe Acrobat and Adobe LiveCycle product families. Adobe Acrobat enables sponsors to publish, share, review, and mark up Intelligent Documents, while Adobe LiveCycle products, such as Adobe LiveCycle Reader Extensions and Adobe LifeCycle Policy Server automate document processes.

FOR MORE INFORMATION

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

Adobe automates data capture, document assembly, and electronic submissions



- Speed time to market by automating processes that capture existing information, while reducing errors and administrative costs
- Simplify approval processes by easily creating and sharing Adobe PDF files that combine multiple document formats into a single searchable package
- Capitalize on the FDA e-CTD specifications for making electronic submissions during the critical Investigational New Drug (IND) phase
- Protect submission components with passwords and encryption, plus add advanced security policies to restrict copying, printing and forwarding during submission development

Adobe solutions streamline document assembly and electronic submissions

Using Adobe solutions, your organization can create and finalize e-CTD components by scanning and transforming paper documents into intelligent electronic documents for easy access online or offline. Adobe Intelligent Documents combine the familiarity, security, and visual fidelity—including 3D images—of Adobe PDF with the business logic and data exchange capabilities of XML. Standards-based Adobe Intelligent Documents interact with J2EE-based document services and enable efficient processes that can span multiple back-end systems.

Adobe protects data integrity with more secure, intelligent information sharing

With Adobe solutions, your organization can secure the exchange of electronic information between contributing departments, regulatory agencies, and partners around the world. Adobe offers you advanced document security and control features that restrict access to sensitive data through the use of passwords, and rules- and roles-based security policies. Throughout the submission process, you can protect information inside and outside the firewall. Adobe digital signature support is designed to enable sponsors to meet the chain-of-custody security mandates of a 21 CFR, Part 11 compliant-system, providing greater assurances of authenticity and integrity.

Increase efficiency and reduce time-to-market with Adobe enterprise solutions

PDF is already the required submission format at the U.S. Food and Drug Administration. Adobe solutions, including PDF and the free Adobe Reader® software, are extensively used by life sciences organizations to create, collaborate, combine, and control access to sensitive documents in the electronic submission process. Deploying Adobe solutions to automate and streamline processes can help your organization reduce development cycle time and realize increased revenue opportunities.

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