

# OpenText Documentum for Research and Development

Effectively manage the creation, review and approval of regulatory submission documentation



Ensure **submission-ready documentation**



Streamline **collaborative document creation, review and approval processes**



Demonstrate compliance with **extensive audit trails, access control, lifecycle management and version control**



Deploy cloud-native technology to run on-premise and in any cloud

**Streamlining the regulatory submission process is essential to getting products to market faster. But, users still need to do so in a controlled and compliant manner while adhering to regulatory rules and requirements that vary by region and country.**

**OpenText™ Documentum™ for Research and Development accelerates this process by efficiently managing the creation, review and approval of regulatory submission documentation. Users will not only speed up the submission process, but also benefit from uncompromised compliance, complete global control of content and secure information sharing across the extended enterprise.**

Part of OpenText™ Documentum™ for Life Sciences, the solution uses cloud-native technologies for on-premise or deployment in any cloud. Predefined taxonomies, workflows and templates reduce deployment time and ensure adherence to industry standards, while collaborative authoring capabilities and automated workflows improve productivity and streamline review and approval processes. Intuitive, role-based interfaces boost user adoption and reduce training costs. And, with the ability to link and share content across various Documentum for Life Sciences solutions, it has never been easier to quickly search for, identify and retrieve submission-ready content.

## OpenText Documentum for Research and Development feature chart

<b>Compliant document creation</b>	Easily assemble submission content for pharmaceutical and medical device products using controlled templates with predefined inheritance rules and metadata based on industry leading practices.
<b>Collaborative authoring, editing and review</b>	Allow multiple contributors to co-author documents with realtime, simultaneous authoring and editing of document content using the standard "track changes" functionality of Microsoft® Word®.
<b>Search and retrieval</b>	Quickly find submission-related documentation using faceted navigation to automatically reduce the document list, reflecting only relevant results. This boosts productivity and increases content and metadata reuse.
<b>Compliance with realtime visibility</b>	Leverage access control, detailed audit trails, e-approvals and e-signatures to easily meet compliance. Answer questions about progress and readiness with "where used" reports and gain insight on day to day performance of applications around the globe.
<b>Link content throughout drug lifecycle</b>	Support full product lifecycle with a common data model. No manual intervention is required to share documents from the early development phase through to clinical trials and submissions to product.

### Associated OpenText products

- **OpenText™ Documentum™ for Life Sciences**
- **OpenText™ Life Sciences Express**
- **OpenText™ Documentum™ for eTMF**
- **OpenText™ Documentum™ Submission Store and View**
- **OpenText™ Documentum™ for Quality and Manufacturing**
- **OpenText™ Documentum™**
- **OpenText™ Documentum™ D2**

### Improve submission accuracy

Documentum for Research and Development helps eliminate redundant, manual data entry activities and improve the accuracy of submission-ready content. To achieve this, it includes dictionaries, taxonomies and object models leveraging the Drug Information Association (DIA) Electronic Document Management (EDM) reference model. The solution also provides preconfigured document inventories based on industry standards and regulatory guidance. Documentum for Research and Development facilitates authoring compliance in accordance with International Committee on Harmonization Common Technical Document (ICH CTD) formats.

Learn more

OpenText Documentum for Research and Development »

A path to excellence in the global regulatory submissions process white paper »

Clinical Study Report  
053110-12: A randomized, active placebo-controlled, double-blind study comparing efficacy of Adisimine by 25mg and 125 mg. Confidential  
ADS Page 1 of 61

**CLINICAL STUDY REPORT FOR  
053110-12  
A randomized, active placebo-controlled, double-blind study  
comparing efficacy of Adisimine by 25mg and 125 mg.**

**1 TITLE PAGE**

Protocol Number:	053110-12
Test Drug:	ADS
Indication:	Multiple Sclerosis
Study Design:	Placebo
Study Phase:	3
Study Dates:	<Start> to <Completion>
Early Termination:	<Enter the Early Termination Date>
Principal Investigator:	<Enter the Investigator Name>, <Enter his or her affiliation>

Submission data is automatically pushed into document content to ensure accuracy and reduce manual steps.

### Boost author productivity

Authors can select from a predefined inventory of reusable, industry-standard documents that are automatically linked with the associated document types required for submissions. Also, documents are created from controlled, approved templates. This ensures that authors always work from the most current, up-to-date templates.

Streamline the review and approval process with collaborative editing. Multiple contributors can simultaneously make changes using the standard "track changes" functionality in Microsoft Word. The solution allows the designated primary author to accept, reject and review changes on a rolling basis.

### Speed search and retrieval of documentation

With Documentum for Research and Development, users can quickly identify submission-related documentation using faceted navigation, which identifies and classifies documents using industry leading practice. When a category is selected, the solution automatically reduces the document list to reflect only relevant documents.

Further, all Documentum for Life Sciences solutions interoperate, allowing content to be linked across solutions to eliminate manual workarounds, simplify access and provide an authoritative source for content.

### About OpenText

OpenText, The Information Company, enables organizations to gain insight through market leading information management solutions, on-premises or in the cloud. For more information about OpenText (NASDAQ: OTEX, TSX: OTEX) visit: [opentext.com](https://www.opentext.com).

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