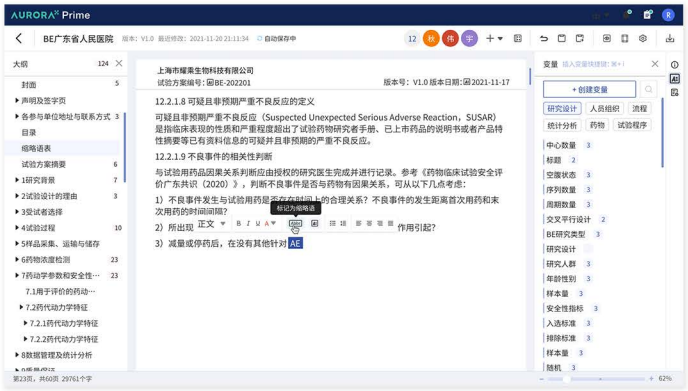
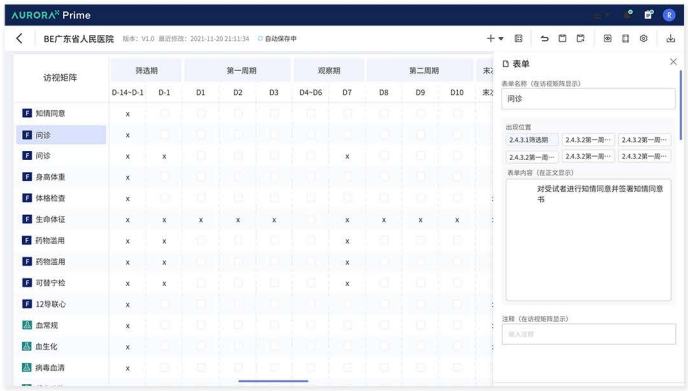
Prime Create
Clinical Study Protocol Design

An integral part of the AuroraPrime Clinical Trial Management Platform, Prime Create is a protocol writing system that supports the standardization, structuring, and digitalization of key documents from the onset of clinical trials. Prime Create aims to assist experts from medical, biostatistics, clinical operations, and other departments to efficiently write study protocols, facilitate collaborative editing, review, approval and finalizing within and across teams, as well as gain insights from the protocol and built-in knowledge retention in the form of structured, digital content. By automating database build from the point of protocol development, Prime Create streamlines and accelerates the initial step of clinical trial process.





Modules

Protocol Generation

Prime Create integrates the basic structure and content of a variety of clinical study protocol templates, and provides multiple automatic writing functions such as global formats, variables, generation of abbreviation lists and references. It provides interactive visit schedule matrix to build clinical trial workflow in a visual manner, so as to reduce repetitive work, minimize human error, and boost productivity.

Teamwork

Prime Create features collaborative tools and processes for writing study protocols. Author in charge of the study protocol development can delegate writing tasks to multiple collaborators, who can perform edits, reviews, and approvals in parallel in an efficient manner based on assigned permissions, which promotes synergy across teams. Managers can also easily view the overall writing progress through statistics and dashboards.

Automated Database Build

Prime Create uses a CDISC-compliant data model and automatically structures contents and data in the study protocol through the clinical logic engine to seamlessly integrate the protocol design, database build, and data collection processes. The clinical trial workflow and form designs in the study protocol can be exported to CDASH-compliant files, or directly imported into Prime Construct, reducing the cost of constructing the clinical database.

Features

Study Protocol Template

Standardized, reusable contents are built into study protocol templates, including content structure, paragraphs, writing guidelines, parameters and their default values, etc., to improve the efficiency and quality of the study protocol using standardized, structured contents.

Variable Repository

The study protocol template has a large number of variables built in. Any change to a variable in one place is automatically propagated across the board throughout the entire protocol, eliminating the trouble of checking and updating variables manually and repeatedly.

Visualized Workflow Editing

The system lets you build the clinical trial workflow through visual and interactive means. You can easily and efficiently edit the visit schedule matrix through simple point-and-click, drag-and-drop.

2-Way Interaction Between Trial Workflow and Textual Description

The system features 2-way interaction between trial workflow and textual description. By composing paragraphs of the study procedures automatically generates the visit schedule matrix, and editing the matrix in turn updates the textual descriptions.

Custom Export

You can tailor contents for export into PDF or Word format to meet different needs, including custom abstract, chapters, comments, and references.

Collaborative Authoring

The system supports collaborative editing of a study protocol by multiple writers, with the capability to assign different editing permissions to writers on the paragraph level. This ensures maximum flexibility while keeping everything under control in a collaborative authoring environment.

Review In Parallel

The system supports review of a study protocol by multiple reviewers in parallel, with independent review progress and results. This is conducive to unified versioning of protocols and streamlined review process.

Document Descriptions

The system supports writers to add detailed descriptions of the document when writing the study protocol, so as to retain relevant information and knowledge effectively. These descriptions will not be exported along with the protocol, but serve as supplementary information for reference by subsequent writers with the aim to bridge information gaps and facilitate communication throughout the study lifecycle.

Instant Database Build

The trial workflow and form definitions in the study protocol can be exported as CDASH-compliant standard files or directly imported into Prime Construct for building the clinical database, significantly increasing productivity.

Assisted Generation of Study Documentation

Prime Create assists in generating trial relevant documents required by your study, such as Subject Informed Consent Form, Project Management Plan, Monitoring Guidelines, etc. This significantly streamlines communications and cuts back on time and cost in developing respective study documents.

Benefits

Increased Productivity in Writing Study Protocols

Prime Create is a professional tool for writing clinical study protocols, boasting a host of features ranging from standardized templates to the automated generation of references and numbering sequences. Each function helps to crystallize the knowledge of clinical trials and study protocols. These functions and built in tools can greatly increase efficiency, accuracy of the contents and reduce repetitive work.

Increased Efficiency in Collaborative Review

Seamlessly integrated with the collaborative authoring process, Prime Create supports co-editing of a protocol by multiple writers with different permissions as well as cross-department review and approval workflow with granular editing permission assignment and locking at the paragraph level. This drastically boosts efficiency, enforces order, and prevents potential errors in a collaborative authoring environment.

Continuous Accumulation of Organizational Knowledge

Leveraging templates and other key features, Prime Create helps to distill organizational knowledge and experience including protocol content structure, trial workflow, authoring guidelines, and parameter configuration, which continuously accumulates to form valuable enterprise assets. These assets can be safely handed over to new employees with the same role and permissions granted without the risk of being lost in attrition or brain drain.

Structured Content

Use of structured and standardized protocol development tool allows users to export related contents and develop project plans as well as associated documents in an direct fashion. Whether the user wants to export the files required for project management, or build a database with one click, it can be done easily. Prime Create not only improves the efficiency of protocol writing, but also accelerates the process of subsequent implementation of clinical trials .

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