Class STUDY-EXPERIMENTAL CONCEPT: PROTOCOL AUTHORING

Systems of Interest:
Author Protocol

Author Protocol

Trigger
New digital study design information is approved for downstream use.

Primary Scenario
The Medical Writer initiates creation of a new study protocol document by searching for a study identifier in the USDM-Compliant Information stream. The USDM Information is then transformed into a textual representation within a protocol document. The Medical Writer in consultation with the Study Team creates content for the remaining sections of the protocol template using a combination of curated content (e.g., from the Content Library), generative AI, and study-specific *de novo* content authoring as is deemed appropriate.

The Medical Writer may request updates to the digital study design elements through consultation with the Study Designer, who then updates the design elements as in **STUDY-EXPERIMENTAL CONCEPT: STUDY DESIGN** and supplies an updated digital study design to the USDM-Compliant Information stream.

The resulting protocol draft is checked for consistency with the content provided from the USDM-Compliant Information stream and then sent for final Study Team Review.

The finished protocol textual content is written back to the USDM-Compliant Information stream. The Information stream now contains a complete informational representation of the protocol document suitable for document re-creation. The finished protocol is also deposited to the Sponsor's regulatory content management system for version management and distribution tracking.

Note: This System of Interest in conjunction with **STUDY-EXPERIMENTAL CONCEPT: ANALYTICS** and **STUDY DESIGN** have the potential to reduce need for subsquent protocol admendments. Rationale: study design reviews tend to be "front loaded" and driven by analytical considerations, meaning that fewer design changes should occur during protocol authoring.

Result
A partial (draft) or complete protocol version is rendered as a document in the Sponsor's Regulatory Information Managment System and made available to the USDM-Compliant Information stream.