

S-Cubed[®] CRT

Electronic Clinical Data Submission to the FDA

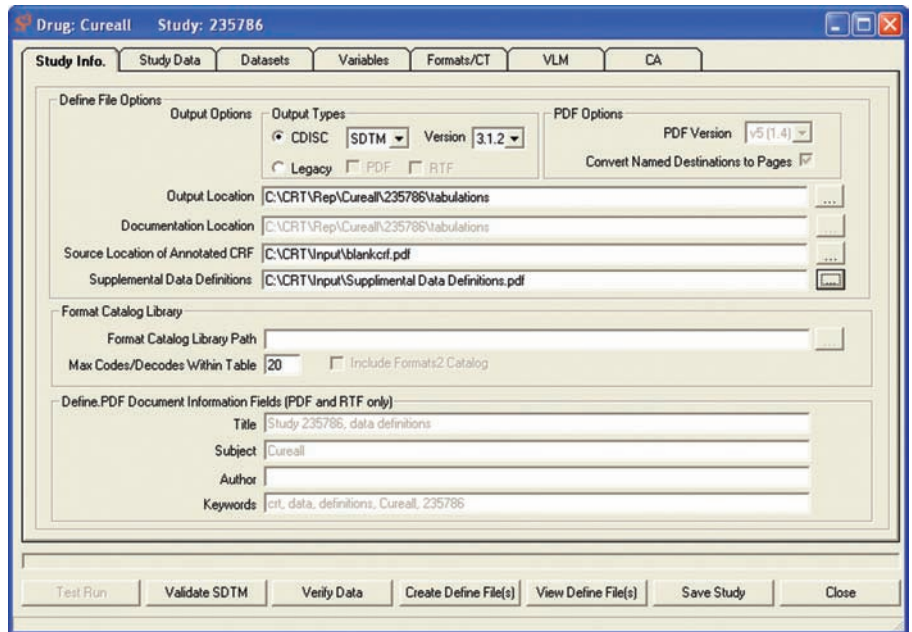
S-Cubed[®] CRT is Datafarm's answer to a complete solution that automatically creates the entire CRT section of an electronic submission along with the define.pdf and/or define.xml files, SAS transport files and Table of Contents files, including all of the necessary links and bookmarks. As a Certified CDISC Solutions Provider, Datafarm designed S-Cubed CRT according to the Case Report Tabulation Data Definition Specification (CRT-DDS) developed by the CDISC define.xml team.

S-Cubed CRT helps ensure clients are compliant with the FDA regulatory requirements that clearly stipulate that all study data must be delivered in an electronic format - even if the marketing application is in paper format.

The solution lets users automatically create the CRT in a required format for the study data that would commonly include the following:

- SAS Transport files
- Data Definitions file
- Annotated CRF

Regulations in 21 CFR Part 11 require that all datasets submitted in electronic format provide an accurate and complete copy of the data suitable for inspection, review and copying. Currently, the FDA requires that all clinical data be submitted in the SAS System XPORT transport format (Version 5 SAS transport file) for review and archiving. The data definition file describes the format and content of the submitted datasets. In order to increase the level of automation and improve the efficiency of the regulatory review process, the FDA announced specifications for dataset data definitions using CDISC SDTM standards. These are then incorporated into the Case Report Tabulation Data Definition Specification (CRT-DDS) developed by the CDISC define.xml team.



A screen capture of the main S-Cubed CRT interface highlighting the CDISC SDTM output option.

Dataset	Description	Class	Structure	Purpose	Keys	Location
AE	Adverse Events	Events	One record per adverse event per subject	Tabulation	STUDYID, USUBJID, AEDECOD, AESTDTC	ae.xpt
CM	Concomitant Medications	Interventions	One record per recorded medication occurrence per subject	Tabulation	STUDYID, USUBJID, CMTRT, CMSTDTC	cm.xpt
CO	Comments	Special Purpose Domains	One record per comment per subject	Tabulation	STUDYID, USUBJID, COSEQ	co.xpt
DM	Demographics	Special Purpose Domains	One record per subject	Tabulation	STUDYID, USUBJID	dm.xpt

S-Cubed CRT define.XML output using CDISC stylesheet



S-CUBED CRT FEATURES

- Define files in PDF, XML and RTF formats to meet current and future requirements
- Create an entire CRT section for a given submission
- Store, manage and edit metadata in a central repository
- Supports multi-user access with security, using domain user-id and password
- Provides 21 CFR Part 11 compliant audit-trail
- Offers administrative features for application maintenance
- Supports multiple data sources and SAS dataset versions
- Enables multi-study operations within a session through the MDI feature
- Allows user-defined table properties, font attributes and page orientation
- Verifies CDISC SDM (Submission Data Model)
- Verifies and reports whether datasets and variables are in compliance with the SDM model
- Supports the ability to create links to the annotated case report form (blankcrf.pdf) and to external documents
- Facilitates maintenance for the client such as information management on a shared network area with multiple user access
- Provides simple metadata import/export

COMPLIANCE ENSURED

Included in S-Cubed[®] CRT is a function that automates the process of annotating case report forms (blankcrf.pdf), which are required by the FDA in all electronic submissions.

- Connects directly to metadata (data dictionary) stored in ODBC compliant database
- Supports the ability to filter data view by protocol and table names
- Sorts items by any column
- Supports the option to define annotation attributes (e.g. table, field, derived field...)
- Enables adding notes for decodes next to annotation
- Allows annotating multiple pages in one instance
- Offers the option to save annotation data to a log (CSV) file

S-CUBED[®] - WHEN IT IS THIS EASY AND EFFECTIVE, WHY CHOOSE ANYTHING ELSE?

S-Cubed[®] CRT is part of the S-Cubed suite of software that integrates to provide a complete electronic submission solution. The S-Cubed suite includes state of the art modules that deliver comprehensive authoring, publishing, compilation, review, printing and complete lifecycle management of the submission throughout the entire drug development process.

Working with Datafarm as a partner and using the S-Cubed[®] solution helps ensure regulatory operations delivers compliant applications to the global regulatory agencies today and in the future.

TRUST IN A PARTNER THAT DELIVERS –eSUBMISSIONS MADE EASY

Datafarm approaches each client as a partner to create the optimum solution for each specific business challenge. With more than a decade of experience in eSubmissions software and services, Datafarm has partnered with hundreds of life science companies to help ensure compliant eSubmissions. Whether the organization needs software, services or a combination of the two, Datafarm will help design a comprehensive, cost-effective solution.

ABOUT DATAFARM

Established in 1997, Datafarm is a world leader in high performance electronic regulatory submission solutions for the Life Sciences industry. Datafarm's open, modular technologies and professional services experts enable Life Sciences companies to meet the strict standards of regulatory authorities across the world, helping them achieve quality, accuracy, and compliance to efficiently deliver regulatory reports and submissions. Datafarm has helped hundreds of sponsor companies compress the regulatory submissions approval process, improving speed to market, cost control and productivity in order to achieve their ultimate goal of ensuring patients' and physicians' timely access to new drugs.

As a total solutions provider, Datafarm employs some of the industry's pioneers in document-based software development as well as world renowned life sciences regulatory specialists who proactively work with customers and business partners to drive new initiatives and maintain a market lead approach to development and services.

GLOBAL LOCATIONS:

Corporate office:
Marlborough, MA, USA
+1 508 624 6454
info@datafarminc.com

North America:
San Diego, CA, USA
+1 858 453 5256
wc@datafarminc.com

Philadelphia, PA, USA
+1 610 914 2146
pa@datafarminc.com

Europe:
Slough, England
+44 (0) 870 774 4298
uk@datafarminc.com

Paris, France
+33 (0) 1 56 60 50 22
eu@datafarminc.com

Asia:
Bangalore, India
+91 (0) 80 3290 3619
in@datafarminc.com

Japan:
Tokyo, Japan
+81 (3) 4580 1744
jp@datafarminc.com