Automation for Submission Deliverables

Clinical Study Data Reviewer's Guide (cSDRG)

Paulin Charliquart

10-Oct-2023

Agenda

01 cSDRG

02 Objectives

03 Automation

04 App

05 Conclusion

01 - cSDRG

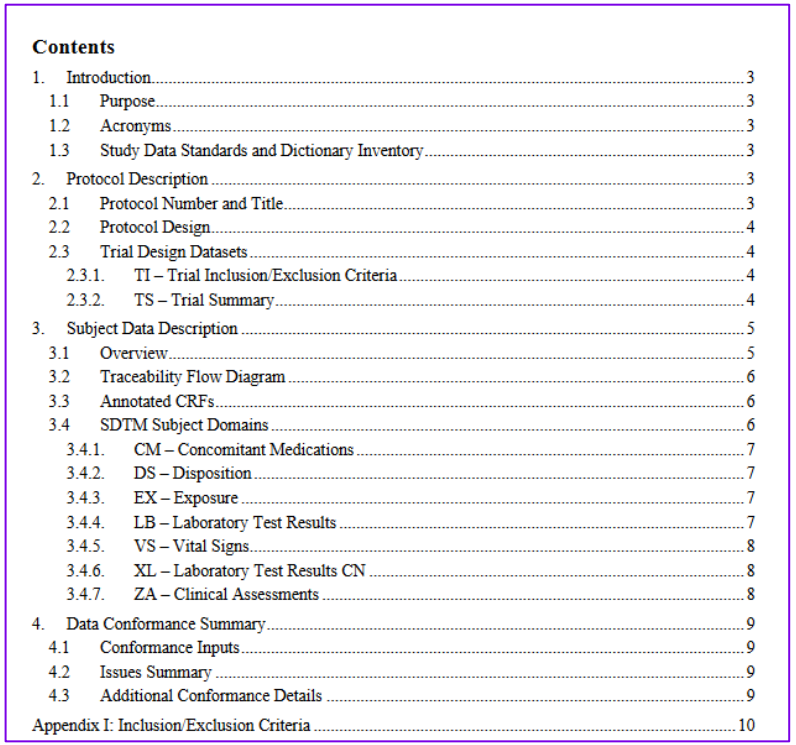
What is the cSDRG?

The Clinical Study Reviewer's Guide (cSDRG) is part of any FDA submissions.

It provides definitions that may help the reviewer understand the relationships between the data and the study report (CSR).

Most of the content can be found in

- SDTM metadata
- Protocol
- SDTM datasets



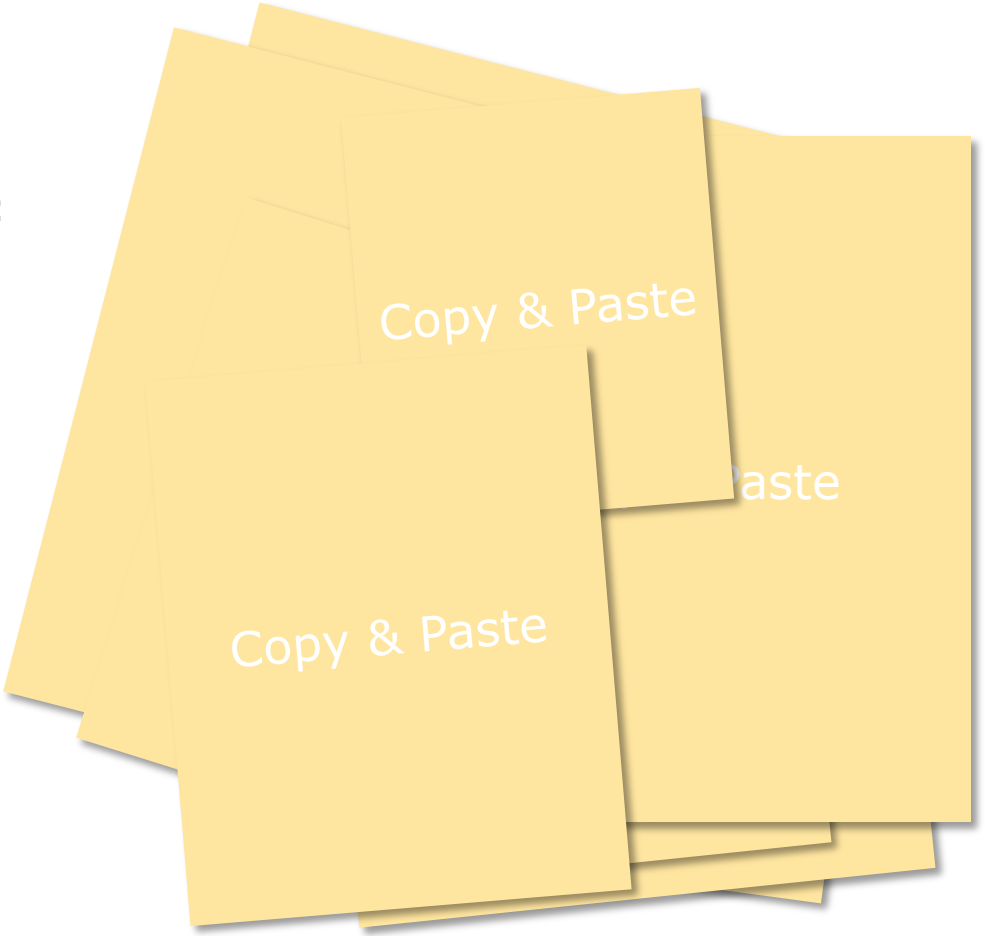
Contents

Source: PHUSE template

Context

Before automation, the process was:

1. Download Word template
2. Copy and Paste
3. Copy and Paste
4. Copy and Paste
5. Copy and Paste
6. Copy and Paste
7. Copy and Paste
8. Copy and Paste
9. Copy and Paste



Observations

- This is error prone
- This is boring
- There is no added value
- Waste of time

Perfect for automation!

02 - Objectives

Objectives

- Automate as much as possible
- Review cSDRG template to simplify it
- Build an app to edit, manage and generate documents

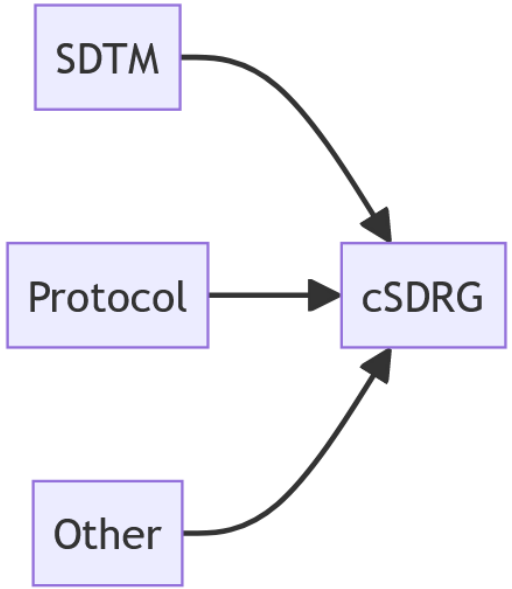
03 – Automation

Data sources

SDTM:
- Trial Design dataset (TI,TS,TA, etc..)
- SDTM Metadata

Protocol:
- Title and description
- Study Design Chart

Other:
- Forms excluded
- Pinnacle 21 reports

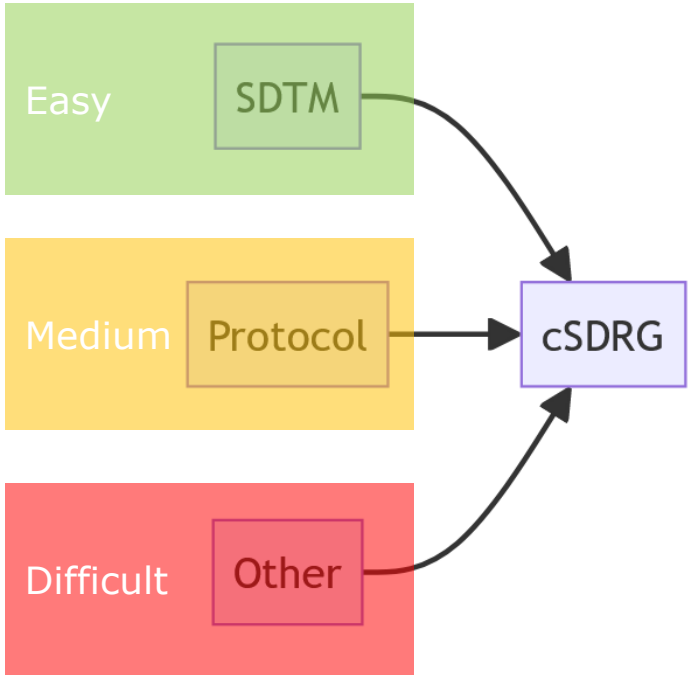


Data collection

SDTM:
- Standardized
- Easy to find

Protocol:
- Only available in Word

Other:
- Various data format
- Not standardized

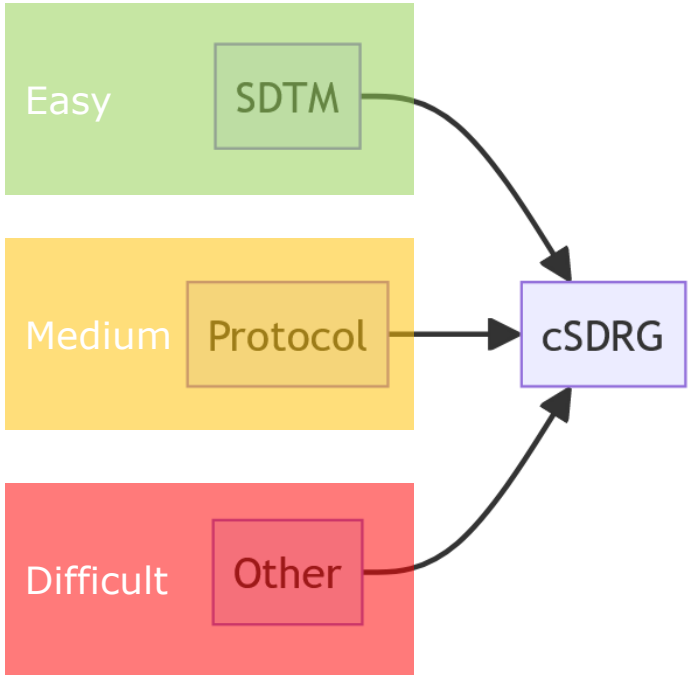


Data processing

SDTM:
1. Read data
2. Load into the cSDRG

Protocol:
1. Find protocol
2. Read
3. Analyse (NLP)
4. Extract

Other:
- Offer an easy way to import them



Data API

Create an API to :

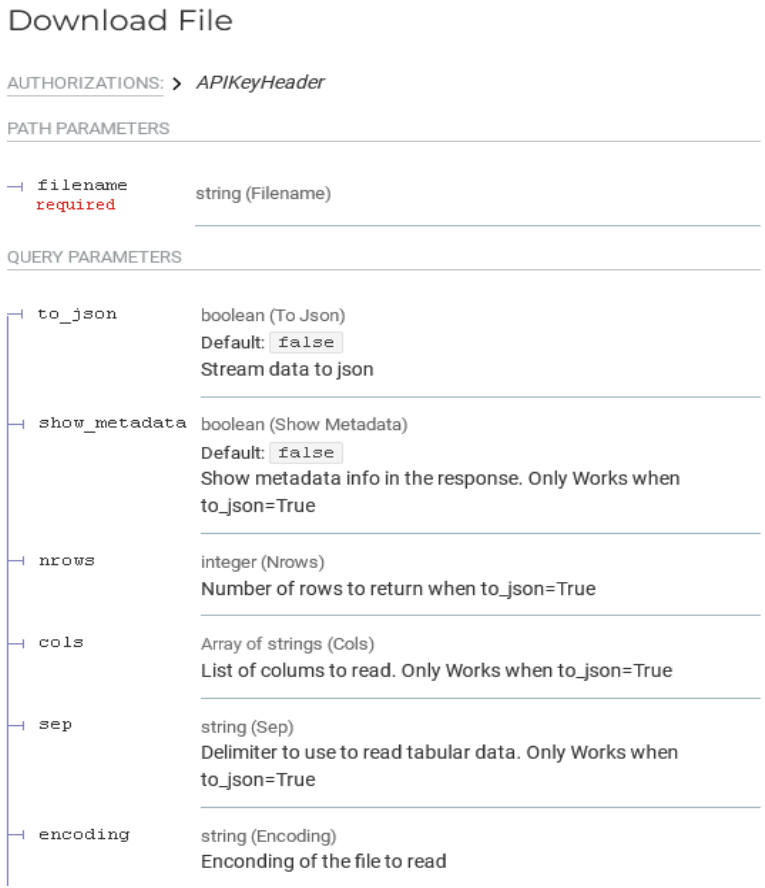
- connect to SDTM data source
- Stream them as json

Description:

- FastAPI (Python framework for API)
- Pandas: to read and stream data

Features:

- Read common formats (sas, csv, excel)
- Subset data



Protocol API

Create an API to :

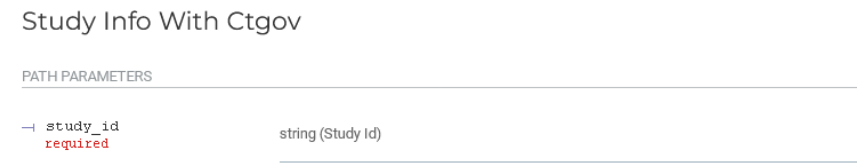
- Fetch protocol info
- Process data

Description:

- FastAPI (Python framework for API)
- Use AACT database (copy of ClinicalTrials.gov)

Features:

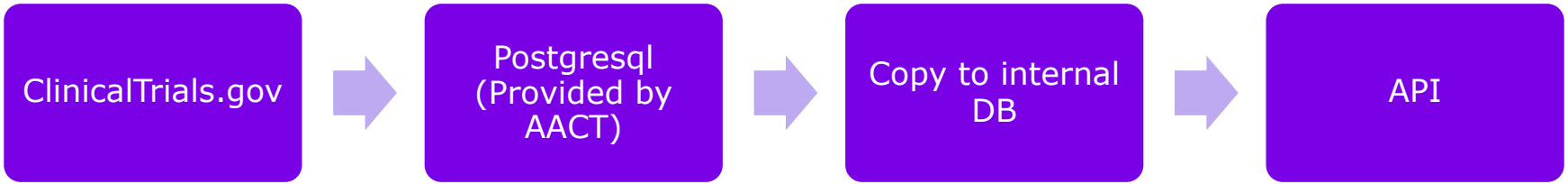
- Fetch info using study ID




```
[
  {
    "nct_id": "NCT02898454",
    "nlm_download_date_description": null,
    "study_first_submitted_date": "2016-09-08",
    "results_first_submitted_date": "2019-08-23",
    "disposition_first_submitted_date": null,
    "last_update_submitted_date": "2019-10-03",
    "study_first_submitted_qc_date": "2016-09-08",
    "study_first_posted_date": "2016-09-13",
    "study_first_posted_date_type": "Estimate",
    "results_first_submitted_qc_date": "2019-10-03",
    "results_first_posted_date": "2019-10-23",
    "results_first_posted_date_type": "Actual",
    "disposition_first_submitted_qc_date": null,
    "disposition_first_posted_date": null,
    "disposition_first_posted_date_type": null,
    "last_update_submitted_qc_date": "2019-10-03",
    "last_update_posted_date": "2019-10-23",
    "last_update_posted_date_type": "Actual",
    "start_month_year": "November 28, 2016",
    "start_date_type": "Actual",
    "start_date": "2016-11-28",
    "verification_month_year": "October 2019",
    "verification_date": "2019-10-31",
    "completion_month_year": "November 16, 2018",
    "completion_date_type": "Actual",
    "completion_date": "2018-11-16",
```

Protocol API

In details



Template

- Transform template to html
- Use Templating engine to include data (Jinja)
- Convert template using Pandoc to PDF or Word

```
<!DOCTYPE html>
<html lang="en">
<head>
    <meta charset="UTF-8">
    <title>Clinical Study Data Reviewer's Guide</title>
    <meta name="author" content="Sanofi">
    <meta name="subtitle" content="{{ study }}">
    <meta name="date" content="{{ date.strftime('%Y-%m-%d') }}">
</head>
<body>
    <h1>Introduction</h1>
    <h2>Purpose</h2>
    <p>This document provides context for tabulation datasets and terminology that ben
    <h2>Acronyms</h2>
    <table>
        <tr>
            <th>Acronym</th>
            <th>Definition</th>
        </tr>
        {% for dic in document.acronyms %}
        <tr>
```

04 - App

Objectives

A user friendly interface to edit, review and manage cSDRG

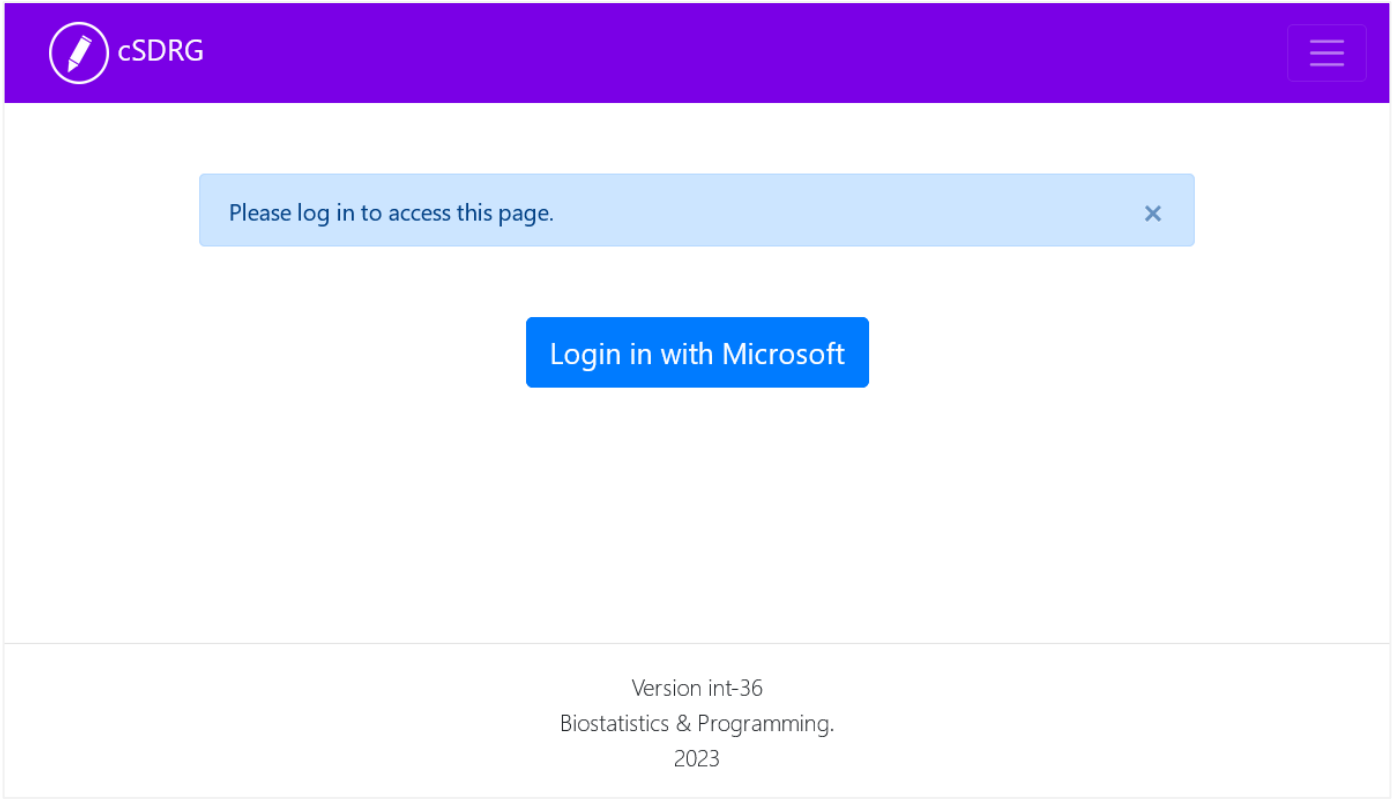
Solution

Web application:

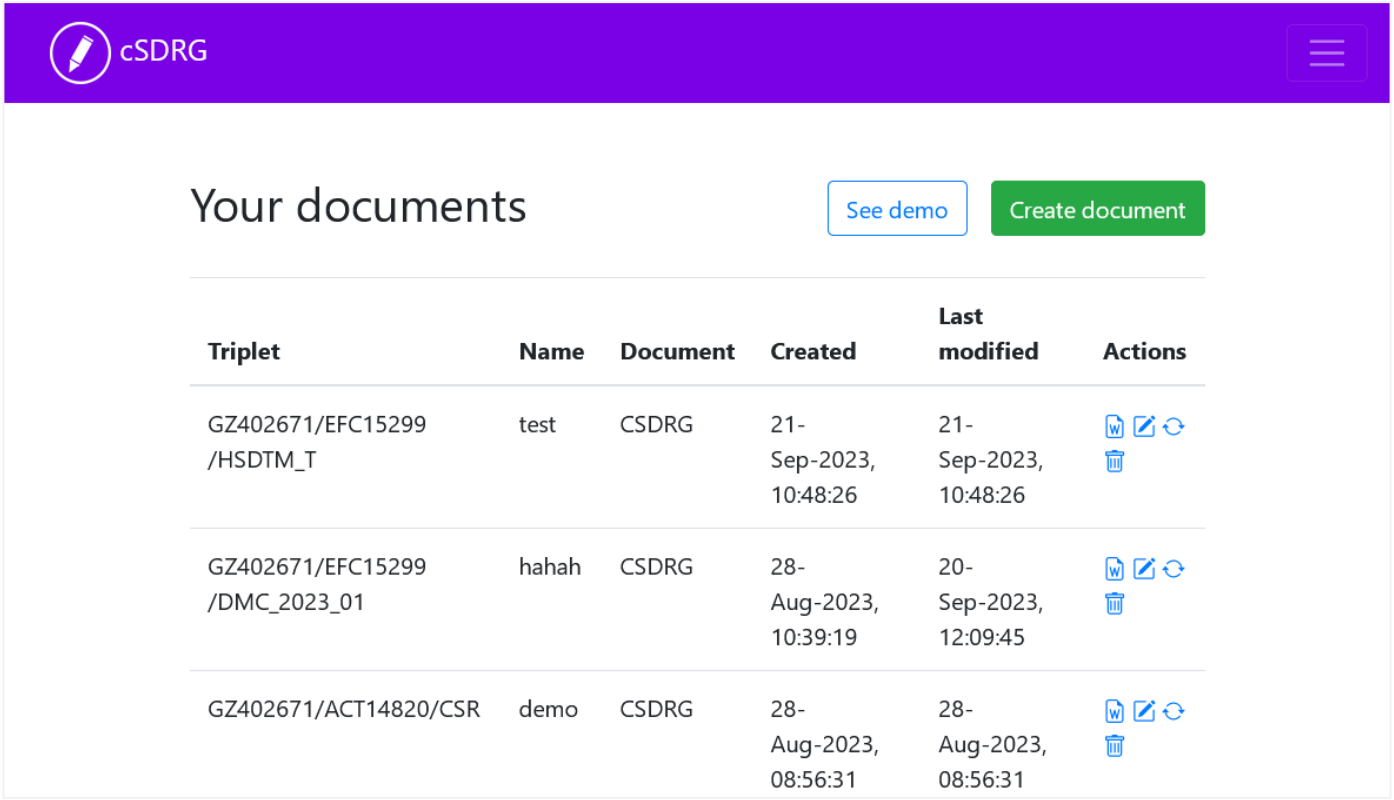
- Built with Flask (Python)
- Use SSO for easy login
- Boostrap CSS for UI
- Easy Workflow
- Form to upload data

Workflow

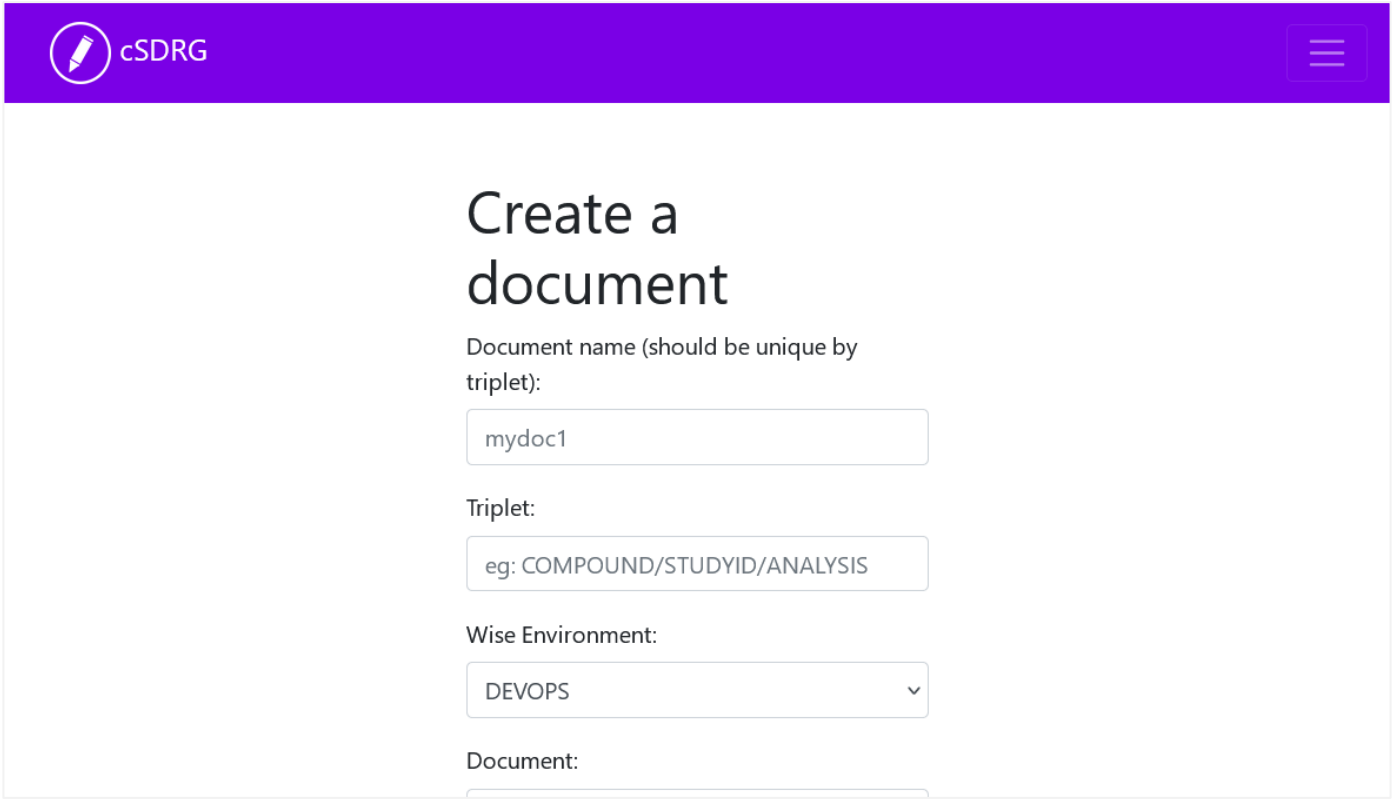
Screenshots



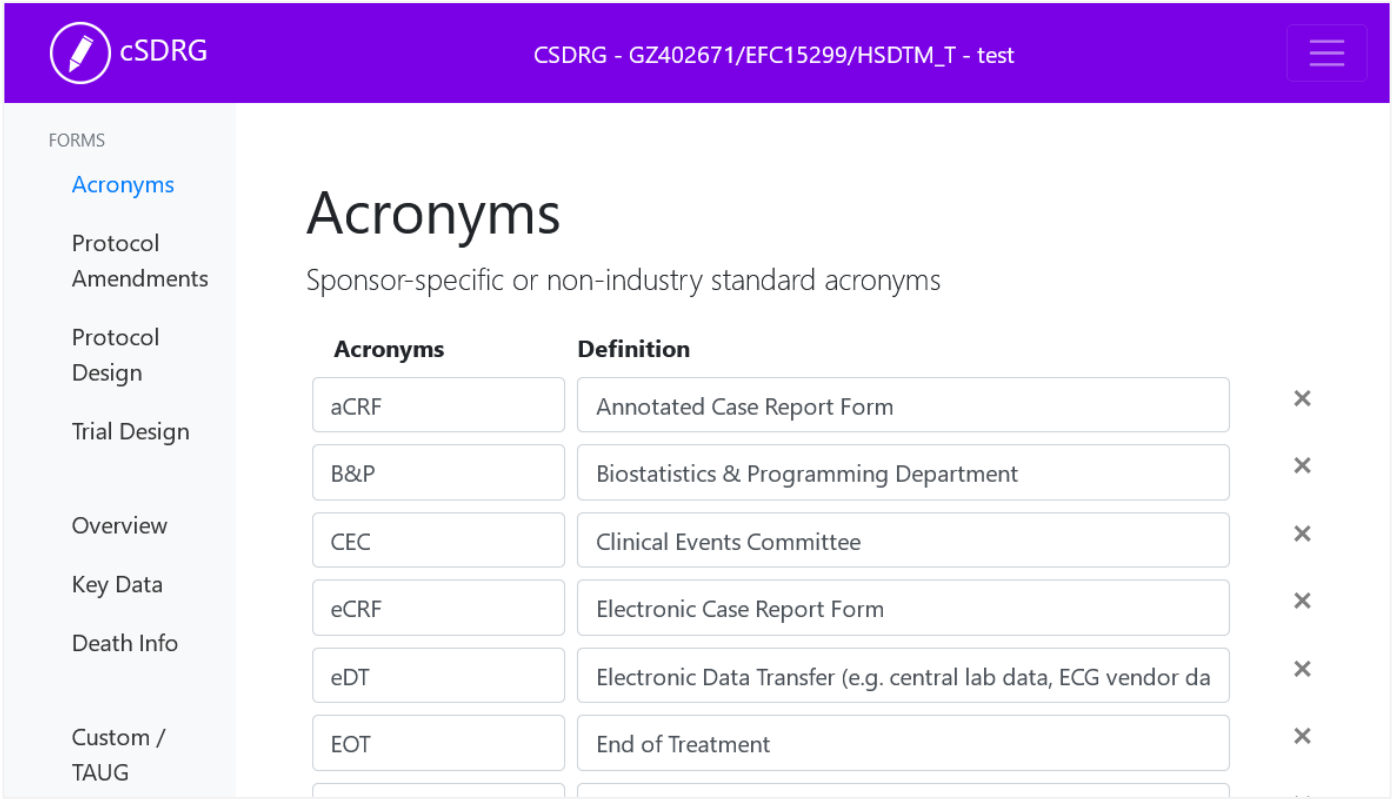
Screenshots



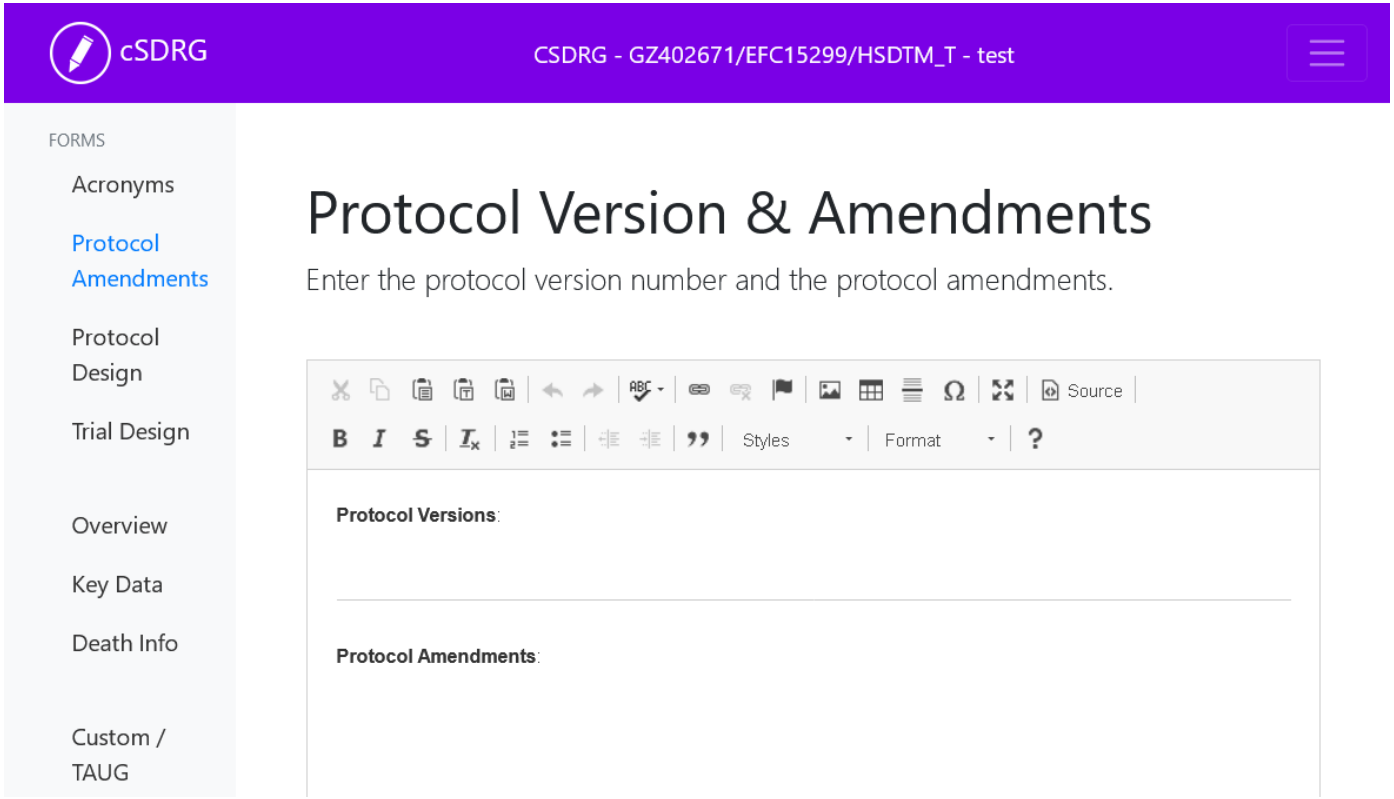
Screenshots



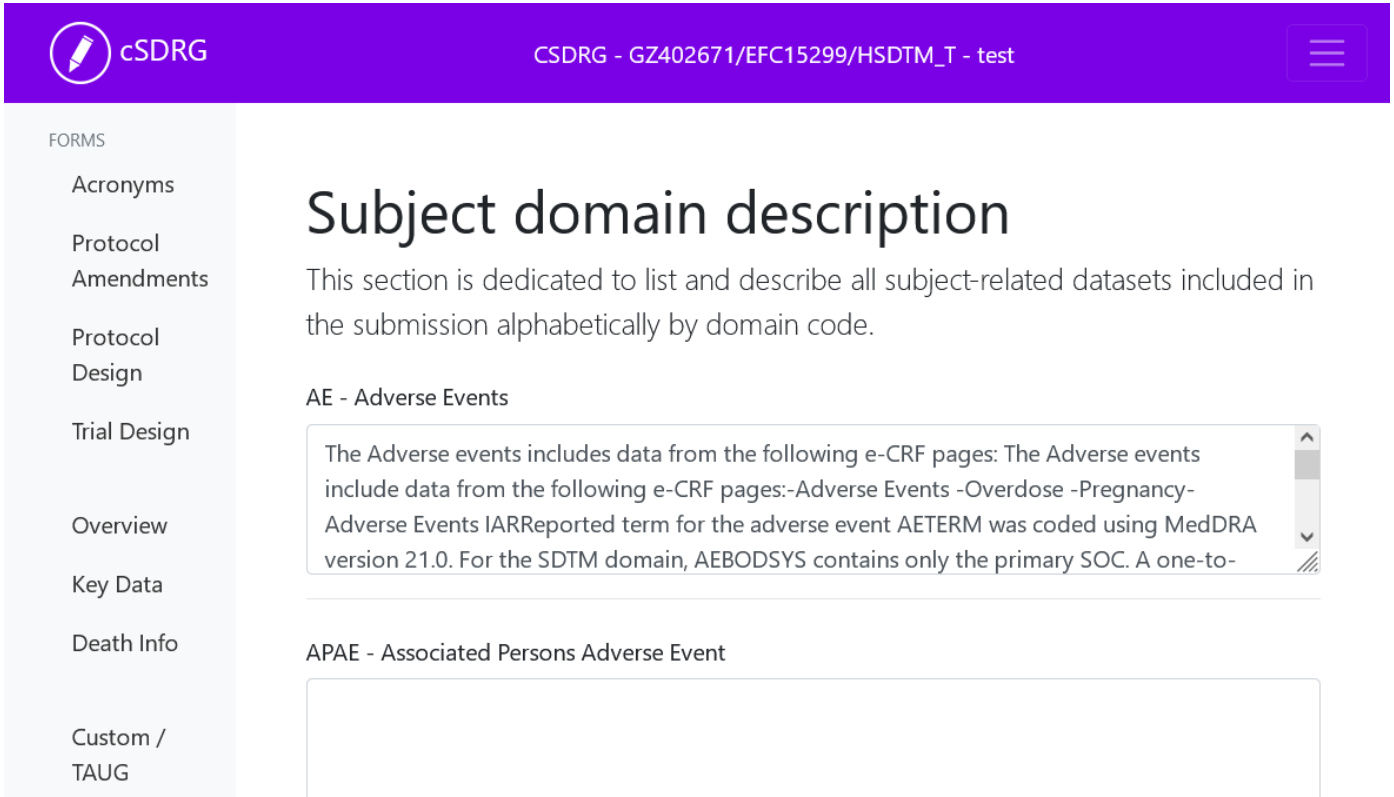
Screenshots



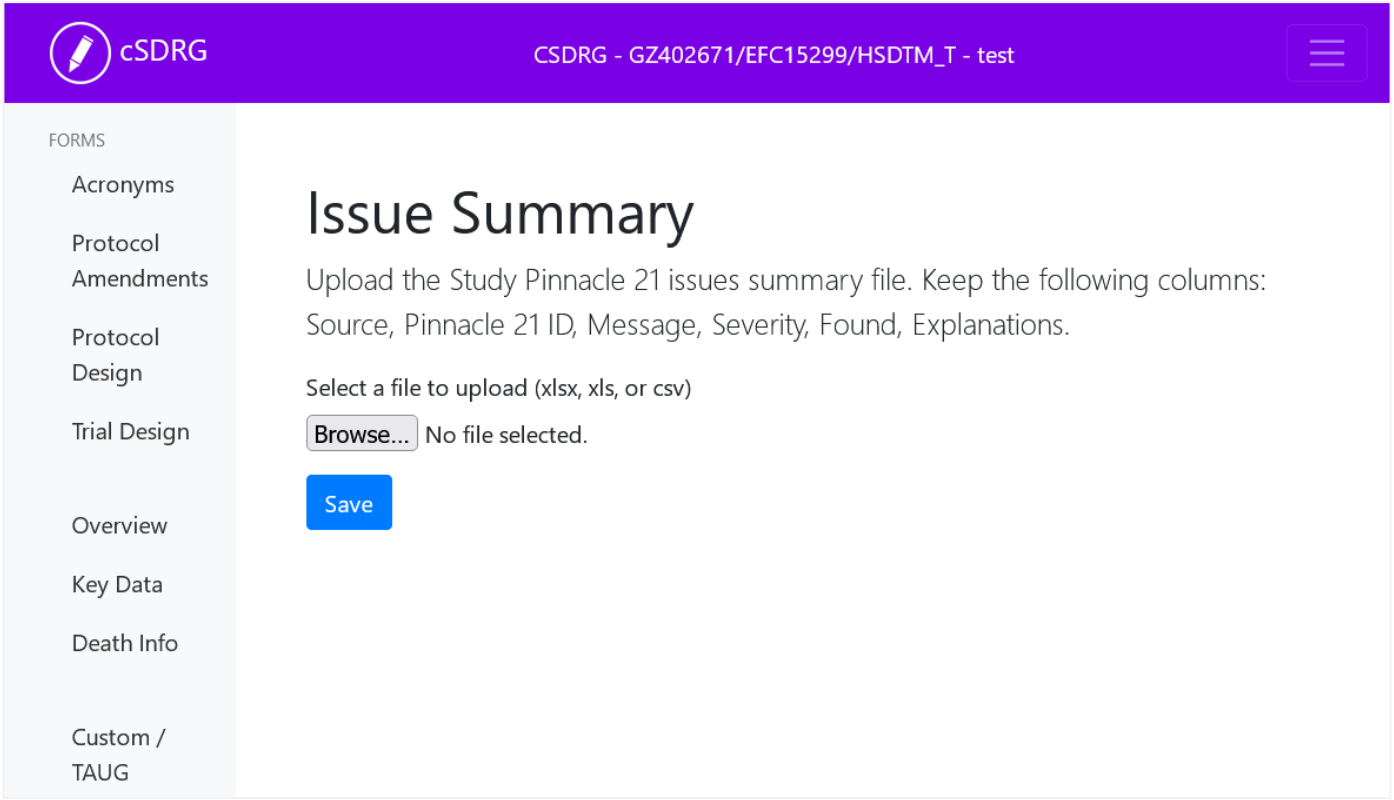
Screenshots



Screenshots



Screenshots



Screenshots

1 Introduction

1.1 Purpose

This document provides context for tabulation datasets and terminology that benefit from additional explanation beyond the Data Definitions document (define.xml). In addition, this document provides a summary of SDTM conformance findings.

1.2 Acronyms

Acronym	Definition
aCRF	Annotated Case Report Form
B&P	Biostatistics & Programming Department
CEC	Clinical Events Committee
eCRF	Electronic Case Report Form
eDT	Electronic Data Transfer (e.g. central lab data, ECG vendor data, PK data, etc.)
EOT	End of Treatment
IMP	Investigational Medicinal Product
IRT	Interactive Response Technology
ISR	Injection Site Reaction
IVRS	Interactive Voice Response System

1.3 Study Data Standards and Dictionary Inventory

Standard or Dictionary	Versions used
SDTM	CDISC01.SDTMIG.3.2.SDTM.1.4
Controlled Terminology	SDTM CT 27Mar2015
Data definitions	Define.xml 2.0.0

Report

05 - Future & Conclusion

Results

Time spent:

x5

Quicker to create cSDRG

Results

New tools available for future projects:

Future

This new platform helps to quickly generate cSDRG and soon to follow Trial Summary Dataset!

Next step
Trial Summary

Trial Summary - EFC15299

TSPARMCD		TSVAL
ACTSUB	74	
AGEMAX	None	PINF
AGEMIN	2	
FCNTRY	Argentina	
FCNTRY	Austria	
FCNTRY	Brazil	
FCNTRY	Czechia	

Thank *you!*

Questions

Paulin.Charliquart@Sanofi.com

sanofi