**Annotation CRF Implementation Plan in Melodie Platform**

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| **File:** |  |
| **Version:** | 1.0.0 |

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# Purpose

This standard operating specification (SOP) stipulate the whole process for generate the standard annotation CRF, which meet the FDA requirements, in B&P department by Melodie platform.

# Scope

This SOP apply to the all UNIFY project in SANOFI B&P department. This document specifies the detailed process of create annotation CRF file from the first version blank CRF be released to finalize the last version CRF for submission.

# Terminology

| **Terminology** | **Definition** |
| --- | --- |
| Melodie | Metadata Element Library Operation&Development Integrated Environment |
| Analyze Module | Melodie metadata analysis module:  This module will extract the protype file of MCRF. |
| Editor Module | Melodie metadata editor module:  The customer be able to edit MCRF file by this module. |
| Blank CRF | Blank Case Report Form |
| Annotation CRF | Annotation Case Report Form  It is a combined file through of each version CRF file. |
| MCRF | Metadata CRF file |
| XFDF file | This file extension is associated with Adobe Acrobat.  Melodie can create annotation file by this format. |

# Responsibility

| **Role** | **Responsibility** |
| --- | --- |
| PSE | Project Standard Expertise, who will lead to implement, generate, modify, validate and approve MCRF and the annotation file. |
| Submission Expertise | Submission Expertise, who will in charge of the quality of annotation CRF. Usually, the PSE should play this role. |
| Melodie Annotation Module Supporter | Melodie Annotation Module Supporter, C-ART team should provide maintenance of the editor part of Melodie. The scope should include below items   1. To correct the known system bugs, 2. To optimize the module of editor as well as design a new feature base on editor module. 3. To provide technical guild for operate the Melodie platform. 4. For each version editor module update to provide whole user guide support.   But the above range should exclude the modify, refactor the structure of MCRF as well as to design new Melodie Module. |

# Contents

## Introduction

When preparing a annotation CRF file in submission project, it will involve but not limited to: PSE should build the mapping rule from the CDASH dataset to the SDTM dataset follow the standard operation process, and implement the process of annotate CRF file in order to create the annotation CRF file which compliance with the regulatory requirements.

## Flow Chart

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## Description

| **Process** | **Description** | **Reference File** |
| --- | --- | --- |
| 1 | The PSE who will take responsible for implement the annotation process for submission CRF. The PSE should make a preparation from the first version CRF be finalized. the protype of MCRF file will be generated by Melodie analysis module. Them should use the editor module in Molodie to build mapping rule at TA level, the standard SDTM mapping rule for study level should be generate at the same times for each version CRF.   1. To get the consistent version CRF file and SDS file from TO department 2. Loading CRF and SDS to the Melodie analysis module. 3. To create the protype of MCRF file. 4. To implement the TA mapping rule to the protype of MCRF file. 5. To check the TA mapping rule and adapt it according to the study specific rule. 6. To recreate the first version final MCRF file. | CRF  SDS  MCRF |
| 2 | **The new version CRF released.**  It is inevitable for the CRF be modified, the PSE should build new mapping rule for each update and validate the existed mapping rule. For prepare the new mapping rule, the PSE should re-execute the process of extraction step in Melodie analysis model, then create the new protype MCRF for this version.   1. To acquire the updated version CRF and SDS file. 2. To extract the new version protype MCRF. 3. To check and build new items mapping rule in Melodie annotation editor module. 4. To generate the new version final MCRF file. | CRF  SDS  MCRF |
| 3 | **For submit purpose, we should use final CRF, which will combine ever version’s CRF file in one combine CRF file.**   1. To summary every version CRF and SDS file 2. To extract the combine MCRF file by Melodie. 3. Every version MCRF will be implement as the reference mapping rule to create the combine CRF file. 4. To create the final XFDF file. 5. To load XFDF file in combine CRF. 6. To inspect and adapt the position of annotation. | CRF  SDS  MCRF  XFDF |
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# Associated Documents

Blank CRF

Annotation CRF

MCRF

# Revision History

| Version | Abstract | Modifier | Effective Date |
| --- | --- | --- | --- |
| 1.0.0 | New effectiveness | Jianfeng YE |  |
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