

Implementing a Meta data Repository (MDR) using Functional Service Provider (FSP) How does it work?

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GUF CDISC

BELGIUM 2017



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Agenda



- Introduction
- Familiarization
- Transition of internal knowledge to the FSP
- Impact and scope of each change
- Governance
- Use of JIRA® software
- First study, theory versus reality
- What is next?
- Conclusions
- Questions

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Introduction



- The sponsor developed an SDTM+ library, a centralized metadata model
 - used since July 2015 and includes:
 - SDTM+ metadata + user guide
 - SDTM+ Standard CRF Library + user guide
 - The SDTM+ metadata is administered within an MDR tool
- Sponsor approach:
 - Trial conduct and the creation of CDISC SDTM+ datasets are outsourced
 - Maintenance and governance of the data standards is kept in-house

Introduction



- Chiltern was selected as FSP to **maintain** the SDTM+ standard library and **review** key SDTM+ deliverables
 - Annotated CRF
 - Trial Design Domains (TDD)
 - Metadata structure
- Team: Clinical Programmers with SDTM experience
 - MDR tool
 - sponsor SDTM+ library (what the '+' was)
- The implementation of MDR tool added new processes and modified existing ones
 - Governance had to be defined for the tool users and reviewers
- Tasks specific flow charts were created and implemented in JIRA



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Familiarization



- MDR tool and SDTM+ sponsor philosophy
- Series of trainings were scheduled by the sponsor:
 1. Sponsor SDTM+ library
 - SDTM+ metadata library (with SDTM+ user and administrator guide)

Familiarization



- SDTM+ library:

Domain	Description	DB Requirement	Mandatory Requirement	Custom	Class	Structure	Purpose
AE	Adverse Events	Mandatory	FDA Expected	No	Events	One record per adverse event per subject	Tabulation STUDYID, U
BE	Biospecimen Events	Optional		Yes	Events	One record per instance per biospecimen event per bios	Tabulation STUDYID, U
CE	Clinical Events	Optional		No	Events	One record per event per subject	Tabulation STUDYID, U
DS	Disposition	Mandatory	FDA Expected	No	Events	One record per disposition status or protocol milestone	Tabulation STUDYID, U
DV	Protocol Deviations	Mandatory		No	Events	One record per protocol deviation per subject	Tabulation STUDYID, U
HO	Healthcare Encounters	Optional		No	Events	One record per healthcare encounter per subject	Tabulation STUDYID, U
MH	Medical History	Mandatory		No	Events	One record per medical history event per subject	Tabulation STUDYID, U

Dataset Level | Variable Level | Controlled Terminology | Value Level Metadata | External Dictionaries | Computational Algorithm | ... (+)

- The “+” illustrates the sponsor vision of the CDISC SDTM

Familiarization



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 - Standard CRF library (with CRF library user guide)

Familiarization



- CFR library:

[DM]	[SUPPDM]	Demography		SITEID	SUBJID																				
		Visit Name	VISIT																						
Country Identifier	<table border="1"> <tr> <td> </td> <td> </td> <td> </td> </tr> </table>				<i>Pre-print this if only a single country is being used, or provide a list of country codes in which the study is being conducted.</i>																				
	COUNTRY																								
Date of Birth	<table border="1"> <tr> <td> </td> <td> </td> <td> </td> <td> </td> <td> </td> <td> </td> <td> </td> <td> </td> </tr> <tr> <td>Day</td> <td>Month</td> <td colspan="2">Year</td> <td colspan="4"></td> </tr> </table>									Day	Month	Year						Age	<table border="1"> <tr> <td> </td> <td> </td> <td> </td> </tr> </table>				Years	AGEU	
Day	Month	Year																							
	BRTHDTC	AGE																							
Sex	SEX	<i>Age field has to be used ONLY if regulatory Authorities/Requirements do not accept the full date of birth for data privacy reason.</i>																							
Male																									
Female																									
Ethnicity	ETHNIC																								
Hispanic/Latino																									
Not Hispanic/Latino																									



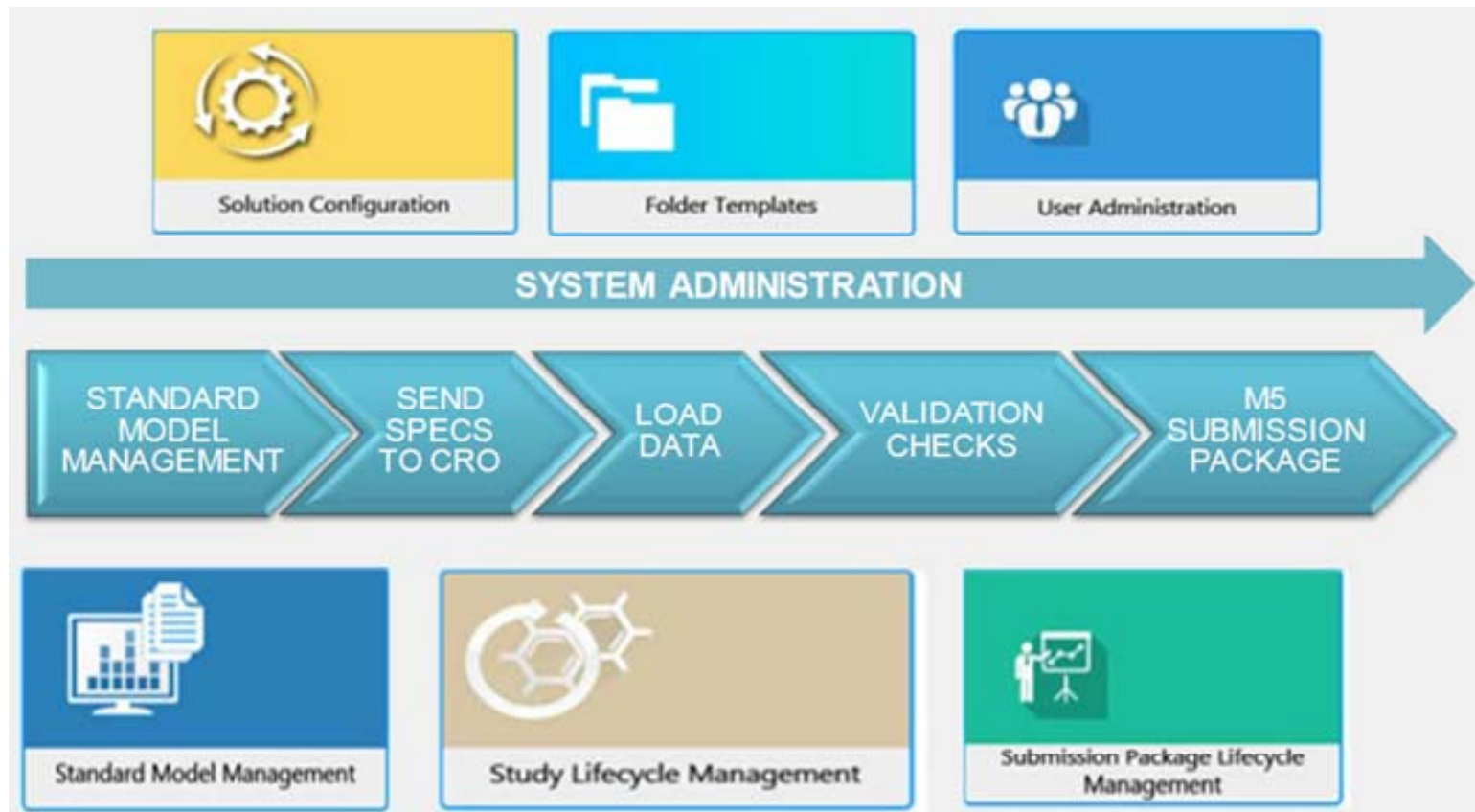
Familiarization



- MDR tool and SDTM+ sponsor philosophy
- Series of trainings were scheduled by the sponsor:
 1. Sponsor SDTM+ library
 - SDTM+ metadata library (with SDTM+ user and administrator guide)
 - Standard CRF library (with CRF library user guide)
 2. Introduction to the MDR tool
 3. SDTM+ MDR tool process workshop

Familiarization

- MDR tool:



Familiarization



- MDR tool and SDTM+ sponsor philosophy
- Series of trainings were scheduled by the sponsor:
 1. Sponsor SDTM+ library
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 - Standard CRF library (with CRF library user guide)
 2. Introduction to the MDR tool
 3. SDTM+ MDR tool process workshop
- Training and a pilot practice were organised by Chiltern
 - **JIRA® pilot practice** was in place for a period of approximately 4 weeks

Familiarization



- JIRA functionality:

☰
SDTM+ Library Portal
Dashboards
Projects
Issues
Boards
Create

?
⚙️
👤

SDTM+ library Portal

+ Add gadget
✎ Edit layout
⚙️

Introduction

Welcome to the SDTM+ standard library maintenance and deliverable review task management system

Please use CREATE to create SDTM+ deliverable tasks or maintenance requests. Select the appropriate Project, task type and complete the required fields.

Please provide as much information as you can. For further information please contact your Standards Library Team.

Favourite filters

- Completed Tasks 8
- Failed Tasks 0
- Ready for Review 2
- Unassigned Tasks 12
- With Ipsen for review 1
- Work in Progress 4

[Create filter](#) [Manage filters](#)

Issues Calendar: Standards library requests

Standards library requests (Due Date)
July 2016

June
August

Sun	Mon	Tue	Wed	Thur	Fri	Sat
	26	27	28	29	30	1
2						
Issues: 1	3	4	5	6	7	8
						9

Two Dimensional Filter Statistics: SDTM review tasks

Issue Type	Emma	Jason	Unassigned	T:
<input type="checkbox"/> aCRF review	0	1	2	3
<input type="checkbox"/> mock up CRF review	0	0	2	2
<input type="checkbox"/> SDTM+ database specification review	0	0	2	2
<input type="checkbox"/> Trial Design Dataset review	1	0	1	2
Total Unique Issues:	1	1	7	9

Grouped by: Assignee Showing 4 of 4 statistics.

Two Dimensional Filter Statistics: Filter for library tasks

Status	<input type="checkbox"/> aCRF review	<input type="checkbox"/> Maintain user guide	<input type="checkbox"/> mock up CRF review	<input type="checkbox"/> New SDTM+ object	<input type="checkbox"/> New standard CRF page	<input type="checkbox"/> Run QC model checks	<input type="checkbox"/> SDTM+ database specification review	<input type="checkbox"/> Trial Design Dataset review	<input type="checkbox"/> Update to CRF	<input type="checkbox"/> Upc to Exc Mac
OPEN	1	1	2	1	2	0	1	1	2	0
BUILDING	0	0	0	0	0	1	0	0	2	0
DONE	2	0	0	0	2	0	0	0	1	2
APPROVED	0	0	0	0	0	0	0	1	0	0
DELIVERABLE INITIAL...	0	0	0	1	2	0	1	0	0	0

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Transition of internal knowledge to the FSP



- Two months working hand in hand with the sponsor SDTM Specialist

User (CDPM)



SDTM Specialist



Maintainers
Chiltern Library
Analysts (CLA)



- CLAs could focus on specific discussions, regarding the SDTM+ metadata, the CRF library or TDD and the use of the MDR tool
- The sponsor gained trust and CLA's gained self-confidence, which had a direct positive impact on efficiency

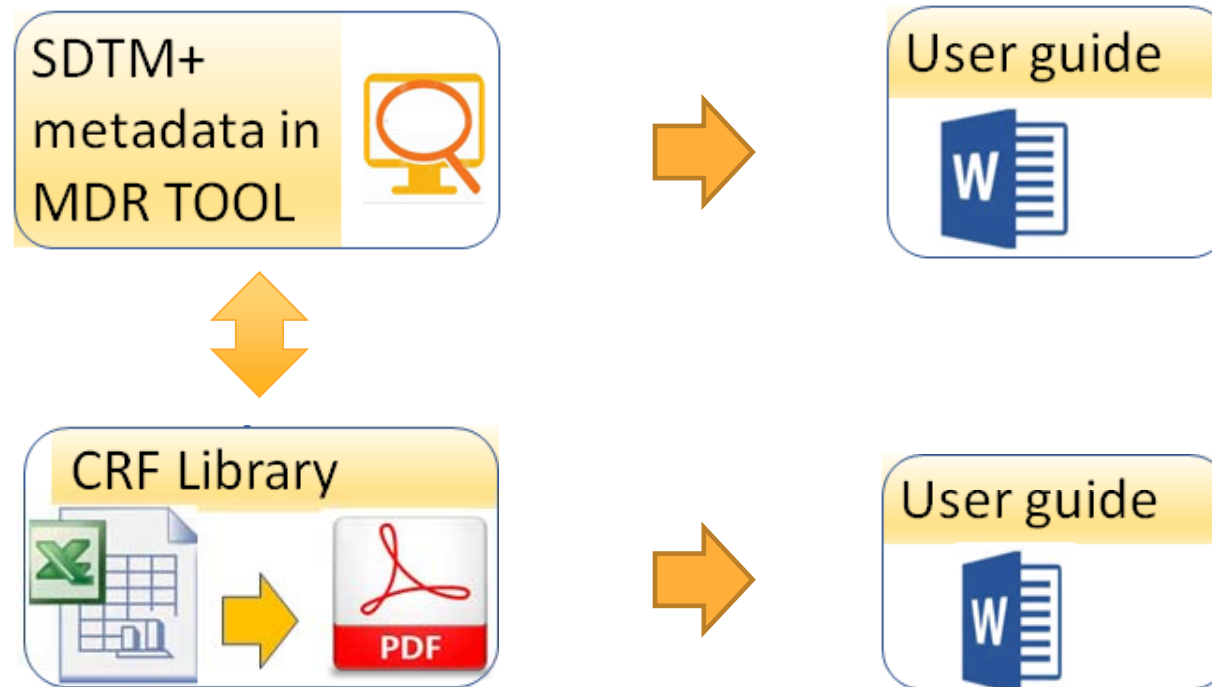
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Impact and scope of each change

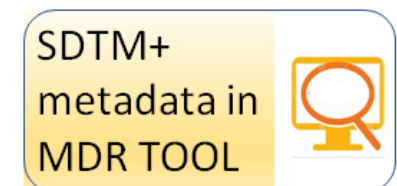
- The SDTM+ library elements:
 - SDTM+ Metadata
 - SDTM+ Standard CRF Library



Impact and scope of each change



- The **SDTM+ Metadata** in MDR tool: follows the philosophy of define.xml Version 2.0 and is broken down into the following sections:
 - Dataset Level
 - Variable Level
 - Controlled Terminology
 - Value Level Metadata
 - Computational Algorithm
 - External Dictionary
 - Standard Unit-Conversion Factors



Impact and scope of each change



Dataset Level | Variable Level | Controlled Terminology | Value Level Metadata | External Dictionaries | Computational Algorithm | Standard Unit-Conv

+ Add | Edit | Replicate | Delete / Inactive | Refresh | Save | Copy | Merge | Ready for Review

Domain*	Description	DB Requirement	Regulatory Requirement	Custom	Blinded Data	Class
AE	Adverse Events	Mandatory	FDA Expected	No		Events
BE	Biospecimen Events	Optional		Yes		Events
BM	Bone Measurements	Optional		Yes		Findings

Dataset Level | Variable Level | **Controlled Terminology** | Value Level Metadata | External Dictionaries

Codelist | Code

+ Add | Edit | Replicate | Delete / Inactive | Refresh | Save | Copy | Merge

Codelist	Code	Code	Submission Value*
DA...	C66769	Severity/Intensit...	C41338 MILD
DA...	C66769	Severity/Intensit...	C41339 MODERATE
DA...	C66769	Severity/Intensit...	C41340 SEVERE

Dataset Level | Variable Level | Controlled Terminology | Value Level Metadata

+ Add | Edit | Replicate | Delete / Inactive | Refresh | Save

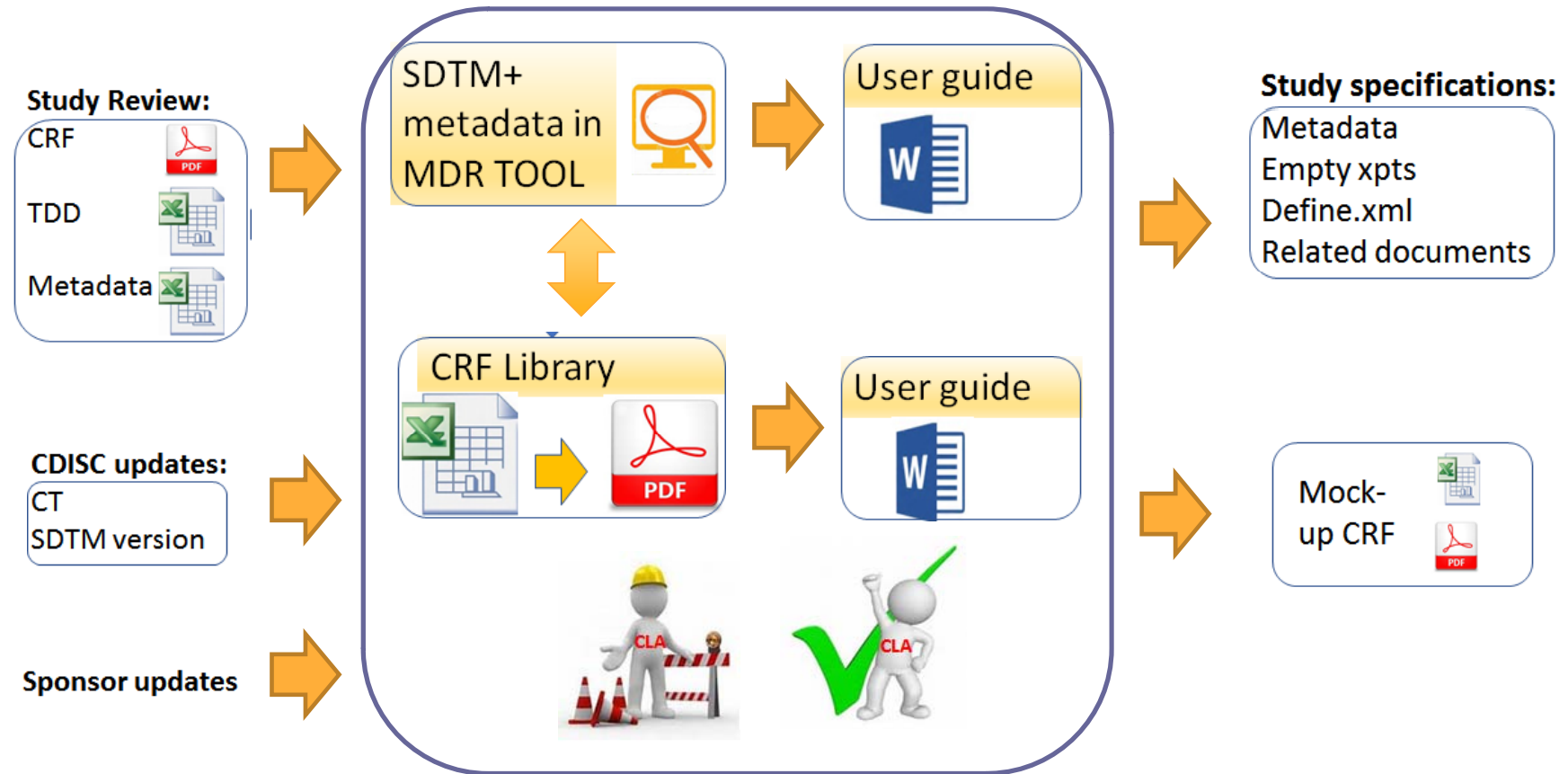
Domain*	Variable Name*	Variable Label	Keys	Text	Controlled Terms
AE	AEPRESP	Pre-Specified A...		20	AESEV
AE	AEBODSYS	Body System or...			
AE	AEBDSYCD	Body System or...			
AE	AESOC	Primary System...			
AE	AESOCCD	Primary System...			
AE	AELOC	Location of Event			
AE	AESEV	Severity/Intensity		20	AESEV
AE	AESER	Serious Event		1	NY
AE	AEACN	Action Taken wi...		40	ACN
AE	AEACNOTH	Other Action Ta...		200	

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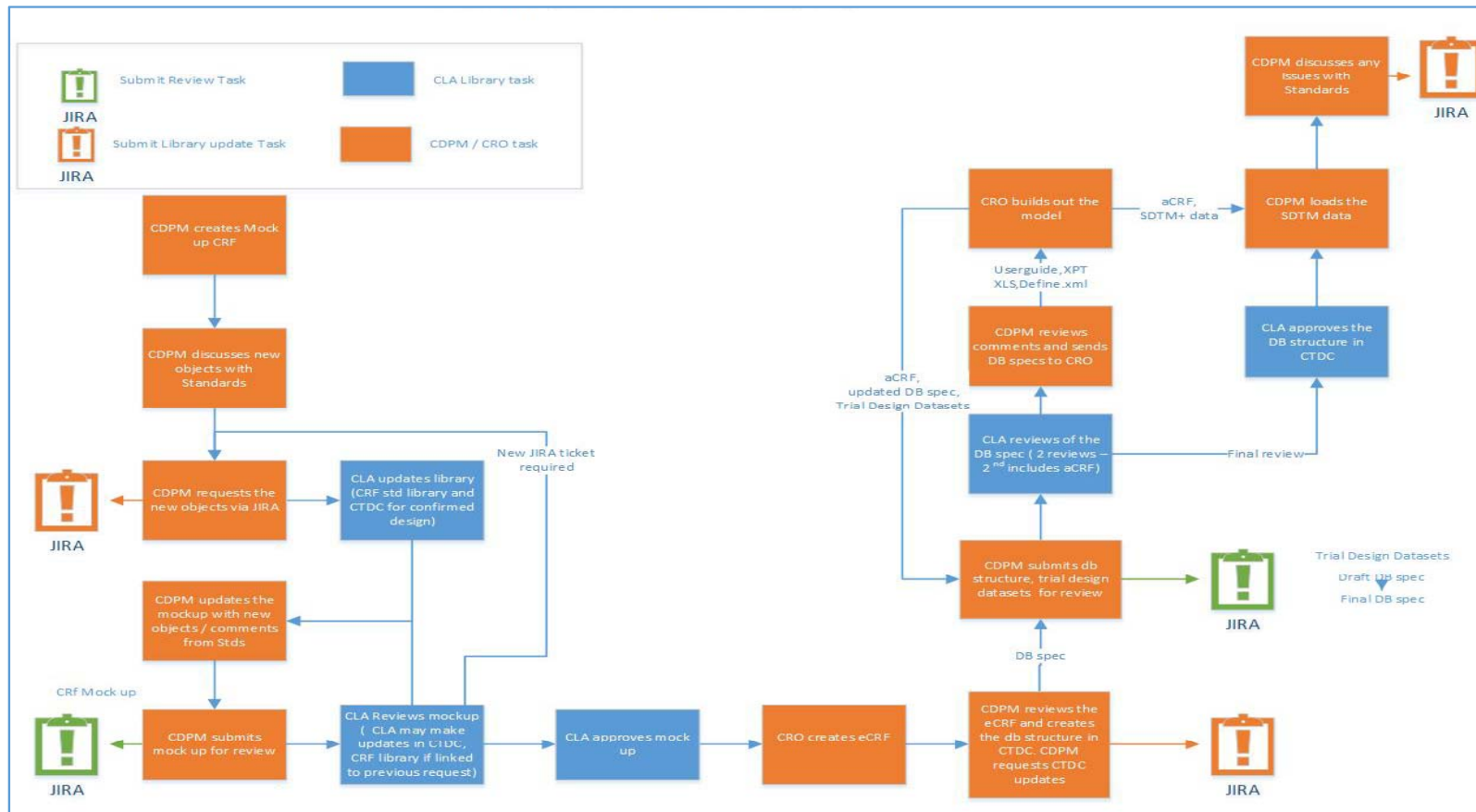
Governance



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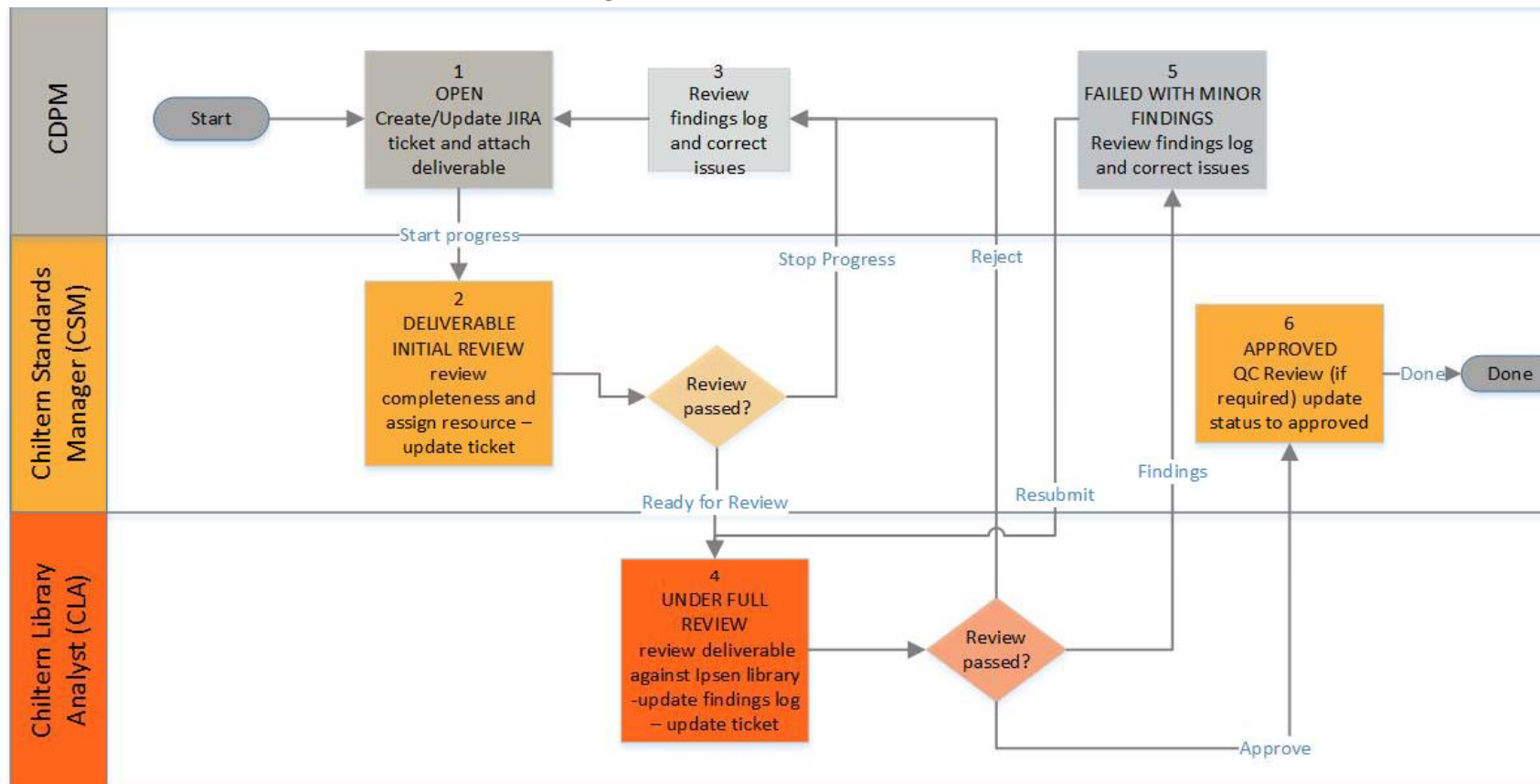
- First high level Study deliverable Review workflow



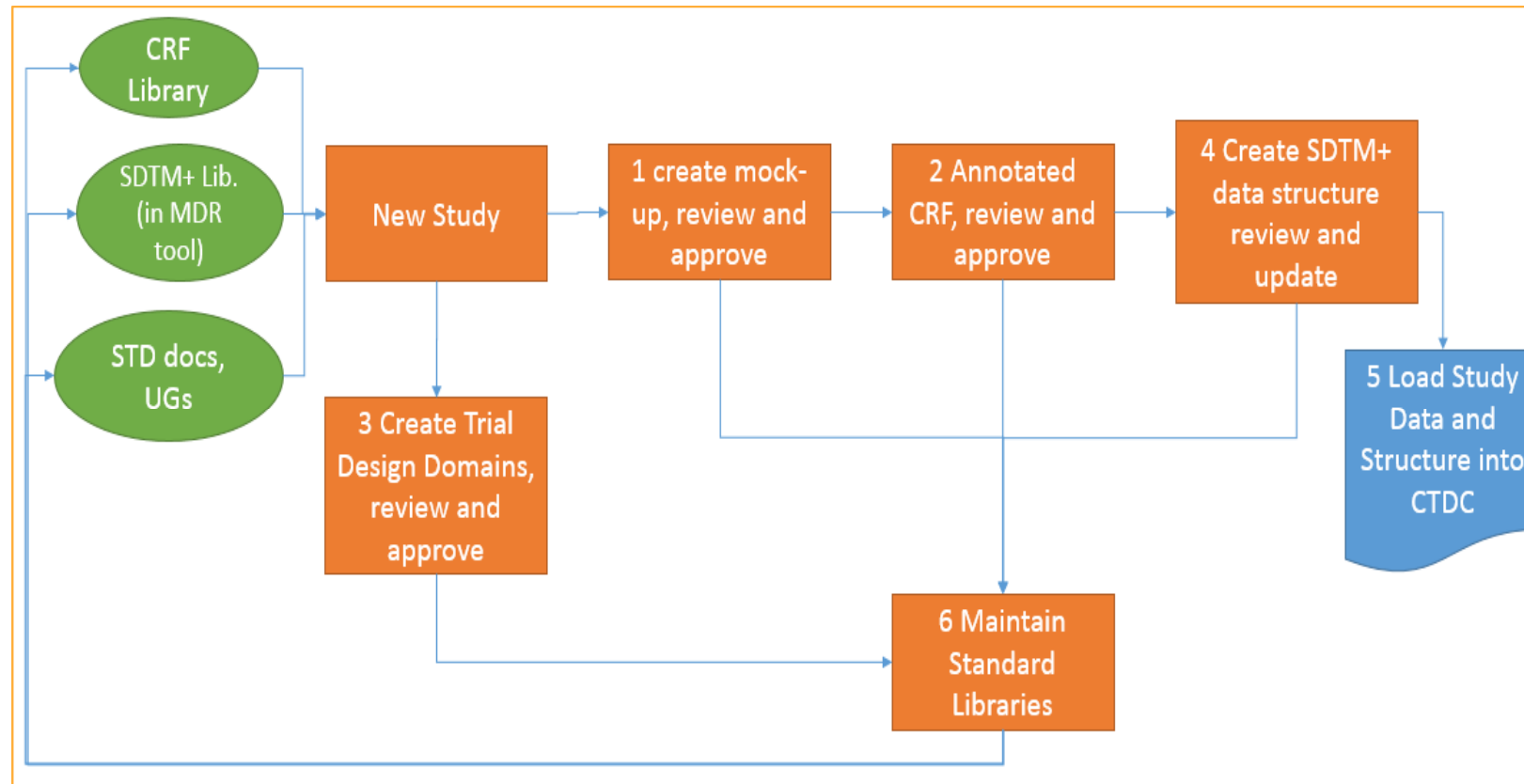
Governance



- One standard workflow for study deliverable review tasks



- CLAs tasks general flow chart



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Use of JIRA® software



Navigation bar containing: CHILTERN logo, SDTM+ Library Portal, Dashboards, Projects, Issues, Boards, and a Create button.

Search bar with a search icon, a help icon, a settings icon, and a user profile icon. Below the search bar are options: + Add gadget, Edit layout, and a settings dropdown.

SDTM+ library Portal

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OPEN	1	1	2	1	2	0	1	1	2	0
BUILDING	0	0	0	0	0	1	0	0	2	0
DONE	2	0	0	0	2	0	0	0	1	2
APPROVED	0	0	0	0	0	0	0	1	0	0
DELIVERABLE INITIAL...	0	0	0	1	2	0	1	0	0	0

Use of JIRA® software



Standards library requests / SLR-186

LBMETHOD: Numbers of CRF pages should be checked/updated

1 of 3 [Return to search](#)

[Edit](#) [Comment](#) [Assign](#) [Start Progress](#) [Admin](#)

Details

Type:	Update to SDTM+ metadata	Status:	OPEN
Priority:	Low		(View workflow)
Labels:	None	Resolution:	Unresolved
Parameter:	LBMETHOD		
Domain Name:	LB		
Attribute:	CRF first page/Page references		

People

Assignee: Unassigned [Assign to me](#)

Reporter: Oksana Voevutska

Votes: [Vote for this issue](#)

Watchers: [Start watching this issue](#)

Dates

Due: 13/Jan/17

Created: 1 hour ago

Updated: 1 hour ago

HipChat discussions

Do you want to discuss this issue? Connect to HipChat.

[Connect](#) [Dismiss](#)

Description

As CRF pages were updated (added LBMETHOD), MD should be updated accordingly.

Attachments

Drop files to attach, or [browse](#).

Activity

[All](#) [Comments](#) [History](#) [Activity](#) [Transitions](#)

Oksana Voevutska created issue - 1 hour ago

[Comment](#)

Task reference number

Once ready to submit
Click start progress

Click edit to make changes
Once submitted no edits
can be made

CLA
assigned
to the task

Click
here to
watch a
task

Click on the
tab to see info

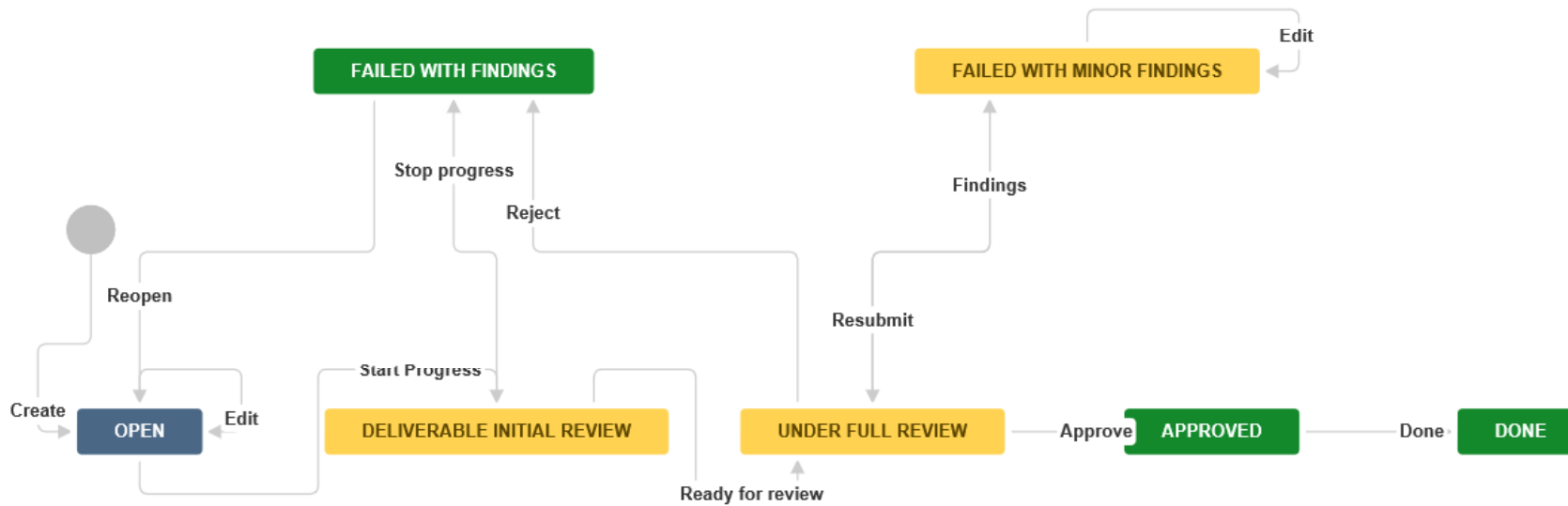
Include any
attachments

Add comments
at any time

Use of JIRA® software



- Issues need to be **transitioned** from **status** to **status**
- Statuses are classified as To Do (**blue**), In Progress(**orange/yellow**), Done(**green**)
- Click on Transition buttons (in the task detail view) to move tasks through the workflow



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First study, theory versus reality



- In a period of ten months we have worked on more than 350 JIRA® tickets related to changes to the SDTM+ and CRF libraries, with each ticket involving one or more change requests. We implemented 25 updates to user guides, and reviewed 14 studies
- Average study requires from 1 to 15 changes (cases with >50 changes)
- Example report from JIRA®, filtered on one study number

Issue Type	Issue key	Issue id	Summary	Assignee	Reporter	Priority	Status	Resolution	Created	Due Date	QC	Study ID
mock up CRF review	SDR-95	17201	001 - Cabozantinib PASS - CRF Mock	CLA3	CDPM1	High	Done		12/12/2016 19:02	13/12/2016 00:00	admin1	999-777--001
New SDTM+ object	SLR-300	15510	Need for a new variable FTPT	CLA1	CDPM4	Medium	Done	Done	18/01/2017 10:40	27/01/2017 00:00	admin	999-777--001
New SDTM+ object	SLR-301	15511	Need for new VLM : QNAM EQ GRO	CLA1	CDPM4	Medium	Done	Done	23/02/2017 15:06	28/02/2017 00:00	admin	999-777--001
New SDTM+ object	SLR-333	16600	Need for a code Average of 3	CLA1	CDPM4	Medium	Review failed with f		23/02/2017 15:36	28/02/2017 00:00	admin	999-777--001
SDTM+ Full DB spec review	SDR-93	17103	Please approve DB Specs	CLA1	CDPM4	High	Done	Done	28/02/2017 12:36	02/03/2017 00:00	admin	999-777--001
Trial Design Dataset review	SDR-96	17302	FR01072-001	CLA3	CDPM4	Medium	Done	Done	30/03/2017 11:47	30/03/2017 23:00	admin	999-777--001
Update to Codelist	SLR-112	12211	Codelist Unit, mA value: Synonym t	CLA1	CDPM4	High	Approved		12/04/2017 15:03	18/04/2017 23:00		999-777--001
Update to Codelist	SLR-213	13800	Need for a Immunogenicity Specim	CLA1	CDPM4	Medium	Done	Done	26/05/2017 10:27	30/05/2017 23:00	admin	999-777--001
Update to Codelist	SLR-306	15800	Need for creation of missing metad	CLA3	CDPM5	Medium	Failed with Minor Fi		24/04/2017 11:26	27/04/2017 23:00		999-777--001
Update to Codelist	SLR-374	17900	Please create new codes for UNIT	CLA1	CDPM5	Medium	Done	Done	08/08/2017 09:31	15/08/2017 00:00	CLA2	999-777--001
Update to Codelist	SLR-460	19639	Please update codelist FASCAT (se	CLA1	CDPM5	Medium	Done	Done	08/08/2017 09:36	15/08/2017 00:00	CLA2	999-777--001
Update to SDTM+ metadata	SLR-459	19638	Please create few items for domai	CLA1	CDPM12	Medium	Failed with Minor Fi		14/04/2017 15:20	27/04/2017 23:00		999-777--001
Update to SDTM+ metadata	SLR-452	19631	Add domain SC to CTDC and add res	CLA3	CLA3	Medium	Open		07/08/2017 14:10			999-777--001
Update to SDTM+ metadata	SLR-453	19632	Add FATESTCD needed for RCC Hist	CLA3	CLA3	Medium	Building		07/08/2017 14:24		admin	999-777--001
Update to SDTM+ metadata	SLR-454	19633	Add categories for PR/FAPR/CM/EX	CLA2	CLA3	Medium	Done	Done	07/08/2017 14:43		CLA1	999-777--001
Update to SDTM+ metadata	SLR-455	19634	Add needed updates to HO/SUPPH	CLA3	CLA3	Medium	Done	Done	07/08/2017 15:01		admin	999-777--001
Update to SDTM+ metadata	SLR-456	19635	Add variable EXDOSFRQ to EX and C	CLA2	CLA3	Medium	Done	Done	07/08/2017 15:07		admin	999-777--001
Update to SDTM+ metadata	SLR-457	19636	Add QNAMs for SUPPPR and SUPPC	CLA2	CLA3	Medium	Done	Done	07/08/2017 15:14		admin	999-777--001

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What is next?



- We are currently working on the updates needed to the SDTM+ library due to the latest version of CDISC controlled Terminology
- Can we relate the elements from the two libraries CRF and SDTM+ automatically? And from that can we then somehow automate the QC of study specific CRFs?

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Conclusions



- Providing valid standards and clear user guides for the sponsor is a need due that the trial conduct and the creation of CDISC SDTM+ for all trials, is outsourced by the sponsor. Although the sponsor is responsible of the development and governance of their own data standards.
- Working with an MDR tool keeps things aligned, the study cannot be conducted if it does not follow the SDTM+ metadata. Although there are some gaps to fill in.
- Chiltern responsibilities: maintenance and validation of SDTM+ metadata, aCRF/CRF in SDTM+, and Trial design datasets in SDTM+.
- Each of these tasks or any sponsor request is tracked into JIRA the collaborative tracking system
- Chiltern proposed a high level Study Deliverable Review workflow, introducing JIRA and its interaction with the MDR tool

Conclusions



- The use of FSP helps to test what is not working properly from an outsider point of view, as user, developer and admin. The FSP experience implementing SDTM in other environments also brings questions and ideas on what to improve or how. It was very helpful to have standard documentation in place, although at each study we found either a small clarification was needed or a complete section should be added or changed.
- We value the use of JIRA an intuitive and easy to use tracking tool, it can be customised to specific tasks and roles. Also allows us to evaluate the amount of work done by study, per period of time and so on.
- We understand the impact of our decisions, we try to automate and ensure consistency in each task, and keep ourselves constantly looking for possible improvements.

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