



# CDISC Standards Governance: What does JIRA bring to the party?

CDISC UK Network Face to Face Meeting  
Roche, Welwyn Garden City

Tuesday, 07JUN2016



# Agenda

- Introduction
- CDISC standards governance
- JIRA
  - Introduction
  - Create an Issue
  - JQL (JIRA Query Language)
  - Dashboards
  - CRO Workflows
- Questions

# My Standards Background

- Astellas Pharma 2008-2010
  - Early Phase CDASH Standardization and RAVE Automation project participant then project manager
- Novartis Vaccine and Diagnostics 2010-2013
  - CDASH/SDTM/InForm standardization and Metadata Repository (MDR) project participant
  - Worked under a standards governance process
- Business & Decision Life Sciences (BDLS) 2013-2015 **(JIRA)**
  - Client CDASH/SDTM/RAVE Standardization and MDR project participant then line manager
- InVentiv Health Clinical 2015 **(JIRA)**
  - Client Specific Standards Governance - Project Participant
  - inVentiv Early Stage CDASH Governance - Project Participant
  - inVentiv eSource/CDASH - Project Participant

# CDISC Standards Governance



# Standards Governance is Challenging

- Standards Governance is challenging from a project management perspective
- Timelines and priorities can shift and be unclear
- Projects can be delayed or put on hold with significant investments in standards creation already in place
- Further information to support standards creation may be difficult to obtain

# Project Management Frameworks



Waterfall

- PRINCE2
  - <https://www.axelos.com/best-practice-solutions/prince2/what-is-prince2>
- Project Management Professional
  - <http://www.pmi.org/default.aspx>



- Iterative
  - Agile/Scrum
    - <https://www.scrumalliance.org/certifications/practitioners/certified-scrummaster-csm>



Service Desk Framework

- Information Technology Infrastructure Library
  - <https://www.axelos.com/best-practice-solutions/itil>



# Resourcing and Coordinating Standards Requests

- Assess
  - Size
  - Complexity
  - Experience with Therapeutic Area
  - Familiarity with standards (CDASH, SDTM, ADaM, company specific)
- Coordinate
  - Due Date
  - Prioritization
- Project management
  - Client meetings
  - Timesheet, reporting and budgeting

# CDISC Standards Maturity Levels

CDISC Level	Reliance on Internal Company Standards	Potential Scenarios
High	Low	Assist with the implementation of CDISC standards systems and processes.
Low	Low	Assist with the implementation of CDISC standards systems and processes. ~25% of time CDISC familiarization and training. Encourage the use and adherence to standards.
Low-Medium	High	Standards team may have to negotiate the use of CDISC standards over company standards. ~25% of time CDISC familiarization and training. Assist with the redesign of company systems and process to incorporate CDISC standards.



**JIRA**

# JIRA Pronunciation - JIRA [*JEE-rə*]



- Gojira is the Japanese for Godzilla
- When JIRA was created Bugzilla was JIRA's biggest competitor
- Ergo JIRA [*JEE-rə*]
- <https://confluence.atlassian.com/pages/viewpage.action?pageId=223219957>
- By Source (WP:NFCC#4), Fair use, <https://en.wikipedia.org/w/index.php?curid=39423572>

# Atlassian JIRA Platform

- JIRA is a bug tracking system from Atlassian
- It is available in as a cloud or as an onsite server installation
- From JIRA 7.0 it comes in three different versions

 **JIRA Core**

 **JIRA Software**

 **JIRA Service Desk**

- <https://confluence.atlassian.com/jirasoftwareserver071/jira-applications-overview-800707058.html>

# JIRA 7.0

- JIRA Core is a part of every JIRA instance
- It includes issues, workflows and reports
  - Core (Business)
    - Task Management – basic workflow
    - Project Management – time tracking as default
    - Process Management – approvals built in
- JIRA Software is aimed at development teams and features Scrum and Kanban boards. It has developer tools extensions available.
  - Software
    - Scrum software development
    - Kanban software develop development
- Service Desk is aimed at IT Services desks and company customer ticket management. It deals with queues, prioritization and SLAs (Service Level Agreements).

# JIRA Cloud vs Server

- Cloud is quicker and easier to setup and maintain.
- However
  - Cloud is only a production environment there is no development area to test new workflows or screens
  - Missing system administrator rights
  - Not all add-ons are available
  - Storage limitations

Users	JIRA	Confluence	Combined
0-500	25GB	25GB	25GB
500+	100GB	50GB	100GB

- A complete list is available on the Atlassian site.
- <https://confluence.atlassian.com/cloud/restricted-functions-in-atlassian-cloud-apps-744721664.html>

# JIRA Software and Core Licenses - June 2016

Users	Core Cloud Per Year	Software Cloud Per Year	Core Server One Off	Software Server One Off
10	\$ 120	\$ 120		
15	\$ 600	\$ 900		
25	\$ 1,200	\$ 1,800	\$ 1,200	\$ 1,800
50	\$ 2,400	\$ 3,600	\$ 2,200	\$ 3,300
100	\$ 3,600	\$ 5,400	\$ 4,000	\$ 6,000
250			\$ 8,000	\$ 12,000
500	\$ 6,000	\$ 9,000	\$ 12,000	\$ 18,000
2,000	\$ 12,000	\$ 18,000	\$ 16,000	\$ 24,000
10,000			\$ 20,000	\$ 30,000
10,000+			\$ 24,000	\$ 36,000

JIRA Software is 1.5 time the price of JIRA Core

JIRA Software Enterprise is a JIRA hosted data center starting from 500 users

<https://www.atlassian.com/software/jira/pricing?tab=host-in-the-cloud>

# CDISC JIRA & Confluence

- CDISC qualifies for the Atlassian Community License
- New Rheumatoid Arthritis Therapeutic Area User Guide Draft v1
  - Comments Due 19 June 2016.
    - <http://wiki.cdisc.org/display/TARA/ReadMe+for+TAUG-RA>
- New Draft Cardiovascular Imaging Therapeutic Area User Guide v1
  - Comments Due 29 June 2016
    - <http://wiki.cdisc.org/display/TACVI/Instructions+for+Reviewers>
- CDASH 2.0 - Webinar 16 June 2016
  - <http://www.cdisc.org/cdisc-public-webinar-series-standards-updates-and-additions-16>
- Public review expected end of June
  - <http://wiki.cdisc.org/display/CMIG/ReadMe+for+CDASH+v2>

# Creating JIRA Tickets in Confluence

- Creating JIRA tickets through Confluence / Wiki
- <http://wiki.cdisc.org/display/TARA/ReadMe+for+TAUG-RA>



Rheumatoid Arthritis Therapeutic Area Data S

## ReadMe for TAUG-RA

Created by Darcy Wold, last modified by Alana St. Clair on May 1

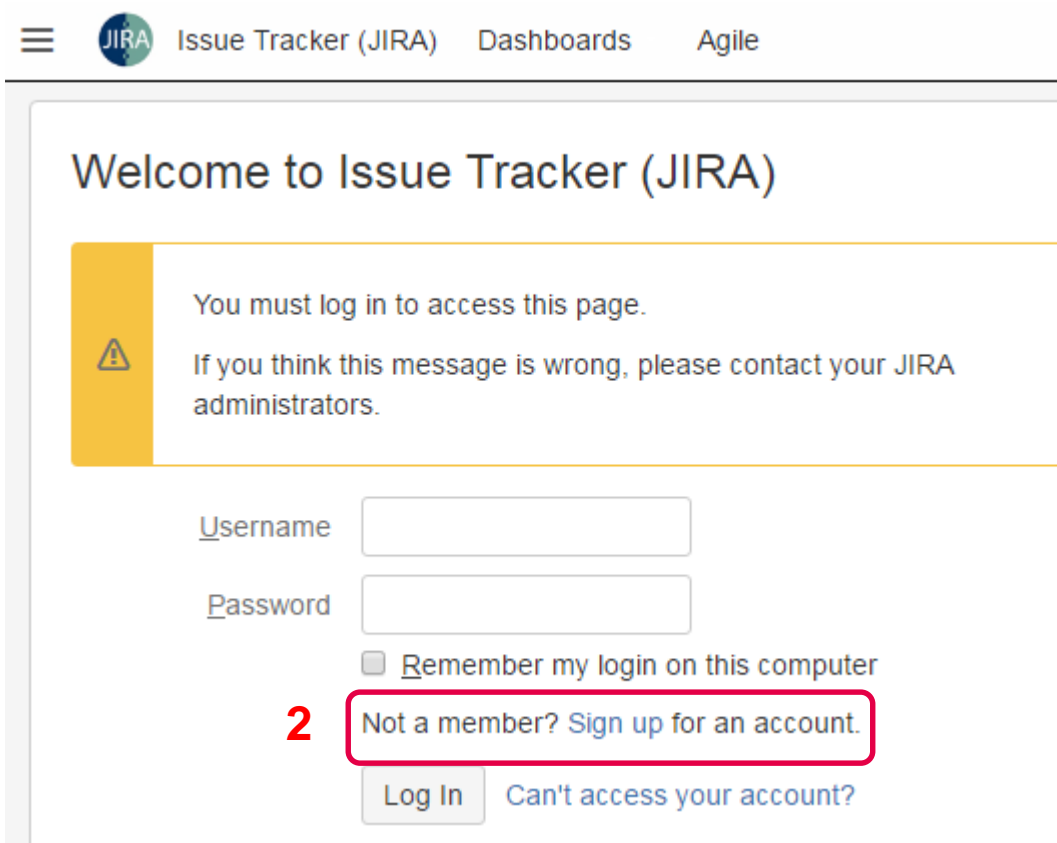
The TAUG-RA package for Public  
Review consists of:

Cc

- The ReadMe for TAUG-RA (this page)
- The [TAUG-RA v1.0 Draft](#)
- A [CDASH Metadata](#) Excel File
- 1 • [A project in JIRA for adding, tracking, and resolving comments.](#)



# Create a CDISC JIRA Account



The screenshot shows the JIRA login interface. At the top, there is a navigation bar with a hamburger menu icon, the JIRA logo, and the text 'Issue Tracker (JIRA) Dashboards Agile'. Below this is a heading 'Welcome to Issue Tracker (JIRA)'. A yellow warning box contains the text: 'You must log in to access this page. If you think this message is wrong, please contact your JIRA administrators.' Below the warning box are two input fields for 'Username' and 'Password'. There is a checkbox labeled 'Remember my login on this computer'. A red box highlights the link 'Not a member? Sign up for an account.' Below this link are two buttons: 'Log In' and 'Can't access your account?'.

# Review the RA TAUG Wiki – Find an Issue


 Rheumatoid Arthritis Therapeutic Area Data Standard User Guide  
**Annotated CRF - Bone Erosion**  
 Created by Nikki Flores, last modified by Darcy Wold on May 18, 2016

This CRF is only an example and is not meant to imply that any particular CRF annotated to show mapping. SDTM variables are in **RED**. If CDASH v

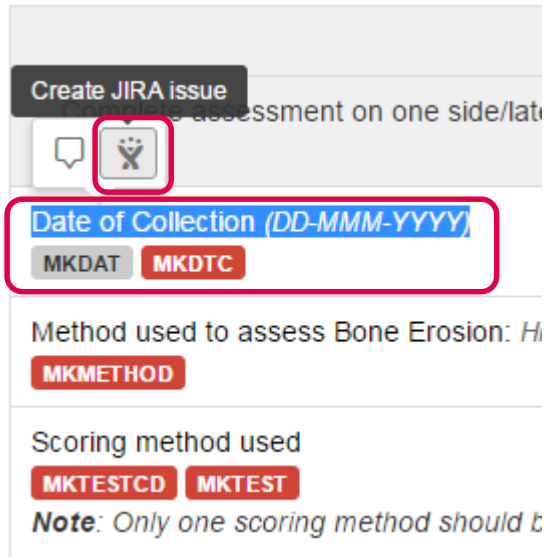
<b>B</b>
Complete assessment on one side/laterality before beginning assessment
<div style="border: 2px solid red; padding: 5px;">           Date of Collection (DD-MMM-YYYY)            MKDAT MKDTC         </div>
Method used to assess Bone Erosion: <i>Hidden/Pre-specified</i> MKMETHOD
Scoring method used MKTESTCD MKTEST <i>Note: Only one scoring method should be used for all assessments</i>

- The 'Date of Collection' prompt is not in line with CDASH V2.0 - CDASH Domain Metadata

Prompt	CDASH Variable
Collection Date	HODAT
Collection Date	MHDAT
Collection Date	DDDAT
Collection Date	LBDAT

- <http://wiki.cdisc.org/display/TARA/Annotated+CRF+-+Bone+Erosion>

# Create an JIRA issue by Highlighting the Text



- Highlight the text
- A tool tip with 'Inline Comments' and 'Create JIRA Issue' appears
- Create a JIRA issue

# Check the JIRA Project

Date of Collection (DD-MMM-YYYY)

## Create Issue

CDASH Error/Typo Edit

Summary\*

Date of Collection (DD-MMM-YYYY)

Description

Create Cancel

*Looks like you are creating issues from a table.  
Create 30 issues from this table.*

- If you are doing multiple reviews it may be necessary to change the JIRA project.

# Changing the JIRA Project and Issue Type

Date of Collection (DD-MMM-YYYY)

## Create Issue

Rheumatoid Arthritis

- Review Comments
- Review Comments
- Error/Typo
- Question
- Improvement
- Format
- Missing Materials
- Content Error
- Err...

*i* Looks like you are creating issues from a table.  
[Create 30 issues from this table.](#)

- Follow the instructions for setting issues types.
- According to the RA TAUG JIRA instructions issues type should be set to 'Review Comments'

# Enter the Description and Create

Date of Collection (DD-MMM-YYYY)

## Create Issue

Rheumatoid Arthritis

Improvement

Summary\*

Date of Collection (DD-MMM-YYYY)

Description

Please consider changing to 'Collection Date'.  
In CDASH V2.0 - CDASH Domain Metadata all prompts are 'Completion Date'.

Create Cancel

**i** Looks like you are creating issues from a table.  
[Create 30 issues from this table.](#)

# Go to JIRA (CDISC Issue Tracker)



**This CRF is only an example and is not meant to imply that any particular layout CRF annotated to show mapping. SDTM variables are in **RED**. If CDASH variable differ**

- To view the issue that you have created go to the Issue Tracker

# CDISC JIRA Default Dashboard

## System Dashboard

Projects					
<a href="#">Asthma (ASTHMA)</a>			<a href="#">Breast Cancer (BRCA)</a>		
<a href="#">COPD (COPD)</a>			<a href="#">CV Imaging (CVIMAG)</a>		
<a href="#">Diabetic Kidney Disease (DKD)</a>			<a href="#">Hepatitis C (HEPC)</a>		
<a href="#">Kidney Transplant (KT)</a>			<a href="#">Major Depressive Disorder (TAMDD)</a>		
<a href="#">Prostate Cancer (PRCA)</a>			<a href="#">Rheumatoid Arthritis (TARA)</a>		
<a href="#">Schizophrenia (SCHIZ)</a>			<a href="#">Traumatic Brain Injury (TBI)</a>		
<a href="#">Virology (VIROLOGY)</a>					

### Introduction

Welcome to CDISC JIRA. An issue tracking system used by the teams to track, respond and resolve issues identified by the teams the public within the standards being developed.

- ### Quick Links
- [My Unresolved Reported Issues](#) | [Votes](#) | [Watch](#)
  - [Browse Projects](#) | [Search for Issues](#) | [Create Issues](#)

### Assigned to Me

You currently have no issues assigned to you. Enjoy your day!

### Activity Stream

CDISC Jira

Yesterday

**Dany Guerendo** started progress on MTT-223 - Check that Controlled Terminology is consistent with

11 hours ago [Comment](#) [Vote](#) [Watch](#)





# RA Project Backlog

RA Comments

Board ▾

## Backlog

QUICK FILTERS: Only My Issues Recently Updated

Backlog 13 issues

Create Sprint

		TARA-134 PARQUAL	B
		TARA-135 CDASH_RA_Metadata_Spreadsheet - Question Text in Sentence Case, Prompts in Title Case	N
		TARA-136 Consistency of names in 5.1	B
		TARA-141 Section 5.1, Subject Level Analysis Data	B
		TARA-142 Section 5.1, Subject Level Analysis Data	B
		TARA-144 Section 5.1, Subject Level Analysis Data	B
		TARA-145 Section 5.1.1 Additional Highly Derived Baseline Values, Metadata Table	B
		TARA-146 Section 5.3, Analysis Data for Joint Scores	B
		TARA-147 Section 5.3, Analysis Data for Joint Scores	B
		TARA-148 Section 5.3, Analysis Data for Joint Scores	B
		TARA-150 Section 5.4.2, Analysis Dataset for Derived Efficacy Endpoints	B
		TARA-151 Provide LOINC codes for all lab tests named	E
		TARA-152 Date of Collection (DD-MMM-YYYY)	

Navigation sidebar with icons for Versions, Epics, and other JIRA features.



# RA Project Issues

## Issues: Open Issues ▾

[View all issues and filters](#)

Order by Priority ▾

TARA-136

Consistency of names in 5.1

TARA-152

Date of Collection (DD-MMM-YYYY)

TARA-151

Provide LOINC codes for all lab tests named

TARA-135

CDASH\_RA\_Metadata\_Spreadsheet - Question Text...

TARA-150

Section 5.4.2, Analysis Dataset for Derived Efficacy E...

TARA-148

Section 5.3, Analysis Data for Joint Scores

TARA-147

Section 5.3, Analysis Data for Joint Scores

TARA-146

Section 5.3, Analysis Data for Joint Scores

TARA-145

Section 5.1.1 Additional Highly Derived Baseline Valu...

TARA-144

Section 5.1, Subject Level Analysis Data

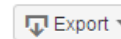


Rheumatoid Arthritis / TARA-152

## Date of Collection (DD-MMM-YYYY)



Agile Board More ▾



### Details

Type:

Improvement

Status:

**OPEN** (View Workflow)

Priority:

To be assigned

Resolution:

Unresolved

Labels:

None

### Description

Please consider changing to 'Collection Date'. In CDASH V2.0 - CDASH Domain Metadata all prompts are 'Completion Date'.

<http://wiki.cdsc.org/display/CMIG/CDASH+Dom>

### People

Assignee:

Unassigned

Reporter:

Eanna Kiely

Votes:

0

Watchers:

Stop watching this issue

### Dates

Created:

2 days ago

Updated:

2 days ago

# CDASH RA Metadata Review

- CDASH\_RA\_Metadata\_Spreadsheet.xlsx


Question Text	CDASH Variable Name
What <b>is</b> the imaging method used to assess bone erosion?	MKMETHOD
What <b>is</b> the scoring method used to assess bone erosion?	MKTEST

- CDASH\_Model\_Fields\_CDASH 2.0\_Public Review.xlsx

Question Text	CDASH Variable Name
What <b>was</b> the method (used for the [measurement/test/examination])?	--METHOD

# Create an Issue in JIRA

## Create Issue



Project  Rheumatoid Arthritis (TARA)

Issue Type  Review Comments 











Some issue types are unavailable due to incompatible field configuration and/or workflow associations.

Summary

Component/s **None**

Priority  To be assigned  

Description

Style  **B** *I* U A         

Should the tense of the CDASH Questions Text be changed to the past tense in line with the examples in CDASH V2.0 CDASH Domain Metadata and CDASH Model Fields?

Please consider changing

"What **is** the XXXX method..."

To

"What **was** the XXXX method..."

Please note that if it is needed for the purposes of the study it is possible to change the tense of the Question Text. See CDASH 2.0 section 5.1 Conformance Rules.

<http://wiki.cdisc.org/display/CMIG/CDASHIG+v2+compiled#CDASHIGv2compiled-5.1ConformanceRules>



Create another **Create** Cancel

# See All JIRA Issues

[View all issues and filters](#)



Rheumatoid Arthritis / TARA-153

## CDASH Questions Text Tense - Change to Past Tense

Agile Board More ▾

Export ▾

### Details

Type:

Review Comments

Status:

**OPEN** (View Workflow)

Priority:

To be assigned

Resolution:

Unresolved

Labels:

None

### Description

Should the tense of the CDASH Questions Text be changed to the past tense in line with the examples in CDASH V2.0 CDASH Domain Metadata and CDASH Model Fields?

Please consider changing

### People

Assignee:

Unassigned

Reporter:

Eanna Kiely

Votes:

0

Watchers:

Stop watching this issue

### Dates

Created:

2 minutes ago

Updated:

2 minutes ago

# JIRA Core Issues List

Issue Tracker (JIRA) Dashboards Projects **Issues** Agile Portfolio **Create** Search ? [User]

FILTERS << New filter Find filters My Open Issues Reported by Me Recently Viewed All Issues FAVORITE FILTERS **CDASH: Reported by...**

Search Save as Export Tools

Rheumatoid Ar... Type: All Status: All Assignee: All Contains text More **Advanced**

Resolution: Unresolved

1-14 of 14 Columns

T	Key	Summary	Assignee	Reporter	P	Status	Resolution	Created	Updated	D
[?]	TARA-136	Consistency of names in 5.1	Beth Seremula	John Salkeld	↓	OPEN	Unresolved	25/May/16	27/May/16	
[I]	TARA-153	CDASH Questions Text Tense - Change to Past Tense	Unassigned	Eanna Kiely	[?]	OPEN	Unresolved	04/Jun/16	04/Jun/16	
[I]	TARA-152	Date of Collection (DD-MMM-YYYY)	Unassigned	Eanna Kiely	[?]	OPEN	Unresolved	03/Jun/16	03/Jun/16	
[I]	TARA-151	Provide LOINC codes for all lab tests named	Erin Muhlbradt	Jozef Aerts	[?]	OPEN	Unresolved	01/Jun/16	02/Jun/16	
[I]	TARA-135	CDASH_RA_Metadata_Spreadsheet - Question Text in Sentence Case, Prompts in Title Case	Nikki Flores	Eanna Kiely	[?]	OPEN	Unresolved	20/May/16	27/May/16	













- Select the Favorite Filter “CDASH: Reported by Me” and Advanced

# JQL (JIRA Query Language)

CDASH: Reported by Me Save as Details ★ Export Tools

✓ project = CDASH AND reporter in (currentUser()) ORDER BY createDate DESC ? Basic ≡

1–36 of 36 Columns

T	Key	Summary	Assignee	Reporter	P	Status	Resolution	Created ↓	Updated	D
	CDASH-415	Sheet 1, MOLOC, PCDATFL, PECLSIG, SRRFTTIM, SRNRIND	Michael J. Ward	Eanna Kiely		CLOSED	Fixed	31/Mar/16	03/Apr/16	
	CDASH-414	Sheet 1, [SCTESTCD]_SCPERF	Michael J. Ward	Eanna Kiely		CLOSED	Fixed	31/Mar/16	03/Apr/16	
	CDASH-413	Sheet 1, VISDAT	Michael J. Ward	Eanna Kiely		CLOSED	Fixed	31/Mar/16	03/Apr/16	
	CDASH-412	Sheet 1, Sub-category and Subcategory	Michael J. Ward	Eanna Kiely		CLOSED	Fixed	31/Mar/16	03/Apr/16	
	CDASH-411	Sheet 1, RPSCAT	Michael J. Ward	Eanna Kiely		CLOSED	Fixed	31/Mar/16	03/Apr/16	
	CDASH-410	Sheet 1, PEDAT	Michael J. Ward	Eanna Kiely		CLOSED	Fixed	31/Mar/16	03/Apr/16	

- “project = CDASH AND reporter in (currentUser()) ORDER BY createDate DESC”

# JQL – Unassigned and Unresolved

✓ project in (CDASH, TARA) AND reporter in (currentUser()) AND assignee IS EMPTY AND resolution = Unresolved ORDER BY createdAt DESC



Basic



1–2 of 2

Columns ▾

T	Key	Summary	Assignee	Reporter	P	Status	Resolution	Created ↓	Updated
	TARA-153	CDASH Questions Text Tense - Change to Past Tense	Unassigned	Eanna Kiely		OPEN	Unresolved	04/Jun/16	04/Jun/16
	TARA-152	Date of Collection (DD-MMM-YYYY)	Unassigned	Eanna Kiely		OPEN	Unresolved	03/Jun/16	03/Jun/16

- project in (CDASH, TARA) AND reporter in (currentUser()) AND assignee IS EMPTY AND resolution = Unresolved ORDER BY createdAt DESC



# JQL – Issue Summary (Name)

project !=cdash AND summary ~ "cdash" AND resolution = Unresolved ORDER BY createdDate DESC

1–26 of 26

T	Key	Summary	Assignee	Reporter	P	Status	Resolution	Created ↓	Updated
	TARA-153	CDASH Questions Text Tense - Change to Past Tense	Unassigned	Eanna Kiely		OPEN	Unresolved	04/Jun/16	04/Jun/16
	TARA-135	CDASH_RA_Metadata_Spreadsheet - Question Text in Sentence Case, Prompts in Title Case	Nikki Flores	Eanna Kiely		OPEN	Unresolved	20/May/16	27/May/16
	RDF-68	TA Exports - Missing import files for Medical Devices, Routine Data, and CDASH TAUG	Unassigned	Tasneem Shahmalak		TO DO	Unresolved	20/May/16	20/May/16
	DKD-241	Blank Cells in CDASH metadata s/s	Rachael Zirkle	Anthony Chow		OPEN	Unresolved	16/May/16	02/Jun/16

- project !=cdash AND summary ~ "cdash" AND resolution = Unresolved ORDER BY createdDate DESC
  - <https://confluence.atlassian.com/jirasoftwarecloud/advanced-searching-764478330.html>
- JQL queries can be saved as favorites and emailed to users according to schedules

# Dashboard System Dashboard

The screenshot shows the JIRA System Dashboard. At the top, there is a navigation bar with the JIRA logo, menu items for Dashboards, Projects, Issues, and Boards, a 'Create' button, a search bar, and a user profile icon. A 'Tools' button with a gear icon is highlighted with a red box in the top right corner.

The main content area is divided into several sections:

- Introduction:** A blue header with a white icon of three people. Below it, the text reads: "Welcome to JIRA" and "New to JIRA? Check out the JIRA User's Guide."
- Assigned to Me:** A table listing issues assigned to the user. The table has columns for 'T' (type), 'Key', 'Summary', and 'P' (priority).

T	Key	Summary	P ↓
■	TDEMO-14	CR-512 Mapping of EX for Oncology Trial	↑
■	T-2	CR 1846: QS domain - new questionnaire on Fatigue Scale from FACIT.org	↑
■	T-4	Ad hoc: COMPASS CRF design	↑
■	T-5	Ad hoc: ALF OneAndDone Project	↑
■	T-28	CR 1921: QS - TSQM Ver.1.4	↑
■	T-30	CR 1994: XF domain - Verbal Learning and memory test	↑
■	T-34	CR 2000: XF domain - Tests	↑
- Activity Stream:** A section titled "Your Company JIRA" showing recent activity. It includes icons for calendar, list, and RSS. The activity stream shows:
  - Shanthi Chintala** changed the Assignee to 'Shanthi Chintala' on 007-75 - Programming- TA
  - Shanthi Chintala** changed the status to QC on 007-75 - Programming- TA
  - Nancy Brucken** changed the status to To Do on 007-82 - Specs- SE domain
  - Nancy Brucken** changed the status to Develop on 007-82 - Specs- SE domain

# Customizable Dashboard

JIRA Dashboards Projects Issues Boards Create Search

EEK Dashboard System Dashboard

EEK Dashboard

Assigned to Me Activity Stream

+ Add Gadget Edit Layout Tools

Agile Wallboard Gadget

To Do Pending In Progress Resolved Done

To Do	Pending	In Progress	Resolved	Done
Ad hoc: COM (160)	CR 1994: XF (8)	CR 2002: XF (8)	Ad hoc: PD (20)	CR 1538: Critica
CR 1871: QS (24)	Ad hoc: CDIS (16)	Ad hoc: G_CR (16)	CR 1930: CE FA (8)	CR 1873: QS (16)
Ad hoc: ALF (160)	Ad hoc: OAD (16)	CR 1846: QS (16)		CR 1903: DM (4)
Ad hoc: 16277 (40)	Ad hoc: 13605	Ad hoc: Revie (40)		CR 1907: AE (4)
CR 1961: XF (8)	CR 1923: TR (4)			CR 1880: TR (4)
				CR 1884: (4)

Two Dimensional Filter Statistics: Filter for

Status	David Neubauer	Eanna Kiely		
IN PROGRESS	1	2	1	0
RESOLVED	2	0	0	0
TO DO	1	4	0	0
DONE	9	2	3	1
PENDING	4	1	0	0
<b>Total Unique Issues:</b>	<b>17</b>	<b>9</b>	<b>4</b>	<b>1</b>

Grouped by: Assignee Showing 5 of 5 statistics.

Expand  
Delete  
Edit  
Refresh

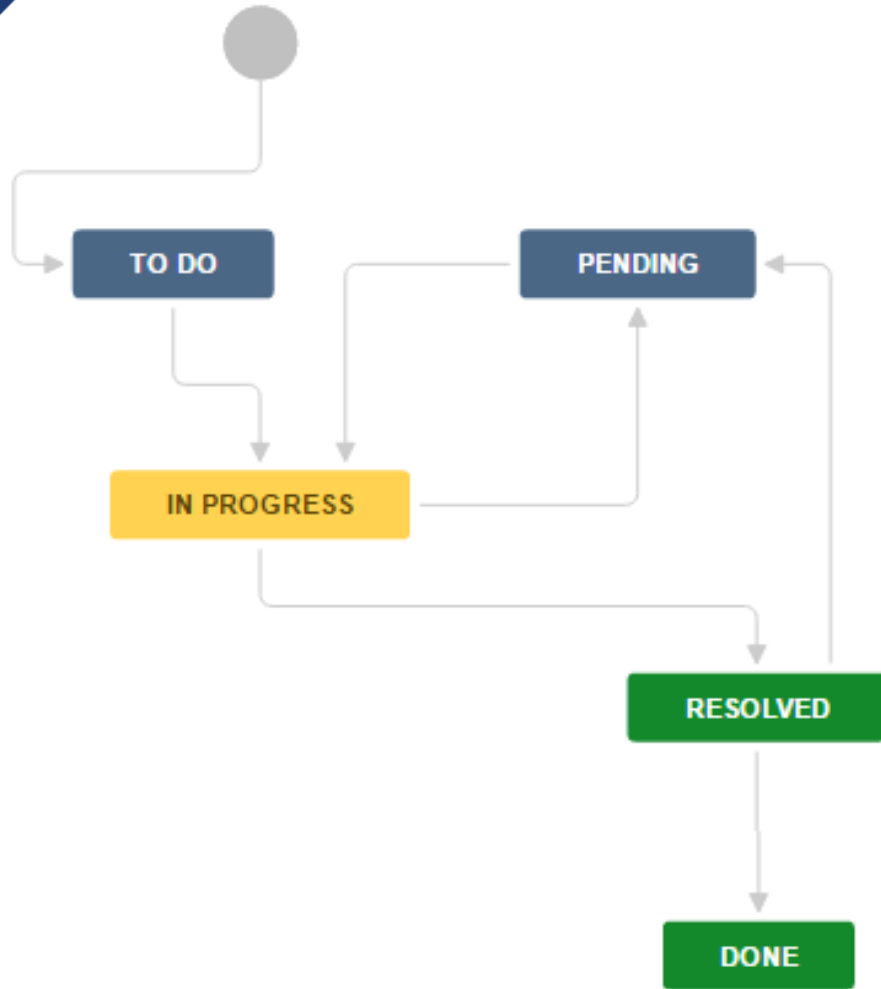
# Create and Share Dashboards

The screenshot shows the JIRA interface. At the top, the navigation bar includes 'Dashboards', 'Projects', 'Issues', and 'Boards'. A dropdown menu for 'Dashboards' is open, listing 'EEK Dashboard', 'System Dashboard', and 'View all dashboards'. The 'View all dashboards' option is highlighted. In the top right corner, there are buttons for 'Create dashboard' and 'Restore defaults'. Below the navigation, the 'Favorite Dashboards' section is visible, containing a table with the following data:

Name	Owner	Shared with
★ EEK Dashboard	Eanna Kiely (eanna.kiely)	• Private dashboard
★ System Dashboard	System	• Shared with everyone

- <https://confluence.atlassian.com/adminjiracloud/using-dashboard-gadgets-776636252.html>
- Includes list of pre-installed gadgets and instructions for creating new dashboards

# CRO Basic Workflow Diagram



- Setting up a JIRA workflow requires organizing the process steps and approvals needed to complete tasks
- Based on the “Software Simplified Workflow Scheme”
- Takes “To Do”, “In Progress” and “Done”
- Adds “Pending” for questions to the sponsor
- Adds “Resolved” for submissions to the sponsors
- If returned from the sponsor it can go to “Pending” again or if it is accepted the tasks is closed.

# CRO Basic Workflow Text

From	Transition	To
<b>TO DO</b>	Work Started No Screen	→ <b>IN PROGRESS</b>
<b>IN PROGRESS</b>	More Info Needed No Screen	→ <b>PENDING</b>
	Resolved Pending Acceptance No Screen	→ <b>RESOLVED</b>
<b>DONE</b>	There are no transitions out of this status	
<b>PENDING</b>	Information Received No Screen	→ <b>IN PROGRESS</b>
<b>RESOLVED</b>	Solution Accepted No Screen	→ <b>DONE</b>
	Not Accepted by Client No Screen	→ <b>PENDING</b>



# JIRA Software

# JIRA Software Backlog

The screenshot shows the JIRA Software Backlog interface. The top navigation bar includes 'JIRA', 'Dashboards', 'Projects', 'Issues', 'Boards', and a 'Create' button. A search bar and user profile are on the right. The left sidebar contains navigation options: 'Backlog' (highlighted with a red box), 'Active sprints', 'Reports', 'Issues', and 'Components'. The main content area is titled 'Backlog' and features a search bar and 'QUICK FILTERS' for 'Non Archived', 'Recently Updated', and 'Only My Issues'. A 'VERSIONS' dropdown menu is open, showing options: 'EPICS', 'All issues', 'Archive' (highlighted with a red box), and 'Issues without epics'. The backlog items are grouped into three sections: 'T CW 16' (3 issues), 'T CW 16' (3 issues), and 'T CW 19' (3 issues). Each item includes a status icon, priority, key, and title. Issue counts are shown in colored circles on the right of each group, with the summary counts (0, 8, 16) for the first group highlighted with a red box.

Section	Key	Title	Count
T CW 16	T-20 CR 1923	TR domain - follow-up for CR 1880	4
	T-25 CR 1929	QS domain - Number connection test	4
	T-21 Ad hoc	PD Rejection and PD Confirmation Concept	20
	T-28 CR 1921	QS - TSQM Ver. 1.4	8
T CW 16	T-27 CR 1937	PR domain - map the Oncology forms from XP to PR	8
	T-24 CR 1930	CE FA domain - Acute Myeloid Leukemia (AML) Classification	8
	T-22 CR 1927	RP domain - Menstrual-Bleeding - Annotation for new CRF	8
T CW 19	T-4 Ad hoc	CRF design	160



# JIRA Software Sprint Board

**T EEK** Board Switch sprint

QUICK FILTERS: [Non Archived](#) [Recently Updated](#) [Only My Issues](#)

To Do	Pending	In Progress	Resolved	Done
<p><b>T-12</b> ↑ CR 1871: QS domain - EHP-30 questionnaire (24)</p>	<p><b>T-30</b> ↑ CR 1994: XF domain - Verbal Learning and memory test (8)</p>	<p><b>T-4</b> ↑ Ad hoc: CRF design (160)</p>	<p><b>T-21</b> ↑ Ad hoc: PD Rejection and PD Confirmation Concept (20)</p>	<p><b>T-7</b> ↑ CR 1538: Critical Digital Ischemia Requiring Hospitalization</p>
<p><b>T-5</b> ↑ Ad hoc: Project (160)</p>	<p><b>T-17</b> ↑ Ad hoc: CDISC: PrCa TAUG ADRESP Spec (16)</p>	<p><b>T-31</b> ↑ CR 2002: XF domain - Taste Strip test (8)</p>	<p><b>T-24</b> ↑ CR 1930: CE FA domain - Acute Myeloid Leukemia (AML) (8)</p>	<p><b>T-15</b> ↑ CR 1873: QS domain - Numerical Rating Scale (16)</p>
<p><b>T-29</b> ↑ Ad hoc: Trial Design (40)</p>	<p><b>T-6</b> ↑ Ad hoc: OAD Codelist Report Review (16)</p>	<p><b>T-19</b> ↑ Ad hoc: Adjudication-Committee (16)</p>		<p><b>T-18</b> ↑ CR 1903: DM domain - new field for Was subject enrolled in (4)</p>
<p><b>T-32</b> ↑ CR 1961: XF domain - Questionnaire for taste disturbances (8)</p>	<p><b>T-9</b> ↑ Ad hoc: Trial Design</p>	<p><b>T-2</b> ↑ CR 1846: QS domain - new questionnaire on Fatigue Scale from (16)</p>		<p><b>Archive</b></p>
	<p><b>T-20</b> ↑ CR 1923: TR domain - follow-up for CR 1880 (4)</p>	<p><b>T-8</b> ↑ Ad hoc: Review OAD assumptions (40)</p>		<p><b>T-26</b> ↑ CR 1907: AE domain - Relationship to Conc Sys AC Ther (4)</p>
				<p><b>T-14</b> ↑ CR 1880: TR domain - label for Size of T1 measurement on CRFs (4)</p>
				<p><b>T-16</b> ↑ CR 1884: XB domain - Results Mutational (16)</p>

# JIRA Software Sprint Board – Quick Filters

T EEK

All sprints [Switch sprint](#) ▾

QUICK FILTERS: **Non Archived** Recently Updated Only My Issues

Board ▾

To Do	Pending	In Progress	Resolved	Done
<p>T-12 ↑ CR 1871: QS domain - EHP-30 questionnaire 24</p>	<p>T-30 ↑ CR 1994: XF domain - Verbal Learning and memory test 8</p>	<p>T-4 ↑ Ad hoc: CRF design 160</p>	<p>T-21 ↑ Ad hoc: PD Rejection and PD Confirmation Concept 20</p>	<p>T-7 ↑ CR 1538: Critical Digital Ischemia Requiring Hospitalization</p>
<p>T-5 ↑ Ad hoc: Project 160</p>	<p>T-17 ↑ Ad hoc: CDISC: PrCa TAUG ADRESP Spec 16</p>	<p>T-31 ↑ CR 2002: XF domain - Taste Strip test 8</p>	<p>T-24 ↑ CR 1930: CE FA domain - Acute Myeloid Leukemia (AML) 8</p>	<p>T-15 ↑ CR 1873: QS domain - Numerical Rating Scale 16</p>
<p>T-29 ↑ Ad hoc: Design 40</p>	<p>T-6 ↑ Ad hoc: OAD Codelist Report Review 16</p>	<p>T-19 ↑ Ad hoc: Adjudication-Committee 16</p>		<p>T-26 ↑ CR 1907: AE domain - Relationship to Conc Sys AC Ther 4</p>
<p>T-32 ↑ CR 1961: XF domain - Questionnaire for taste disturbances 8</p>	<p>T-9 ↑ Ad hoc: Design Trial</p>	<p>T-2 ↑ CR 1846: QS domain - new questionnaire on Fatigue Scale from 16</p>		<p>T-14 ↑ CR 1880: TR domain - label for Size of T1 measurement on CRFs 4</p>
	<p>T-20 ↑ CR 1923: TR domain - follow-up for CR 1880 4</p>	<p>T-8 ↑ Ad hoc: Review OAD assumptions 40</p>		<p>T-16 ↑ CR 1884: XB domain - Results Mutational 16</p>
				<p>T-3 ↑ CR 1853: QS domain - assessment of ovarian activity 4</p>

# Create Quick Filters

Configure TEEK [← Back to board](#)

CONFIGURATION

- General
- Columns
- Swimlanes
- Quick Filters**
- Card colors
- Card layout
- Estimation
- Working days
- Issue Detail View

### Quick Filters

Quick Filters can be used to further filter the issues in the board based on the additional JQL query.

Name	JQL	Description	
<input type="text"/>	<input checked="" type="checkbox"/>	<input type="text"/>	<input type="button" value="Add"/>
☰ Non Archived	("Epic Link" is null)	Display active issues that have not been added to the Archive Epic	<input type="button" value="Delete"/>
☰ Recently Updated	updatedAt >= -1d	Displays issues which have been updated in the last day	<input type="button" value="Delete"/>
☰ Only My Issues	assignee = currentUser()	Displays issues which are currently assigned to the current user	<input type="button" value="Delete"/>

- The active tasks are not kept in an Epic
- ("Epic Link" is null)

# View Issue Comments



CDASH / CDASH-207

## CDASHIG Section 4.3.3 Data Standards expert reviewer

Comment

Agile Board

More ▾

### Description

Companies are increasingly adding a data standards expert review to all CRFs. This can be on a study level or standard CRF review level. This ensure that the CRF conforms to CDASH (or company collection standard) and is SDTM compliant. Additionally they review the controlled terminology to ensure it is consistent and unambiguous.

Should we add:

1)  
Data Standards expert should review the CRF to ensure that the data collected is in line with company standards, SDTM and controlled terminology.

or

2)  
Data Standards expert should review the CRF to ensure that the data collected is in line with company standards, all required, expected and permissible (when applicable) SDTM variables are accounted for and controlled terminology is used and unambiguous.

If this is to be added will it be 1 or 2? Or should this be separated into a separate Best Practice Recommendation?

### Activity

All **Comments** History Activity



✓ Kim Truett added a comment - 11/Feb/16 1:51 PM

for general discussion - but what reviewer is talking about here is 'big company practices' - to have someone whose job is to review all CRFs before usage would be restricted to larger companies, and therefore, seems only partially applicable.

✓ Eanna Kiely added a comment - 11/Feb/16 2:04 PM

In larger companies these reviewer roles are usually split between different people, department or even can be outsourced. However they do not have to be. The CRF designer or programmer could be the Data Standards expert and usually are. The CRF designer may be trained in CDASH while the programmer could be the SDTM expert.

The purpose of mentioning the Data Standards expert specifically is that each CRFs should be reviewed to ensure compliance with CDASH/SDTM before the data is collected. This practice is becoming more common but it is still not in all companies. When this is not done there can be numerous issues.

# Agile Reports – Cumulative Flow Diagram

T board

Board ▾

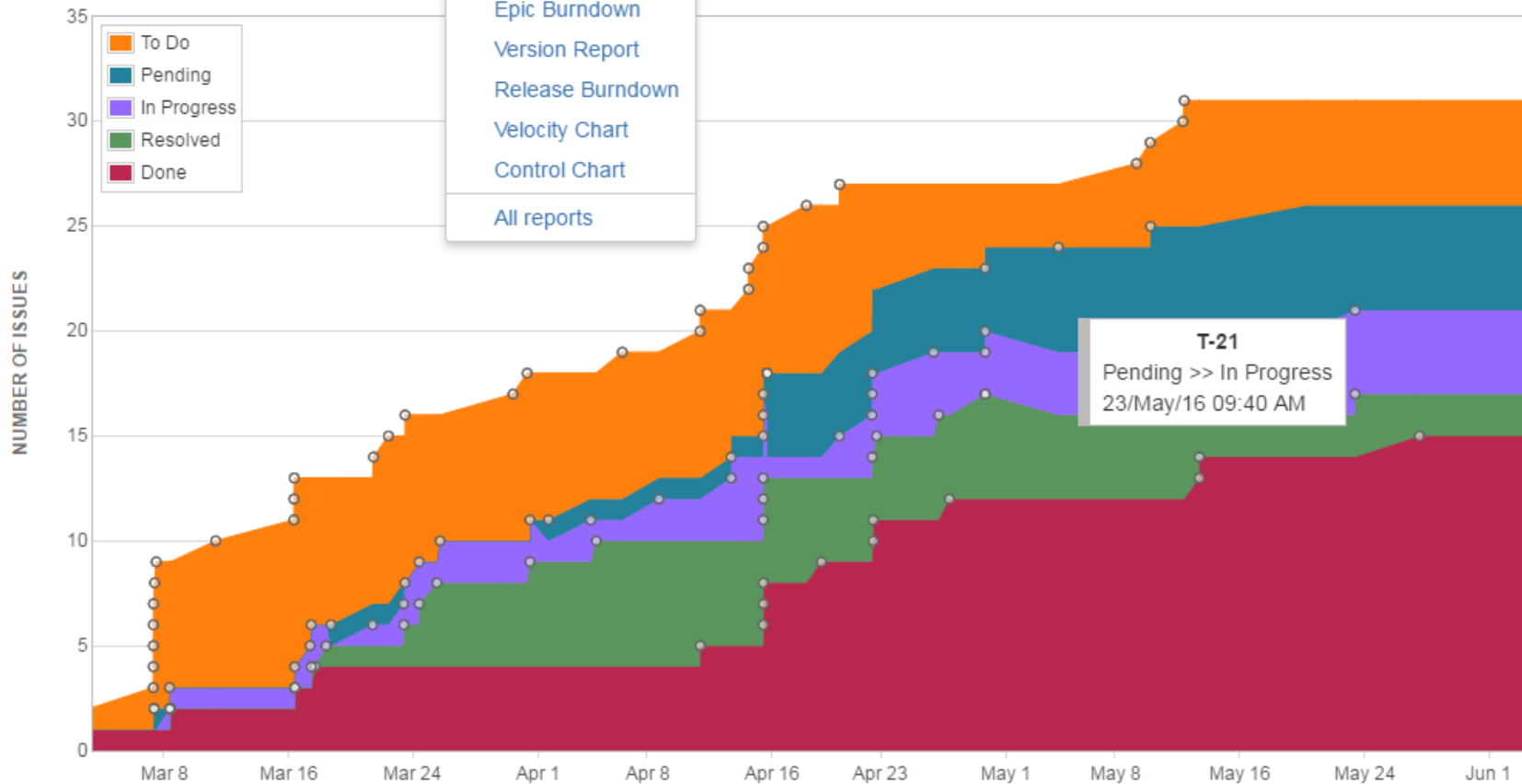
## Cumulative Flow Diagram

Switch report ▾

3/Mar/16 to 4/Jun/16 (All Time) ▾

Refine

Read this chart



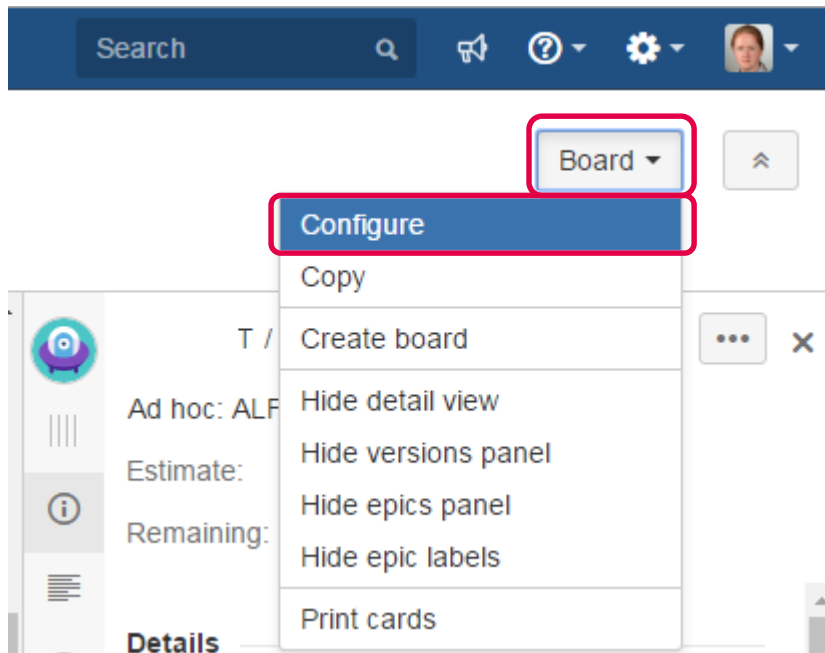


# Permissions and Time Tracking

- Edit issues is disabled in CDISC JIRA
- Delete issues should be only be assigned to the Admins
- **Comments permissions**
  - Add comments
  - Edit own comments
- **Attachments permissions**
  - Create attachments
  - Delete own attachments
- **Time-tracking Permissions**
  - Work on issues
  - Delete own worklogs
  - Edit own worklogs
- If time is not logged most of the sprint reports do not work effectively.

# Time Tracking in Original Time Estimates

- “Story Points” vs “Original Time Estimates”
  - Original Time Estimates can be tracked by logging work
- Configure your Scrum board to take estimates in Original Time Estimates (JIRA Admin and Board Admin)



# Time Tracking in Original Time Estimates

- Change Estimation Statistic from “Story Points” to “Original Time Estimates”
- Time Tracking is set to “None”
- If “Remaining Estimate and Time Spent” is selected values do not burn down when an issue is completed only when the time is entered.

## CONFIGURATION

- General
- Columns
- Swimlanes
- Quick Filters
- Card colors
- Card layout
- Estimation** 1
- Working days
- Issue Detail View

## Estimation

Issues can be estimated when in the Backlog to get an idea of how much work is being committed to in a sprint. [Read](#)

2

Estimation Statistic

Estimate issues in the Backlog using durations (e.g. hours, ideal days). Your velocity from sprint to sprint will be measured against these estimates. This estimate will be stored against JIRA's **Original Estimate** field on the issue.

3

Time Tracking  None  
Issues will burn down their **Original Time Estimate** value upon completion.

Remaining Estimate and Time Spent  
Track time against issues using JIRA's **Remaining Estimate** and **Time Spent** fields.



# Time Tracking

T EEK Board

## Backlog

QUICK FILTERS: Non Archived Recently Updated Only My Issues

VERSIONS

- EPICS
- All issues
- Archive
- Issues without epics

T CW 15 4 issues 0 0 1d

11/Apr/16 9:48 AM • 18/Apr/16 9:48 AM

- T-20 CR 1923: TR domair
- T-25 CR 1929: QS domair
- T-21 Ad hoc: PD Rejection
- T-28 CR 1921: QS - TSQM** 1d

T CW 16 3 issues

18/Apr/16 9:44 AM • 25/Apr/16 9:44 AM

T / T-28

CR 1921: QS - TSQM Ver.1.4

Estimate: 1d

**Details**

Status: **DONE**

Component/s: None

Labels: None

Affects Version/s: None

Fix Version/s: None

Epic: None

**People**

Reporter: Stefan Bordasch

Assignee: Eanna Kiely

**Dates**

Resolved: None

Due Date: 19/Apr



# Questions



**Thanks you!**

**Éanna Kiely**  
**CDISC Engineer**