



Innovation
Never
Sleeps

M&I
(Methodology & Innovation)

ADaM Planning Tool (APT): A web-based application to collect, create and maintain ADaM Metadata in Clinical Trials

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Outline

- Background
- Quick Look
- Key Features
- Technical Stack and Challenges
- Demo
- Q&A

What is the ADaM Planning Tool (APT)?

APT is a component of the Janssen AUTOCODE project. APT is a web-based application, designed to create and maintain study level ADaM metadata from global standard metadata libraries, therapeutic area (TA) level metadata libraries and reference studies.

Background

- In Janssen, Statistical requirements and metadata is stored in DOCX and XLSX formats called DPS and planning sheets:
- DPS has two components, DPS part 1 and DPS part 2
- Current spreadsheet Metadata (planning sheets) has separate tabs for:
 - Dataset – ADM dataset
 - Variable - Specific domain name e.g. ADAE
 - Codelist – ADM codelist

Background

- Creating metadata without APT:
 - Time-consuming manual creation, updating, and reviewing of spreadsheets
 - Locking issues when collaborating on spreadsheets
 - Difficulty maintaining consistency across multiple spreadsheets manually
 - Manual efforts required to ensure spreadsheets align with standard metadata
- Results with:
 - Numerous discrepancies and flaws arise in spreadsheets
 - Extensive back-and-forth communications required for updates, reviews, and general maintenance

Background

- To help with the challenges, the Janssen AUTOCODE project began and APT was developed.

Without APT	With APT
Manual xlsx management	Interactive tool
Metadata in several files	All in one place
No Status tracking	Status tracking ability (review/validated)
3 different version (dev, review and final)	Only one copy in the tool with status
Manually copy standards	In-built standards can be used
Manual email notifications for tracking	Automatic notifications for tracking

Quick Look

Application Layout

[illegible]

Breadcrumb



 Compound

 Dashboard

Compound

Search

Compound > Standards > Suite 2 NSC

Suite 2 NSC 

Tree hierarchy

janssen

AUTOCODE

Dashboard

Compound

Compound

Compound

>

Sample_test_30

REPORTING EFFORT

All

Draft

Review

Validated

	NAME	STATUS	DESCRIPTION	PRO
☐	General__1		Global Standards General	Global Stand
☐	General		Global Standards General	Global Stand

Parent (compound)

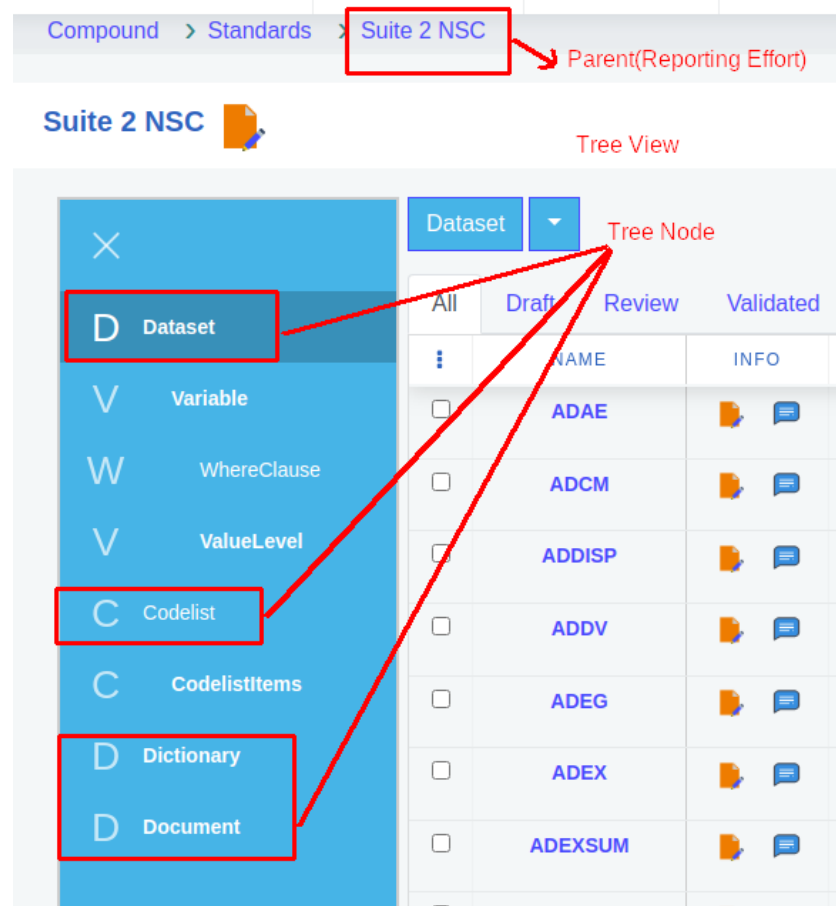
Tree Node (RF)

janssen

PHARMACEUTICAL COMPANIES OF

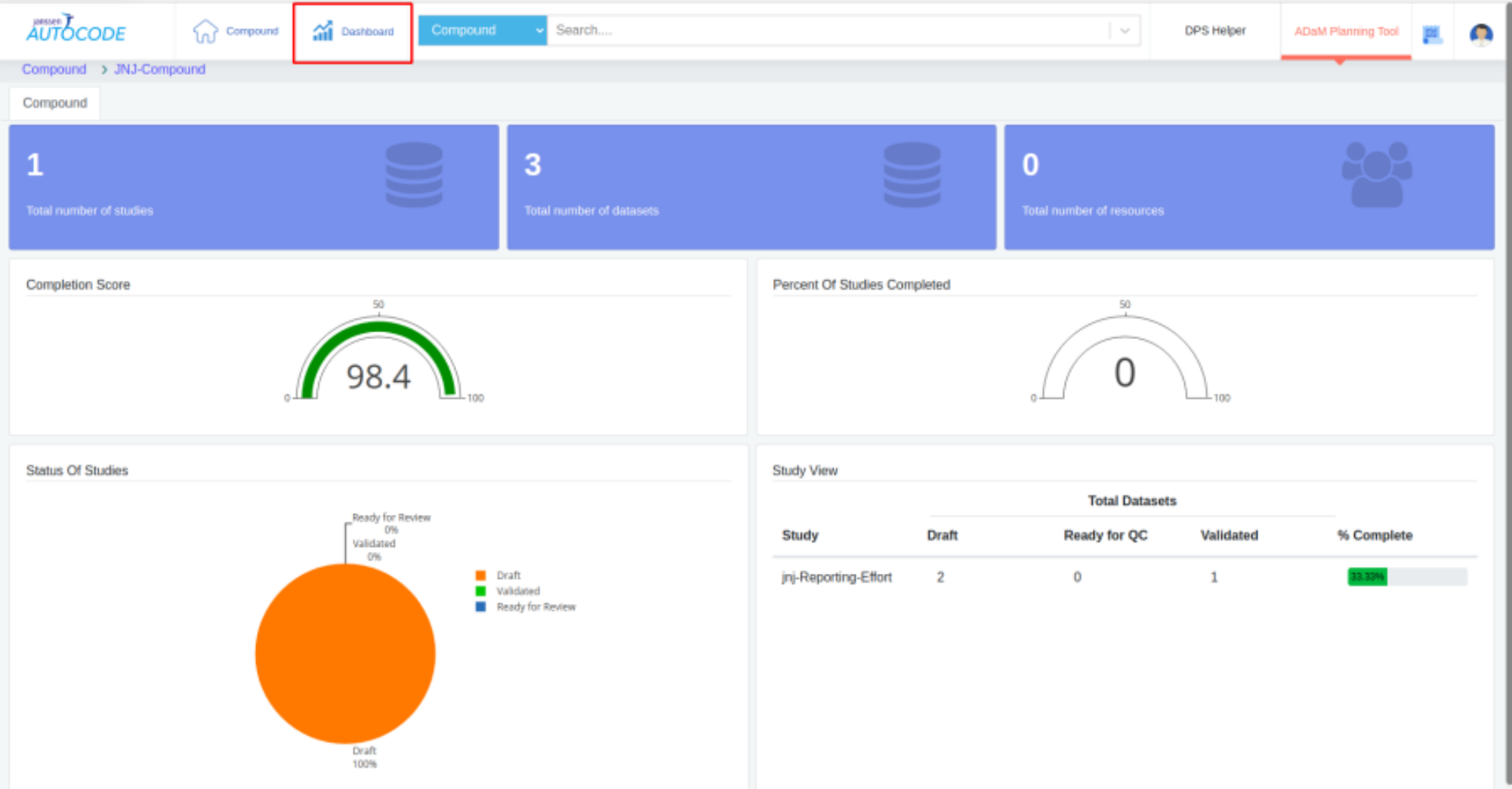
Johnson & Johnson

Tree hierarchy



- TreeView for Study, Dataset, Codelist, Dictionary and Document

Dashboard



Dependency Graph

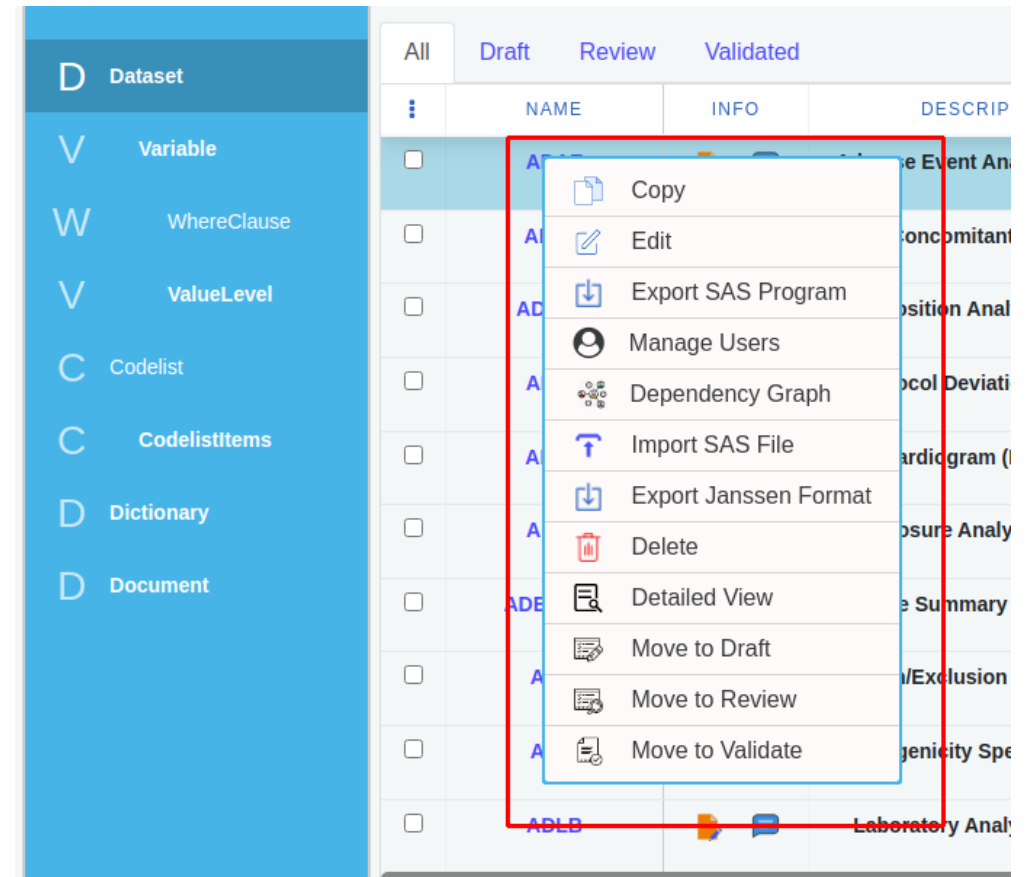
All	Draft	Review	Validated
	NAME	INFO	
☐	ADAE		Adve
☐			&
☐			s
☐			ro
☐			c
☐			Ex
☐			st
☐			si
☐			n
☐			al

- Copy
- Edit
- Export SAS Program
- Manage Users
- Dependency Graph
- Import SAS File
- Export Janssen Format
- Delete
- Detailed View
- Move to Draft
- Move to Review
- Move to Validate



Key UI component and operation

- Right click on a tree node, and a menu opens, with several actions such as copy, paste, delete and edit



Key Features

Key Features

- Central repository
 - Global and TA standards
 - All the clinical trial studies
- Inbuilt standardization
- Aligned with a 'Copy and Paste' design approach to efficiently reuse similar items at various levels such as:
 - Reporting effort
 - Dataset, variable, codelist
- Export DPS part 2 to .docx and metadata to submission ready .xlsx
- Import

Key Features

- Multiple ways to create metadata
 - Copy from standards
 - Copy from another study
 - Create from scratch
 - By importing
- Global search at many level such as, specific datasets, variables, and compounds
- Dashboard to track progress during metadata development
- Integration with SCE system allows users to read and write metadata directly from programming tools such as SAS/R

Technical Stack and Challenges

Technical Stack and Challenges

Frontend

- HTML + CSS
- JavaScript
 - React UI library

Backend

- Python
 - Django web framework
- PostgreSQL

Technical Stack and Challenges

- Challenges
 - Bulk changes in APT
 - System/structure changes vs. spreadsheet changes

Demo

Demo

Creating an RE, Dataset and Variable

Outline

- Create a new Reporting Effort
 - From scratch
 - From a previously created RE
 - Using import (P21 format)
- Create a new Dataset
 - From scratch
 - From a previously created dataset
- Modify a dataset
- Create a new Variable
 - From scratch
 - From a previously created dataset

From scratch

Compound

CREATE COMPOUND

Select Columns

All

Draft

Review

Validated

	NAME	STATUS	DESCRIPTION	NO OF STUDIES	LAST ACTION BY	LAST ACTION DATE	CREATED DATE
☐	Standards		Standards	49	ktarap	2020-11-11 16:56:15 UTC	2020-11-09 15:58:13 UTC
☐	TuesDayCompound		TuesDayCompound	7	RDenduk1	2020-11-10 07:05:55 UTC	2020-11-10 07:05:55 UTC
☐	Training Test		Test Compound for instructional videos	0	ktarap	2020-11-29 15:31:56 UTC	2020-11-16 13:31:01 UTC
☐	TestRavi		TestRaviTestRavi	25	RDenduk1	2020-11-07 16:14:02 UTC	2020-11-07 16:14:02 UTC
☐	Test P		Description	0		2020-10-20 13:38:18 UTC	2020-10-20 13:38:18 UTC
☐	TEstingRavi		TEstingRavi	6	admin	2020-10-01 04:52:29 UTC	2020-10-01 04:52:29 UTC
☐	Test_Compound			5	KMedikon	2020-10-16 11:40:26 UTC	2020-10-16 11:40:26 UTC
☐	Test com		t coom	0	PPrakas7	2020-11-08 11:56:41 UTC	2020-11-08 11:56:41 UTC
☐	Test 2		desc	21	admin	2020-09-28 11:52:43 UTC	2020-09-28 11:52:43 UTC
☐	Test1103		sample	2	SBegari	2020-11-03 13:52:23 UTC	2020-11-03 13:52:23 UTC

Previous

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10 Compound

Next

Create a new Reporting Effort

The screenshot displays the Janssen AUTOCODE web application interface. At the top, there is a navigation bar with the Janssen AUTOCODE logo, a home icon, and tabs for 'Compound' and 'Dashboard'. A search bar is present with the text 'Search by name'. Below the navigation bar, the breadcrumb 'Compound > TrainingTest' is visible. The main content area is titled 'REPORTING EFFORT' and includes a filter icon, a search input, and a 'Select Columns' dropdown. Below this, there are tabs for 'All', 'Draft', 'Review', and 'Validated'. The 'All' tab is selected, showing a table with the following columns: NAME, STATUS, DESCRIPTION, PROTOCOL, STANDARD, STANDARD VERSI..., LANGUAGE, LAST ACTION BY, and LAST ACTI. The table contains one row with the following data: NAME: BlankRE, STATUS: (document icon), DESCRIPTION: Blank Reporting Effort, PROTOCOL: Test, STANDARD: ADaM-IG, STANDARD VERSI...: 1.1, LANGUAGE: en, LAST ACTION BY: ktarap, and LAST ACTI: 2020-12-03 1. Below the table, there is a pagination bar with 'Previous', 'Page 1 of 1', '10 Reporting Efforts', and 'Next'.

	NAME	STATUS	DESCRIPTION	PROTOCOL	STANDARD	STANDARD VERSI...	LANGUAGE	LAST ACTION BY	LAST ACTI
☐	BlankRE		Blank Reporting Effort	Test	ADaM-IG	1.1	en	ktarap	2020-12-03 1

From a previously created RE using a lookup technique

Create a new Reporting Effort

Compound > TrainingTest

REPORTING EFFORT

All Draft Review Validated

	NAME	STATUS	DESCRIPTION	PROTOCOL	STANDARD	STANDARD VERSION	LANGUAGE	LAST ACTION BY	LAST ACTION
☐	BlankRE		Blank Reporting Effort	Test	ADaM-IG	1.1	en	ktarap	2020-12-03 1
☐	Global ADaM Standards		Global ADaM Metadata Standards (Suite 2)	Global ADaM Metadata St...	ADaM-IG	1.1	en	ktarap	2020-12-03 1

Previous Page 1 of 1 10 Reporting Efforts Next

Using
import

From scratch

Create a new Dataset

The screenshot displays the Janssen AUTOCODE web application interface. At the top, there is a navigation bar with the Janssen AUTOCODE logo, a 'Compound' dropdown menu, a search bar, and links to 'DPS Helper' and 'ADaM Planning Tool'. Below the navigation bar, the breadcrumb trail shows 'Compound > TrainingTest > BlankRE'. The main content area is titled 'BlankRE' and features a 'Dataset' dropdown menu. A table lists existing datasets with columns for NAME, INFO, DESCRIPTION, DATASET CLASS, KEY VARS, STRUCTURE, COMMENT, LAST ACTION BY, LAST ACTION DATE, and CREATED. Two datasets are listed: ADSL (Subject Level Analysis Dataset) and ADAE (Adverse Event Analysis Dataset). The table is followed by a pagination bar showing 'Page 1 of 1' and '10 datasets'.

	NAME	INFO	DESCRIPTION	DATASET CLASS	KEY VARS	STRUCTURE	COMMENT	LAST ACTION BY	LAST ACTION DATE	CREATED
☐	ADSL		Subject Level Analysis Dataset	SUBJECT LEVEL ...		One record per su...		ktarap	2020-12-03 13:15:47 UTC	2020-12-03
☐	ADAE		Adverse Event Analysis Dataset	OCCURRENCE DA...	STUDYID, USUBJI...	One record per su...	Based on data fro...	ktarap	2020-12-03 13:17:37 UTC	2020-12-03

From a
previously
created
dataset

From scratch

BlankRE

CREATE VARIABLE

ADSL - (0)

All Draft Review Validated Invalid

DATASET ▲	VARIABLE	INFO	ORDER ▲	DATA TYPE	LENGTH	DATETIME	ORIGIN	CODE LIST	ORIGCOM	METHOD TYPE	HISTORY	DOCUMENT
No variables found												

Create a new Variable

The screenshot shows the Janssen AUTOCODE interface. At the top, there's a navigation bar with 'Compound', 'Dashboard', and a search bar. Below this, the breadcrumb trail shows 'Compound > TrainingTest > BlankRE'. The main header area includes 'BlankRE' and some utility icons. The central part of the screen is titled 'CREATE VARIABLE' and features a dropdown menu currently set to 'ADSL - (1)'. Below this, there are tabs for 'All', 'Draft', 'Review', 'Validated', and 'Invalid'. A table lists the variables for the selected dataset. The table has columns: DATASET, VARIABLE, INFO, ORDER, DATA TYPE, LENGTH, DATETIME, ORIGIN, CODE LIST, ORIGCOM, METHOD TYPE, HISTORY, and DOCUMENT. The first row shows 'ADSL' as the dataset, 'USUBJID' as the variable, an icon in the INFO column, '2' in the ORDER column, 'text' as the data type, and 'Copied from Source' as the origin. The bottom of the screen shows a pagination bar with 'Previous', 'Page 1 of 1', '20 variables', and 'Next'.

DATASET	VARIABLE	INFO	ORDER	DATA TYPE	LENGTH	DATETIME	ORIGIN	CODE LIST	ORIGCOM	METHOD TYPE	HISTORY	DOCUMENT
ADSL	USUBJID		2	text			Copied from Source		DM.USUBJID	Computation		

From a
previously
created
dataset

Q&A

Thank You