

Agile Way of Working With Azure DevOps In Clinical Trials

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ABSTRACT

In an era marked by dynamic transformation, industries are transitioning away from conventional static libraries and driving towards cloud-based environments.

The time has changed, and so have we. We at Novo Nordisk, have recognized the need for evolution and modernized our ways of working by harnessing the potential of cloud computing through Azure DevOps (ADO). With the implementation of ADO, internal collaboration and structured discussions have improved. The new agile methodologies and technologies offered through ADO, have facilitated a comprehensive overview of the project's progress along with version controlling. Furthermore, ADO empowers us to address various project issues through dedicated issue logs and share knowledge efficiently via wikis, Kanban Boards, Pictorial presentations, documentation, and much more. This strategic shift underscores our commitment to staying at the forefront of clinical project management. In this presentation I will walk through some of the wins we have achieved by embracing the new technologies and methodologies.

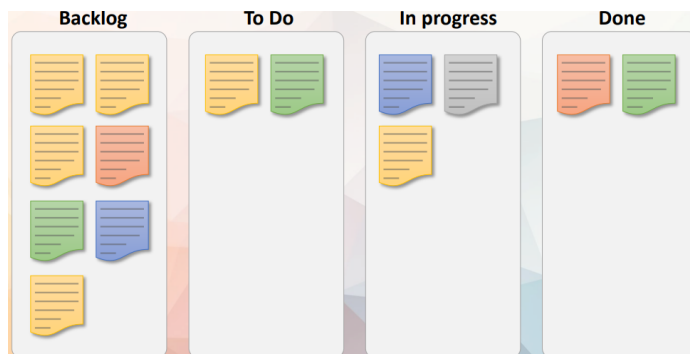
INTRODUCTION

Azure DevOps supports a collaborative culture and set of processes that bring together the programming team, project managers, and contributors to the project. It allows organizations to create and improve products at a faster pace than they can in the traditional way. Novo Nordisk built a delivery platform to deploy its research collaboration platform in a multi-cloud setup which has Kanban Boards, Git (version control), Issue logs, and Wiki pages with integration from Azure DevOps.

In Novo Nordisk, Azure DevOps is used widely in day-to-day work. The following are the list of various Azure tools that helps us in the clinical trial process conduct.

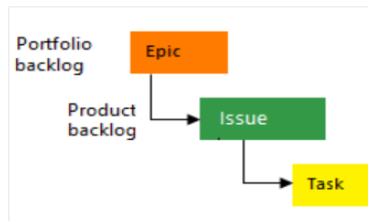
KANBAN BOARDS

A Kanban board is a tool commonly used in Agile methodologies. "Kanban" is Japanese for "visual signal", and the goal of the board is to visually represent the work-life cycle of a task through each step of the completion process. Each programming task is independently represented in a card, which contains all the necessary information to complete the request. The cards are used to track the work in progress, including who is assigned to the task, the due date, and any other relevant information needed to complete the request. The columns provide a visual representation of the current state of each request as it progresses through the different stages of the workflow. These columns are highly customizable and can be adapted by the scrum master as per the needs of the job and simply consist of columns such as "Backlog", "To-Do", "In Progress", and "Done". The cards normally flow from left to right, but if issues arise then cards may move backward to an earlier stage, before resuming their normal progression. The Kanban board is an ongoing process, in our approach we use it cyclically, though typically tasks only make their way across the board once. Below is an example of a simple Kanban board.

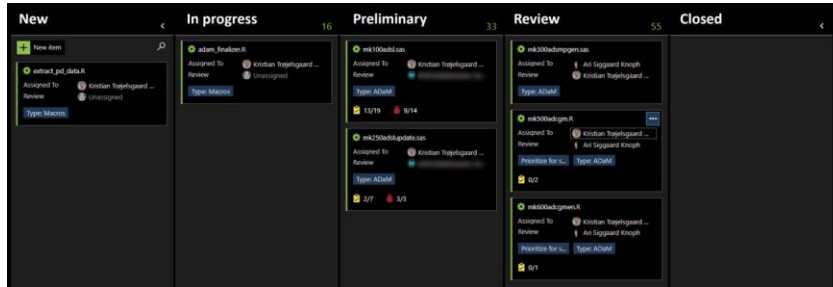


IMPLEMENT AGILE, SCRUM AND KANBAN

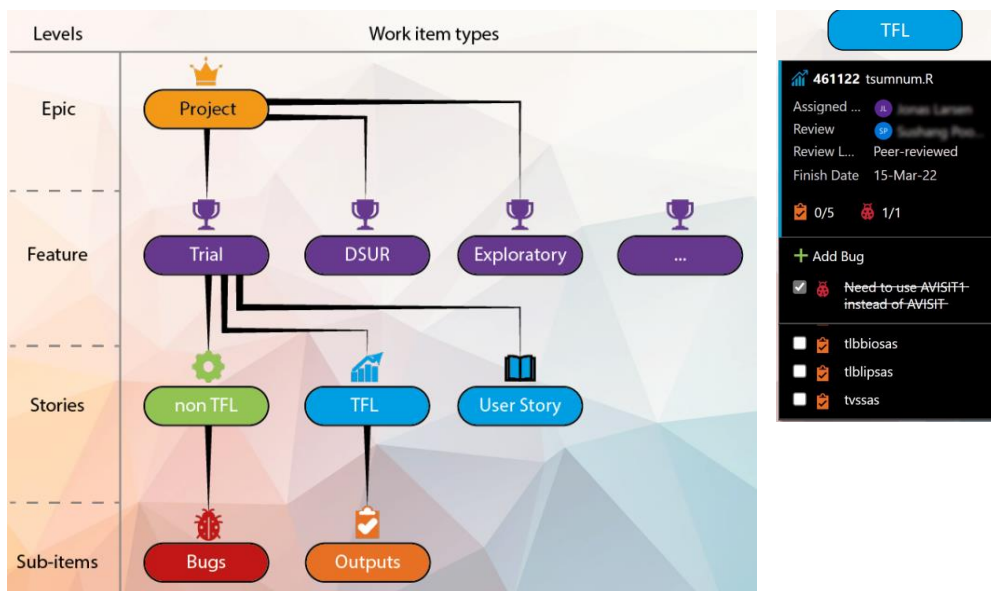
Basic provides the simplest model that tracks work through Issues, Tasks, and Epics.



Example of a Kanban Board

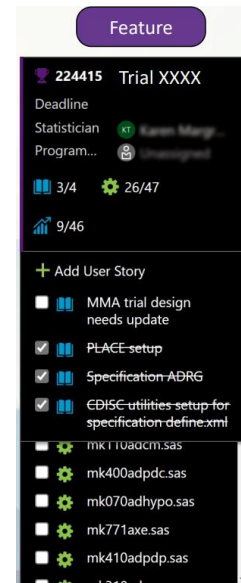
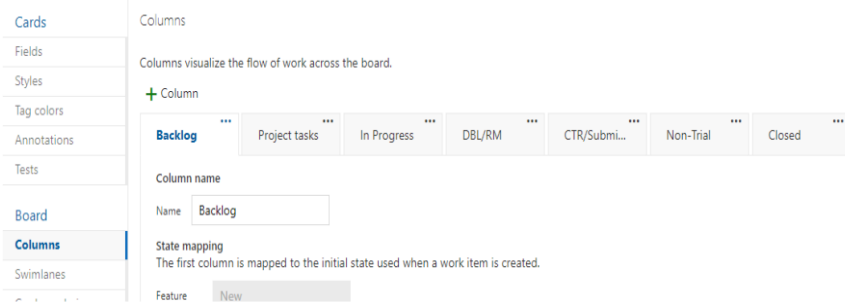


In Kanban boards, we can view the items by Epic/Feature/Story level as mentioned above figure.



The Epic is generally known as a Project overview, and the Feature level is described as the Trial/Study level and All tasks (stories) we know of that are coming up, e.g. TFL and non-TFL for all studies.

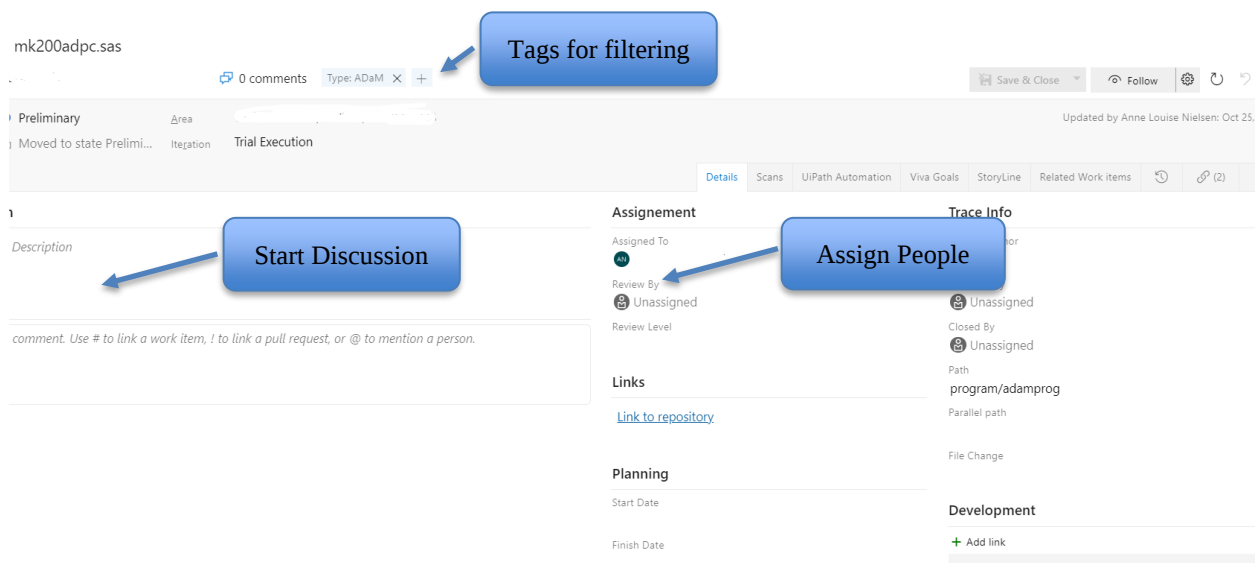
FEATURE LEVEL



TAGS AND COLORS

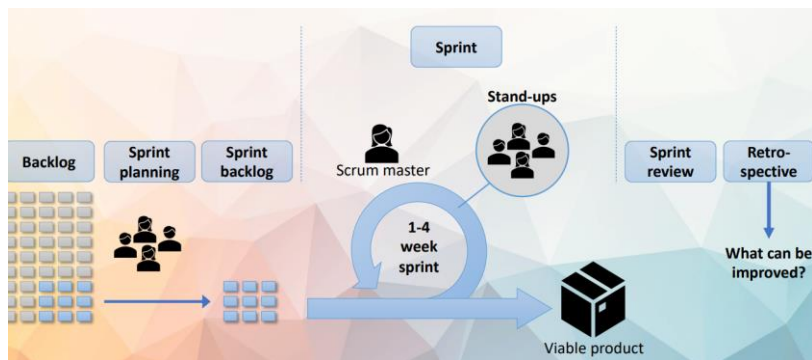
When using the boards in this way to multiple projects it can be nice to have the option to filter based on a tag. We can always filter by area paths, but sometimes it can be an advantage to have multiple projects together under one tag e.g., early-phase projects. So what we have decided to do is to tag all studies by their study name and early phase projects will moreover have the tag 'Early XXXXX'

You set the colors of the card in Settings -> Cards -> Styles. If you want the tag itself colored, go to Settings -> Cards -> Tag Colors. Use different colors for the different projects (use same color for Early XXXXX projects) to create a better overview on the board.



SCRUM

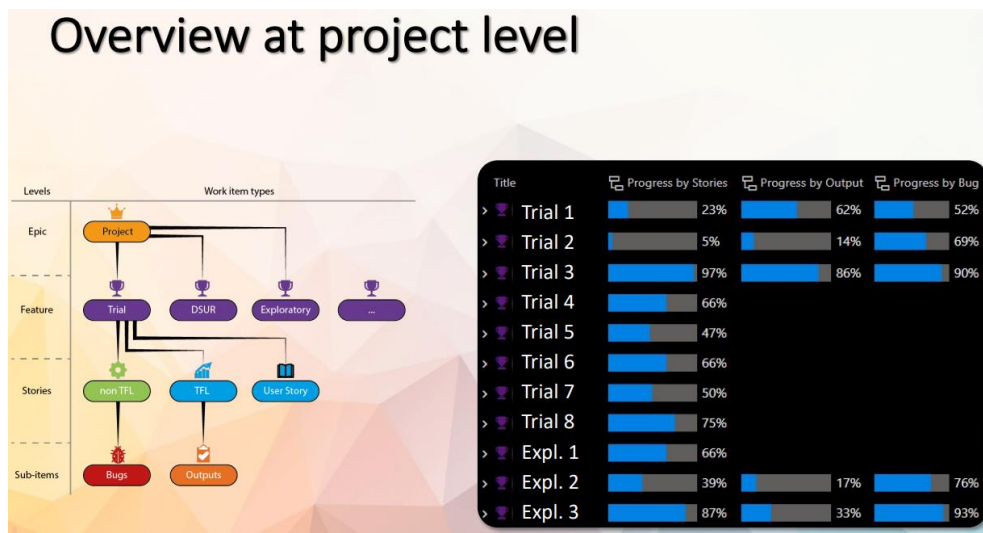
Scrum is an iterative and incremental project management approach that emphasizes flexibility, transparency, collaboration, and continuous improvement. This approach helps reduce time and energy by enabling teams to constantly inspect, align, and adapt their work. By leveraging the Scrum framework, teams can break their work into short cycles, so that they have an opportunity to course correct before reaching their end goal.



PICTORIAL STATUS OF THE BOARDS

Azure DevOps provides status graphs that can be used to visualize the progress and status of a project.

By using status graphs in Azure DevOps, teams can have a better understanding of the project's progress and take corrective actions more efficiently.





ADVANTAGES OF KANBAN BOARDS:

The Kanban boards are used as a project management tool which gives an overview of studies under a particular project as well as to allocate tasks to the resources according to the priority.

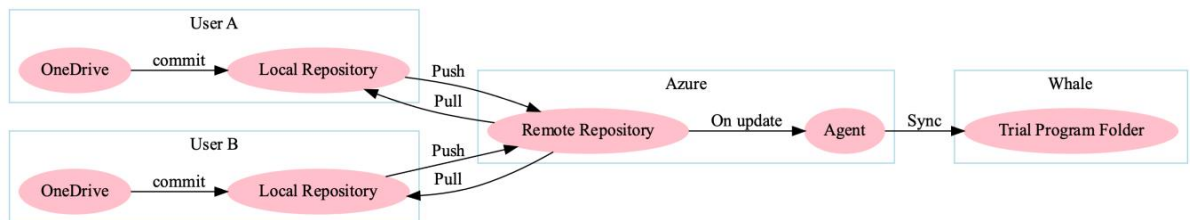
WHAT IS VERSION CONTROL AND GIT?

Git is a distributed version-control system for tracking changes in source code during software development. It is designed for coordinating work among programmers, but it can be used to track changes in any set of files. Its goals include speed, data integrity, and support for distributed, non-linear workflows.

HOW DOES IT WORK?

Git works by setting up what is called a repository within a folder where you want version control on your files. Essentially the repository is a database that keeps track of the differences between versions of your files. Since Git keeps a log of all the changes you have made, it can roll these changes back and forth, and provide you with the content of your files in a specific version. While it has no real impact on how you interact with the system, this means that Git always considers the changes to the repository, rather than what the current content is.

In addition, Git allows users to share their changes and work together. This is typically done through a central hub, referred to as a remote repository. Here is a simple sketch of the infrastructure related to sharing code between the users.



The typical operations you will perform using Git are

1. pull
2. add
3. commit
4. push

With the Git version control, we can track the history of changes who, when, and what was updated with the SAS codes within the respective repository as below.

CHANGE HISTORY

main / adamprog / mk200adlb.sas				
mk200adlb.sas				
Contents	History	Compare	Blame	
Graph	Commit	Change	Pull Request	Status
	removing excess comments fdc2607b (LIVKO (LIVKO Sergey (s.vargard))) Jun 23, 2023 at 2:22 AM	edit		✓ succeeded
	updating adlb 7aae24cf (LIVKO (LIVKO Sergey (s.vargard))) Jun 15, 2023 at 6:56 AM	edit		✓ succeeded
	should run now 90e34502 (LIVKO (LIVKO Sergey (s.vargard))) Jun 9, 2023 at 3:31 AM	edit		✓ succeeded
	updating for caion 1309a3f4 (LIVKO (LIVKO Sergey (s.vargard))) Jun 9, 2023 at 3:24 AM	edit		✓ succeeded
	updating normal, abnormal etc 6ced3de2 (LIVKO (LIVKO Sergey (s.vargard))) Jun 7, 2023 at 9:34 AM	edit		✓ succeeded
	updating decimals on aval to allow for corre... 63698ad5 (LIVKO (LIVKO Sergey (s.vargard))) Jun 7, 2023 at 2:26 AM	edit		✓ succeeded
	updating avisit2n 1511c7da (LIVKO (LIVKO Sergey (s.vargard))) May 26, 2023 at 5:09 AM	edit		✓ succeeded
	testing git and updating comment e034afb4 (LIVKO (LIVKO Sergey (s.vargard))) May 26, 2023 at 1:22 AM	edit		✓ succeeded

CHANGES IN THE CODE

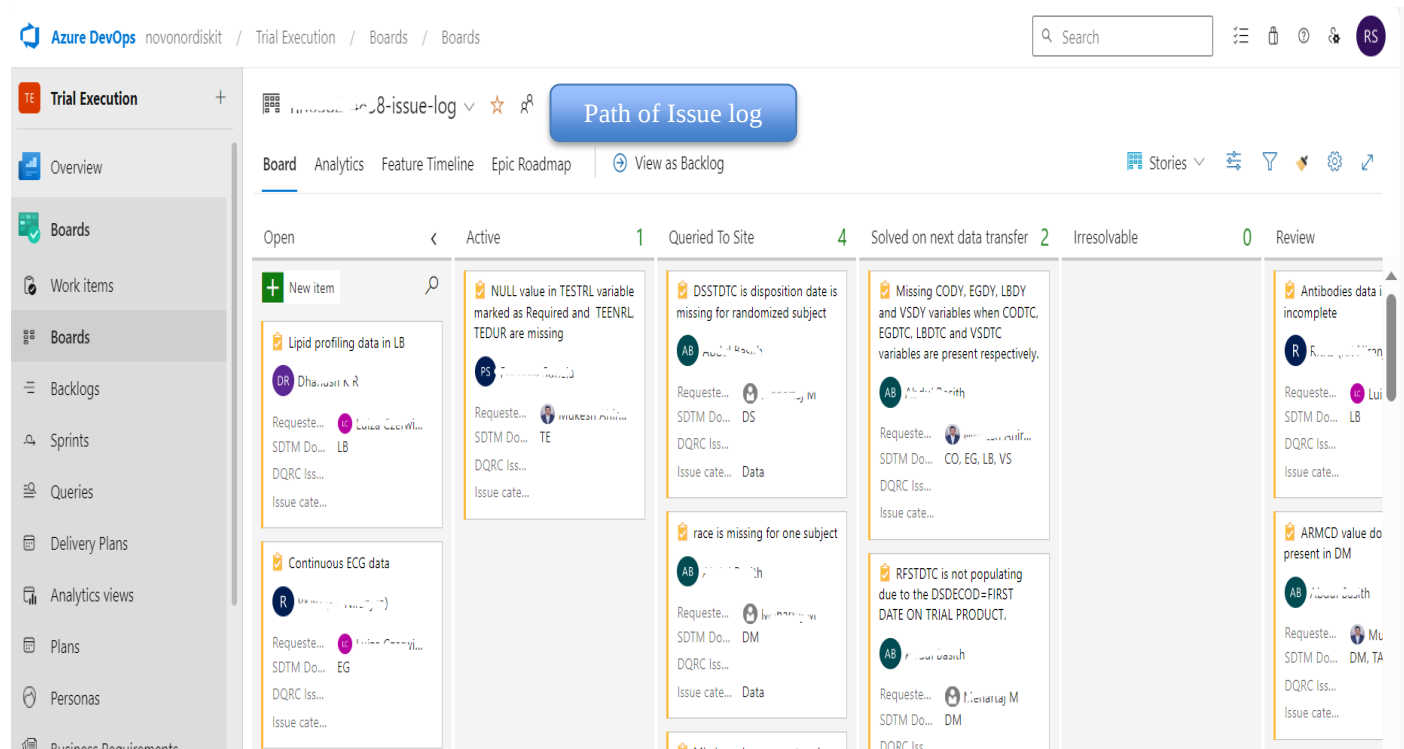
ContentsHistoryCompareBlame		↗	
1309a3f4 a1ed5d9a (head)		-14+6 ↑ ↓ 📄 Side-by-side	
298 299 300 301 302 303 304 305 306 307 308 309 310 311 312 313 314 315 316 <pre>if not missing(atptn) then do; if atptn >= 24 then avisit2n=avisit1n; if atptn < 24 then avisit2n=avisit1n+(atptn/24); end; else avisit2n=avisit1n; /* if missing(atptn) then do; avisit2n=avisit1n; end; else avisit2n=atptn; */ *extract day from visit; if index(avisit,'D') then day = substr(avisit,length(avisit)-1,1); else if index(avisit,'screening') then day = substr(avisit,length(avisit)-1,1); else if index(avisit,'follow-up') then day = substr(avisit,length(avisit)-1,1); else if index(avisit,'Visit 4') then day = substr(avisit,length(avisit)-1,1);</pre>	298 299 300 301 302 303 304 <pre>if not missing(atptn) then do; if atptn >= 24 then avisit2n=avisit1n; if atptn < 24 then avisit2n=avisit1n+(atptn/24); end; else avisit2n=avisit1n;</pre>		

ADVANTAGES OF GIT:

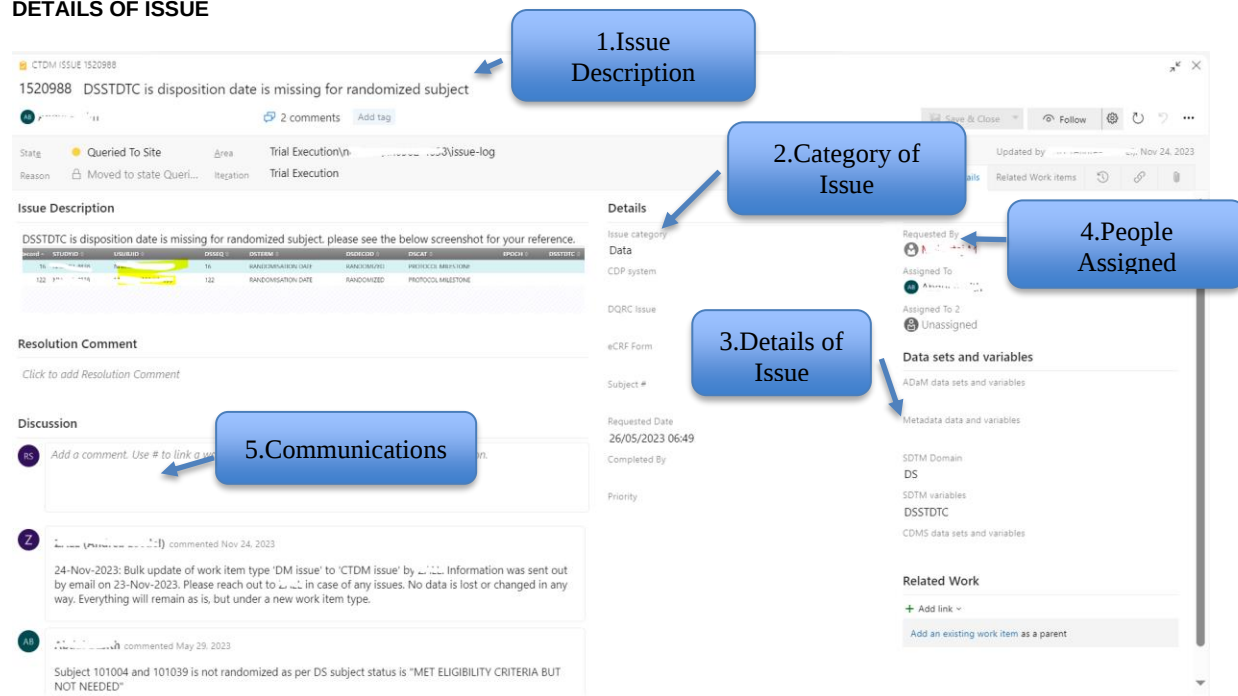
Git in Azure DevOps allows developers to keep track of changes made to the code over time and maintain the versions of the program as well as maintaining an audit trail of the communications regarding code changes.

ISSUE LOGS IN AZURE

In ADO we can add the issue log as well. To This issue logs we can add all relevant stakeholders according to the trial squad like DM, SDTM, Bio-stats, etc.



DETAILS OF ISSUE



TYPE OF CARDS

Open - All newly created issues will start here.

Active - Once you've been assigned to fix or investigate an issue, and you have read the issue and investigated fixing it, you as the "Assigned to" should move the issue to 'Active'. Meaning you're actively working on it.

Queried to the site - Once the issue has moved to active and you're actively working on it, you might realize it's a site issue. So, then you forward the site the issue, and you add a comment under Discussion to inform the stakeholder who Requested it.

Solved on the next data transfer - Once an issue has been corrected from site or vendor, you might then have it resolved the next time you receive an updated data transfer.

Review - Whether the issue has been fixed internally or based on a data transfer, you can now move the issue to 'Review' which means that the "Requested By" stakeholder should review if the issue has indeed been fixed, or not.

Irresolvable - Some issues are not resolvable. In that case, they can be moved to this state.

Closed - This state is the goal with all issues. Once an issue has been reviewed and agreed that it's been fixed accordingly.

ADVANTAGES OF ISSUE LOGS:

- It provides centralized tracking mechanism for all the issues in a project/study.
- Team members can collaborate more efficiently by sharing information about issues, assigning tasks, and updating the status of issues.
- Users will receive an automatic notification when the issue log is updated with an edit or addition.
- It helped us to share snippets, add links, and attach files to the issue log.

PROJECT WIKI

Project wiki is a write-up of details that are shared by several drug projects and skill areas. Each project has its subsection dedicated to the project. It is primarily meant to be edited by members of their project. All other content is shared between all projects that are part of the wiki. This wiki page use as a central repository for project-related information, such as project plans, tools used, timelines, meeting minutes, and other documentation. This wiki page can be used as a on-boarding tool for new members to the project to share the project and processes. Team members to contribute to the wiki by adding their own insights, feedback, and ideas. Use the wiki as a platform for collaboration and knowledge sharing.

On the Wiki page, we can add the sub-pages for each category based on the content that we want to add/share.

Below is an example of the wiki pages for each sub-section.

ADaM ToolBox Cheat Sh... Follow 1 Edit

Durga Ramana Majeti 8 Feb 2023

Contents

- [Common warnings/errors while creating define and how to...](#)

Common warnings/errors while creating define and how to handle

1. WARNING: [CSTLOGMESSAGE.DEFINEUTIL_SPLITWHERECLAUSE] Column in WhereClause not found: WhereClauseOID=WC.ARM.AR.figure 14.2.00008.R.001.ADV5.00001 ItemOID=IT.ADV5.LMWEEK Comparator=EQ CheckValue=68
 Solution: Check for the variables mentioned in dataset. They should be present in dataset. Else you will get this warning. In above example LMWEEK was missing in ADV5
2. WARNING: [CSTLOGMESSAGE.DEFINEUTIL_VALIDATEWHERECLAUSE] Record with invalid WhereClause deleted from _cstSourceAnalysisResults_4259 : N=1 displayidentifier=RD.table 14.2.00001 displaydescription=Pharmacokinetic endpoints descriptive statistics full analysis set table=ADDP WhereClause=

ADVANTAGES OF WIKI:

- It helps us to get an overview of all the projects in the drug development area.
- Wiki gives us a knowledge sharing platform as well as promotes collaborative environment among all the team members around the globe.
- It also helps in onboarding new joiners and smooth transition of stake holders from different projects.

CHALLENGES TO ADO

Processes



SOPs, guidelines, workflows

Azure DevOps is a complex platform with many features and capabilities, which can make it challenging for teams to follow specific SOPs, guidelines to implement and maintain the workflows.

IT



Servers, access permissions, software

Azure DevOps integrates with many other tools and services, which can make it challenging to set up and configure the integration correctly. Teams may need to spend time troubleshooting integration issues to ensure that everything works seamlessly together.

People



Change management

Azure DevOps is highly configurable, making changes to the platform can be challenging and require significant technical expertise. Azure DevOps is a complex platform with many features and capabilities, which can make it challenging for teams to learn and master. It may require significant time and effort to train team members on how to use the various tools and services effectively.

CONCLUSION

Data Analytics and Statistical Programming is a complex environment that can be benefited from implementing Kanban Boards, GIT with the help of Scrum, Agile planning, tracking work items, reporting and visualization, teams can control risk, minimize investments, and improve predictability and team collaboration. It offers native support for Scrum and Kanban for Agile on the backend. In addition to it, development team can use a group of version control tools which help to manage codes and their various versions. As a result, track changes made to the code(s) over time and between various versions makes it easy. The visual representation and documentation made the work much easier to share between programmers. Azure DevOps adoption at project level, make some enhanced results in business productivity and streamlined processes.

DISCLAIMER

The views and opinions expressed in this presentation belong solely to the presenter and do not necessarily reflect those of the presenter's employer, organization, committee, or any other group or individual. The purpose of this presentation is to highlight the advantages of the Azure DevOps in clinical trials. No data or confidential information belonging to Novo Nordisk has been utilized in this presentation.

REFERENCES

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Our technical implementation of scrum and Kanban

[HTTPS://WWW.LEXJANSEN.COM/PHUSE-US/2022/ET/PRE_ET04.PDF](https://www.lexjansen.com/phuse-us/2022/ET/PRE_ET04.PDF)

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