

Microsoft OneNote: A Treasure Box for Managers and Programmers

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ABSTRACT

Microsoft OneNote has many functionalities that are helpful for managers and lead programmers who have increasing responsibility of managing project deliverables as well as understanding staff availability to ensure quality deliverables with compliance to department SOPs. Additionally, managers and leads have the responsibility to keep upper management informed of the overall status in the group operation, including project progress, success stories, challenges as well as potential problems within the group. To effectively perform their daily operations with so many responsibilities in different directions, it is essential for managers and programming leads to find an efficient and effective way to organize the necessary information for the entire process so that they can locate files and information quickly to resolve any unexpected issues. Microsoft OneNote is a tool that can serve this purpose.

This paper briefly introduces some key features of Microsoft OneNote as well as the hierarchy of Notebook, Section and Page within OneNote. It also provides three examples of using OneNote on how to organize information in different categories (i.e., project management, people management, study specific information management) as the manager or lead programmer of statistical programming group in the pharmaceutical industry.

INTRODUCTION

OneNote is one of the best products from Microsoft. It is worthwhile to understand what the features are, and what it can do for us as managers or programming leads in the pharmaceutical industry. Microsoft released its first product version in 2003. Since then, it releases a new version every 2-3 years with its most recent version OneNote 2016.

Microsoft OneNote can host multiple notebooks simultaneously. Each notebook can include multiple sections, and each section can contain multiple pages. Users can include text, tables, pictures and drawings, movie clips on a page. Unlike a word processor, OneNote page features a virtually unbounded document window, which users can click anywhere on the page to create a new text box at that location. Users do not need to explicitly save their work – OneNote auto saves.

Microsoft OneNote also provides a way for multiple-user collaboration in a team. Since more than one notebook is allowed, different project team can have its own dedicated notebook with strict access control: the notebook can be saved in a shared network where access control is strictly enforced. On the other hand, a user can have a private notebook, which can be saved on his or her local drive, which means no other team members can access that private notebook.

With this hierarchy of notebook, section and page, OneNote provides a 3-dimensional space to organize information that a manager or program lead needs to collect and process. As managers, they bear many responsibilities, such as assigning tasks to team members, managing projects timelines, recruiting and hiring qualified employees, setting expectations for direct reports and reviewing year end performance, and properly handling employee with identified performance issues. As programmer leads, they ensure study deliverables can be made with high quality and SOP compliance as per established study timeline, keep the upper management team informed of the general status of the group operation, circulate lessons learned as well as successful stories, and alert management team of potential challenges in resource and project timelines. To successfully fulfill these duties, managers and programmer leads can use OneNote to organize the information they need to perform their daily functions, as well as access the information very efficiently when they need to. This paper provides 3 real-life examples of how the information can be organized using OneNote: namely project management, people management and study related information management.

PROJECT MANAGEMENT USING ONENOTE

Managers and programming leads have a major responsibility to guide their team members to efficiently and effectively work on all assigned studies based on the company portfolio. They support various tasks from the statistical programming perspective, such as providing statistical outputs periodically to Data Monitoring Committee (DMC) to evaluate the safety profile of the study investigational drug; generating tables, listings and graph (TLG) for Study Summary Report (CSR); creating data define packages for regulatory submissions to the worldwide health agencies such as FDA or PMDA, etc. Additionally, they are part of the essential team to answer agency information requests after a regulatory submission. Each one of these tasks comes with a strict and tight timeline, and requires the team to act in a timely and effective manner.

The programming team can be divided into several sub teams based on the indication(s) they are working on and each sub team has an indication programming lead. The manager ensures that each program lead has enough programming resource as per established study timeline, and the study team can deliver the required outcomes to various stakeholders with quality and compliance. To make this process as smooth as possible, a clear communication channel should be built and maintained throughout the life cycle of each programming task, so that each team member knows his/her role, responsibility and its corresponding timeline. Any issues that might lead to potential delay or comprise can be detected as early as possible, and if needed, follow-up with management team to take proper action or make better arrangement. For the illustration purpose an imaginary programming team A is used as an example, all the study numbers, name of employees, date of deliverables or milestones are not taken from real programming practice.

Indication Prog. Team A ▾ Study 101 Study 201 Study 301 Study 401 Study 501 Study 601 Study 701 Out of Office + Search (Ctrl+E)

2019-03-15 Add Page

Sunday, June 23, 2019

Type of Deliverables	Tables, Listings and Graph for CSR
LPLV	2019-04-01
Dry Run Date	2019-04-15
DBL	2019-05-02
Final Up-Version Date	2019-05-03
Wave 1 Date	2019-05-06
Wave 2 Date	2019-05-13
Wave 3 Date	2019-05-18
e-Sub Drop Off Date	2019-07-02
Submission Date	US: 2019-07-12 EU: JAPAN:

Note: All dates are for illustration purpose of this paper.

Discussion items:

- Programming Spec and Mock up tables
 - Final spec has received
 - Programming spec needs fine tune so that it can be imported to Pinnacle 21
 - Code List and Parameter Level Meta Data
- Dataset Development Status
 - MedDRA updates to the most recent version, AEO SI Excel Spreadsheet needs update for the ADAE dataset
 - Safety datasets are in good shape, next step is to perform Pinnacle 21 compliance before dry run
 - The team is still working on the efficacy datasets, needs additional 1 weeks for the validation to be done
- Tables/Listings/Graph
 - Safety package has been ready and under STAT review
 - Efficacy package programming has not started yet, will refer to the study 099, and expect to be finish development by the end of the month.
- E-sub package:
 - Not start yet.
- Technical Difficulty
 - The existing utility to combine the tables and graph works fine with the tables, but not for some study specific graphs, need find a work around solution
 - There are a few discrepancies/mismatch in the spec for Code List, which prevents P21 to read in the spec. Need to find a more efficient way to generate Code List, or detect the discrepancies/mismatch in the spec. It takes too much effort by eye-browsing or update manually.
 - Special characters found in the Protocol Deviation Excel spreadsheet, which is not allowed in the DV dataset, need to report to clinical team
- Resource Concerns
 - So far so good

Display 1. Screen Print of OneNote for Project Management: Individual Study

There are 6 statistical SAS programmers in the programming group A to work on a total of 7 ongoing studies. Each study team has its own study lead. The indication programming lead schedules regular meetings (weekly or bi-weekly) to go over the assignments and programming status. The team discussion is documented in great details in Microsoft OneNote as illustrated in Display 1. In this case, a dedicated

Notebook has been built for the Indication team A, each team member has read and write access. Then a dedicated Section is built for each ongoing study within the indication. The study number is used as the name of the Section for easy reference. Furthermore, a dedicated OneNote Page is built for each meeting, with the name of the page is the date of the meeting, which will be sorted by the calendar date when the meeting was held.

Please note, on Display 1: “Indication Prog. Team A” is a OneNote notebook for the entire indication, “Study 101” is a Section within this OneNote notebook, which can be used to document all the timelines and deliverables for the study 101 during the conduct of the trial. Each section can contain multiple OneNote pages, all the team discussions and decisions made can be documented in detail in a chronological order. Since the study timeline could change over the time during the conduct of the trial, the table in the top of the screen print will need to carry over from meeting to meeting with the most recent updates. By doing so it reminds each study team member to make necessary adjustments in programming priority to adopt the evolving timeline during the conduct of the trial. In Display 1 there are 7 meetings recorded for the study 101, all the study team members can come back and check information of interest when necessary, including the team lead as well as the manager.

In addition, the contact information of the team members and important stakeholders can be saved in OneNote. Sometimes situation arises that requires an immediate response from an individual team member. For example, a critical request was received from external stakeholders, and there is a business need to turn around very quickly. It becomes extremely important to secure programming and statistical resources in a timely manner to address these urgent requests/queries. With this contact information handy in Microsoft OneNote, it can help the manager/indication lead to reach to necessary team members and avoid any potential delay in response.

Indication Prog. Team A ▾ Study 101 Study 201 Study 301 Study 401 Study 501 Study 601 Study 701 Out of Office + Search (Ctrl+E) Add Page

Point of Contact
Sunday, June 23, 2019 2:08 PM

Role	Name	email	Best Number to Reach	Note
Data Manager	Abby	Abby@mycompany.com	(732) 501-0001	
Lead Statistician	Bob	Bob@mycompany.com	(732) 501-0002	
Clinical Scientist	Carl	Carl@mycompany.com	(732) 501-0003	
Medical Writer	Derek	Derek@mycompany.com	(732) 501-0004	
Submission SME	Eric	Eric@mycompany.com	(732) 501-0005	
Study Programming Lead	Frank	Frank@mycompany.com	(732) 501-0006	732-501-1006 (Cell)
Indication Programming Lead	Greg	greg@mycompany.com	(732) 501-0007	732-501-1007 (Cell)

Point of Contact
2019-01-01
2019-01-15
2019-02-01
2019-02-15
2019-03-01
2019-03-01
2019-03-15

Display 2. Screen Print of OneNote for Project Management: Point of Contact

Additionally, a separate section has been created to track planned vacation and flexible work arrangement in the team. Each team member is strongly encouraged to plan his/her vacation as early as possible. Once the manager approves the planned vacation, the indication lead will record the approved vacation in this section. The purpose of this page is to have an overall picture of all planned vacations, which helps the indication programming lead to oversee the programming resource available in a given period of time, and also help the manager in making decision to approve further requests from the same team down the road.

Indication Prog. Team A ▾ Study 101 Study 201 Study 301 Study 401 Study 501 Study 601 Study 701 OOO-FWA + Search (Ctrl+E) Add Page

Approved Vacation
Sunday, June 23, 2019 2:08 PM

Name	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
Ava		3 - 8										
Bob				6, 7, 19,					22			
Emily						2 - 8						
Ethan											1 - 18	
Jaya							20 - 28					

Approved Vacation
Flexible Work Arrangement

Display 3. Screen Print of OneNote for Project Management: Out of Office tracking

Similar Page is built to track the flexible work arrangement (working from home or an approved location off the site) for the same programming team, and the best number to reach if there is any urgent need.

The screenshot shows a OneNote page titled 'Flexible Work Arrangement' with a date of Sunday, June 23, 2019, at 4:10 PM. The page contains a table with the following data:

Name	Monday	Tuesday	Wednesday	Thursday	Friday	Best Number to reach if work from home
Ava		X			X	(732) 501-2001
Bob			X			(732) 501-2002
Emily		X			X	(732) 501-2003
Frank			X			(732) 501-1006
Greg	X		X			(732) 501-1007

Display 4. Screen Print of OneNote for Project Management: Flexible Work Arrangement Tracking

PEOPLE MANAGEMENT USING ONENOTE

A manager's goal is to build a solid and stable programming team with the capability to deliver. It involves many steps such as recruiting, hiring, onboarding employees, working with each team member and developing him/her on an ongoing basis. Each one of these steps requires specific knowledge and information to handle. For example, when a position opens, a talent acquisition system is used to attract internal and external candidates. Since this is not a task we do every day, it might be difficult for a manager to remember the exact link for posting job openings, resume review etc. Similarly, when onboarding a new team member, usually there is a check list, which is a living document sitting in a shared drive, to help managers to go through the process. But again, remembering the exact link of the checklist can be a difficult task for managers. In these cases, a shortcut or a bookmark will be very handy. To address the need of managing information for people management related tasks, a OneNote notebook can be created for this purpose. Since it may involve some confidential information, it can be saved in a personal folder, which prevents any unauthorized access. See Display 5 for a few examples of OneNote sections, namely Recruiting, Onboarding, Exiting and Employee monthly 1:1 meeting, etc. Information could be further broken down by categories. For example, different pages in the Recruiting Section, namely Talent Acquisition, Interview Agenda Template, Things to ask in a Phone Screen, Huddle Meeting Template, and Hiring Decision Tracking Sheet.

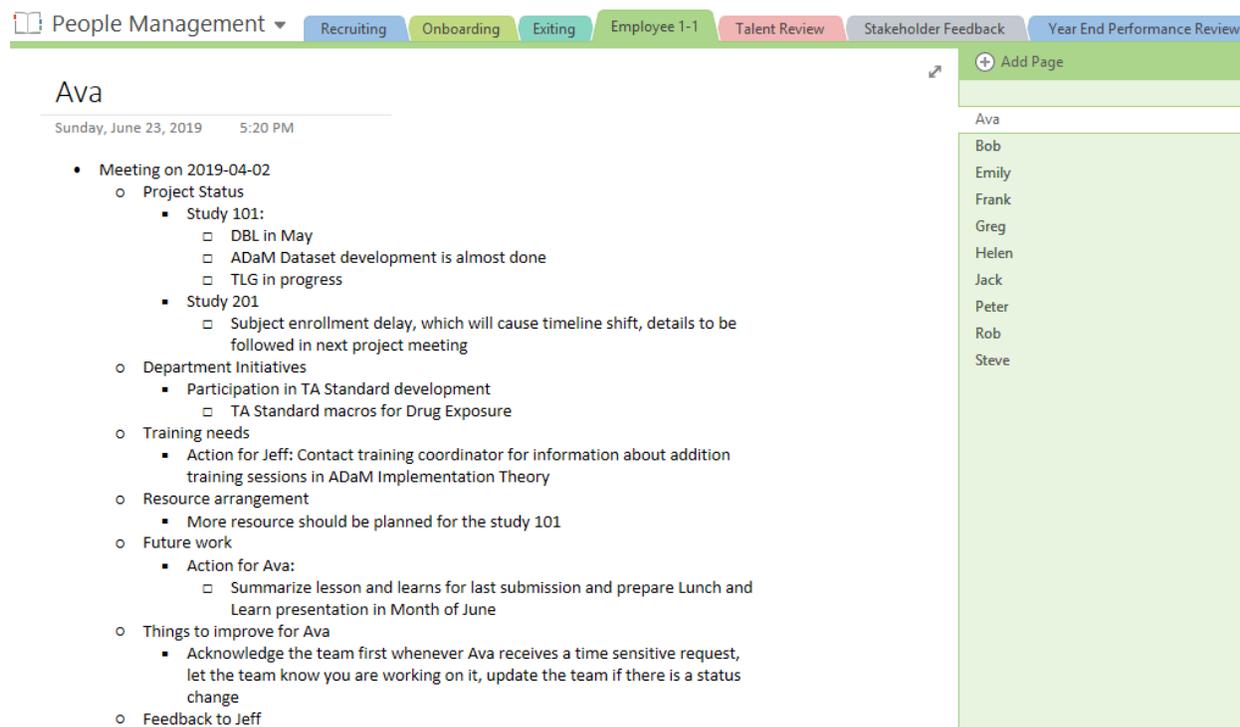
The screenshot shows a OneNote page titled 'Talent Acquisition' with a date of Sunday, June 23, 2019, at 5:19 PM. The page contains a list of instructions and links:

- Link to the system:
 - www.talentacqisionsystem.com
- How to extract resumes:
 - Login using work ID and password
 - Locate the job post ID and then select **ALL** candidates (Important!)
 - Select export to a local drive (it is better to review a local copy)
- Phone to call if any technical issues:
 - 1-800-999-9999
- Human Resource Contact:
 - Abby
- Candidate tracking Excel Spreadsheet (Important: interview summary needs to be documented in details in the tracking)
 - <https://collaboration.merck.com/x:/r/sites/ldsp-us/Shared%20Documents/Oncology/00-%20Oncology%20Virtual%20PC%20Reservation.xlsx?d=w21b196750cf74b7eb5fd27d5bd6f0690&csf=1>

Display 5. Screen Print of OneNote for People Management: Recruiting and Hiring

The benefit of OneNote pages is that it provides a one-click-away access to the important information that usually resides in different website or team sites. Significant time and effort can be saved when related information is put together by following business logic order.

Another good example is the employee 1:1 with the manager, which is expected to be held on a regular basis, mostly monthly. For newly joined team members, the frequency can be increased as necessary, such as biweekly. The 1:1 meeting with manager is an essential step to build a strong and effective team, and should always be treated with priority, and not rescheduled if there is no absolute reason. The conversation of 1:1 meeting is private between the employee and the manager in a mutually respectful manner. Any project-related or work environment related topics are welcome. Therefore, it serves as a great channel for the manager to communicate with direct reports, understand the concerns and difficulties from the team, collect feedback and lessons learned in recent programming activities, as well as suggestions to improve efficiency and resource usage. During the conversation with direct reports, manager should encourage two-way communication to understand and resolves any concerns or issues. Each team member has his or her own unique strength and weakness, mutual understanding between the manager and the direct report can help each other to improve, and eventually build a highly effective team with the capacity and confidence to complete required deliverables. Specifically, a manager can advocate smooth communication inside the study team, for example: each team member to acknowledge whenever a request is received, discuss with stakeholders for actions to take and establish a mutually agreed timeline for the request, maintain the open channel, periodically update the team on the progress, and finally deliver the output with quality and compliance within the agreed timeline. These communication techniques help the team to build high execution power and the ability to be depended on; and establish mutual trust between the programming team and stakeholders.



Display 6. Screen Print of OneNote for People Management: Employee 1-1 Meeting

To make the manager's life a little bit easier, separate sections for 1:1 meetings can be built to document the discussion and action items. Each time the manager documents the key points of discussion in OneNote, and send a copy in PDF format to the direct report after the meeting if necessary. Manager can revisit some of the main points in next session to check the status of each other's action items.

Additionally, manager can ask direct reports for feedback, suggestions, and concerns in every 1:1 meeting. As the time passes, the meeting minutes accumulate, gradually trust and confidence can be found amongst team members.

INFORMATION MANAGEMENT USING ONENOTE

To remain technical savvy and maintain programming proficiency is another challenge for managers and programming leads. The more a manager or a programming lead understands the details in the department process, programming tools and utilities, and work around solutions for existing technical difficulties, the better he or she can estimate resource and time needed for a specific task or deliverable, and the better he/she can plan ahead and allocate resource accordingly. Information can be obtained from different channels, such as monthly staff meetings, periodical release of standard macro updates from the standard group, department newsletters, lunch and learn presentations, training and workshops, e-learnings and industry conferences, etc. Over time, all the information can become scattered, which makes it more and more difficult to find when there is a need to reference them. Therefore, a OneNote section can be specifically created for this purpose. The benefit of OneNote is all the text are searchable: a simple search can easily locate the information of interest. See Display 7 for all topics of interest obtained from different sessions in the department lunch and learn event. A column of “My Notes” is added to remind readers about the details covered in that presentation.

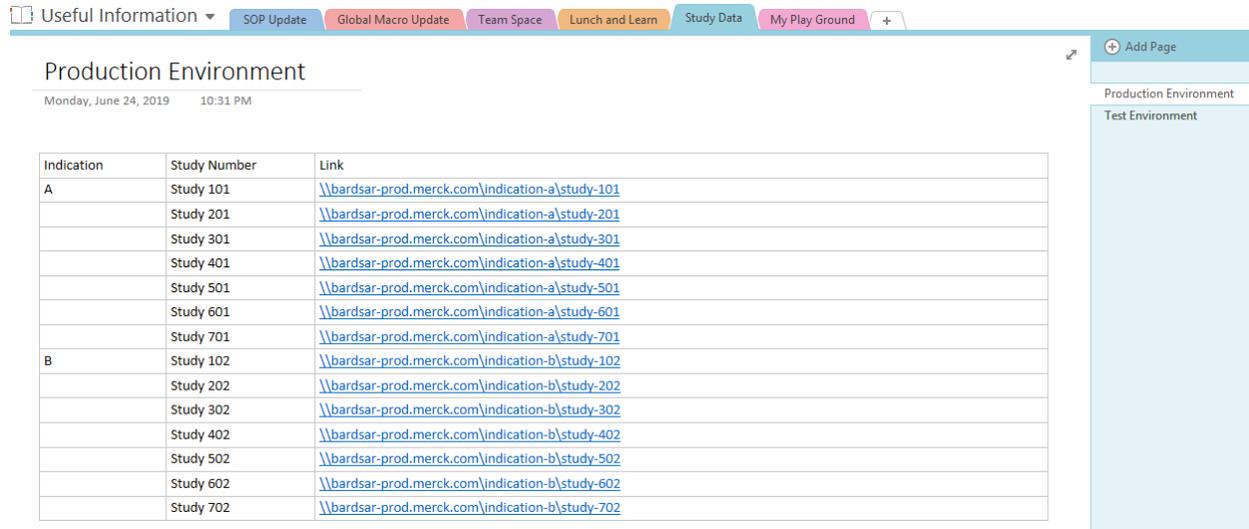
Useful Information ▾ SOP Update Global Macro Update Team Space Lunch and Learn Study Data My Play Ground +

Year 2019
Monday, June 24, 2019 10:33 PM

Name of the presentation	Date	Link to presentation	My Notes
Introduction to SDTM IG 3.2	Jan	https://collaboration.merck.com:/p:/r/sites/ldsp-us/Shared%20Documents/Oncology/Lunch%20and%20Learn/2019-Lunch%20and%20Learn/Lunch_and_Learn_2019-01-24-Changes%20at%20SDTM%20IG%203_2.pptx?d=w3260bbacca8f4ce3bbf72c435ea69c29&csf=1	Comparison to SDTM IG 3.1.3, what is changed and what remain unchanged
Lesson learned in a recent DMC	Feb	https://collaboration.merck.com:/p:/r/sites/ldsp-us/Shared%20Documents/Oncology/Lunch%20and%20Learn/2019-Lunch%20and%20Learn/Lunch_and_Learn_2019-01-24-Changes%20at%20SDTM%20IG%203_2.pptx?d=w3260bbacca8f4ce3bbf72c435ea69c29&csf=1	Things to pay attention between blinded and unblinded teams; macros used to extract blinded data
Building Bookmarks Automatically for OSI listings	Mar	https://collaboration.merck.com:/p:/r/sites/ldsp-us/Shared%20Documents/Oncology/Lunch%20and%20Learn/2019-Lunch%20and%20Learn/Lunch_and_Learn_2019-01-24-Changes%20at%20SDTM%20IG%203_2.pptx?d=w3260bbacca8f4ce3bbf72c435ea69c29&csf=2	VB macros to convert combined RTF with bookmarks in hierarchy by site by listing
A utility for programmers to aid the safety stack spot check	Apr	https://collaboration.merck.com:/p:/r/sites/ldsp-us/Shared%20Documents/Oncology/Lunch%20and%20Learn/2019-Lunch%20and%20Learn/Lunch_and_Learn_2019-01-24-Changes%20at%20SDTM%20IG%203_2.pptx?d=w3260bbacca8f4ce3bbf72c435ea69c29&csf=1	Output of all important safety counts in the format of Excel spreadsheet

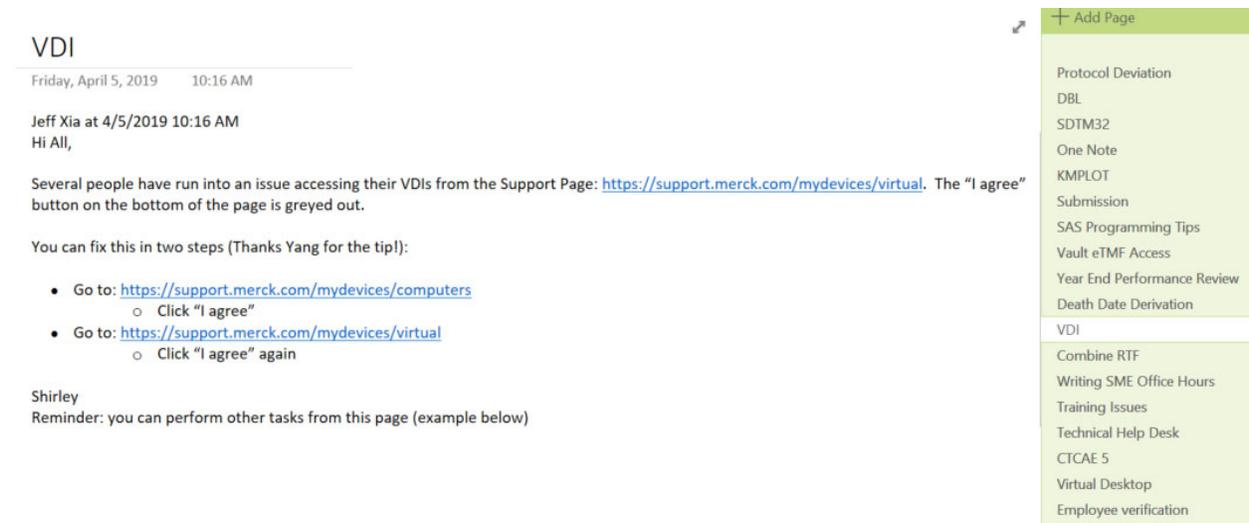
Display 7. Screen Print of OneNote for Information Management: Lunch and Learn Presentations

Periodically there is a need for manager/program lead to go to the study folder and check the status of programming activities, compliance, and quality of the ADaM datasets and TLF. One method is to map drive in MS Window File Explorer. But there are limited drive letters to use. A better solution is to organize all direct links of study folders in OneNote by environment by indication by study, which provides a central place that is only one-click-away to the study data. There is no limitation on how many links to the study data that can be stored in OneNote.



Display 8. Screen Print of OneNote for Information Management: Access to Study Folders

Another good example is the Frequent Ask Questions (FAQ). Putting the questions and answers in a central place is extremely helpful for team members to locate the information when they need it.



Display 9. Screen Print of OneNote for Frequent Ask Questions

CONCLUSION

Microsoft OneNote is a useful tool that can be used to organize information in a 3-dimensional space: Notebook, Section and Page. It provides an efficient and effective way for managers and programming leads to collect, store, manage, and retrieve information that they need to perform their daily operations.

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REFERENCES

Microsoft OneNote, https://en.wikipedia.org/wiki/Microsoft_OneNote

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