

Paper TT10

Overcoming hurdles in clinical programming project management using Microsoft Teams®

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ABSTRACT

Clinical trials are becoming increasingly complex. Clinical programming project management requires planning, initiation, execution, and closure by working with multiple cross-functional teams under strict timelines. Collaborating across diverse systems can lead to delays and decreased productivity. Monitoring project status across different resourcing models makes workflow overview challenging. Gleaning essential information from communications (emails, chats, meeting minutes, etc.) takes a long time. High volume and diversity of trial documents contribute to inefficiencies. Working documents requiring to be updated and shared by multiple users in real time can be laborious. Evolving trial complexity and increasing cross-functional team communication has created a need for a project workspace where projects can be boot-strapped to address scattered information. This paper explains how Microsoft Teams provides a robust platform for better collaboration, planning, and communication to overcome some common hurdles and achieve more efficient clinical programming project management.

INTRODUCTION

Let us look at a typical working day of a clinical programming lead. The work usually revolves around communicating, collaborating and planning with multiple cross-functional groups and among team members. Communication usually flows in and out in several different forms such as emails, phone calls, instant messages and face to face meetings/teleconferences. The information that is generated or communicated in the form of clinical trial documents, planning documents, tracking sheets, presentations, memos and other miscellaneous related documents are stored over multiple platforms. These storage platforms could be local drives, network-mapped drives, email attachments, cloud-based repositories such as MS SharePoint amongst others. Some documents such as specifications, meta-data spreadsheets, mapping documents or tracking spreadsheets need to be updated constantly, often by multiple authors. The lead needs to ensure that the team always has access to the latest version of documents. The lead assigns work to each teammate in the most informative and efficient manner while being able to keep track of the work distribution in real time. He/she then needs to have regularly scheduled and impromptu meetings with the team to stay on top of things and get status updates. Sometimes the lead needs to send out reminders to the team before certain events which can become a time-consuming administrative task.

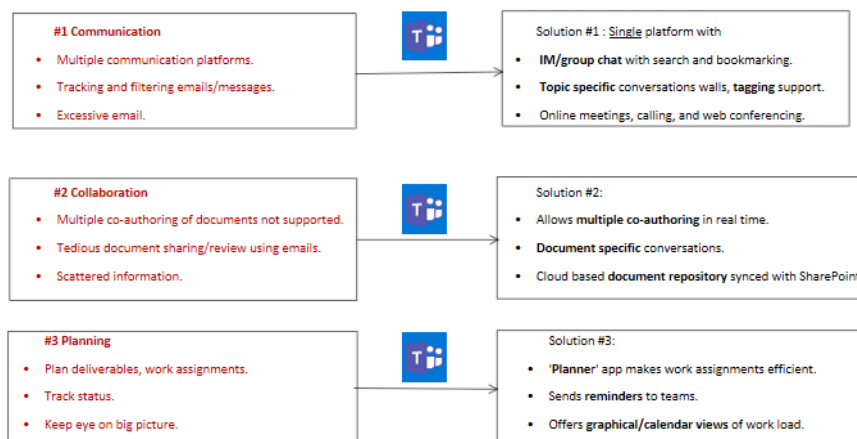


Figure 1.1: Problems solved using MS Teams

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There are a variety of tools that the lead must utilize effectively tackle each of the tasks above. However, most of these tools are designed to tackle specific problems, and not necessarily to work with each other seamlessly. Tools such as emails have out-grown their original purpose and are often misused (e.g. Using emails for document storage). Emails take a long time to filter and search for information. Information often ends up being scattered. Important messages need to be flagged. A lot of time and effort is wasted in accessing multiple tools/platforms to access information. Excessive email is a real problem Co-authors must take turns when updating the same document with tools such as MS Excel or MS Word. Keeping track of latest version of documents can be tricky in such instances. Efficient work allocation and keeping track of assignments/work load takes up a lot of time, especially in bigger teams.

Microsoft Teams is a digital hub that can centralize programming tools and information, bringing conversations, content, assignments, and apps together in one place. It helps the team communicate more effectively with group chat, online meetings, calling and web conferencing. The integrated calendar syncs seamlessly with MS Outlook making it easy to schedule meetings, record meetings and take meeting notes. Team members can better work together by collaborating on files with built-in Office 365 apps like Word, Excel, PowerPoint, OneNote and SharePoint. It acts as a secure, central, easy to access cloud-based repository for team documents. Team members also get to customize their workspace by adding third-party apps to MS Teams such as Planner.

At Janssen, we decided to use two separate clinical programming teams as pilots for testing MS Teams' capabilities. Instead of trying to use every feature that MS Teams offers, we focused on the ones that we felt would be most effective for our work. The purpose of this paper is to share our experiences and findings. We will begin by describing how we utilized some of the most frequently used features and apps, followed by what we liked about each one. We also share what kind of challenges we faced and end with our recommendations for anyone who is considering MS Teams.

COMMUNICATION

CHAT

During the conduct of a clinical trial or project, day to day discussions take place frequently. As the telephone is rarely used these days, chat is the way of communicating in workgroups. MS teams offers a chat tool that allows us to have team discussions in group or private chats.

A few built-in features of MS teams are very useful in clinical trial workgroups.

1. File sharing. Microsoft Teams makes it easy to share documents such as Word documents, PowerPoint presentations, and Excel spreadsheets. Documents can be attached to chats while they are being discussed and reviewed, and notes can be left on them by all team members to ensure that they're processed correctly. The collaborative functions make it possible for everyone to work on documents at the same time without the fear of data being overwritten, lost, or corrupted.
2. Screen sharing is an easy way for team members to work on projects together, in real-time. Through screen sharing, team members can discuss projects while making changes to shared documents.
3. Bookmark chats is a useful piece of functionality that allows you to save a message, or more accurately a position in a conversation or chat, just by clicking on the sash icon at the top of the message. You can recall all your saved messages by clicking on your profile picture top right and selecting 'Saved' or possibly quicker would be to type in the command bar /saved. This gives you a list of all your saved points and on clicking on them takes you back to the point in the conversation you saved from.
4. Use @mentions to get someone's attention in Teams. To get someone's attention in a channel conversation or a chat, @mention them. Just type @ before their name and then select them from the menu that appears. They receive a notification, which they can click to go directly into the point in the conversation where they were mentioned. To get the attention of an entire team, try @team or @channel. Good to know that you automatically receive a notification when there comes in a chat message, whether the sender used the @mention or not. In a channel conversation this doesn't happen automatically, so be aware to use @mention when it is important.
5. When a chat conversation turns out that a call would more straightforward at that moment, just start a conference call or video chat with one click on the button.
6. A whole conversation, even the shared files, are saved automatically once a chat is closed or the working day is over.

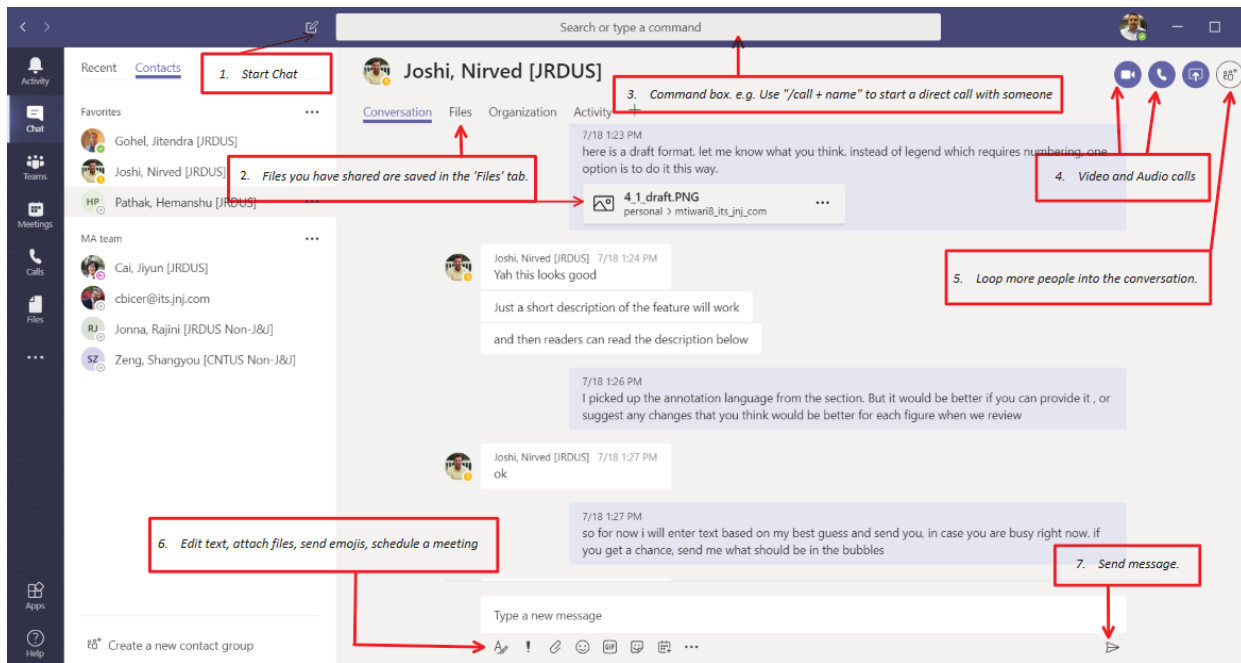


Figure 2.1 Chat box.

CONVERSATIONS

1. The Conversation tab in MS Teams appears in the General channel, as well as in any additional channels you create. Conversations are different from chats because they are not private and visible to everyone in a channel, which is a huge advantage. You all recognize this: You send an email about a topic to some colleagues. They reply to you but not to all. Then someone else replies to you. Suddenly the conversation is splitting out into seven separate conversations with everyone's ideas being directed at one person when it should be a group discussion. With Teams this doesn't happen. There is an open and transparent communication, and everyone stays in the loop and always knows what the status of the discussion is, without the feeling of missing important information. This enables everyone to catch up without having to deal with cumbersome documents and makes onboarding of new team members easier.
2. Equal to the chat tool you can notify the entire team or someone individually by using @mentions (example: @submissions @bryan).
3. You will still receive emails in your outlook which are related to your project. Fortunately, Microsoft makes it easy to forward any email message from Outlook to a related channel in MS Teams so they show up in both platforms. Just click the ellipsis next to any channel name and select Get email address. This generates an email address for the channel, which you can copy and use to forward files, documents, and messages.

Channel vs Chat		
	Public	Private
	No notification (use @ to notify)	Notification every time
	Up to 5000 people in a team	Up to 50 people
	Can be used to inform people such as email's CC	Can be used to replace phone call, skype direct messages or email
	Showing history by default	Conditionally shows history
	More apps integration	Some apps integration
	On the spot video meeting	Call, video conference or screensharing

Figure 2.2 Channel vs Chat

MEETINGS

Working as clinical programmer on clinical trial projects, some days are filled with kick-off, cross-functional, data review or planning meetings. The challenge is to optimize the way of setting up and having online meetings.

MS Teams provides you with the option to view your outlook calendar and to set up a meeting for your team. After the meeting is scheduled it appears in the channel so every team member, whether they are invited or not, is aware that the meeting is scheduled. As Outlook calendar is completely integrated in MS teams, the meeting is also visible in your calendar.

The screenshot shows the 'New meeting' dialog in Microsoft Teams. Red boxes and arrows highlight specific features:

- Add subject/title:** Points to the 'Title' field where 'Kick-off meeting' is entered.
- Select appropriate channel for your meeting:** Points to the 'Select a channel to meet in' dropdown menu, which currently shows 'CLINICALTRIAL1001/Efficacy'.
- Option for specifying physical location:** Points to the 'Location' field.
- Helps the organizer browse availability on all attendees' calendars:** Points to the 'Scheduling assistant' link.
- If you select a specific channel, only members of the team can be invited. Otherwise anyone in the organization can be invited.** This text is inside a box pointing to the channel selection dropdown.

Other visible elements include the 'Start' and 'End' time fields (19 Jul 2019, 08:30 to 09:00), the 'Repeat' checkbox, the 'Invite people' section with 'Invite someone' button, and the 'Organiser' field showing 'Cambre, Sofie - Statistical Progr...'.

Figure 2.3 Setting up a new meeting in MS Teams

MS Teams platform permits your team members to review files before meetings, write meeting notes during, and save all notes after the meeting ends.

1. Before the meeting: go to Meetings on the left side of the app, select the meeting, and then Chat with participants. Select the Meeting Notes tab, then Start taking meeting notes. This can be interesting to share the agenda or other important discussion points. (Note: Pre-meeting notes are currently only available for meetings that don't take place in a channel. If you click Chat with participants in a meeting that takes place in a channel, you'll be taken to that channel.
2. Once you're in the meeting, select Start taking meeting notes (If you have not taken any notes yet) or Meeting Notes in the upper right corner. Use the controls at the top of the panel to format and lay out the text. To add a new note, select Add a new section here. Again, you can use @mentions to draw someone's attention to a specific note or assign an action item. In a recurring meeting, the notes persist from meeting to meeting. Each meeting becomes a new section in the notes.
3. After the meeting you can go to the channel where the meeting occurred (or the meeting chat for a private meeting) and find the meeting. Beneath it, select Show notes in full screen. The meeting notes open in a Wiki tab that you can read or add to. Edit and format the tab just like you would do with any other Wiki tab.

PLANNING

Over the years, clinical trial projects are becoming more complex and agile with increasing demands of short phases of tasks and managing their timelines for concurrent deliverables. These tasks are often characterized by frequent reassessment for which teams are required to quickly adapt for any change of plans with regards to timelines, deliverables as well as the operational resources provided to the team. Co-ordinating workload, monitoring progress

and sharing status helps to tackle complexity of such projects.

In MS Teams creating channels within a project team site helps to segregate the project into different categories of interest and keep respective content separate from each other. Channels can be created for different analysis such as efficacy, safety and health economics or even across various efforts such as submissions or publications within a clinical project.

MS Teams features an application called Planner for project management along with different Microsoft Office tools are also featured within the team site. For people with advanced skill set or prefer using MS Excel, OneNote and other applications as tools for project management can greatly benefit from this functionality. It provides autosave as well as multi user edit feature to work on the project document simultaneously. There are several third-party project management applications that can be downloaded into MS Teams and used as per user or company preferences. For instances OneNote notebook for a trial consisting of different sections to manage multiple tasks across cross-functional teams can be efficiently managed and remains in sync with the desktop OneNote desktop application.

PLANNER

Planner makes it easy for your team to stay organized, assign tasks, and keep track of your progress. To better understand and examine its features we implemented planner for development and finalization of statistical analysis deliverables, electronic submission package including reviewing deliverables with the cross functional team. Planner provides a high-level visual presentation of the project by generating boards, charts and a schedule calendar for a thorough discussion with project manager and to plan deliverables accordingly.

Within the Planner application individual buckets of tasks (Programs, TLF's and Submissions) were created and within those buckets programming assignments were allocated to team members. This greatly reduced the email conversations as persons of interest could notify each other via MS Teams conversations or chats as those assignment statuses get updated.

1. Multiple color labels can be used separately or together to identify and differentiate buckets or assignments based on the scope, criticality of the assignment or any other priorities.
2. Set and update progress, start date and due date for the tasks and sends notification and reminder to the task initiator and the assignee via Outlook with the information conveyed only to the specific person of interest.
3. Create checklist of sub-tasks and can be checked off the list as they get completed.

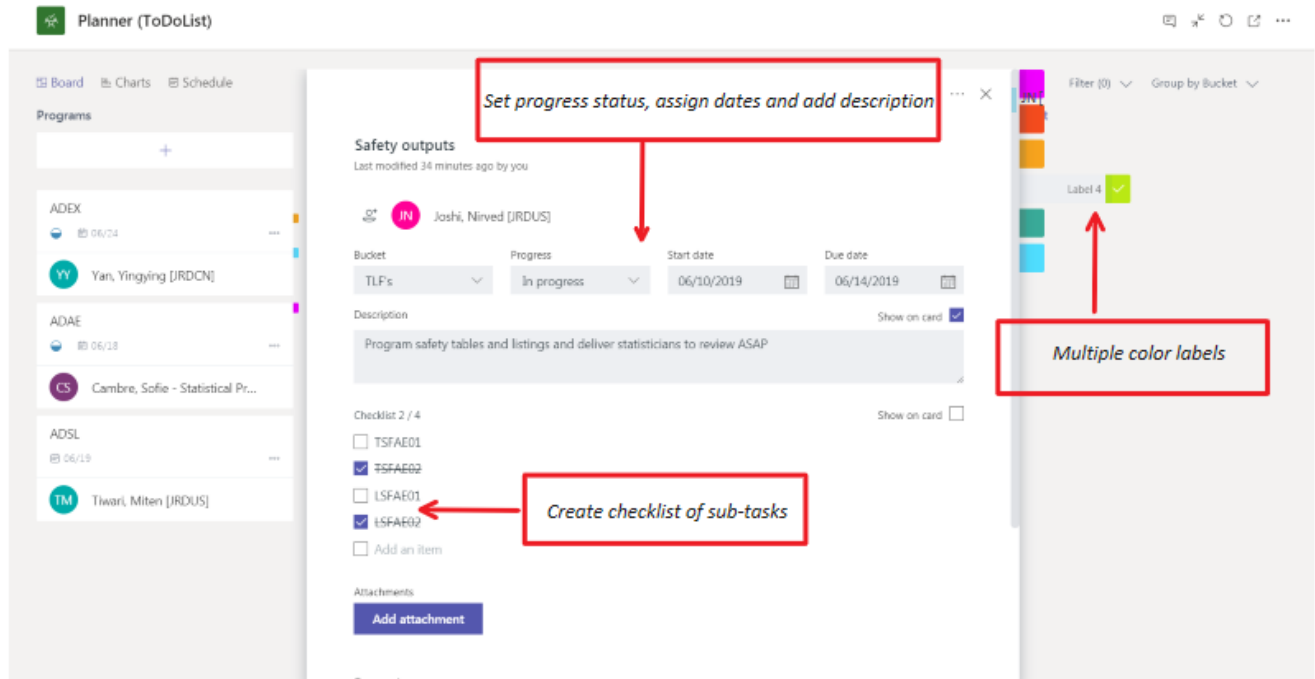


Figure 3.1 : Creating a new task using Planner.

BOARD VIEW

Board view gives an overall representation of all the buckets of tasks (Programs, TLF's and Submissions) and the progress of assignments.

1. Displays individual buckets of task (Programs, TLF's and Submissions) which helps to streamline project work.
2. A list of sub tasks within those buckets displaying the name of assignment such as datasets, tables, publications etc.
3. Shows assignee name to identify the person working on those tasks.
4. A pull-down feature shows name and description of tasks that are completed.

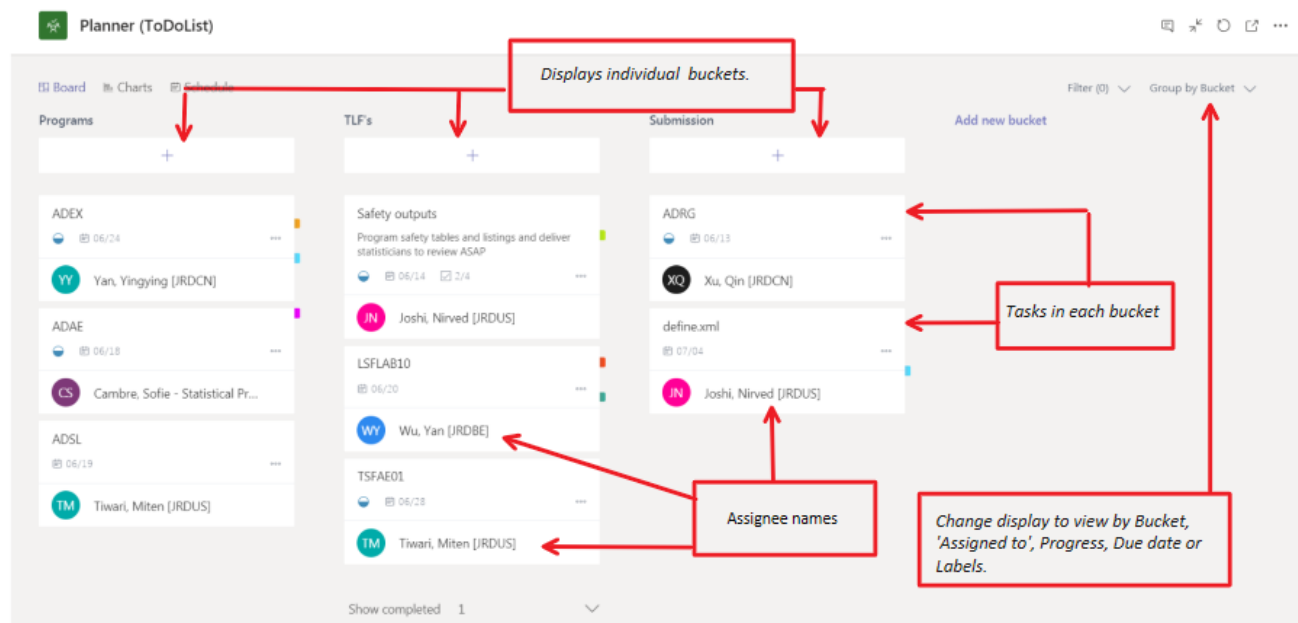


Figure 3.2 : Board view of the Planner.

CHART VIEW

A chart view shows the overall status of the project along with the status of each individual assignment. This view is helpful for discussing resources and progress of tasks especially while committing to deliverables across cross functional requests.

1. Overall status of all tasks.
2. Displays the overall workload among the members of the team along with the status of their respective tasks.

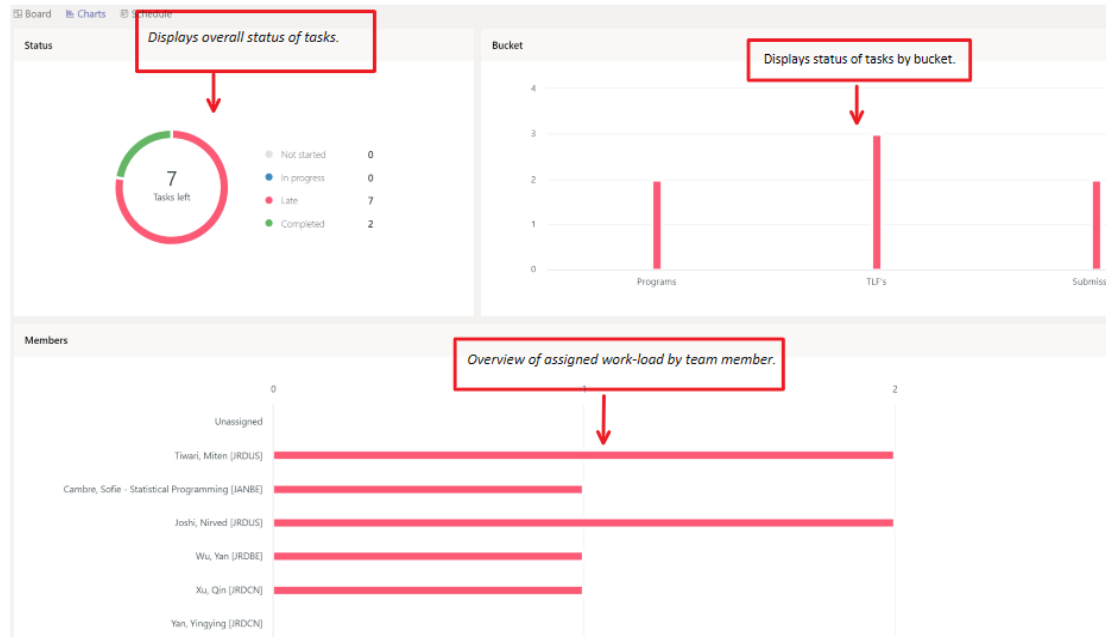


Figure 3.3: Chart view of the Planner.

SCHEDULE VIEW

A schedule view gives a high-level project view within the calendar and helps to plan day-to-day activities. It provides a visual aid of defined priorities and space tasks accordingly to meet database lock timelines and deliveries.

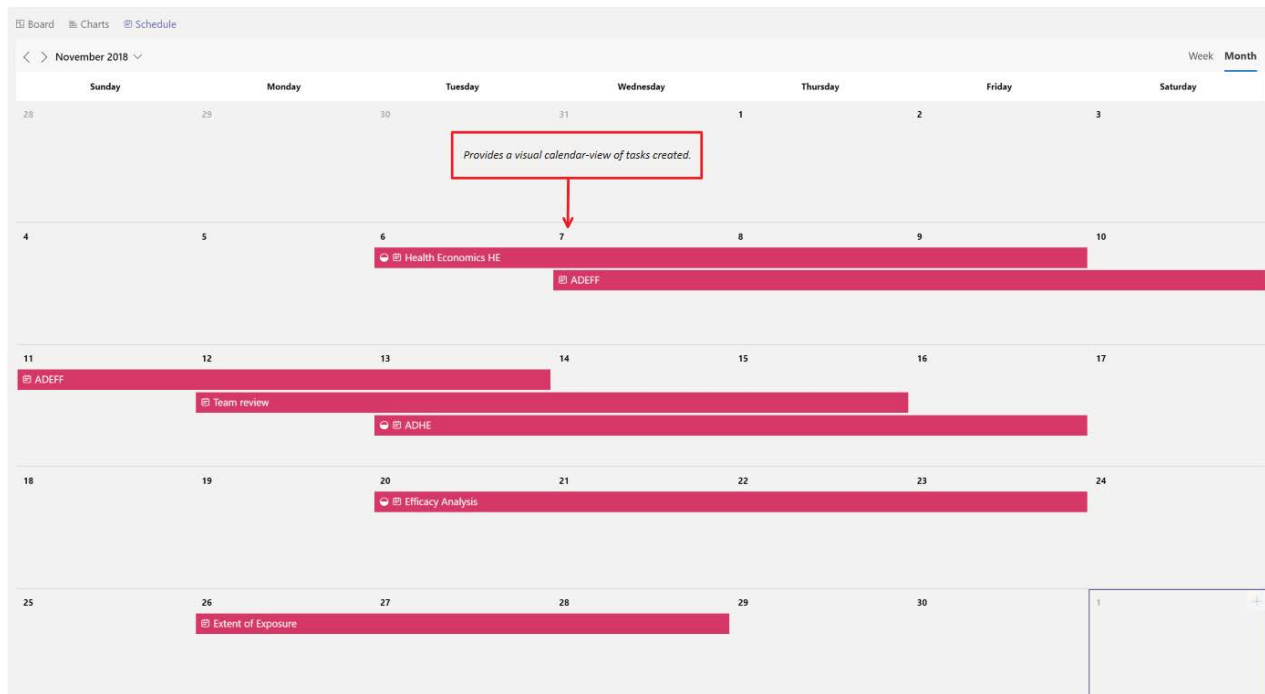


Figure 3.4: Calendar view of the Planner.

COLLABORATION

As a chat-based collaboration space, MS Teams allows a group of people to communicate and organize information

in a single area. Within MS Teams, it is simple to find exactly what you're looking for or know who to ask and it is effortless to define who is working on what and how they're involved in the project.

INFORMATION REPOSITORY

MS Teams creates a central location to work on projects, saving users time and enhancing productivity. One of the main features is that all your meta-documents are accessible (via Team's Files function), searchable, shareable and editable, which highly boost team document collaboration. Content collaboration such as chats, calls, and meetings can all be hosted in the app. Information that would be lost in emails is saved in discussions, which makes finding information and auditing much easier. Also, the data is stored in the cloud, so people can work together wherever they are.

The easier we as a group find it to get our work done, the more work we can do. Technology is about empowering team members to do our best. Teams (often in addition with SharePoint) keeps work easily accessible and easy to modify. Project files, shared documents, notes, and other information can all be connected to directly through the MS Teams dashboard, as well as linked directly through the MS Teams channels. This lets all group members quickly access the files that they need to work on, work on these files together, and show these files to other members (and management) for review. As shown in the figure below, for instance, documents that are commonly used in our trial such as emails messages, list of reports, are centered in the **General** channel. Documents that are specific for each domain, such as the communication trackers with CRO in different domains of **Safety** and **Efficacy**, are well organized in the corresponding channels. In this way, our group member can directly click into channel and easily access to the tracker they need to edit with effortless searching. Similar files structure can be also applied to ADAMS inventory or coding inventory.

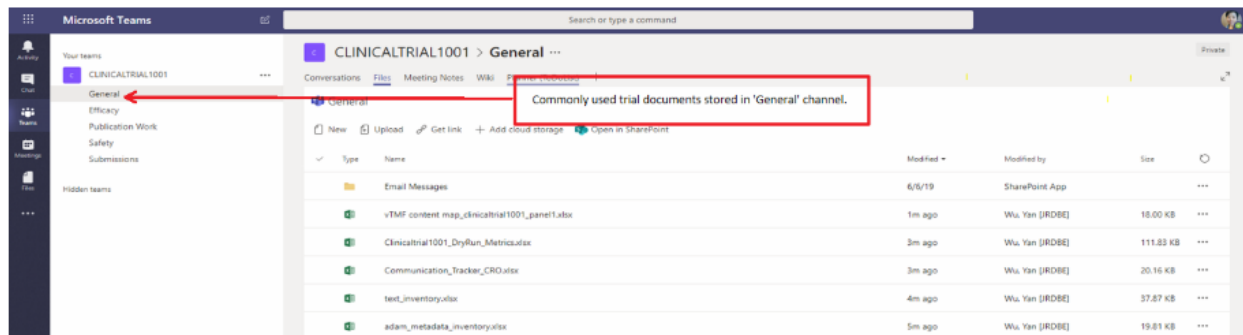


Figure 4.1a Channels can function as information repositories.

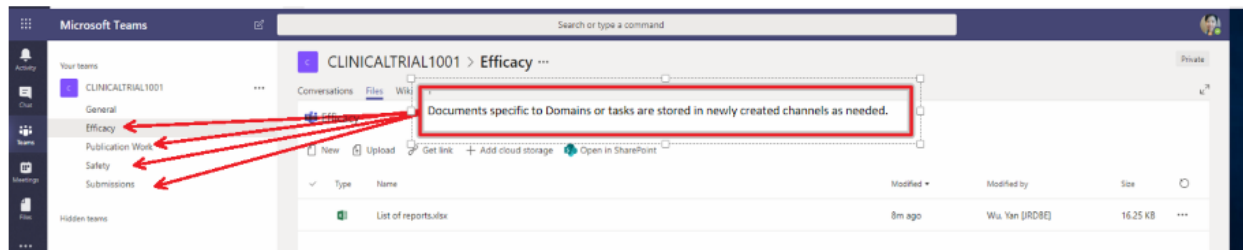


Figure 4.1b Channels can function as information repositories.

As a result, we can focus our attention on work-related topics and prioritize our time better. Instead of spending time going through an inbox that contains messages from everyone about everything, Teams compartmentalizes information into channels. The channel only contains conversations, meetings and documents related to the topic of that specific channel. So instead of getting side-tracked with random email, or get stuck trying to clean up our inbox, we can focus our valuable attention and spend our limited time on the channels where we actually do the work.

REAL TIME CO-AUTHORING DOCUMENT

We work and live in a world where sharing ideas and information can't always wait. In fact, a lot of real-time collaboration went into delivering this paper—weaving comments and contents by cross-functional teams located in different countries. At times, multiple people were in the document making changes at the same time. Thus, there are numerous common occurrences which expose this process as prone to error and far from efficient. For example:

- **Duplicated Effort** - Different people may make the same comments. Multiple people may write the same comment because they are unaware of others' comments or edits. Similarly, the lead author has to read all comments even if they are the same comment. Both these scenarios cost unnecessary time.
- **Time-consuming** - The lead author has to read, absorb and condense the comments of multiple contributors in order to create a second draft document. This is a tedious process which has to be repeated for every draft.
- **Non-traceable** - The onus is on the lead who creates the first draft to chase and follow up. Has the lead author's initial email been opened or read? Is the recipient dealing with the request? here is no transparency on where things are in the road to completion. This means uncertainty and longer times to document sign off.

Where deadlines are tight and you need quick feedback, email is not an ideal medium. In the rush to completion, things may get missed, versions of documents may get mixed up and formatting may go astray.

Whether document co-authoring is a substantial activity in your organization or not, there are significant benefits which MS teams offers over traditional means of collaboration.

- **Real-time co-authoring** - You and other users can work on the same document simultaneously making things much simpler and more efficient.
- **Identify Contributors** - Color coded identification of contributors makes it easy for you to identify who is making changes.
- **Control** - You can decide in advance who can be a document editor or once you get to a certain stage you can lock a version to ensure no further edits are made.
- **Mobility** - You can work at your desktop, on the train or from a client office. Your documents can be edited from any mobile device.
- **Shared Storage** - No problems access files for any contributors. Everything is stored in the cloud and you can be confident that the version you are working on is the latest one.
- **Transparency** - Shared storage and version control means that all contributors can see where you are in the process and who has to make the next contribution.
- **Flexibility** - You can prepare reports, or work on spreadsheets and presentations in the same way. In some situations, you may even decide that using a wiki is the most appropriate option.

Document co-authoring in MS teams can transform the way your organization works, leading to significant efficiencies and the production of much better documents.

DOCUMENT SHARING

Few documents, presentations, reports, spreadsheets, or projects are developed by just one person. At its core, document collaboration involves designated shared access to files for editing by groups of any size – be it two or 2,000. Usually a document initiator or owner manages revisions, but today's collaboration tools can simultaneously incorporate all contributors' edits and still maintain the integrity of prior revisions. Many platforms act as a central repository or holding area for the work of a group and can incorporate elements such as task and assignment lists, calendars, agendas, and feedback.

Document collaboration goals will vary for each organization, so before you choose a tool, define your needs. For example, a group building a social media campaign may require video, graphs, and pictures as part of brainstorming or mind mapping. By contrast, a technical build for software values document integrity through controlled revisions, so security and access may be more important. Consider your company's functions and needs when adopting a document collaboration solution.

There's a pretty good chance we will need to dig up some old document shared with a team months ago. Microsoft saves your back and backs up your files. Even if you delete a channel, files remained stored in a SharePoint site, so you didn't lose them. If you're currently working on an important document, you can add it into a separate tab to distinguish it from others. As we already mentioned, you can work on a file in real time without leaving a chat.

INTEGRATION WITH MICROSOFT RECURSE POOL

Another handy feature is that it integrates with other Microsoft and third-party services, including PowerPoint, OneNote, and SharePoint. Each team gets a SharePoint site collection and a group.

You can add third-party tools into your channels as TABS. Using Teams doesn't mean you need to give up on the other tools you normally use. For example, **you can add Trello and cloud storage platforms like Google Drive or Dropbox**. There are also many fun options like emoticons, gifs, and stickers. It may not sound like a big deal, but emoticons can truly lighten up your working day.

CHALLENGES

Learning curve. Needs a week or two to get comfortable.

Microsoft's new chat-based collaboration software has many rich features that enable teams to be more efficient and

save valuable time and resources. However, as with all software, there is a learning curve for new users and need to have a thorough understanding of how and when to use Teams versus other Office 365 applications, and they need to slowly shift their mindset to one that's Teams-first. Teams may appear to many as a chat platform with a quick onramp for new users, but Teams' ability to bring together multiple systems in one platform will need new users more time to get familiar and comfortable.

Needs clearly defined rules about role/usage within a team.

By default, Teams wants to keep everyone well informed about what's happening, for a very large team that could become overwhelming. Team owners can control what's allowed by members from the Teams settings.

It's key to think about your General Channel, all your members are favorited and will be notified by about any post that @mentions the channel. For other channels they get the choice, they can favorite and follow the channel if they are interested but can remove these if it's getting annoying.

Under Manage Team ... Settings ... Member permissions you can choose Only owners can post messages for the General channel. We would suggest making these owners only then adding the people that need to speak to the entire company as owners. We also recommend that these posts are @General, then all your members will receive a notification. They can't reply, so it's really a broadcast notification rather than anything collaborative, but if you keep your stories as SharePoint News in the associated Team Site and using Teams to post a link then people get the best of both worlds. For the same reason, under @mentions I would turn off Allow @team or @ [team name] mentions (this will send a notification to everyone on the team).

In fact, if you have any group less than 5000 members then Teams is a perfectly acceptable solution for notification and replace team distribution lists, check out whether Yammer is a better fit first, and plan how to avoid notification spam upsetting your members.

When MS Word documents are edited online, certain capabilities are not available. (e.g. formulae or certain macros in Excel).

When MS Word documents are edited online, the files get locked so that you cannot move it to another folder and some certain capabilities are not available. On the one hand, you do want SharePoint to lock a document because not everyone has the ability (or uses the right software) to do collaborative co-editing online. On the other hand, it's a pain that SharePoint keeps the lock in place and doesn't release it as quickly as you might like.

RECOMMENDATION

The most important aspect of clinical programming management is planning of resources and timing for delivering highest quality of work. This usually involves breaking down the work into smaller tasks that are assigned to different team members based on their strengths. The lead needs to create an effective plan that is practical and flexible enough to tweak depending upon unforeseen challenges. Next, there is a need of a platform to effectively assign the work, communicate the relevant specifications/documents/timelines and be able to monitor progress. As discussed in the paper, MS Teams provides a variety of tools and applications to make all this work easier.

Having said that, there are certain lessons we have learnt along the way that might prove to be useful for programming leads considering adopting MS Teams.

In general, users are reluctant to change working habits and try new things. It is worthwhile to take some time and present MS Teams as an alternative to some of the tools they have been used to working on for many years. MS Teams has some learning curve involved and some might find the interface initially to be non-intuitive. It is a good idea to give your team some basic training and time to familiarize themselves for a few days.

Well defined ground rules need to be laid out up-front for communication and collaboration within the team. It is strongly recommended that the lead comes up with a robust plan to use MS Teams judiciously along with taking up the role of a moderator to maintain the team site. Certain portions of communication (eg. A complex efficacy derivation with multiple rules, FDA submissions) could be assigned a dedicated channel. Work assignments could be distributed using Planner application within MS Teams. Working documents that are updated regularly by the team, preferably by the lead, could be hosted in MS Teams in accordance of compliance for trial documents. This would free up email for more important, study-specific correspondence. Meetings could be moved to MS Teams to take advantage of meeting notes feature.

The idea is to find the correct, balanced level of MS Teams integration into your project along with the more traditional tools to make it as efficient as possible.

Getting more cross functional teams on board is recommended to use MS teams more effectively. This will create a more seamless and less fractured platform.

CONCLUSION

Nowadays clinical trials have become more and more complex. The designs and procedures have been increasingly complicated. Working as a statistical programmer in the pharmaceutical industry comes along with working in a

rapidly changing environment. Frequently communicating with cross-functional teams, strict timelines, resource planning and sharing multiple documents are just some of the challenges clinical programming project management is currently facing. Such challenges have led to a new concern: how to collaborate effectively. The paper proposes an evolving idea in clinical programming project management – to use MS Teams as a chat-based collaboration tool to provide global, remote, and dispersed teams with the ability to work together and share information via a common space.

MS Teams is a powerful communication and collaboration tool. It brings together all your team members, their conversations and their content for a more productive way of working. And it is also fully integrated with many other Office 365 services, such as Skype, SharePoint, Exchange, and Yammer.

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