Trans NCI NCTN PMI Informatics Committee Meeting

March 20th, 2024

Meeting Agenda:

A. Roll Call
B. Project Updates
C. Open Discussion

Attendance

Group	Attended
Alliance	Yes
NRG	Yes
Nationwide	Yes
ECOG-ACRIN	Yes
COG	Yes
COG	Yes
CCTG	Yes
SWOG	Yes
MOCHA	Yes
MD Anderson	No

Action Items

Action Item	Owner
Identify a date to present the feedback survey findings to the PMI Committee	Chioma Ani
Reassignment workflow with 2 Scenarios: Integrations team to identify a date to present the upcoming changes to the PMI committee	Integrations Team
Add the information for how to suspend a protocol for interim analysis, and associated communication of numbers, to the user guide.	Leila Abraham

Meeting Notes:

1. Project Updates
   a. There were no new deliverables distributed by the PMI Integrations Team since our last meeting.
   b. There were no new EC Templates distributed by the PMI Project Team since our last meeting.
   c. The PMI Integrations team received feedback from a number of Groups on the Survey. The PMI Integrations team will bring this back to the PMI Committee and come up with action plan to move forward together [Action Item]
   d. Group UAT Status: Screening Protocol ALS v2.0 (Beta)
      i. Targeted completion date is 3.28.2024

2. ComboMATCH Priority Lists

Protocol #	Updates 3.20.2024
ComboMATCH Priority 1 Lists	
EAY 191	No updates
EAY 191-N4	No updates
EAY191-E4	No Updates
EAY191-N2	No updates
EAY191-S3	No updates
ComboMATCH Priority 2 Lists	
EAY191-A6	No Updates
EAY191-A3	Suspend Cohort 3
ComboMATCH Priority 3 Lists	
EAY 191-A2	DROPPED
EAY-191-C1	DROPPED
EAY191-E5	No updates
EAY191-N5	No updates

3. Questions: {Shauna Hillman}: *Is there any way for sites to see or get information on a suspension of a cohort? Should the Groups be sending out a notification on how this is communicated to the sites?*
      i. {Lyndsay Harris}: NCI Leadership is working with the PMI Integrations Team to brainstorm solutions to notify sites and clinicians when a protocol is suspended or close to the accrual. There is a known issue about physicians not knowing if cohort was closed while registering a patient on the MSRP.
      ii. {Mike Montello}: We will generate a daily report tracking accrual to date, by all the various factors, which arms are open, etc. and that will be posted on the CTSU website. We are looking into putting a link into OPEN that will take the site user directly to the report.
      iii. {Shauna Hillman}: Physicians do not put patients on the MSRP if they do not know what treatment trials are available. It is important to make it more visible to the sites. From a patient perspective, it would be nice to have a communication process.
   b. {Shauna Hillman}: Our Team Ended up suspending the cohort [Cohort 3] in RSS, by changing the status. {Shuana Hillman} *Should we be updating the status or the target accrual number? Should the target number set be based on the interim analysis?*
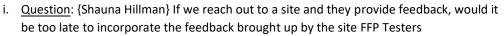
     i. {Matt Smith}: MATCHBox will make assignments as long as there are slots available on the cohort/strata. That is controlled by the number in the RSS protocol application. The algorithm considers the status and number. The intent in this particular case, if you needed to pause enrollment at a particular number, then yes set that number in the protocol app, at that point MATCHBox will not assign anymore patients beyond that. MATCHbox considers the number of assignments that are pending. If the stop number was 60, 11 patients enrolled, 5 patients that are pending and 1 does not want to enroll, this means there are no slot available, and MATCHBox will not assign. If the patient does not enroll, after the 21-day window, MATCHbox will enroll in that open slot.

     ii. {Mike Montello} Agreed that the ideal situation would be to the final target and initial interim analysis. Some of the treatment protocols have that language written in. Ensure that this is the same across all protocols

     iii. **Recommendation**: {Shauna Hillman} Add the information for how to suspend a protocol for interim analysis, and associated communication of numbers, to the user guide. <mark>[Action Item]</mark>

4. MyeloMATCH Protocol Updates

Protocol #	Status 3.20.24
MyeloMATCH Priority 1 List	
MYELOMATCH	Pending FFP; having trouble getting a volunteer for testing. If we do not identify someone soon, leadership recommends we use an internal person instead to keep things going
MM1YA-S01	Halfway through integration testing, have a few bugs that are being worked through
MM1YA- CTG01	Working on integration testing. Received extra test patients, Put in a request with CTSU for a fix. Have identified sites for FFP testing
MM1OA- EA02	Working on integration testing, hoping to complete in the next few days. Reached out to sites for FFP testing, waiting on the sites to get back to us.
MyeloMATCH Priority 2 List	
MM2YA-EA01	No updates
MM1OA-S02	No updates
MM1MD2- EA03	Withdrawn

5. MM Testing Update Discussion
    a. Certain groups having issues with recruiting sites to FFP testing.
      i. Leadership decision: If absolutely no-one from the site can be identified soon to contribute to FFP testing, have the groups to stand-in as a site user in order to not delay the FFP effort
      ii. {Dani Weatherbee} Recommended using testers from the stat center to support FFP testing if no site volunteers.
        1. {Rich Little} In support off that idea to help minimize any delays
      iii. FFP targeted to begin week of 3/25/24. All groups working on timing and hoping to confirm soon.
        1. <u>Note</u>: {Leila Abraham} Groups MUST complete integration testing with no outstanding issues before FFP testing begins for the Group
    b. User Feedback from FFP testing: Their feedback would be valuable

      i. <u>Question</u>: {Shauna Hillman} If we reach out to a site and they provide feedback, would it be too late to incorporate the feedback brought up by the site FFP Testers

      ii. <u>Response</u>: {Neesha Desai} Depends on the complexity of the issue or recommendation. If it is a showstopper, then can be handled asap. If it is not a showstopper for activation, we can track for future updates, if required.

      iii. For ComboMATCH FFP: The integrations team did not receive any showstopper feedback at that time. Some minor recommendations including descriptive text

6. <u>OPEN Discussion</u>
   a. Question: {Melinda Flood} Is there a defined process for MRD results being returned to sites or to the stats and study chair?
      i. {Rich Little} Results are sent back to the sites. It should be entered in the same way they would do the standard approach and enter it in.
   b. Question: {Shauna Hillman} Updates on EC Workflow for Reassignment:
      i. Response: {Matt Smith} Hoping to have conversations with ECOG to roll out the updates to their UAT soon including the 2 initial use-cases
         1. 3rd requested use-case for reassignment after slot expires would require an amendment to the protocol and is not currently planned.
         2. Once base workflow is implemented, additional updates can be made to add other use cases
      ii. **Requested**: {Shauna Hillman} Demo to the PMI Committee on Reassignment workflow [Action Item]
         1. {Rich Little} Difference for the reassignment flow between MM and CM. For MM it would have the TAP assignment button.

7. <u>Meeting Closeout</u>
   a. Meeting completed. Notes to be distributed.