

## Trans NCI NCTN PMI Informatics Committee Meeting

March 20<sup>th</sup>, 2024

### Meeting Agenda:

- A. Roll Call
- B. Project Updates
- C. PMI Committee Call Process Updates
- D. Reassignment Workflow- Demo
- E. 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
For the Reassignment workflow- determine where documentation needs to be updated to include the reassignment process, along with screenshots for completing a reassignment	Leila Abraham
For the Reassignment workflow- Review with protocol team to note if a "Slot expired" option would require a protocol amendment	Dani Weatherbee

## 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.

### 2. ComboMATCH Priority Lists

<b>Protocol #</b>	<b>Updates 4.3.2024</b>
<b>ComboMATCH Priority 1 Lists</b>	
EAY 191	No updates
EAY 191-N4	No updates
EAY191-E4	Suspended at this time. No timeframe for suspension
EAY191-N2	Amendment approved. Question on ineligibility will be released on 4/15
EAY191-S3	No updates
<b>ComboMATCH Priority 2 Lists</b>	
EAY191-A6	Going through the process of getting IDs into Open to work on ECs
EAY191-A3	Suspended
<b>ComboMATCH Priority 3 Lists</b>	
EAY 191-A2	DROPPED
EAY-191-C1	DROPPED
EAY191-E5	No updates
EAY191-N5	No updates

### 3. MyeloMATCH Protocol Updates

<b>Protocol #</b>	<b>Updates 4.3.24</b>
<b>MyeloMATCH Priority 1 List</b>	
MYELOMATCH	Going through FFP almost complete. No additional items to complete before activation
MM1YA-S01	Going through FFP, almost completed. Email template messages being reviewed by team member, feedback upcoming on the email templates
MM1YA- CTG01	Working on integration. Still having issue with withdrawal of consent and end of treatment communication issues
MM10A- EA02	FFP is completed. Finalizing Rave Build, working on validation. OPEN setup is done and a success.
<b>MyeloMATCH Priority 2 List</b>	
MM2YA-EA01	No updates
MM10A-S02	No updates. Will pickup build now that FFP is done for SO1. Expected to take about 1 month before integration testing
MM1MD2- EA03	Withdrawn

### 4. PMI Committee Meeting Process Updates

- a. Official Meeting minutes being documented and posted on the PMI Committee Wiki page
  - b. New section added to the Wiki page with the meeting minute and recording
5. Action Items follow up from 3.20.24 Meeting
- a. Stakeholder Feedback that was presented, Integrations team is reviewing it and planning to present to PMI Committee at the 5/24 meeting
  - b. Reassignment workflow with 2 scenarios
    - i. Item to be reviewed today during the call.
    - ii. Demo to include the currently developed items
  - c. Request to add information for how to suspend a protocol to the User guide
    - i. This item will be updated to the RSS user guide by 5/15/24
6. Reassignment Workflow Demo
- a. Workflow scenarios currently implemented:
    - i. Participant is ineligible for the assigned treatment protocol
    - ii. Protocol assigned to the patient is not open at the site
    - iii. If either of the 2 are selected assignment should be regenerated excluding the initially selected assignment
    - iv. This feature is currently available in OPEN UAT
  - b. Any requested enhancements for this feature can be submitted. It will be reviewed by the Integrations team and Leadership before moving forward for implementation.
    - i. Planned implementation: Add a “TAP Assignment button” for MyeloMATCH
  - c. Demo Reviewed the OPEN page and details available regarding assignments. Then walked through clicking the “Request Reassignment” and reviewed what occurs upon clicking the button. Matchbox sent back a new assignment for the participant
  - d. Demo Questions:
    - i. {Shauna Hillman}: What page are you on, where exactly in OPEN?
      - 1. [Leila Abraham] I am in the History tab in OPEN. Under the screening enrollment that I'm requesting reassignment for.
    - ii. [Dani Weatherbee]: Is the plan to do this for ComboMATCH first and then in MyeloMATCH after activation?
      - 1. In OPEN, it is currently available for both ComboMATCH and MYELOMATCH
      - 2. In MATCHBox, it is available in ComboMATCH, but is ready for testing in MYELOMATCH and could be included in activation if tested before-hand
    - iii. [Shauna Hillman]: This process should probably include an “Other” option in the options to capture other weird issues that may occur.
      - 1. OTHER option not currently included, but would require additional discussion
      - 2. [Umit Topaloglu]: Currently avoiding the generic usage of the word “other”
      - 3. [Shauna Hillman]: Can have some details to capture what the rationale is for the “other” option. For example, if the person is out of window would require a different process.
      - 4. [Mike Montello]: Using other, could require specification of what the other is referring to with an additional field. Suggestion: Start small, create a picklist, evaluate and flesh out additions based on feedback from the team.
      - 5. [Umit Topaloglu]: Agreed. Please follow up with the Intergrations team to send any additional recommended language.
      - 6. Discussion about the timeline for extending the timeframe for enrollment out to 5 weeks. Team confirmed that extension was activated on March 27<sup>th</sup>
      - 7. [Rich Little]: Asked a question if the patient could request reassignment as a way to “extend” the enrollment time and get enrolled in the same protocol they were previously assigned to.

8. [Matt Smith]: No, that would not be an option because reassignment would exclude any previously assigned protocols. There is no way for extension. This option was reviewed, and the understanding was that it would need a protocol amendment to be done.
  9. [Dani Weatherbee]: Yes, that is correct based on our previous discussion. If this is something worth reviewing, we can follow up with the protocol department and see if this edit can be made
    - a. Summary: Dani Weatherbee to take back the slot expiration item back to the protocol team. Will bring back additional feedback to the next Committee meeting. {Action Item}
  - iv. [Melinda Flood]: Can the patient request reassignment more than once? Answer is no. Demo reviewed the popup message displayed for a participant who has been reassigned indicating that they cannot request reassignment again.
  - v. [Shauna Hillman]: Is there going to be a user guide for this reassignment process
    1. [Leila Abraham]: The team would review including the information for the reassignment process in already existing documentation, including screenshots. {Action Item}
  - vi. Participant can only request reassignment once
  - vii. [Allision Booth] Where is the reassignment information history captured? Is there somewhere you can see this information? Is it overwritten on their protocol assignment form
    1. [Kasi Perumal]: The treatment assignment is overwritten on the form in OPEN, but OPEN does have the historical information. The system has a record, but it's currently not displayed. It could be displayed if that is needed.
7. OPEN Discussion
- a. [Melinda Flood]: BETA PMI Screening Protocol ALS 2.0. Has it been released?
    - i. [Neesha Desai]: Was released in January, posted on the wiki. Priority was given to the testing for MM Activation so no current rush on this item at this time.
  - b. [Dani Weatherbee]: What are specifications for the performance status date:
    - i. [Rich Little]: The critical performance status value comes in for the master screening and reassessment protocol as part of their initial data analysis. The data should be entered immediately as part of the data needed for treatment assignment.
    - ii. [Dani Weatherbee]: Sometimes the visit is not in the same day as the enrollment. Is there a cutoff for the
    - iii. [Rich Little] It could have been done at any time prior, but it needs to be entered at the same time they send out their laboratory assays. There is no specific time prior, as long as the entry is done at the same time.
8. Meeting Closeout
- a. Meeting completed. Notes to be posted to Wiki page.