










Precision Medicine Initiative (PMI) Committee Meeting

May 18, 2023

Stakeholder Representation

	Alliance		ECOG-ACRIN		CCTG
	NRG		COG		SWOG
	Nationwide		MD Anderson		MOCHA

Agenda

- Roll Call
- Review Stratification Options

MYELOMATCH: STRATIFICATION OPTIONS

May 18, 2023
MYELOMATCH IT and Steering Committee Meeting

Options for Sending Stratifications

OPTION 1: Send Stratification Factors Manually

- MATCHBox sends stratification factors manually

OPTION 2: MATCHBox assigns to stratum

- MATCHBox assigns down to stratum splitting strat factors (different from ComboMATCH concatenated)

OPTION 3: Utilize OPEN EC

- Approach 1: No Validations
- Approach 2: Validations
- Approach 3: Use Group's Randonode
- Approach 4: Preloaded Responses

Option 1: Send Stratification Factors Manually

- **Description:** MATCHBox assigns only to the protocol level and passes on the stratification factors to the group that owns the protocol.
- **Approaches:**
 - Collect Stratification factors and send via a secure encrypted email or a TBD method. Manual activity completed by the Bioinformatics team. Will coincide with treatment assignment approval.
 - Upload Stratification factors to a document store or a location of choice
 - MATCHBox can develop an end point through which the groups can pull this data and push this data to the groups.
 - Notifications can be sent to inform that the stratification factors were uploaded.

MATCHBOX REQUIREMENT - The final stratification for each patient needs to be reported back to MATCHBox by OPEN when sending the treatment protocol enrollment message to perform analytics and generate correlative reports by downstream systems.

Not optimal for Groups based on discussions earlier this week.

Option 2: MATCHBox assigns to stratum

- **Description:** MATCHBox assigns down to stratum splitting strat factors
 - This approach is different from ComboMATCH which is concatenated

Not optimal for Groups based on discussions earlier this week.

Option 3: Approaches: Utilize OPEN EC

Approach A

Use OPEN EC Form with no validations

- Stratification factors are questions on the OPEN enrollment EC form for sites to complete
- No validations checking against information in MATCHBox
- All validations handled by the group.

Approach B

Use OPEN EC Form with Validations

- Stratification factors are questions on the OPEN enrollment EC form for sites to complete
- Validation check in OPEN that checks the responses to the stratification questions against the Assignment Reason returned from MATCHBox.

Approach C

Use Groups Randonode

- Stratification factors would not be on the OPEN enrollment EC form.
- Once the patient has been assigned a treatment trial by MATCHBox the group can pull the assignment reason information from OPEN via a web service call.
- The stratification would then take place via the group's randonode on the backend.

Approach D

Use OPEN EC Form with Pre-Populated Responses

- The stratification factors would be questions on the OPEN enrollment EC form but responses would be pre-loaded in OPEN from MATCHBox.

Option 3A: Use OPEN EC Form **With No** Validations

■ Pros

- No additional development work for NCI
- Approach is familiar to some of the Groups
- No impact to timelines

■ Cons

- Could not validate responses for stratification questions against MATCHBox
- Risk for user error, a user can enter in a response that may not be consistent with information in MATCHBox.
- For stratification factors, such as lab results, there would need to be a process or mechanism in place to get this information to the enrolling site so they can answer the stratification question at the time of enrollment.

■ Potential Impacts to Groups

- Groups would manage CDE curation for stratification questions
- Groups would manage any kind of validation regarding stratification either through the randonode or through edit checks in OPEN.

Approach A Use OPEN EC Form with no validations

- Stratification factors are questions on the OPEN enrollment EC form for sites to complete
- No validations checking against information in MATCHBox
- All validations handled by the group.

Option 3B: Use OPEN EC Form **With** Validations

■ **Pros**

- There will be a validation with information in MATCHBox
- Minimize User Error

■ **Cons**

- Will require development work to create this validation.
- Stratification factors would need to be included in the assignment reason information returned back to OPEN

■ **Potential Impacts to Groups**

- Groups would manage CDE curation for stratification questions.

Approach B Use OPEN EC Form with Validations

- Stratification factors are questions on the OPEN enrollment EC form for sites to complete
- Validation check in OPEN that checks the responses to the stratification questions against the Assignment Reason returned from MATCHBox.

Option 3C: Use Groups Randonode

■ Pros

- No potential for user error
- Does not require user entry
- Limited development work : Use the existing OPEN web service

■ Cons

- Stratification information would need to be included in the assignment reason information returned back
- Additional development effort for Groups to call the web service and integration into their database to use for randomization.

■ Potential Impacts to Groups

- Groups would have to configure their randonode to use the stratification information received from the web service.
- Groups would have to make updates to their randonode to be able to retrieve the stratification information from the web service.

Approach C Use Groups Randonode

- Stratification factors would not be on the OPEN enrollment EC form.
- Once the patient has been assigned a treatment trial by MATCHBox the group can pull the assignment reason information from OPEN via a web service call.
- The stratification would then take place via the group's randonode on the backend.

Option 3D: Use OPEN EC Form with Pre-Populated Responses

- **Pros**
 - Minimizes user error and data entry
- **Cons**
 - Requires development work for every treatment trial
 - Impact to timelines for treatment study activations
 - Groups cannot allow the user to change the response
- **Potential Impacts to Groups**
 - Groups would manage CDE curation for stratification questions

Approach D Use OPEN EC Form with Pre-Populated Responses

- The stratification factors would be questions on the OPEN enrollment EC form but responses would be pre-loaded in OPEN from MATCHBox.

Group Consensus

Group	Option 1:	Option 2:	Option 3: Utilize OPEN EC			
	Send Stratification Factors Manually	MATCHBox assigns to stratum	Approach A Use OPEN EC Form with no validations	Approach B Use OPEN EC Form with Validations	Approach C Use Groups' Randonode	Approach D Use OPEN EC Form with Pre-Populated Responses
SWOG				X		
Alliance				X		
ECOG-ACRIN				X		
CCTG				X		X (Ideal)
NRG				X		
COG				X		

Next Steps

Next Steps

- Next meeting will be on 5/31/2023 at 1:00pm EST
- Agenda
 - Role Call
 - Project Status Update
 - Group Status Update
 - Review FAQs

 - Future Demos/Workflows

Communication

- Contact PMI Mailbox for any PMI related questions
 - pmistandards@nih.gov
 - The project team will respond within 48 hours with a response or a follow up
- PMI Wiki
 - <https://wiki.nci.nih.gov/display/CDISC/Precision+Medicine+Initiative>
 - All presentations, recordings, minutes, project documents and releases will be posted on this wiki