Precision Medicine Initiative (PMI) Committee Meeting

January 11, 2023

Agenda

- Role Call
- Project Status Updates
- PMI Test Plan
- Group Project Status Updates
- Review FAQs
- Open Discussion
- Next Steps

Stakeholder Representation

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

Project Status Updates

Project Updates

- Beta PMI Central Study Updates
  - The Beta PMI Central Study patch ALS v1.0.1.0 includes changes relevant to the Practice environment.
  - Custom Functions (CFs) modified to:
    - Remove ‘(T)’ from Subject ID in the Payload for Practice mode
    - Include ‘practice’ in the payload to redirect transactions to the practice environment in MATCHbox for Screening Protocol forms ‘PMI CDISC Off Study Standard Form’ and ‘PMI CDISC Consent Withdrawal Standard Form’, and Treatment Protocol Forms ‘PMI CDISC Off Treatment Standard Form’ and ‘PMI CDISC Consent Withdrawal Standard Form’

Project Updates

- PMI CDISC Screening Protocol EC Template Updates
  - ***Screening Protocol & Drug & Disease Service Module 2*** updated to contain only 1 CDE repeated 20 times
  - ***Prior therapy name*** CDE (20 repetitions) remains unchanged
  - ***Prior therapy code*** CDE (all 20 repetitions) removed
  - ***Prior therapy code type*** CDE (all 20 repetitions) removed

Project Updates

UPDATED PMI EC Template Screening Protocol Drug & Disease Service Module 2

	10984702	1.00	5	Screening Protocol Drug & Disease Service Module 2	0	PRTHRPNM_1	Prior therapy name
	10984702	1.00	5	Screening Protocol Drug & Disease Service Module 2	1	PRTHRPNM_2	Prior therapy name
	10984702	1.00	5	Screening Protocol Drug & Disease Service Module 2	2	PRTHRPNM_3	Prior therapy name
	10984702	1.00	5	Screening Protocol Drug & Disease Service Module 2	3	PRTHRPNM_4	Prior therapy name
	10984702	1.00	5	Screening Protocol Drug & Disease Service Module 2	4	PRTHRPNM_5	Prior therapy name
	10984702	1.00	5	Screening Protocol Drug & Disease Service Module 2	5	PRTHRPNM_6	Prior therapy name
	10984702	1.00	5	Screening Protocol Drug & Disease Service Module 2	6	PRTHRPNM_7	Prior therapy name
	10984702	1.00	5	Screening Protocol Drug & Disease Service Module 2	7	PRTHRPNM_8	Prior therapy name
	10984702	1.00	5	Screening Protocol Drug & Disease Service Module 2	8	PRTHRPNM_9	Prior therapy name
	10984702	1.00	5	Screening Protocol Drug & Disease Service Module 2	9	PRTHRPNM_10	Prior therapy name
	10984702	1.00	5	Screening Protocol Drug & Disease Service Module 2	10	PRTHRPNM_11	Prior therapy name
	10984702	1.00	5	Screening Protocol Drug & Disease Service Module 2	11	PRTHRPNM_12	Prior therapy name
	10984702	1.00	5	Screening Protocol Drug & Disease Service Module 2	12	PRTHRPNM_13	Prior therapy name
	10984702	1.00	5	Screening Protocol Drug & Disease Service Module 2	13	PRTHRPNM_14	Prior therapy name
	10984702	1.00	5	Screening Protocol Drug & Disease Service Module 2	14	PRTHRPNM_15	Prior therapy name
	10984702	1.00	5	Screening Protocol Drug & Disease Service Module 2	15	PRTHRPNM_16	Prior therapy name
	10984702	1.00	5	Screening Protocol Drug & Disease Service Module 2	16	PRTHRPNM_17	Prior therapy name
	10984702	1.00	5	Screening Protocol Drug & Disease Service Module 2	17	PRTHRPNM_18	Prior therapy name
	10984702	1.00	5	Screening Protocol Drug & Disease Service Module 2	18	PRTHRPNM_19	Prior therapy name
	10984702	1.00	5	Screening Protocol Drug & Disease Service Module 2	19	PRTHRPNM_20	Prior therapy name

Project Updates

- Beta PMI CDISC Eligibility Checklist Template Fact Sheet v1.1 Updates
  - ***PMI Screening Protocol CDE Requirements*** table updated for ***"Screening Protocol Drug & Disease Service Module 2"*** changes
    - ***Prior therapy code*** CDE removed
    - ***Prior therapy code type*** CDE removed
    - Notes updated to reflect these removals
  - ***PMI Screening Protocol CDE Requirements*** table & ***PMI Treatment Protocol CDE Requirements*** table updated for OPEN details
    - New column for OPEN Widget Type added
    - OPEN Widget Type specified for each field/CDE
  - Fact Sheet Version updated to v1.1

Project Updates

UPDATED Beta PMI CDISC Eligibility Checklist Template Fact Sheet v1.1

Drug & Disease Service Module 2 (drug): this field supports the PMI Drug Service integration.					
10984702	Prior therapy name	Req.	Req.	Type Ahead List	This field will be populated with pharmacological substance/drug details per the NCI Thesaurus. Twenty occurrences of this CDE are specified in the PMI CDISC EC Template.

IV. CDE Requirements for PMI Treatment Protocol EC Forms/Worksheets (caDSR II Form PID 12130477):

PMI Treatment Protocol CDE Requirements					
PMI EC CDE PID	**PMI EC QT/Prompt**	**Combo MATCH**	**Myelo MATCH**	**OPEN Widget Type**	**Notes**
Treatment Protocol Module 1					
6380045	Screening protocol ID	Req.	Req.	Edit Box	These fields will be (1) validated against the data on the CTSU Demography Standard Form, (2) are required for successful transactions for the PMI CDISC Off Treatment (OT) and PMI CDISC Consent Withdrawal (CW) Forms, and (3) used to validate
6380049	Screening participant ID	Req.	Req.	Edit Box	

Project Updates

- Use Cases
  - Assignment has been made → Patient has enrolled and not started treatment → Patient is Off Treatment, and a reassignment will happen
  - Assignment has been made → Patient has enrolled and started treatment → Protocol Violation → CTEP reviews violation → Patient is reassigned
  - Bad Data → No rollback needed for Group Systems

PMI Testing Plan

PMI Beta Screening Protocol Group Testing Plan Reminders

- Expectations:
  - Use the 'Screening Protocol Group Testing Plan' to test the Screening and Treatment protocols as part of UAT activities
  - Complete the 'Group' designated tasks
- Includes:
  - Multiple testing scenarios
  - Tasks associated with each testing scenario
  - Contact information for MATCHBox staff and Westat

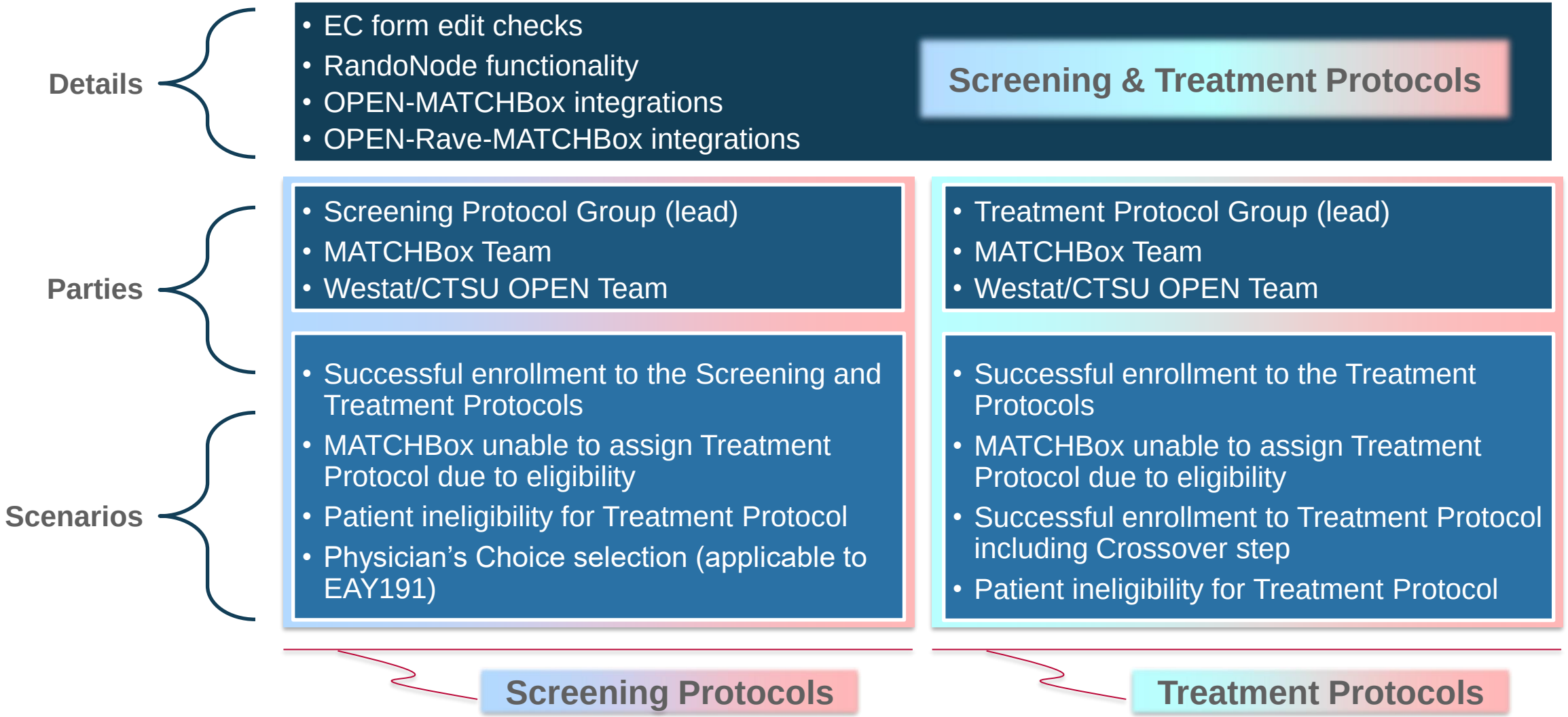
PMI Beta Screening Group Testing Plan Activities				
Scenario #1: Successful Enrollment to Screening and Treatment				
Task #	**User**	**Task Description**	**Notes**	**Pass/Fail**
1	**Group**	Complete multiple Step 1 enrollments to Screening protocol	Group user(s) would test the screening protocol EC form using test script provided. Screening EC form testing of: 1. Proper working of edit checks 2. Proper working of randonode 3. Ensure OPEN/PMI integrations are working.	☐ Pass ☐ Fail
2	**Group**	Fifteen minutes after step 1 enrollments are completed, upload Path and CLIA reports in OPEN.	CLIA reports not required for MyeloMATCH	☐ Pass ☐ Fail
3	**Group**	Send all screening PIDs to MATCHBox staff and the CTSU OPEN team	Include the Protocol and Scenario number in the subject line CTSU OPEN Team: CTSUOPENFORMS@westat.com ComboMATCH Staff: combo-match-support@nih.gov MyeloMATCH Staff: myelo-match-support@nih.gov	
4	**MATCHBox Staff**	Tx protocol assignments are generated and confirmation sent to the group	MATCHBox staff should reply back to group's initial email for confirmation.	☐ Pass ☐ Fail
5	**Group**	Confirm the Tx protocol assignments are displaying in OPEN and Rave	Assignments are displayed in the following screens: 1. OPEN Summary screen 2. OPEN enrollment confirmation screen 3. Step Information Form (in Rave) 4. Treatment Assignment Form (in Rave)	☐ Pass ☐ Fail
6	**Group**	Enroll test patients to the your Tx protocol (step 1) in OPEN	Group user(s) would test the Tx protocol EC form. EC form testing of: 1. Proper working of edit checks 2. Proper working of randonode 3. Ensure OPEN/PMI integrations are working	☐ Pass ☐ Fail

PMI Beta Treatment Protocol Group Testing Plan Reminders

- Expectations:
  - Use the 'Treatment Protocol Group Testing Plan' to test the Treatment protocols as part of UAT activities
  - Complete the 'Group' designated tasks
- Includes:
  - Multiple testing scenarios
  - Tasks associated with each testing scenario
  - Contact information for MATCHBox staff and Westat

PMI Beta Treatment Group Testing Plan Activities				
Testing Set Up: Creating Test patients in the Screening Protocol				
Task #	**User**	**Task Description**	**Notes**	**Pass/Fail**
1	**CTSU OPEN Team**	Complete multiple Step 1 enrollments to the Screening protocol	Task should be completed once Tx protocl EC form has been downloaded to OPEN UAT. OPEN team would use teste script to trigger assignment to Tx protocol the group is testing.	☐ Pass ☐ Fail
2	**CTSU OPEN Team**	Fifteen minutes after step 1 enrollments are completed, upload Path and CLIA reports in OPEN.		☐ Pass ☐ Fail
3	**CTSU OPEN Team**	Send all screening PIDs to MATCHBox staff	ComboMATCH Staff: combo-match-support@nih.gov MyeloMATCH Staff: myelo-match-support@nih.gov	
4	**MATCHBox Staff**	Generate Tx protocol assignment and send notification to the OPEN team	CTSU OPEN Team: CTSUOPENFORMS@westat.com	☐ Pass ☐ Fail
5	**CTSU OPEN Team**	Confirm Tx protocol assignment is displayed in OPEN and send screening protocol PIDs to the group	In addition to the Screening protocol ID numbers notification should include: Cohort and stratum assignment for each test patient	☐ Pass ☐ Fail
Scenario #1: Successful Enrollment to Screening and Treatment				
Task #	**User**	**Task Description**	**Notes**	**Pass/Fail**
1	**Group**	Enroll test patients to the Tx protocol in OPEN	Group user(s) would test the Tx protocol EC form. EC form testing of: 1. Proper working of edit checks 2. Proper working of randonode 3. Ensure OPEN/PMI integrations are working.	☐ Pass ☐ Fail
2	**Group**	Send Tx protocol PIDs to the OPEN Team and MATCHBox staff	Include the Protocol and Scenario number in the subject line Include Screening protocol PIDs in notification Westat: CTSUOPENFORMS@westat.com ComboMATCH Staff: combo-match-support@nih.gov MyeloMATCH Staff: myelo-match-support@nih.gov	

PMI Beta Group Testing Plan Overview



Group Project Status Updates

ECOG-ACRIN

EC Template Build			Beta Central Study ALS		Beta Screening Protocol ALS		Beta Treatment Protocol ALS		Screening/Treatment Group Testing Plan		
caDSR II	EC Build in Rave	Target Completion Date	Completed Upload	Target Completion Date	Completed Upload	Target Completion Date	Completed Upload	Target Completion Date	Initiated Beta UAT	Group Testing scenarios	Target Completion Date
Screening (Y) Treatment (N)	Yes pending new updates	1/20/2023	V1.0 – Completed V1.0.1.0 - Pending	1/20/2023	Completed in Sandbox	1/13/2023	Completed in Sandbox	1/18/2023			

1/11/2023:

- *Need direction on how best to update the Central Study and update custom functions. Westat will be providing a ReadMe document with instructions. Westat is targeting to send this out by 1/12/2023.*
- *Successfully performing registrations on screening study.*

SWOG

EC Template Build			Beta Central Study ALS		Beta Screening Protocol ALS		Beta Treatment Protocol ALS		Screening/Treatment Group Testing Plan		
caDSR II	EC Build in Rave	Target Completion Date	Completed Upload	Target Completion Date	Completed Upload	Target Completion Date	Completed Upload	Target Completion Date	Initiated Beta UAT	Group Testing scenarios	Target Completion Date
Screening (Y) Treatment (Y)	Yes pending new updates	1/20/2023	V1.0 – Completed V1.0.1.0 - Pending	1/20/2023	50% done, needs additional work	1/20/2023	Completed for Combo MM - Pending	Combo Ready for testing MM - TBD			

1/11/2023 – Need list of final Off Study Lists, as well as Off Treatment Reasons

NRG

EC Template Build			Beta Central Study ALS		Beta Screening Protocol ALS		Beta Treatment Protocol ALS		Screening/Treatment Group Testing Plan		
caDSR II	EC Build in Rave	Target Completion Date	Completed Upload	Target Completion Date	Completed Upload	Target Completion Date	Completed Upload	Target Completion Date	Initiated Beta UAT	Group Testing scenarios	Target Completion Date
					N/A	N/A					

1/11/2023:

- *Will provide update offline*

Alliance

EC Template Build			Beta Central Study ALS		Beta Screening Protocol ALS		Beta Treatment Protocol ALS		Screening/Treatment Group Testing Plan		
caDSR II	EC Build in Rave	Target Completion Date	Completed Upload	Target Completion Date	Completed Upload	Target Completion Date	Completed Upload	Target Completion Date	Initiated Beta UAT	Group Testing scenarios	Target Completion Date
In Progress	In Progress	TBD	V1.0 – Completed V1.0.1.0 - Pending		N/A	N/A	Completed				

1/11/2023:

- *Need to do additional work to build the EC Template in Rave, need to build an integration in Rave*

CCTG

EC Template Build			Beta Central Study ALS		Beta Screening Protocol ALS		Beta Treatment Protocol ALS		Screening/Treatment Group Testing Plan		
caDSR II	EC Build in Rave	Target Completion Date	Completed Upload	Target Completion Date	Completed Upload	Target Completion Date	Completed Upload	Target Completion Date	Initiated Beta UAT	Group Testing scenarios	Target Completion Date
Completed	Completed	1/10/2023	V1.0 – Completed V1.0.1.0 - Pending	1/20/2023	N/A	N/A	Complete	Ready for testing			

1/11/2023:

- *None*

COG

EC Template Build			Beta Central Study ALS		Beta Screening Protocol ALS		Beta Treatment Protocol ALS		Screening/Treatment Group Testing Plan		
caDSR II	EC Build in Rave	Target Completion Date	Completed Upload	Target Completion Date	Completed Upload	Target Completion Date	Completed Upload	Target Completion Date	Initiated Beta UAT	Group Testing scenarios	Target Completion Date
			Feb/March		Feb	N/A	N/A		Feb		

1/11/2023:

- *Waiting on schema and protocol review from CTEP*

Review FAQs

PMI Committee Questions

Question	Response
Is there language that we should include in protocols regarding the helpdesk?	ComboMATCH URL: https://service.cancer.gov/ComboMATCH Email: combo-match-support@nih.gov MyeloMATCH URL: https://service.cancer.gov/MyeloMATCH Email: myelo-match-support@nih.gov
The OIDs should be abbreviations of the form, rather than the entire form name all spelled out.	Westat can change the Form OID in Rave once they have the ALS from caDSR. Moving forward for PMI forms, the Form OIDs will be abbreviated. Current ones will not be changed.
What roles does CTSU use to upload the Central Study ALS?	Going forward Central Study xGlobal CFs-Matchbox will be used for PMI trials, and if it is created in iMedidata it will allow you to invite users and restrict access for PMI central study via iMedidata.

PMI Committee Questions

Question	Response
What's the quickest way to get a form builder account for caDSR II?	Contact caDSR.RA@mail.nih.gov. Everyone that had a legacy caDSR Form Builder account has one in the caDSR II. Groups will need to work with the NCI CBIIT team to ensure they can sign on and submit curation requests if needed.
Where (what folder) does this EC template need to be in? Can it be in the Enrollment Folder with the other enrollment forms (Demography, Step Information, and Treatment Assignment)?	The EC template can be placed in the Enrollment Folder.
Is timing being considered and assessed? Is there too much time between elapsing and enrolling a test case? Time period is 21 days, may need to look into shortening testing time.	This solution only applies to ComboMATCH. Slot expiration time is configurable and has been changed to expire after 7 days for testing. Also, this can be easily changed to increase or decrease depending on what the Group wants.

PMI Committee Questions

Question	Response
For the ineligible status, is there a new field to use to ensure proper set up?	This test case is now optional.
What is the max number of steps to build into Combo-MATCH. Has this been determined already?	NCI is still currently working on reregistration requirements.
What is the Rave EC Checklist Form OID?	The Group specific Rave EC Checklist Form OID is study specific and is determined by the caDSR II Form Build activities. Use the caDSR II Form Long Name of the Form (all capital letters, spaces replaced with "_") for the Rave Form OID.

PMI Committee Questions

Question	Response
How will the screening ID, cohort, and stratum fields be validated on the treatment trial OPEN forms to ensure the correct responses were entered? Will these be auto-filled on the form in some way or will there be an edit check that needs to be configured for these fields?	Configured group look up windows based on the screening patient ID that was entered. Group lookup will only display the cohort and stratum assigned to patient at screening. Site user would click on group lookup and click on cohort, will only show 1 cohort and stratum for the patient. Westat advises make the field non editable and FACT sheet will provide instructions. For crossover – Step 2. In OPEN they would need to create a step 2 enrollment or enter patient ID of step 1 of treatment protocol.
Can you confirm that we can use our standard patient IDs for the treatment trial or if we are expected to use a different format?	Groups allowed to use any format if they stay within the character length.
What fields on the EC Template are expected to be populated in Rave?	Groups are expected to populate the • *Screening protocol ID* • *Screening participant ID* • *Cohort* • *Stratum*

PMI Committee Questions

Question	Response
How are the permissible values for the Cohort and Stratum CDEs added for each treatment trial? Are we responsible for submitting a request to the CBIIT curation team or will these be added in another way to ensure screening trial and treatment trial groups are using the same permissible values?	Cohort and Stratum are being populated in OPEN through a group lookup window that is being populated with the Cohort and stratum that was assigned to the patient at screening. No curation activities are required or should be managed for the Cohort & Stratum CDEs/ fields. These are non-enumerated fields that should be used as already specified on the PMI EC Template.
The Cohort and Stratum are free text fields in OPEN. NRG randonode is going to use Stratum filed to stratify patients on EAY191-N4 study and we are concerned about possible issues with spelling. Will these two fields have a 'Group lookup' configurated? Also, what are the permissible values associated with them?	The cohort and the stratum fields should be using the "Group Lookup" widget type in OPEN. Enhanced have been made to OPEN so that the only values populating in these lookup windows are the assigned cohort and stratum that was assigned to the patient in the screening protocol. There are no associated PVs with Cohort and Stratum.

PMI Project Discussion Items

Open Discussion

- Questions

Next Steps

Next Steps

- Next meeting will be on 1/25/2023 at 1:00pm EST
- Agenda
  - Role Call
  - Project Status Update
  - Group Status Update
  - Review FAQs

- Future Demos/Workflows
  - MM Demo – Target in Feb

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

Appendix

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Target Timeline

Nov – Mid Dec 2022

Group Activities
- Develop Study-specific Rave CRFs

NCI Activities
- ComboMATCH UAT Matchbox Environment
- MyeloMATCH UAT Matchbox Environment
- MATCHBox & OPEN Integrations for UAT
- Prepare Beta Screening & Treatment ALS files

Mid Dec 2022

NCI Activities
- Release EC Templatev1
- Release Beta Screening Protocol ALS
- Release Beta Treatment Protocol ALS
- aMOI List Approval and MATCHBox Upload

Mid Dec to Jan 30, 2023

Group Activities
- UAT Testing

NCI Activities
- Iterative updates to test findings (show-stoppers)

Target Timeline

Jan 31, 2023

NCI Activities
- Release EC Template v1
- Release Prod Screening Protocol ALS
- Release Prod Treatment Protocol ALS
- Release Prod Central Study ALS
- Release NCI OPEN Integrations for Prod
- Release NCI Genexus Installation (MyeloMATCH)

Jan 31 to Feb 14, 2023

NCI + Group Activities
- Support Group Study Builds

Feb 14, 2023

NCI + Group Activities
- Launch BOTH Initiatives

Spring 2023

NCI Activities
- Release Additional ALS(s)

ComboMATCH Priority 1 List

Study #	Document Number	Document Title	Group	Current Status	Next Steps	Primary Agent Name (P) Other Agent Name (O)
1	EAY191	Molecular Analysis for Combination Therapy Choice (ComboMATCH)	ECOG-ACRIN	8/15/2022 Approval on Hold	Revision 3 back from CIRB with approval. On hold for DTL, funding sheet and IND filing.	
2	EAY191-N4	Molecular Analysis for Combination Therapy Choice (ComboMATCH) EAY191-N4: A Randomized Trial of Selumetinib and Olaparib or Selumetinib Alone in Patients with Recurrent or Persistent RAS Pathway Mutant Ovarian and Endometrial Cancers A ComboMATCH Treatment Trial	NRG	8/15/2022 Approval on Hold	Revision 4 back from CIRB with approval. On hold for DTL, funding sheet and IND filing.	(P) Olaparib (AZD2281) (747856) (O) Selumetinib (AZD6244 hydrogen sulfate) (748727)
3	EAY191-E4	A ComboMATCH Treatment Trial ComboMATCH Treatment Trial E4: Nilotinib and Paclitaxel in Patients with Prior Taxane-Treated Solid Tumors	ECOG-ACRIN	8/26/2022 Approval on Hold	Revision 3 back from CIRB with approval. On hold for DTL, funding sheet and IND filing.	(P) Nilotinib (747599) (O) Paclitaxel (Taxol) (673089)
4	EAY191-N2	A ComboMATCH Treatment Trial EAY191-N2: Phase 2 Trial of Fulvestrant and Binimetinib in Patients with Hormone Receptor-Positive Metastatic Breast Cancer with a Frameshift or Nonsense Mutation or Genomic Deletion in NF1	NRG	8/26/2022 Approval on Hold	Revision 3 back from CIRB with approval. On hold for DTL, funding sheet and IND filing.	(P) Binimetinib (788187) (O) Fulvestrant (Faslodex) (719276)
5	EAY191-S3	Phase 2 Study of Paclitaxel + Ipatasertib in Taxane-Refractory Participants with AKT-Altered Advanced Non-Breast Solid Tumors	SWOG	8/29/2022 Approval on Hold	Revision 4 back from CIRB with approval. On hold for DTL, funding sheet and IND filing.	(P) Ipatasertib (781451) (O) Paclitaxel (Taxol) (673089)

ComboMATCH Priority 2 List

Study #	Document Number	Document Title	Group	Current Status	Next Steps	Primary Agent Name (P) Other Agent Name (O)
6	EAY191-A6	A ComboMATCH Treatment Trial: FOLFOX in Combination with Binimetinib as 2nd Line Therapy for Patients with Advanced Biliary Tract Cancers with MAPK Pathway Alterations	Alliance	Approval on Hold 9/14/2022	Rev 4 approved by CIRB on 10/24. CTEP currently reviewing stips.	(P) Binimetinib (788187) (O) OXALIplatin (Eloxatin) (266046) (O) 5-Fluorouracil (5-FU) (19893) (O)Leucovorin calcium (3590)
7	EAY191-A3	Palbociclib and Binimetinib in RAS-Mutant Cancers	Alliance	Approval on Hold 8/26/2022	Rev 2 sent to CIRB . Reviewed on 10/6, study team responding to stips	(P) Palbociclib (PD-0332991) (772256) (O) Binimetinib (788187)

ComboMATCH Priority 3 List

Study #	Document Number	Document Title	Group	Current Status	Next Steps	Primary Agent Name (P) Other Agent Name (O)
8	EAY191-A2	Olaparib Plus Low-Dose Alpelisib for Breast Cancer	Alliance	In Review 4/4/2022	Rev 3 recv;d 10/19, currently with LR. Looks like it'll be another disapproval. Not yet sent to CIRB for initial review.	(P) Olaparib (AZD2281) (747856) (O) Alpelisib (BYL719) (801658)
9	EAY191-C1	Phase 2 Subprotocol of the Combination of a MEK Inhibitor and a Pan-RAF Inhibitor in Patients with Relapsed/Refractory Tumors Harboring Activating MAPK Pathway Mutations	COG	In Review 9/29/2022	Protocol reviewed at PRC 10/20; CR is being put together	(P) Selumetinib (AZD6244 hydrogen sulfate) (748727) (O) DAY101 (TAK-580, MLN-2480) (800798)
10	EAY191-E5	ComboMATCH Treatment Trial E5: A Randomized Phase II Study of AMG 510 (Sotorasib) with or Without Panitumumab in Advanced Solid Tumors	ECOG-ACRIN	In Review 2/22/2022	Waiting for revision 2 since 9/28; reminder was sent to EA 10/24	(P) AMG 510 (Sotorasib) (825510) (O) Panitumumab (742319)
11	EAY191-N5	Molecular Analysis for Combination Therapy Choice (ComboMATCH) EAY191-N5: A Randomized Trial of Neratinib, A Pan-ERBB Inhibitor, Alone or in Combination with Palbociclib, a CDK4/6 Inhibitor, in Patients with HER2+ Gynecologic Cancers and Other Solid Tumors A ComboMATCH Treatment Trial	NRG	In Review 11/22/2021	Rev 3 disapproval sent 10/15; waiting for Rev 4	(P) Neratinib (783782) (O) Palbociclib (PD-0332991) (772256)

MyeloMATCH Priority 1 List

Study #	Document Number	Document Title	Group	Current Status	Next Steps
1	MYELOMATCH	Master Screening and Reassessment Protocol (MSRP) for the NCI MyeloMATCH Clinical Trials	SWOG	11/12/2021: Approval on Hold	CIRB Reviewed on 9/15, version with stips under CTEP review now.
2	MM1YA-S01	A Randomized Phase II Study Comparing Cytarabine + Daunorubicin (7 + 3) to (Daunorubicin and Cytarabine) Liposome, Cytarabine + Daunorubicin + Venetoclax, and Azacitidine + Venetoclax in Patients Aged 59 or Younger with High-Risk (Adverse) Acute Myeloid Leukemia; A MYELOMATCH Clinical Trial	SWOG	9/2/2022: Approval on Hold	CIRB Reviewed on 9/15, version with stips under CTEP review now.
3	MM1YA-CTG01	A Measurable Residual Disease (MRD) Driven, Phase II Study of Venetoclax Plus Chemotherapy for Newly Diagnosed Younger Patients with Intermediate Risk Acute Myeloid Leukemia: A Tier 1 MYELOMATCH Clinical Trial	CCTG	9/2/2022: Approval on Hold	CIRB Review Oct 6, responding to stips
6	MM1OA-EA02 (Concept)	A Randomized Phase II Study of HMA-Based Therapies for the Treatment of Older Adults with Newly Diagnosed FLT3-Mutated Acute Myeloid Leukemia: A myeloMATCH Treatment Trial	ECOG-ACRIN	8/29/2022: Approved, no protocol yet	Waiting for protocol

MyeloMATCH Priority 2 List

Study #	Document Number	Document Title	Group	Current Status	Next Steps
4	MM2YA-EA01	Eradicating Measurable Residual Disease in Patients with Acute Myeloid Leukemia (AML) Prior to StEm Cell Transplantation (ERASE): A MyeloMATCH Treatment Trial	ECOG-ACRIN	1/21/2022: In Review	Reviewed by CIRB, responding to stips
5	MM1OA-S02	A Randomized Phase II Study of Targeted Agents with the Oral DNMT1 Inhibitor Cedazuridine-Decitabine (ASTX727) for the Treatment of Newly Diagnosed TP53-Mutated Acute Myeloid Leukemia in Older Patients: A myeloMATCH Treatment Trial	SWOG	10/17/2022: In Review	Scheduled for PRC 11/4
7	MM1MDS-EA03 (Concept	ERADICATE MDS with TP53 Study: Efficacy of taRgeted Agents Combinations with Oral DNMT1 Inhibitor C-DEC (ASTX727) for TrEatment of Higher Risk myElodysplastic Syndromes with TP53 Mutations: A Non-Comparative, Parallel, Multi-Arm Phase 2 Study	ECOG-ACRIN	8/12/2022: Approval on hold, waiting for drug commitment	W+A6:G8aiting for Astex commitment, Genentech has provided commitment on 10/20

Review Schemas

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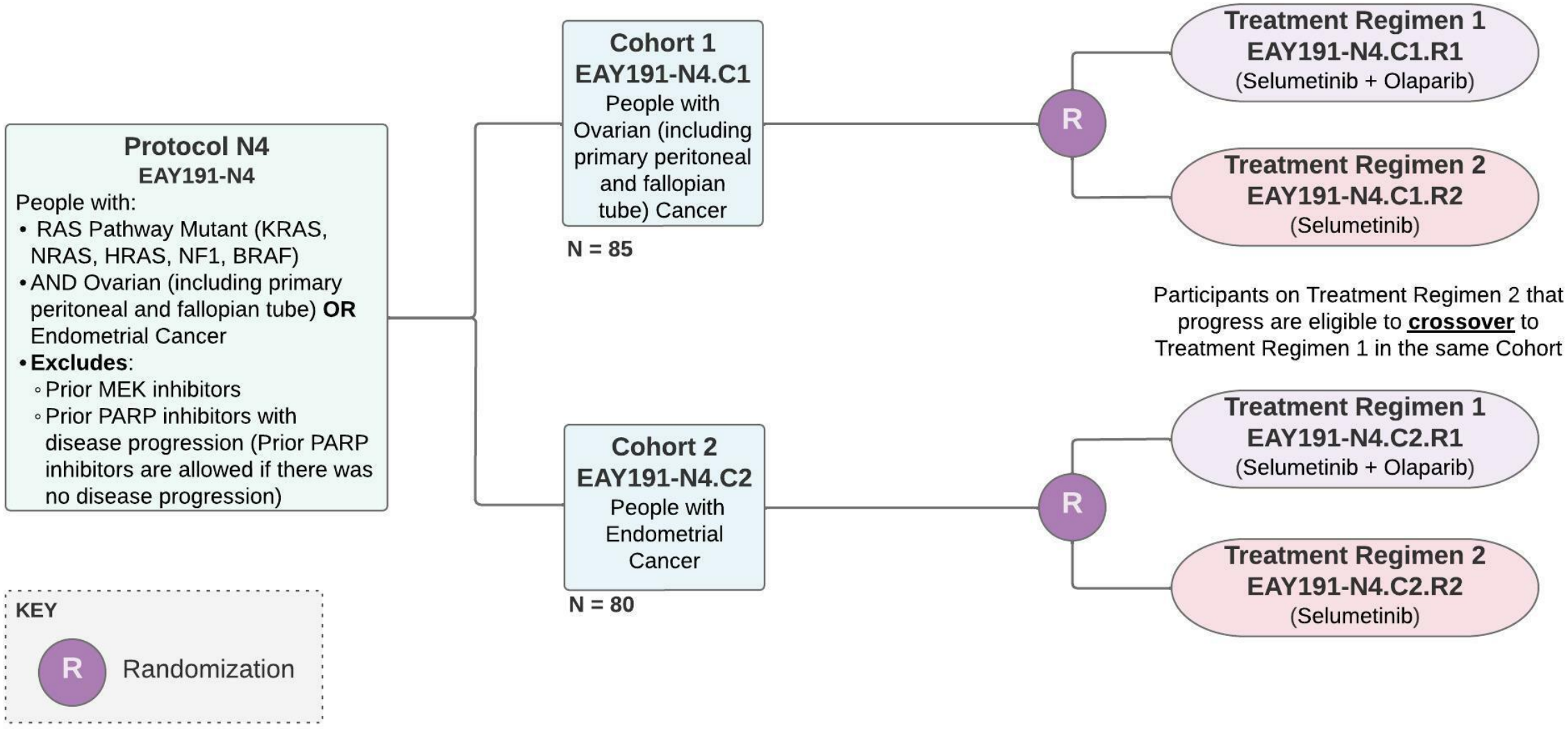
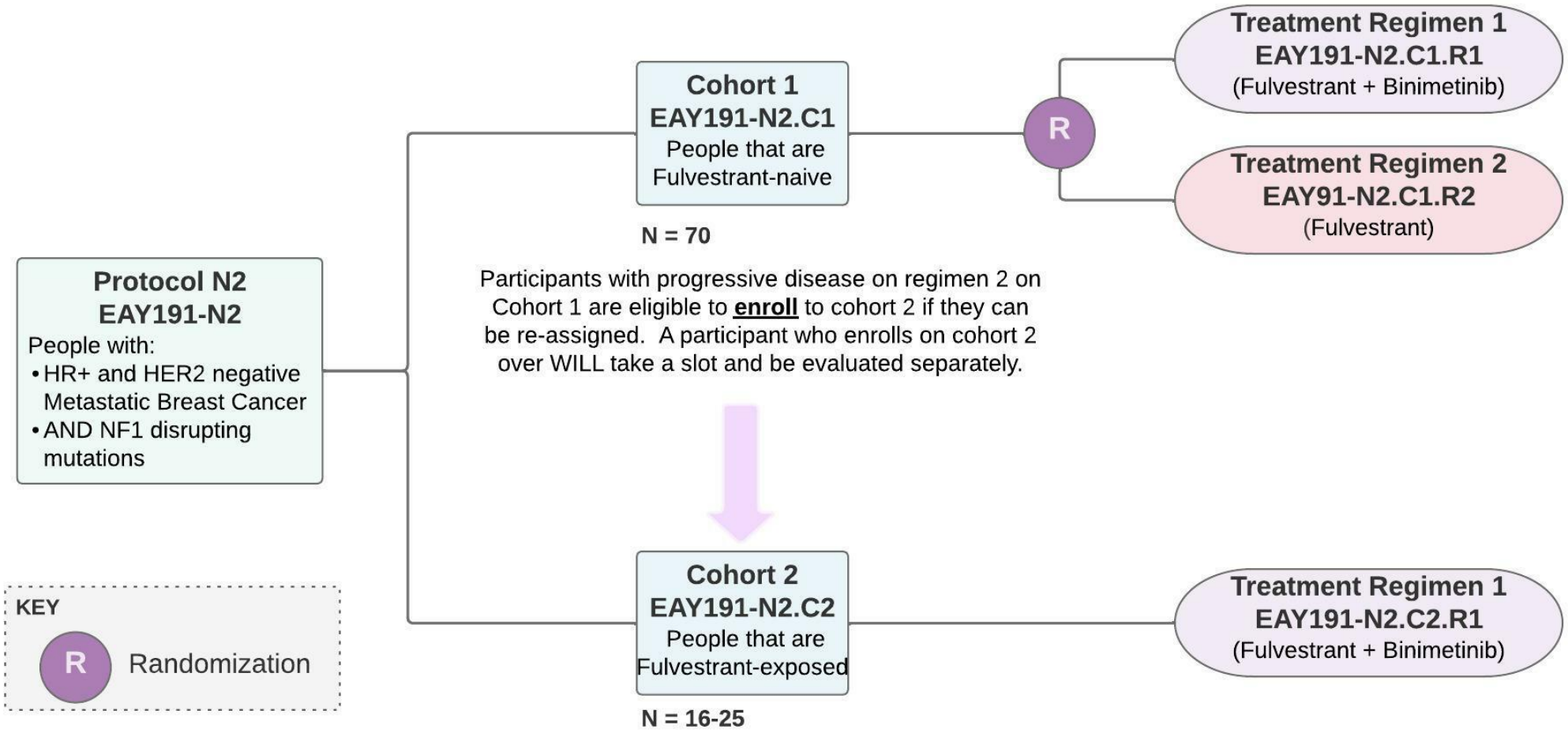
EAY191-N4


Protocol N4
EAY191-N4
People with:
• RAS Pathway Mutant (KRAS, NRAS, HRAS, NF1, BRAF)
• AND Ovarian (including primary peritoneal and fallopian tube) OR Endometrial Cancer
• Excludes:
◦ Prior MEK inhibitors
◦ Prior PARP inhibitors with disease progression (Prior PARP inhibitors are allowed if there was no disease progression)
Cohort 1
EAY191-N4.C1
People with Ovarian (including primary peritoneal and fallopian tube) Cancer
N = 85
Cohort 2
EAY191-N4.C2
People with Endometrial Cancer
N = 80
R
R
Treatment Regimen 1
EAY191-N4.C1.R1
(Selumetinib + Olaparib)
Treatment Regimen 2
EAY191-N4.C1.R2
(Selumetinib)
Participants on Treatment Regimen 2 that progress are eligible to crossover to Treatment Regimen 1 in the same Cohort
Treatment Regimen 1
EAY191-N4.C2.R1
(Selumetinib + Olaparib)
Treatment Regimen 2
EAY191-N4.C2.R2
(Selumetinib)
KEY
R
Randomization

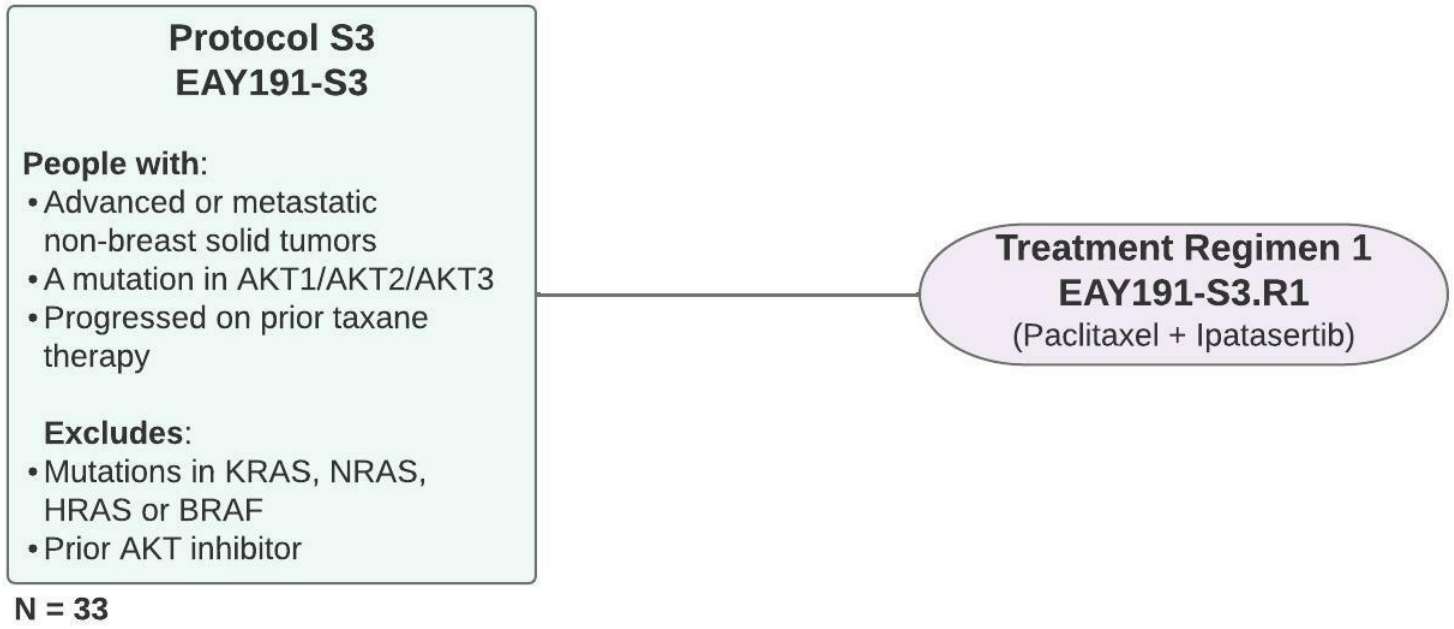
EAY191-E4


Protocol E4
EAY191-E4
People with:
• Previous taxane therapy (metastatic setting)
• Excludes:
◦ Platinum-resistant epithelial serous ovarian cancer
◦ cKIT variants
◦ PDGFRA D842V variants
N = 40
Treatment Regimen 1
EAY191-E4.R1
(Nilotinib + Paclitaxel)

EAY191-N2- Draft



EAY191-S3


Protocol S3
EAY191-S3
People with:
• Advanced or metastatic non-breast solid tumors
• A mutation in AKT1/AKT2/AKT3
• Progressed on prior taxane therapy
Excludes:
• Mutations in KRAS, NRAS, HRAS or BRAF
• Prior AKT inhibitor
N = 33
Treatment Regimen 1
EAY191-S3.R1
(Paclitaxel + Ipatasertib)

MMIYA-CTG01 Draft