Precision Medicine Initiative (PMI) Committee Meeting

November 16, 2022

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Agenda

- Role Call
- Meeting Purpose
- Stakeholder Communication
- Project Status Updates
- Review Schemas
- Review FAQs
- Open Q & A

Stakeholder Representation

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

Meeting Purpose

- Streamline communication for project deliverables across stakeholders
- Review incoming questions from PMI mailbox
- Present progress of project deliverables and timelines
- Present workflows (OPEN/RAVE/MATCHbox)
- Discuss ad hoc items as needed across the PMI initiative

Communication

- Contact PMI Mailbox for any PMI related questions
  - ncipmistandards@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

ComboMATCH & MyeloMATCH Launch Plan Approach

Target Launch BOTH Initiatives 2/15/23

Plan Study Activation

- Select a sub-set of trials for implementation

Dedicate Resources

- BOTH NCI and Groups must reprioritize workload
- Potential additional funding available for Groups
- Prioritize PMI; *NCI has recently shifted multiple contracts to focus on PMI activities*

Prioritize Forms

- Focus on the core set of forms needed to launch each trial
- Incremental Targeted Individual ALS releases (2 per study)

Reduce Number of ALS Releases

- The NCI will NOT release any other ALS (ex. CTEP-AERS, Protocol Deviation) between 12/1/22 to 3/1/23
- If possible, AND with Group consultation, the NCI may combine ALS releases next Spring

Project Status Updates

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PMI Screening Protocol ALS v1.0

Beta Release Screening Protocol ALS v1.0

Target Date: December 16, 2022

Production Release Screening Protocol ALS v1.0

Target Date: January 31, 2023

Form/Deliverable	Completed	Pending
PMI CDISC Step Information Form	Created beta form/field listing for Groups Performed Rave study build and edit check updates Updated custom functions Compliance Review	Perform additional testing
PMI CDISC Treatment Assignment Form	Created beta form/field listing for Groups Performed Rave study build and edit check updates Updated custom functions Compliance Review	Perform additional testing
PMI CDISC Off Study Form	Documented use cases Created beta form/field listing for Groups Performed Rave study build and edit check updates Updated custom functions Compliance Review	Deliver beta form/field listing for Groups Integration + QA testing
PMI CDSIC Consent Withdrawal Form	Documented use cases Created beta form/field listing Performed Rave study build and edit check updates	Deliver beta form/field listing for Groups Custom functions Integration + QA testing Compliance review
Beta Release Screening Protocol ALS v1.0		Integration + QA testing Final compliance review Update release notes Release Beta ALS for UAT

PMI Treatment Protocol ALS

Beta Release Screening Protocol ALS v1.0

Target Date: December 16, 2022

Production Release Screening Protocol ALS v1.0

Target Date: January 31, 2023

Form/Deliverable	Completed	Pending
PMI CDISC Off Treatment Form	Documented use cases Created beta form/field listing Performed Rave study build and edit check updates Updated custom functions Compliance Review	Deliver beta form/field listing for Groups Integration + QA testing
PMI CDSIC Consent Withdrawal Form	Documented use cases Created beta form/field listing Performed Rave study build and edit check updates	Deliver beta form/field listing for Groups Custom functions Integration + QA testing Compliance review
Beta Release Treatment Protocol ALS v1.0		Integration + QA testing Final compliance review Update release notes Release Beta ALS for UAT

PMI Central Study ALS v1.0

Beta Release Central Study ALS v1.0

Target Date: December 16, 2022

Production Release Central Study ALS v1.0

Target Date: January 31, 2023

Tasks	Completed	Pending
Integration Testing		X
Release Beta ALS to Groups		X

PMI CDISC Eligibility Checklist Template v1.0

Target Date: December 16, 2022

Tasks	Completed	In Progress	Pending
Identify cohort and stratum CDEs	X		
Create custom edit checks in OPEN			X
Harmonize and curate new EC CDEs		X	
Create beta form/field listing for Groups		X	
Rave form build activity for testing			X
End to end integration testing + QA testing			X
EC Template Use Fact Card			X
Release PMI CDISC Eligibility Checklist Template v1.0 in caDSR II			X
Support Groups as needed			X
Retest integrations as needed			X

PMI Drug and Disease Service Integration

Target Date: December 16, 2022

Tasks	Completed	In Progress	Pending
End to end integration + QA testing			X
Deploy OPEN updates to UAT/Production			X
Release Drug & Disease CDE's in caDSR			X
Support Groups as needed			X
Retested integrations as needed			X

PMI MyeloMATCH Patient Fitness Integration (OPEN/MATCHbox)

Target Date: December 16, 2022

Tasks	Completed	In Progress	Pending
Finalize requirements	X		
Content + CDISC Review		X	
CDE Curation			X
Integration + QA Testing			X

OPEN-Pathology/CLIA Upload/Download

Target Date: January 30, 2023

Tasks	Completed	In Progress	Pending
Verify integration			X
Manage end to end testing			X
Deployment to UAT/PROD			X

UAT Environments

ComboMATCH Date: Dec 16, 2022
MyeloMATCH Date: TBD; project teams are meeting this week to identify a date

Tasks	Completed	In Progress	Pending
Deploy ComboMATCH UAT Environment		X	
Deploy MM UAT Environment		X	

Group Specific Activities

Tasks	Dates
Develop Study Specific CRFs	November to 12/16/2022
UAT Testing	12/16/2022 to 1/30/2023

Review Schemas

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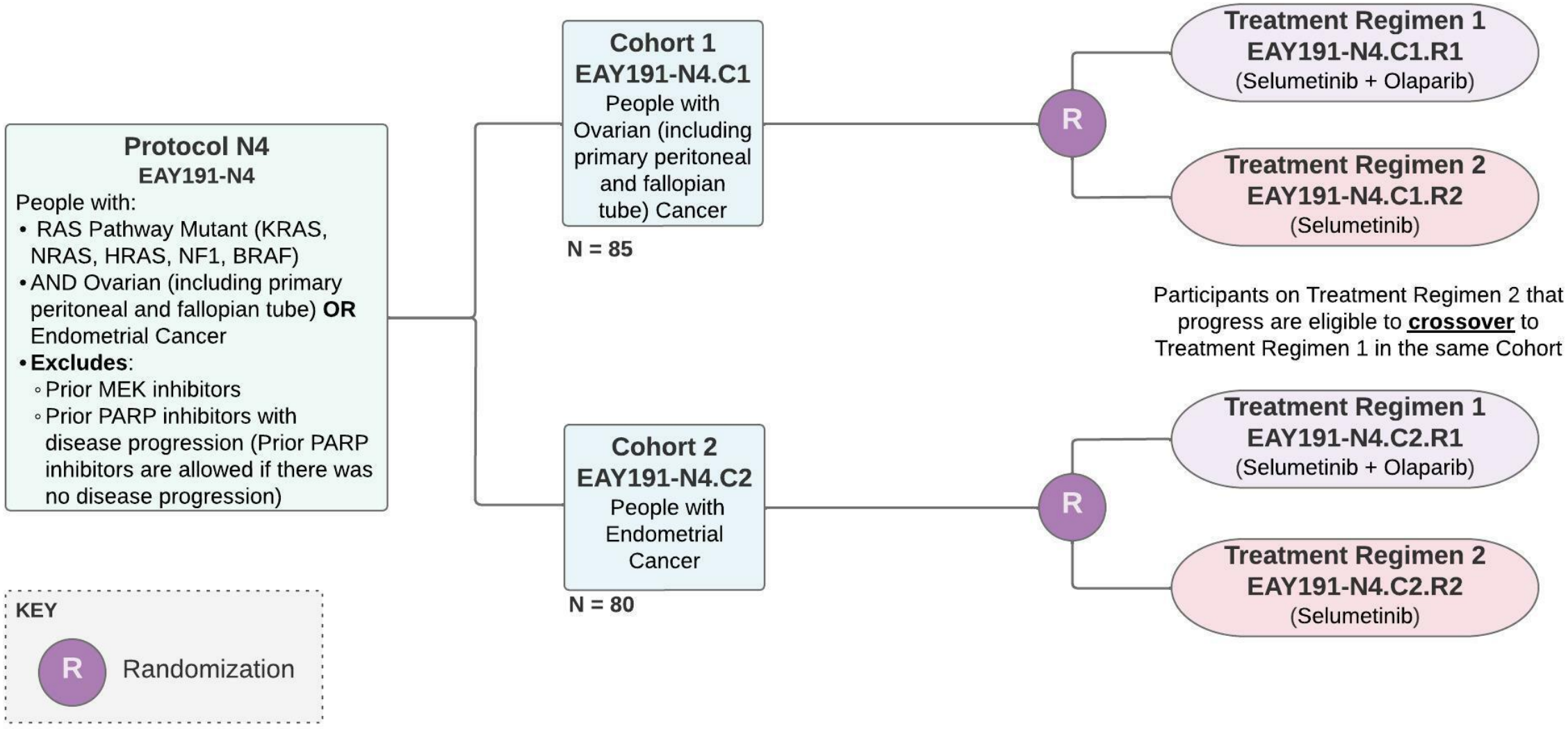
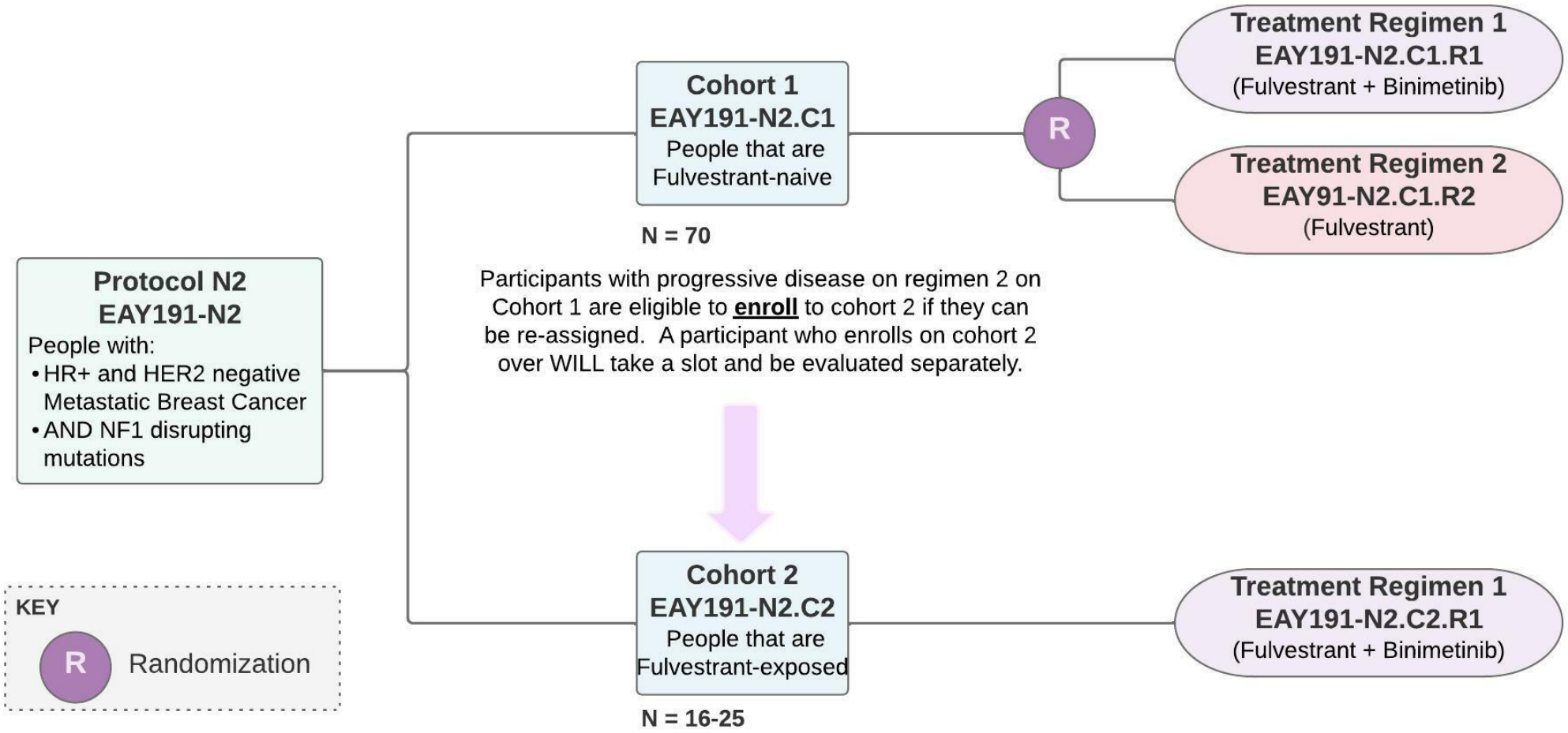
EAY191-N4


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

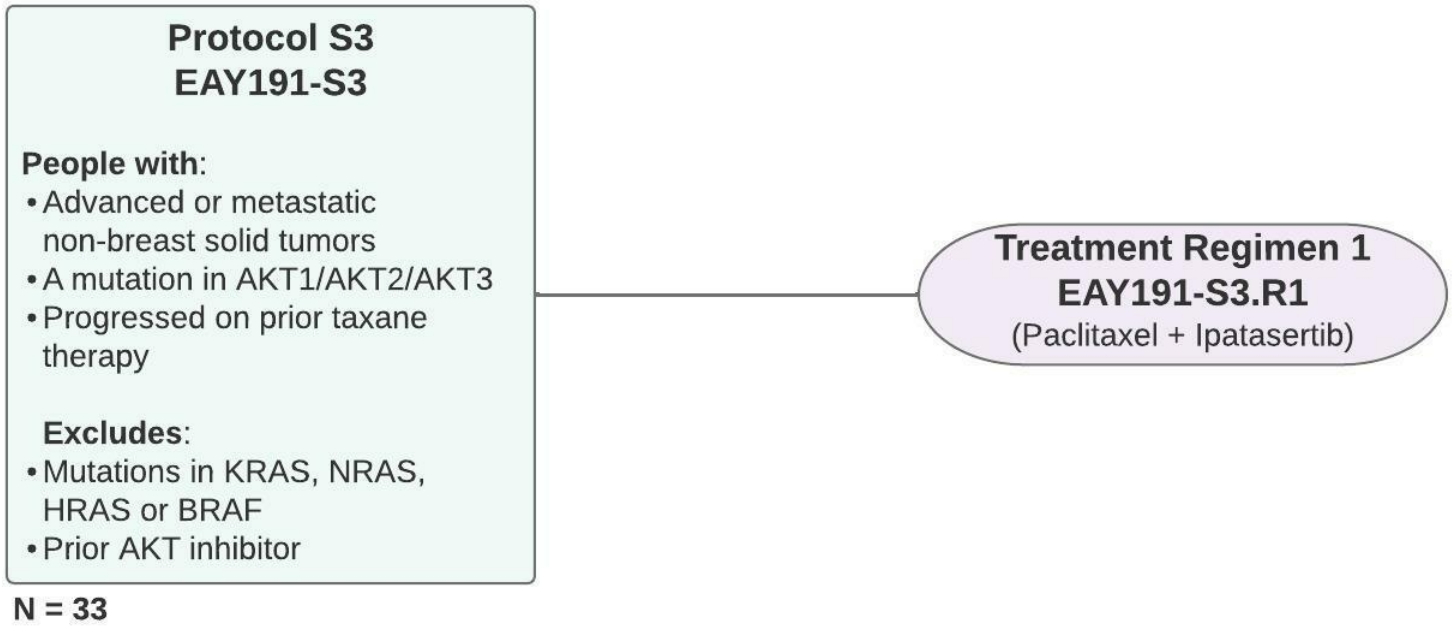
EAY191-E4


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)

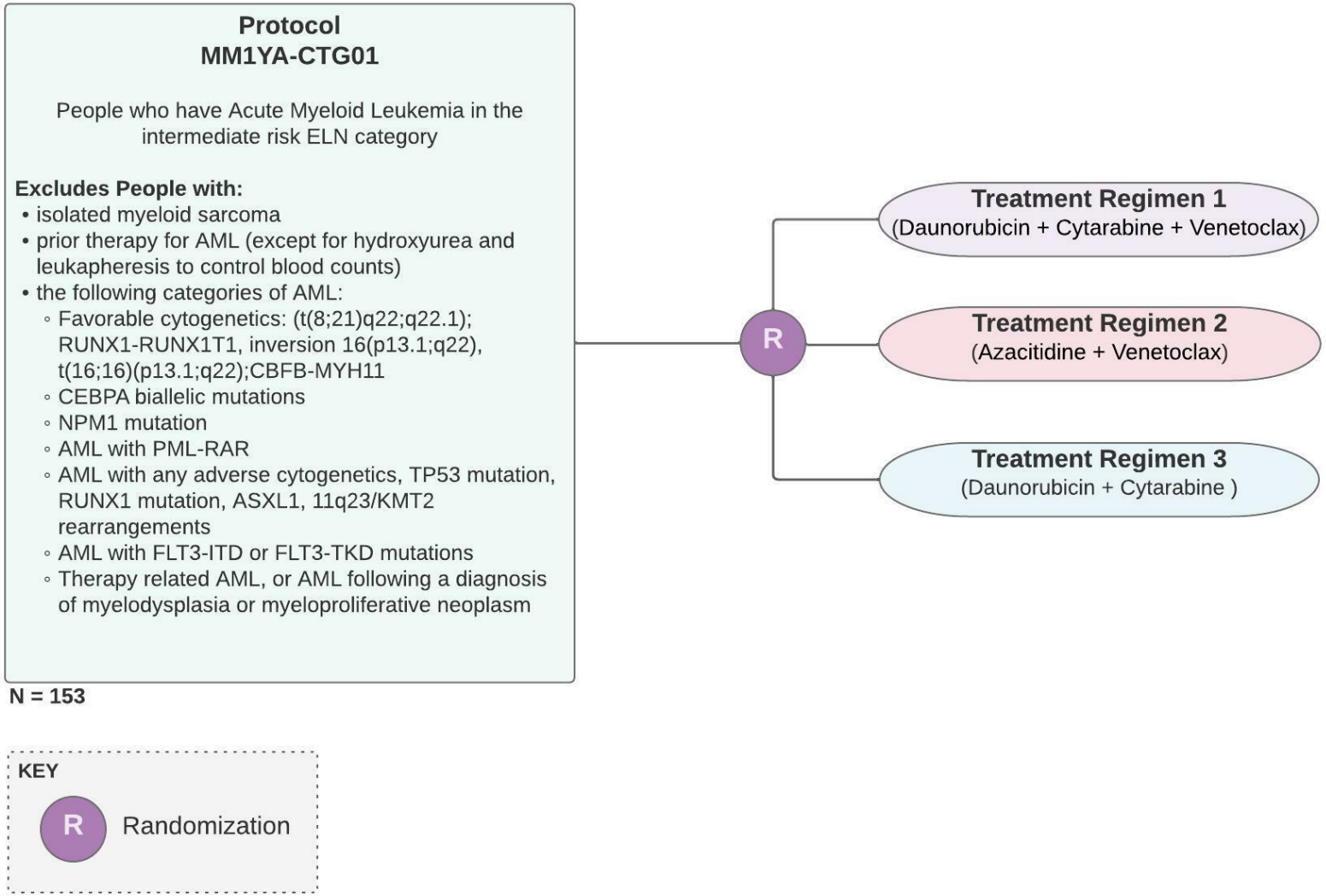
EAY191-N2- Draft



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



Review FAQs

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PMI Forms + Deliverables Release Schedule

Form/Deliverable	ComboMATCH	MyeloMATCH	Target Release Date
Eligibility Checklist Template	x	x	January 31, 2023
OPEN Enhanced MyeloMATCH (Patient Fitness) Integration		x	January 31, 2023
OPEN Drug & Disease Terminology Services Integration	x	x	January 31, 2023
OPEN Physician's Choice Integration	x		January 31, 2023
OPEN Pathology/CLIA Upload	x	x	January 31, 2023
CTSU RSS Modifications	x	x	January 31, 2023
PMI Central Study ALS	x	x	January 31, 2023
PMI Screening Protocol ALS	x	x	January 31, 2023
PMI Treatment Protocol ALS	x	x	January 31, 2023
OPEN Designated Lab Fields (Integration)	x		January 31, 2023
OPEN Novel aMOI Fields (Integration)	x	x	TBD
Specimen Tracking Manifest Form	*x*	*x*	TBD
CLIA Submission Form	*x*	*x*	TBD
Pathology Group Form	*x*	*x*	TBD

PMI Committee Questions

Question	Response
What are the Status Fields in Off Treatment and Consent Withdrawal trying to obtain for the Screening Protocol?	This Status field is used to collect the reason why the patient is going off treatment or withdrawing consent as per CDISC requirements so an action can be taken. CTEP CDISC CDE PID 6355981 is used to collect this data for the PMI Standard Off Treatment Form and the PMI Standard Consent Withdrawal Form.
Where will the Standard PMI Forms 'live' in RAVE? Can we place these forms within a folder, or must it be outside of a CRF folder at the patient level?	The PMI Standard Off Treatment and Consent Withdrawal form will be provided in two separate forms. The folder setup for these PMI CDISC Treatment Protocol Standard Forms is configurable and will be determined by the NCTNs based on protocol requirements. Westat will provide a suggested PMI CDISC Standard Form folder setup for your Rave study build.
Will the Groups receive a central patient ID?	There will be a Screening Protocol Participant ID and a Treatment Protocol Participant ID. There will not be a central Patient ID.

PMI Committee Questions

Question	Response
What is the mechanism for transfer of the three separate fields the protocol ID, cohort ID, and stratum ID to RandoNode?	Groups will need to collect the *screening protocol name, cohort*, and stratum fields on the Treatment Protocol Eligibility Checklist (EC). These fields will be provided on the PMI Standard EC Template; this template will be available in the caDSR II and should be used to create the needed protocol-specific ECs. There will a validation check in OPEN that will verify that the enrolling site is being assigned to the treatment protocol for that location. The PMI Project team will provide a one-page document how to set up your RandoNode.
For crossovers from cohort 1 to cohort 2 (example: EAY191-N2) are patients expected to submit the PMI Off Treatment Standard Form and go back to central study?	N2 is not a crossover, it is a reassignment because the cohorts are based on prior drug exposure. Participants with progressive disease on regimen 2 on Cohort 1 are eligible to enroll to cohort 2 if they can be re-assigned. A participant who enrolls on cohort 2 over WILL take a slot and be evaluated separately.

PMI Committee Questions

Question	Response

How long will it take for the patient to be able to come down the pipeline to re-enter our study as a cohort 2 candidate? EAY191-N2 study will have a second Eligibility Checklist in OPEN for these patients.	The reassignment will take 24 or less hours depending on what time the reassignment was completed. N2 is not considered a crossover.
	
	For crossovers, they are immediate. Crossovers were implemented as a Step 2 on the Treatment Protocols. The PMI Off Treatment Standard Form should NOT be completed for crossover, the patient should be registered to Step 2 on the Treatment protocol.
	The sequence of events would be:
	• [Site] Register patient to Screening protocol Step 1 in OPEN.
	• MATCHbox assigns to N4 and sends it back to OPEN.
	• [Site] Register patient to N4 Treatment protocol Cohort 1 Step 1 in OPEN (Single-agent regimen).
	• Patient progresses.
	• [Site] Register patient to N4 Treatment protocol Cohort 2 in OPEN on Treatment protocol Step 2 to Crossover. (Multi-agent regimen.)
	• [Site] Complete PMI Off Treatment Standard Form for N4 when treatment on N4 is completed.
	• [Site] Perform one of the below actions:
	  • Register patient for Screening protocol Step 1 in OPEN to get a new treatment assignment for said patient, OR
	  • Complete the PMI Off Study Standard Form for the Screening protocol.

PMI Committee Questions

Question	Response
How will patients that discontinue treatment for reasons other than progression, go into follow-up, have a progression, proceed to crossover to cohort 2? How will that be handled since PMI Off Treatment form was submitted with a reason other than progression?	The crossover is immediate. You cannot crossover or be reassigned if there is an AE of the single agent. Cannot be reassigned to a dual agent therapy if you had an AE on the single agent.
What about those who progressed but do not want to consent to crossover to cohort 2?	The patient would complete the Off Treatment Form and be off treatment.
If patients need to go through central study when crossing from cohort 1 to 2, how is crossover from treatment 1 to treatment 2 within the same cohort? At what does the point PMI Off Treatment standard form needs to be submitted?	Crossover is for disease-based cohorts and going from cohort 1 to cohort 2 is for drug exposure-based cohorts. The latter requires reassignment. For crossover, once they have enrolled to the first step and gotten their treatment assignment and patient progresses, they are eligible for a crossover. They would • Enroll to step 2 on the treatment protocol • Assign a crossover treatment
Will Groups have access to data for patients on our studies that were later assigned to a different ComboMatch protocols?	Group users can only view the web pages for their own Treatment Protocols on the ComboMATCH website ; there are no restrictions on viewing participant details. Hence, if a former participant of a Group's treatment protocol is currently on another Group's treatment protocol, the group user can view everything about that participant on the ComboMATCH website. The PMI Project team is in the process of identifying permission requirements.

PMI Committee Questions

Question	Response
In addition to verifying that they provided the correct patient ID from the Screening study, how will we verify they selected the appropriate strat or grouping factor based on the ComboMATCH results? Will this be another edit check? Do we need to use specific CDEs so they match what is provided by the MATCH program?	ComboMATCH sends the assignment to the Screening Protocol's instance of OPEN. There is a validation step that is done during the enrollment to the Treatment Protocol. These validations include: • the screening enrolling site = the treatment enrolling site • the assigned treatment study = the enrolled treatment study • the cohort and stratum match • the screening patient demography data (last initial, first initial, middle initial, date of birth, ethnicity, gender, country, zip code and race) = the treatment patient demography data. When the ENROLLMENT message is sent to ComboMATCH, it will return an error to OPEN if the patient was enrolled to something other than which they were assigned which checks for the assigned cohort and strata, as applicable.
The screening trial will assign the same patient ID the second time they register; how will the treatment trial know which assignment to look for (i.e., Cohort 1 vs Cohort 2 on EAY191-A2)? Do we need to write any special edit checks for this, or will it know which assignment to verify for re-registration?	The re-registration is another step in the screening study, so the same patient ID will be used once the next phase of the requirement starts and cohort would change from C1 to C2.

PMI Committee Questions

Question	Response
If a study has a planned follow up after the treatment completion and PMI Off Treatment form will be used to roll out, follow up folders in Rave. Will the Groups receive information that patient is assigned to a different ComboMATCH protocol?	No, the Groups will not receive information that the patient is assigned to a different ComboMATCH protocol. MATCHbox will send an email notification to the enrolling site when assignment is confirmed for a patient. No email notification will be sent to the groups if a patient goes off treatment, or if a patient is reregistered and assigned to another protocol.

Next Steps

- Next meeting will be on 11/30/2022 at 1:00pm EST
- This meeting will be 2 hours long
- Agenda
  - Role Call
  - Project Status Update
  - OPEN/Rave/MATCHbox Integration Demo

- Groups will be receiving an email regarding the RSS app, please respond with your feedback

Open Discussion

- Would like to see a MM demo
- Follow up on status field (primary may be not be AE)

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