# Precision Medicine Initiative (PMI) Committee Meeting

Feb 22, 2023

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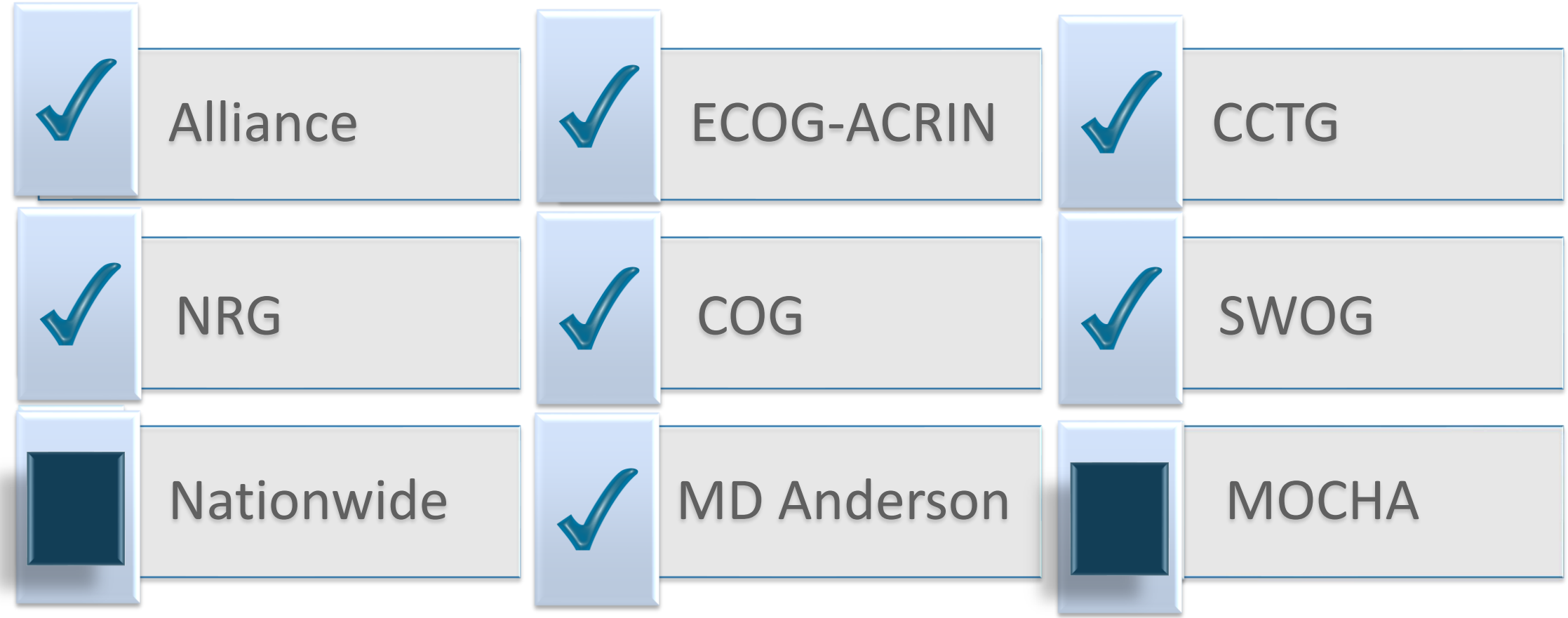
# Agenda

- Role Call
- Project Status Updates
- Group Project Status Updates
- Fit for Purpose (FFP) Testing
- Review FAQs
- Target Project Timelines
- Open Discussion
- Next Steps

# Stakeholder Representation



# Project Status Updates

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# Project Updates

- Released Prod v1.0 ALS files and documentation
- Addressing UAT findings as reported by groups
- Preparing for an Open/Rave/Matchbox MyeloMATCH Demo
- Provided FFP Scripts for Groups
- Preparing for FFP Testing

# Group Project Status Updates

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| EC Template | | | Beta Central Study ALS | | Beta Screening Protocol ALS | | Beta Treatment Protocol ALS | | Screening/Treatment Test Cases (%done) | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| caDSR II (Y/N) | EC Build in Rave (Y/N) | Target Completion Date | Completed Upload (Y/N) | Target Completion Date | Completed Upload (Y/N) | Target Completion Date | Completed Upload (Y/N) | Target Completion Date | Initiated Beta UAT (Y/N) | Group Test Cases (%) | Target Completion Date |
| Screening (Y)<br><br>Treatment (Y) | Current Version (Y)<br><br>Screening New Version (Y)<br><br>Treatment New Version (N) | Both Completed as of 1/27/23 | v1.0- Yes<br>v1.0.1.0 - Yes | 1/20/2023 | 100% | 1/18/2023 | 100% | 1/18/2023 | Screening (Y)<br><br>Treatment (In Progress) | Screening (100%)<br><br>Treatment (100%) | Screening 2/01/2023<br><br>Treatment 2/01/2023 |
| Screening (Y)<br><br>Treatment (Y) | Current Version (Y)<br><br>Screening New Version (Y)<br><br>Treatment New Version (Y) | 1/20/2023 | v1.0- Yes<br>v1.0.1.0 - Yes | 1/20/2023 | 50% | Not able to move forward without more info | Combo – Ready<br><br>MM – Pending | Combo done, finishing internal testing and will copy the standard forms into MM | Screening (N)<br><br>Treatment (Complete for Combo) | Screening ()<br><br>Treatment (Complete for Combo) | Screening<br><br>Treatment (Complete for Combo) |
| Treatment (Y) | N4 - In Progress<br><br>N2 – In Progress | 1/27/2023<br><br>1/31/2023 | v1.0- Yes<br>v1.0.1.0 - Yes | 1/25/2023 | N/A | N/A | Completed | | Treatment (Y) | Treatment N2 100%<br>N4 100% | Treatment 2/2/2023<br>2/2/2023 |
| Treatment (Y) | Treatment (Y) | 1/25/2023<br><br>Starting with A3 first | v1.0- Yes<br>v1.0.1.0 - Yes | 1/25/2023 | N/A | N/A | Completed | | Treatment (Y) | Treatment (25%) | Treatment (3/1/2023) |
| Treatment (Y) | Current Version (Y)<br>New Version (N) | 1/30/2023 | v1.0- Yes<br>v1.0.1.0 - Yes | 1/25/2023 | N/A | N/A | Completed | | Treatment (N) | Treatment (0%) | Treatment TBD |
| Treatment (N) | New Version (N) | 2/24/2023 | v1.0- Yes<br>v1.0.1.0 –Yes | 2/01/2023 | N/A | N/A | Completed | | Treatment (N) | Treatment (0%) | Treatment 03/31/2023-C1 |

# Group Testing Updates

| Group | Internal UAT | Prod Screening Protocol ALS | | Prod Treatment Protocol ALS | |
|---|---|---|---|---|---|
| | Progress (% Complete) | Completed Upload (Y/N) | Target Completion Date | Completed Upload (Y/N) | Target Completion Date |
| **ECOG-ACRIN** | 95%<br><br>80% | Ran a diff report, used existing version and matched production version (Y) | | Imported Central Study, Ran a diff report, used existing version and matched production version (Y) | |
| **SWOG** | 100%<br><br>100% | | | Imported Central Study, Used diff report, used existing version and matched production version (Y) | |
| **NRG** | N4 - 100%<br>N4 – 75% | N/A | N/A | Imported Central Study, Used diff report, used existing version and matched production version (Y) | |
| **Alliance** | 70% | N/A | N/A | Imported Central Study, Used diff report, used existing version and matched production version (Y) | |
| **CCTG** | | N/A | N/A | | |
| **COG** | | N/A | N/A | | |

# ComboMATCH FFP Testing Updates

| Group | Enrollment Forms |
|---|---|
| | Finalized Enrollment Forms (EC forms and Rave Treatment forms) |
| **ECOG-ACRIN** | Screening: OPEN checklist has a change<br><br>Working on language to populate instructions field on 15 min delay for uploading Path and CLIA reports<br><br>Treatment – Complete<br><br>Screening: Rave Forms – Forms are set<br>Treatment – Forms are set but could be minor changes due to validation checks |
| **SWOG** | Treatment – Completed but had to add consent questions outside of PMI Integrations, should be done by today |
| **NRG** | Treatment entry forms are finalized in OPEN and Rave<br><br>Other forms are also built; still running validation checks |
| **Alliance** | N/A |
| **CCTG** | N/A |
| **COG** | N/A |

# Group Testing Roadblocks

| Group | Roadblock |
|---|---|
| **ECOG-ACRIN** | ***2/8/2023***<br>• *Compiling a list of questions*<br><br>***2/22/2023*** |
| **SWOG** | ***2/8/2023***<br>• *MM Need more information*<br>***2/22/2023***<br>• *Consent spec, sending that information to NCI if a bank does not consent to banking*<br>  • *Once we move towards electronic, it will be available for tracking. For now we are using a manual process*<br>• *Prior Therapy section for MM – Had particular things to be entered and may not be the same definition for prior therapy..waiting on instructions*<br>• *Morphology List – Reviewing the list of full items and will have a subset to use for MM; will send those values to the PMI mailbox* |
| **NRG** | ***2/22/2023*** |
| **Alliance** | ***2/8/2023***<br>• *Routing rule not found – Working with Team to get it fixed*<br>• *Missing screening protocol ID and Patient ID*<br>***2/22/2023*** |
| **CCTG** | ***2/8/2023***<br>• *Everything is installed as required*<br>***2/22/2023***<br>• *Test patients pending* |
| **COG** | ***2/8/2023***<br>• *Waiting on derivations* |

# Fit for Purpose (FFP) Testing

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# FFP Testing Overview

- Fit-for-Purpose (FFP) testing is a ‘dress rehearsal’ to make sure all components that make up the precision medicine trial are ready and capable of meeting its objectives
- Allows NCI and external sites to check software and physical processes work according to expectations
- Will be testing scenario of least-restraint (happy path) as well as potentially other scenarios
- Systems involved in Testing: OPEN, Rave, MATCHBox, DLAP, Disease Service, VariantRX Service
- FFP Testing will take place in the User Acceptance Testing (UAT) environment.
- Target start date: Friday 2/24/23

# FFP Testing- Enrolling Site Involvement

- ECOG-ACRIN has identified two sites that can participate in FFP testing.
- Sites will identify the users who will act as site registrars for FFP.
- Sites will be responsible for:
  - Creating enrollments in UAT for the ComboMATCH screening and treatment trials.
  - Uploading Pathology and CLIA reports in OPEN.
  - Reporting any issues found during their testing.
- The PMI Project team will meet with the participating sites to discuss expectations and logistics.
  - Go over OPEN enhancements.
  - Discuss enrollment workflow.
  - Go over FFP testing script .
  - Expectations

# FFP Testing- Oncology Group Involvement

- Groups should have their OPEN EC and Rave forms finalized by the start of FFP testing (2/24/23).
- Group expectations:
  - Address and assist participating sites with issues related to their randonode and/or OPEN form edit checks.
  - Site Users will not have access to UAT environment so Groups would need to complete Rave portion
  - Complete the Rave portion of the FFP testing:
    - Off Treatment
    - Off Study
    - Consent Withdrawal
- Appropriate group staff would need to be identified for these tasks.

# FFP Testing- Next Steps

- The PMI Project team will meet with participating sites to prepare for testing.
- Groups will identify appropriate group contacts that will participate in FFP testing.
- The PMI Project team will send groups the current FFP Testing script.
- FFP testing to kickoff on Friday 2/24/23
  - Sites will enroll patients in OPEN UAT to:
    - EAY191
    - EAY191-E4
    - EAY191-N2
    - EAY191-N4
    - EAY191-S3

# Review FAQs

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# PMI Committee Questions

| Question | Response |
| --- | --- |
| What is the proposed process if a patient does not consent to banked specimens? How will each group relay that information to the NCI so that they do not expect banking material from that patient? | Groups can have consent question in OPEN. We are also looking into the creation of a custom report to relay information to NCI. |
| We have consensus that the format you described below would be acceptable, though some concerns/questions have been raised:<br><br>Can you confirm this method would require updates to the OPEN Checklist to add a field?<br><br>Can you confirm that sites would only need to “pick” from the list once, after which their selection would be parsed out to populate both the code and name fields | No new fields should be needed. We are planning on concatenating like the prior therapy field, just that there might be some updates needed to the CDEs to accommodate the full value. |

# PMI Committee Questions

| Question | Response |
| --- | --- |
| With regards to Regimen, can you please confirm if the Regimens presented in the schematic are equivalent to TACs in OPEN? Or are these PMI specific treatment codes. | The treatment regimens are just associated with the drug, but it is not specific to the dose level (as is with the TACs). |

# Project Timeline

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# Target Project Timelines

- 2/15/2023 Production ALS Release
- 2/22/2023
  - Complete deployment of production forms
  - Kick off end-to-end testing
- 3/1/2023
  - Priority 1 Study Activation
  - Complete end-to-end testing

# PMI Project Discussion Items

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# Open Discussion

- ECOG –
  - Updates for screening study checklist.  ECOG is removing and adding lab names to match the labs that are participating at go live. If a lab stops participating, will ECOG be notified by CTSU and do we need to update Rave.
    - Lyndsay:  There are 2 places where the designated labs can check to see if the centers are accepting or not accepting. Websites are ECOG-ACRN website and CTSU website.
    - We have not looked into notification, but we can provide that if we need it.
    - Site must select a lab from a dropdown list in OPEN in the backend as it changes, how does it get changed and will we have a defined process to ensure the list of labs in the OPEN checklist is up to date.
    - Project Team – CTSU can hide values in OPEN to remove items; if labs are added, CDE would need to be updated and form would need to be downloaded again
    - In the process of getting agreements signed with the labs, so labs will be added as the study progresses.
    - We want to mitigate risks from a Rave Study Build perspective and avoid doing a migration each time a change is made.

# Open Discussion

- **ECOG** –
  - Under physicians' choice, when you select the treatment protocol assignment, (e.g.,E4), currently in UAT environment, all treatment trials are in that list.
  - When we go to production on 3/1, will all those treatment trials from the start or will they be added as studies open?
  - If they are going to be added as trials OPEN, how will that impact Rave migration?
  - Project Team: Physicians choice is related to protocol application so only active trials will show. When you go to production, only the open trials will be there, but you can see all of them in the UAT environment.
- **Alliance**
  - Will we have access to data coming from screening trial (for those running treatment trial), ICOD-3 topography?
  - Set up for the cohorts and stratum, is the information about (e.g., 102 patients matched to Cohort 1, but not matched yet, will the site be able to see that status that the patient cannot be matched because the 3 week window have closed and have hit the target), how visible will that be to the sites and the group Sponsoring the treatment trial?
  - Project Team – no notification on why the patient didn't get assigned, there is no automatic notification. Verification could review the report and determine that information and not confirm the assignment report until the patient is assigned. (may be on the dashboard) When you log into MATCHbox, you can see patients on A3; verify qualifications of how is getting access to this information
  - Is there a UAT to see the Dashboard to evaluate who would benefit from access. Matt will follow up on this.

# Next Steps

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# Next Steps

- Next meeting will be on 3/8/2023 at 1:00pm EST
- Agenda
  - Role Call
  - Project Status Update
  - Group Status Update
  - Review FAQs
  - Future Demos/Workflows
    - Target Date for MM Demo – March 29, 2023 at 1:00pm EST

# 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)<br>(O) OXALIplatin (Eloxatin) (266046)<br>(O) 5-Fluorouracil (5-FU) (19893)<br>(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)<br>(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)<br>(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)<br>(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)<br>(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)<br>(O) Palbociclib (PD-0332991) (772256) |

# MyeloMATCH Priority 1 List

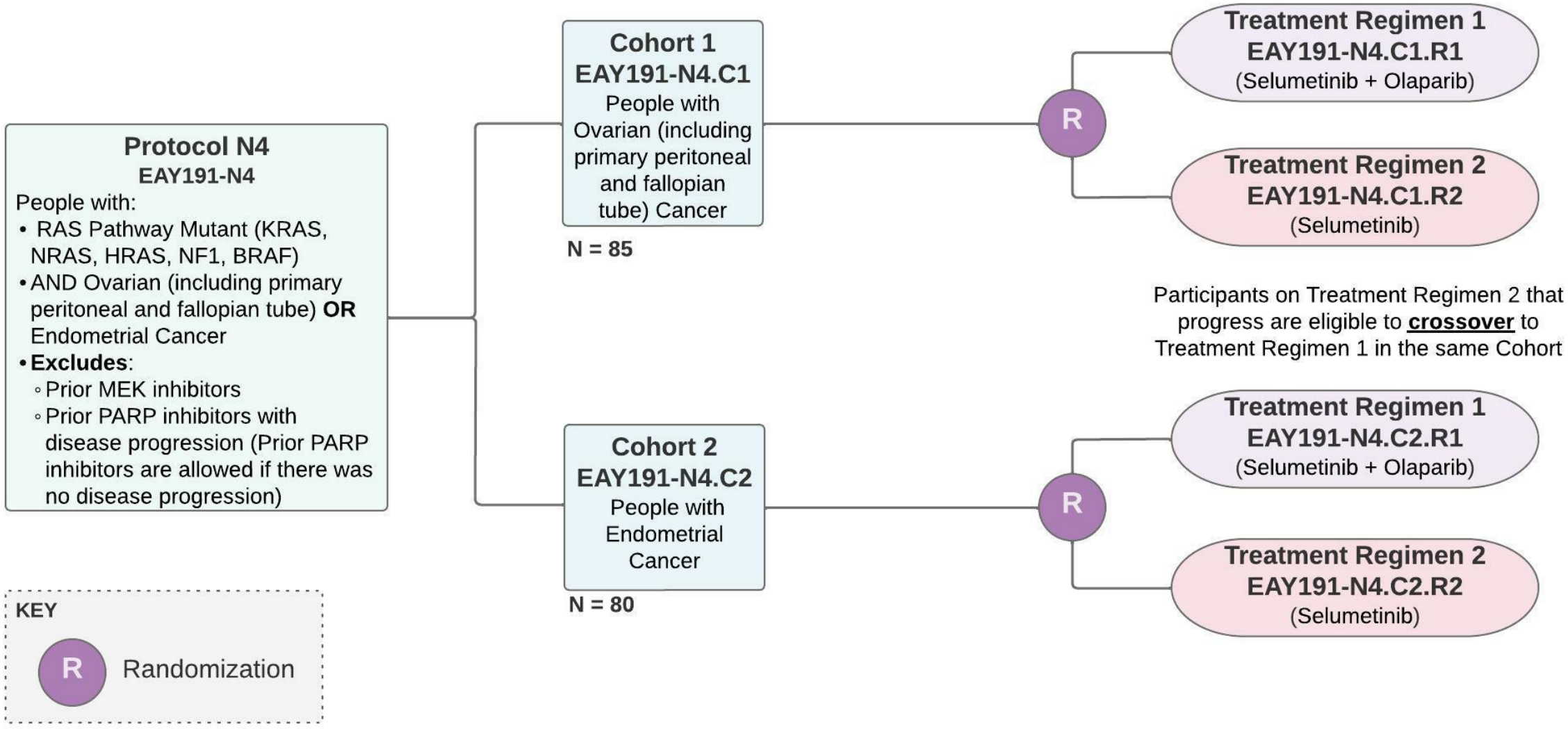
| Study # | Document Number | Document Title | Group | Current Status | Next Steps |
|---|---|---|---|---|---|
| 1 | MYELOMATCH | Master Screening and Reassessment Protocol (MSRP) for the NCI MyeloMATCH Clinical Trials | SWOG | 11/12/2021: Approval on Hold | CIRB Reviewed on 9/15, version with stips 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

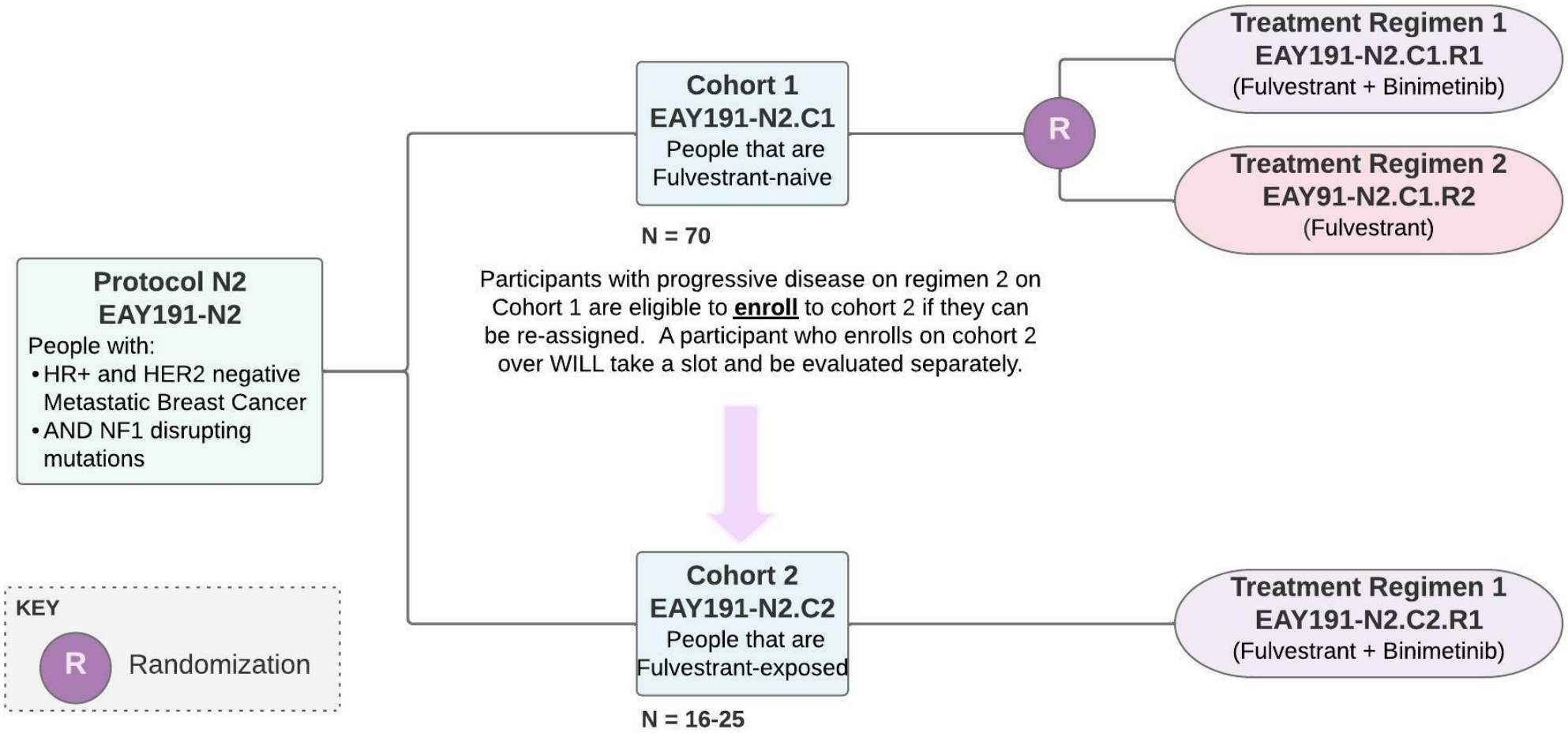
# EAY191-N4


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

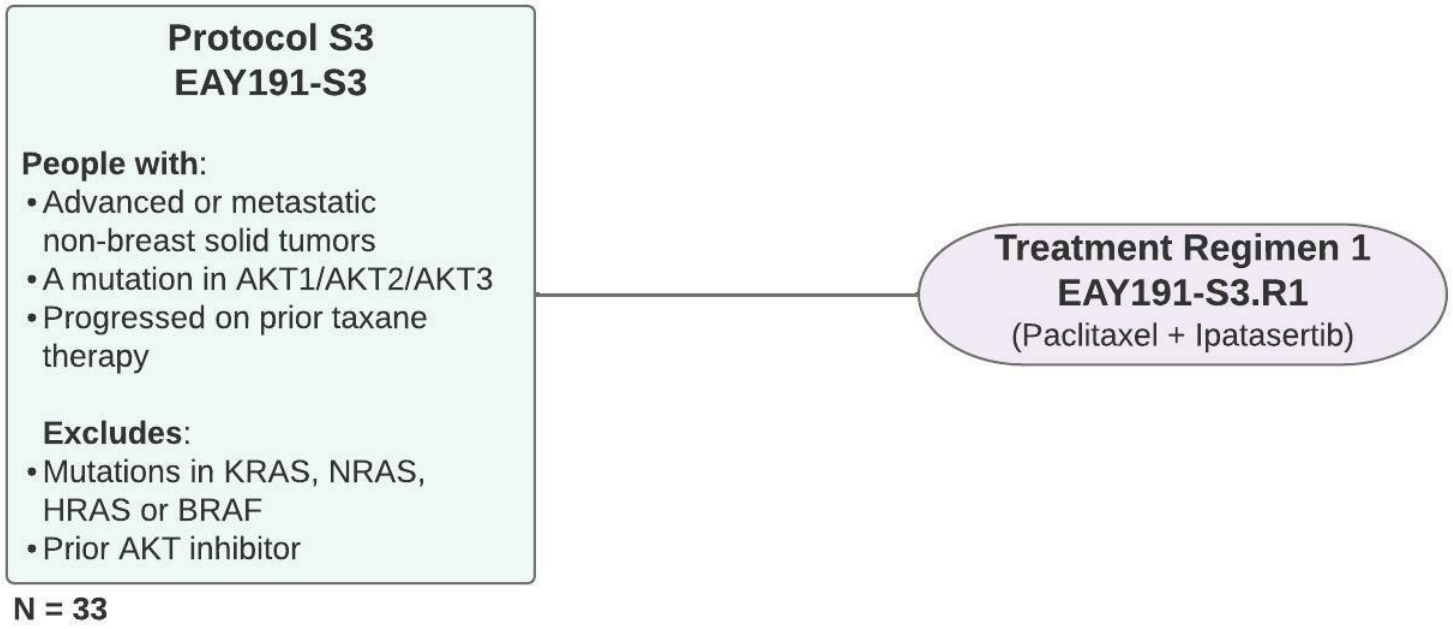
# EAY191-E4


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