










# Precision Medicine Initiative (PMI) Committee Meeting

February 21, 2024

# Agenda










- Role Call
- Project Updates
- MyeloMATCH Testing Plan
- Stakeholder Engagement Plan
- Project Status Updates

# Stakeholder Representation

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

# Project Updates

# Project Updates – PMI Deliverables

|  | Deliverable   | Target Release Date   | Target Release Vehicle   |
|--|---|---|--|
|    | ComboMATCH changes<br>(Disease fields, histology, behavior field code)    | <b>PROD Released:</b> July 17, 2023   | Screening Protocol EC Template v2.0  |
|    | Designated Labs for Combo   | <b>PROD Released:</b> Sept 6, 2023  | Screening Protocol EC Template v3.0<br>(UAT Release w/EA – 07/27/2023)   |
|    | Re-Screening ComboMATCH   | <b>PROD Released:</b> Sept 27, 2023   | MSRP Re-Screening EC Template v1.0<br>(UAT Release w/EA – 07/27/2023)  |
|    | Cohort Migration  | <b>PROD OPEN Released:</b> Sept 28, 2023<br><br><b>PROD EC Temp v1.0 Released:</b> Oct 27, 2023 | Treatment Protocol Cohort Migration EC Template v1.0   |
|    | MyeloMATCH Tx Protocol Crossover<br>(for S01, CTG01 and EA02)             | n/a   | Part of the existing Treatment Protocol workflow; no PRODUCTION OPEN Release required; the Westat team is prepared to support this workflow as Groups begin using it.  |
|    | Re-Screening MM   | <b>PROD RS EC Temp v2.0 Released:</b> Nov 30, 2023  | No PRODUCTION OPEN Release is required for MM Re-Screening activities; the Westat team is prepared to support this workflow as Groups begin using it.<br><br><b>MSRP Re-Screening EC Template v2.0</b><br>(UAT Release w/SWOG – 10/6/2023; 2 <sup>nd</sup> UAT Release w/SWOG – 10/24/2023; 3 <sup>rd</sup> UAT Release to SWOG – 11/07/2023; PROD RS EC Template v2.0 target date 11/30/2023) |
|  | MyeloMATCH Stratification   | PROD OPEN Release: February 12, 2023  | Part of existing Treatment Protocol Workflow.  |
|  | BETA PMI Screening Protocol ALS v2.0<br>New Forms: STMF, CLIA, PATH GROUP | <b>Released:</b> BETA Release: January 12, 2024   | Target date for BETA Release for Groups to initiate UAT activities.<br>(accompanied by BETA Screening Protocol Central Study ALS v2.0)   |
|  | PROD PMI Screening Protocol ALS v2.0<br>New Forms: STMF, CLIA, PATH GROUP | PROD Release: April 22, 2024  | Target date for PRODUCTION Release for Groups to initiate implementation activities.<br>(accompanied by PROD Screening Protocol Central Study ALS v2.0)  |

## Project Updates - EC Template Release Schedule

|   | Template  | Version | UAT Release Date   | PROD Release Date    | Details  |
|---|---|---------|--|----------------------|--|
| ✓ | PMI Screening Protocol EC Template                                    | V1.0    | Released: 12/16/2022   | Released: 02/15/2023 |  |
| ✓ | PMI Screening Protocol EC Template                                    | V2.0    | Released: 05/01/2023   | Released: 07/17/2023 | Includes CM changes (Disease fields, histology, behavior field code)   |
| ✓ | PMI Screening Protocol EC Template                                    | V3.0    | Released: 07/27/2023   | Released: 09/06/2023 | Includes updates for Designated Labs (DLAP fields)   |
| ✓ | <i>PMI Screening Protocol EC Template Fact Sheet</i>                  | v3.1    | n/a  | Released: 10/6/2023  | Administrative version/release of the Fact Sheet to capture MyeloMATCH Field Help/Instructional Text for the 'Prior therapy name' field; to be used in conjunction with the PMI Screening Protocol EC Template v3.0.                                   |
| ✓ | PMI Treatment Protocol EC Template                                    | V1.0    | Released: 12/16/2022   | Released: 02/15/2023 |  |
| ✓ | <i>PMI Treatment Protocol EC Template Fact Sheet</i>                  | V1.1    | n/a  | Released: 11/16/2023 | Administrative version/release of the Fact Sheet to provide a stand-alone TX Protocol-specific document allows Groups to easily access the Fact Sheet information; to be used in conjunction with the PMI Treatment Protocol EC Template v1.0.         |
| ✓ | PMI MSRP Re-Screening EC Template                                     | V1.0    | Released: 07/27/2023   | Released: 09/27/2023 | Supports ComboMATCH MSRP.  |
| ✓ | PMI MSRP Re-Screening EC Template                                     | V2.0    | Re-released: 11/07/2023<br>Re-released: 10/24/2023<br>Released: 10/06/2023 | Released: 11/30/2023 | Supports MyeloMATCH MSRP; PROD release date confirmed.   |
| ✓ | PMI Treatment Protocol Cohort Migration EC Template                   | V1.0    | Released: 09/18/2023   | Released: 10/27/2023 | Supports cohort migration activities for ComboMATCH.   |
| ✓ | <i>PMI Treatment Protocol Cohort Migration EC Template Fact Sheet</i> | v1.1    | Re-Release: 10/4/2023  | Released: 10/27/2023 | Administrative version/re-release of the UAT Fact Sheet to capture updated Field Help/Instructional Text for the 'Cohort migration assignment' field; to be used in conjunction with the UAT PMI Treatment Protocol Cohort Migration EC Template v1.0. |

## Group UAT Status : Screening Protocol ALS v2.0 (BETA)

- Beta ALSv2.0 Released on 1/15/24.
- Group UAT is underway
- Target date to complete Group UAT Testing (BETA) is **3/28/24**

# ComboMATCH Priority 1 List

| # | Protocol # | Protocol Title   | Group      | Activated | Current Status   |
|---|------------|--|------------|-----------|--|
| 1 | EAY191     | Molecular Analysis for Combination Therapy Choice (ComboMATCH)   | ECOG-ACRIN | Yes       | 12/13: No Updates<br>1/10: No Updates<br>2/7: No Updates<br>2/21: No Updates   |
| 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        | Yes       | 12/13: No Updates<br>1/10: No Updates<br>2/7: No Updates<br><br>2/21: No Updates   |
| 3 | EAY191-E4  | A ComboMATCH Treatment Trial ComboMATCH Treatment Trial E4: Nilotinib and Paclitaxel in Patients with Prior Taxane-Treated Solid Tumors  | ECOG-ACRIN | Yes       | 12/13: No Updates<br>1/10: No Updates<br>2/7: No Updates<br><br>2/21: No Updates   |
| 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        | Yes       | 12/13: Protocol amendment resubmitted.<br>1/10: No Updates<br>2/7: Got comments from Amendment 1, need to update EC template and need an updated protocol<br>2/21: Protocol Submitted – working on updates |
| 5 | EAY191-S3  | Phase 2 Study of Paclitaxel + Ipatasertib in Taxane-Refractory Participants with AKT-Altered Advanced Non-Breast Solid Tumors  | SWOG       | Yes       | 12/13: No Updates<br>1/10: No Updates<br>2/7: Removed the SSN and full name and released<br>2/21: No updates   |



## ComboMATCH Priority 2 List

| # | Protocol # | Protocol Title  | Group    | Activated | Current Status  |
|---|------------|---|----------|-----------|---|
| 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 | Yes       | 12/13: No Update<br>1/10: No Updates<br>2/7: No Updates<br><br>2/21: No Updates |
| 7 | EAY191-A3  | Palbociclib and Binimetinib in RAS-Mutant Cancers   | Alliance | Yes       | 12/13: No Update<br>1/10: No Updates<br>2/7: No Updates<br><br>2/21: No Updates |

## ComboMATCH Priority 3 List

| #  | Protocol # | Protocol Title  | Group      | Current Status  |
|----|------------|---|------------|---|
| 8  | EAY191-A2  | Olaparib Plus Low-Dose Alpelisib for Breast Cancer  | Alliance   | <b>DROPPED</b>  |
| 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        | <b>DROPPED</b>  |
| 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 | <p><b>12/13: Almost complete with internal OPEN testing; contacting CTSU and Engineering for FFP Cohort Migration.</b></p> <p><b>1/10: No Updates</b></p> <p><b>2/7: Active</b></p> <p><b>2/21: No Updates</b></p>                      |
| 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        | <p><b>12/13: Updated protocol submitted to CTEP on 12/4. Waiting to get test patients and working on the build.</b></p> <p><b>1/10: No Updates</b></p> <p><b>2/7: Released to production on 2/12</b></p> <p><b>2/21: No updates</b></p> |

# MyeloMATCH Priority 1 List

| # | Protocol #  | Protocol Title  | Group      | Current Status  |
|---|-------------|---|------------|---|
| 1 | MYELOMATCH  | Master Screening and Reassessment Protocol (MSRP) for the NCI MyeloMATCH Clinical Trials  | SWOG       | <p><b>12/13: Completed testing.</b></p> <p><b>1/10: No Updates</b></p> <p><b>2/7: SWOG sent wording suggestions on site notification in November; need feedback on messages</b></p> <p><b>Sent a message about MM data that may need since SWOG, if we download from the portal – we have to pay for specimens</b></p> <p><b>Dialogue box in OPEN where you add the path report – Redaction instruction;</b></p> <p><b>2/21: Completed, working through step to prep for activation – Westat is reviewing the bug found in OPEN...Westat will provide an update EOD</b></p> |
| 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       | <p><b>12/13: Delay because study structure; removing step 2 enrollment so SWOG has to redo work before they can move forward.</b></p> <p><b>1/10: No Updates</b></p> <p><b>2/7: Ready for MATCHbox integration testing on Jan 29.</b></p> <p><b>2/21: - Pending patient registration – until Westat bug is updated</b></p>  |
| 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       | <p><b>12/13: Testing in progress</b></p> <p><b>1/10: No Updates</b></p> <p><b>2/7: Testing should be done soon, MATCHbox Integration Testing – Send over instructions -</b></p> <p><b>2/21: Waiting on new testing patients to complete testing – have a request in</b></p>   |
| 6 | MM10A-EA02  | 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 | <p><b>12/13: Working on getting rando files to start OPEN testing</b></p> <p><b>1/10: No Updates</b></p> <p><b>2/7: Cohort/Stratum Assignment – Redoing the checklist – won't be ready for FFP by this week but working to meet that date.</b></p> <p><b>2/21: Working with randostats team to get files in place to begin testing</b></p>  |

## MyeloMATCH Priority 2 List

| # | Protocol #            | Protocol Title   | Group      | Current Status  |
|---|-----------------------|--|------------|---|
| 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 | 1/10: No Updates<br>2/7: No Updates<br>2/21: No Updates   |
| 5 | MM10A-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       | 1/10: No Updates<br>2/7: Started creating forms, waiting on integration testing to complete for SO1<br>2/21: No Updates |
| 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 | 1/10: No Updates<br>2/7: No Updates<br>2/21: Withdrawn  |

# MyeloMATCH Testing Plan

# Testing Plan - MyeloMATCH

| PMI MyeloMATCH Treatment Group Testing Plan Activities                  |                     |   |   |               |          |
|---|---------------------|---|---|---------------|----------|
| <i>Testing Set Up: Creating Test patients in the Screening Protocol</i> |                     |   |   |               |          |
| Task #  | User                | Task Description  | Notes   | Pass/<br>Fail | Comments |
| 1   | CTSU OPEN Team/SWOG | Complete multiple Step 1 enrollments to the Screening protocol                                    | Task should be completed once Tx protocol EC form has been downloaded to OPEN UAT.<br><br><b>MSRP Group:</b> SWOG would use test script to trigger assignment to their Tx protocol.<br><b>Non-MSRP Groups:</b> OPEN team would use test script to trigger assignment to Tx protocol the group is testing. |               |          |
| 2   | CTSU OPEN Team/SWOG | Fifteen minutes after step 1 enrollments are completed, upload Path and CLIA reports in OPEN.     | MyeloMATCH Staff: myelo-match-support@nih.gov<br><br>OPEN team/SWOG should identify which treatment protocol they need assigned.  |               |          |
| 3   | CTSU OPEN Team/SWOG | Send all screening PIDs to MATCHBox staff   |   |               |          |
| 4   | MATCHBox Staff      | Generate Tx protocol assignment and send notification to the OPEN team or SWOG                    | CTSU OPEN Team: CTSUOPENFORMS@westat.com  |               |          |
| 5   | CTSU OPEN Team      | Confirm Tx protocol assignment is displayed in OPEN and send screening protocol PIDs to the group | -   |               |          |

# Testing Plan - MyeloMATCH

## Scenario #1: Successful Enrollment to Screening and Treatment

| Task # | User           | Task Description   | Notes  | Pass/Fail | Comments |
|--------|----------------|--|--|-----------|----------|
| 1      | Group          | Enroll test patients to the Tx protocol in OPEN  | Group user(s) would test the Tx protocol EC form.<br>EC form testing of:<br>1. Proper working of edit checks<br>2. Proper working of randonode<br>3. Ensure OPEN/PMI integrations are working.               |           |          |
| 2      | Group          | Send Tx protocol PIDs to the OPEN Team and MATCHBox staff  | Include the Protocol and Scenario number in the subject line<br><br>Include Screening protocol PIDs in notification<br><br>Westat: CTSUOPENFORMS@westat.com<br>MyeloMATCH Staff: myelo-match-support@nih.gov |           |          |
| 3      | MATCHBox Staff | Confirm receipt of Tx protocol enrollment information and send notification to group.                                      | MATCHBox staff should reply back to group's initial email for confirmation.  |           |          |
| 4      | Group          | Complete Off Treatment and Consent Withdrawal forms for 1-2 patients in Rave.  |  |           |          |
| 5      | Group          | Send notification to MATCHBox staff and the CTSU OPEN team that 1-2 patients have gone off treatment and withdrew consent. | Include Tx protocol PID and Screening protocol PID in notification<br><br>Westat: CTSUOPENFORMS@westat.com<br>MyeloMATCH Staff: myelo-match-support@nih.gov  |           |          |
| 6      | MATCHBox Staff | Confirm receipt of Off Treatment, Off Study and Consent Withdrawal information and send notification to group.             | MATCHBox staff should reply back to group's initial email for confirmation.  |           |          |

# Testing Plan - MyeloMATCH

## *Scenario #2: Enrolling a Patient Assigned to TAP*

| Task # | User Group | Task Description   | Notes   | Pass/Fail | Comments |
|--------|------------|--|---|-----------|----------|
| 1      |            | Attempt to enroll patient who is assigned to TAP to a Tx protocol and confirm inability to enroll. | An error should be displayed after the patient ID assigned at screening is entered and saved. |           |          |



# Stakeholder Engagement Plan

## Stakeholder Feedback- Reminder

- Please provide all feedback by 2/23/24
- <https://forms.office.com/g/Ly8UTMXvBt>
- Any questions on feedback or issues with the form, please email the PMI Standards Mailbox ([pmistandards@nih.gov](mailto:pmistandards@nih.gov))

# Open Discussion

- Testing: To confirm for MM Matchbox is not matching at the cohort level. If we match to a treatment trial and the cohort is full, what happens next since we are not controlling for MM unlike CM.
  - In this case, would get an ineligibility notice or reach out to the help desk and let them know they were not assignable.
  - Rich: If the groups stats office knows the cohort has filled, that information should be transmitted over to Matchbox.
  - Revisit the other specify value on the reassignment screen -

# Next Steps

# Communication



## Contact the PMI Mailbox for any PMI related questions & comments

[pmistandards@nih.gov](mailto: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



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[www.cancer.gov](http://www.cancer.gov)

[www.cancer.gov/espanol](http://www.cancer.gov/espanol)

# Appendix

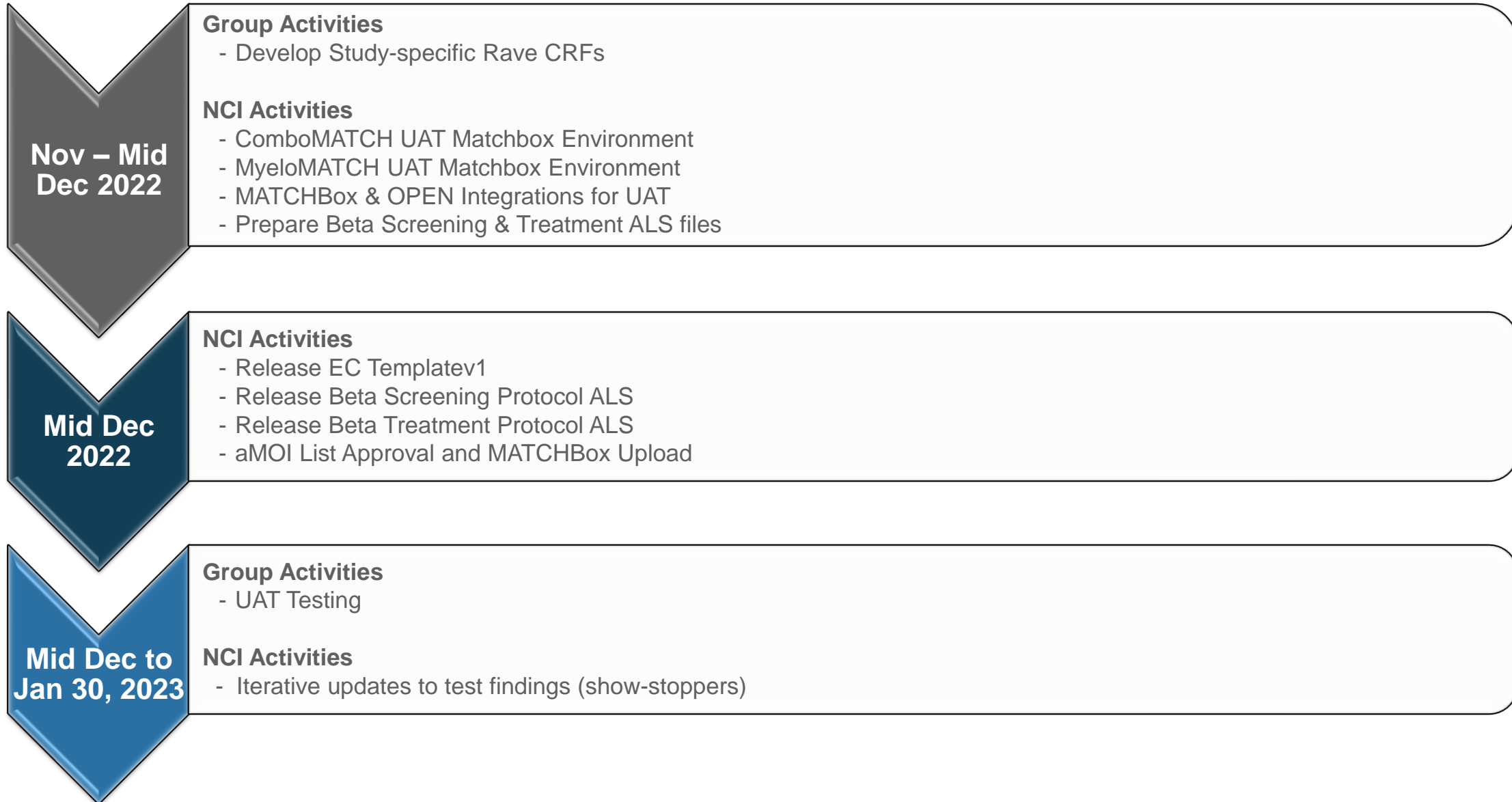
# CTEP CDISC Policy Governance Review



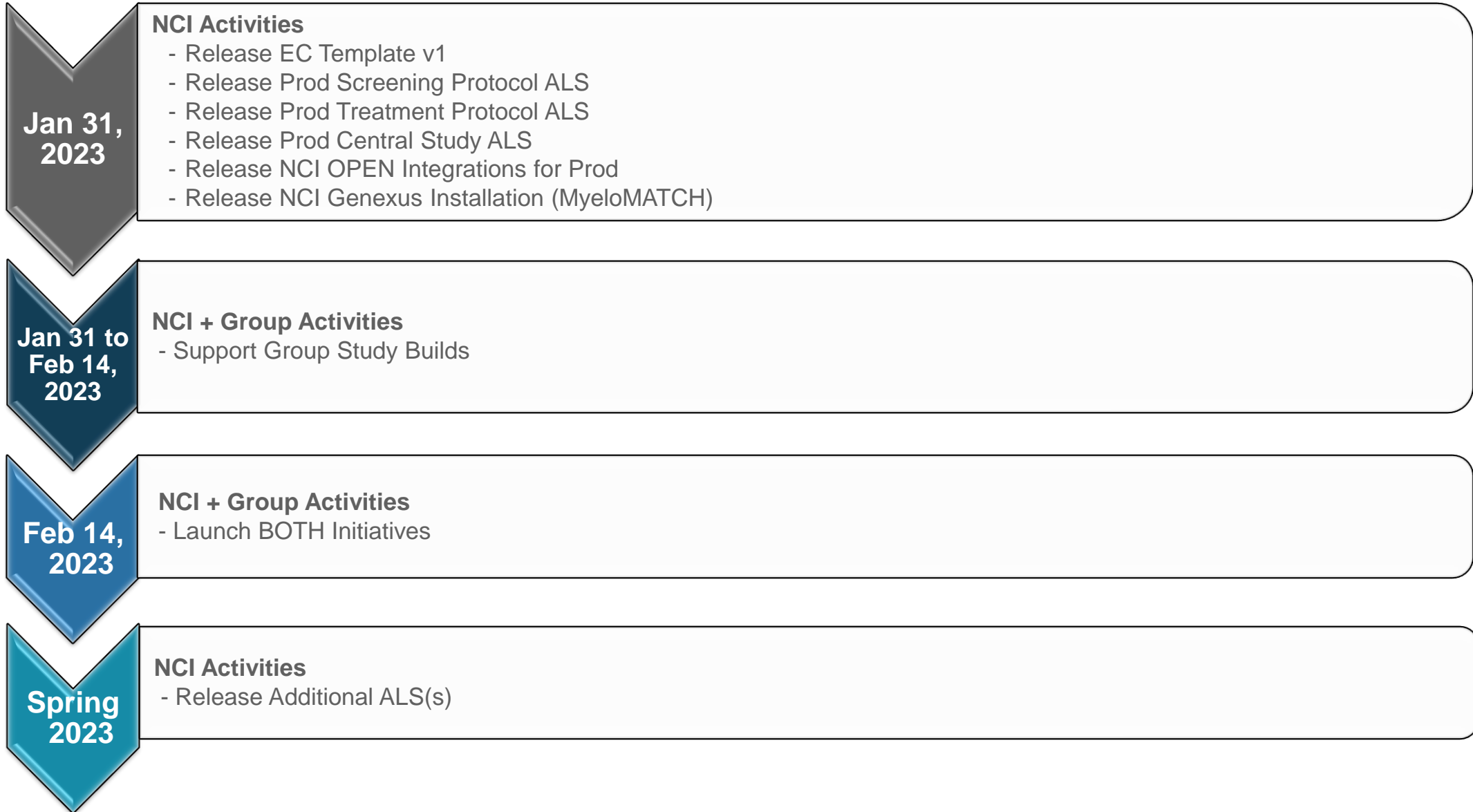
# Compliance for Use of ALS Versions

- Standard forms built in the LPO's Global Library within **60 days** of production ALS release to reflect additions/updates included in the ALS
  - Example: Release ALSv7.X on November 1, LPOs would be expected to incorporate the ALSv7.X into their Global Library by January 1
  - ALS versions for new study builds
    - LPOs will be required to use the most current version of the ALS available at the time of each study build

# Target Timeline



# Target Timeline



## ComboMATCH Priority 1 List

| Study # | Document Number | Document Title   | Group      | Current Status                | Next Steps  | Primary Agent Name (P)<br>Other Agent Name (O)   |
|---------|-----------------|--|------------|-------------------------------|---|--|
| 1       | EAY191          | Molecular Analysis for Combination Therapy Choice (ComboMATCH)   | ECOG-ACRIN | 8/15/2022<br>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<br>Approval on Hold | Revision 4 back from CIRB with approval. On hold for DTL, funding sheet and IND filing. | (P) Olaparib (AZD2281) (747856)<br>(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<br>Approval on Hold | Revision 3 back from CIRB with approval. On hold for DTL, funding sheet and IND filing. | (P) Nilotinib (747599)<br>(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<br>Approval on Hold | Revision 3 back from CIRB with approval. On hold for DTL, funding sheet and IND filing. | (P) Binimetinib (788187)<br>(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<br>Approval on Hold | Revision 4 back from CIRB with approval. On hold for DTL, funding sheet and IND filing. | (P) Ipatasertib (781451)<br>(O) Paclitaxel (Taxol) (673089)                            |

## ComboMATCH Priority 2 List

| Study # | Document Number | Document Title  | Group    | Current Status                | Next Steps  | Primary Agent Name (P)<br>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<br>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<br>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)<br>Other Agent Name (O)   |
|---------|-----------------|---|------------|-------------------------|--|--|
| 8       | EAY191-A2       | Olaparib Plus Low-Dose Alpelisib for Breast Cancer  | Alliance   | In Review<br>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<br>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<br>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<br>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       | MM10A-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   |

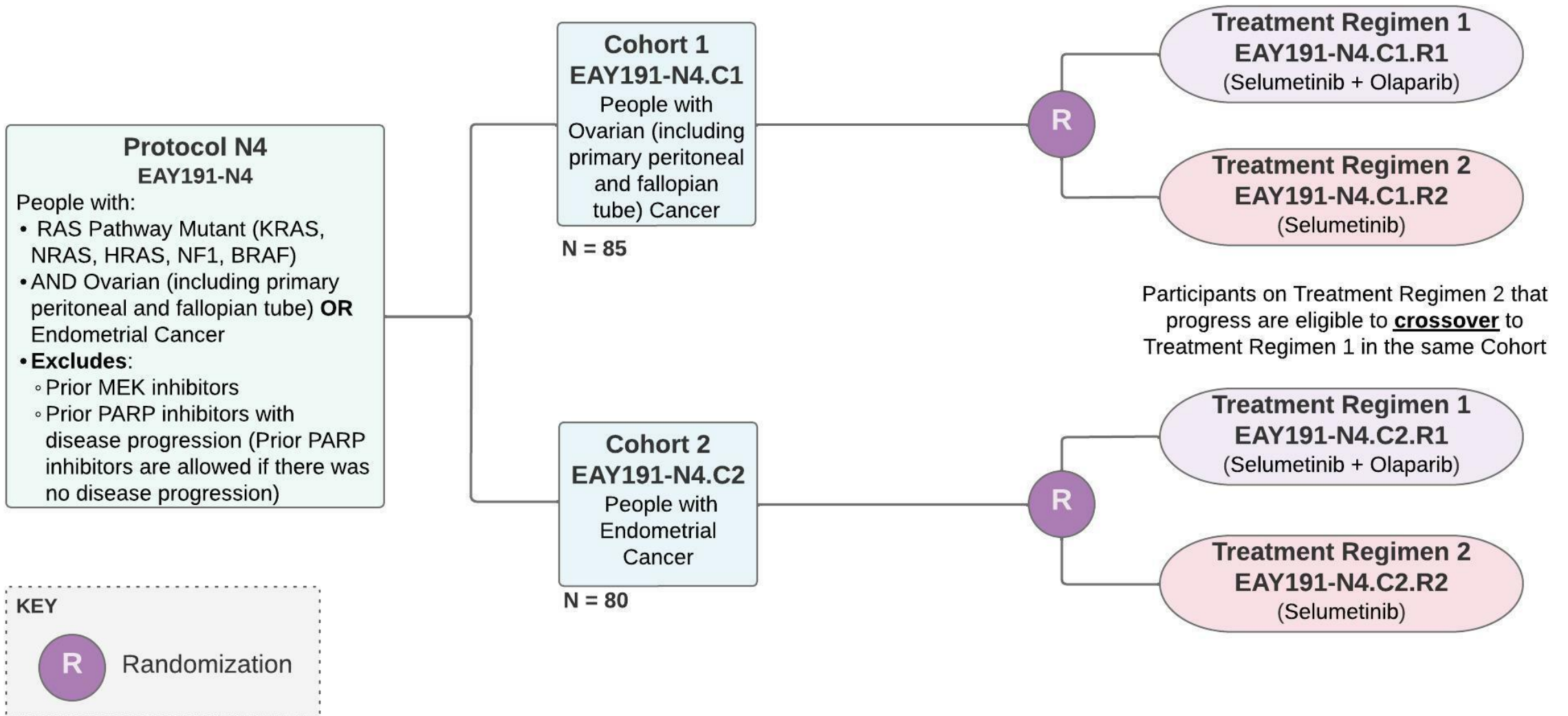
## MyeloMATCH Priority 2 List

| 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:<br>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:<br>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:<br>Approval on hold, waiting for drug commitment | W+A6:G8aiting for Astex commitment, Genentech has provided commitment on 10/20 |



# Review Schemas

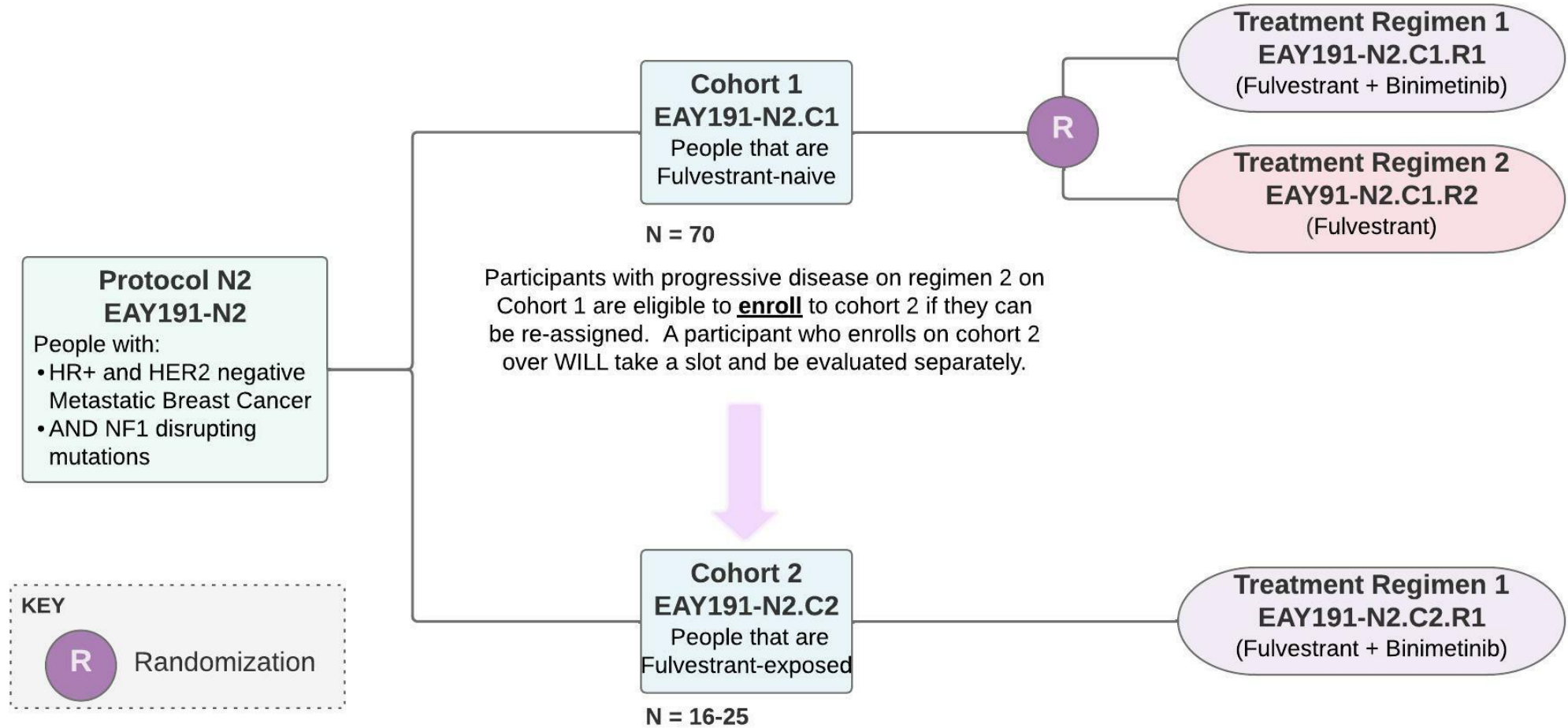
# EAY191-N4



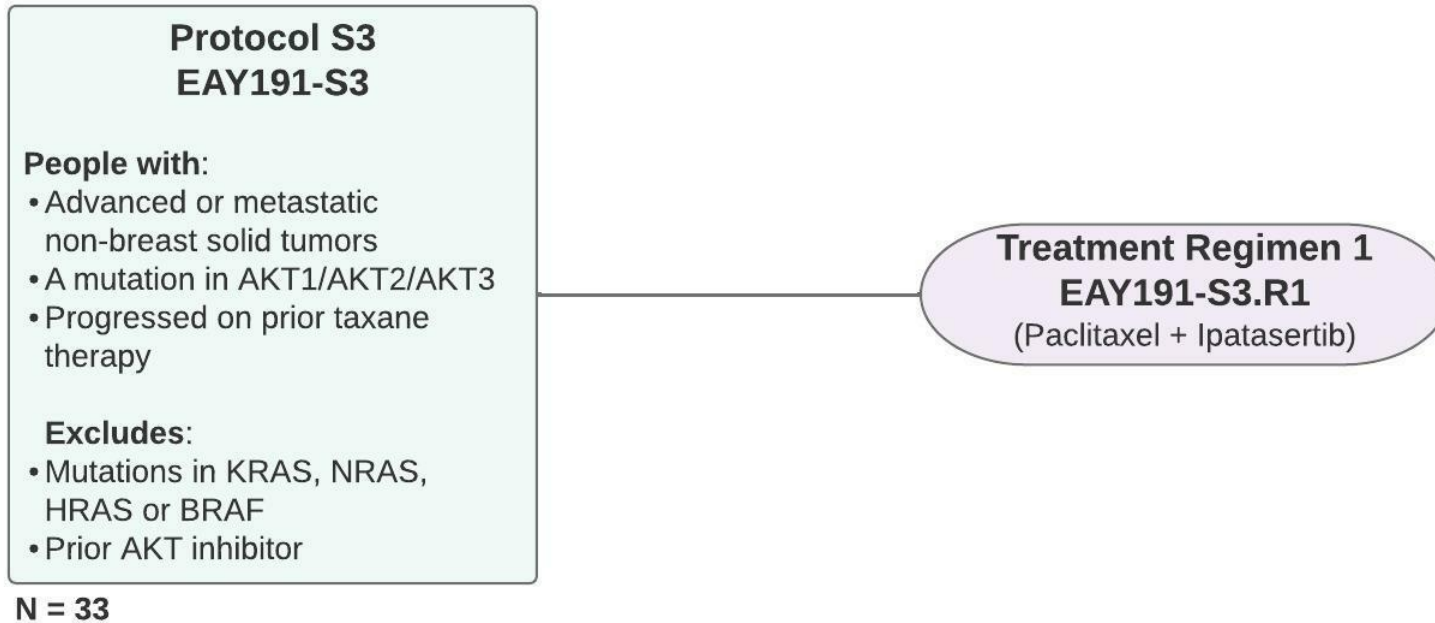
# EAY191-E4



# EAY191-N2- Draft



# EAY191-S3



# MMIYA-CTG01 Draft

