










Precision Medicine Initiative (PMI) Committee Meeting

August 9, 2023

Agenda

- Role Call
- Project Status Updates
- Project Discussion Items
- Next Steps

Stakeholder Representation

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

Project Status Updates

Project Updates

PMI Project Deliverable	Target Release Date	Release Vehicle
ComboMATCH changes (Disease fields, histology, behavior field code)	Released: July 17, 2023	Screening Protocol EC Template v2.0
Designated Labs for Combo	August 18, 2023	Screening Protocol EC Template v3.0
Re-Screening ComboMATCH	August 18, 2023	Screening Protocol Re-Screening EC Template v1.0
MyeloMATCH Tx Protocol Crossover (for S01, CTG01 and EA02)	October 3, 2023	Part of the existing Treatment Protocol workflow.
Cohort Migration	September 25, 2023	Treatment Protocol Cohort Migration EC Template v1.0
Re-Screening MM	Oct 10, 2023	Screening Protocol Re-Screening EC Template v2.0
STMF	Oct 27, 2023	PMI Screening Protocol ALS v2.0
CLIA	Oct 16, 2023	PMI Screening Protocol ALS v2.0
Path	Oct 16, 2023	PMI Screening Protocol ALS v2.0
PMI Screening Protocol ALS v2.0	~ mid-October 2023	Target to start Group Beta UAT
MyeloMATCH Stratification	Oct 20, 2023	Part of existing Treatment Protocol Workflow

EC Screening Template Release Schedule

Release	Details	Tentative Release Date
V1.0	Production Release	February 15 th 2023
V2.0	Includes CM changes (Disease fields, histology, behavior field code)	July 17 th 2023
V3.0	Includes updates for Designated Labs (DLAP fields)	August 18 th 2023
V4.0	MM MSRP changes (Provisional Diagnosis Question)	TBD

Group Roadblocks

Group	7/26/2023	8/9/2023
ECOG-ACRIN	<ul style="list-style-type: none"> • Need the EC template 	<ul style="list-style-type: none"> • Need to wait until the end of Sept to build with the template. • David Patton: Cohort Migration will not be in production until end of Sept. Guidance is to activate with the treatment trial checklist and update with the new version at the end of Sept. Want to make sure the language is consistent across protocols. • Related to E5: Working on updating the protocol template, received that memo from CTEP on what to insert in the protocol; one of the edits is an edit to the schema. • Melinda/Shauga will send to David to review. • ECOG ACRIN can activate E5 for review and OPEN checklist
SWOG	<ul style="list-style-type: none"> • Need v4 to complete study build for MM • Need confirmation and timeline on ineligible process 	<ul style="list-style-type: none"> • Need v4 to complete study build for MM
NRG	<ul style="list-style-type: none"> • No questions 	
Alliance	<ul style="list-style-type: none"> • No questions 	<ul style="list-style-type: none"> • Getting ready to A6 – • {Q} - Protocol developer reached out to CTSS for RSS setup... • Alliance just needs to update RSS, every time the patient goes through the pipeline, MATCH will update via RSS. • Access to the hub; would like it before the 11th, • CDISC Derivations
CCTG	<ul style="list-style-type: none"> • No questions 	<ul style="list-style-type: none"> • No updates...waiting on test patients
COG	<ul style="list-style-type: none"> • No updates; • Waiting on mappings 	

PMI Project Discussion Items

Open Discussion

- ECOG/ACRIN – Will we be doing FFP on every treatment trial
- David: We do one test case per trial; David to provide the test case ahead of time
- Does the FFP include site participation for every trial? Yes we should include them

Next Steps

Next Steps

Next meeting will be on 8/23/2023 at 1:00pm EST

Agenda

- Role Call
- Project Status Update
- Group Status Update
- Review FAQs

Communication



Contact the PMI Mailbox for any PMI related questions & comments

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



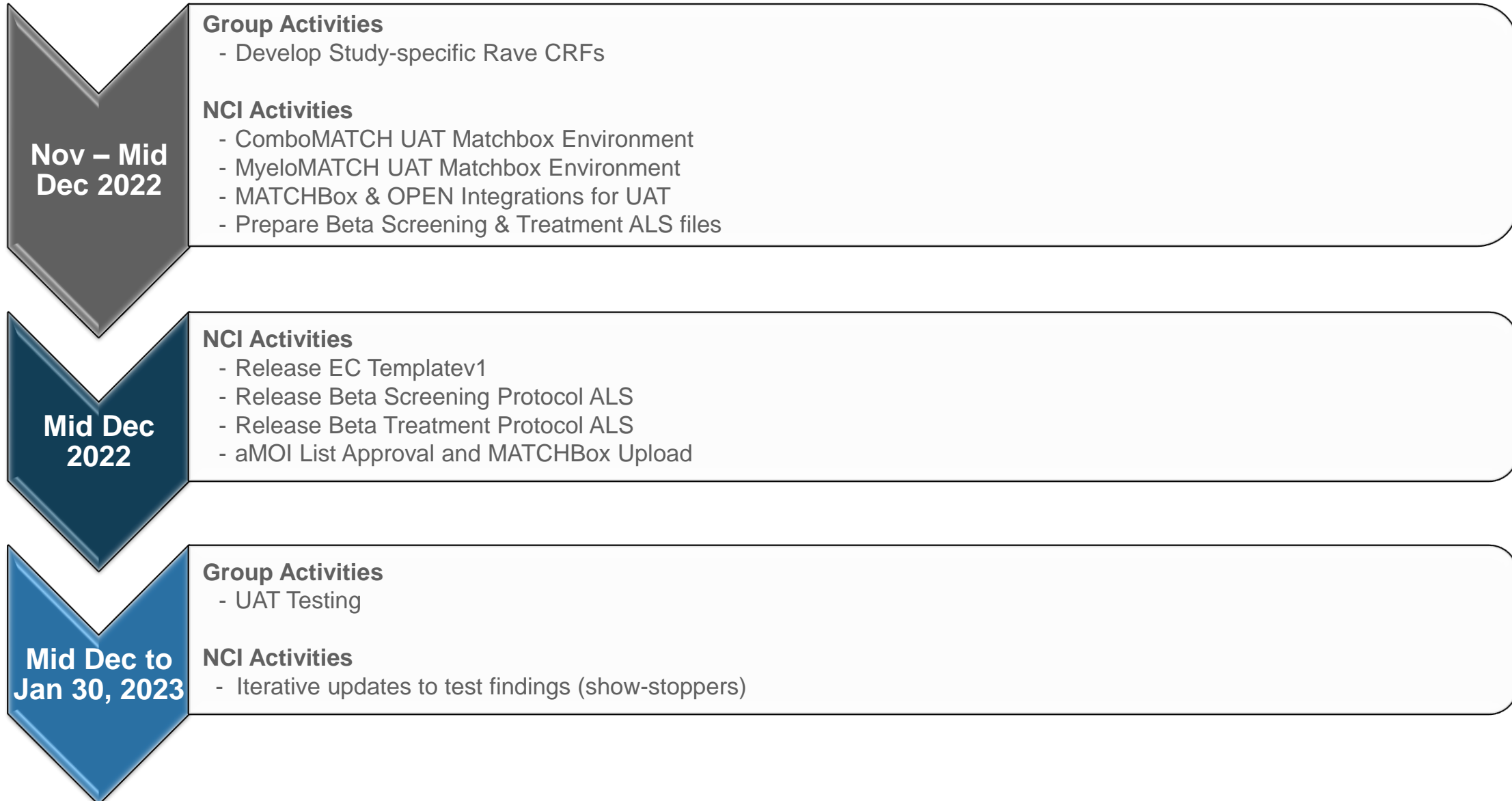
**NATIONAL
CANCER
INSTITUTE**

www.cancer.gov

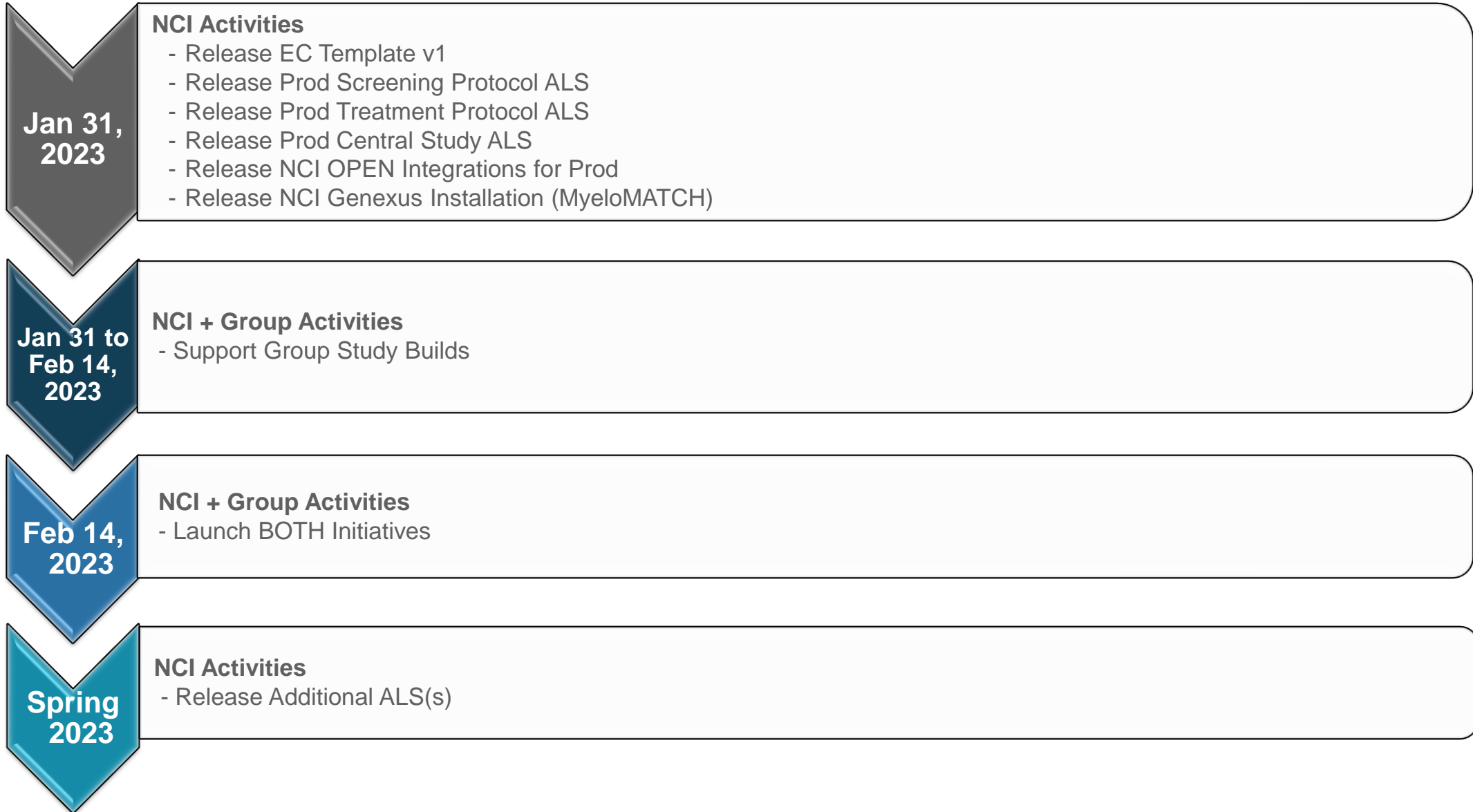
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Appendix

Target Timeline



Target Timeline



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

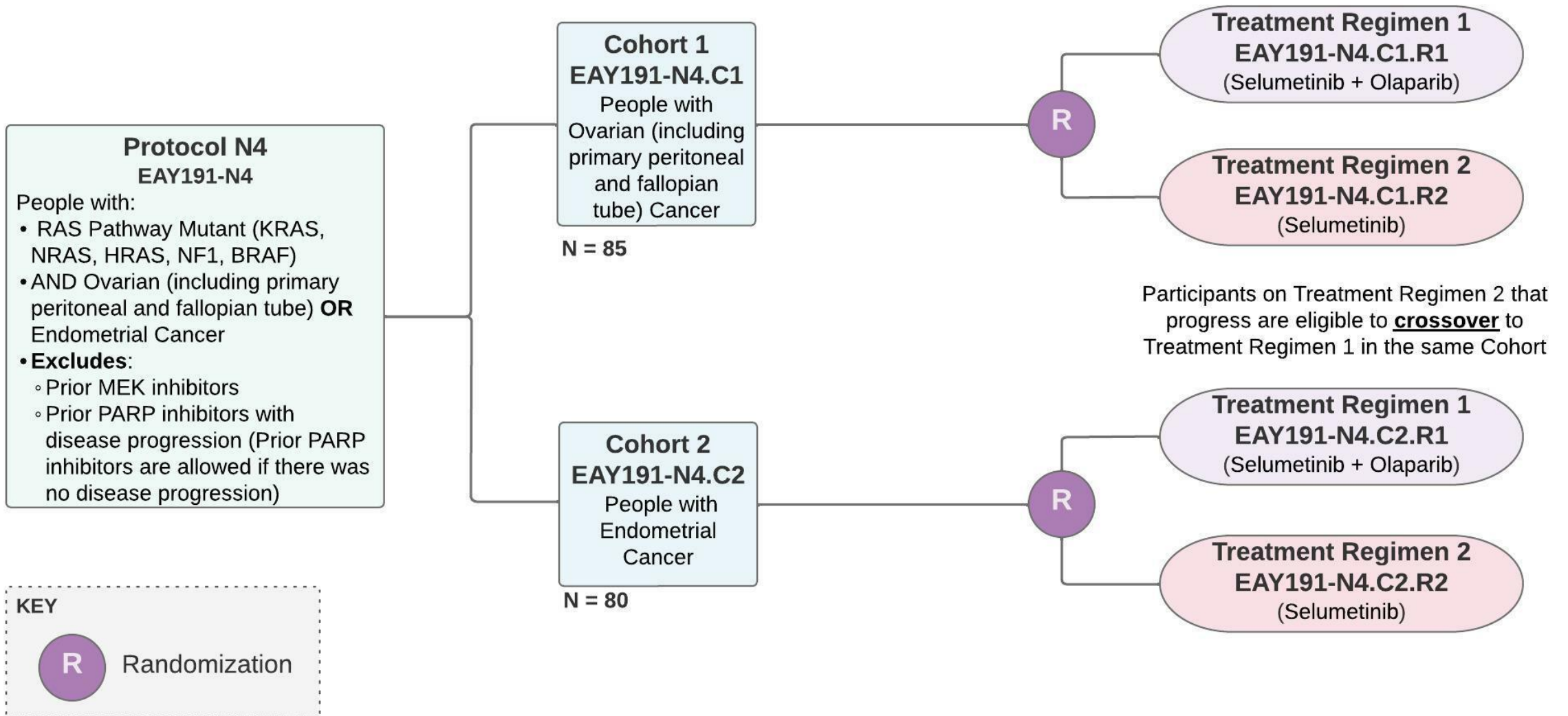
Study #	Document Number	Document Title	Group	Current Status	Next Steps
1	MYELOMATCH	Master Screening and Reassessment Protocol (MSRP) for the NCI MyeloMATCH Clinical Trials	SWOG	11/12/2021: Approval on Hold	CIRB Reviewed on 9/15, version with stips under CTEP review now.
2	MM1YA-S01	A Randomized Phase 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	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: In Review	Reviewed by CIRB, responding to stips
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	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

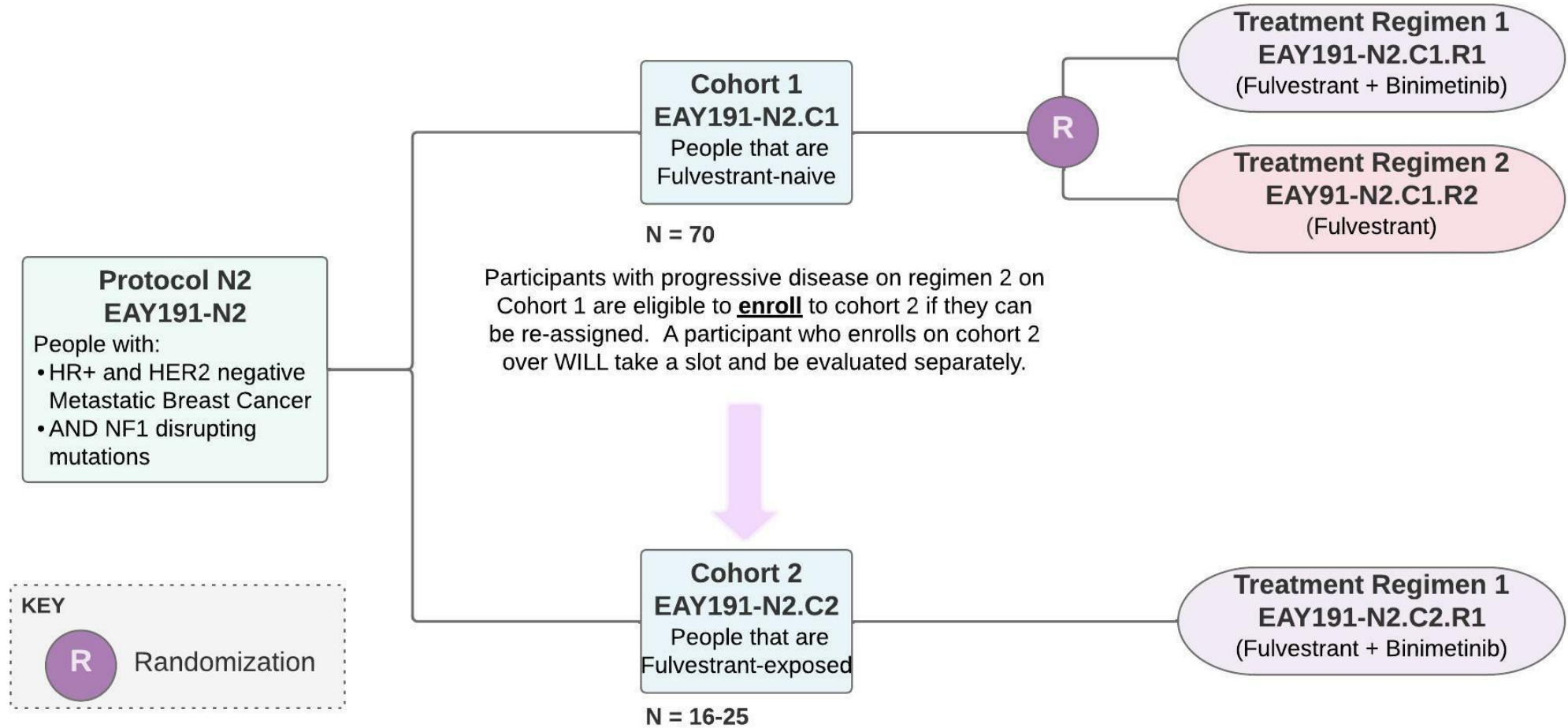
EAY191-N4



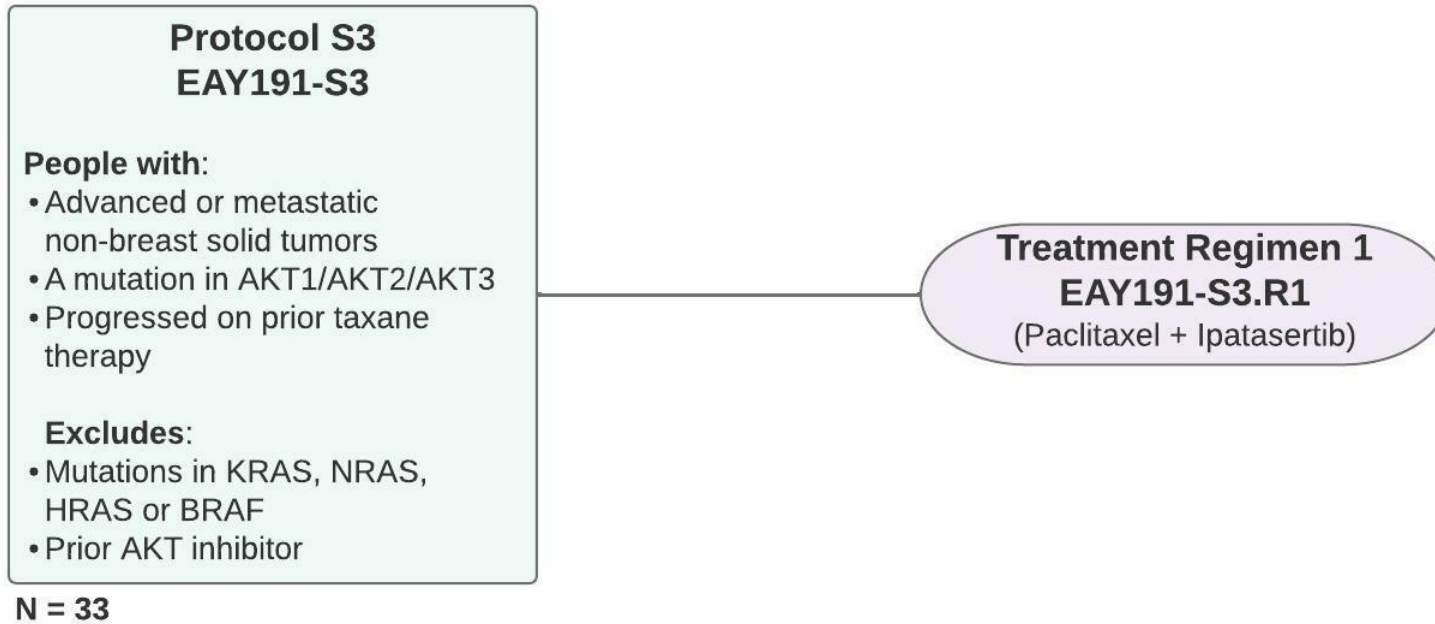
EAY191-E4



EAY191-N2- Draft



EAY191-S3



MMIYA-CTG01 Draft

