






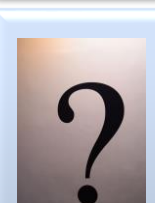
Precision Medicine Initiative (PMI) Committee Meeting

November 30, 2022

Agenda

- Role Call
- Project Status Updates
- OPEN/Rave/MATCHbox Demo
- Next Steps

Stakeholder Representation

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

Project Status Updates

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	In Progress	Not Started
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 Compliance review Deliver beta form/field listing for Groups Custom functions	Integration + QA testing	
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 Treatment Protocol ALS v1.0
Target Date: December 16, 2022

Production Release Treatment 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 Compliance review Deliver beta form/field listing for Groups Custom functions	Integration + QA testing	
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			

CTSU Protocol Application (RSS) Requirements

Target Date: January 30, 2023

Tasks	Completed	In Progress	Pending
Review rules for protocol status changes	X		
Verify required field population logic	X		
Review target and count validations	X		
Create RSS User Guide		X	
Deploy to UAT			X
Deploy RSS updates to Production			X
Release updated RSS User Guide			X

OPEN-Pathology/CLIA Upload/Download

Target Date: January 30, 2023

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

UAT Environments

ComboMATCH Date: Dec 16, 2022

MyeloMATCH Date: Dec 16, 2022 (Potential risk to run a week or two late)

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

OPEN/RAVE/MATCHbox

Demo Expectations

- There may be a few bugs, but we are working towards giving as much information as possible.
- Questions around re-registration will be tabled for a future meeting. Re-registration is not part of the 1st implementation.
- Please ask questions throughout the demo, this is a collaborative call.
- In the interest of time, we may ask for you to send your questions to the PMI Mailbox

Next Steps

Next Steps

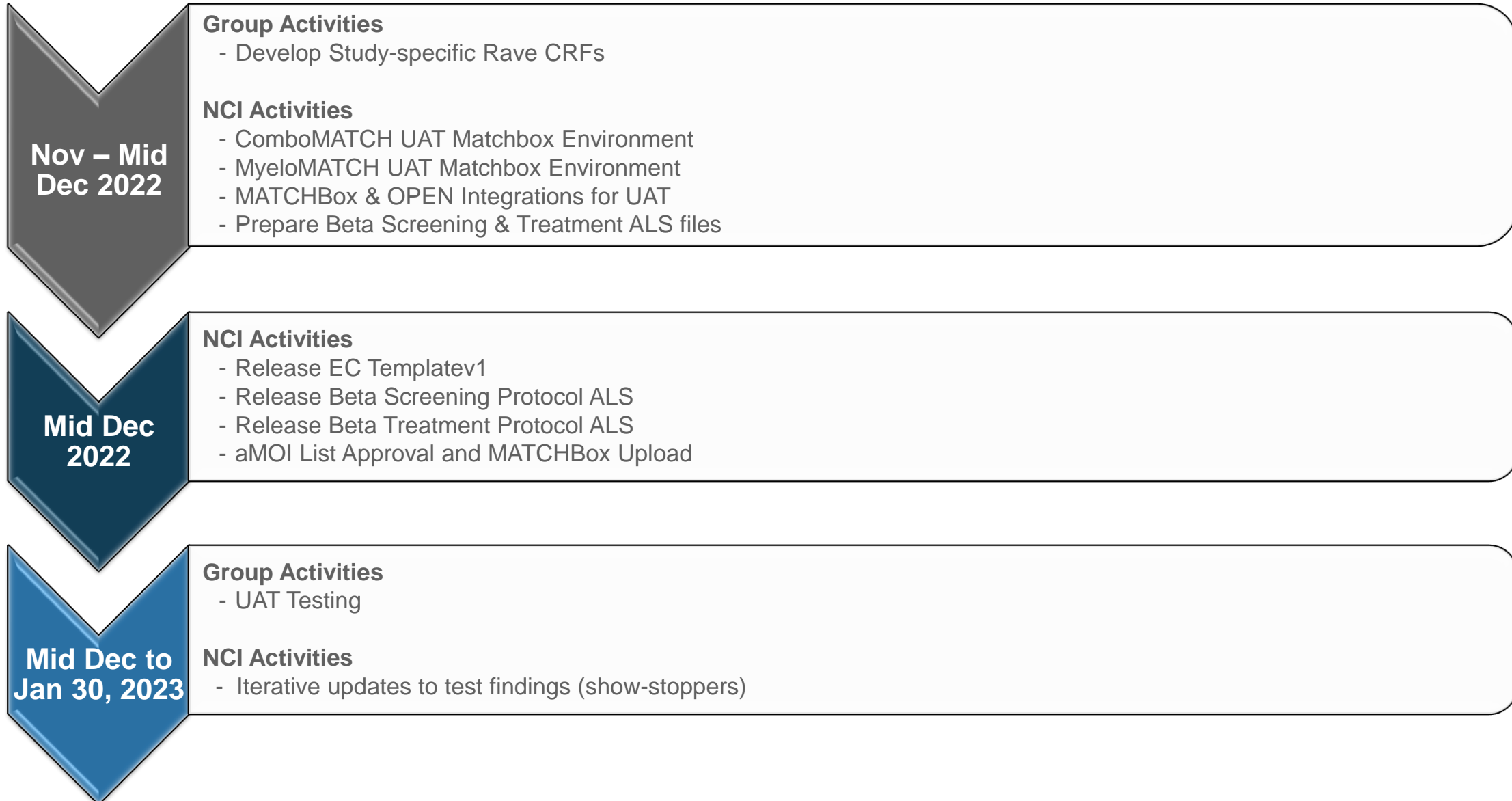
- Next meeting will be on 12/14/2022 at 1:00pm EST
- Agenda
 - Role Call
 - Project Status Update
 - Review FAQs
 - Demos TBD
- Groups will be receiving an email regarding the RSS app, please respond with your feedback
- If you have schema discrepancies, please contact the PMI mailbox

Communication

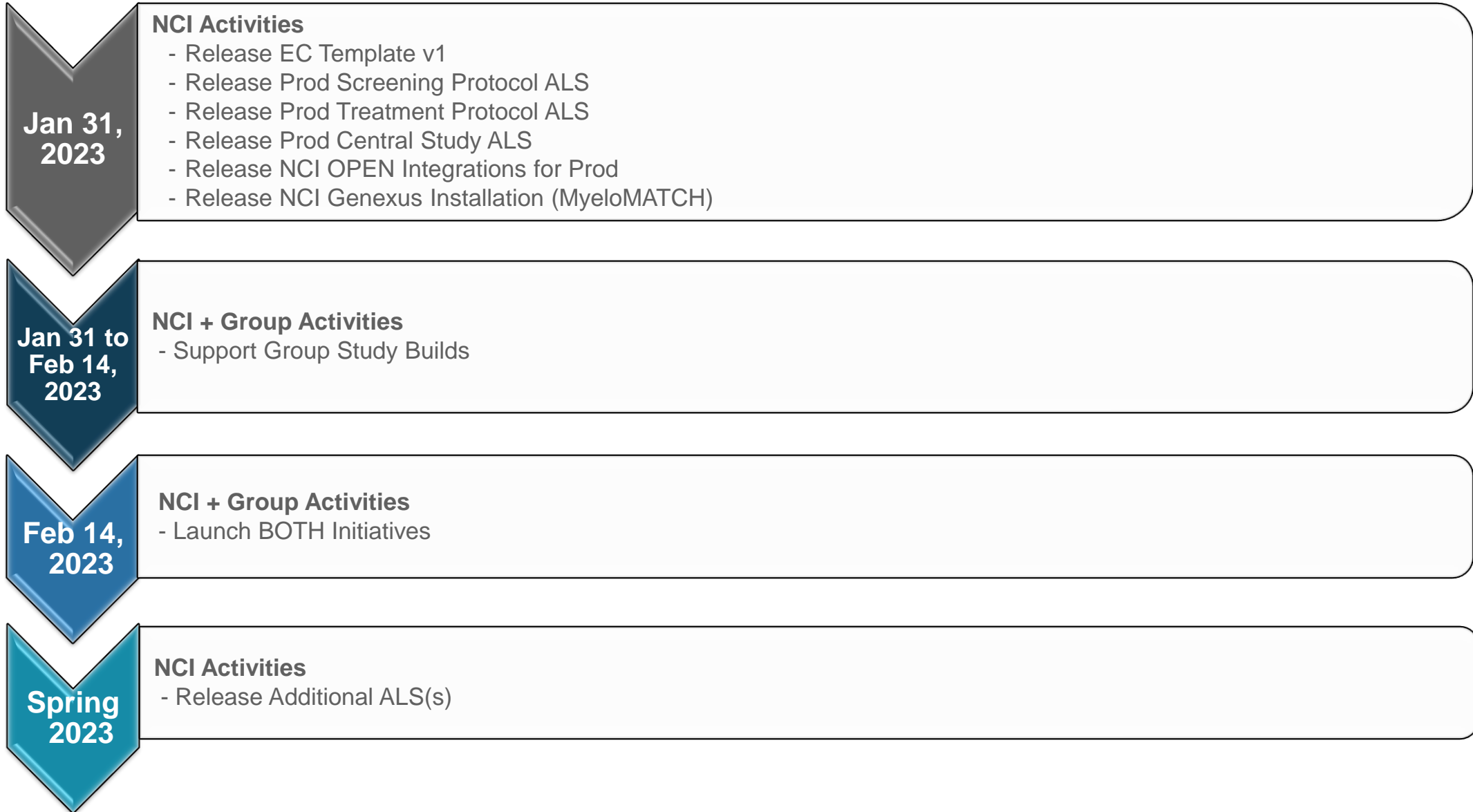
- Contact PMI Mailbox for any PMI related questions
 - ncipmistandards@nih.gov
 - The project team will respond within 48 hours with a response or a follow up
- PMI Wiki
 - <https://wiki.nci.nih.gov/display/CDISC/Precision+Medicine+Initiative>
 - All presentations, recordings, minutes, project documents and releases will be posted on this wiki

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

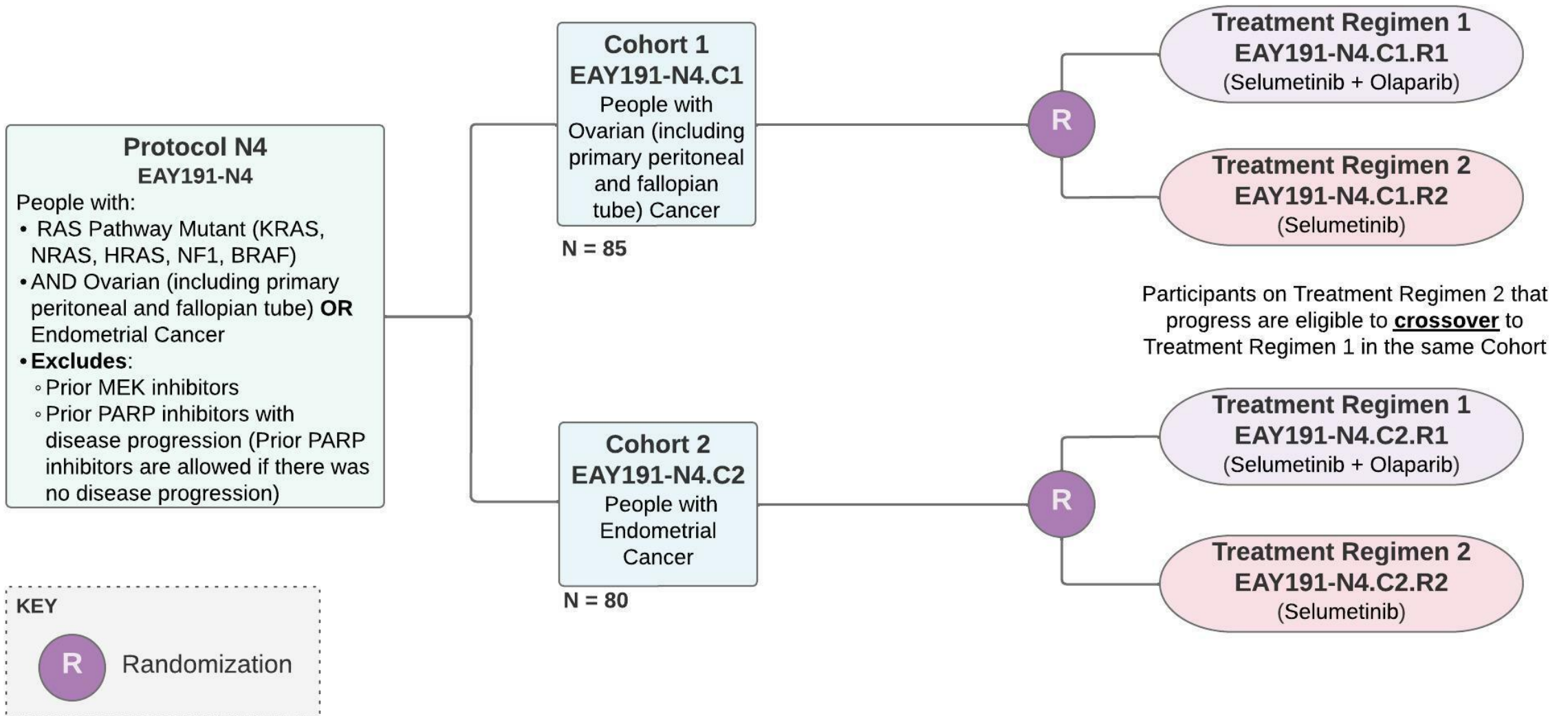
Study #	Document Number	Document Title	Group	Current Status	Next Steps
1	MYELOMATCH	Master Screening and Reassessment Protocol (MSRP) for the NCI MyeloMATCH Clinical Trials	SWOG	11/12/2021: Approval on Hold	CIRB Reviewed on 9/15, version with stips under CTEP review now.
2	MM1YA-S01	A Randomized Phase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

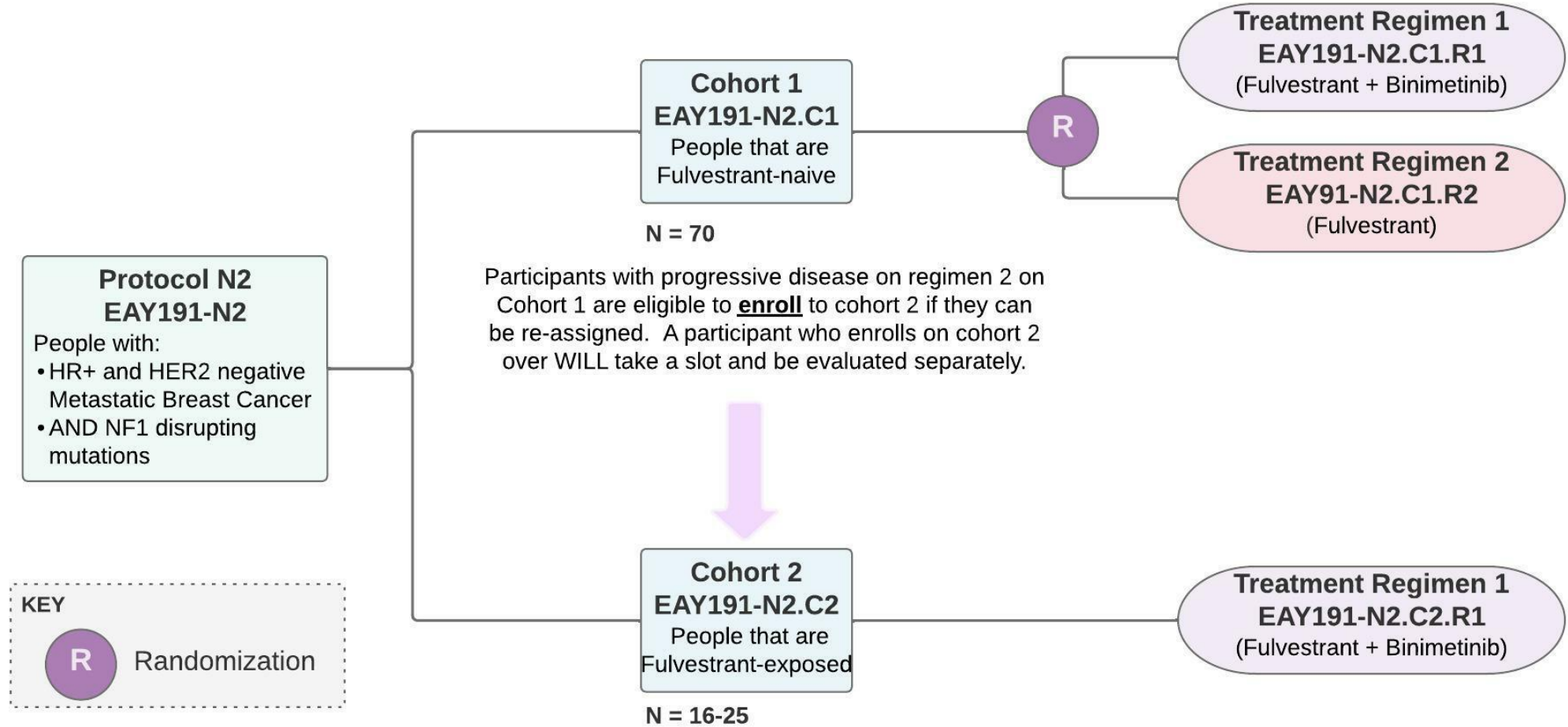
EAY191-N4



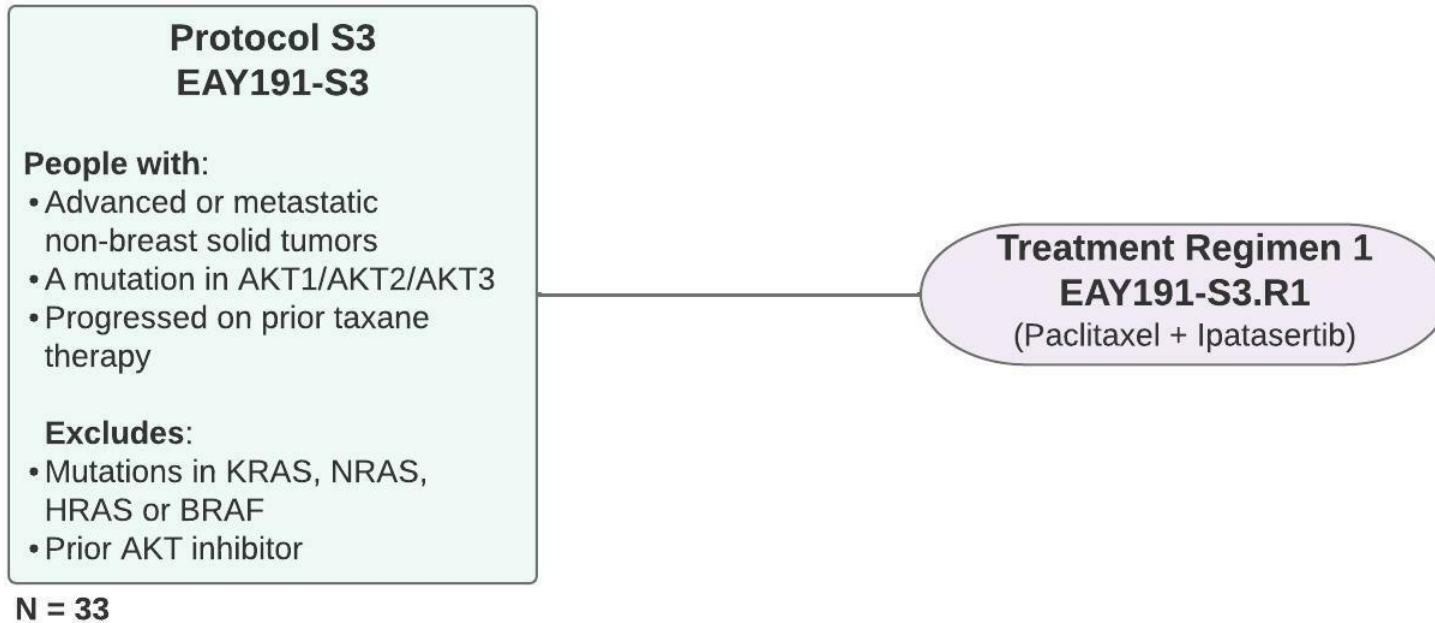
EAY191-E4



EAY191-N2- Draft



EAY191-S3



MMIYA-CTG01 Draft

