CTSU

Cancer Trials Support Unit

Beta CTSU-PMI RandoNode Setup

Version 1

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1. Acronyms

This section describes acronyms that are used within this document.

Table 1: Acronyms

Acronym	Description
caDSR	Cancer Data Standards Registry and Repository
CCDR	Cancer Care Delivery Research
CDASH	Clinical Data Acquisition Standards Harmonization
CDE	Common Data Element
CDISC	Clinical Data Interchange Standards Consortium
CDUS	Clinical Data Update System
CLIA	Clinical Laboratory Improvement Amendments
CSMS	MATCHBox's Clinical Samples Management System
CTEP	Cancer Therapy Evaluation Program
CTEP-AERS	Clinical Therapy Evaluation Program Adverse Event Reporting System
CTSU	Cancer Trials Support Unit
DCP	Division of Cancer Prevention
EC	Eligibility Checklist
FDA	Food and Drug Administration
IND	Investigational New Drug
LPO	Lead Protocol Organization
NCI	National Cancer Institute
NRDS	Network Rave Data Standards
OPEN	Oncology Patient Enrollment Network
PMI	Precision Medicine Initiative
SDTM	Study Data Tabulation Model
STS	Rave Sample Tracking System

2. Background

The Precision medicine studies funded by the National Cancer Institute (NCI) require exchange of participant and other trial data between various applications like the Oncology Patient Enrollment Network (OPEN), Group systems, Rave and Study-specific MATCHBox systems.
Data can range from participant enrollment data, demographic data, genomic assay data, histology data, and other necessary data to enable proper protocol/treatment assignment, tracking and reporting. Data points come from multiple locations like OPEN, Rave, MDNet Clinical Laboratory Improvement Amendments (CLIA) Labs, MATCHBox's Clinical Samples Management System (CSMS), Rave Sample Tracking System (STS), the MATCHBox routing service, and study-specific MATCHBox systems.

2.1 Scope

The Cancer Trials Support Unit (CTSU) is supporting the NCI's Precision Medicine Initiative (PMI) initiative to support multi-protocol clinical trials (master screening protocol with multiple treatment protocols) conducted with co-ordination across multiple oncology groups with a study specific centralized MATCHBox system housing all the participant data.

In order for RandoNode to process this PMI initiative, the Lead Protocol Organizations (LPOs) will use this setup document to process the screening and treatment study enrollments.

3. RandoNode Setup Instructions

3.1 Overview

OPEN has been enhanced to allow patient enrollment to NCI's Precision medicine's screening and treatment studies. The PMI studies that OPEN will support to start with are as follows:

- ComboMATCH: ECOG-ACRIN (Master, Sub), Alliance (Sub), SWOG (Sub), NRG (Sub), COG (Sub)
- MyeloMATCH: SWOG (Master, Sub), Alliance (Sub), ECOG-ACRIN (Sub), CCTG (Sub)

The RandoNode will process the OPEN registrations in the same way that it would process the other regular non-PMI studies. The only difference would be how it sends the treatment assignments back to OPEN, as for these PMI studies the treatment assignment is done by the MATCHBox systems. Please refer to the distributed "PMI CDISC Eligibility Checklist Template Fact Sheet" on how to setup the Eligibility checklist forms. The following sections will cover what type of information needs to be sent back to OPEN based on the PMI study the patient is enrolling onto.

3.2 Screening Study

1. Generate the screening patient ID.
2. Return "N/A" or "Not Applicable" in the "OpenRegistration.treatmentAssignment" field returned back to OPEN. The actual treatment study assignment will be generated by MATCHBox and sent to OPEN.
3. Provide instructions in the "OpenRegistration.siteInstructions" field to indicate to the site user that the assignment will be provided by MATCHBox and to check for an email from MATCHBox after which the user can continue on to the assigned treatment study.
4. Everything else remains the same as you would setup any regular study from the integration's perspective.

3.3 Treatment Study

1. Generate the treatment patient ID (The screening patient ID would be captured in the Eligibility Checklist which can be used for further processing as needed).
2. Return the corresponding regimen that the patient will be assigned to like "R1" or R2" in the "OpenRegistration.treatmentAssignment" field returned back to OPEN. This information is required by MATCHBox to capture the regimen assigned by the Group. This regimen should map to the codes in the Protocol Schema.
3. Everything else remains the same as you would setup any regular study from the integration's perspective.

3.4 Sample ComboMATCH Workflow

Below is a sample workflow of a ComboMATCH screening and treatment study enrollment followed by a crossover event.

NOTE: Re-Registration is scheduled for the next phase rollouts.

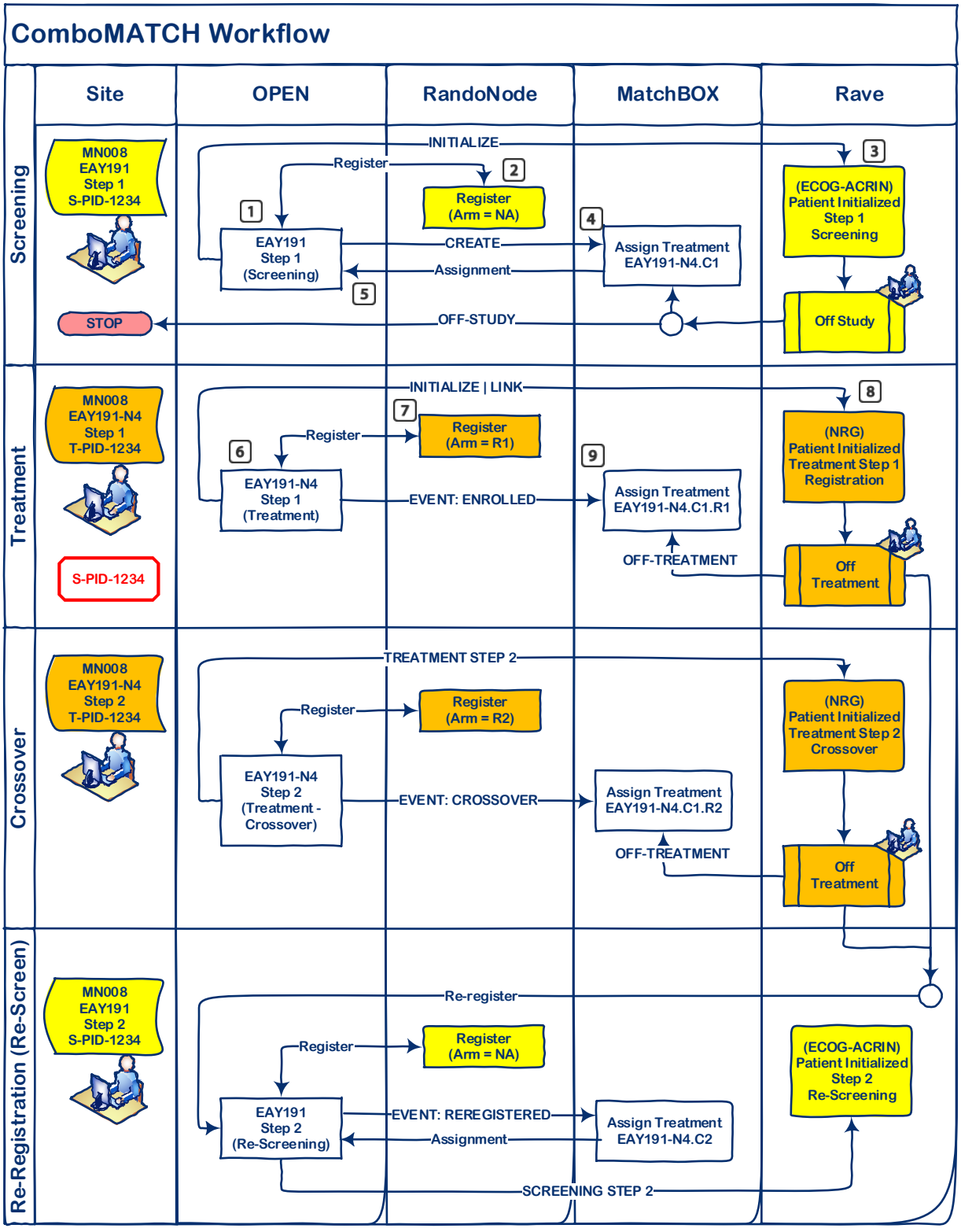

Figure 1: ComboMATCH Sample Workflow

4. References

Table 2: References

#	Name	Location (Intranet)	Location (Internet)
1.	PMI CDISC Eligibility Checklist Template Fact Sheet		Refer to the distribution package
2.	RandoNode Starter Kits		https://www.ctsu.org/open/default.asp?fName=open/Group_Resources/Randonode/RandoNode_Starter_Kit
3.	RandoNode Documentations		https://www.ctsu.org/open/default.asp?fName=open/Group_Resources/Randonode/Documents