Cancer Research Consortium of West Michigan
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FAST FACTS

EA1241: Extended Clinical Follow up and Biospecimen Collection for Patients Enrolled in TAILORx and RxPONDER: A Companion Protocol

Eligibility Criteria

3.1.1 Patient must have met the criteria for 1 of the 3 possible cohorts described below:

- **Cohort 1:** Previously enrolled on TAILORx (PACCT-1) with recurrence score (RS) 0-100 AND had a biopsy confirmed locoregional, distant, or both locoregional and distant recurrence prior to registration on this protocol.
- **Cohort 2:** Previously enrolled on Step 2 of RxPONDER (S1007) with a recurrence score (RS) of 0-25 AND had a biopsy-confirmed locoregional, distant, or both locoregional and distant recurrence prior to registration on this protocol.
- **Cohort 3:** Previously enrolled on Step 1 of RxPONDERand found to have a high Oncotype DX RS 26-100.

NOTE: Only for patients enrolled at US sites.

NOTE: To facilitate accrual, a list of potentially eligible participants who enrolled on TAILORx or RxPONDER, who meet Cohort 1-3 requirements, are last reported to be alive in follow-up will be provided to all currently active sites that open EA1241 and who enrolled patients on TAILORx or RxPONDER.

3.1.2 Patient must have been a TAILORx (RS 0-100) or RxPONDER (RS 0-100) study participant who has the ability to understand and the willingness to sign a written informed consent document for participation in this non-intervention study (cohorts 1, 2, or 3 described above in Section 3.1.1). Patients with impaired decision-making capacity (IDMC) who have a legally authorized representative(LAR) or caregiver and/or family member available will also be considered eligible.

3.1.3 Patient must have tumor tissue available from each cohort as outlined below:

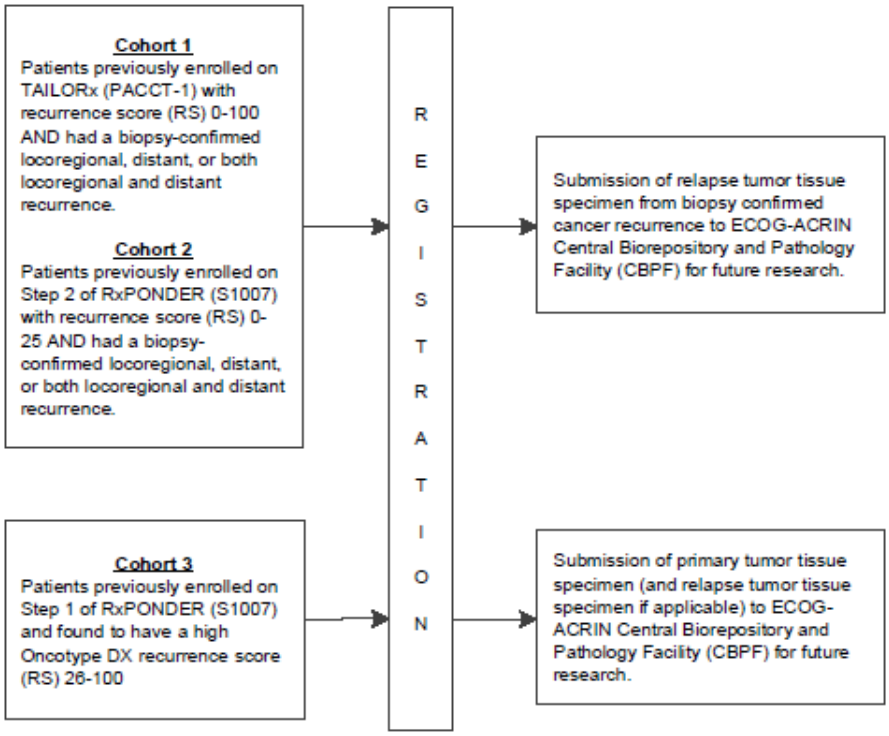
- Patients from Cohorts 1 and 2 must have relapse tumor tissue specimen available at the time of registration for submission to ECOG-ACRIN Central Biorepository and Pathology Facility within 30 days of registration.

- Patients from Cohort 3 must have primary tumor tissue specimen available at time of EA1241 registration for submission to ECOG-ACRIN Central Biorepository and Pathology Facility within 30 days of registration

NOTE: For Cohorts 1, 2, and 3 submission of tumor block is preferred, but if unavailable alternative material may be submitted as outlined in Section 9.

NOTE: Patients in Cohort 3 who have a recurrence and have a recurrence tumor specimen available must provide the relapse sample within 30 days of EA1241 registration. If recurrence occurs after EA1241 registration, the relapse sample must be submitted within 30 days of collection.

Schema



Accrual Goal: 600 (300 from Cohort 1 and 2, and 300 from Cohort 3)