
RUSTIC

S1919

PHASE II, MULTI-ARM, **R**RANDOMIZED **U**MBRELLA **S**TUDY TO EVALUATE THE
THERAPEUTIC EFFICACY AND SAFETY OF **I**MMUNE-ONCOLOGY DRUG
COMBINATIONS IN METASTATIC BREAST CANCER

Study Chairs: Lajos Pusztai, MD, PhD
& Priyanka Sharma, MD

Study Lead Statistician: William Barlow, PhD



SWOG CLINICAL
TRIALS PARTNERSHIPS

Declaration

**Trial funded by AstraZeneca
through the Hope Foundation SWOG CTP**

**Statistical and Data Management Center
receives support from this funding**



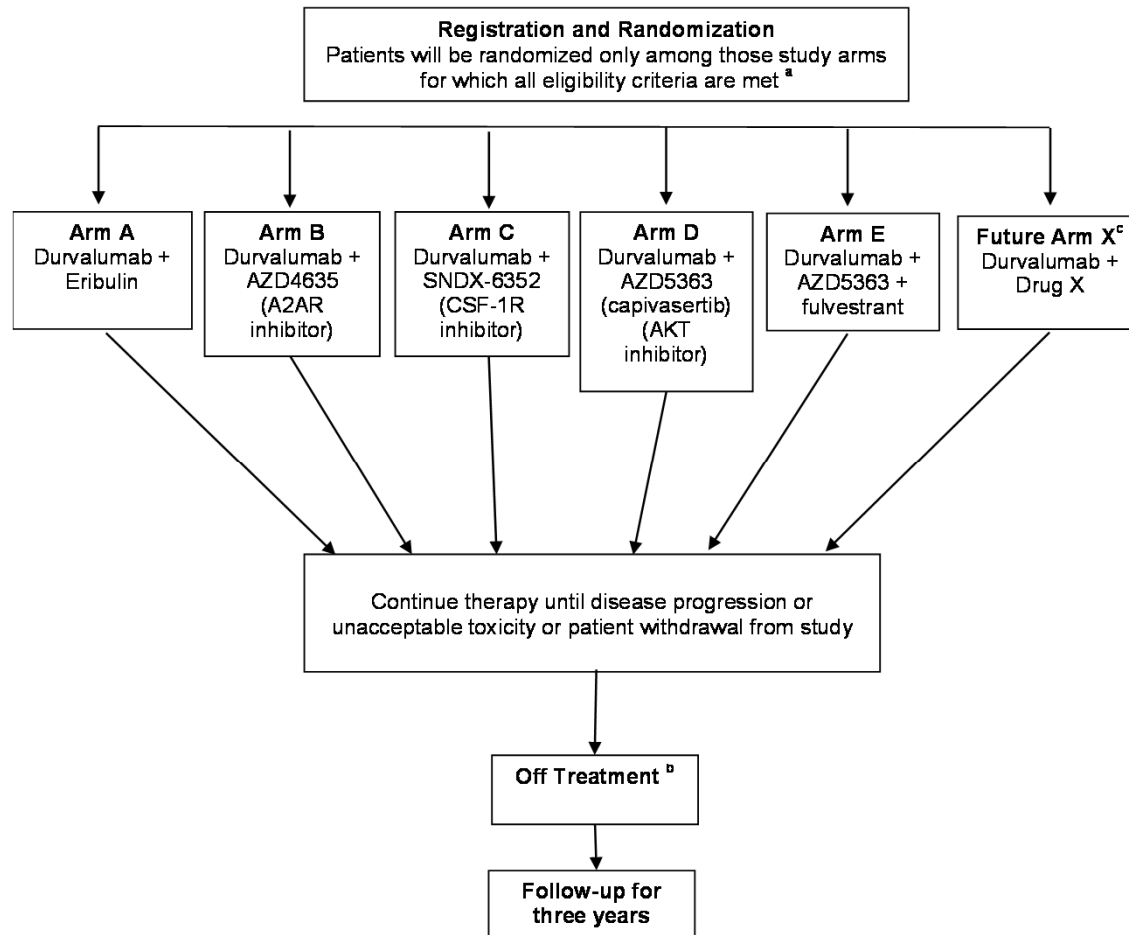
**SWOG CLINICAL
TRIALS PARTNERSHIPS**

Overview

- Basic overview of the trial
- Subsequent speakers will describe additional details about RUSTIC
- S1919 (RUSTIC) Training Session
Friday Oct 4 8:00-9:00 AM
Wrigley (Concourse Level, West Tower)

Eligibility

- Metastatic breast cancer that is HER2-negative
- Can be either hormone-receptor positive or negative
- Either 0 or 1 lines of previous chemotherapy
- Additional eligibility for the overall trial
- Additional eligibility criteria for each treatment arm (assessed prior to randomization)



Treatment Arms

- Arms A, B, C
 - Hormone-receptor positive cohort
 - Hormone-receptor negative cohort
- Arms D, E
 - Hormone-receptor positive cohort only
- Each arm has two co-Chairs (Arms D & E share co-Chairs)

Arms

- Patients are randomized only among the arms for which they are eligible
 - HR-positive Arms A to E may be possible
 - HR-negative Arms A to C may be possible
- Each cohort operates independently
- One cohort in an arm could close but the other cohort in that arm would remain open
- Safety run-ins will be conducted for each arm where necessary

Design

- Outcome: Clinical benefit (Complete or partial response or stable disease)
- Design: Each cohort is a Simon two-stage design with up to 38 patients total
- → 8 parallel cohorts for a total of 304 patients in the overall trial
- Activation early 2020

Questions?

S1919 RUSTIC

Jacqueline Scurlock
SDMC

How is RUSTIC Different?

- Rave EDC (RUSTIC Rave) differences
- Registration Process
- Source Documentation

A whole new Rave

Rave Classic

The Rave Classic interface displays a patient's visit schedule and task summary. The patient ID is S1418, and the current vital status is Alive. The enrollment date is 19 Jan 2017. The patient initials are LFM: IAT, and the current date of last contact or death is 19 Jan 2019.

Visit	Date	Task Summary: Subject	Pages
Baseline	19 Jan 2017	NonConformant Data	0
Baseline Step 2 (1)	07 Feb 2017	Open Queries	0
Arm 2 Cycle 01	15 Feb 2017	Answered Queries	0
Arm 2 Cycle 02	29 Mar 2017	Sticky Notes	0
Arm 2 Cycle 03	10 May 2017	Requiring Review	0
Arm 2 Cycle 04	21 Jun 2017	Overdue Data	0
Arm 2 Cycle 05	31 Jul 2017	Cancel Queries	0
Arm 2 Cycle 06	13 Sep 2017		
Arm 2 Cycle 07	23 Oct 2017		
Arm 2 Cycle 08	05 Dec 2017		
Arm 2 Cycle 09	18 Jan 2018		
Off Treatment (1)	14 Mar 2018		
Follow-up Forms			
Follow-up 2018-08-09	09 Aug 2018		
Follow-up 2019-01-07	07 Jan 2019		
Follow-up 2019-06-19	19 Jun 2019		
Follow-up (new)	19 Dec 2019		

New Rave EDC (RUSTIC Rave)

The New Rave EDC (RUSTIC Rave) interface displays a grid view of subject data. The grid includes columns for Subject, Visit Status, Baseline, 1 Week, 2 Weeks, 4 Weeks, Off Treatment, Status (Completed/Other), L1L Reports, L1L, Consent Withdrawal, Death, Patient Check Dates, Questionnaire 2 weeks, Questionnaire 4 weeks, Questionnaire 8 weeks, and Report Priority. The grid shows data for various subjects, including S1418, and their visit status and completion dates.

Site Level View

Rave Classic

The Rave Classic interface features a top navigation bar with the SWOG logo and 'CANCER RESEARCH NETWORK' text. A user profile bar shows 'User: Jacqueline Scurlock (Data Manager)'. A sidebar on the left contains a search box and an 'Advanced Search' link. The main content area is dominated by a 'Task Summary: Site' sidebar with the following items:

- NonConformant Data: 0
- Open Queries: 0
- Answered Queries: 0
- Sticky Notes: 0
- Requiring Review: 4
- Overdue Data: 2
- Cancel Queries: 0

The main area displays a list of subjects with a search bar and a 'Subjects' column showing counts.

Rave EDC (RUSTIC Rave)

The Rave EDC interface shows a 'Test Site (99999) - Subjects' page. It includes a top navigation bar with 'medidata' and various site-specific links. The page features a 'Filter By Subject Status' dropdown set to 'All Statuses' and a 'Find Subject' search box. A table displays subject information:

Subject Information	Subject Status
301	Screening
302	Screening
New Subject	Screening

At the bottom, a summary row shows '3 Total' and a pagination control for 'Per page' with options 10, 25, 50, 100.

Queries

Rave Classic

The screenshot shows the Rave Classic interface for a patient record. The patient ID is S1418. The current vital status is 'Alive' and the current date of last contact or death is '19 Jul 2019'. The page is titled 'Onstudy: Patient and Disease Description - Baseline'. A message indicates that the form is saved and that data entry errors will be resolved upon the next system query. The 'PATIENT AND DISEASE DESCRIPTION' section contains the following data:

Field	Value	Status
Performance status (Zubrod)	0	Valid
Height	167 cm (xxx)	Valid
Weight	115.2 kg (xxx.x)	Valid
Date of history and physical exam:	25 Jun 2019	Valid
Date of initial pathologic diagnosis:	30 Mar 2018	Valid
Receptor Status: (positive is considered ≥ 1% positive nuclear staining)		
ER Status:	Negative	Valid
% nuclear staining	(xxx.xx)	Invalid: This field is required.
PgR Status:	Negative	Valid
% nuclear staining	(xxx.xx)	Invalid: This field is required.
HER2 results/IHC:	0	Valid
HER2 results/ISH (gene amplification):	Not done	Valid
Date current staging assessment completed:	17 Oct 2018*	Valid

Rave EDC (RUSTIC Rave)

The screenshot shows the Rave EDC (RUSTIC Rave) interface for patient demographics. The fields and their values are:

- Patient First Name: [Empty] - Invalid: Data Entry Error. This field is required.
- Patient Middle Name: [Empty] - Valid.
- Patient Last Name: [Empty] - Invalid: Data Entry Error. This field is required.
- Birthdate: dd / ... / yyyy - Invalid: Data Entry Error. This field is required.
- Ethnicity: Radio buttons for Hispanic or Latino, Not Hispanic or Latino, and Unknown. Invalid: Data Entry Error. This field is required.

Subject Registration

medidata

swog-ctp ▾ STUDIES S1919 ▾ ACTIONS EDC ▾ ENVIRONMENTS Development ▾ SITES 99999 - Test Site (99999) ▾ Help ▾ Study Builder ▾ Margaret Joosten ▾

Test Site (99999) - Subjects

+ Add Subject

Enrollment Target 0 Enrolled 0 Completed 0

Filter By Subject Status Find Subject

All Statuses ▾ Q Reset

View Site Reports

Subject Information	Subject Status
<p>⚠ No Subjects Add subjects with the "+ Add Subject" button in the upper right.</p>	

1 / 1

Per page 10 25 50 100

(Power User) Rave EDC 2019.1.1 Copyright © 1999-2019 Medidata Solutions, Inc.

Registration

Registration will happen in Rave EDC

 New Subject

 Subject Enrollment

INSTRUCTIONS: To enroll a subject on S1919, complete this form and click Save. On the Subject Tab, click the Subject Enrollment form for important notes. If the Subject Enrollment form does NOT have a green checkmark next to it, then this form has errors to correct and the enrollment was NOT successful.

HOW TO TELL IF THE ENROLLMENT WAS SUCCESSFUL:

- 1) the Subject Tab appears and includes a SWOG Patient ID (e.g. 700024);
- 2) the Subject Enrollment form link will have a green checkmark icon next to it.

SWOG Patient ID Status New Patient Previous Patient

PATIENT DEMOGRAPHY

Patient First Name

Patient Middle Name

Patient Last Name

Birthdate

Source Documentation

- There is no Source Documentation upload in the Rave EDC (Rustic Rave)
- Currently working on new location
- Stay tuned

Up Next is Katie Minichiello

Process Overview for RUSTIC

PROCESS OVERVIEW OF SWOG-CTP STUDIES (S1919)

Katie Minichiello

Statistics and Data Management Center

Seattle, WA

Overview

- CRA Access
- Site Access
- SAE Process

SWOG Way: CRA Access

- CRA Access

SWOG-CTP Way: CRA Access

- CRA Access

SWOG Way: Site Access

- Site Access

SWOG-CTP Way: Site Access

- Site Access

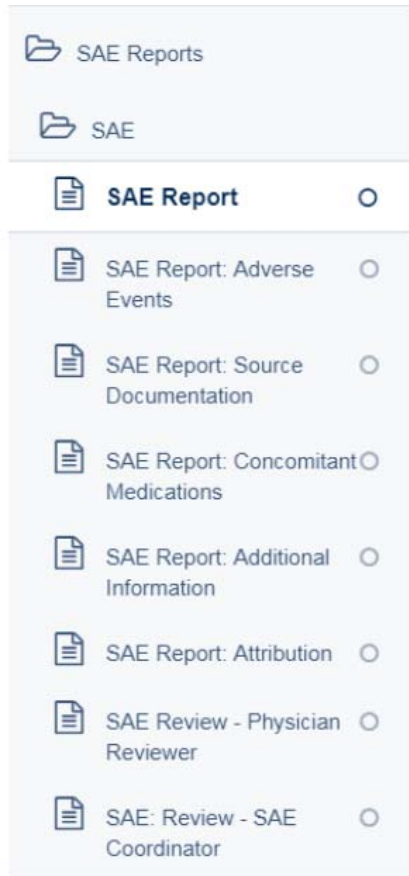
SWOG Way: SAE Process

- Reported to SWOG Operations Office using the Cancer Therapy Evaluation Program Adverse Event Reporting System (CTEP-AERS)
- Then SWOG Ops forwards reports and documentation to the appropriate regulatory agencies and drug companies as required

SWOG-CTP Way: SAE Process

- Will not use CTEP-AERS
- Report via Medidata Rave
- SWOG Ops will still forward reports and documentation to the appropriate regulatory agencies and drug companies as required

SWOG-CTP Way: SAE Process



- SAE Report
 - Reporter Information
 - Treating Physician
 - Patient Information
 - Cycle/Course Information
 - Description of Event
 - Protocol Agents

Want to learn more about S1919 (RUSTIC)?

Come to our Training Session + Kick-Off Meeting!

Friday @ 8AM in XXX

Open to all SWOG members

And light refreshments will be provided!



SWOG

CANCER
RESEARCH
NETWORK