ETCTN Specimen Tracking User Guide
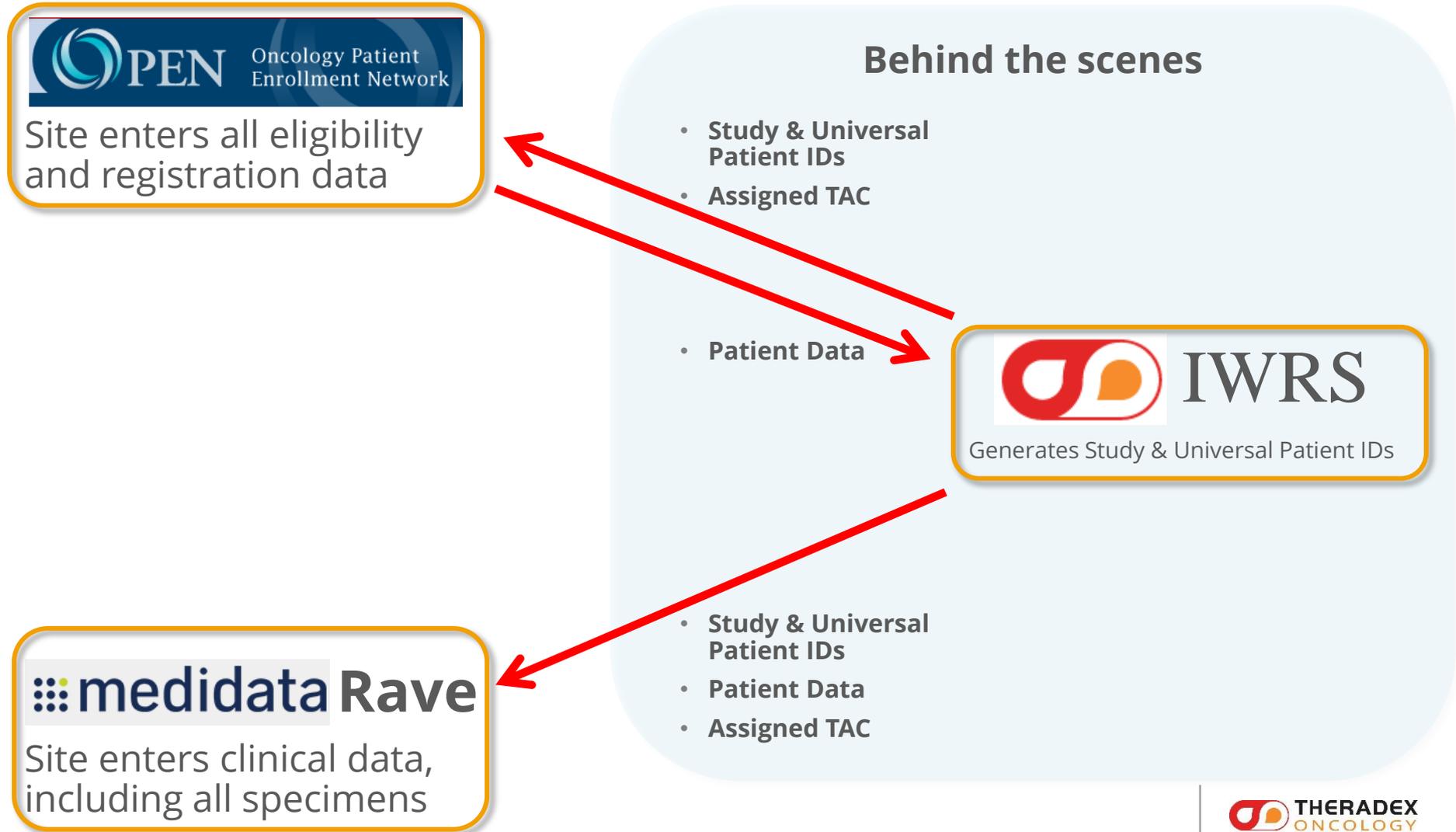
version 2.0
21-Mar-2019

THERADEX
ONCOLOGY
The early phase specialists
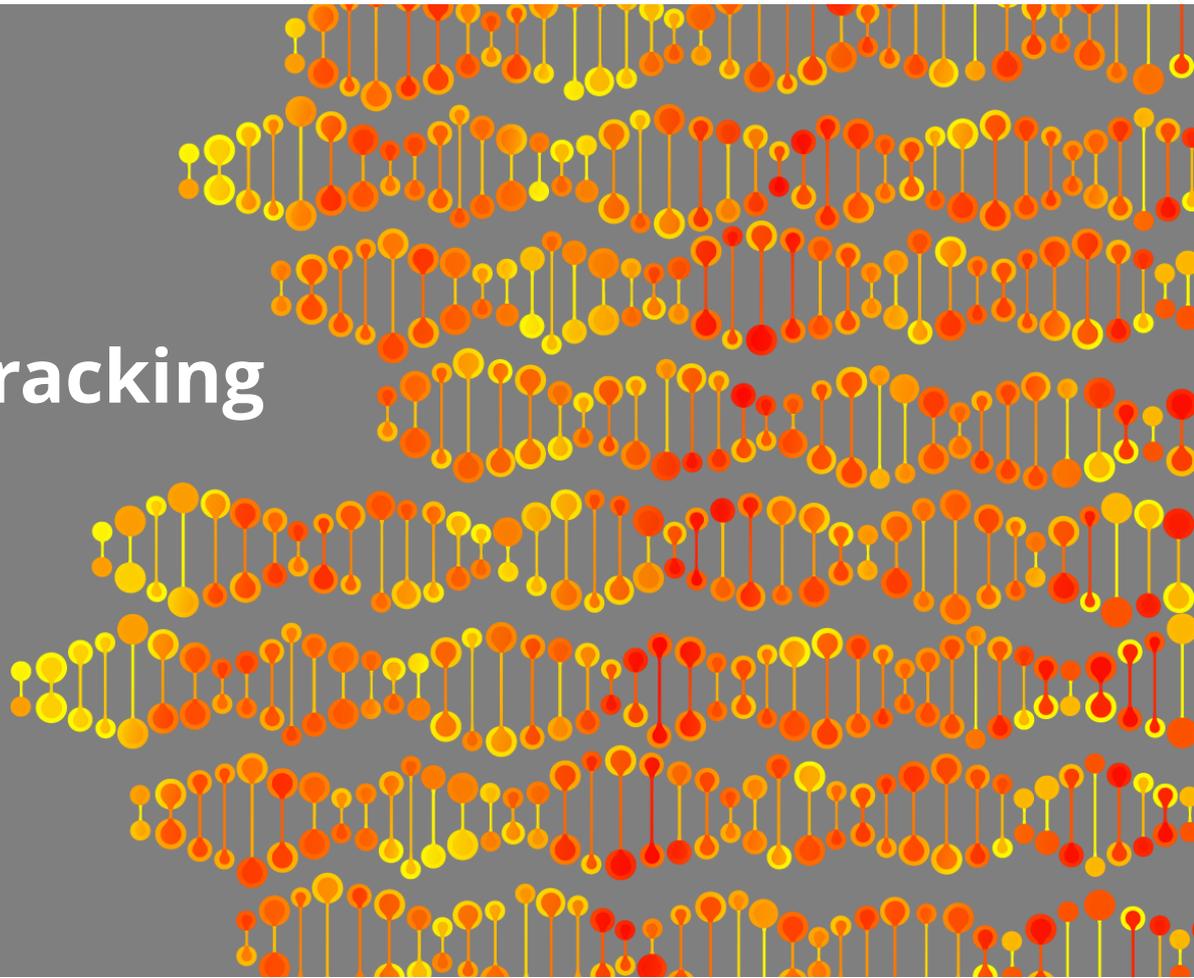
Introduction

- This user guide contains three sections:
  - Single step registration data on page 3
  - Two or more step registration on page 5
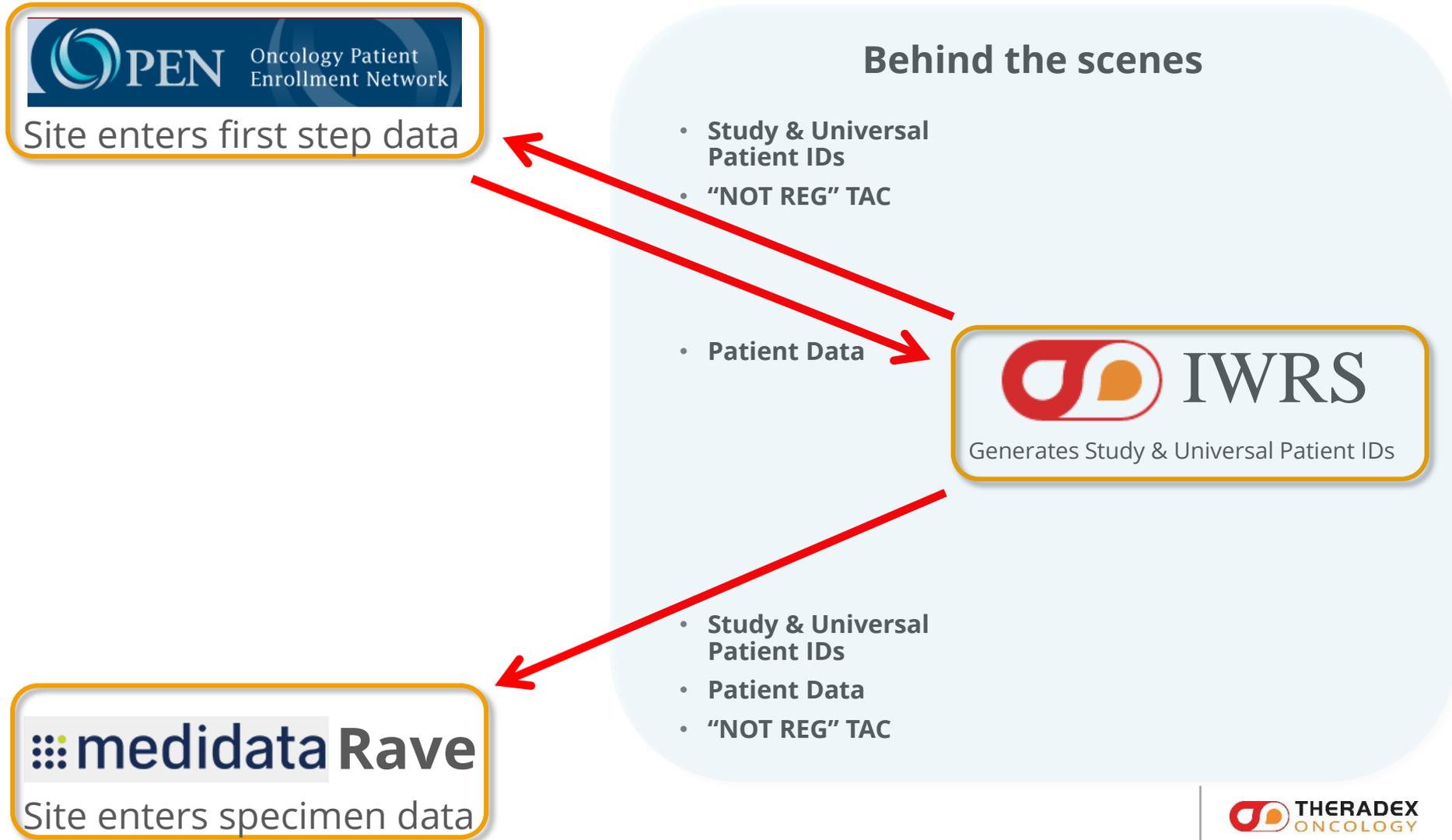 - Specimen tracking instructions on page 8

Data Flow for single step Patient Registration

OPEN — Oncology Patient Enrollment Network

Site enters all eligibility and registration data

Behind the scenes

- **Study & Universal Patient IDs**
- **Assigned TAC**

- **Patient Data**

IWRS

Generates Study & Universal Patient IDs

- **Study & Universal Patient IDs**
- **Patient Data**
- **Assigned TAC**

medidata Rave

Site enters clinical data, including all specimens
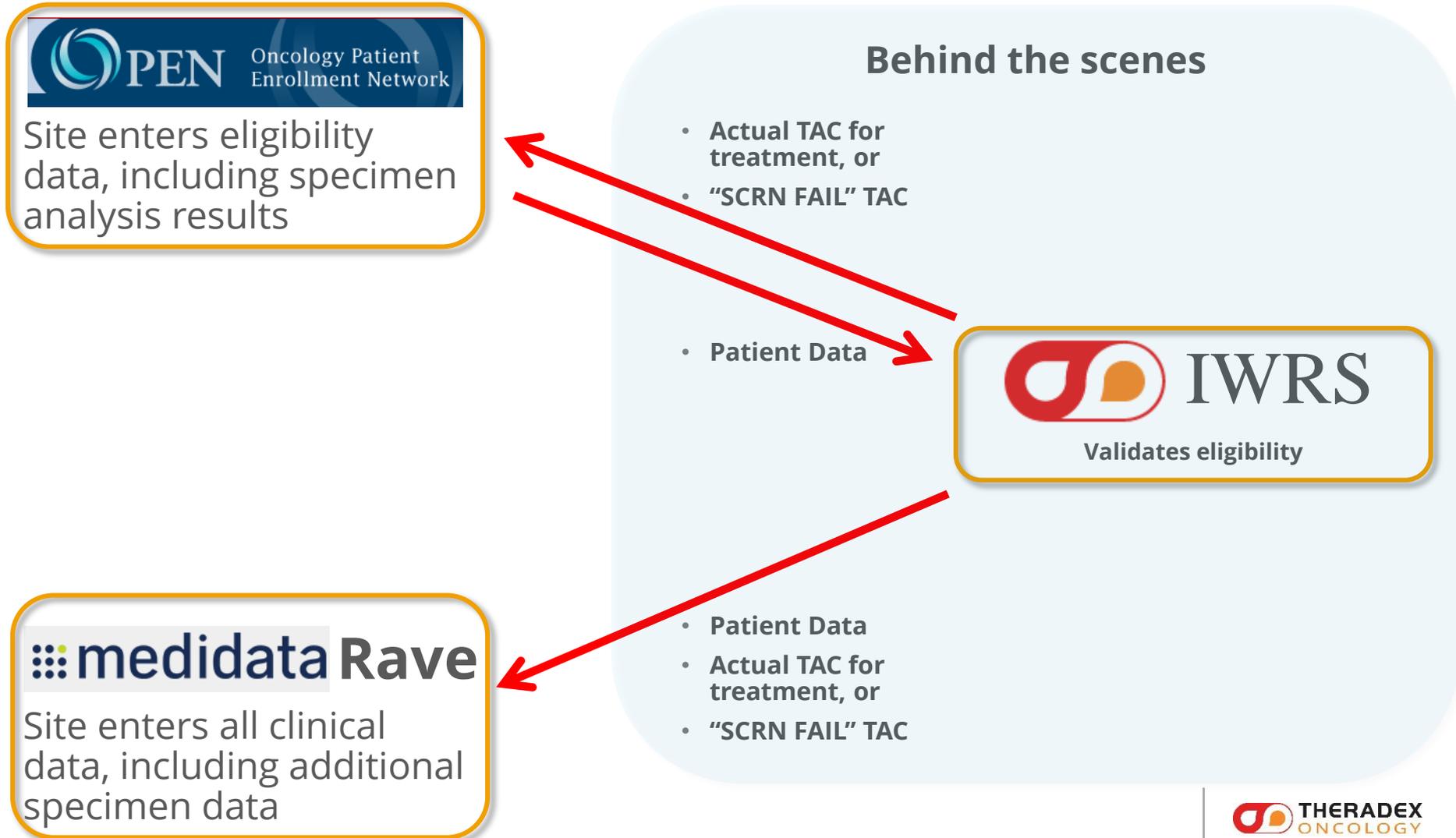
THERADEX ONCOLOGY

Single Step Patient Registration

o Site enters registration data into OPEN.

o IWRS receives data from OPEN, generates the Patient Study ID and the Universal Patient ID, both of which are sent back to OPEN along with the assigned TAC.

o IWRS sends all patient registration data, including the IDs and the TAC directly to Rave.

o Data is entered in the Histology and Disease form – before specimen data. Generally, baseline medical history and prior therapies would be entered concurrently.

o Go to page 8 for the next steps.

THERADEX ONCOLOGY

Data Flow for Patient Registration First Step

OPEN Oncology Patient Enrollment Network

Site enters first step data

Behind the scenes

- **Study & Universal Patient IDs**
- **"NOT REG" TAC**

- **Patient Data**

IWRS

Generates Study & Universal Patient IDs

- **Study & Universal Patient IDs**
- **Patient Data**
- **"NOT REG" TAC**

medidata Rave

Site enters specimen data

THERADEX ONCOLOGY

Data Flow for Patient Registration Second Step

Behind the scenes

OPEN — Oncology Patient Enrollment Network

Site enters eligibility data, including specimen analysis results

- **Actual TAC for treatment, or**
- **"SCRN FAIL" TAC**

- **Patient Data**

IWRS

Validates eligibility

medidata Rave

Site enters all clinical data, including additional specimen data

- **Patient Data**
- **Actual TAC for treatment, or**
- **"SCRN FAIL" TAC**

THERADEX ONCOLOGY

Two Step Patient Registration With Specimen Analysis

o Site enters first step data into OPEN.

o IWRS receives data from OPEN, generates the Patient Study ID and the Universal Patient ID, both of which are sent back to OPEN.

o IWRS sends first step registration data, including the IDs and a TAC of "NOT REG" directly to Rave.

o The specimen tracking system in Rave is utilized for the specimen that contributes to eligibility determination.

o Site enters second and any subsequent step data into OPEN including results of specimen analysis.

o IWRS receives all data from OPEN, then sends it onto Rave with either the treatment TAC or a TAC of "SCRN FAIL".

o In addition to the specimen tracking forms completed to determine eligibility, data entry for screen failure patients should include Histology and Disease, all forms in the Baseline folder, any lab forms connected to eligibility determination, and Off Treatment/Off Study.

THERADEX
ONCOLOGY

Specimen Tracking Step 1
Preliminary data and specimen enrollment

o Complete the **Histology and Disease** form (but do not upload reports until a specimen label can be applied to them) and the Baseline forms regarding **Prior Therapies**. Enter the initial clinical specimen data:

- **Specimen Tracking Enrollment** CRF**:** Complete the Primary Diagnosis Disease Group field at the top, then enter a log record for each specimen including Time Point, Specimen Category, Specimen Type, optional Block number, Tissue type if relevant, Surgical Path ID if relevant, number of labels needed (include extra labels to apply to reports to be uploaded). CRF generates unique Specimen ID.

- The number of specimen labels must be specified, even if you intend to use your own label printing system. Send or take system generated PDF of labels to the lab.

THERADEX ONCOLOGY

Specimen Tracking Step 2
Print labels using report in EDC and collect specimen

o Print labels, then use to label specimen containers and write collection date and time (collection time is optional, unless required for downstream assay processing [*e.g.*, PK]) on each label.

o After collection, store labeled specimens as described in Protocol.

o Apply an extra specimen label to _each_ report before scanning. Uploaded reports should have PHI data like name, mailing address, medical record number or SSN redacted. Do not redact SPID, block number or relevant dates.

o Return to the **Histology and Disease** form to upload any initial Pathology, Radiology, or Surgical reports, Molecular Reports (up to 4), and Pathology Verification form (when applicable).

o Return to **Specimen Tracking Enrollment** CRF to upload any specimen specific reports: pathology or other relevant report and/or targeted molecular report in the log line.

THERADEX ONCOLOGY

Complete specimen data entry

After the specimen is collected:

o In Rave, go back to the All Specimens folder, and then into the particular specimen's subfolder. Enter all relevant specimen data there in the **Specimen Transmittal** form. Not all fields must be completed for each specimen – just complete what is relevant.

Specimen Tracking Step 4
When ready to ship, enter shipment information

o **Shipping Status** CRF**:** Enter tracking number, your contact information, recipient, number of containers and ship date once for the 1st specimen in a shipment.

o **Copy Shipping** CRF**:** To include multiple specimens in a shipment, navigate to another specimen's folder and utilize the Copy Shipping form there. This form – once refreshed, contains all tracking numbers and ship dates and may be sorted by either. Pagination is possible – you may need to look beyond the first page. Even specimens from a different patient may be included in the same box.

o Back in the **Shipping Status** CRF, confirm the shipping environment is correct (make changes as needed) and enter the proper number of specimen containers.

THERADEX ONCOLOGY

Specimen Tracking Step 5
Print shipping list report and prepare to ship

o Print two copies of the shipping list, one to provide in the box, the other for your own records. Note that the Shipping List report is available at the site level in Rave, not at the patient level. You will need to know the tracking number to print the proper report.

o Print pathology or other required reports to include in the box. Be sure the printed copy includes the specimen label.

o Confirm that all specimens are properly labeled with all data generated in the Label report – whether you are using the report directly or printing your own labels with the report as reference.

o Make sure the box is properly packed with all specimens and documentation.

THERADEX ONCOLOGY

Specimen Tracking Step 6
Send email notification

o For only one of the specimens in the shipment, click "Send Email Alert" checkbox on the **Shipping Status** CRF to email recipient.

THERADEX
ONCOLOGY

Specimen Tracking Step 7
Shipment

○ Ship the specimen(s) in a timely manner as specified in the protocol.

THERADEX
ONCOLOGY

Specimen Tracking Step 8
Acknowledgement

o At **receiving site**, specimen shipment is acknowledged in **Shipping Status** form.

THERADEX
ONCOLOGY