

SWOG Clinical Trials Partnerships (CTP)

HOW SWOG PARTNERS WITH INDUSTRY TO CONDUCT CANCER CLINICAL TRIALS

SWOG CTP Update Forum

October 8, 2026

<https://www.swogctp.org/>



SWOG CLINICAL
TRIALS PARTNERSHIPS

SWOG Clinical Trials Partnerships (SWOG CTP)

Kathy S. Albain, MD, FACP, FASCO
SWOG Vice-Chair for Clinical Trials Partnerships

Casey Dawson	Crystal Miwa	Sharon Palmer	Dana Sparks, MAT
Deputy Director of Administration	Protocol Department Manager	Clinical Trials Program Manager	Director of Operations and Protocols

AND MANY MORE...



SWOG CLINICAL
TRIALS PARTNERSHIPS

SWOG Clinical Trials Partnerships (SWOG CTP)

CTP Executive Committee (EC)

CTP Scientific Advisory Board (SAB)

CTP Executive Review Committee (ERC)

SWOG Network Operations Protocol Project Managers and Protocols Coordinator

SDMC Statisticians and other staff

Clinical Trial Budget Analysts

Research Site Coordination Manager

Contract Attorneys and Paralegal

Quality Assurance Team/Auditors

Meetings and Membership

The Hope Foundation staff

SWOG Communications team

Patient Advocates Committee members

SWOG CTP Update Forum Agenda

- **SWOG CTP overview**
- **Active CTP trials**
- **CTP registration trial, closed to accrual**
- **CTP studies in development**
- **Site logistics, operations, activation process**
- **Novel CTP projects and other collaborative opportunities**

SWOG CTP establishes and administers scientific partnerships between SWOG and industry... from idea to study completion

- **Mechanism whereby SWOG Cancer Research Network collaborates with industry as a research partner outside of NCI/NCTN**
- **Facilitates testing novel agents or combinations across disease sites or within a disease (including uncommon scenarios)**
- **Offers wide range of study design options**
- **Taps over 8000 investigators at academic and community sites**

Important Things to Know

NCI vs. SWOG CTP Differences

Item	NCI	SWOG CTP
Funding	Grant and pharma	NON-PROFIT Non-Federal (Flows from SWOG CTP)
Participating Sites	All NCTN/NCORP sites	Selected SWOG sites
Centralized IRB	CIRB	WCG IRB
Systems	CTSU Medidata RAVE	Florence CRAB Nebula

SWOG CTP process: joint study design and conduct with SWOG committees and industry partners



- Stakeholders' engagement up front - Committee chair, study chair(s) CTP leadership and pharma partner
- Confirmation of interest and support by senior scientific leadership in company (by Committee chair and study PI)
- Operations and Scientific calls jointly with industry partner prior to and during protocol development process

Preferred Partnerships and Industry-Supported Trials

Studies conducted outside of the NCI framework must be fully supported by our industry partner.

Cost categories include, but are not limited to:

- **SWOG Operations**
- **Biostatistics and Data Management**
- **Site Costs – start up activities, per patient payments, etc.**
- **Biobanking (if applicable)**
- **Drug/Drug Distribution (if applicable)**

Multiple scientific areas of interest for potential CTP collaborations

- Most common solid tumors, across stages and lines of therapy
- Lymphomas, myeloma
- Acute and chronic leukemias, myeloid and lymphoid
- Rare diseases can also be studied (given large SWOG network)
- Myelofibrosis, MDS/MPN, CMMoL
- Early therapeutics
- Immunotherapeutics
- Symptom management and survivorship (with NCORP partnership)
- Health care delivery (with NCORP partnership)
- Prevention, screening, surveillance (with NCORP partnership)
- Surgical, radiotherapy and theranostics questions

CTP offers wide range of types of trials and partnerships

- Phases IB/II, II, randomized II, II/III, III, FDA registration
- Single arm signal-finding pilots
- “Preferred” partnerships (pipeline)
- Master Protocols - disease specific or disease agnostic
 - Platform
 - Basket
 - Umbrella
- Pragmatic designs
- Registration trials

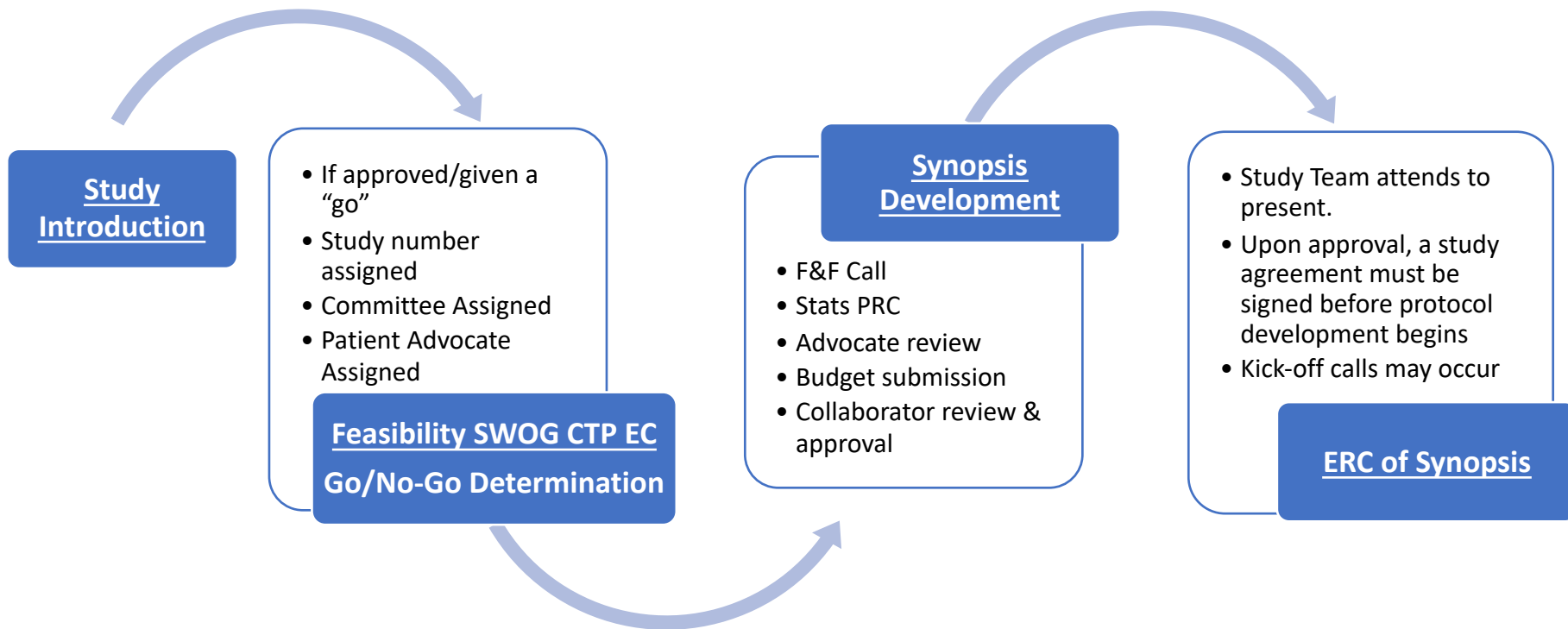
SWOG CTP Acronyms/Shorthand Explanation

- **EC = Executive Committee**
- **ERC = Executive Review Committee**
- **PRC = Protocol Review Committee**
- **SAB = Scientific Advisory Board**
- **Go/No-Go = EC feasibility review to determine if a study can be conducted through SWOG CTP**
- **CTSA = Clinical Trials Site Agreement**
- **Study Team = Study Chairs, Statisticians, Patient Advocate, and Protocol Project Manager**

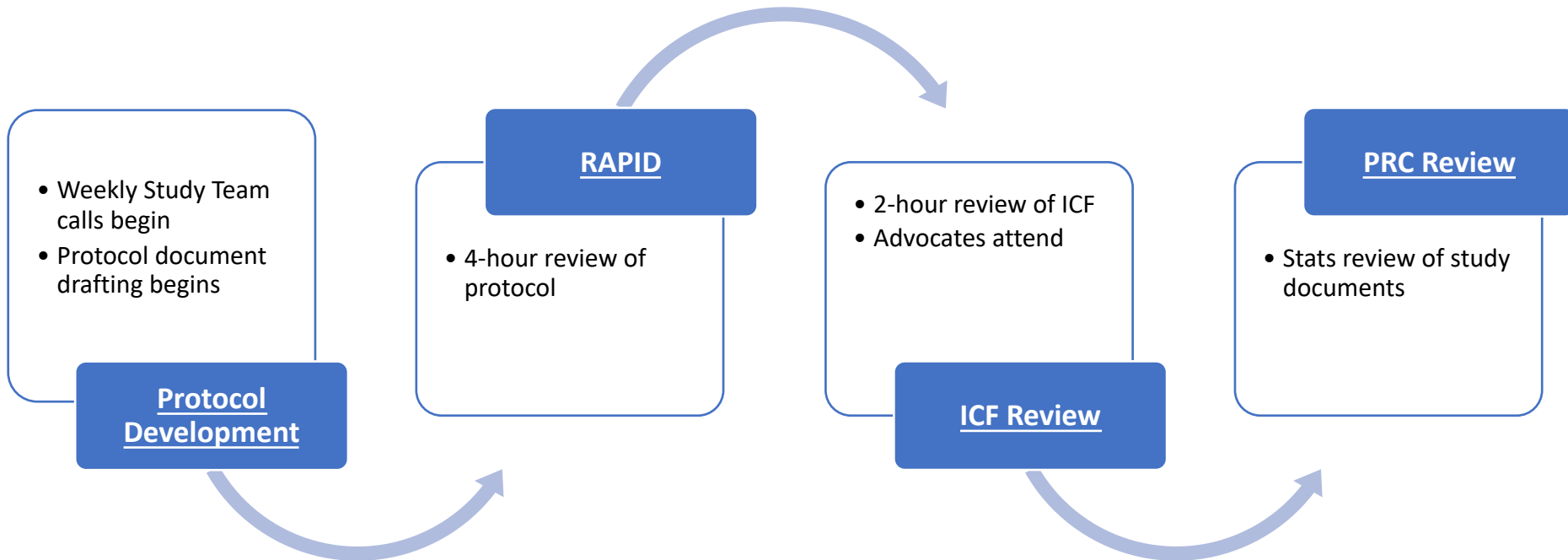
NCI vs SWOG CTP Equivalents

NCI	SWOG CTP
SWOG Triage	Feasibility Go/No-Go
CTEP Steering Committee/PRC Review	CTP ERC Review of the Synopsis
CTEP Study Review	CTP ERC Review of the Study Documents
CIRB Review	WCG IRB Review
CTSU	Florence
Medidata RAVE	CRAB Nebula
Concept/LOI/Capsule	Synopsis

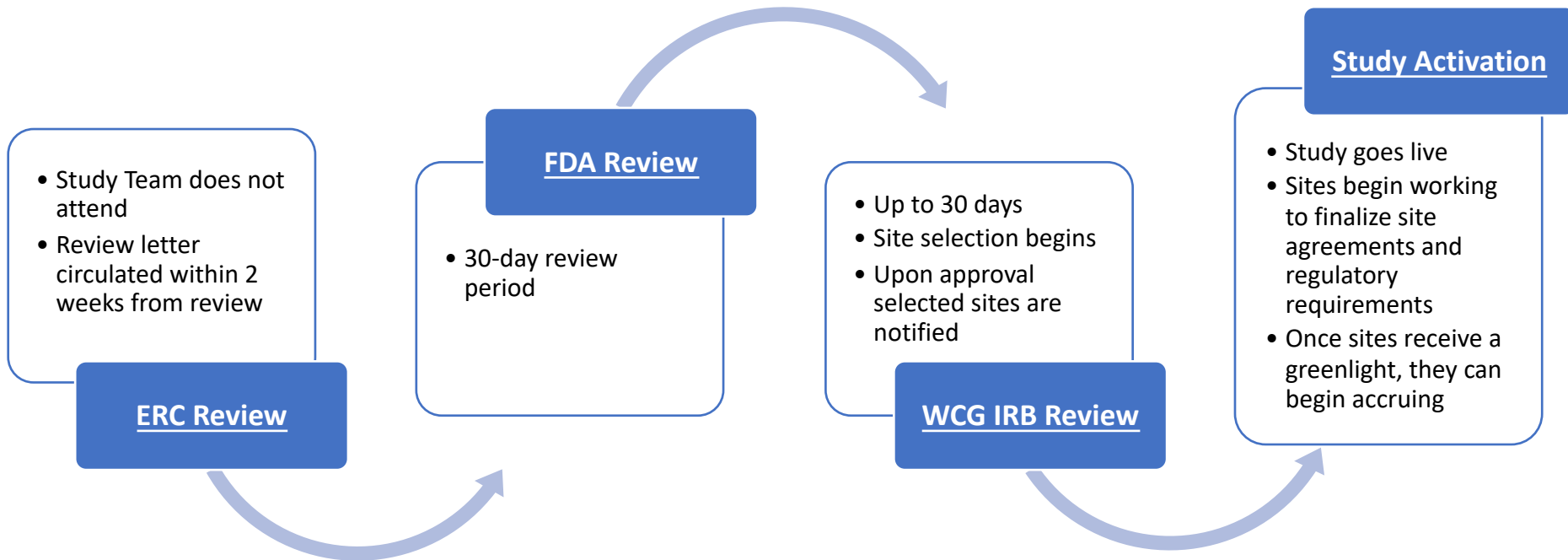
SWOG CTP Processes



SWOG CTP Processes



SWOG CTP Processes



SWOG CTP Active Studies

- **26CTP.LEUK02 (“APEX-MF”)**

A Randomized OPen Label Trial Comparing MomElotinib vs Dose-Adjusted RuXolitinib for Treatment-Naïve, Cytopenic MyeloFibrosis

PIs: Alexander Coltoff, MD; Aaron Gerds, MD

- **21CTP.LEUK01**

Phase II trial of asciminib, dasatinib, prednisone, and blinatumomab for patients with newly diagnosed Philadelphia chromosome positive acute lymphoblastic leukemia

PIs: Anjali Advani, MD; Michaela Liedke, MD

- **21CTP.HN01 (“CAPT-HN”)**

Phase II study of Combined Amivantamab, carboPlatin and pacliTaxel in unresectable locally recurrent or metastatic Head and Neck cancer

PI: Paul Swiecicki

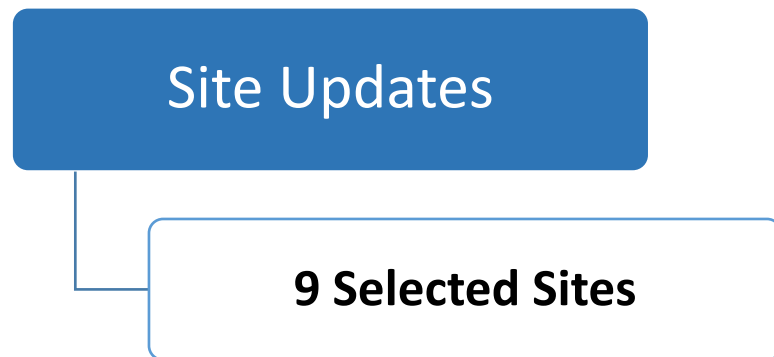
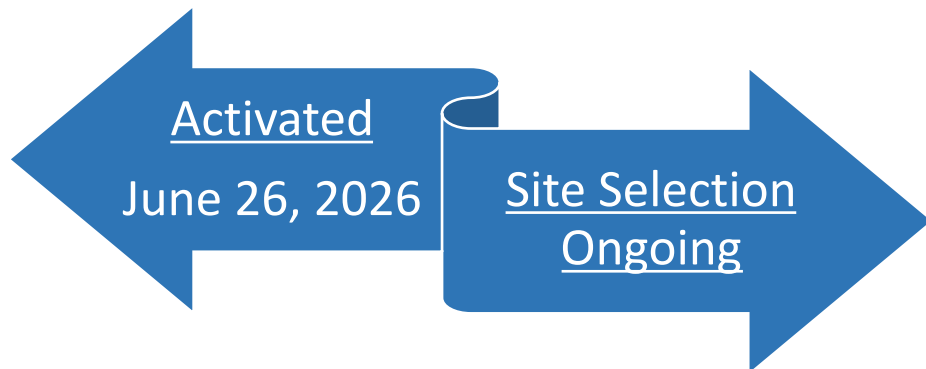


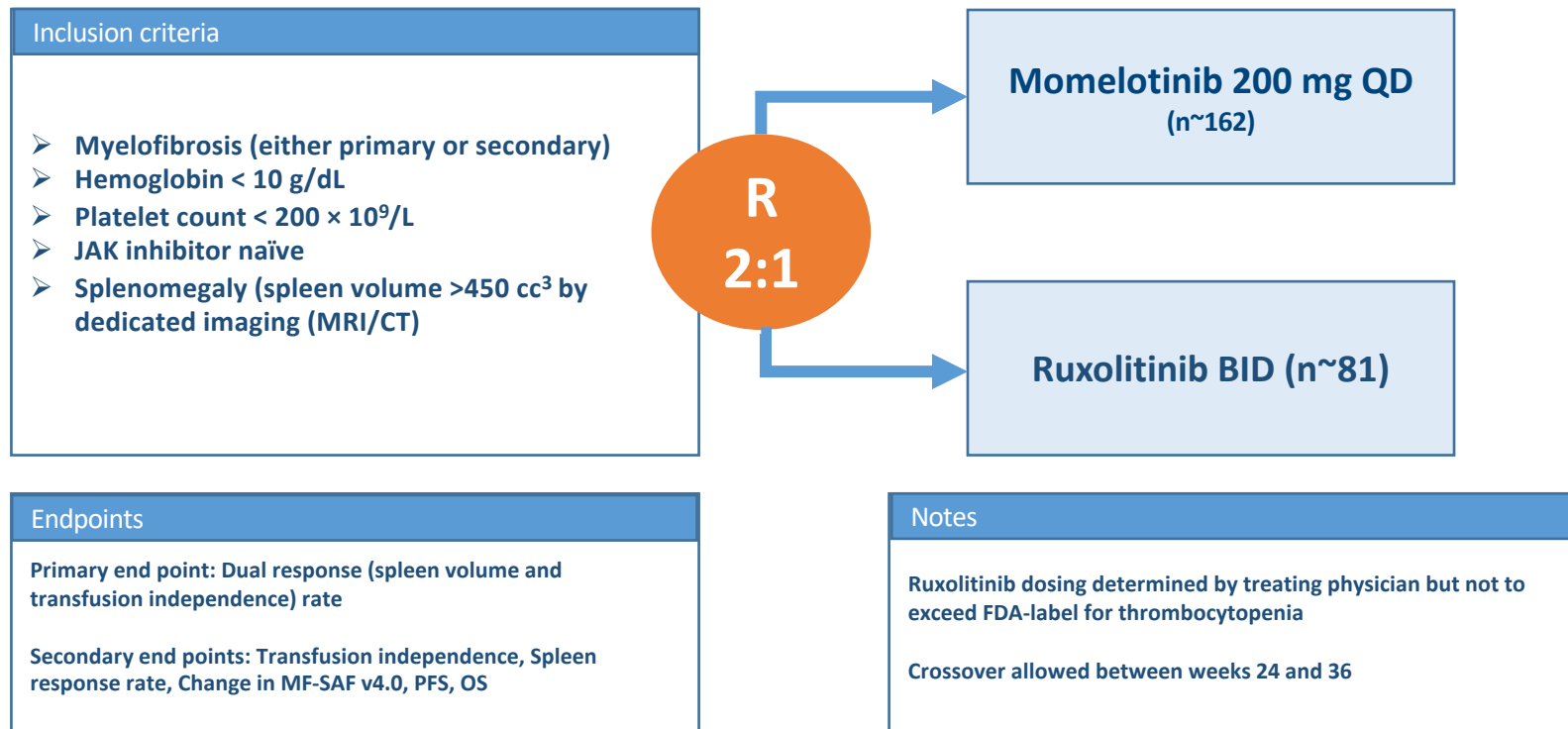
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26CTP.LEUK02

APEX-MF, “A Randomized Open Label Trial Comparing Momelotinib vs Dose-Adjusted Ruxolitinib for Treatment-Naïve, Cytopenic Myelofibrosis”

PIs: Alexander Coltoff, MD; Aaron Gerds, MD, Uma Borate, MD, MS, and J. Xueyan Chen, MD., PhD.





Why This Study?

- Pragmatic study
- Most study related activities are standard of care
- Broad inclusion and exclusion criteria
- Crossover allowed if suboptimal response
- Great option for patients with new MF

How to Participate?

- For more information on **LEUK02**:
<https://www.swogctp.org/trials/26ctpleuk02/>
- Feasibility Survey:
<https://www.surveymonkey.com/r/Q3FKD5X>

21CTP.LEUK01

“Phase II Trial of Asciminib, Dasatinib, Prednisone, and Blinatumomab for Patients With Newly Diagnosed Philadelphia Chromosome Positive Acute Lymphoblastic Leukemia”

PIs: Anjali Advani, MD; Michaela Liedke, MD

Background:

- Ph+ ALL is caused by the Bcr-Abl tyrosine kinase and is common in older adults
- Standard TKI **Dasatinib** is associated with high response rates but relapse is common
- **Asciminib** is a potent allosteric inhibitor of Bcr-Abl
- Bi-specific antibody **Blinatumomab** reliably eradicates Minimal Residual Disease and deepens response

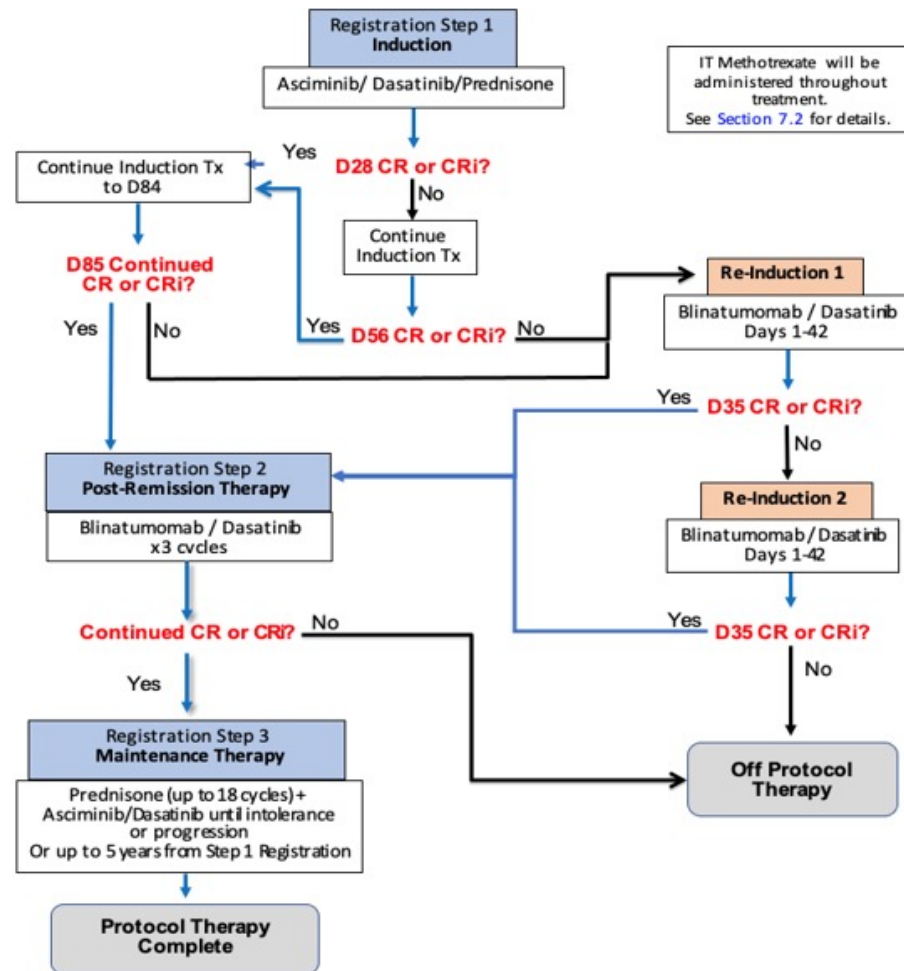
Study objectives:

- Rate and depth of remission
- Disease free and overall survival
- Correlatives to study mechanisms of resistance

Statistics:

- Phase 2 study
- Hypothesis: Day 84 Major Molecular Response 52% -> **72%**
- Approximately 50 patients are enrolled over 2 years

21CTP.LEUK01 Study Schema



21CTP.LEUK01 Site Updates

27 Selected Sites

Active Sites:

Cleveland Clinic Foundation
University of California - Irvine
Baptist Clinical Research Institute
Duke University Hospital
University of Cincinnati Medical Center
R.J. Zuckerberg Cancer Center/Northwell Health
UPMC/Hillman Cancer Center
University of Rochester Medical Center
Henry Ford Health Center
Rhode Island/Brown University
University of Arizona Cancer Center
University of Nebraska Medical Center
University of New Mexico Comp Cancer Center

**7 patients have been enrolled and 3 have completed
induction therapy**

To Participate:



<https://www.surveymonkey.com/r/3TYCW63>

21CTP.HN01

CAPT-HN: “A Phase II Study Of Combined Amivantamab, Carboplatin And Paclitaxel In Unresectable Locally Recurrent Or Metastatic Head And Neck Cancer”

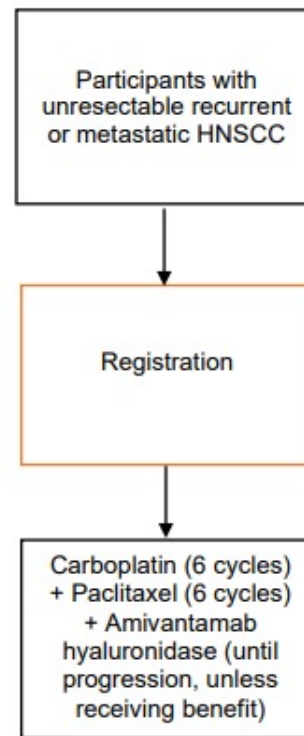
PIs: Paul Swiecicki, MD; Cristina Rodriguez, MD, and J. Chad Brenner, Ph.D.

Primary Objectives

- To assess the overall response rate (ORR) of amivantamab hyaluronidase + carboplatin + paclitaxel in participants with platinum naïve unresectable recurrent or metastatic head and neck squamous cell carcinoma previously treated with a PD-1 inhibitor.

Key Eligibility

- Participants must have histologically documented unresectable recurrent or metastatic squamous cell head and neck carcinoma
- Participants must have received prior therapy with a Programmed death ligand 1 (PD-(L)1) inhibitor or PD-1 inhibitor for treatment of head and neck cancer (in any setting).
- Participants must not have received more than two prior systemic therapy regimens for recurrent and/or metastatic disease.
- Participants must not have received treatment with a platinum or taxane agent as part of a prior treatment for recurrent or metastatic disease.
- Participants must not have had prior treatment with cetuximab or another Epidermal Growth Factor Receptor (EGFR) inhibitor in the locally recurrent advanced unresectable or metastatic setting.



21CTP.HN01 Site Updates

17 Selected Sites

Active Sites:

University of Nebraska Medical Center
University of Arizona Cancer Center
University of Michigan Rogel Cancer Institute
Karmanos
University of California – Irvine
Carle Cancer Institution
Medical University of South Carolina
University of Pittsburgh Medical Center / Hillman Cancer Center

10 patients enrolled

To Participate:

<https://www.surveymonkey.com/r/CZJCBW9>

SWOG CTP Active Studies – In Follow-up with Accrual Completed

TROPION-BREAST03 FDA Registration Trial

A Phase III, Open Label, Randomised Study of Datopotamab Deruxtecan (Dato-Dxd) with or without Durvalumab Versus Investigator's Choice of Therapy in Patients with Stage I-III Triple-Negative Breast Cancer who Have Residual Invasive Disease in the Breast and/or Axillary Lymph Nodes at Surgical Resection Following Neoadjuvant Therapy (D926XC00001)

SWOG CTP is the lead academic partner in this international trial



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SWOG CTP Studies In Development

21CTP.BREAST01

MONITOR, “Molecular Assessment and Identification of ctDNA and Optimizing Treatment for HR-positive, Her2-negative Metastatic Breast Cancer”

PIs: Kevin Kalinsky, MD; Manali Bhawe, MD, and Azka Ali, MD

Activating Late Fall 2026

26CTP.BMT01

HA-1 TCR T Cell Phase II Treatment Trial

PIs: Marie Bleakley, MD, PhD and Elizabeth Krakow, MD

On Pause

21CTP.BREAST01

MONITOR, “Molecular Assessment and Identification of ctDNA and Optimizing Treatment for HR-positive, Her2-negative Metastatic Breast Cancer”

PIs: Kevin Kalinsky, MD, Manali Bhave, MD, and Azka Ali, MD

Next Steps

- WCG IRB submission & approval
- Site selection
- Activation

Background

- CDK 4/6i + endocrine therapy remains standard first-line therapy for metastatic HR+/HER2- breast cancer
- ctDNA offers an early, non-invasive biomarker of resistance; dynamics often precede imaging by weeks-months
- SERENA-6 (Phase III): ctDNA-guided switch in therapy improved PFS (16.0 vs 9.2 mo; HR 0.44, $p < 0.001$) with recent FDA approval of camizestrant in combination with a CDK 4/6i upon detection of an *ESR1* mutation during aromatase inhibitor and CDK4/6 inhibitor therapy
 - Median time for detection of ESR1m on SERENA-6: 22 mos
 - Proof of concept for molecularly guided treatment intensification

Rationale for AKT Inhibition

- PIK3/AKT/mTOR pathway activation is an established driver of endocrine resistance
 - Capivasertib is an oral pan-AKT inhibitor FDA-approved with fulvestrant for HR+/HER2-, AKT-pathway–altered metastatic breast cancer
- Preclinical: PI3K/mTOR inhibitors can reverse resistance to CDK 4/6i and ET regardless of PIK3/AKT pathway alteration

MONITOR will evaluate whether early therapeutic modification in patients with HR+ HER2- mBC with a switch to triplet therapy (CDK 4/6i + capivasertib + ET) in patients who do not achieve a molecular response within 3 months of starting first-line CDK 4/6i + ET will lead to improved progression-free survival (PFS)

Eligibility Criteria

Disease Specific Criteria:

- Unresectable or metastatic breast cancer (ER-positive, PR-positive, HER2 negative or low per ASCO-CAP)
 - Measurable or non-measurable disease is allowed
- Participants must not have had endocrine resistance. Prior adjuvant CDK4/6 inhibitor use is allowed as long as patients did not have a recurrence within 12 months of completion of adjuvant CDK4/6 inhibitor
- Postmenopausal or premenopausal receiving ovarian ablation with a GnRH agonist such as goserelin. Males must also receive a GnRH agonist.

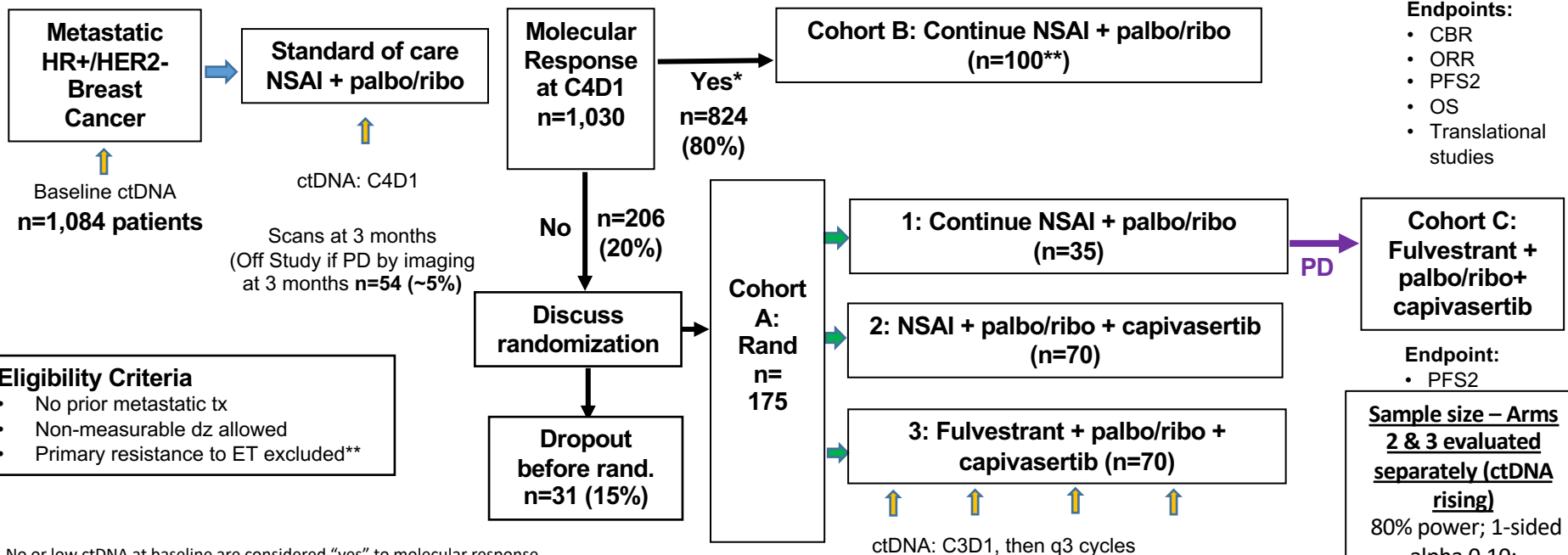
Clinical/Laboratory Criteria:

- ECOG PS 0-1
- Adequate blood counts (hemoglobin ≥ 9.0 g/dL and ANC $\geq 1.0 \times 10^3/\mu\text{L}$) and organ function (total bilirubin ≤ 1.5 institutional upper limit of normal)

Key Exclusionary Criteria:

- Insulin required for routine diabetic management and control
- Hemoglobin A1c $\geq 8.0\%$ (63.9 mmol/mol)

MONITOR (Molecular Assessment and Identification of ctDNA and Optimizing Treatment)



Primary Endpoint:

- PFS

Secondary Endpoints:

- CBR
- ORR
- PFS2
- OS
- Translational studies

Eligibility Criteria

- No prior metastatic tx
- Non-measurable dz allowed
- Primary resistance to ET excluded**

* No or low ctDNA at baseline are considered “yes” to molecular response

** Cohort B will be capped at 100 pts

*** Recurrence within 12 months of adjuvant hormone tx or adjuvant CDK 4/6i

Why This Study?

- MONITOR will evaluate a therapeutic modification based on molecular response earlier in the disease course at 3 months
 - Builds on the SERENA-6 treatment paradigm of ctDNA assessment to guide front-line therapy which started at 6 months (median time to ctDNA+: 22 months)
- Patients will have access to an AKT inhibitor-based combination therapy regardless of biomarker/mutation status
- Pragmatic study design with practical eligibility and schedule of assessments to allow for robust enrollment in the first-line setting for pts with HR+ HER2- metastatic breast cancer

Getting Started with SWOG CTP...

- **SWOG Member sites will be notified about CTP studies via email**
 - Study Synopsis
 - Study Feasibility Questionnaire
 - Study Funding
- **Interested sites will complete a short study feasibility questionnaire**
- **Once selected, sites will receive the following study documents and must complete the site agreement for the study:**
 - The WCG IRB approved protocol and consent
 - Funding Memo
 - Site Agreement (CTSA)



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AN LLC OF THE HOPE FOUNDATION FOR CANCER RESEARCH

Dear SWOG Site Leadership:

SWOG Clinical Trials Partnerships (CTP) invites your site, as a SWOG member site, to consider participation in our first trial in head and neck cancer -- [21CTPHN01](#) (the CAPT-HN trial). We expect to activate CAPT-HN this fall!

This email provides details on this clinical trial, including:

- Study Synopsis
- Study Background
- Study Calendars
- Funding Memo

If after reviewing these materials your site is interested in applying to open this study, please complete the linked [feasibility questionnaire](#). It collects essential information to help us assess each site's suitability for the study. We will select only a limited number of sites to open the 21CTPHN01 trial, so we urge you to complete the feasibility questionnaire as soon as possible.

About SWOG CTP

SWOG CTP is an independent, limited liability corporation with its own leadership, processes, and funding agreements. But the missions of SWOG and SWOG CTP are the same -- to significantly improve lives through cancer clinical trials and translational research.

If you have questions about SWOG CTP or any of our trials, which include no federal funding, please reach out to us at protocols@swogctp.org.

Sincerely,

Paul Swiecicki, MD (Primary Chair)
Cristina P. Rodriguez, MD (Medical Oncology)
21CTPHN01 Study Chairs

Kathy S. Albain, MD, FACP, FASCO
SWOG Vice-Chair for Clinical Trials Partnerships

swogctp.org/abstracts/21ctphn01



SWOG CTP Sites

We want to hear from you!

Schedule a one-on-one appointments during Group Meeting by emailing sitecoordination@swogctp.org

SWOG CTP/Industry Collaborations in Process or Under Discussion

- Novartis-CTP PPP Pipeline Retreat
- Foundation Medicine Strategic Partnership
- Other companies - pipelines or PPP interest
- Others molecular platforms
- NCORP Committees' engagement
- Real world data analyses
- CNS Working Group
- SWOG VA Committee
- Other novel collaborative opportunities
- Immunotherapeutics
- GI Malignancies
- GU Committee – new bladder design
- Early Therapeutics/Rare Diseases
- Lymphoma Committee
- GU Committee – New Bladder Design
- Melanoma Committee
- Myeloma Committee
- Radiation Oncology, Theranostics

Additional CTP collaborative opportunities

- Protocol and study design input
- Prognostic and predictive model development and/or validation, their applied uses
- Other SDMC collaborations such as statistical analyses of study endpoints
- Operational assistance in site selection, study start-up, assessment of site efficiency
- Consultations from NCORP experts for PRO review/development, design of patient materials, data analyses options
- Consider designs for real world safety, survival or other health outcomes endpoints
- Collaborate on trials that study outcomes and safety in special populations

SWOG CTP Milestones and the Future

- Successful upfront engagement among all stakeholders
- 3 active studies, 1 study in final development process, TROPION-Breast 03 registration trial accrued ahead of schedule
- Early and mid-career investigator involvement
- Timeline process refined
- Implementation of other internal processes, such as up front feasibility review, kickoff calls after contract signed, and feasibility/site selection (with feedback from participating sites)
- Exciting new initiatives are pending with other companies
- Broadened menu of options are being explored

More interested partners are welcome!

SWOG CTP invites YOU to get involved!

PLEASE EMAIL CTP@SWOG.ORG WITH YOUR INTEREST,
APPLICABLE IDEAS, AND/OR INDUSTRY CONTACTS

For more information visit

<https://www.swogctp.org>