SWOG Clinical Trials Partnerships (CTP)

HOW SWOG PARTNERS WITH INDUSTRY TO CONDUCT CANCER CLINICAL TRIALS

https://www.swogctp.org/

SWOG CANCER RESEARCH NETWORK

SWOG CLINICAL TRIALS PARTNERSHIPS

SWOG Clinical Trials Partnerships (SWOG CTP)

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

Huizenga Family Endowed Chair in Oncology Research
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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 as well as other collaborative opportunities**
- **Utilizes an Executive Review Committee, “replacing” NCTN Steering Committee and CTEP reviews of initial capsule and subsequent full protocol**
- **Flows through dedicated CTP channels using SWOG operations, statistics and data management personnel**

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Our Members

- Network of 1,300+ sites, including:
  - 37 NCI-designated cancer centers
  - 19 NCTN Lead Academic Participating Sites (LAPS)
  - Canadian collaborations
  - Member sites and collaborations in Saudi Arabia, Mexico, Japan, Korea, Colombia, Peru, Chile, Uruguay and Brazil
- Membership consists of:
  - 8,000+ researchers/clinicians
  - 10,000+ research nurses, clinical research associates, pharmacists, patient advocates, and others

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

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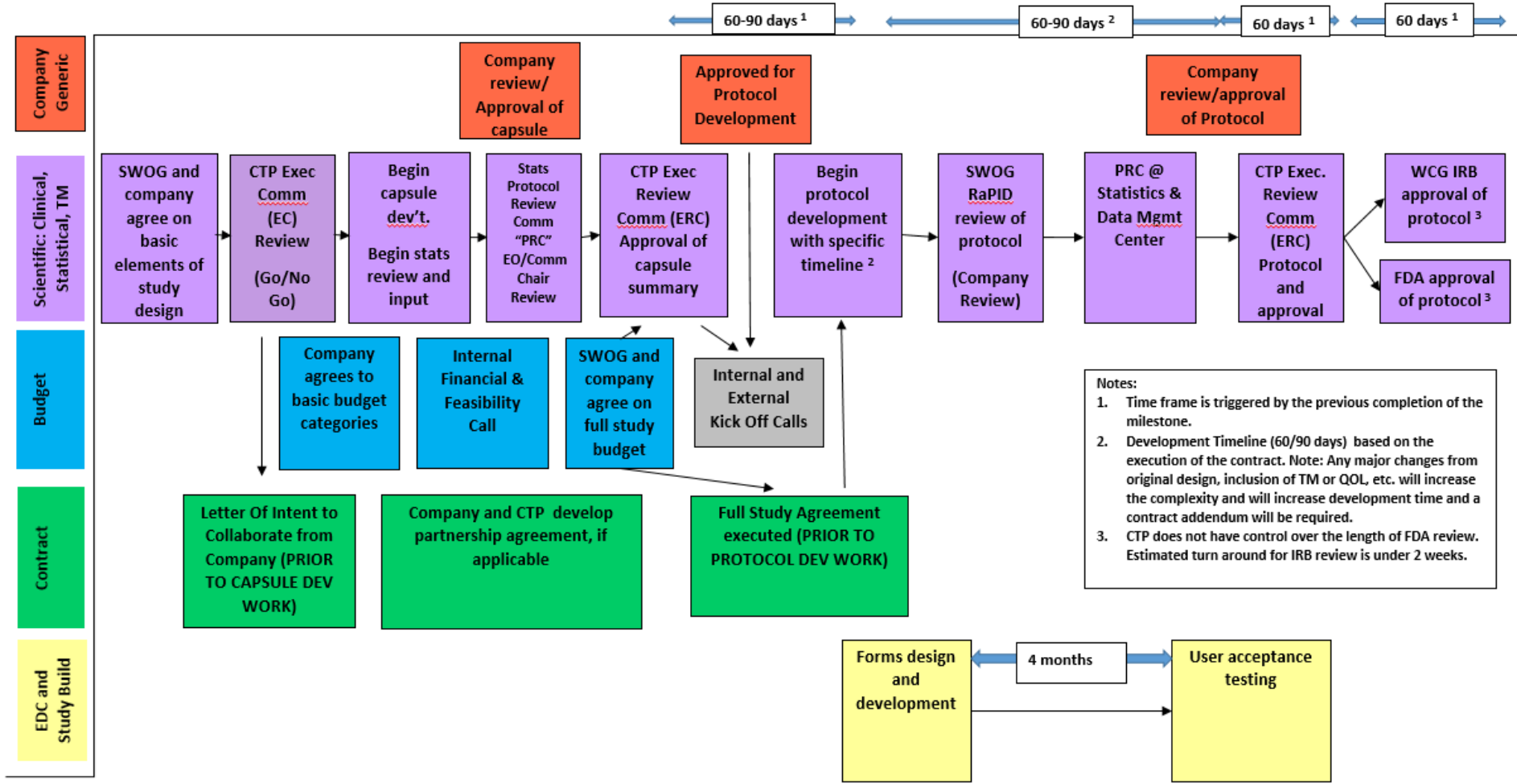
Current CTP Process

- 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
- Peer review via CTP Executive and Executive Review Committees

SWOG CTP Study Development Process



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 studied (given large SWOG network)
- 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 and radiotherapy questions

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SWOG Clinical Trials Partnerships (SWOG-CTP)

Federally-funded SWOG trials

- SWOG-CTP obtains and distributes industry funding
- Drug costs, other support
- Ongoing, successful for many years

SWOG CTP-run rigorous, scientifically relevant industry supported (100%) trials*

Single SWOG Committee-initiated studies

- Single arm trials
- Phase IB/II or phase II
- Randomized phase II
- Pilot studies
- Hypothesis-generating

Preferred Partnerships Program (PPP)

- New mechanism
- Pipeline access – or – complex multi-arm platforms
- Joint scientific development and governance
- Dedicated CTP infrastructure

*No overlap or "competition" with active federally-funded studies

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

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SWOG CTP Studies - Active

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)

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AstraZeneca

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TROPION-Breast03

A Phase 3, 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

Steering Committee:

SWOG
Aditya Bardia (US; ICI & co-chair)
Kathy Albain (US)
Dawn Hershman (US)
Kevin Kalinsky (US)
Priyanka Sharma (US)
Lajos Pusztai (US)
William Barlow (US)

Translational Research Committee:

SWOG
Priyanka Sharma (US; co-chair)

Symptom & QOL Committee:

SWOG
Dawn Hershman (US; co-chair)

TROPION-Breast03: Study Design

TROPION-Breast03

- **Patients with Stage I–III TNBC**
- **Residual invasive disease after neoadjuvant therapy**
- **No evidence of locoregional or distant relapse**
- **No adjuvant systemic therapy**
- **ECOG PS 0 or 1**

N≈1,075 Randomised 2:1:2

Dato-DXd
6 mg/kg IV Q3W x 8 cycles
+
Durvalumab
1120 mg IV Q3W x 9 cycles

Dato-DXd
6 mg/kg IV Q3W x 8 cycles

Investigator's Choice of Therapy*

Primary Endpoint
iDFS:
Dato-DXd + durvalumab
vs ICT

Stratification factors:

- Prior neoadjuvant pembrolizumab (Yes vs No); cap No at 40%
- Residual disease (< 1 cm vs ≥ 1 cm); cap < 1 cm (in the absence of lymph node involvement) at 20%
- Prior neoadjuvant platinum chemotherapy (Yes vs No)

*Capecitabine, pembrolizumab, or capecitabine + pembrolizumab; only patients who have received prior pembrolizumab in the neoadjuvant setting should receive pembrolizumab as part of their adjuvant therapy in the ICT arm.

Status of recruitment caps
1) Patients with high-burden residual disease remain eligible:
- **≥ 1 cm in the breast +/- positive lymph nodes**
- **< 1 cm in the breast + positive lymph nodes**

2) Patients with prior neoadjuvant pembrolizumab remain eligible.

Daiichi-Sankyo AstraZeneca SWOG CLINICAL TRIALS PARTNERSHIPS

Study NCT05629585. ClinicalTrials.gov website.

TROPION

Global Study Update as of 04 Apr 2025

Metrics	Status	Comments
Number of Countries Activated	16 of 16	Completed
Number of Patients Screened	1485 of 1433	264 in the US
Number of Patients Randomized	1174 of 1075	197 in the US
Screen Failure Rate	21%	20% in US

- Last subject randomized (LSR) milestone was achieved by 20 Mar 2025.

SWOG CTP Studies - In Development

- **21CTP.LEUK01**
  A Phase II Trial of Asciminib, Dasatinib, Prednisone, and Blinatumomab for Participants with Newly Diagnosed Philadelphia Chromosome Positive (Ph+) Acute Lymphoblastic Leukemia

- **21CTP.HN01, CAPT-HN**
  A Phase II Study of Combined Amivantamab, Carboplatin and Paclitaxel in Unresectable Locally Recurrent or Metastatic Head and Neck Cancer

- **21CTP.BREAST01, MONITOR**
  A Phase II Platform Trial Using Circulating Tumor DNA to Monitor Treatment Response in HR+, HER2-Metastatic Breast Cancer

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First SWOG CTP Preferred Partnership

- SWOG CTP/Novartis Preferred Partnership - Collaborative Master Agreement signed
- Novartis pipeline (platform, basket, other designs; disease-specific or agnostic)
- Solid tumor, hematology, immunotherapeutics, and early therapeutics/rare cancers
- Committee chairs and other SWOG scientific leaders are in collaboration with Novartis

To date, one platform trial jointly designed and is now ERC, FDA and IRB approved; activation in progress -21CTP.LEUK01 (Ph+ ALL)

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21CTP.LEUK01

A Phase II Trial of Asciminib, Dasatinib, Prednisone, and Blinatumomab for Participants with Newly Diagnosed Philadelphia Chromosome Positive (Ph+) Acute Lymphoblastic Leukemia

… ***testing asciminib, dasatinib, prednisone, and blinatumomab in partnership with Novartis…***

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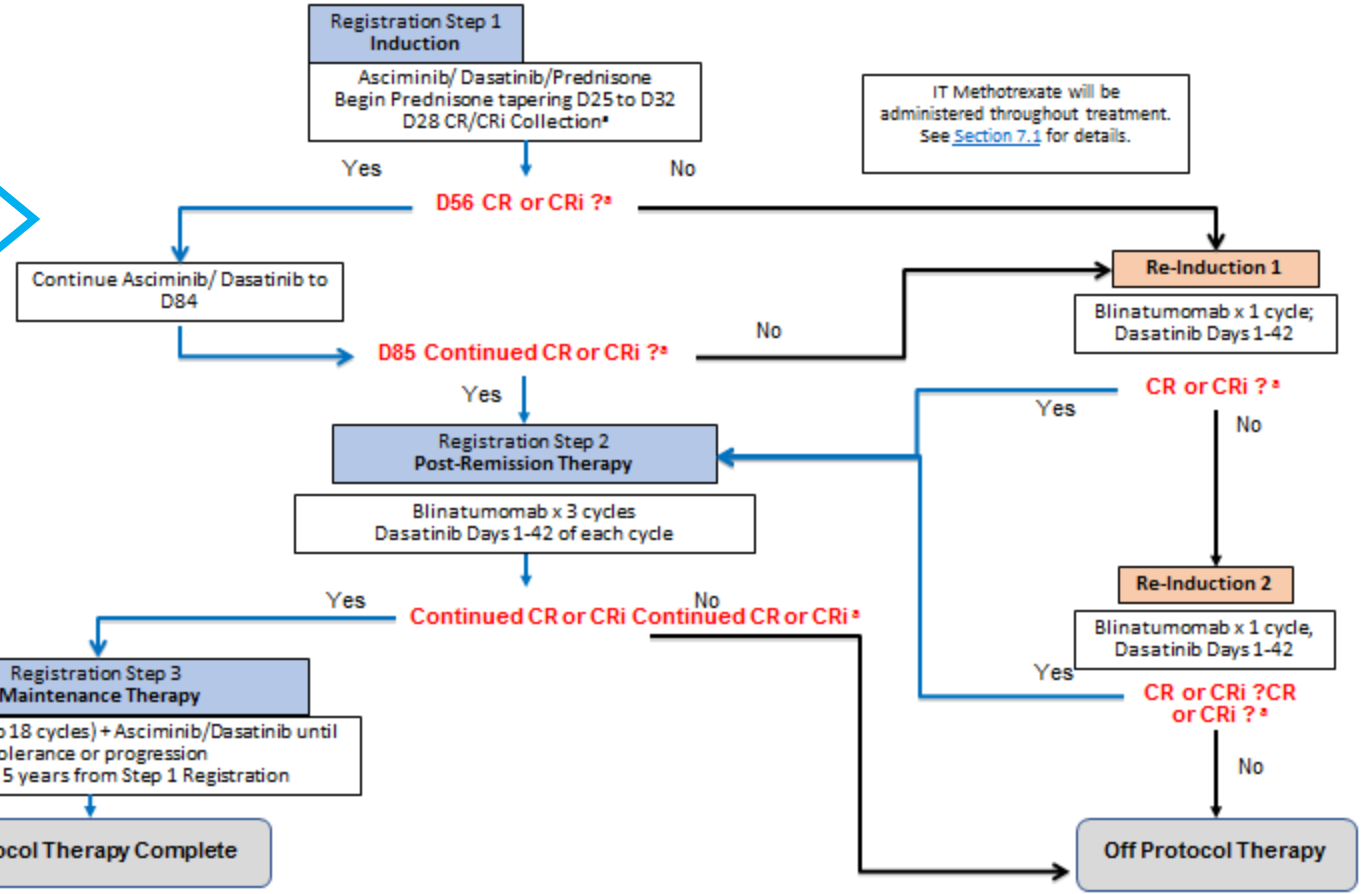
21CTP.LEUK01: Phase II study of asciminib, dasatinib, prednisone and blinatumomab for patients either over 60 or if younger, not fit for intensive therapy in newly diagnosed Ph+ ALL

wcg™
IRB APPROVED!!



21CTP.LEUK01 – Site Selection

- **Invitation to participant – sent April 2nd to SWOG Site PIs and Head CRAs**
- **Activation May 15, 2025**

swogctp.org/trials/21ctpleuk01

SWOG CLINICAL TRIALS PARTNERSHIPS

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 leukemia -- 21CTP.LEUK01. This study will be activating May of 2025!

This email provides details on this clinical trial, including:

- Study Synopsis
- Study Calendars
- Specimen Collection Details
- Funding Memo

If after reviewing these materials your site is interested in applying to open this study, please complete the linked **feasibility questionnaire** **no later than May 16th**. It collects essential information to help us assess each site's suitability for the study. We expect to select approximately 30 more sites to open the 21CTP.LEUK01 trial.

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,

Anjali S. Advani, MD
Michaela Liedtke, MD
21CTP.LEUK01 Study Chairs

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

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21CTP.LEUK01, Site Funding

Study Component	Collect Type	System	Required Data	Funding per Patient (a)
Patient Registration		Nebula	Registration Worksheet Submission	$12,000
Biospecimens	Mandatory	Specimen Tracking	Baseline Specimen Shipment	$500
EKG – Baseline	Mandatory	Nebula	Submission of EKG Date on the Onstudy form	$47.76
Lumbar Puncture - Baseline	Mandatory	Nebula	Submission of lumbar puncture Date on the Onstudy form	$607
Total Potential Funds per Participant				**$13,154.76**
Additional Per Site Payments				
Site Regulatory and Training Requirements Fulfilled	Mandatory	Florence	Pre-Activation Checklist Completed*	$10,000 per site
Site IRB Approval	Mandatory	Florence	IRB Initial Approval	$10,000 per site

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21CTP.HN01, CAPT-HN

A Phase II Study of Combined Amivantamab, Carboplatin and Paclitaxel in Unresectable Locally Recurrent or Metastatic Head and Neck Cancer

… in partnership with Janssen…

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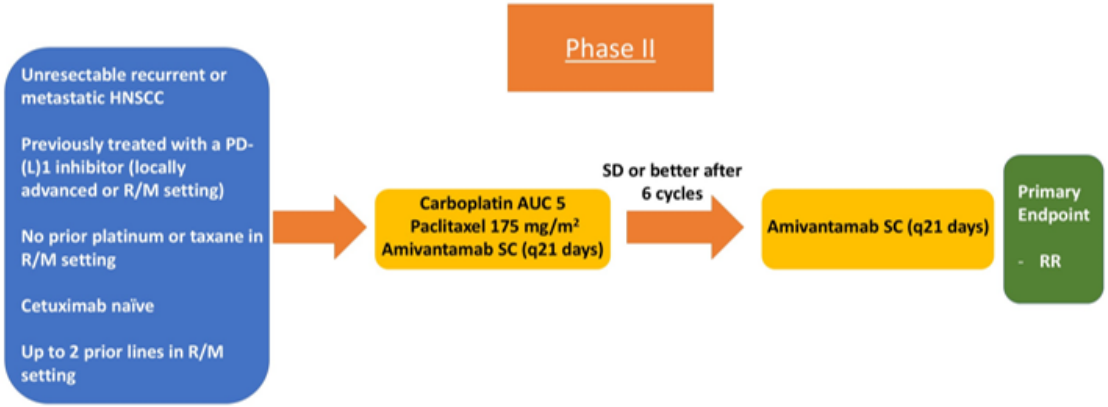
21CTP.HN01 Schema



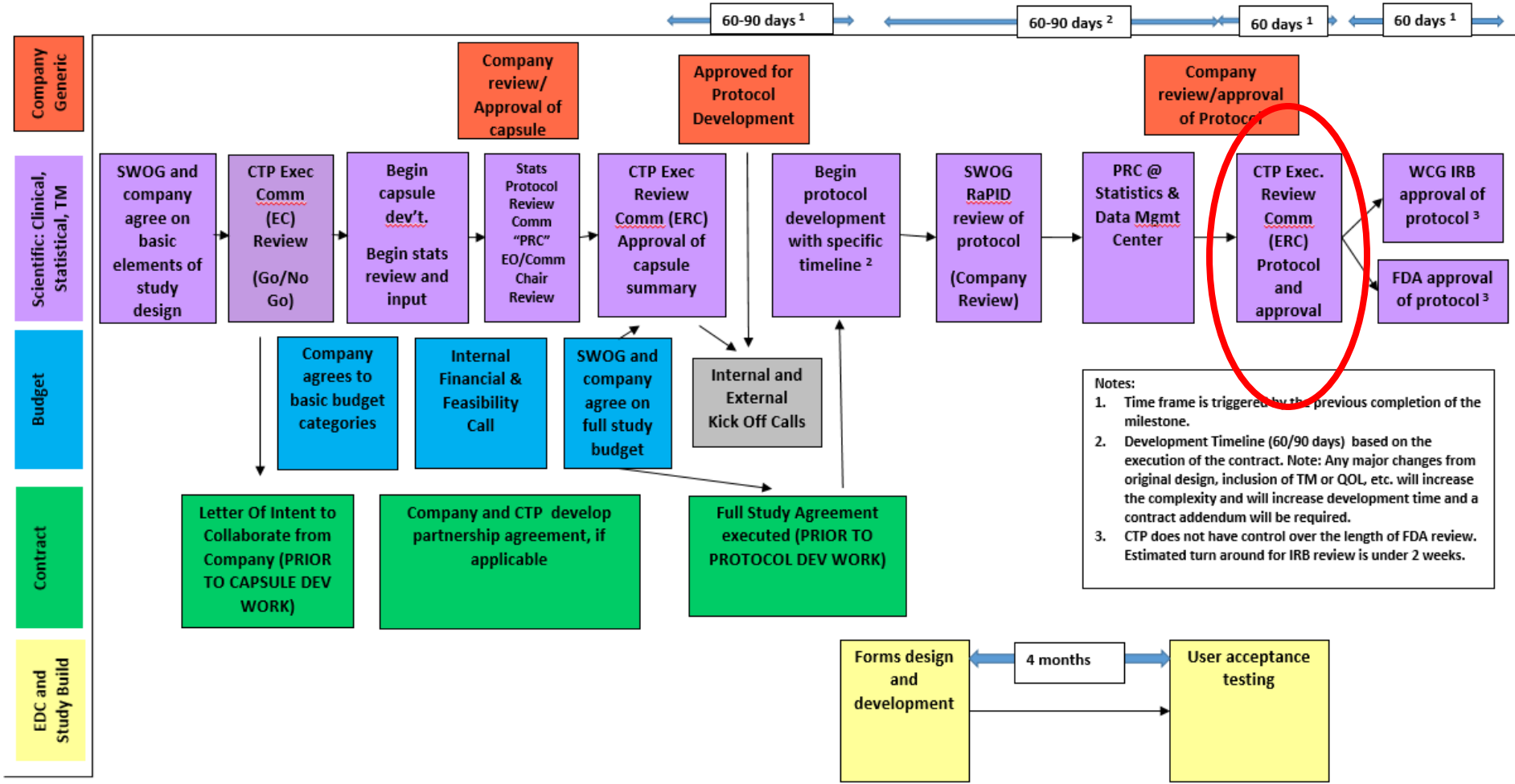
Key Inclusion

1. Histologically documented locally recurrent or metastatic head and neck squamous cell carcinoma defined as those originating from the wet lip, oral cavity, oropharynx, larynx, hypopharynx, nasopharynx, and sinuses
2. ECOG performance status of 0-1
3. Up to two prior systemic therapy regimens for recurrent and/or metastatic disease.
4. Must have received prior treatment with a systemic PD-(L)1 inhibitor (in any setting)

Key Exclusion

1. Patient has received treatment with a platinum agent as part of prior treatment for recurrent or metastatic disease
2. Patient has received treatment with a taxane agent as part of prior treatment for recurrent or metastatic disease
3. Prior treatment with cetuximab or another EGFR inhibitor in the locally advanced or metastatic setting

SWOG CTP Study Development Process



21CTP.HN01 Protocol in Development!

Contract has been signed

CTP Executive Review of the protocol → next are FDA and WCG IRB submissions

Anticipated site selection and activation
Q3/Q4 2025

Learn more at www.swogctp.org

Upcoming SWOG CTP trial in leukemia

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Anjali S. Advani, MD
Michaela Liedtke, MD
21CTP LEUK01 Study Chairs

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21CTP.BREAST01, MONITOR

A Phase II Platform Trial Using Circulating Tumor DNA to Monitor Treatment Response in HR+, HER2- Metastatic Breast Cancer

… ***industry partner cannot be named yet pending final contract, investigational agents remain confidential***

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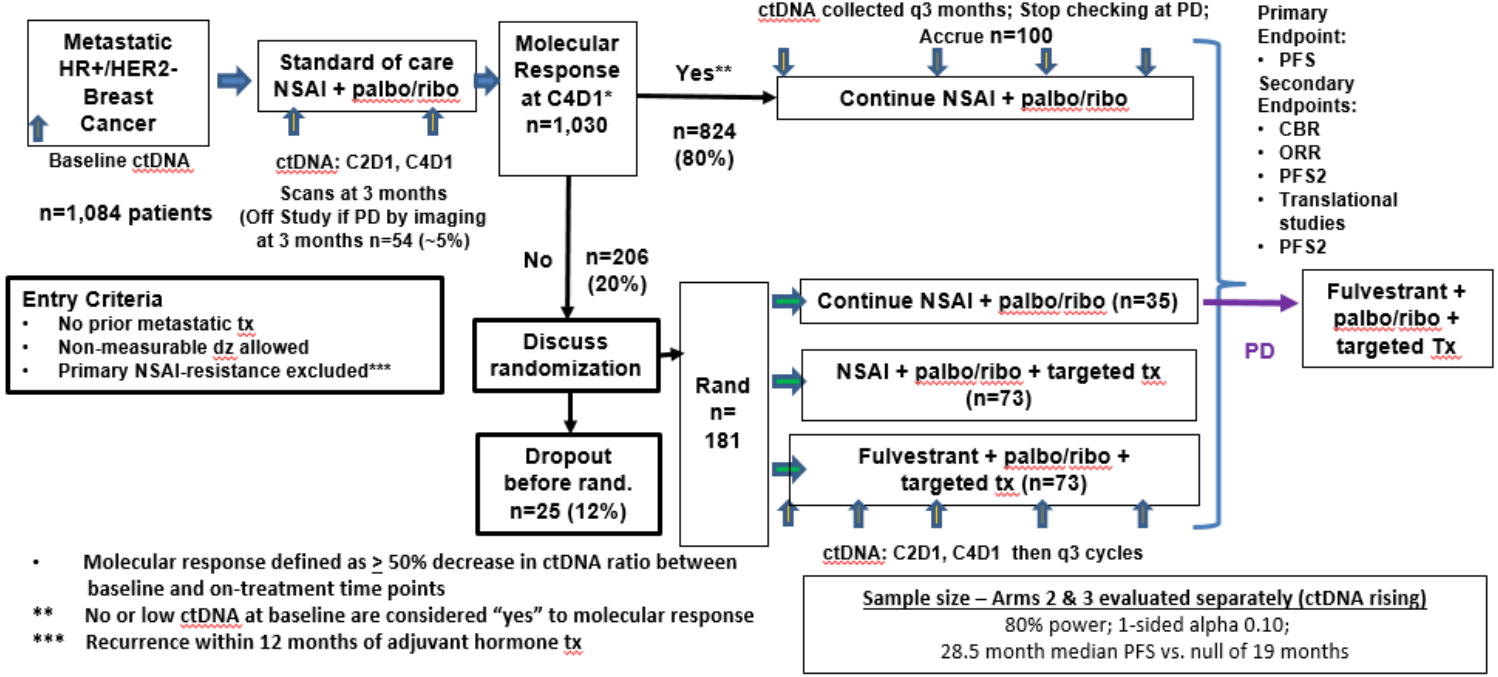
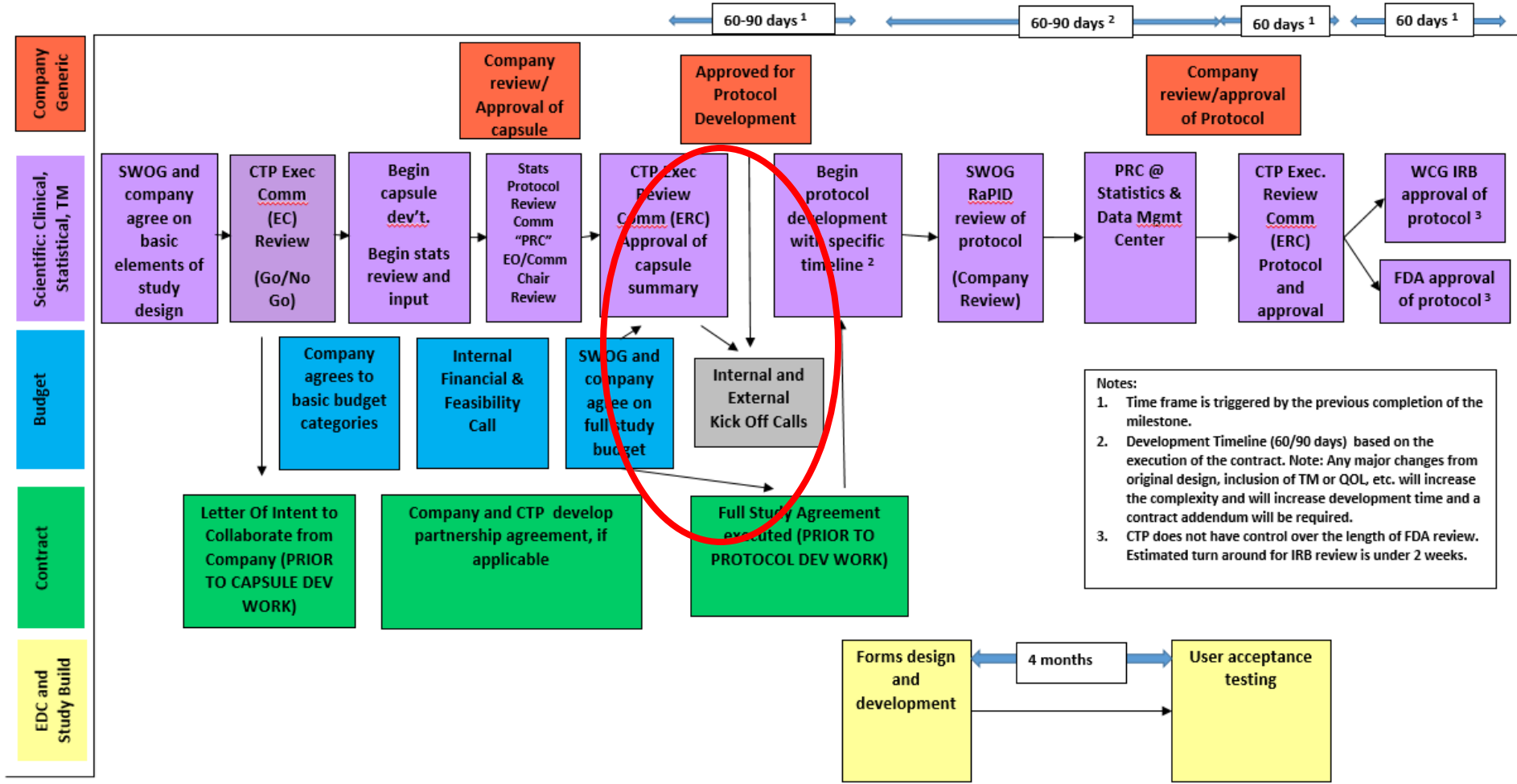
21CTP.BREAST01 - *MONITOR* (Molecular assessment and identification of ctDNA and optimizing treatment)



SWOG CTP Study Development Process



What Sites Can Expect

CTP Partnerships and Industry Supported Trials

- **Study Feasibility and Site Selection Process**
- **Study Funding**

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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 complete contract for the study**

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Selected Sites Study Start-Up
Frequently Asked Questions

Q: Who is the study sponsor?

A: SWOG CTP, there is no CRO for this study. The funding for CTP studies flows between SWOG CTP and the selected sites.

Q: Are patients receiving reimbursement?

A: No

Q: Are any study materials being provided?

A: No

Q: Are there external vendors?

A: No

Q: Where can I find the protocol number, IND#, and overall accrual goal of the study?

A: The Title Page and Section 2 of the protocol.

Q: Where can I get the manuals, IB, Medicare Coverage Analysis, Budget, and Clinical Trials Agreements?

A: The Site Agreement, Funding Memo, and Protocol are provided upon site selection notification. The protocol serves as the IB and manuals for this study. All other documents are provided in Florence upon Site Agreement Finalization.

Q: What are the electronic systems being used?

A: Florence will be the clinical trials management system used with study information being provided through Florence. CRAB Nebula will be the electronic data capture system used. There will be no IVRS or IXRS.

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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)**

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SWOG CTP Study Funding

- **CTP study funding will be set based on complexity of the study**
  - **Site start up activities - $20K**
  - **Per patient enrollment - $12K**
  - **Additional funds available for study specific requirements such as submission of specimen and/or images**
- **No invoicing required**

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Learn more at the ORP Open Forum!

Friday, May 2nd at 11:00pm – 12:30pm

Pacific L-O (Pacific Concourse Level)

In Person Only

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Pending CTP/Industry Collaborations in Process or Under Discussion

- CNS Working Group
- Digital Engagement
- Immunotherapeutics
- GI malignancies
- Early Therapeutics/Rare Diseases
- New Breast adjuvant proposal
- SWOG VA Committee
- GU Committee – new bladder design
- Other companies - pipelines or PPP interest
- NGS/molecular platforms – several companies
- Melanoma committee

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Potential novel CTP collaborative opportunities

- Program & study design input (e.g. pre-protocol review for study design, protocol review)
- Prognostic and predictive model development and/or validation, their applied uses; other SWOG Statistical Center collaborations
- Give operational assistance in site selection, study start-up and assessment of site efficiency, such as EHR-to-EDC
- Provide statistical analyses of study endpoints
- Offer consultations from NCORP experts for PRO review or development, or of patient materials
- Conduct compliance reviews that address mandates for broad participation
- Collaborate on trials that study outcomes and safety in special populations

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SWOG CTP Milestones and the Future

- Successful upfront engagement among all stakeholders
- 4 studies in active protocol development; TROPION-Breast 03 registration trial accrued ahead of schedule
- Early and mid-career investigator opportunities
- Timeline process refined
- Implementation of other internal processes, such as up front feasibility review, kickoff calls after contract signed, and feasibility/site selection
- Exciting new initiatives are pending with other companies
- Planned broadened menu of options to explore

More interested partners are welcome!

SWOG CANCER RESEARCH NETWORK

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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

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