SWOG Clinical Trials Partnerships (SWOG CTP)

Update Forum

Wednesday, October 19 | 11:30 am-12:30 pm CT

SWOG CLINICAL TRIALS PARTNERSHIPS

AN LLC OF THE HOPE FOUNDATION FOR CANCER RESEARCH

https://www.swogctp.org/

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SWOG Clinical Trials Partnerships (SWOG CTP)

Update Forum

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

Huizenga Family Endowed Chair in Oncology Research
Professor of Medicine, Division of Hematology/Oncology
Loyola University Chicago Stritch School of Medicine
Cardinal Bernardin Cancer Center

Casey Dawson
Director of Administration, SWOG-CTP
SWOG Cancer Research Network
Group Chairs Office
OHSU Knight Cancer Institute

Crystal Miwa
Clinical Trials Project Manager, SWOG-CTP
SWOG Operations Office
San Antonio, Texas; Ann Arbor, Michigan

Chrissy Laubach
Protocol Program Manager, SWOG-CTP
SWOG Operations Office
San Antonio, Texas

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Acknowledging SWOG CTP's Executive Leadership, Scientific Advisory and Operations Expertise

- ***CTP Executive Committee*** **(Drs. Charles Blanke, Primo "Lucky" Lara, Michael LeBlanc, Dawn Hershman, and James Rae; Casey Dawson, Dana Sparks, Nathan Eriksen and Jo Horn)**
- ***Committee Chairs and Executive Officers*** **(Partners/Advisory)**
- ***Scientific Advisory Board (SAB)*** **(SWOG experts across all disease sites)**
- ***CTP Protocol Operations*** **(Dana Sparks, Director; Crystal Miwa, Chrissy Laubach)**
- ***Administrative Assistance*** **(Whitney Leslie, Valerie Durling)**

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SWOG CTP Update Forum Agenda

- CTP and its Preferred Partnerships Program (PPP)
- Joint CTP/Industry study development process
- Executive Review Committee procedures and progress
- Infrastructure and eResearch platform
- CTP's study portfolio – approved, in process, planned
- CTP/AstraZeneca registration trial update
- Milestones and vision

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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

- Previously named CTI
- Not "one-offs" like an IIT
- If successful, a broadened collaboration via other agents/designs within company may evolve

Preferred Partnerships Program (PPP)

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

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

SWOG-CTP establishes and administers scientific *preferred* partnerships between SWOG and industry

- **Mechanism whereby SWOG Cancer Research Network (1000+ member institutions) collaborates concurrently with industry as a preferred research partner**
- **Offers range of study platform options (phases IB, IB/II, randomized II, III, registration)**
- **Facilitates testing novel agents or combinations across disease sites or within a disease**
- **Flows through dedicated CTP channels (study design, approval, development, contracting, monitoring, analysis, reporting)**
- **Utilizes outstanding SWOG operations, statistics and data management personnel**

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

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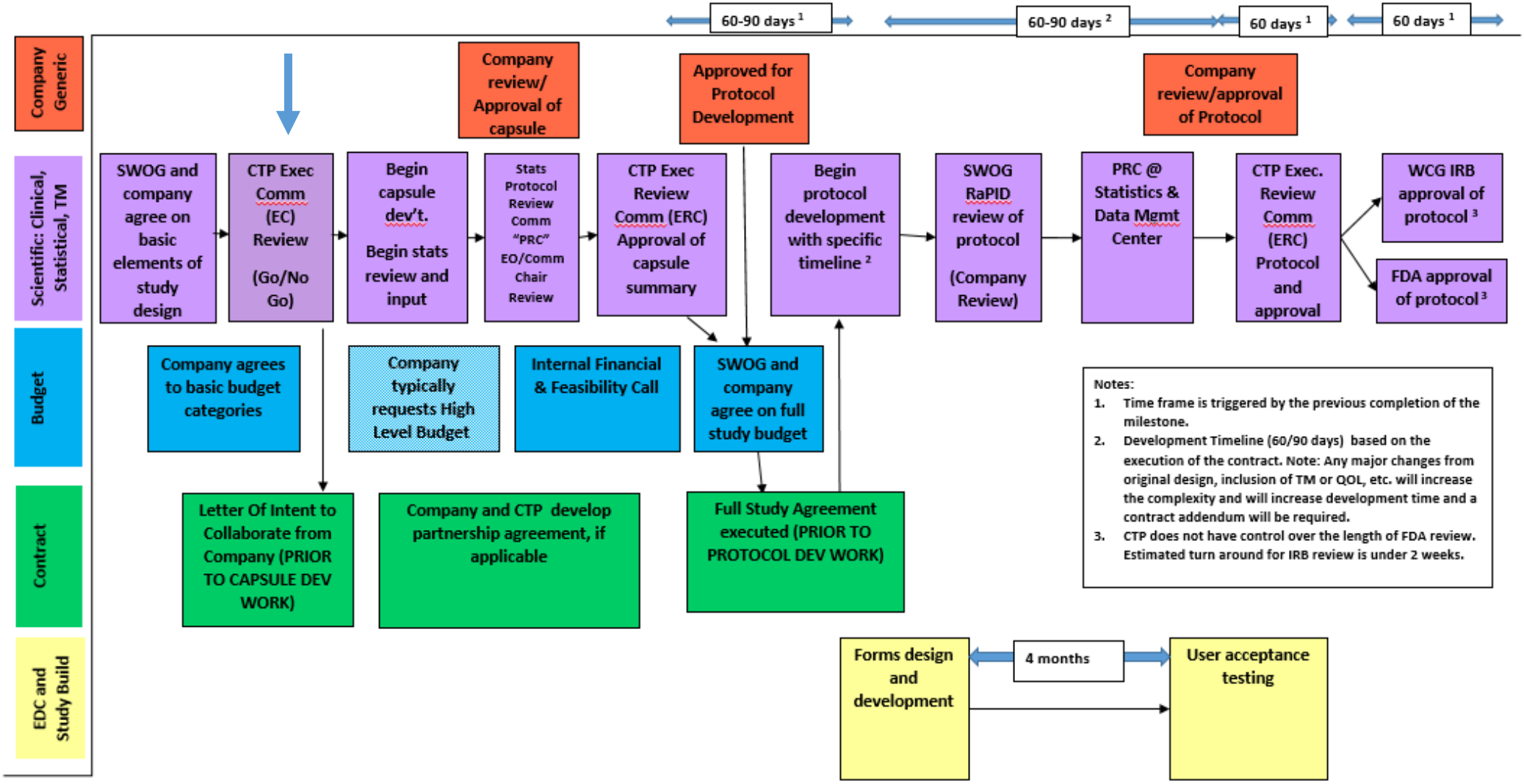
SWOG CTP Study Development Process



SWOG Clinical Trials Partnerships (SWOG-CTP) Proposal
Initial Executive Committee Review/Approval - I

Principal Investigator: **Co-PI(s):**

Study title: **Industry partner:**

Study background, rationale, hypothesis and objectives

Basic study design (platform, basket, other; sample size, need for safety run in)

Translational medicine correlatives (if applicable); integral, integrated and/or exploratory biomarkers

Banking plans (if applicable)

Additional ancillary studies (QOL/PRO, Imaging) (if applicable)

SWOG Clinical Trials Partnerships (SWOG-CTP) Proposal
Initial Executive Committee Review/Approval - II

Disease and/or Research Committee(s) sponsorships/approvals

Name(s) of sponsoring Committee(s) Chair(s)

Statement from disease committee chair(s) supporting the study

Justification for why the study needs to be conducted in CTP in contrast to NCTN

Confirm there are no competing trials within SWOG or the NCTN either open or planned to open to the best of your knowledge.

Study Chair/Team has obtained approval from Executive Officer and if applicable, also from Translational Medicine Executive Officer

Study Chair/Team has had discussion with Vice Chair for Clinical Trials Partnerships to review process.

SWOG Clinical Trials Partnerships (SWOG-CTP) Proposal
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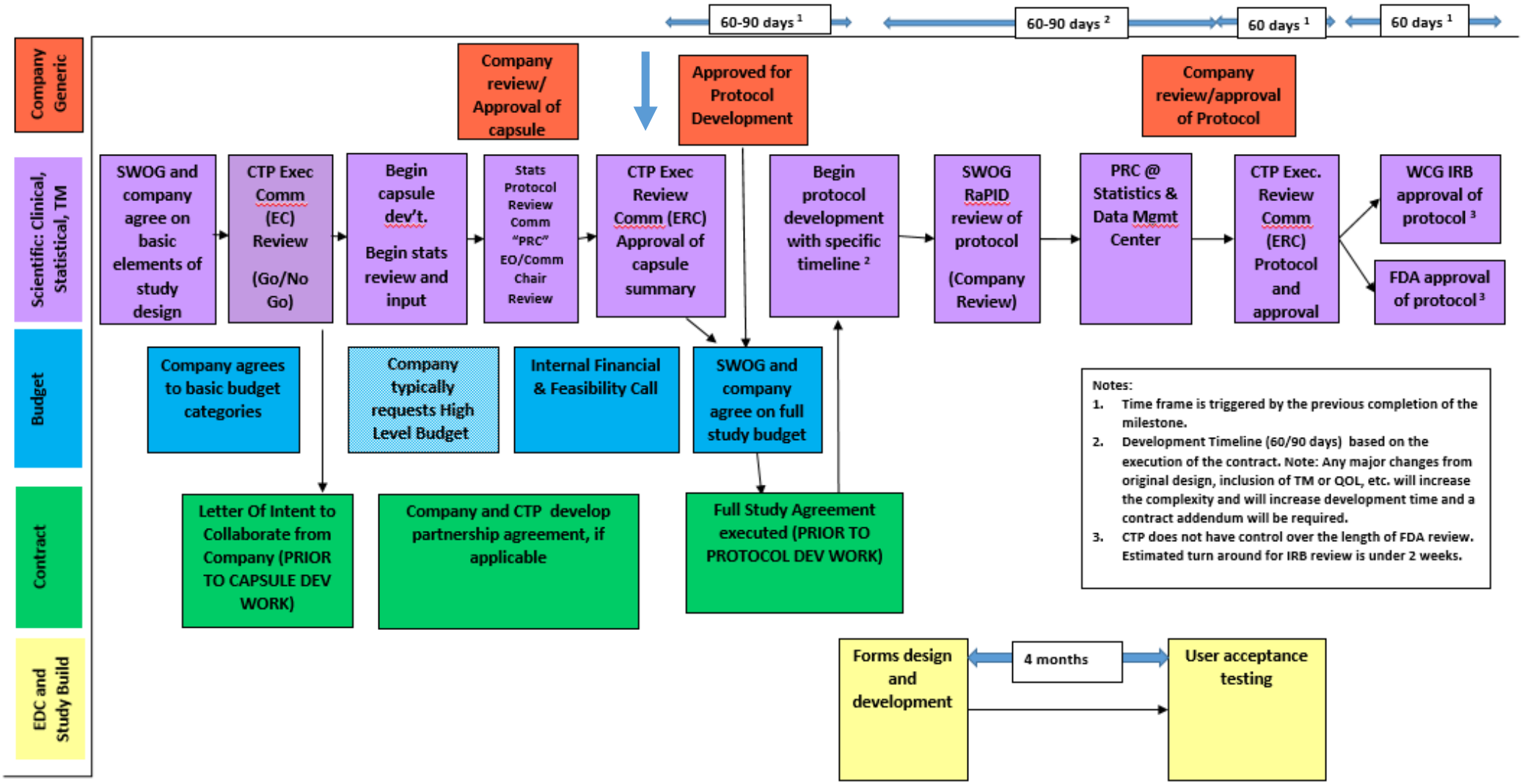
Go-No Go

SWOG CTP Study Development Process



SWOG CTP Executive Review Committee

- **"Replaces" NCTN Steering Committee reviews of initial capsule and subsequent full protocol (and requested revisions as needed)**
- **Core group selected from CTP Executive Committee and Scientific Advisory Board, plus two *ad hoc* reviewers with project-specific expertise**
- **New capsule template modeled after NCTN submission version, with CTP-specific Committee Chair, Executive Officer sections/other additions**
- **Standardized voting process: open session with study team presentation including Lay Advocate, followed by closed session and vote**

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CTP Executive Review Committee – Closed Session

1. Primary and Secondary Reviewers
   - Reviewers will provide verbal and written reviews and a relevance/impact score revealed to all
2. Member Voting Group
   - Members will provide their relevance/impact score on the study based on their individual review and Response Category for each proposal.
   - Comments and vote will be provided verbally and via Survey Monkey
3. Non-voting Members
   - Will provide comments, as appropriate
4. Response Category:
   - Acceptable as is - The proposal passes scientific and statistical reviews without any concerns that require further consideration, the Executive Review Committee will issue an approval
   - Acceptable, with modifications - This is basically an approval but will include language that the proposal is approved "providing" certain considerations are met and included in the protocol as appropriate.
   - Requires Resubmission - Overall supportive of the proposal but have significant concerns regarding scientific or statistical considerations, the committee may "table" the proposal. The committee is willing to review the proposal further providing the investigator(s) provide additional information to fill any gaps in knowledge/science/background, and/or correct any study design flaws, before further ERC review.
   - Rejected - The committee feels that the proposal has major concerns regarding study hypothesis, conduct, drug, design, or other major study aspect, they may reject the study. If a study is rejected, the committee generally does not wish to entertain the proposal moving forward, and no follow up submission is requested.

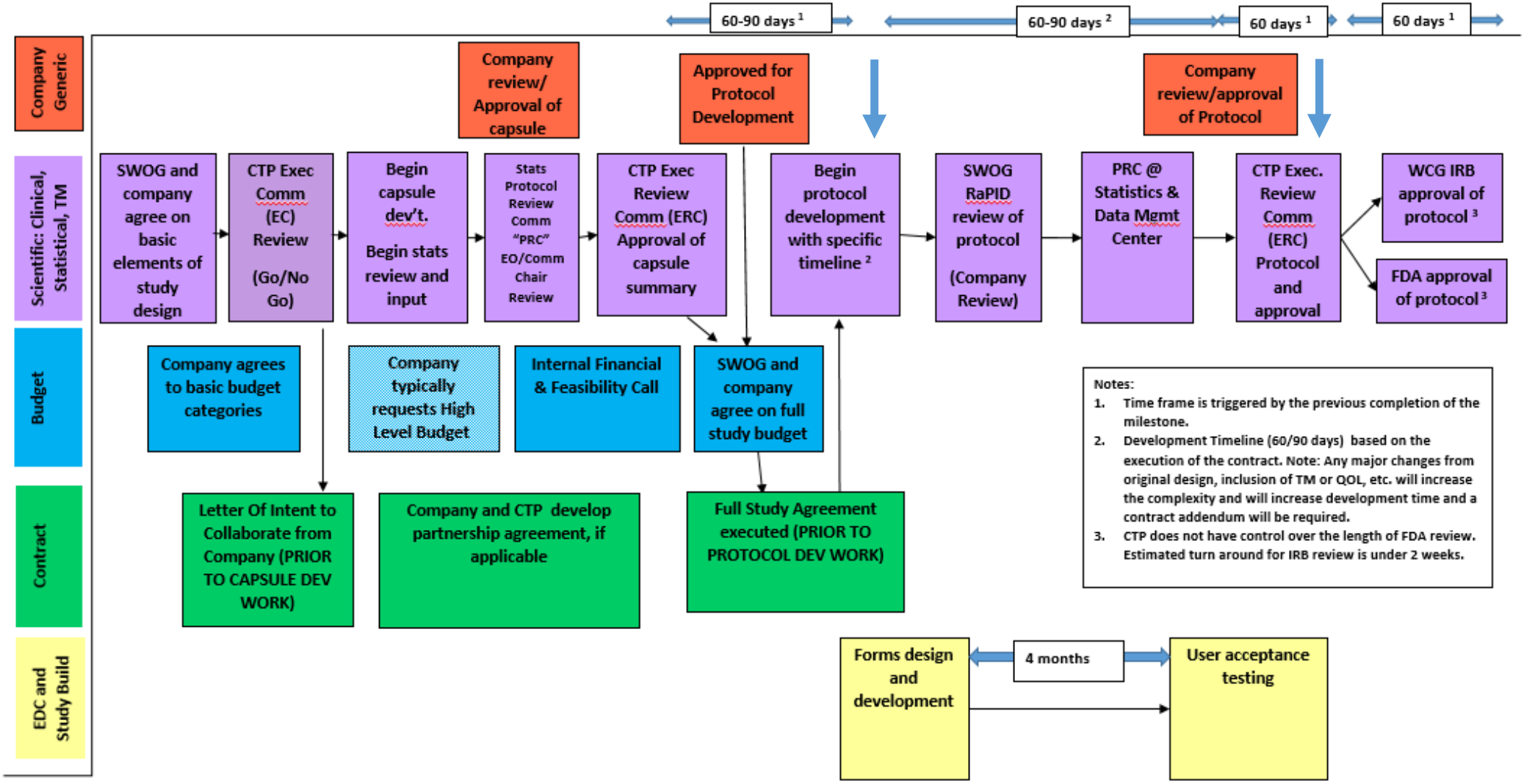
*Scores are combined to determine the outcome of the proposal review and considered in conjunction with the Response Category for final recommendation.

Relevance/Impact Score

Degree of Impact	Impact Score	Descriptor	Additional Guidance on Strengths/Weaknesses
High	1	Exceptional	Exceptionally strong with essentially no weaknesses
	2	Outstanding	Extremely strong with negligible weaknesses
	3	Excellent	Very strong with only some minor weaknesses
Moderate	4	Very Good	Strong but with numerous minor weaknesses
	5	Good	Strong but with at least one moderate weakness
	6	Satisfactory	Some strengths but also some moderate weaknesses
Low	7	Fair	Some strengths but with at least one major weakness
	8	Marginal	A few strengths and a few major weaknesses
	9	Poor	Very few strengths and numerous major weaknesses

Definitions
Minor: easily addressable weakness that does not substantially lessen the impact of the project.
Moderate: weakness that lessens the impact of the project.
Major: weakness that severely limits the impact of the project.

SWOG CTP Study Development Process



SWOG CTP Infrastructure and eResearch Platform - I

- **All SWOG sites will be notified of CTP studies close to activation to determine interest and accrual potential**
- **Sites will need to complete a brief feasibility questionnaire**
- **WCG (Western) IRB will be the central IRB for CTP studies**
- **Banking SOPs (SWOG bank, institution banks, company banks)**

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SWOG CTP Infrastructure and eResearch Platform - II

- **CRAB Nebula Electronic Data Capture (EDC)**
- **Integrated Clinical Trial Management System (CTMS) and electronic Trial Master File (eTMF) through Velos and Florence**

  These tools will streamline site communications and start-up efforts, house study documents, assist in management of Investigator Site Files (ISF), regulatory requirements, as well as monitoring and auditing

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SWOG CTP Platform Designs in Development

Caveat: **Unable to reveal compounds and details of designs in open sessions, per request of two of our active collaborators, pending final ERC approval and contract**

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Active Industry Collaborations*

- Acute lymphocytic leukemia
- Breast cancer triple negative - adjuvant
- Breast cancer ER+ HER2 - metastatic
- Bladder cancer - neoadjuvant
- Non-small cell lung cancer - metastatic
- Head/neck squamous cell - advanced

pipeline, platform, subtype

Pending Collaborations

- CNS Working Group
- Digital Engagement
- Immunotherapeutics
- GI malignancies
- Several company pipelines
- SWOG VA Committee

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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**
- **Hematology Franchise pipeline call first (next month)**
- **Committee chairs and other SWOG scientific leaders will be included**
- **Two platform trials jointly designed: 21CTP.LEUK01 (Ph+ ALL) will be submitted to CTP's ERC next month and the other (MPN/MDS/CMML) on long pause awaiting trial readouts**

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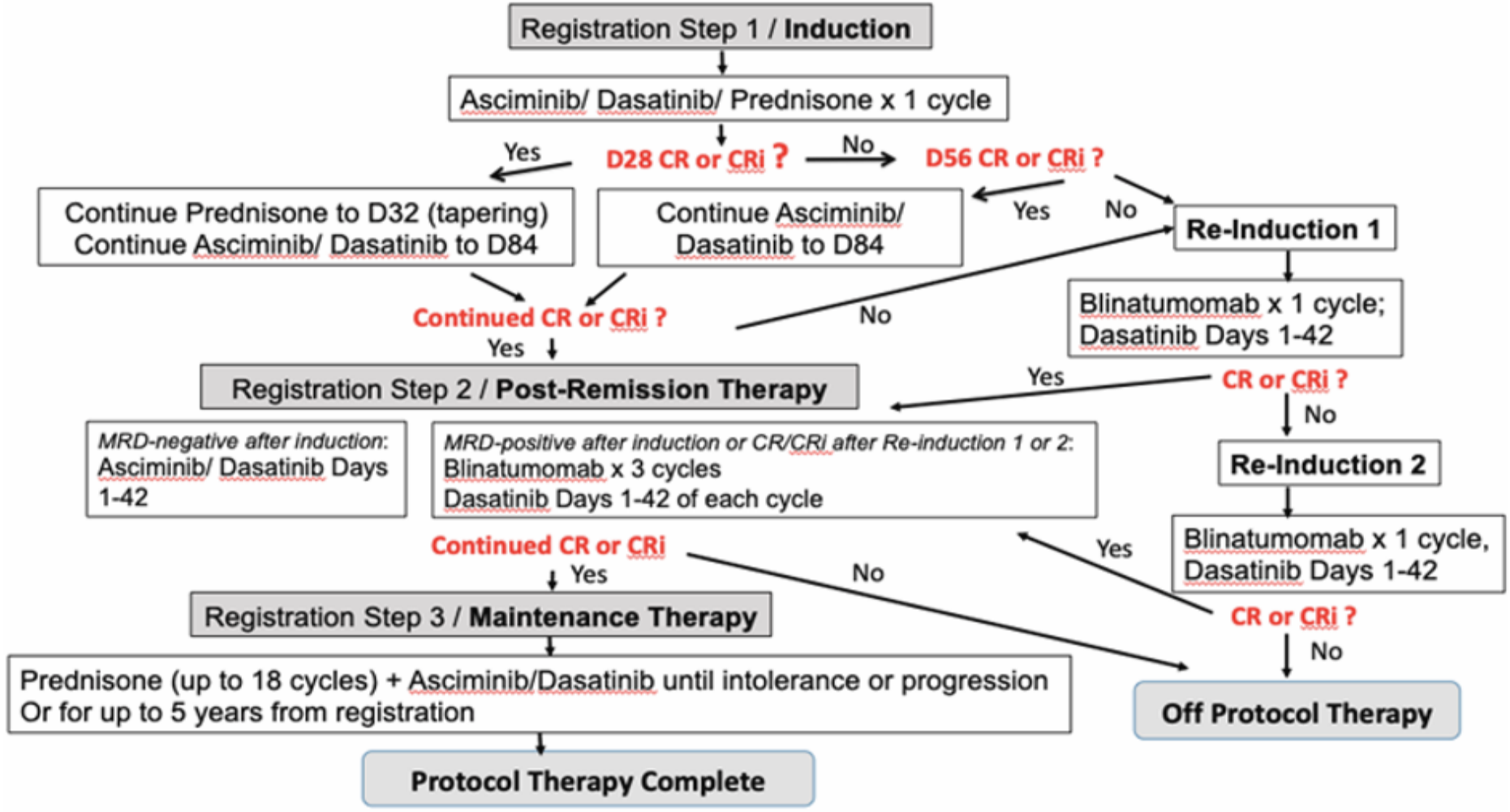
21CTP.LEUK01: Phase II study of asciminib, dasatinib, prednisone and blinatumomab for patients either over 60 or if younger, not fit for intensive therapy in newly diagnosed Ph+ ALL



SWOG CTP Platform Designs in Development

- **PARTNERSHIP: Lung Committee/Company X (+ partner biomarker company)**
- **DISEASE CATEGORY: Platform (21CTP.LUNG01)**
- **PATIENTS: Non-small cell lung cancer with typical EGFR mutations**
- **PROJECT DESIGN: ctDNA-based decision-making, multi-cohort design with 2 agents finalized**
- **STATUS: Letter of Collaboration Intent received; process followed, capsule approved by SWOG CTP Executive Review Committee; partner biomarker company secured; protocol development awaiting final contracting/budget approvals**

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SWOG CTP Platform Designs in Development

- **PARTNERSHIP: Breast Committee/AstraZeneca (+ partner biomarker company)**
- **DISEASE CATEGORY: Platform (21CTP.BREAST01)**
- **PATIENTS: Metastatic ER+, HER2-negative breast cancer on first line standard of care aromatase inhibitor plus CDK4/6 inhibitor**
- **PROJECT DESIGN: Molecular match, study flow based on ctDNA status; if rising, randomized to multiple parallel arms with investigational agent/combinations**
- **STATUS: Letter of Collaboration Intent received, collaborator for ctDNA studies secured; joint capsule development, revisions in progress; submission to ERC pending**

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SWOG CTP Platform Designs in Development

- **PARTNERSHIP: GU Committee – Bladder/Genentech (Tempus RNAseq platform partner)**
- **DISEASE CATEGORY: Platform - Subtype (21CTP.GU01)**
- **PATIENTS: First line muscle invasive, neoadjuvant**
- **PROJECT DESIGN: Parallel cohorts defined by molecular subtype**
- **STATUS: Letter of Collaboration Intent received; recurring operations and scientific calls, joint proposal development; agents and platform partner selected; submitted to and revised version approved by SWOG CTP Executive Review Committee; protocol development awaiting final contracting/budget approvals**

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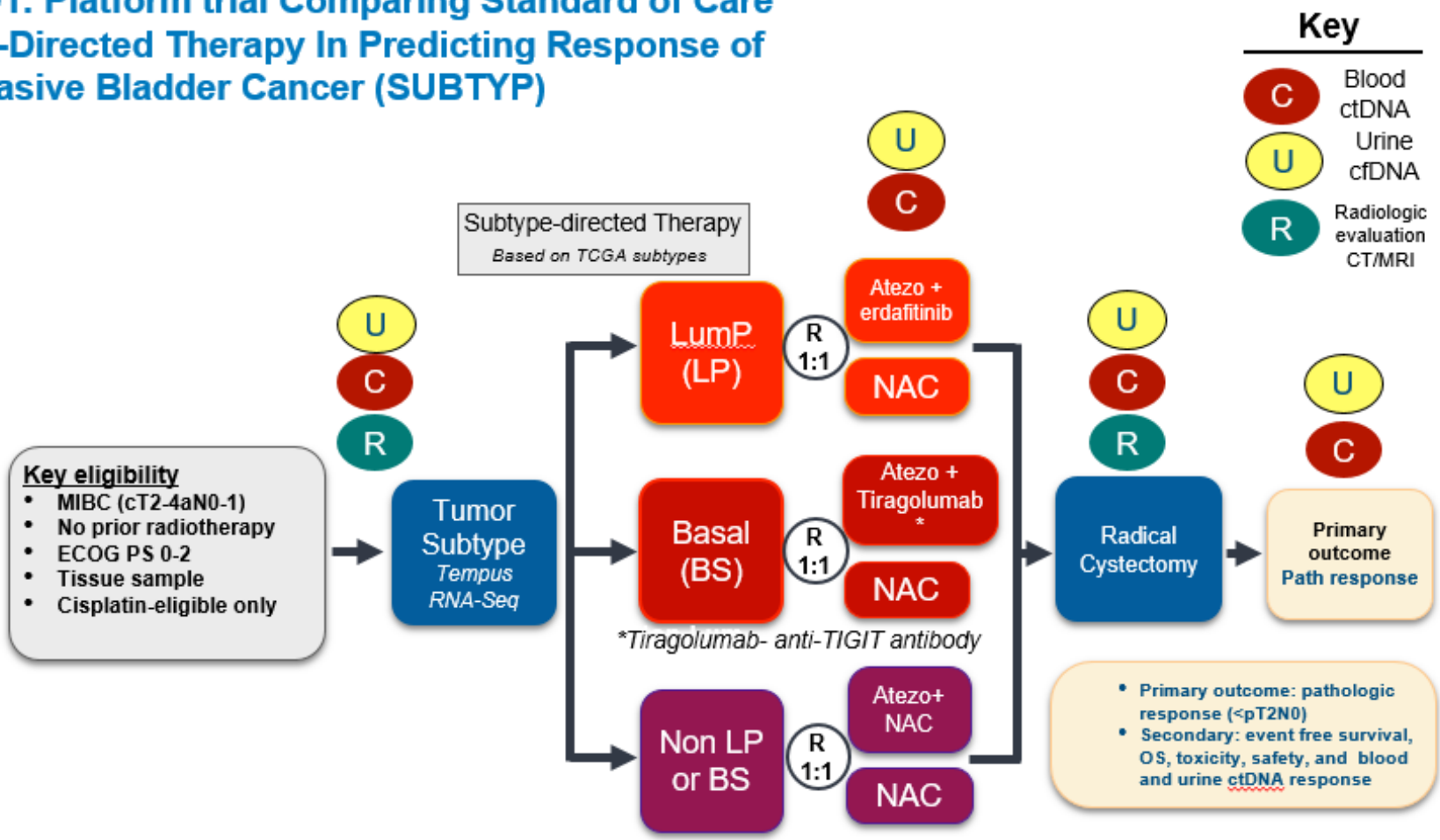
21CTP.GU01: Platform trial Comparing Standard of Care to Subtype-Directed Therapy In Predicting Response of Muscle Invasive Bladder Cancer (SUBTYP)



The same two stratification factors will be used for each of the three trials:
i) Clinical stage T2N0 vs. T3/T4aN0 vs. TanyN1
ii) NAC regimen (if assigned to a NAC arm): MVAC vs. GC.

SWOG CTP Platform Designs in Development

- **PARTNERSHIP: Head and Neck Task Force/Company Y**
- **DISEASE CATEGORY: Platform 21CTP.HN01**
- **PATIENTS: Metastatic squamous of head and neck and metastatic cutaneous squamous cell carcinoma (cohorts defined by type of/response to prior systemic therapies, if any)**
- **PROJECT DESIGN: Parallel phase II cohorts with two agents**
- **STATUS: Letter of Collaboration Intent received, capsule jointly designed and approved by SWOG CTP, Statistical Center PRC and industry partner**
- **CTP ERC REVIEW: Requested revisions to a single arm phase IB/II for safety, given first in human doublet and in HN cancer only; capsule revised accordingly, resubmitted to ERC this month; assuming approval, protocol development pending contracting/budget approvals.**

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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:

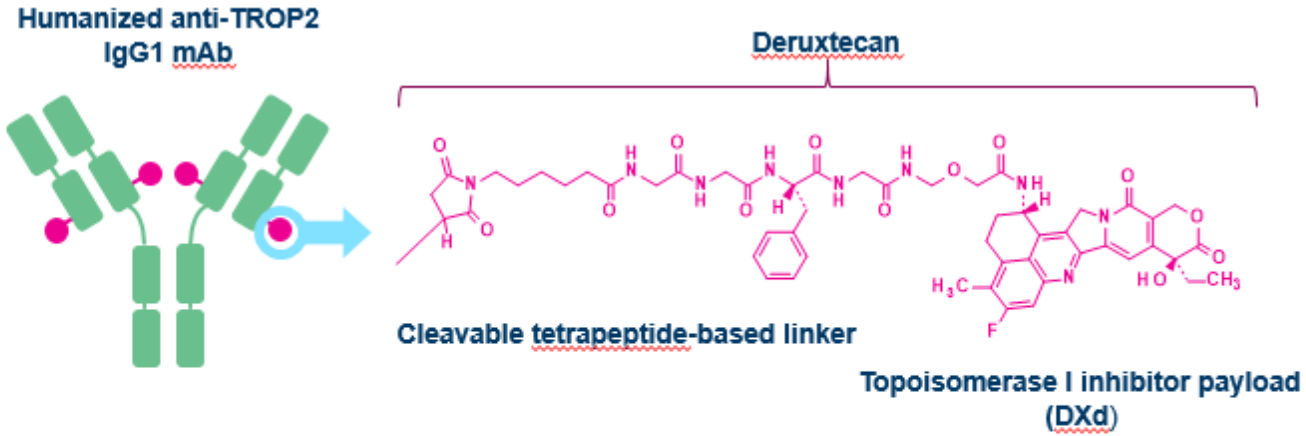
SWOG
Dawn Hershman (US; co-chair)

Dato-DXd (datopotamab deruxtecan) structure

TROPION-Breast03

Dato-DXd is an ADC composed of three components:

- A humanized anti-TROP2 IgG1 mAb covalently linked to:
- A topoisomerase I inhibitor payload, an exatecan derivative, via
- A tetrapeptide-based cleavable linker



- Payload mechanism of action: topoisomerase I inhibitor
- High potency of payload
- Optimized drug-to-antibody ratio ≈4
- Payload with short systemic half-life
- Stable linker-payload
- Tumor-selective cleavable linker
- Bystander antitumor effect

Daiichi-Sankyo | AstraZeneca

TROPION-Breast03 Study Design FSI November 2023

TROPION-Breast03

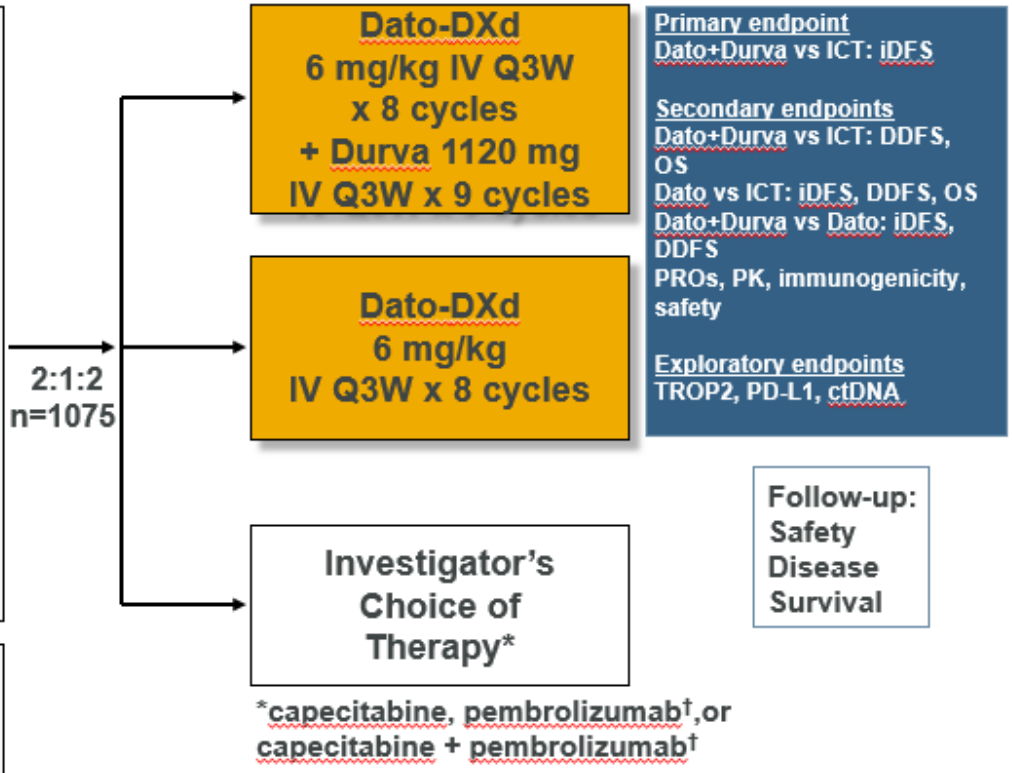
Phase 3 Dato-DXd +/- Durvalumab in Adjuvant Residual Disease TNBC

Key Eligibility Criteria

- Histologically confirmed invasive TNBC (ER<1%, PR<1%, HER2-negative)
- Completed at least 6 cycles of neoadjuvant therapy containing an anthracycline and/or a taxane with or without carboplatin, with or without pembrolizumab.
- Residual invasive disease after neoadjuvant therapy
- No evidence of locoregional or distant relapse
- Radiotherapy delivered before the start of study treatment
- No adjuvant systemic therapy
- ECOG PS 0 or 1
- Adequate bone marrow reserve and organ function
- No known germline BRCA1 or BRCA2 mutation

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 participants who have received prior pembrolizumab in the neoadjuvant setting should receive pembrolizumab as part of their adjuvant therapy on Arm 3.

Daiichi-Sankyo | AstraZeneca

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TROPION-Breast03

- Approved by SWOG CTP Executive Committee
- Approved by FDA
- MSA and Statement of Work completed
- Budget finalized
- Attend Saturday's Breast Committee meeting for details!

Site selection is in progress.

SWOG Sites - your contact at AstraZeneca for further information is:

Laura DeLong
Local Study Associate Director
laura.delong@astrazeneca.com

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A SWOG CTP Task Force

- **Emerging opportunities with non-pharmaceutical interventions and tools**
- **Stand-alone trials, or combined with therapeutic studies**
- **CTP Task Force formed, meetings with industry in progress**
- **Collaborations with SWOG Digital Engagement Committee and others**

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SWOG CTP Milestones and the Future

- **Successful development/implementation of internal processes (operations, administrative, contracting, statistical center, infrastructure and eResearch)**
- **Upfront engagement among SWOG Committee chairs, SAB, industry partners and CTP leadership**
- **Parallel study development & timeline process refined**
- **Six projects reached capsule stage, with CTP Executive Review Committee approval in four to date**
- **Exciting new initiatives to explore are pending with other companies – more interested partners are welcome!**

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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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SWOG CTP Update Forum

OPEN DISCUSSION

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