City of Hope®

Southeastern Multidisciplinary Approaches to Cancer Symposium

The Evolving Landscape of Oncology Clinical Research: From National Networks to Alliance Clinical Trials

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Disclosures

I do not have any relevant financial relationships.

This presentation and/or comments will provide a balanced, non-promotional, and evidence-based approach to all diagnostic, therapeutic and/or research related content.

Cultural Linguistic Competency (CLC) & Implicit Bias (IB)

STATE LAW:
The California legislature has passed Assembly Bill (AB) 1195, which states that as of July 1, 2006, all Category 1 CME activities that relate to patient care must include a cultural diversity/linguistics component. It has also passed AB 241, which states that as of January 1, 2022, all continuing education courses for a physician and surgeon **must** contain curriculum that includes specified instruction in the understanding of implicit bias in medical treatment.

The cultural and linguistic competency (CLC) and implicit bias (IB) definitions reiterate how patients' diverse backgrounds may impact their access to care.

EXEMPTION:
Business and Professions Code 2190.1 exempts activities which are dedicated solely to research or other issues that do not contain a direct patient care component.

This presentation is dedicated solely to research or other issues that do not contain a direct patient care component.

The Evolution of Oncology Clinical Trials

1. THE MODERN REALITY

- Shift toward Precision Medicine
- Hyper-Targeted Molecular Subsets
- Fragmented, "Niche" Populations

Treating the Driver, Not the Organ

IMPACT

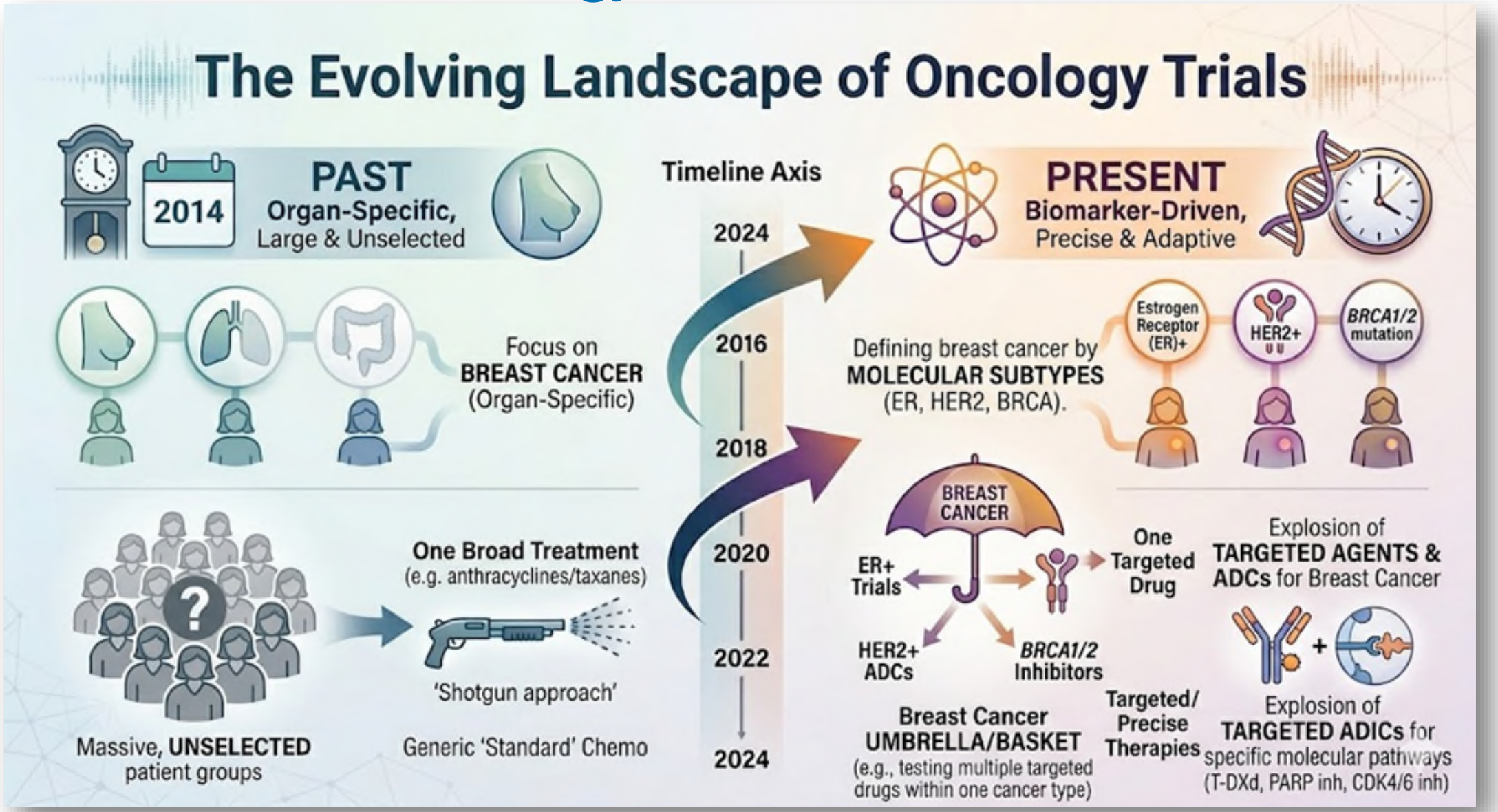
Drives the Operational Imperative

2. THE OPERATIONAL CHALLENGE

- Traditional Single-Site Models Fail
- Rapid National Screening Required
- Activating Academic and Community Sites

Scale Needs to Match Precision

The Evolution of Oncology Clinical Trials



What is the NCTN?

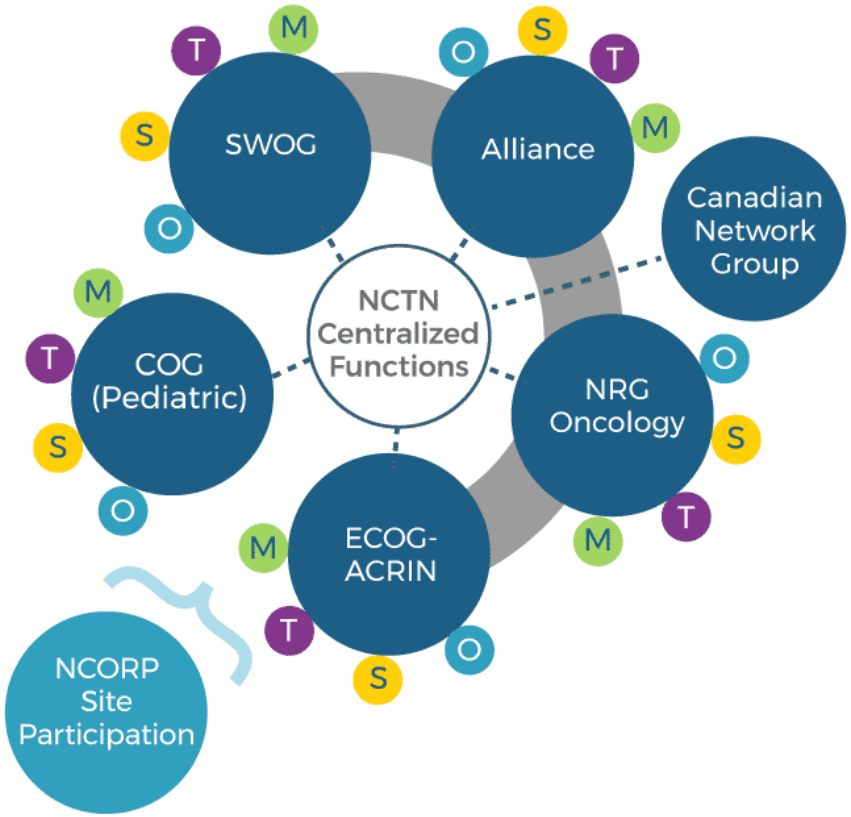
NCTN: NCI's National Clinical Trials Network

- NCTN is a collection of organizations and clinicians that coordinates and supports cancer clinical trials at more than 2,200 sites across the United States, Canada, and internationally. NCTN provides the infrastructure for NCI-funded treatment and primary advanced imaging trials to improve the lives of people with cancer.

- The network's organizational structure is ideal for screening large numbers of patients to find those whose tumors exhibit the molecular features that give them the best chance of responding to new, targeted treatments.

https://www.cancer.gov/research/infrastructure/clinical-trials/nctn

The NCTN Network Structure



LEGEND

- Centralized Functions:
  - Centralized Institutional Review Board
  - Cancer Trials Support Unit
  - Imaging and Radiation Oncology Core (IROC) Group
  - Common Data Management System Central Hosting
- 32 Lead Academic Participating Sites (LAPS)
- O Operations
- S Statistics & Data Management
- T Tissue Banks
- M Member Sites

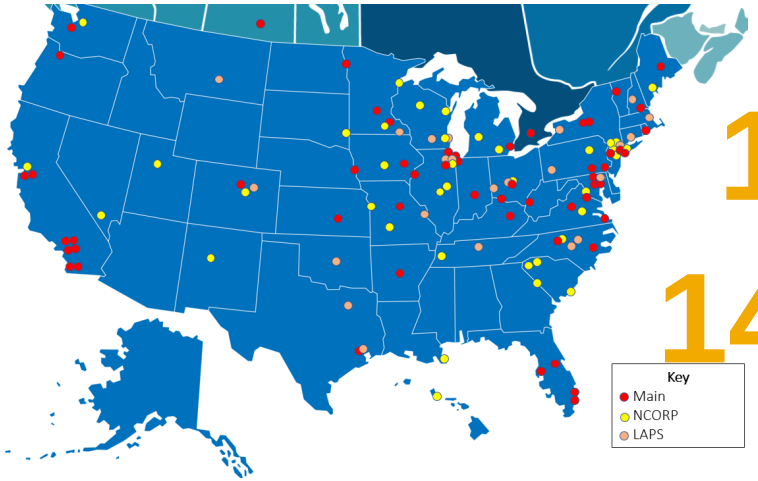
cancer.gov

ALLIANCE FOR CLINICAL TRIALS IN ONCOLOGY

Vision: To reduce the impact of cancer by uniting a broad community of scientists and clinicians from many disciplines, committed to discovering, validating and disseminating effective strategies for the prevention and treatment of cancer

Alliance by the Numbers: March 2019 – August 2024

MEMBERSHIP



115 Main Member Sites

1400 Affiliate Institutions

22 LAPS Members

40 NCORP Members

12 Minority NCORP Members

26,562
Rostered individual members engaged in clinical trials

PATIENT ACCRUAL

15,408
Total Accrued Patients
(3/01/2019 – 8/31/2024)

Accrual to Alliance-led Trials	**10,339**
Accrual to Trials led by other Cooperative Groups	**5,095**
Unique Biospecimen Collected	**101,516**

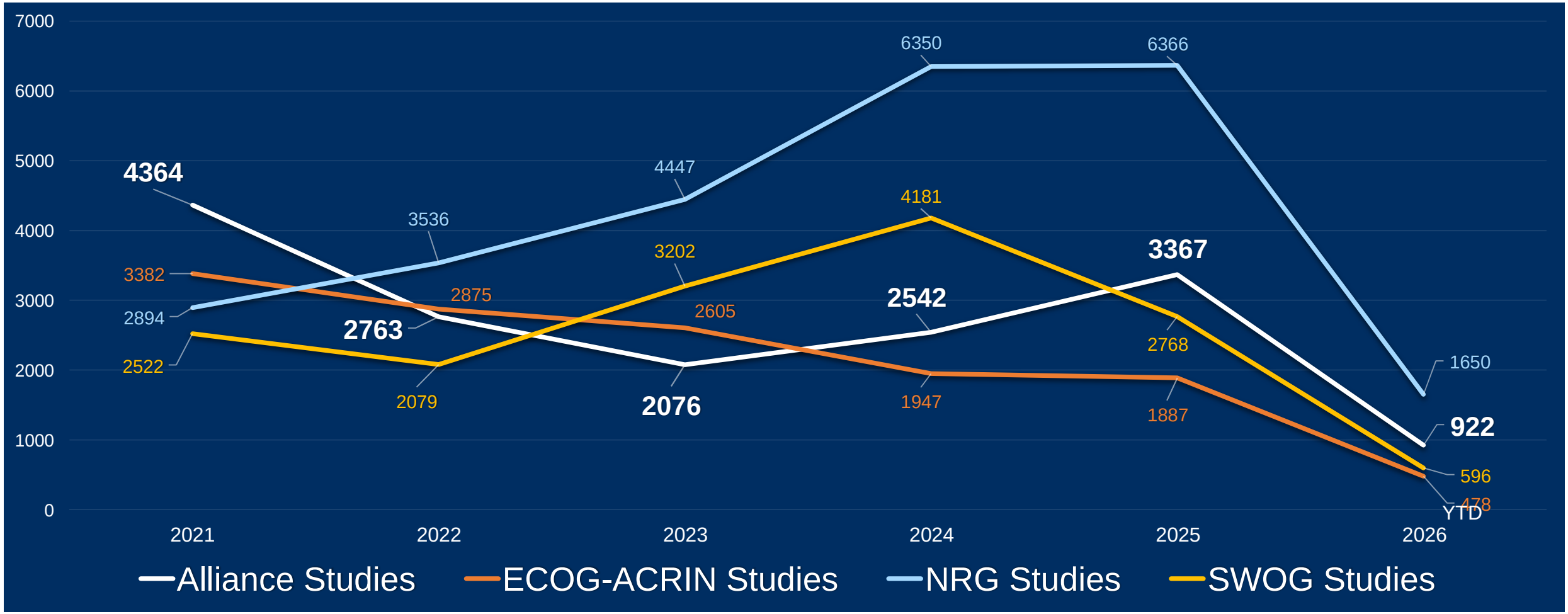
PUBLICATIONS

239
Total Manuscripts

56
Impact Factor > 15

249
Total Abstracts

NCTN Accrual to NCTN by Calendar Year (Intervention Accrual thru 3/27/26)



NCI National Clinical Trials Network
a National Cancer Institute program

NCI Community Oncology Research Program
A program of the National Cancer Institute of the National Institutes of Health

Study Design & Scientific

ALLIANCE FOR CLINICAL TRIALS IN ONCOLOGY

- 8 Disease Committees
- 6 Modality Committees
- 10 Administrative Committees

Study Operations

ALLIANCE NCTN FOUNDATION

ALLIANCE NCTN/NCORP

ALLIANCE FOUNDATION TRIALS

ALLIANCE FOUNDATION TRIALS, LLC

Disease Committee Structure

May 2026 Alliance Led Trials

NCTN
Disease and Modality

Committee	Accruing (In Dev)
Breast	3 (3)
ETRT (+ComboMatch)	5 (5)
GI	3 (0)
GU	7 (2)
IO	1 (0)
Leukemia (+MyeloMatch)	3 (4)
Lymphoma	3 (2)
Myeloma	2 (3)
Neuro-Oncology	3 (2)
PBTP	0 (1)
Respiratory	5 (4)
Transplant	0 (0)

NCORP
Cancer Control

Committee	Accruing (In Dev)
CCDR	2 (0)
PEAR	0 (0)
Cancer in the Older Adult	1 (1)
Prevention	3 (0)
Symptom Intervention	4 (1)

NCORP/NCTN Total
Accruing: 45
In Development: 28

AFT

Committee	Accruing (In Dev)
Breast	2 (2)
CCDR	1 (0)
ET	0 (0)
GU	0 (1)
Multiple	0 (0)
Myeloma	0 (2)
Respiratory	1 (0)

AFT Total
Accruing: 4
In Development: 5

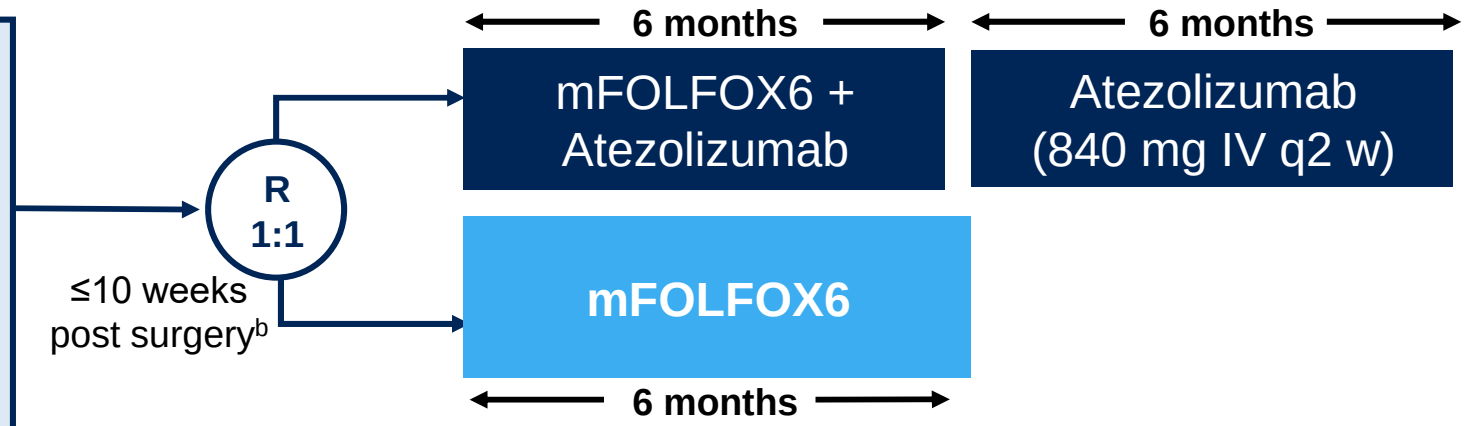
Alliance Registration Trials: Summary

Trial	Details	Current Status
A011801: COMPASS	T-DM1 and Tucatinib in HER2+ Breast Cancer	• Enrollment period: 01/06/2021 – 05/01/2025 • Ongoing: data collection, cleaning, verification
A021502: ATOMIC	Atezolizumab in Stage III CRC with Deficient DNA Mismatch Repair	• Feb 2025: data released by DSMB • Jun 2025: ASCO Presentation • Mar 2026: NEJM Publication • Ongoing: prep for submission to FDA & secondary analyses
A021602: CABINET	Cabozantinib in Advanced NET	• March 2025: FDA approval granted • Ongoing: ex-US regulatory filings (approval in 11+ countries) & secondary analyses
AFT-38: PATINA	Addition of Palbociclib to SOC therapy after Induction in HR+/HER2+ mBC	• Aug 2025: Submitted to FDA • Dec 2025: Submitted to EMA • Jan 2026: NEJM Publication

A021502: ATOMIC

Atezolizumab in Stage III CRC with Deficient DNA Mismatch Repair

Key eligibility criteria
- Age ≥ 12 years old
- Histologically confirmed, R_0 resected stage III colon adenocarcinoma
  - Any T, N_1/N_{1c}, N_2, M_0
- Presence of dMMR by IHC[a]
- ECOG PS ≤ 2
- No active, known autoimmune disease
- No prior systemic therapy or radiation[b]



Stratification factors
- T-stage (T1-3 vs. T4)
- N-stage (N1/N1c vs. N2)
- Tumor location: proximal vs. distal

Primary endpoint
- Disease-free survival (DFS)

Secondary endpoints
- Overall survival (OS), adverse event (AE) profile

The addition of atezolizumab to mFOLFOX6 significantly improved disease-free survival among patients with stage III dMMR colon cancer.

[a] dMMR by immunohistochemistry (IHC) locally or at site-selected reference laboratory, includes Lynch syndrome. Retrospective central confirmation of dMMR.
[b] One cycle of FOLFOX prior to randomization permitted.

N Engl J Med 2026;394:1155-1166

AFT-38: PATINA

Addition of Palbociclib to SOC therapy after Induction in HR+/HER2+ mBC

Pre-Study

- Histologically confirmed HR+,HER2+ mBC
- No prior treatment in the advanced setting beyond induction treatment
- 6-8 cycles of treatment, including trastuzumab ± pertuzumab and taxane/vinorelbine

Key eligibility criteria

- Completion of induction chemotherapy and no evidence of disease progression (ie, CR, PR, or SD)

N=518

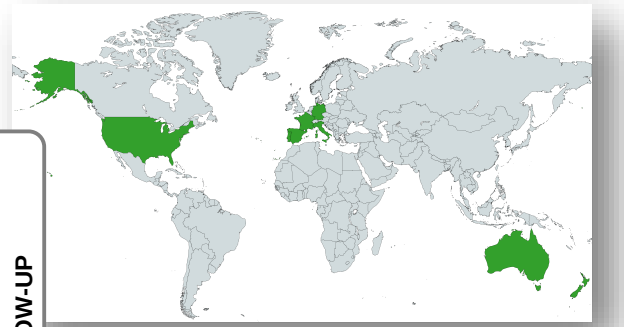
R 1:1

Palbociclib (125 mg PO QD D1-D21) Trastuzumab ± pertuzumab + endocrine therapy*

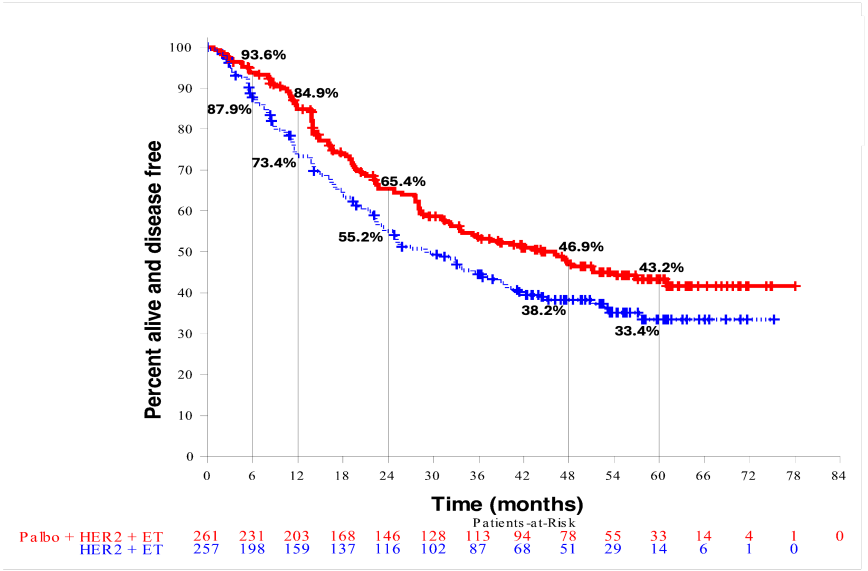
Trastuzumab ± pertuzumab + endocrine therapy*

Until PD or toxicity

SURVIVAL FOLLOW-UP



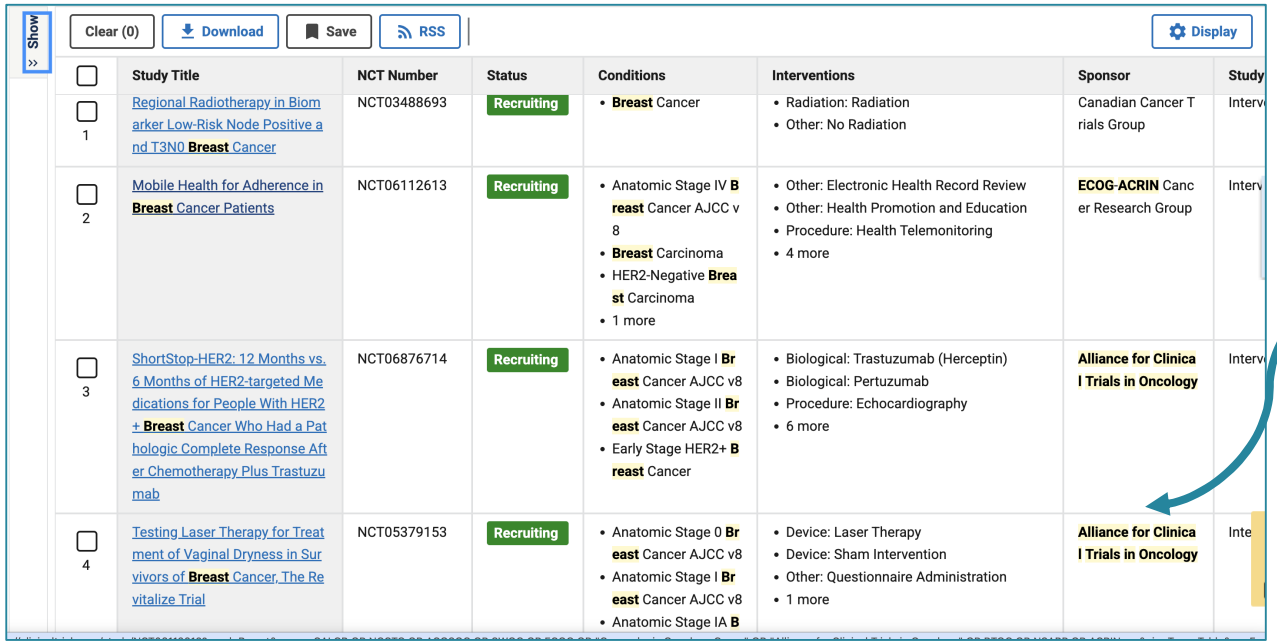
- Demonstrates a **clinically meaningful** improvement in PFS among patients diagnosed with HR+,HER2+ breast cancer
  - Median PFS increased from 29.1 to 44.3 months (Δ15.2 months)
  - Manageable toxicity
- **Treatment regiment received FDA approval, 24 June 2026**

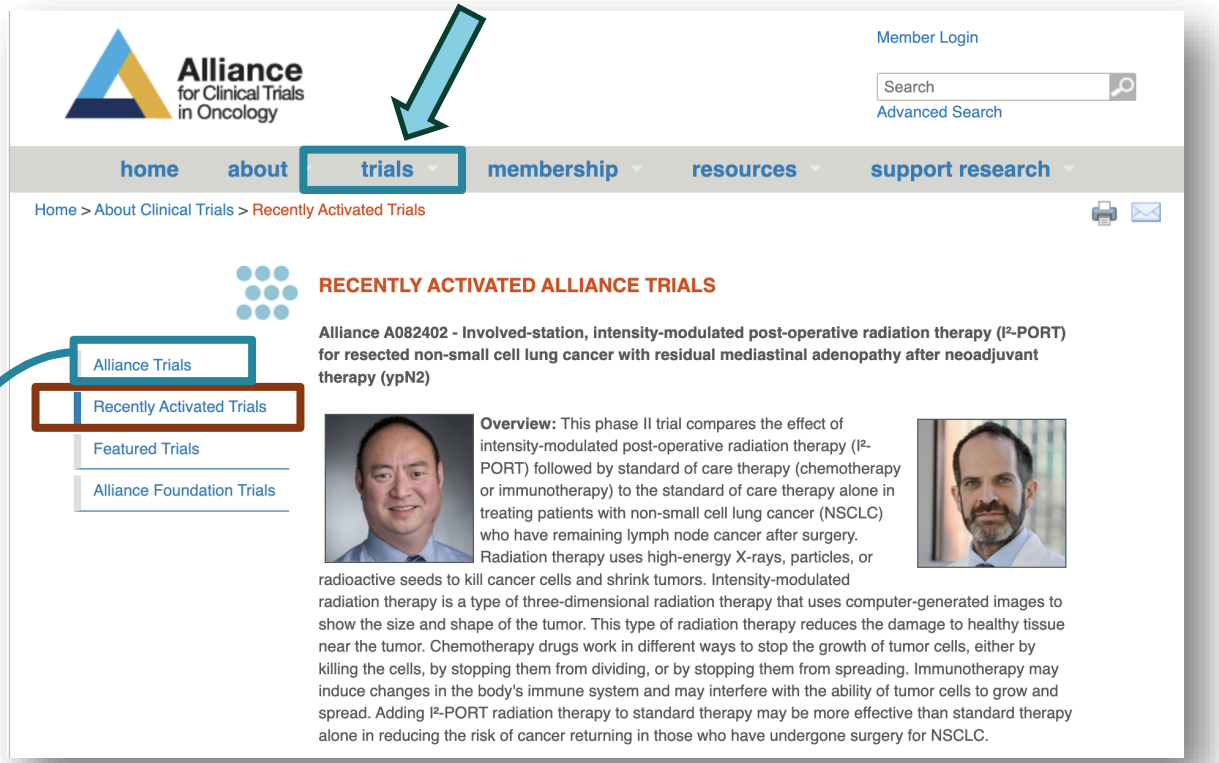


N Engl J Med 2026 Jan 29;394(5):451-462.

Finding Alliance Trials

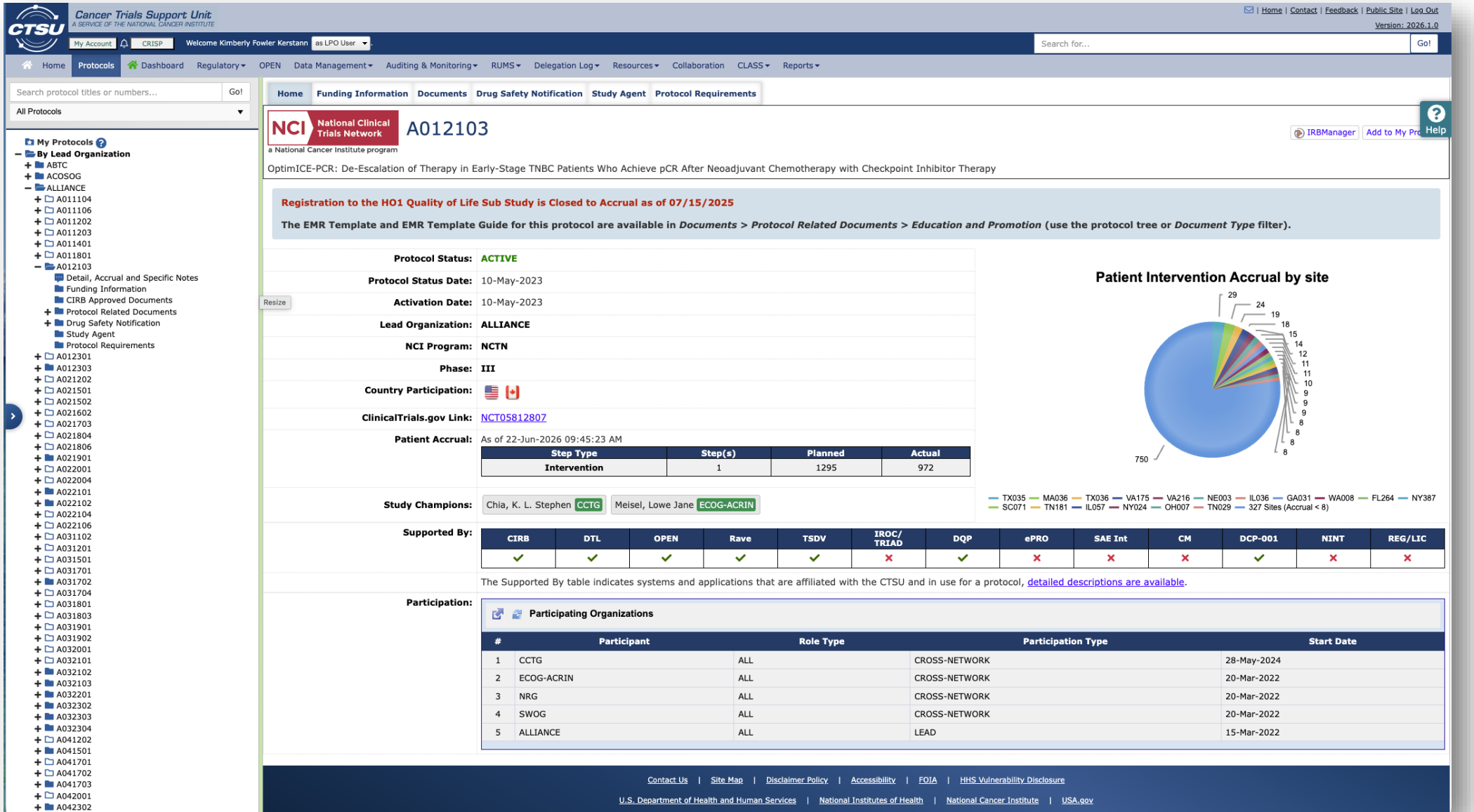
www.AllianceforClinicalTrialsinOncology.org





Finding NCTN Trials

www.CTSU.org



Alliance Breast Cancer Trials

Trial #	Title	% of Target Enrollment
A012303	ShortStop-HER2: Shortened Duration of Adjuvant Therapy in Patients with Early-Stage HER2+ Breast Cancer Who Achieve pCR After Neoadjuvant Chemotherapy with HER2 Blockade	10%
A012103	OptimICE-PCR: De-Escalation of Therapy in Early-Stage TNBC Patients Who Achieve pCR After Neoadjuvant Chemotherapy with Checkpoint Inhibitor Therapy	74%
A222101	An Early Phase and Phase II Clinical Trial to Evaluate Ganglioside-Monosialic Acid (GM1) for Preventing Paclitaxel-Associated Neuropathy	7% **temporary close*
A221801	The Revitalize Trial: Reducing Vaginal Atrophy with Fractional CO2 Laser for Breast Cancer Survivors	5.6%

Thank you!

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