



Southeastern Multidisciplinary Approaches to Cancer Symposium

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

Kimberly F. Kerstann, PhD

Chief Operating Officer
Alliance for Clinical Trials in Oncology



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



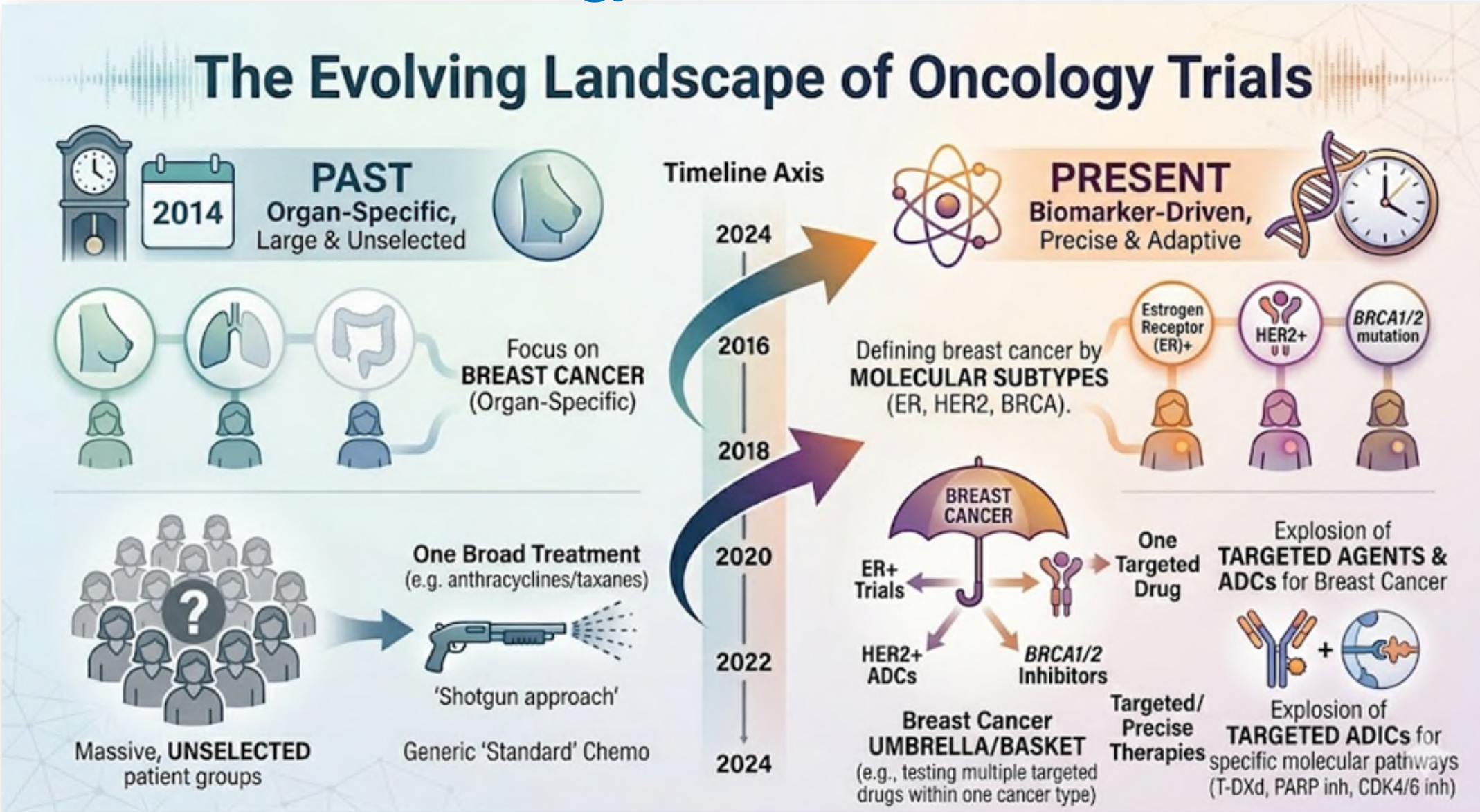
Rapid National Screening Required



Activating Academic and Community Sites

Scale Needs to Match Precision

The Evolution of Oncology Clinical Trials



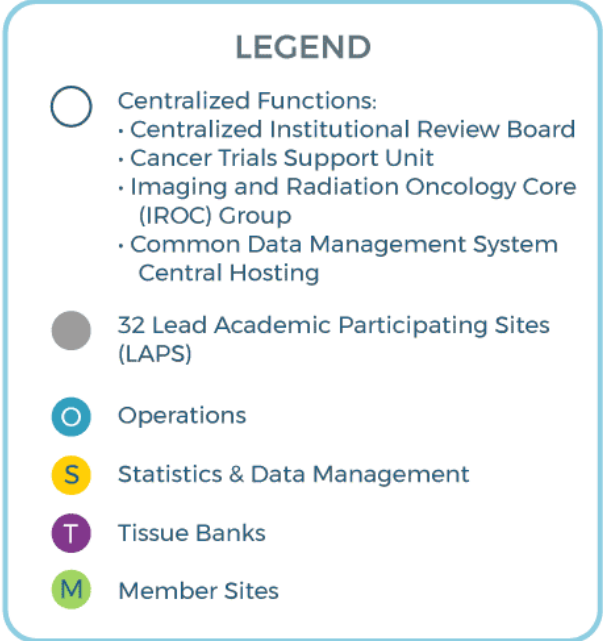
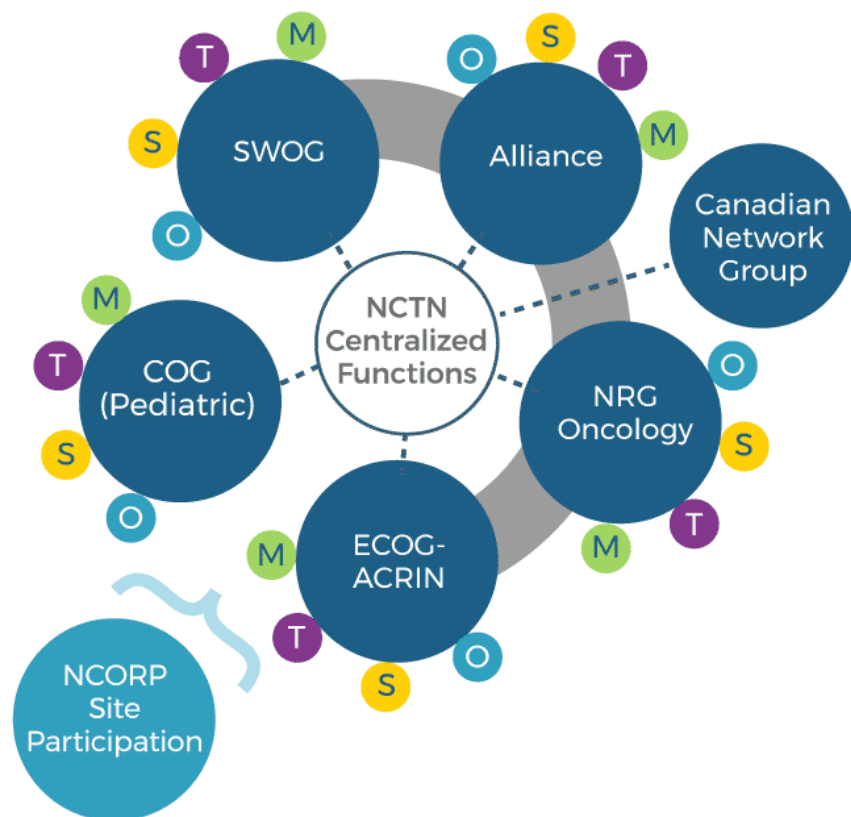
What is the NCTN?



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.

The NCTN Network Structure



cancer.gov

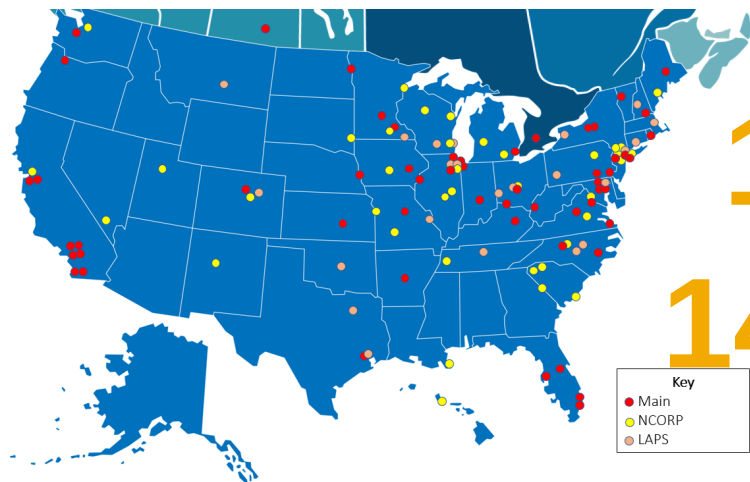


Vision: To reduce the impact of cancer by uniting a broad community of scientists and clinicians from many disciplines, committed to discovering, validating and disseminating effective strategies for the prevention and treatment of cancer



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

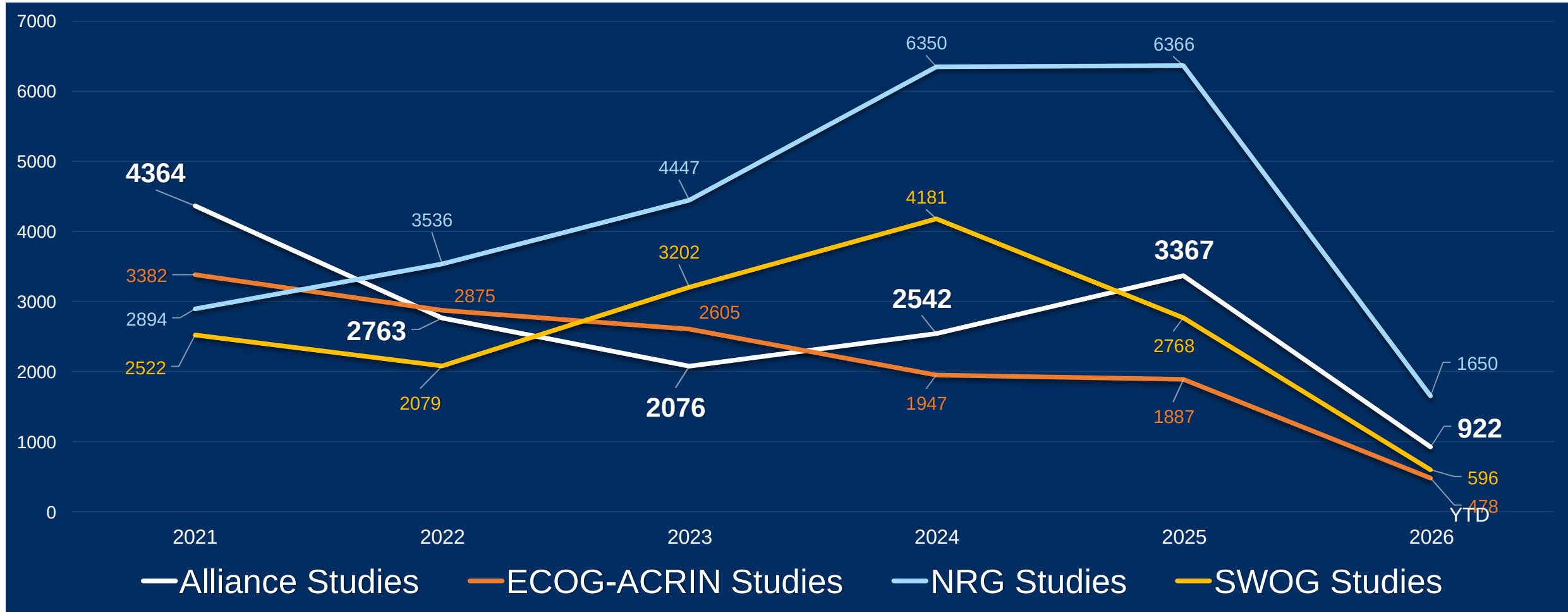
Impact Factor > 15

249

Total Abstracts



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



**Study Design
&
Scientific**



8 Disease Committees

6 Modality Committees

10 Administrative Committees

**Study
Operations**



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

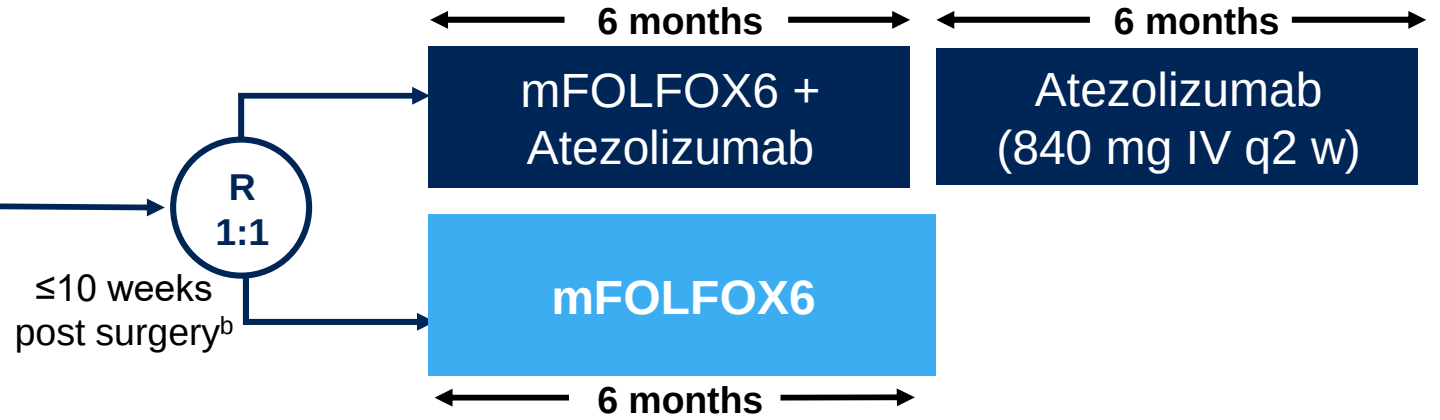
Atezolizumab in Stage III CRC with Deficient DNA Mismatch Repair

Key eligibility criteria

- Age ≥ 12 years old
- Histologically confirmed, R₀ resected stage III colon adenocarcinoma
 - Any T, N₁/N_{1c}, N₂, M₀
- 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.

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

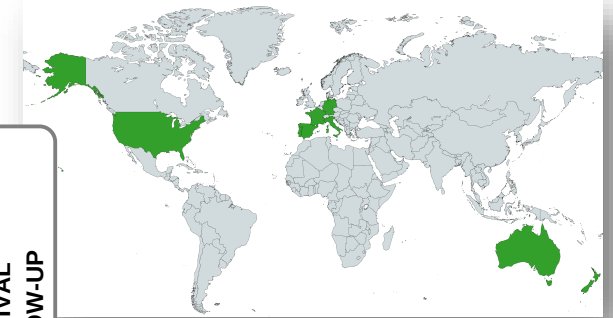
R
1:1

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

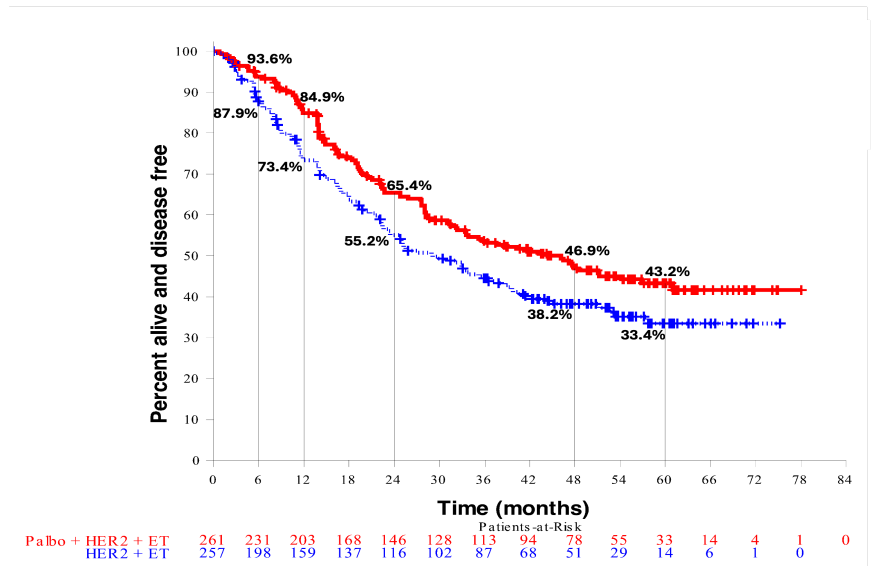
Trastuzumab ±
pertuzumab + endocrine
therapy*

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 regimen received FDA approval, 24 June 2026**



Finding Alliance Trials

www.AllianceforClinicalTrialsinOncology.org

Clear (0)DownloadSaveRSSDisplay							
	Study Title	NCT Number	Status	Conditions	Interventions	Sponsor	Study
☐	Regional Radiotherapy in Biomarker Low-Risk Node Positive and T3N0 Breast Cancer	NCT03488693	Recruiting	• Breast Cancer	• Radiation: Radiation • Other: No Radiation	Canadian Cancer Trials Group	Interv
☐	Mobile Health for Adherence in Breast Cancer Patients	NCT06112613	Recruiting	• Anatomic Stage IV Breast Cancer AJCC v8 • Breast Carcinoma • HER2-Negative Breast Carcinoma • 1 more	• Other: Electronic Health Record Review • Other: Health Promotion and Education • Procedure: Health Telemonitoring • 4 more	ECOG-ACRIN Cancer Research Group	Interv
☐	ShortStop-HER2: 12 Months vs. 6 Months of HER2-targeted Medications for People With HER2+ Breast Cancer Who Had a Pathologic Complete Response After Chemotherapy Plus Trastuzumab	NCT06876714	Recruiting	• Anatomic Stage I Breast Cancer AJCC v8 • Anatomic Stage II Breast Cancer AJCC v8 • Early Stage HER2+ Breast Cancer	• Biological: Trastuzumab (Herceptin) • Biological: Pertuzumab • Procedure: Echocardiography • 6 more	Alliance for Clinical Trials in Oncology	Interv
☐	Testing Laser Therapy for Treatment of Vaginal Dryness in Survivors of Breast Cancer: The Revitalize Trial	NCT05379153	Recruiting	• Anatomic Stage 0 Breast Cancer AJCC v8 • Anatomic Stage I Breast Cancer AJCC v8 • Anatomic Stage IA B	• Device: Laser Therapy • Device: Sham Intervention • Other: Questionnaire Administration • 1 more	Alliance for Clinical Trials in Oncology	Inte



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Home > About Clinical Trials > Recently Activated Trials

Alliance TrialsRecently Activated TrialsFeatured TrialsAlliance Foundation Trials

RECENTLY ACTIVATED ALLIANCE TRIALS

Alliance A082402 - Involved-station, intensity-modulated post-operative radiation therapy (I²-PORT) for resected non-small cell lung cancer with residual mediastinal adenopathy after neoadjuvant therapy (ypN2)

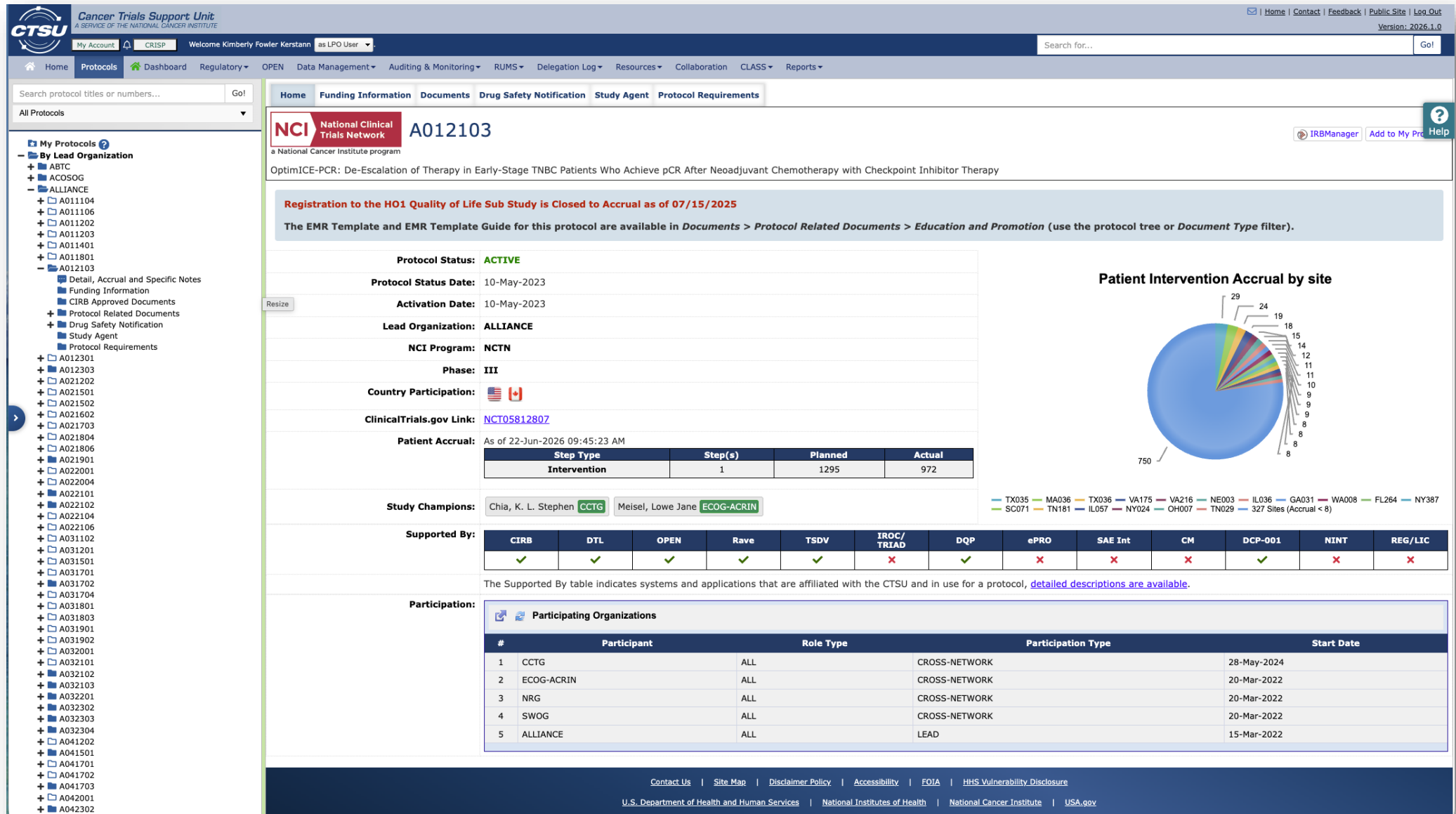


Overview:

This phase II trial compares the effect of intensity-modulated post-operative radiation therapy (I²-PORT) followed by standard of care therapy (chemotherapy or immunotherapy) to the standard of care therapy alone in treating patients with non-small cell lung cancer (NSCLC) who have remaining lymph node cancer after surgery. Radiation therapy uses high-energy X-rays, particles, or radioactive seeds to kill cancer cells and shrink tumors. Intensity-modulated radiation therapy is a type of three-dimensional radiation therapy that uses computer-generated images to show the size and shape of the tumor. This type of radiation therapy reduces the damage to healthy tissue near the tumor. Chemotherapy drugs work in different ways to stop the growth of tumor cells, either by killing the cells, by stopping them from dividing, or by stopping them from spreading. Immunotherapy may induce changes in the body's immune system and may interfere with the ability of tumor cells to grow and spread. Adding I²-PORT radiation therapy to standard therapy may be more effective than standard therapy alone in reducing the risk of cancer returning in those who have undergone surgery for NSCLC.



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% <i>*temporary close</i>
A221801	The Revitalize Trial: Reducing Vaginal Atrophy with Fractional CO2 Laser for Breast Cancer Survivors	5.6%



Thank you!

