

Managing Compliance as an NCI National Community Oncology Research Program (NCORP) Site

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The content presented today represents the thoughts and opinions of the speakers. You are advised to consult your institution legal, compliance, or other leadership for any specific questions or issues.

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NATIONAL CANCER INSTITUTE

The NCI Community Oncology Research Program (NCORP) brings cancer research studies and results to patients in a variety of community settings across the United States.

7 RESEARCH BASES
Develop and coordinate clinical trials and cancer care research

for

32+ COMMUNITY SITES + 14 MINORITY/UNDERSERVED COMMUNITY SITES
to bring NCI approved trials to patients

including

1,000+ LOCATIONS
at diverse, community-based hospitals, private practices and more

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

NCORP.cancer.gov

NCORP

The National Cancer Institute (NCI) Community Oncology Research Program is a national network that brings cancer clinical trials and care delivery studies to people in their own communities

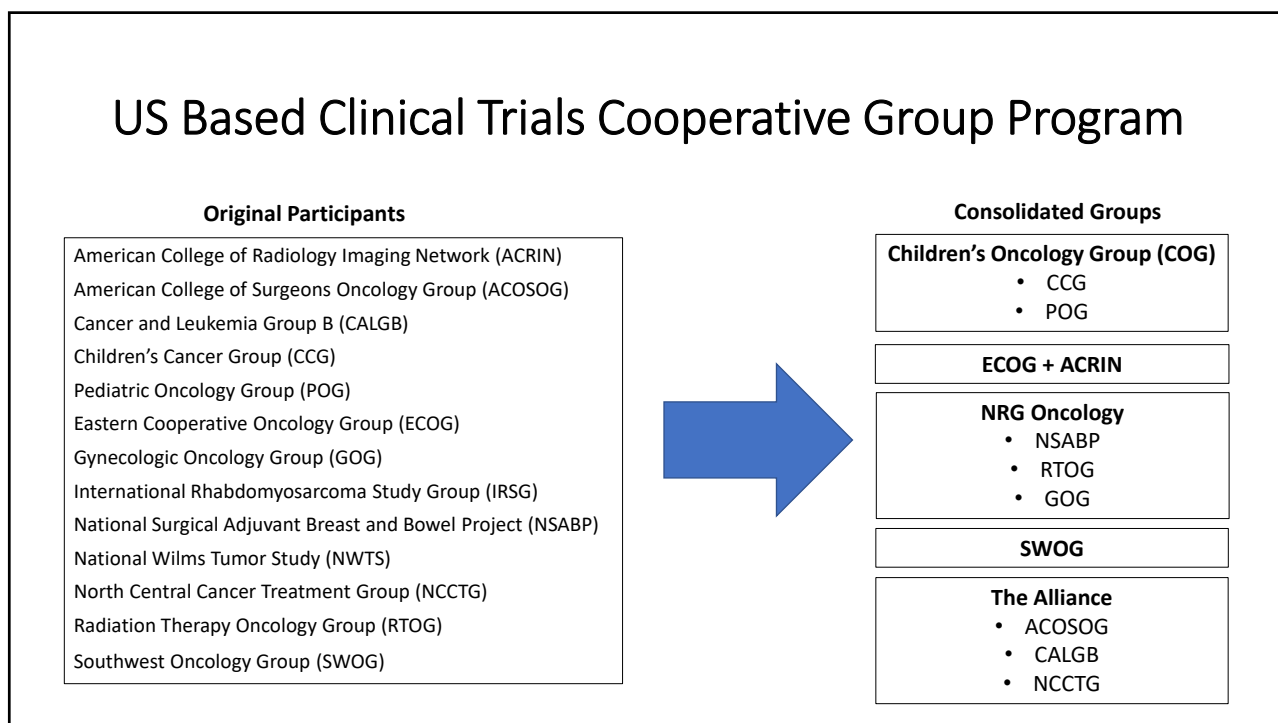
The NCORP network designs and conducts clinical trials in the following focus areas:

- Cancer prevention
- Screening
- Supportive care
- Surveillance
- Health-related quality of life
- Cancer care delivery

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NCORP MYTHS: All trials are phase 3

Clinical Trial Number	Study Title
S1900B	A Phase II Study of LOXO-292 in Patients with RET Fusion-Positive Stage IV or Recurrent Non-Small Cell Lung Cancer
S1900C	A Phase II Study of Talazoparib plus Avelumab in Patients with Stage IV or Recurrent Non-Squamous Non-Small Cell Lung Cancer Bearing Pathogenic STK11 Genomic Alterations
S1922	Randomized Phase II Study of Ramucirumab and Paclitaxel versus FOLFIRI in Refractory Small Bowel Adenocarcinoma
Alliance A031803	A Phase II Trial of Intravesical Gemcitabine and MK-3475 (Pembrolizumab) in the Treatment of Patients with BCG-Unresponsive Non-Muscle Invasive Bladder Cancer
Alliance A0311801	A Phase II Randomized Trial of Radium-223 Dichloride and Cabozantinib in Patients with Advanced Renal Cell Carcinoma with Bone Metastasis (RadiCal)
E4412	A Phase I Study with an Expansion Cohort/Randomized Phase II Study of the Combinations of Ipilimumab, Nivolumab and Brentuximab Vedotin in Patients with Relapsed/Refractory Hodgkin Lymphoma

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NCORP MYTHS: All billing is standard of care and no coverage analysis is needed



- Good clinical practice does not mean billable
- Coverage analysis need for all studies including NCORP
- Medical Necessity must be documented in coverage analysis

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NCORP MYTHS: Cooperative group trials do not get audited

NIH NATIONAL CANCER INSTITUTE
DCTD Division of Cancer Treatment & Diagnosis

OHRP
Office for Human
Research Protections

NRG
ONCOLOGY
Advancing Research. Improving Lives.™

FDA

ORI THE OFFICE OF
RESEARCH
INTEGRITY

SWOG
Leading cancer research. Together.

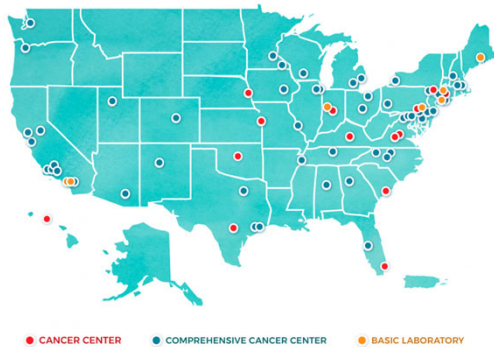
**CHILDREN'S
ONCOLOGY
GROUP**

ALLIANCE
FOR CLINICAL TRIALS IN ONCOLOGY

ECOG-ACRIN
cancer research group
Reshaping the future of patient care

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Why do Cooperative Group Studies



Status

- Commission on Cancer (CoC) Designation – more than 1,500 CoC-accredited cancer programs in US and Puerto Rico
- NCI-Designated Cancer Center –
 - 71 Sites located in 36 states
 - 13 Cancer Centers
 - 51 Comprehensive Cancer Centers
 - 7 Basic Laboratory Cancer Centers

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Why do Cooperative Group Studies



Access to research studies



The goal of each of the cooperative groups is to bring the combined talents and resources of many institutions together to improve the treatment options for patients with cancer.



Access to these studies/trials allows sites that have smaller numbers to enroll patients, offering patients novel treatment options.

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Why do Cooperative Group Studies



Children's Oncology Group Research



The Children's Oncology Group provides [important information for children and their families](#) from the time of diagnosis, through treatment and following cure.



Children's Oncology Group's Project: EveryChild is COG's ambitious initiative to find better cures for every type of childhood cancer.

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NCORP Site Designations

Research Base

Community Sites

Affiliates

Sub-Affiliates

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NCORP Research Bases



NCORP Research Bases serve as research hubs for the NCORP program.

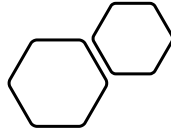


Research Bases are expected to:

1. Provide an established organizational structure
2. Assume responsibility for study operations and data management
3. Conduct their research activities at an institution with comprehensive expertise in cancer clinical research
4. Integrate health disparities across all focus areas as appropriate.

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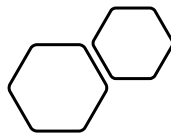
NCORP Community Sites



- Consortia of community hospitals and/or oncology practices
- May or may not be formally affiliated in a healthcare system
- Accrues participants to cancer control, prevention, treatment and care delivery clinical trials and other human subjects research

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NCORP Minority/Underserved Community Sites



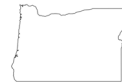
- Consortia of community hospitals and/or oncology practices, a public hospital, or academic medical center
- Patient population comprising at least 30% racial/ethnic minorities or rural residents
- Accrues participants to cancer control, prevention, treatment and care delivery clinical trials and other human subjects research.

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PSJH NCORP Research Base: Pacific Cancer Research Consortium (PCRC)



Alaska (8 sites)



Oregon (8 sites)



Washington (18 sites)



California (1 site)



Idaho (5 sites)



Montana (1 site)

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Research Compliance Risks



Study Monitoring



Data and Safety Monitoring



On-site Auditing



Ensuring Security and Confidentiality of Participant and Other Sensitive Data



Use of Standard Informed Consent Template for clinical trials



Conflict of Interest

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Questions?

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