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.

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
HOW WE GOT HERE

- Originally cooperative groups started for communities to gain access to off-label drugs
- Major cooperative groups formed

US Based Clinical Trials Cooperative Group Program

**Original Participants**
- American College of Radiology Imaging Network (ACRIN)
- American College of Surgeons Oncology Group (ACOSOG)
- Cancer and Leukemia Group B (CALGB)
- Children’s Cancer Group (CCG)
- Pediatric Oncology Group (POG)
- Eastern Cooperative Oncology Group (ECOG)
- Gynecologic Oncology Group (GOG)
- International Rhabdomyosarcoma Study Group (IRSG)
- National Surgical Adjuvant Breast and Bowel Project (NSABP)
- National Wilms Tumor Study (NWTS)
- North Central Cancer Treatment Group (NCCTG)
- Radiation Therapy Oncology Group (RTOG)
- Southwest Oncology Group (SWOG)

**Consolidated Groups**

<table>
<thead>
<tr>
<th>Children’s Oncology Group (COG)</th>
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<tbody>
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<td>- CCG</td>
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<td>- POG</td>
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<th>ECOG + ACRIN</th>
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<th>NRG Oncology</th>
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<td>- CALGB</td>
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<td>- NCCTG</td>
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NCORP MYTHS: All trials are phase 3

<table>
<thead>
<tr>
<th>Clinical Trial Number</th>
<th>Study Title</th>
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<tbody>
<tr>
<td>S1900B</td>
<td>A Phase II Study of LOXO-292 in Patients with RET Fusion-Positive Stage IV or Recurrent Non-Small Cell Lung Cancer</td>
</tr>
<tr>
<td>S1900C</td>
<td>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</td>
</tr>
<tr>
<td>S1922</td>
<td>Randomized Phase II Study of Ramucirumab and Paclitaxel versus FOLFIRI in Refractory Small Bowel Adenocarcinoma</td>
</tr>
<tr>
<td>Alliance A031803</td>
<td>A Phase II Trial of Intravesical Gemcitabine and MK-3475 (Pembrolizumab) in the Treatment of Patients with BCG-Unresponsive Non-Muscle Invasive Bladder Cancer</td>
</tr>
<tr>
<td>Alliance A0311801</td>
<td>A Phase II Randomized Trial of Radium-223 Dichloride and Cabozantinib in Patients with Advanced Renal Cell Carcinoma with Bone Metastasis (RadiCal)</td>
</tr>
<tr>
<td>E4412</td>
<td>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</td>
</tr>
</tbody>
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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
NCORP MYTHS: Cooperative group trials do not get audited

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
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.

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.
NCORP Site Designations

Research Base
- Community Sites
- Affiliates
- Sub-Affiliates

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.
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

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

Alaska (8 sites)
Washington (18 sites)
Idaho (5 sites)
Oregon (8 sites)
California (1 site)
Montana (1 site)

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
Questions?

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