

Overview of Thoracic Oncology Trials in Cooperative Groups Around the Globe

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Abstract

Survival rates of patients with either early and advanced stage non–small-cell lung cancer (NSCLC) have improved with newer systemic therapy and radiation techniques, including combination regimens, targeted therapies, and immunotherapies. The cancer cooperative groups have historically played a critical role in the advancement of NSCLC therapy. Annually, representatives from cooperative groups worldwide convene at the International Lung Cancer Congress (ILCC). In summer 2015, the ILCC reached its 16th anniversary. This article highlights the NSCLC studies presented by participating groups in 2015.

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Introduction

Survival rates of patients with either early and advanced stage non–small-cell lung cancer (NSCLC) have improved with newer systemic therapy and radiation techniques, including combination regimens, targeted therapies, and immunotherapies.¹⁻⁴ The cancer cooperative groups have historically played a critical role in the advancement of NSCLC therapy. Table 1 lists cooperative group trials currently accruing. Annually, representatives from cooperative groups worldwide convene at the International Lung Cancer Congress (ILCC). In summer 2015, the ILCC reached its 16th anniversary. Here we highlight the NSCLC studies presented by the following participating groups in 2015: the National Clinical Trials

Network (NCTN) groups supported by the National Cancer Institute (NCI), including Eastern Cooperative Oncology Group–American College of Radiology Imaging Network (ECOG-ACRIN), represented by Suresh Ramalingam, MD; NRG (composed of the legacy groups NSABP [National Surgical Adjuvant Breast and Bowel Project], RTOG [Radiation Therapy Oncology Group], and GOG [Gynecology Oncology Group]), represented by Walter Curran Jr, MD; the Southwest Oncology Group (SWOG), represented by David Gandara, MD; the Alliance for Clinical Trials in Oncology (Alliance), represented by Everett Vokes, MD; the Chinese Thoracic Oncology Group (CTONG), Asia Thoracic Oncology Research Group (ATORG), and Korean Cancer Study Group (KCSG), represented by Tony Mok, MD; the European Organisation for Research and Treatment of Cancer (EORTC) and the European Thoracic Oncology Platform (ETOP), represented by Paul Baas, MD; and the NCIC CTG, represented by Glenwood Goss, MD.

Cooperative group efforts in other thoracic malignancies will also be discussed in brief.

ECOG-ACRIN

ECOG-ACRIN was formed in 2012 by the merger of the Eastern Cooperative Oncology Group and the American College of Radiology Imaging Network. The group's Thoracic Committee objectives are to individualize treatment options on the basis of specific genotypic aberrations and to integrate targeted therapy into the treatment of lung cancer with a specific emphasis on biologic and imaging biomarker discovery.

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Overview of Thoracic Oncology Trials

Table 1 Cooperative Group Trials Currently Accruing

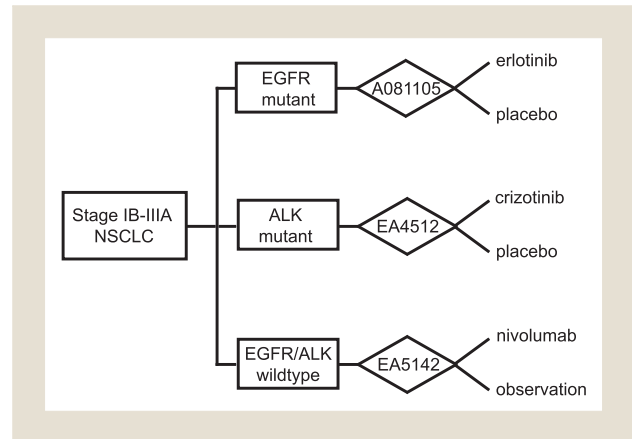
Study	National Clinical Trial Identifier
NSCLC	
EA4512 (ALCHEMIST)	NCT02201992
A081105 (ALCHEMIST)	NCT02193282
EA5142 (ANVIL)	NCT02595944
RTOG 1308	NCT01993810
RTOG 1106	NCT01507428
RTOG 1306	NCT01822496
S1400 (Lung-MAP)	NCT02154490
S1403	NCT02438722
CALGB 140503	NCT00499330
AFT-09	NCT02591615
ACCRU RC1126	NCT01532089
CTONG 1103 (EMERGING)	NCT01407822
CTONG 1104 (ADJUVANT)	NCT01405079
EORTC 22055-08053 (LUNG ART)	NCT00410683
EORTC 08114 (GEM)	NCT01838577
BR31	NCT02273375
IND219	NCT02337530
SCLC	
CALGB 30610/RTOG 0538	NCT00632853
ETOP 4-13 (STIMULI)	NCT02046733
Mesothelioma	
CALGB 30901	NCT01085630

Abbreviations: NSCLC = non–small-cell lung cancer; SCLC = small-cell lung cancer.

ECOG-ACRIN Early Stage Studies

ECOG-ACRIN early stage studies focus on optimal adjuvant therapy for resectable disease. These adjuvant therapies include chemotherapy and bevacizumab in E1505, targeted therapy in E4512, and immunotherapy in EA5142. The primary results of the phase 3 E1505 study, where patients with resected IB-IIIa disease were randomized to receive 4 cycles of a platinum doublet with or without bevacizumab, were presented in fall 2015. The study showed no reported benefit from adjuvant bevacizumab; however, subset analyses and correlative work is ongoing. EA4512, part of the umbrella protocol from the Adjuvant Lung Cancer Enrichment Marker Identification and Sequencing Trial (ALCHEMIST), investigates targeted adjuvant therapy with a primary end point of overall survival (OS) (Figure 1). Specifically, patients with resectable stage I-IIIa *ALK*-positive nonsquamous NSCLC who have completed surgical and adjuvant treatment are randomized to receive either crizotinib or placebo for 2 years. The soon-to-open EA5142, the Adjuvant Nivolumab in Resected Lung Cancers (ANVIL), expands ALCHEMIST and is a phase 3 randomized controlled trial evaluating the efficacy of nivolumab administered after resection and adjuvant treatment of IB-IIIa NSCLC. Patients without *EGFR* mutations or *ALK* translocations will be randomized 1:1 to receive either nivolumab or placebo, and the expected primary end points are median OS and disease-free survival (DFS). Patients with squamous-cell histology will also be eligible to enroll in EA5142 (Figure 1).

Figure 1 ALCHEMIST Aims to Determine Survival Impact of Additional Targeted Therapy or Immunotherapy in Patients Who Have Undergone Resection and Standard Adjuvant Chemotherapy for Stage IB-IIIa Nonsquamous NSCLC. A081107 Investigates 2 Years of Erlotinib Versus Placebo in *EGFR*-Mutant NSCLC. EA4512 Compares Crizotinib Versus Placebo in *ALK*-Mutant NSCLC. EA5142 Randomizes Patients to Receive Either 1 Year of Nivolumab Versus Observation in PD-L1 Positive Patients Defined by >3% Staining by Immunohistochemistry



Abbreviation: NSCLC = non–small-cell lung cancer.

ECOG-ACRIN Advanced Stage Studies

For patients with advanced stage lung cancer, ECOG-ACRIN has 2 studies focusing on the roles of different chemotherapy and targeted therapy regimens. E5508, which has completed accrual but does not yet have results, investigates the impact of differing maintenance therapy regimens on OS. In this study, patients with IIIB-IV stage nonsquamous NSCLC who have at least stable disease after 4 cycles of first-line treatment with carboplatin, paclitaxel, and bevacizumab are randomized to receive maintenance bevacizumab, pemetrexed, or the combination of both. The primary end point to be measured will be OS. E1512, a phase 2 study, demonstrated improved progression-free survival (PFS) with cabozantinib alone (4.2 months, $P = .02$) or in combination of cabozantinib with erlotinib (4.7 months, $P = .02$) compared to erlotinib monotherapy (1.9 months) in the setting of second- or third-line treatment of advanced NSCLC lacking actionable *EGFR* mutations. A follow-up study is in development.

NRG Oncology

In 2015, NRG Oncology reported on lung cancer trials from the legacy RTOG group that emphasized the following questions: Can radiotherapy be improved with better use of functional imaging? What are the benefits of proton therapy? Can targeted therapy improve outcomes over conventional chemotherapy when combined with radiotherapy?

NRG-RTOG Early Stage Studies

RTOG 0813 is a phase 1/2 study that aims to assess the safety and efficacy of stereotactic body radiotherapy for centrally localized

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