

Adult CIRB - Late Phase Emphasis Meeting Agenda

December 5, 2024

I Amendment

NRG-LU008, Phase III Prospective Randomized Trial of Primary Lung Tumor Stereotactic Body Radiation Therapy Followed by Concurrent Mediastinal Chemoradiation for Locally-Advanced Non-Small Cell Lung Cancer (Version Date 10/17//24)

II Continuing Review

A022001, Phase II Randomized, Prospective Trial of Lutetium Lu 177 Dotatate PRRT Versus Capecitabine and Temozolomide in Well-Differentiated Pancreatic Neuroendocrine Tumors: The ComPareNET Trial (Version Date 10/12/23)

III Continuing Review

A022101, A Pragmatic Randomized Phase III Trial Evaluating Total Ablative Therapy for Patients with Limited Metastatic Colorectal Cancer: Evaluating Radiation, Ablation, and Surgery (ERASur) (Version Date 05/08/24)

IV Continuing Review

EA1211, Interim FDG-PET/CT for PreDIcting REsponse of HER2+ Breast Cancer to Neoadjuvant Therapy: DIRECT trial (Version Date 03/29/24)

V Continuing Review

A031701, A Phase II Study of Gemcitabine Plus Cisplatin Chemotherapy in Patients with Muscle-Invasive Bladder Cancer with Bladder Preservation for Those Patients Whose Tumors Harbor Deleterious DNA Damage Response (DDR) Gene Alterations (Version Date 01/13/21)

VI Continuing Review

NRG-BR008, Phase III Randomized Trial of Radiotherapy Optimization for Low-Risk HER2-Positive Breast Cancer (HERO) (Version Date 02/23/23)

VII Continuing Review

A051902, A Randomized Phase II Study of CHO(E)P vs CC-486-CHO(E)P vs Duvelisib-CHO(E)P in Previously Untreated CD30 Negative Peripheral T-Cell Lymphomas (Version Date 09/11/24)

VIII Continuing Review

CCTG-PR24, Androgen Suppression Combined with Elective Nodal Irradiation and Dose Escalated Prostate Treatment: A Non-Inferiority, Phase III Randomized Controlled Trial of Stereotactic Body Radiation Therapy versus Brachytherapy Boost in Patients with Unfavourable Risk Localized Prostate Cancer (ASCENDE SBRT) (Version Date 12/04/23)

IX Continuing Review

CCTG-NE1, NET RETREAT: A Phase II Study of 177 Lutetium-DOTATATE Retreatment vs. Everolimus in Metastatic/Unresectable Midgut NET (Version Date 02/10/23)

X Continuing Review

E3A06, Randomized Phase III Trial of Lenalidomide versus Observation Alone In Patients with Asymptomatic High-Risk Smoldering Multiple Myeloma (Version Date 09/26/19)

XI Continuing Review

NRG-BR007, A Phase III Clinical Trial Evaluating De-Escalation of Breast Radiation for Conservative Treatment of Stage I, Hormone Sensitive, HER2-Negative, Oncotype Recurrence Score ≤ 18 Breast Cancer (Version Date 10/20/23)

XII Continuing Review

EA3211, Phase III Randomized Trial of Immunotherapy with or without Consolidative Radiotherapy for Oligometastatic Head and Neck Squamous Cell Carcinoma (Version Date 11/06/24)
