

Adult CIRB - Late Phase Emphasis Meeting Agenda

December 19, 2024

I New Study - Initial Review

EA1241, Extended Clinical Follow Up and Biospecimen Collection for Patients Enrolled in TAILORx and RxPONDER: A Companion Protocol (Version Date 11/15/24)

II New Study - Initial Review

S2409, PRISM: PReCIson in SCLC via a Multicohort Study: Randomized Phase II Studies Evaluating Maintenance Durvalumab with or without Biomarker-Directed Therapy for Extensive Stage Small Cell Lung Cancer (ES-SCLC) (Version Date 10/31/24)

III Amendment

S2015, Melanoma Margins Trial (MelMarT-II): A Phase III, Multi-Centre, Multi-National Randomised Control Trial Investigating 1cm v 2cm Wide Excision Margins for Primary Cutaneous Melanoma (Version Date 10/01/24)

IV Amendment

NRG-BR008, Phase III Randomized Trial of Radiotherapy Optimization for Low-Risk HER2-Positive Breast Cancer (HERO) (Version Date 11/25/24)

V Continuing Review

A031902, CASPAR - A Phase III Trial of Enzalutamide and Rucaparib as a Novel Therapy in First-Line Metastatic Castration-Resistant Prostate Cancer (Version Date 12/10/21)

VI Continuing Review

A042001, A Randomized Phase II Study Testing the Combination of Inotuzumab Ozogamicin and Lower Dose Chemotherapy plus Blinatumomab Compared to Usual Chemotherapy plus Blinatumomab for Adults with B-Cell Acute Lymphoblastic Leukemia or B-Cell Lymphoblastic Lymphoma (Version Date 08/30/24)

VII Continuing Review

A062102, Randomized Phase 2 Study of Iberdomide Maintenance Therapy Following Idecabtagene Vicleucel CAR-T in Multiple Myeloma Patients (Version Date 11/07/24)

VIII Continuing Review

A091902, A Multicenter Phase II Trial of Paclitaxel with and without Nivolumab in Taxane Naive, and Nivolumab and Cabozantinib in Taxane Pretreated Subjects with Angiosarcoma (Version Date 11/13/24)

IX Continuing Review

CCTG-CO32, The NEO-RT Trial: A Phase 3 Randomized Trial of Neoadjuvant Chemotherapy, Excision and Observation versus ChemoRadioTherapy for Early Rectal Cancer (Version Date 01/03/24)

X Continuing Review

EA2182, A Randomized Phase II Study of De-Intensified ChemoRadiation for Early-Stage Anal Squamous Cell Carcinoma (DECREASE) (Version Date 09/19/23)

XI Continuing Review

EA8191, Phase III Study of Local or Systemic Therapy INTensification DIrected by PET in Prostate Cancer Patients with Post-ProstaTEctomy Biochemical Recurrence (INDICATE) (Version Date 07/09/24)

XII Continuing Review

NRG-GY026, A Phase II/III Study of Paclitaxel/Carboplatin Alone or Combined with Either Trastuzumab and Hyaluronidase-oysk (HERCEPTIN HYLECTA) or Pertuzumab Trastuzumab and Hyaluronidase-zzfx (PHESGO) in HER2 Positive, Stage I-IV Endometrial Serous Carcinoma or Carcinosarcoma (Version Date 10/04/24)

XIII Continuing Review

S1802, Phase III Randomized Trial of Standard Systemic Therapy (SST) versus Standard Systemic Therapy Plus Definitive Treatment (Surgery or Radiation) of the Primary Tumor in Metastatic Prostate Cancer (Version Date 06/07/24)

XIV Continuing Review

S1931, Phase III Trial Of Immunotherapy-Based Combination Therapy With Or Without Cytoreductive Nephrectomy For Metastatic Renal Cell Carcinoma (Probe Trial) (Version Date 10/24/24)
