

**Adult CIRB - Late Phase Emphasis Meeting Agenda**

**April 6, 2023**

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**I New Study - Initial Review**

**EA2222**, A Randomized Phase III Study of Systemic Therapy with or without Hepatic Arterial Infusion for Unresectable Colorectal Liver Metastases: The PUMP Trial (Version Date 03/09/23)

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**II New Study - Initial Review**

**S2207**, Randomized Phase II Study of the Addition of Targeted Therapeutic Agents to Tafasitamab-Based Therapy in Non-Transplant-Eligible Patients with Relapsed/Refractory Large B-Cell Lymphoma (Version Date 02/24/23)

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**III New Study - Initial Review**

**S2210**, A Phase II Study of Neoadjuvant Carboplatin for Localized, High Risk Prostate Cancer with Germline BRCA1/2 Mutations (Version Date 03/01/23)

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**IV Amendment**

**NRG-HN005**, A Randomized Phase II/III Trial of De-intensified Radiation Therapy for Patients with Early-Stage, p16-Positive, Non-Smoking Associated Oropharyngeal Cancer (Version Date 03/14/23)

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**V Continuing Review**

**NRG-BR003**, A Randomized Phase III Trial of Adjuvant Therapy Comparing Doxorubicin Plus Cyclophosphamide Followed by Weekly Paclitaxel with or without Carboplatin for Node-Positive or High-Risk Node-Negative Triple-Negative Invasive Breast Cancer (Version Date 07/01/19)

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## **VI Continuing Review**

**NRG-GY024**, Groningen International Study on Sentinel Nodes in Vulvar Cancer (GROINSS-V) III: A Prospective Phase II Treatment Trial (Version Date 01/03/23 US Appendix Date)

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## **VI Continuing Review**

**RTOG-1216**, Randomized Phase II/III Trial of Adjuvant Radiation Therapy with Cisplatin, Docetaxel-Cetuximab, or Cisplatin-Atezolizumab in Pathologic High-Risk, Squamous Cell Cancer of the Head and Neck (Version Date 01/05/23)

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## **VII Continuing Review**

**RTOG-1308**, Phase III Randomized Trial Comparing Overall Survival After Photon Versus Proton Chemoradiotherapy For Inoperable Stage II-III B NSCLC (Version Date 10/06/21)

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## **VIII Continuing Review**

**S1922**, Randomized Phase II Selection Study of Ramucirumab and Paclitaxel Versus FOLFIRI In Refractory Small Bowel Adenocarcinoma (Version Date 07/25/22)

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## **IX Continuing Review**

**EA3132**, Phase II Randomized Trial of Radiotherapy with or without Cisplatin for Surgically Resected Squamous Cell Carcinoma of the Head and Neck (SCCHN) with TP53 Sequencing (Version Date 09/20/21)

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## **X Continuing Review**

**A091404**, A Phase II Study of Enzalutamide (NSC# 766085) for Patients with Androgen Receptor Positive Salivary Cancers (Version Date 09/10/19)

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## **XI Continuing Review**

**EA6174**, STAMP: Surgically Treated Adjuvant Merkel cell Carcinoma with Pembrolizumab, a Phase III Trial (Version Date 02/23/23)

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## **XII Continuing Review**

**EA6191**, The BAMB2 (BRAF, Autophagy, MEK inhibition in Melanoma) Study: A Randomized Double Blind Phase II Study of Dabrafenib and Trametinib with or without Hydroxychloroquine in Advanced BRAFV600E/K Melanoma with elevated LDH (Version Date 01/19/23)

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## **XIII Continuing Review**

**A011801**, The COMPASSHER2 Trials (COMprehensive Use of Pathologic Response ASSESSment to Optimize Therapy in HER2-Positive Breast Cancer): CompassHER2 Residual Disease (RD), A Double-Blinded, Phase III Randomized Trial of T-DM1 and Placebo Compared with T-DM1 and Tucatinb (Version Date 06/23/22)

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## **XIV Continuing Review**

**EA8183**, A Phase III Double Blinded Study of Early Intervention after RADICAL ProstaTEctomy with Androgen Deprivation Therapy with Darolutamide vs. Placebo in Men at Highest Risk of Prostate Cancer Metastasis by Genomic Stratification (ERADICATE) (Version Date 09/13/21)

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