



Adult CIRB – Late Phase Emphasis Meeting Agenda

Thursday, January 19, 2017
9:00 am – 9:50 pm (Eastern)

I Continuing Review

GOG-0262, A Phase III Trial of Every-3-Weeks Paclitaxel Versus Dose Dense Weekly Paclitaxel In Combination With Carboplatin With Or Without Concurrent and Consolidation Bevacizumab (NSC #704865, IND #113912) in the Treatment of Primary Stage II, III OR IV Epithelial Ovarian, Peritoneal or Fallopian Tube Cancer and ACRIN 6695: Perfusion CT Imaging To Evaluate Treatment Response in Patients Participating in GOG-0262 (Protocol Version Date 08/31/16)

II Continuing Review

E2112, A Randomized Phase III Trial of Endocrine Therapy plus Entinostat/Placebo in Patients with Hormone Receptor-Positive Advanced Breast Cancer (Protocol Version Date 07/15/16)

III Study Chair Response to Initial Review

A031501, Phase III Randomized Adjuvant Study of MK-3475 (Pembrolizumab) in Muscle Invasive and Locally Advanced Urothelial Carcinoma (Ambassador) Versus Observation (Protocol Version Date 01/09/17)

IV Continuing Review

NSABP-B-49, A Phase III Clinical Trial Comparing the Combination of Docetaxel Plus Cyclophosphamide to Anthracycline-Based Chemotherapy Regimens for Women with Node-Positive or High-Risk Node-Negative, HER2-Negative Breast Cancer (Protocol Version Date 04/16/14)

V Reports of Expedited Reviews December 2016

- Late Phase Emphasis CIRB Local Context Subcommittee Report
 - Expedited Reviews and Study Acknowledgements
 - Study Activation Acknowledgements
 - Amendment Activation Acknowledgements
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