



NCI Central IRB Website Postings Summary

July 1, 2009

The NCI CIRB Operations Office is distributing this Website Postings Summary to all CIRB sites to provide a summary of the review documents posted to the CIRB website (<http://www.ncicirb.org/>) since the last update. Please note: for a complete listing of all documents pertaining to a specific review, visit the study-specific webpage.

Although these summary posting updates are provided on the 1st and 15th of every month, the CIRB Operations Office posts review documents and updates to the CIRB website on a daily basis.

All review documents are posted on the study-specific webpages. All notices are posted under the "What's New" section of the CIRB homepage. If you are unsure of your username and password or have difficulty accessing the website, please email ncicirbcontact@emmes.com or call the CIRB HelpDesk toll-free at 888-657-3711.

CIRB Notices

1. Please note the new name, "Website Postings Summary", replaces the current "Study Activity Update" to clarify the intent of this communication.
 2. Please note that the CIRB has reported an instance of noncompliance to OHRP and FDA regarding review of study SWOG S0023. The report is posted with the most recent continuing review.
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Study-Specific Review Documents Recently Posted

Posted Documents Related to Initial Reviews:

The review documents listed below pertain to initial CIRB reviews. These new studies are now available for facilitated review.

Adult Studies

Study Number

Initial Review Approval

Documents Posted:

- None

Pediatric Studies

Study Number

Initial Review Approval

Documents Posted:

- None

Posted Documents Related to Amendment Reviews:

Adult Studies

CALGB-30607

Amendment Review (AR): Update #2 (Protocol Version Date 04/29/09)

Documents Posted:

- Amendments
 - 06/15/09: Change Memo (Protocol Version Date 04/29/09)
- CIRB Application
 - CIRB Application (Protocol Version Date 04/29/09)
 - Summary of CIRB Application Revisions (Protocol Version Date 04/29/09)



- Correspondence
 - 06/11/09: CIRB Update 2 Approval Letter (Protocol Version Date 04/29/09)
- Protocol
 - Protocol Version Date 04/29/09
- Informed Consent
 - CIRB's Informed Consent Document for Protocol Version Date 04/29/09 [Up2]
- Primary Reviews
 - 06/04/09: Primary Reviewer 1 Comments
 - 06/04/09: Primary Reviewer 2 Comments

CALGB-100104

****Closed to Accrual – Effective July 3, 2009****

Amendment Review (AR): **CIRB Acknowledgement - Permanent Closure to Accrual on July 3, 2009**

Documents Posted:

- Correspondence
 - 06/15/09: CIRB Acknowledgement of Permanent Closure
 - 06/02/09: CALGB Permanent Closure Memo

ECOG-E1105

Amendment Review (AR): Update #2 (Protocol Version Date 06/10/09)

Documents Posted:

- Amendments
 - 06/10/09: Change Memo (Protocol Version Date 06/10/09)
- CIRB Application
 - CIRB Application (Protocol Version Date 06/10/09)
 - Summary of CIRB Application Revisions (Protocol Version Date 06/10/09)
- Correspondence
 - 06/16/09: CIRB Update 2 Approval Letter (Protocol Version Date 06/10/09)
- Protocol
 - Protocol Version Date 06/10/09
- Informed Consent



- CIRB's Informed Consent Document for Protocol Version Date 06/10/09 [up2]

ECOG-E5103

Amendment Review (AR): Addendum #3 (Protocol Version Date 05/21/09)

Documents Posted:

- Amendments
 - 02/11/09: Change Memo (Protocol Version Date 02/11/09)
- CIRB Application
 - CIRB Application (Protocol Version Date 05/21/09)
 - Summary of CIRB Application Revisions (Protocol Version Date 05/21/09)
 - CIRB Application (Protocol Version Date 02/11/09)
 - Summary of CIRB Application Revisions (Protocol Version Date 02/11/09)
- Correspondence
 - 05/26/09: CIRB Approval Letter Addendum 3 (Protocol Version date 05/21/09)
 - 05/21/09: ECOG Response to CIRB
 - 04/27/09: CIRB Approval Pending Modifications (Protocol Version Date 02/11/09)
- Protocol
 - Protocol Version Date 05/21/09
 - Protocol Version Date 02/11/09
- Informed Consent
 - CIRB's Informed Consent Document for Protocol Version Date 05/21/09 [Ad3]
- Primary Reviews
 - 04/03/09: Primary Reviewer 1 Comments
- Minutes
 - 04/03/09: Minutes - Addendum 3

GOG-0213

Amendment Review (AR): Revision #2 (Protocol Version Date 03/06/09)

Documents Posted:

- Amendments



- 03/06/09: GOG Change Memo (Protocol Version Date 03/06/09)
- CIRB Application
 - CIRB Application (Protocol Version Date 03/06/09)
 - Summary of CIRB Application Revisions (Protocol Version Date 03/06/09)
- Correspondence
 - 04/23/09: CIRB Revision 2 Approval Letter (Protocol Version Date 03/06/09)
- Protocol
 - Protocol Version Date 03/06/09
 - Protocol Version Date 03/06/09 (Highlighted)
 - APPENDIX I: FIGO STAGE GROUPING FOR PRIMARY CARCINOMA OF THE OVARY
 - APPENDIX II: SECONDARY CYTOREDUCTIVE SURGICAL PROCEDURE
 - APPENDIX III: Specimen Procedures
 - APPENDIX III: Specimen Procedures (Highlighted)
 - Appendix IV: NCI Standard Protocol Language
- Informed Consent
 - CIRB's Informed Consent Document for Protocol Version Date 03/06/09 [Rev2]
- Primary Reviews
 - 04/20/09: Primary Reviewer 1 Comments
- Minutes
 - 04/20/09: Minutes - Revision 2

GOG-0218

****Suspension of Accrual – Effective June 29, 2009****

Amendment Review (AR): **Suspension of Accrual -- Effective June 29, 2009**

Documents Posted:

- Correspondence
 - 06/23/09: CIRB Acknowledgement of GOG Notification of Suspension to Accrual
 - 06/08/09: GOG Notification of Suspension of Accrual

GOG-0219

Amendment Review (AR): Revision #8 (Protocol Version Date 06/05/09)



Documents Posted:

- Amendments
 - 06/05/09: Change Memo (Protocol Version Date 06/05/09)
- CIRB Application
 - CIRB Application (Protocol Version Date 06/05/09)
 - Summary of CIRB Application Revisions (Protocol Version Date 06/05/09)
- Correspondence
 - 06/11/09: CIRB Revision 8 Approval Letter (Protocol Version Date 06/05/09)
 - 06/24/09: GOG Revision 8 Memo
- Protocol
 - Protocol Version Date 06/05/09
 - Protocol Version Date 06/05/09 Highlighted
 - APPENDIX I: EXTRAPERITONEAL LYMPH NODE SAMPLING
 - APPENDIX II: PELVIC AND PARA-AORTIC NODE SAMPLING
 - APPENDIX III: CLINICAL STAGING - CARCINOMA OF THE CERVIX UTERI
 - APPENDIX IV: HDR BRACHYTHERAPY
 - APPENDIX V: Blank Diagram Anterior
 - APPENDIX VI: Blank Diagram Lateral
 - APPENDIX VII: Description of ICRU Bladder/Rectal Dose Reporting Points
 - APPENDIX VIII: Radiotherapy Information for Canadian Centers
 - APPENDIX IX: Information for ANZGOG Institutions (02/06/2006)
 - APPENDIX IX: Information for ANZGOG Institutions (02/06/2006) Highlighted
 - APPENDIX X: Specimen Procedures
 - APPENDIX XI: Laboratory Procedures
 - APPENDIX XII: NCI Standard Protocol Language
 - APPENDIX XIII: LOGISTICAL GUIDELINES FOR CTSU
- Informed Consent
 - CIRB's Informed Consent Document for Protocol Version Date 06/05/09 [Rev8]

NCCTG-N06C6

****Closed to Accrual – Effective June 19, 2009****

Amendment Review (AR): **CIRB Acknowledgement of Closure to Accrual - Effective June 19, 2009**

Documents Posted:



- Correspondence
 - 06/22/09: CIRB Acknowledgement of Permanent Closure to Accrual
 - 06/19/09: NCCTG Notice of Permanent Closure to Accrual

NSABP-B-35

Amendment Review (AR): [CIRB Acknowledgement of Receipt - Updated Arimidex U.S. Package Insert](#)

Documents Posted:

- Correspondence
 - 06/17/09: CIRB Acknowledgement of NSABP B-35 Updated Arimidex U.S. Package Insert
 - 06/10/09: NSABP Updated Arimidex US Package Insert Notice
- Support Documents
 - December 2008 - Arimidex Highlights of Prescribing Information

NSABP-B-40

Amendment Review (AR): [CIRB Acknowledgement Updated Bevacizumab Investigator's Brochure](#)

Documents Posted:

- Correspondence
 - 06/17/09: CIRB Acknowledgement of NSABP B-40 Updated Bevacizumab Investigator's Brochure Version 16
 - 12/18/08: NSABP Arimidex Updated US Package Insert

NSABP-C-08

Amendment Review (AR): [CIRB Acknowledgement - Updated Bevacizumab Investigator's Brochure](#)

Documents Posted:

- Correspondence
 - 06/17/09: CIRB Acknowledgement of NSABP C-08 Updated Bevacizumab Investigator's Brochure Version 16
 - 12/18/08: NSABP Investigator's Brochure Update Notice

SWOG-S0226

****Closed to Accrual – Effective July 1, 2009****

Amendment Review (AR): [CIRB Acknowledgement - Permanent Closure to Accrual Effective July 1, 2009](#)

Documents Posted:



- Correspondence
 - 06/16/09: CIRB Acknowledgement of Permanent Closure
 - 06/01/09: SWOG Permanent Closure Memo

Amendment Review (AR): Revision #4 (Protocol Version Date 05/19/09)

Documents Posted:

- Amendments
 - 05/19/09: Change Memo (Protocol Version Date 05/19/09)
- CIRB Application
 - CIRB Application (Protocol Version Date 05/19/09)
 - Summary of CIRB Application Revisions (Protocol Version Date 05/19/09)
- Correspondence
 - 05/29/09: CIRB Revision 4 Approval Letter (Protocol Version Date 05/19/09)
- Protocol
 - Protocol Version Date 05/19/09
- Informed Consent
 - CIRB's Informed Consent Document for Protocol Version Date 05/19/09 [Rev 4]

SWOG-0502

Amendment Review (AR): Revision #2 (Protocol Version Date 05/11/09)

Documents Posted:

- Amendments
 - 05/11/09: Change Memo (Protocol Version Date 05/11/09)
- CIRB Application
 - CIRB Application (Protocol Version Date 05/11/09)
 - Summary of CIRB Application Revisions (Protocol Version Date 05/11/09)
- Correspondence
 - 05/28/09: CIRB Revision 2 Approval Letter (Protocol Version Date 05/11/09)



- Protocol
 - Protocol Version Date 05/11/09
- Informed Consent
 - CIRB's Informed Consent Document for Protocol Version Date 05/11/09 [rev2]
 - CIRB's Informed Consent Document (Instructions for Local institutions) for Protocol Version Date 05/11/09

SWOG-S9910

Amendment Review (AR): **Revision #16 (Protocol Version Date 05/26/09)**

Documents Posted:

- Amendments
 - 05/26/09: Change Memo (Protocol Version Date 05/26/09)
- CIRB Application
 - CIRB Application (Protocol Version Date 05/26/09)
 - Summary of CIRB Application Revisions (Protocol Version Date 05/26/09)
- Correspondence
 - 06/02/09: CIRB Approval Letter Revision 16 (Protocol Version Date 05/26/09)
- Protocol
 - Protocol Version Date 05/26/09
- Informed Consent
 - CIRB's Informed Consent Document for Protocol Version Date 05/26/09 [rev16]

Pediatric Studies

COG-AALL0433

Amendment Review (AR): Amendment #2 (Protocol Version Date 05/07/09)

Documents Posted:

- CIRB Application
 - CIRB Application (Protocol Version Date 05/07/09)
- Correspondence



- 06/16/09: CIRB Acknowledgement of COG AALL0433 Posting of Amendment #2 (Protocol Version Date 05/07/09)
- 06/15/09: COG AALL0433 Amendment #2 Activation Memo
- 06/05/09: CIRB Approval of COG AALL0433 Amendment #2 (Protocol Version Date 05/07/09)
- 05/07/09: COG Change Memo (Protocol Version Date 05/07/09)

- Protocol
 - Protocol Version Date 05/07/09
 - Protocol Version Date 05/07/09 - Highlighted Changes

- Informed Consent
 - Informed Consent Document for Protocol Version Date 05/07/09

COG-ADVL0221

****Reactivation of Rhabdomyosarcoma Stratum by COG - Effective June 4, 2009****

Amendment Review (AR): **Reactivation of Rhabdomyosarcoma Stratum -- Effective June 4, 2009**

Documents Posted:

- Correspondence
 - 06/24/09: CIRB Acknowledgement of Reactivation of the Rhabdomyosarcoma Stratum Memo
 - 06/04/09: COG Memo - Reactivation of Rhabdomyosarcoma Stratum

COG-ADVL0821

****Partial Closure of the Osteosarcoma Disease Stratum by COG of ADVL0821 - Effective June 8, 2009****

Amendment Review (AR): **Partial Closure of the Osteosarcoma Disease Stratum (06/08/09)**

Documents Posted:

- Correspondence
 - 06/08/09: COG Notice ADVL0821 Partial Closure for Osteosarcoma Disease Stratum
 - 06/16/09: CIRB Acknowledgement - ADVL0821 Partial Closure for Osteosarcoma Disease Stratum

COG-AHOD0431

Amendment Review (AR): **Acknowledgement of AHOD0431 Family/Patient Letter (Dated 05/22/09) regarding FDG-PET and Gallium Scans**

Documents Posted:



- Correspondence
 - 06/15/09: CIRB Acknowledgement of AHOD0431 Patient/Family Letter
 - 05/22/09: COG Memo re AHOD0431 Patient/Family Letter
 - 05/22/09: AHOD0431 Patient/Family Letter

Amendment Review (AR): **Review of AHOD0431 Family/Patient Letter (Dated 12/15/08) regarding Temporary Closure to Accrual**

Documents Posted:

- Minutes
 - 05/14/09: Minutes - Group Response to Family/Patient Letter Review

Additional documents associated with this action have been previously posted in the Study Activity Update and are available on the website.

COG-AREN0321

Amendment Review (AR): **Review of AREN0321 Family/Patient Letter (Dated 11/10/08) regarding Treatment Regimens UH-1 and UH-2**

Documents Posted:

- Minutes
 - 05/14/09: Minutes - Group Response to Family/Patient Letter Review

Additional documents associated with this action have been previously posted in the Study Activity Update and are available on the website.

COG-ARET0331

Amendment Review (AR): **Acknowledgement of ARET0331 Family/Patient Letter (Dated 06/22/09) regarding Study Closure**

Documents Posted:

- Correspondence
 - 06/26/09: CIRB Acknowledgement of ARET0331 Family/Patient Letter
 - 06/22/09: COG ARET0331 Patient/Family Letter

****Closed to Accrual by COG - Effective June 18, 2009****

Amendment Review (AR): **Acknowledgement of ARET0331 Study Closure 06/18/09)**



Documents Posted:

- Correspondence
 - 06/19/09: COG Memo - Closure of ARET0331
 - 06/26/09: CIRB Acknowledgement of COG ARET0331 Study Closure Memo
- Informed Consent
 - Informed Consent Document for Protocol Version Date 09/14/07

COG-ARST0332

Amendment Review (AR): Amendment #1B (Protocol Version Date 04/07/09)

Documents Posted:

- Minutes
 - 05/14/09: Minutes - Amendment Review

Additional documents associated with this action have been previously posted in the Study Activity Update and are available on the website.

Posted Documents Related to Continuing Reviews:

Adult Studies

ACOSOG-Z1041 A1

Continuing Review (CR): Continuing Review June 2009

Documents Posted:

- Continuing Review Forms
 - CIRB Continuing Review Application (Protocol Version Date 09/18/08)
- Correspondence
 - 06/24/09: CIRB Continuing Review Approval Letter (Protocol Version Date 09/18/08)
 - 05/06/09: Continuing Review Reminder Notice
- Protocol
 - Protocol Version Date 09/18/08
- Informed Consent



- CIRB's Informed Consent Document for Protocol Version Date 09/18/08 [CR09]
- Primary Reviews
 - 06/18/09: Primary Reviewer 1 Comments
- Support Documents
 - 01/08/09: DMC Minutes
 - Study Summary

CALGB-30607

Continuing Review (CR): Continuing Review June 2009

Documents Posted:

- Continuing Review Forms
 - CIRB Continuing Review Application (Protocol Version Date 04/29/09)
- Correspondence
 - 06/19/09: CIRB Continuing Review Approval Letter (Protocol Version Date 04/29/09)
 - 05/07/09: Continuing Review Reminder Notice
- Protocol
 - Protocol Version Date 04/29/09
- Informed Consent
 - CIRB's Informed Consent Document for Protocol Version Date 04/29/09 [CR09]
- Primary Reviews
 - 06/18/09: Primary Reviewer 1 Comments

CALGB-40601

Continuing Review (CR): Continuing Review June 2009

Documents Posted:

- Continuing Review Forms
 - CIRB Continuing Review Application (Protocol Version Date 09/29/08)
- Correspondence
 - 06/19/09: CIRB Continuing Review Approval Letter (Protocol Version Date 09/29/08)



- 05/06/09: Continuing Review Reminder Notice
- Protocol
 - Protocol Version Date 09/29/08
- Informed Consent
 - CIRB's Informed Consent Document for Protocol Version Date 09/29/08 [CR09]
- Primary Reviews
 - 06/18/09: Primary Reviewer 1 Comments

GOG-0209

Continuing Review (CR): Continuing Review June 2009

Documents Posted:

- Continuing Review Forms
 - CIRB Continuing Review Application (Protocol Version Date 05/12/08)
- Correspondence
 - 06/24/09: CIRB Continuing Review Approval Letter (Protocol Version Date 05/12/08)
 - 05/07/09: Continuing Review Reminder Notice
- Protocol
 - Protocol Version Date 05/12/08
- Informed Consent
 - CIRB's Informed Consent Document for Protocol Version Date 05/12/08 [CR09]
- Primary Reviews
 - 06/18/08: Primary Reviewer 1 Comments
- Support Documents
 - 01/24/09: DSMB
 - January 2009 - Study Summary (Protocol Version Date 05/12/08)

NSABP-B-35

Continuing Review (CR): Continuing Review June 2009

Documents Posted:

- Continuing Review Forms



- CIRB Continuing Review Application (Protocol Version Date 03/26/07)
- Correspondence
 - 06/19/09: CIRB Continuing Review Approval Letter (Protocol Version Date 03/26/07)
 - 06/04/09: Cover Memo (Protocol Version Date 03/26/07)
 - 05/04/09: Continuing Review Reminder Notice
- Protocol
 - Protocol Version Date 03/26/07
- Informed Consent
 - CIRB's Informed Consent Document for Protocol Version Date 03/26/07 [CR09]
- Primary Reviews
 - 06/18/09: Primary Reviewer 1 Comments
- Support Documents
 - Study Summary (Protocol Version Date 03/26/07)
 - 04/17/09: DMC Minutes
 - 10/17/08: DMC Minutes

NSABP-B-42

Continuing Review (CR): Continuing Review June 2009

Documents Posted:

- Continuing Review Forms
 - CIRB Continuing Review Application (Protocol Version Date 01/23/09)
- Correspondence
 - 06/18/09: CIRB Continuing Review Approval Letter (Protocol Version Date 01/23/09)
 - 05/15/09: NSABP Continuing Review Cover Memo
 - 04/07/09: Continuing Review Reminder Notice
- Protocol
 - Protocol Version Date 09/12/07
- Informed Consent
 - CIRB's Informed Consent Document for Protocol Version Date 09/12/07 Randomized Study



- CIRB's Informed Consent Document for Protocol Version Date 09/12/07 Optional Registration
- Primary Reviews
 - 06/04/09: Primary Reviewer 1 Comments
- Support Documents
 - 10/17/08: DMC Meeting Minutes
 - 2008 Study Summary

RTOG-0126

Continuing Review (CR): Continuing Review June 2009

Documents Posted:

- Continuing Review Forms
 - CIRB Continuing Review Application (Protocol Version Date 09/19/07)
- Correspondence
 - 06/24/09: CIRB Continuing Review Approval Letter (Protocol Version Date 09/19/07)
 - 05/06/09: Continuing Review Reminder Notice
- Protocol
 - Protocol Version Date 09/19/07
- Informed Consent
 - CIRB's Informed Consent for Protocol Version Date 09/19/07 [CR09]
 - CIRB's Informed Consent for Protocol Version Date 09/19/07: Tissue [CR09]
- Primary Reviews
 - 06/18/08: Primary Reviewer 1 Comments
- Support Documents
 - 01/09/09: DMC Minutes
 - January 2009 Study Summary

SWOG-S0023

Continuing Review (CR): Continuing Review May 2009

Documents Posted:

- Continuing Review Forms
 - CIRB Continuing Review Application (Protocol Version 07/25/07)



- Correspondence
 - 06/24/09: CIRB Continuing Review Approval (Protocol Version Date 07/25/07)
 - 06/23/09: Notification to Sites Accepting Facilitated Review
 - 06/16/09: Letter to OHRP and FDA
- Protocol
 - Protocol Version Date 07/25/07
- Informed Consent
 - CIRB's Informed Consent Document for Protocol Version Date 07/25/07 [CR09]
 - CIRB's Informed Consent Document for Protocol Version Date 07/25/07: Specimen [CR09]
- Primary Reviews
 - 05/07/09: Primary Reviewer 1 Comments
 - January 2009 Study Summary

SWOG-S0421

Continuing Review (CR): Continuing Review June 2009

Documents Posted:

- Continuing Review Forms
 - CIRB Continuing Review Application (Protocol Version Date 06/08/09)
- Correspondence
 - 06/24/09: CIRB Continuing Review Approval Letter (Protocol Version Date 06/08/09)
 - 05/07/09: Continuing Review Reminder Notice
- Protocol
 - Protocol Version Date 06/11/08
- Informed Consent
 - CIRB's Informed Consent Document for Protocol Version Date 06/11/08
 - CIRB's Informed Consent Document (Instructions for Local Institutions) for Protocol Version Date 06/11/08
- Primary Reviews
 - 06/18/08: Primary Reviewer 1 Comments
- Support Documents
 - 04/07/09: Minutes-DSMC Meeting



- April 2009 Study Summary

Pediatric Studies

COG-AAML0523

Continuing Review (CR): Continuing Review May 2009

Documents Posted:

- Minutes
 - 05/14/09: Minutes - Continuing Review

Additional documents associated with this action have been previously posted in the Study Activity Update and are available on the website.

COG-AAML06P1

Continuing Review (CR): Continuing Review June 2009

Documents Posted:

- Continuing Review Forms
 - CIRB Continuing Review Application (Protocol Version Date 02/26/07)
- Correspondence
 - 06/15/09: CIRB Continuing Review Approval Letter (Protocol Version Date 02/26/07)
 - 05/06/09: CIRB Continuing Review Reminder Notice
- Protocol
 - Protocol Version Date 02/26/07
- Informed Consent
 - Informed Consent Document for Protocol Version Date 02/26/07
- Primary Reviews
 - 06/11/09: Primary Reviewer 1 Comments
- Support Documents
 - 03/09/09: DSMC Report - Spring 2009
 - Study Progress Report - Spring 2009



COG-AAML07P1

Continuing Review (CR): Continuing Review May 2009

Documents Posted:

- Minutes
 - 05/14/09: Minutes - Continuing Review

Additional documents associated with this action have been previously posted in the Study Activity Update and are available on the website.

COG-ACCL0431

Continuing Review (CR): Continuing Review June 2009

Documents Posted:

- Continuing Review Forms
 - CIRB Continuing Review Application (Protocol Version Date 01/24/08)
- Correspondence
 - 06/15/09: CIRB Continuing Review Approval Letter (Protocol Version Date 01/24/08)
 - 04/07/09: Continuing Review Reminder Notice
- Protocol
 - Protocol Version Date 01/24/08
- Informed Consent
 - Informed Consent Document for Protocol Version Date 01/24/08
- Primary Reviews
 - 06/11/09: Primary Reviewer 1 Comments
- Support Documents
 - 03/09/09: DSMC Report - Spring 2009
 - Study Progress Report - Spring 2009

COG-ACCL05C1

Continuing Review (CR): Continuing Review June 2009

Documents Posted:

- Continuing Review Forms



- CIRB Continuing Review Application (Protocol Version Date 10/31/08)
- Correspondence
 - 06/15/09: CIRB Continuing Review Approval Letter (Protocol Version Date 10/31/08)
 - 05/06/09: CIRB Continuing Review Reminder Notice
- Protocol
 - Protocol Version Date 10/31/08
- Informed Consent
 - Informed Consent Document for Protocol Version Date 10/31/08
- Primary Reviews
 - 06/11/09: Primary Reviewer 1 Comments
- Support Documents
 - Study Progress Report - Spring 2009

COG-ACNS0222

Continuing Review (CR): Continuing Review June 2009

Documents Posted:

- Continuing Review Forms
 - CIRB Continuing Review Application (Protocol Version Date 05/08/07)
- Correspondence
 - 06/15/09: CIRB Continuing Review Approval Letter (Protocol Version Date 05/08/07)
 - 05/06/09: CIRB Continuing Review Reminder Notice
- Protocol
 - Protocol Version Date 05/08/07
- Informed Consent
 - Informed Consent Document for Protocol Version Date 05/08/07
- Primary Reviews
 - 06/11/09: Primary Reviewer 1 Comments
- Support Documents
 - 03/09/09: DSMC Report - Spring 2009
 - Study Progress Report - Spring 2009



- 08/25/08: Study Progress Report

COG-ACNS0621

Continuing Review (CR): Continuing Review June 2009

Documents Posted:

- Continuing Review Forms
 - CIRB Continuing Review Application (Protocol Version Date 02/27/09)
- Correspondence
 - 06/15/09: CIRB Continuing Review Approval Letter (Protocol Version Date 02/27/09)
 - 04/07/09: Continuing Review Reminder Notice
- Protocol
 - Protocol Version Date 02/27/09
- Informed Consent
 - Informed Consent Document for Protocol Version Date 02/27/09
- Primary Reviews
 - 06/11/09: Primary Reviewer 1 Comments
- Support Documents
 - 03/09/09: DSMC Report - Spring 2009
 - Study Progress Report - Spring 2009

COG-ALTE05N1

Continuing Review (CR): Continuing Review June 2009

Documents Posted:

- Continuing Review Forms
 - CIRB Continuing Review Application (Protocol Version Date 04/15/09)
- Correspondence
 - 06/15/09: CIRB Continuing Review Approval Letter (Protocol Version Date 04/15/09)
 - 05/06/09: CIRB Continuing Review Reminder Notice
- Protocol
 - Protocol Version Date 04/15/09



- Informed Consent
 - Informed Consent Document for Protocol Version Date 04/15/09
- Primary Reviews
 - 06/11/09: Primary Reviewer 1 Comments

COG-ALTE07C1

Continuing Review (CR): Continuing Review May 2009

Documents Posted:

- Minutes
 - 05/14/09: Minutes - Continuing Review

Additional documents associated with this action have been previously posted in the Study Activity Update and are available on the website.

COG-AREN0532

Continuing Review (CR): Continuing Review May 2009

Documents Posted:

- Minutes
 - 05/14/09: Minutes - Continuing Review

Additional documents associated with this action have been previously posted in the Study Activity Update and are available on the website.

COG-ARET0332

Continuing Review (CR): Continuing Review March 2009

Documents Posted:

- Minutes
 - 05/14/09: Minutes - Group Response to Continuing Review

Additional documents associated with this action have been previously posted in the Study Activity Update and are available on the website.



Serious Adverse Events Posted

Adult Studies

Study Number

Study: GOG 0213

SAE Posted: 1034535, 1034535 FU1, 1133874, 1201753, 1277486, 1293580, 1324148 FU1, 1329128, 1360351, 1391765, 1419144, 1475911 FU1, 1580693 FU1, 1809441, 1809808, 1836781, 1951869 FU1, 1951869 FU2, 1987521, 1994045, 1996104, 273064

Study: GOG 0218

SAE Posted: 1034535, 1034535 FU1, 1133874, 1201753, 1277486, 1293580, 1314985, 1324148 FU1, 1329128, 1360351, 1391765, 1419144, 1475911 FU1, 1580693 FU1, 1809441, 1836781, 1951869 FU1, 1951869 FU2, 1987521, 1994045, 1996104, 273064

Study: RTOG 0320

SAE Posted: 1192065, 2009000831 FU1

Study: RTOG 0436

SAE Posted: 09-02-15831 FU2, 09-02-15962 FU2, 09-02-16049 FU1, 09-02-16306 FU2, 09-02-16435 FU3, 09-02-16476 FU2, 09-02-16482 FU1, 09-02-16571 FU1, 09-02-16601, 09-02-16601 FU1, 09-02-16746, 09-02-16791, 09-02-16791 FU1, 09-02-16834, 09-02-16881

Study: RTOG 0522

SAE Posted: 08-02-15483 FU1, 08-02-15541 FU3, 08-02-15660 FU2, 08-02-15765, 08-02-15765 FU3, 08-02-15831 FU1, 09-02-15831 FU2, 09-02-15897 FU1, 09-02-15897 FU2, 09-02-15898, 09-02-15898 FU1, 09-02-15929 FU1, 09-02-15929 FU2, 09-02-15962 FU1, 09-02-15962 FU2, 09-02-15966 FU1, 09-02-15973 FU1, 09-02-15982, 09-02-15982 FU1, 09-02-15989 FU1, 09-02-16049 FU1, 09-02-16124 FU1, 09-02-16124 FU2, 09-02-16130 FU1, 09-02-16130 Fu2, 09-02-16131, 09-02-16131 FU1, 09-02-16131 Fu2, 09-02-16203 FU1, 09-02-16203 FU2, 09-02-16296, 09-02-16296 FU1, 09-02-16306, 09-02-16306 FU1, 09-02-16306 FU2, 09-02-16382 FU1, 09-02-16435 FU2, 09-02-16435 FU3, 09-02-16468 FU1, 09-02-16476 FU1, 09-02-16476 FU2, 09-02-16481 FU1, 09-02-16482, 09-02-16482 FU1, 09-02-16571 FU1, 09-02-16601, 09-02-16601 FU1, 09-02-16746, 09-02-16791, 09-02-16791 FU1, 09-02-16834, 09-02-16881

Study: RTOG 0617

SAE Posted: 08-02-15765 FU3, 09-02-15831 FU2, 09-02-15897 FU1, 09-02-15962 FU1, 09-02-15962 Fu2, 09-02-15966 FU1, 09-02-15982 FU1, 09-02-15989 FU1, 09-02-16131 FU2, 09-02-16203 FU1, 09-02-16203 FU2, 09-02-16296, 09-02-16306 FU2, 09-02-16476 FU2, 09-02-16482 FU1, 09-02-16571 FU1, 09-02-16601 FU1, 09-02-16791 FU1, 09-02-16834, 09-02-16881



Study: SWOG S0518
SAE Posted: 1034535, 1118620 FU1, 1201753, 1324148 FU1, 1360351, 1475911 FU1, 1580693 FU1, 1729567 FU1, 1951869 FU1, 1996104, 273064

Study: SWOG S0600
SAE Posted: 1034535, 1201753, 1324148 FU1, 1360351, 1475911 FU1, 1580693 FU1, 1951869 FU1, 1996104, 273064

Pediatric Studies

Study Number

Study: COG AALL0631
SAE Posted: US024888 FU3

Study: COG AALL07P1
SAE Posted: 1073953, 1673759

Study: COG AALL07P4
SAE Posted: 2009EN000010 FU2, 2009EN000023, 2009EN000033, 2009EN000033 FU1, 2009EN000047, 2009EN000047 FU1, 2009EN000117

Study: COG AAML06P1
SAE Posted: US024888 FU3

Study: COG AAML07P1
SAE Posted: 1073953, 1628411

Study: COG ACNS0621
SAE Posted: 6025021, 6048634

Study: COG ADVL0221
SAE Posted: CH-JNJFOC-20090107035 FU1, DE-JNJFOC-20090102074 FU1, ES-JNJFOC-20090202366, ES-JNJFOC-20090202366 FU2, US-JNJFOC-20080403865 FU2, US-JNJFOC-20080902386 FU3, US-JNJFOC-20080904835 FU2, US-JNJFOC-20081204254 FU1, US-JNJFOC-20081204254 FU2, US-JNJFOC-20081206437 FU3, US-JNJFOC-20090100065 FU1, US-JNJFOC-20090100065 FU2, US-JNJFOC-20090100065 FU3, US-JNJFOC-20090102891 FU1, US-JNJFOC-20090106668 FU1, US-JNJFOC-20090201807 FU1, US-JNJFOC-20090205904

Study: COG ADVL0525
SAE Posted: DE200901000697, US200902004840 FU1

Study: COG ADVL0821
SAE Posted: 09-13-00100, 1450957 FU1



Study: COG AEWS0521
SAE Posted: 1034535, 1201753, 1360351, 1475911 FU1, 1580693 FU1,
1951869 FU1, 1951869 FU2, 1987521

Study: COG AHOD0521
SAE Posted: 1073953, 1628411, 1673759

Corrections to Previous Postings

Adult Studies

Study Number

Documents Posted:
Correction:

- None

Pediatric Studies

Study Number

Documents Posted:
Correction:

- None

If review of this Website Postings Summary has prompted any questions, please forward them to the NCI CIRB_Operations Office Helpdesk at NCICIRBContact@emmes.com or call the CIRB HelpDesk toll-free at 888-657-3711.