



Alliance SDC Updates

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CRP Information Session, May 11th, 2017

Presentation Objectives

- CALGB System Retirement Project
 - Scope and deliverables
 - Timeline
 - Key Success Factors
 - Questions and Discussions
- Central Monitoring Role
- Terminated Studies
- Forms Consistency Task Force

CALGB

Systems Retirement Project

Vision

- Achieve the Alliance Statistics and Data Center 2012 grant objectives to consolidate the legacy cooperative group systems and retire aging systems.

CALGB Systems Retirement Project—Primary Objectives

- Migrate to RAVE or close out legacy trial.
- Deadline—December 29, 2017.
- Communicate as studies move to RAVE.

CALGB Systems Retirement Project

- 31 studies identified for migration to RAVE
 - ❖ 2 studies are actively accruing patients
- ~ 22 studies identified for termination

CALGB Systems Retirement Project

Study builds currently in process

- 10603
- 10701
- 10801
- 11001 (1st study to transition)
- 30601
- 30901
- 40503
- 50303
- 50403
- 50801
- 50803
- 50904
- 80405
- 80702
- 90203
- 90601
- 100104
- 100701
- 140503

What can you expect?

- Notification memos
- RAVE invite from iMedidata
- All your data will be batch uploaded and viewable within RAVE
- All future data collection and amendments done through RAVE
- Limited material tracking

Transition Memorandums

- A Memo will be issued 1 month prior to transition by the Protocol Office
- Second Memo will be issued 1 week prior
- 1 day prior to the transition users will get a iMedidata invite
- After the transition sites will be notified that all patients have been transitioned and the teleform is no longer available.

CALGB Systems Retirement

- Key Project Success Factors
 - Cooperation and patience from you, the memberships
 - Data Management activities
 - Study Build resources
 - SPA and IT support

Terminated Studies



Jennifer Darcy (log out)

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Welcome Jennifer

ANNOUNCEMENTS

Fast Approaching ... 2017 ALLIANCE SPRING GROUP MEETING

Be sure to register for the upcoming **2017 Alliance Spring Group Meeting** May 10-13 in Chicago, IL. [Click here](#) to register.

Agendas for some meeting sessions are now available. Check the meeting schedule aperiodically; it may be subject to change.

For more information about the meeting, feel free to contact Annie Colbert (Alliance Meeting and Operations Coordinator) by e-mail: acolbert1@partners.org or by phone: (617) 525-3022.

NEWS

Protocol

May 01, 2017 -	Alliance May 1, 2017 Bi-Monthly Update
April 19, 2017 -	CALGB 51101 Impending Closure Notice
April 14, 2017 -	Alliance April 15, 2017 Bi-Monthly Update

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STUDY TERMINATIONS OF PATIENT FOLLOW-UP

- ECOG-ACRIN Coordinated Studies Not Needing Further Data Submission - 12/01/2016
- Alliance Study Termination of Patient Follow-up Notices - 12/15/2014
- CALGB Studies with Termination of Patient Follow-up - 12/15/2013

Individual Notices:

- Termination of Patient Follow-up for A051201 & A051202 - 05/01/2017
- Permanent Closure of CALGB 49805 (JMA17) - 05/01/2017
- Termination of Patient Follow-up for CALGB 30504 - 04/01/2017
- Termination of Patient Follow-up for N0871 - 04/01/2017
- Termination of Patient Follow-up for A091102 - 03/15/2017
- Termination of Patient Follow-up for Z0011, Z4033, CALGB 150007, CALGB 20206, CALGB 20801, CALGB 60805, CALGB 90202, CALGB 500105, N03CC, N0539, N063I, N0923, N07C2, N08C1, N08C3, N08CB, N09C6, N10C2 - 01/15/2017
- Termination of Patient Follow-up for Alliance A091103, CALGB 10503, CALGB 30607, CALGB 30801, CALGB 369901, CALGB 80101, CALGB 90206 - 12/01/2016
- Termination of Patient Follow-up for CALGB 79809 - 08/01/2016
- Termination of Patient Follow-up for CALGB 40302 - 07/01/2016
- Termination of Patient Follow-up for CALGB 10501, 50401, 50701, 70301, and 100103 - 06/15/2016
- Termination of Patient Follow-up for CALGB 9710 - 12/15/2015
- Termination of Patient Follow-up for N0147 - 10/01/2015
- Termination of Patient Follow-up for CALGB 70604 - 08/15/2015
- Termination of Patient Follow-up for CALGB 9395, 9793, and 49802 - 05/01/2015
- Termination of Patient Follow-up for N0723 - 12/15/2014
- Termination of Patient Follow-up for CALGB 10105 - 11/15/2014
- Termination of Patient Follow-up for CALGB 10301 - 11/15/2014
- Termination of Patient Follow-up for CALGB 40101 - 11/15/2014
- Termination of Patient Follow-up for CALGB 50501 - 11/15/2014

Central Monitoring performed by the SDC

- Required Source Documentation Verification (SDV)
 - Eligibility
 - Treatment (1st 2 cycles)
 - End Points
- Central Monitor will be required to document review of SDV in RAVE
- Amended data breaks review flag and data will be re-reviewed
- Monitoring reports to be established

Forms Consistency Working Group

- Requesting more RAVE instructional text on the form
- Changes made to the DSS (Data Submission Schedule) to clarify protocol requirements
- Data Managers names added to Protocol landing page
- Cycles are being defined in protocol

Conclusion

- Questions from Audience
- Answers from Presenter