



Alliance Statistics and Data Center Updates

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Alliance 2015 Fall Meeting

Objectives

- Review Data Management Services updates
- Overview of Alliance Service Center news and accomplishments
- Understanding Delinquency/Overdue Reports
- Review Institutional Performance Evaluation Committee (IPEC) requirements and expectations
- Overview of upcoming Alliance SDC efforts

Data Management Services

- All new Alliance and legacy CALGB trials are located at the Alliance Data Management Services Unit at Mayo Clinic
 - Completed September 2015
- What process changes are being managed out of the Alliance Data Management Services Unit in Rochester, Minnesota:
 - Queries to site on data for all studies
 - Individual research files and associated documentation
 - Study Data Management support

Data Management Services

- Fax Number: 507-284-1902
- Please mail forms whenever possible, this allows for more efficient tracking

Alliance Statistic and Data Center(SDC)

Attention: Data Managers

RO FF-3-24-CC/NW Clinic

200 First Street SW

Rochester, MN 55905



Data Management Services

- Protocols are being updated to reflect the current Data Manager assignment
- Alliance Web Site reflects the specific list of studies which have transferred along with the correct contact numbers

Data Management Services

- Questions related to study assignment and overdue materials reports can be addressed at the ASC. Their toll free number is: 877-442-2542
 - allianceservicecenter@alliancencn.org
- AFT Service Center is not located in Rochester, MN, they are located in Boston, MA and can be reach at:
 - Info@alliancefoundationtrials.org

Alliance Service Center Staff



Alliance SDC: Other news/ accomplishments

- Roster Services – moved to Chicago in Mid-March
- Overdue Reports enhancements, tracking of Rave studies
 - Rostered CRP have access to their sites report
 - Legacy Report title changed to Delinquency/Overdue Reports and be found on Quick Links

Delinquency/Overdue Reports



Welcome

ANNOUNCEMENTS

Three Investigators Receive Funding Awards Through Alliance Cancer Control Program

Three Alliance researchers and junior investigators have been selected to receive annual funding awards to support their work through the Alliance NCI Community Oncology Research Program (NCORP) Research Base, which is supported by the NCI Division of Cancer Prevention (DCP) and administered through the Alliance Cancer Control Program (CCP). The annual awards include the **Alliance Cancer Control Program Pilot Project Award** and **Alliance Cancer Control Program Junior Faculty Award**.

PILOT PROJECT AWARD

William Wood, MD, MPH (University of North Carolina at Chapel Hill)

"Assessing physical fitness in cancer patients with cardiopulmonary exercise testing and wearable data generation: An Alliance pilot study proposal"

JUNIOR FACULTY AWARD

Eric Roeland, MD (UCSD Moores Cancer Center)

Mentor: **Charles Loprinzi, MD** (Mayo Clinic)

"A prospective pilot study to evaluate and correlate early lean muscle loss with functional activity in metastatic gastrointestinal and lung cancer patients"

Ashley Rosko, MD

Mentor: **Michelle Naughton, PhD** (Ohio State University Comprehensive Cancer Center)

"Identifying and maintaining fitness in hematologic malignancy: A clinical and biologic approach"

To learn more about the Alliance Cancer Control Program Pilot Project Award and Junior Faculty Award, visit the [Alliance Awards web page](#).

Quick Links

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Delinquency/Overdue Reports



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Delinquency/Overdue Reports

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Overdue Reports for trials utilizing JCCS or Rave data entry system (Alliance, Legacy ACOSOG and NCCTG)

- [Less Than 30 Days Overdue](#)
- [Materials Greater Than 30 Days Overdue](#)
- [Materials Greater Than 120 Days Overdue](#)
- [Materials Submission Completeness Rate](#)

Delinquency Reports for trials utilizing Teleform system (Legacy CALGB)

- [Delinquency](#)

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Overdue Report Example

Materials Due in 30 Days Report

1

Protocol, QCS, Phone	Patient, Initials, Date on, Last contact	Material	Item	Target Date	Overdue Date	Days Overdue
	02/24/2015 08/06/2015	Rave Form	Treatment 07: Discontinue/completed neoadjuvant treatment, proceeding to surgery, Patient Status: Treatment (Intervention)	10/15/2015	10/30/2015	4
	04/14/2015 09/04/2015	Rave Form	Treatment 06: Neoadjuvant endocrine therapy (Anastrozole and/or Fulvestrant), Endocrine Treatment	10/02/2015	10/17/2015	17
		Rave Form	Treatment 06: Neoadjuvant endocrine therapy (Anastrozole and/or Fulvestrant), Adverse Events: Solicited	10/02/2015	10/17/2015	17
		Rave Form	Treatment 06: Neoadjuvant endocrine therapy (Anastrozole and/or Fulvestrant), Patient Status: Treatment (Intervention)	10/02/2015	10/17/2015	17
	06/13/2014 04/10/2015	Rave Form	Clinical Follow-up 04, Adverse Events: Solicited	10/10/2015	11/09/2015	-6
		Rave Form	Clinical Follow-up 04, Patient Status: Clinical Follow-Up/Observation	10/10/2015	11/09/2015	-6
	02/24/2015					

Created on: November 3, 2015



Why so much focus on overdue reports?

Institutional Requirements for Memberships

- Data Quality and Timeliness
- Adherence to Alliance policies and procedures
- Satisfactory Audits

Institutional Performance Evaluation Committee (IPEC)

Performance criteria

- Eligibility rate
- Auditing outcomes
- Specimen quality
- Early termination rate
- Data submission timeliness
- Query response timeliness
- Specimen submission timeliness
- Audit participation

IPEC

- A score of 0 on any parameter means the site is meeting expectations for that criteria with a possibility of earning -2, -1, 0, +1, +2 points for most criteria
- Sites in general are doing very well
 - 92% of sites did well on the overall score across all 8 criteria (scored a 0 or higher)

IPEC, continued

- The majority of sites are NOT meeting expectations for data submission timeliness
 - 67% of sites received negative points (had < 80% of their forms submitted on time)
- IPEC is requesting feedback on the barriers to timely data submission

National Definitions

On Time

- Baseline forms: within 15 days of target date
- Treatment forms: within 15 days of target date
- Follow-up forms: within 30 days of target date

IPEC Scoring for Timeliness

Timeliness

Parameter	Values	Points
Data submission (% of <u>eCRFs</u> submitted on time)	<75%	-2
	75%-80%	-1
	80%-85%	0
	85%-90%	1
	>90%	2
Response to Queries (% of issued queries that were resolved on time)	<75%	-2
	75%-80%	-1
	80%-85%	0
	85%-90%	1
	>90%	2
Specimen Submission (% of baseline samples received on time)	<75%	-2
	75%-80%	-1
	80%-85%	0
	85%-90%	1
	>90%	2

Data Timeliness and Audits

- Delinquent data submission > 6 months is an example of a Major Deficiency in an Audit
- Delinquent data submission >3 but <6 months is a Lessor Deficiency in an Audit

Alliance SDC Future Efforts

- Lost to Follow Procedure
 - Form is being updated to allow sites to choose the manner in which they will consider a patient accessible for study data
- SC enhancements for reviewing eligibility and endpoints

Conclusion

- Questions from Audience
- Answers from Presenter