

Alliance Statistics and Data Center Updates

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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



- 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



- 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



- 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



- Questions related to study assignment and overdue materials reports can be addressed at the ASC. Their toll free number is: 877-442-2542
 - <u>allianceservicecenter@alliancenctn.org</u>
- 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







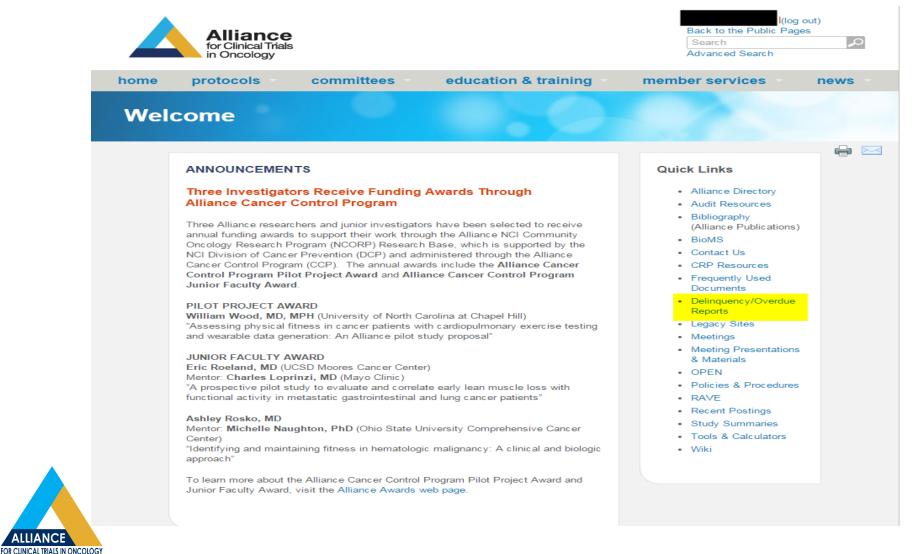
Alliance SDC: Other news/ accomplishments

- 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

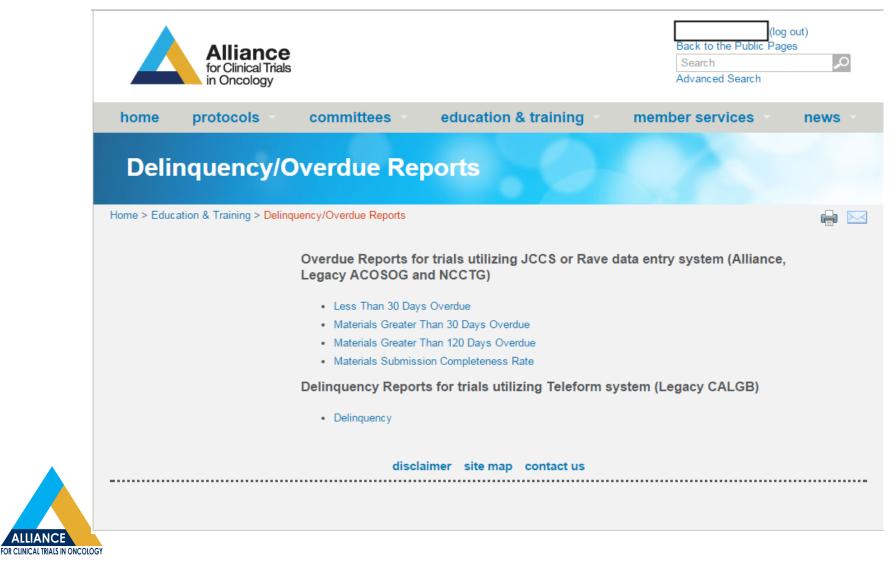


Delinquency/Overdue Reports

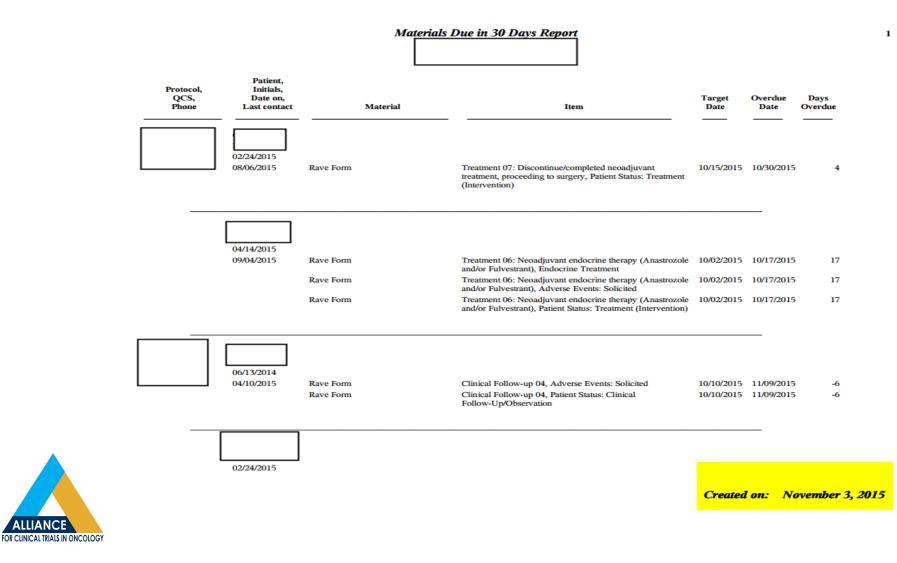
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Delinquency/Overdue Reports



Overdue Report Example



ALLIANCE

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 eCRFs 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

