



Reports and Manuscripts

Constance T. Cirrincione, MS
CALGB Statistical Center

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Reports

- Why monitor?
 - To ensure patient safety
 - To make competent decisions
 - To ensure credibility of results

P&P, Sec 6.4

Reports

- Types of monitoring
 - DSMB monitoring
 - Formal interim analyses
 - Progress reports
 - Conference calls
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Reports

- During patient accrual
 - After patient accrual
 - After release of results (DSMB)
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Reports: Phase I Studies

- Limited access
 - Fax AE data to Data Operations
 - Conference call, weekly/biweekly
 - Adverse events
 - Eligibility
 - Accrual
 - Report prepared by statistician
 - Active studies
 - Statistical summary, biannually to CALGB
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Reports: Phase II Studies

- For active studies
 - Statistical summary
 - Biannually to CALGB membership (web)
 - If NCI investigational drug
 - CDUS report
 - Quarterly to NCI
 - If multi-stage study
 - Interim/final analyses
 - Per analysis plan to study chair
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Reports: Phase III Studies

- For active studies
 - Statistical summary
 - Biannually to CALGB membership (web)
 - If NCI investigational drug
 - CDUS report
 - Quarterly to NCI
 - If treatment study
 - DSMB report
 - Biannually to DSMB
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Reports: Role of DSMB

- Treatment studies, i.e., cancer treatment
 - Biannually at Group meeting
 - Confidential
 - Formal report
 - Toxicity and efficacy by arm
 - Formal interim analyses per protocol
 - Until DSMB releases data to the committee
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Reports: Role of DSMB

- DSMB releases data to the committee
 - Committee decides how to disseminate
 - CALGB Committee (Core) meetings
 - External meetings (ASCO, Intergroup)
 - Press release
 - Abstract/manuscript
 - ‘Final’ statistical analysis
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Manuscripts: Prior to Writing

- Case evaluations
 - All/some cases (250)
 - CALGB database
 - Official repository of data
 - CALGB data ownership
 - Thorough data collection
 - Data forms
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Manuscripts: Writing

- *Timely fashion*
 - Collaboration with Statistician
 - Co-authorship
 - Intellectual and accrual contribution
 - Acknowledgement
 - All contributing institutions
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Manuscripts: Review

- Study team review
 - Group review
 - CALGB and non-CALGB contributors
 - Anne Battershell, Publications Coordinator, Central Office
 - Inform study team of status
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Manuscript: Publication

- Notify study team of publication
 - Send copy of the final manuscript to the Publications Coordinator at Central Office (Anne Battershell)
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Reports and Manuscripts

- Study team is a team effort
 - Study chair
 - Statistician
 - Data coordinator
 - Protocol editor
 - [Publications coordinator]
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