



20 Ways to Improve Your Patient Case Review Audit

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For CALGB Participants Only

Audit Outcome Summary

Component	Assessment	Followup Required (Y/N)	Followup Due	Reaudit Required (Y/N)	Reaudit Time (in months)
IRB and Informed Consent Content Review	Acceptable needs follow-up	Yes	07/01/2007	No	
Accountability of Investigational Agents and Pharmacy Operations Review	Unacceptable	Yes	07/01/2007	Yes	No Reaudit
Patient Case Review	Acceptable needs follow-up	Yes	07/01/2007	No	

Six Categories for Patient Case Review

1. Informed Consent
2. Eligibility
3. Treatment
4. Disease Outcome/Response
5. Adverse Events
6. General Data Management Quality

#20: Informed Consent

Confirm patient signs most recently approved Informed Consent Form (ICF) and be sure all blanks are completed, IRB required signatures obtained, and initials, etc., are present on the patient's ICF **before** registration.

#19: Eligibility

Secure all outside eligibility documentation of diagnostic reports, progress notes, past treatment and/or pathology review **before** patient registration.

#18: Eligibility

Review required surgical resection and path reports for meeting eligibility criteria. (e.g., 79803)

#17: Eligibility

Use a second set of eyes to review documentation for eligibility criteria ***before*** registration.

#16: Eligibility

Assure answers to stratification questions are accurate ***before*** registration.

#15: Treatment

Always review patient's side effects prior to writing chemo orders for each cycle.

#14: Treatment

Double check administration times –
e.g., Cycle 1 over 90 min, all others 30
min. (S0518)

#13: Treatment

If question in dose reductions vs hold,
contact Study Chair and save
documentation of correspondence.

#12: Treatment

Oral medications need clear
documentation of:

- 1) order
- 2) dispensation
- 3) adherence

#11: Disease Outcome/Response

For response criteria, follow the protocol directed requirements, obtaining the response results at the time points required, even in the post-treatment follow-up setting.

#10: Disease Outcome/Response

Refer to protocol definition of response with each response time point. This can differ between protocols.

#9: Disease Outcome/Response

For measurable disease, **ALWAYS** use baseline as comparison for response and utilize same mode for comparison, i.e. CT against CT.

#8: Disease Outcome/Response

Remember – several studies require response *Confirmatory Scans*.

#7: Adverse Events

Never guess – clarify all AE grades with treating investigator.

#6: Adverse Events

Confirm documentation of AE grades for dose modifications.

#5: Adverse Events

Refer to protocol for each unexpected AE for AdEERS and IRB submission instructions.

#4: General Data Quality

For accurate staging selection on data forms, confirm choices with the attending physician.

#3: General Data Quality

Review Data Submission requirements for study required imaging/radiology reports submissions.

#2: General Data Quality

Confirm protocol required Bone Marrow (BM) sample submissions with each scheduled BM along with study required stained and unstained slide submissions.

#1: General Data Quality

Review signed ICF for permission to submit correlative blood specimens at many different time points.

Resources

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**Cancer and Leukemia Group B
Summer Group Meeting**

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