

#19 – Use the Correct AE Codes

- Use correct version of the CTC or CTCAE and MedDRA codes
- There are no studies that use IMT codes

#18 – Use Grade 5 Correctly

- If patient is removed from protocol treatment for “Death on study”, then a Grade 5 event should be reported on the last Adverse Event form
- Report only one Grade 5 event per patient

#17 – Report AEs via AdEERS and AE Form

- Adverse events reported via AdEERS should also be reported on the study-specific adverse event form (*until the AE Reporting System application is available*)
- Event names, grades, and attributions should match exactly

#16 – Use CALGB ID as Patient ID

- On AdEERS reports, use the CALGB ID as Patient ID
- Do not use initials, hospital ID, or include a “C” or “CALGB”

#15 – Use LabTrak

- Use LabTrak
 - Samples can be logged in advance
 - CRAs can modify or delete samples or shipments
 - “Success” messages have been added to confirm sample logging and shipments
- For a complete list of recent changes see the LabTrak page on the CALGB member website (www.calgb.org)

https://www.calgbapps.org - CALGB Information Systems - Microsoft Internet Explorer provided by...

Cancer and Leukemia Group B • LabTrak

Welcome to CALGB LabTrak Login

This is a secure site. Unauthorized access is prohibited.
All activity on this site may be monitored.

Username:

Password:

Login

[change password](#)

LabTrak Documentation (What's New)

- [Initial Login Instructions to LabTrak](#)
- [LabTrak FAQs](#)
- [LabTrak Manual](#)
- [Subsampling Job Aid](#)
- [Logging and Shipping Job Aid](#)
- [Pre-Registration Job Aid](#)

[Contact Help Desk](#) | [CALGB Disclaimer](#)

#14 – Use Boxes Correctly

- Don't add decimal points, boxes, or use < or > signs
- If the value will not fit in the boxes, round the number
- If you think the format of the boxes is incorrect, contact the Data Coordinator (DC) at CALGB Statistical Center

#13 – Mark Boxes Correctly

- Mark Xs in the box. Do not use check marks. Do not X “around” the box .

Correct:

Incorrect:



- If directions say “Mark one with an X”, only mark one.

#12 – Limit Comments to Boxes

- Do not write comments outside the boxes provided on the forms
- Use C-260 or flow sheets to make additional comments

Type of Surgery

SURGERY ON

RIGHT KNEE

#11 – Use Study and Patient ID

- Complete Study number, Patient ID, and other data in upper, right box; including subsequent pages of multi-page forms
- Put Study number, Patient ID, and initials on every page of supplemental documentation
- Ensure dates are valid (i.e., 12/1/2005 – 1/3/2005)

#10 – Print and Fax Correctly

- Print and fax data forms at 100%
- Use a clear copy of the data form that contains the cornerstones and barcodes

#9 – Do Not Use -1

- If the question does not apply, leave the answer blank. Do not use ‘-1’ on TeleForm forms except Adverse Event Forms. Do not draw lines through questions.

#8 – Use Alpha and Numeric Characters Correctly

Do not:

U	N	/	K	N	/	O	W	N	
<i>M</i>	<i>M</i>		<i>D</i>	<i>D</i>		<i>Y</i>	<i>Y</i>	<i>Y</i>	<i>Y</i>

If unknown or not applicable, leave it blank.

#7 – Print, in Capital Letters, in Ink

- Print using CAPITAL letters or complete electronically
- Use blue or black ink only

#6 – Use the Correct Units

- Use the units provided on form
- If the units provided on the form do not match the units on the lab report, convert the value to the units on the form
- Your lab (or internet resources) may be able to assist you with this
- If you think the units are wrong, contact the DC at CALGB Statistical Center

#5 – Right Justify

- Right justify

	9	9	1	0	2
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 instead of

9	9	1	0	2	
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- Adobe 7 issue has been fixed

9	9	1	0	2			
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#4 – Follow the Protocol

- Be sure you are reading the most recent version of the protocol
- Submit data per data submission section of protocol even when resolving delinquent data

#3 – Complete Measurement Forms

- Complete measurement forms carefully, including:
 - Dates of assessment
 - Units
 - Response statuses
 - Lesion descriptions
 - Methods of evaluation

#2 – Understand Delinquency List Procedures

- Sending old data will not remove patient from a delinquency list
- Lost patients will remain on the delinquency list even if new data is submitted to report the patient is still lost

#1 – Report Response Correctly

- Best response, overall response, best overall response, objective response, best overall objective response all mean the same thing.
- Best response is the best response observed since patient started protocol treatment. It cannot worsen over time. For example, if patient achieves a PR but then later progresses, the best response is still PR.

Resources

- Protocol
- CRA Resources at www.calgb.org
- Instructions for Completing Forms
http://www.calgb.org/Private/COOP_Groups/CALGB/studies/forms/TELEform_Instructions.pdf

