

# SWOG Data Submission Tips

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## General

### Reporting periods

1. The reporting period start date is Day 1 of the cycle.
2. The reporting period end date is day 1 of the next cycle, unless final cycle, then it is last day of treatment.
3. There should be no gaps in reporting periods.

### Treatment Dates

These should reflect the first and last day of actual treatment given. A date entered implies treatment was given. If only 1 day of treatment is given, first and last days should be the same.

### Lab Values

This is one of the most common queries and often delays eligibility. Check Lab Test Units. For example: ANC  $\mu$ l (xxxx), this should be reported in microliters and be 4 digits. If you enter in 17 when it is actually 1700 the patient will be coded as ineligible.

### Unknown Dates

If the exact *date* is unknown, and UNK is not an option, enter in 15 and explain in the comments section at the bottom of the form. If the *month* is unknown and UNK is not an option, enter in June then explain in the comments section at the bottom of the form.

### FUTAs (Follow-up Tumor Assessments)

Section 10 of the protocol requires that the same assessment used at baseline be used throughout the study at each assessment.

### Last Contact Date

Is last contact date the same as a clinic visit or toxicity assessment date? Not necessarily. The LCD is simply the last date you can attest to the survival status of a patient. This can be a phone call, a visit to the ER or other office outside your clinic, even a twitter update.

## **Pre-Rave Data Submission**

These studies are not in RAVE. Study Data is submitted through the CRA Workbench on the SWOG website. CTSU sites access the CRA workbench:

<https://crawb.crab.org/TXWB/FormsCS/PatLookup.aspx>

### Edit Checks

Errors (red light  ) must be fixed before form can be submitted

Warnings (yellow light  ) must be acknowledged before form can be submitted

Green light (  ) means successful submission

### Amending Forms

If it is an online amendable form, it needs to be amended online, do not fax or email it. Click the link for the existing form to make changes. Do not create a new form. The new form will not be recognized by the system and can prevent other forms from being submitted successfully.

Forms *not* amendable online, need to be hand amended then faxed or emailed. For forms originally submitted on paper, write "amended" at the top of amended forms and mark amended data and circle. Draw a line through the incorrect entry, write the correction next to it and initial the change. Example: Confirmation of Registration form.

## **RAVE Data Submission**

### Submit Data

There is a link for iMedidata RAVE available through the 'Data Submission' link on the CRA Workbench on the SWOG.org website or directly through the website:

<https://login.imedidata.com/>

### Non-Conformant Errors

Fix them right away. NC errors prevent data transfer and thus do not resolve expectations. If you are unable to fix right away: call your Data Coordinator.

### Common Non-conformant Errors and Fixes:

Entering data instead of choosing from the dropdown options, for example: choosing an AE grade.

- Edit the field by clicking on the pencil icon on the right. Using your mouse, select a grade from the drop-down field (do not enter a digit) and select anything other than current entry and then save your changes. Then, go back in and edit the field, again, selecting the correct option from the drop down using your mouse, and save the changes.

Letters entered where a number is expected and vice versa

- Remove your entry, save the form, then enter in data in the expected format.

Entries made in incorrect format

- Value entered as 26.13 when the field accepts (xx.x)

### Responding to Queries

Perform the task, and then close the query. If you don't understand the query or think the query was written in error, call your DC.

### Conditional Forms

Forms that populate based on information entered on other forms. Example: Off Treatment form populates when a treatment form is submitted that says the patient will *not* continue with treatment. Conditional forms only become available once the form is saved.

### Conditional Fields

Portions (questions) on a form that generate based on supplied answers. Example: S1404 staging, if M0 is selected then T&N field becomes available. Conditional fields only become available once the form is saved.

## **Leukemia, Myeloma and Lymphoma**

### Response Assessments

Section 10 of the protocol explains how your study records response and what methods it uses. The same tests used at baseline must be used throughout the study at each assessment. For example: UPEP (Urine Protein Electrophoresis) and Immunofixation are both required at each assessment for S1304 and S1211.

### Lab Values

This gets its own category because if you've worked on these studies you know how complicated these can get especially since many labs have different names for the same thing. Some studies require the lab to fill out the forms then give them to CRA to submit. If this is not the case with your study you may want to become friends with your Clinical Lab Technician so they can help decipher the forms.

