



TrialMaster EDC System Updates



Changes to the Lab Results Screen in TrialMaster:

1. A date field is now located next to each lab value, in a column titled “Draw”. The same Lab Results Screen is used for both Routine and for Repeat labs.
 - **Routine** labs for Baseline or visits 1, 2, 5, 10, 15, 20, 25, 30, 36 and 40 – enter the date and value for each lab drawn/collected.
 - **Repeat** labs redrawn per protocol due to *Lab Alerts* or *Lab Delays*
 - TrialMaster® automatically adds another lab screen or screens to the same infusion visit. The added lab screen(s) will be numbered **12** or higher. This screen is to be used to enter the redrawn labs. It will already contain the results and dates from the previous lab screen documented in the infusion visit. **Warning: Be careful not to SIGN this form until the redrawn lab values have been entered!**
 - To enter redrawn results and dates on this added lab results screen:
First, delete the date and value of the previous lab(s) and enter the date and value for the redrawn lab(s).
Second, add 2 **Change Notes** for each redrawn lab: one for the changed lab value and one for the changed draw date.
2. **The Unscheduled Lab Screen will no longer be used.**
3. Quest Laboratory reports neutrophil values as both Neutrophils (10^3 cells/ μ L) and Absolute Neutrophils (cells/ μ L). For TACT, enter results as **Absolute Neutrophils** in cells/ μ L. This will be a 4 or 5 digit number and the normal range is 1500 to 7800 cells/ μ L.
 - **Review all previous Absolute Neutrophil results**
 - **Change any result in the iCRF that is not an Absolute Neutrophil**
4. Since Quest Laboratory does not report the LDL cholesterol results when the triglyceride value is greater than 400; the LDL field may be left blank. A general note of explanation should be added.

Other Changes

Subject Information Screen:

The randomization date field will now auto fill as soon as the “Randomized?” question is answered “Yes”.

TrialMaster® E-Mail

The e-mail address book is now in alphabetical order by last name.

Accu-Care Services Pharmacy can now be located in the e-mail list as “Pharmacy”.