CRIO eSource Validation- Study Specific

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1. Validation will occur in the "configure" screen. This is an update as prior to this date validation occurred using a "test subject". This was found to be cumbersome and added an extra cost to the site. Validating in the preview screen of the configure module in CRIO allows for quick edits and has shown to be more effective.
2. Check the order of events to ensure that study procedures are completed in the following order UNLESS DICTATED OTHERWISE IN THE PROTOCOL
    a. Informed Consent/Reconsent
    b. Demographics
    c. Medical History
    d. Concomitant Medications
    e. Patient Reported Outcome (PROs) Questionnaires
    f. Vitals
    g. ECG
    h. Blood/Urine Collection
    i. Physical
3. Using the eCRF completion guidelines and ensure the following FOR EACH page:
    a. For datapoints check if date or date AND time need to be collected
    b. Make sure terms match that found in the eCRF (ie. Death vs Fatal)
    c. Make sure all data points needing to be recorded in eCRF are collected on eSource.
4. Using the Protocol ensure the following:
    a. Ensure any protocol required instructions are included on the eSource (ie. "subject must be sitting for 3 minutes prior to vital measurements being taken"). Cutting and pasting instruction from the protocol directly into the eSource is fine- be sure to check formatting as many times CRIO omits paragraph spacing and this makes reading the instructions difficult.
    b. Ensure protocol data points that are exclusionary (i.e.. subjects BMI is too high) that eSource triggers a warning message to not move on and/or correct criteria)
    c. Double check that all visits are appropriately spaced per the Time & Events schedule.
    d. Ensure all footnotes noted on Time & Events schedule are captured appropriately in eSource
    e. Ensure each procedure (i.e., ECGs, vitals, neuro exam, etc.) are captured in the manner in which they are dictated by the protocol.
    f. Ensure each procedure required in the protocol (both on the Time & Events Schedule AND within the body of the protocol) are captured in each study visit.