<u>Validation CHECKLIST</u>

<u>Informed Consent:</u>
□ Correct ICF(s) uploaded to source (Study-Overview-Documents)
□ SOP language included in ICF instructions

<u>Time and Events Schedule</u>
□ Make sure the T&E and the study table match.
□ Make sure the order the events are in match the order required by the protocol. If the protocol is not specific about some of the procedures (typically when medical history, conmeds, demographics, etc) are captured order it in a manner that makes sense to the workflow at our site.

<u>Inclusion/Exclusion</u>
□ Inclusion and exclusion matching from Protocol to source

<u>IWRS</u>
□ Question stating was the subject ID created
□ Add a question stating what is the ID number with a text box

<u>Individual Pages</u>
□ Page by page match eSource to eCRF completion guidelines to make sure we're capturing what needs to be collected

□ Also look for any redundancy in the eSource. For example, if it's asking for the ICF version number delete this as that version number can be found on the ICF itself.   Or if it's asking for lab accession numbers these, too, can be found directly on the lab requisition form that we already upload into eSource.

<u>Link to Traits Study</u>
□ For Demographics, Vitals, Concomitant Medications, Concomitant Procedures and Medical History, link these to the Trait Study by clicking "Sync with Patient Procedure" in the Configure > Customize Section on the top right site of the page.
□ For these to link to the Trait Study make sure the variable name EXACTLY matches the following:

Demographics
Birth Date: birth_date
Age: age_screening
Gender: gender

Vitals
Height: height_in
Weight: weight_lbs

Concomitant Medication
Medication: medication
Reason: reason
Start Date: start
Stop Date: stop

Concomitant Procedures
Procedure: procedure
Reason: reason
Start Date: start
Stop Date: stop

Medical History
Issue/Finding: finding
Start Date: start_date
End Date: end_date