

**Validation CHECKLIST**

Informed Consent:

□ Correct ICF(s) uploaded to source (Study-Overview-Documents)

□ SOP language included in ICF instructions

Time and Events Schedule

□ 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.

Inclusion/Exclusion

□ Inclusion and exclusion matching from Protocol to source

IWRS

□ Question stating was the subject ID created

□ Add a question stating what is the ID number with a text box

Individual Pages

□ 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.

Link to Traits Study

□ 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