



Note to File

Principal Investigator: XXXXX, XX

Protocol: C4591001

Site Number: XXX

Date: September 17, 2020

Regarding: IMPALA Randomization and drug assignment confirmation printouts in research charts

This Note to File serves as notification that confirmation printouts of research participant drug assignments will not be placed within participant charts for study C4591001. Inclusion of the drug assignment confirmation will disclose drug dosage information contraindicated for study blinding. It is for this purpose that the confirmation of drug assignment is located in Complion within the unblinded binder. This note to file addresses IMPALA drug assignment confirmation requested in study source document versions 1 through 5.

An update the source document removing this requirement has been created in follow-up to this Note to File.

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Signature: Director QA/QC, Regulatory, Training

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