

CCR Number	ESUB-055
Title	Addition of BL BE Study Design Question to BL BE Study QbR Template
Business Owner	ONADE
Change Type	Enhancement
Components	Submission Type: J-E-BQ
Severity	High
Application Release	Version 1.05.00 – 2/12/2018

Change Description

Previously, when selecting “Blood Level Bioequivalence Study” as the type of protocol you are submitting within the General Information screen, the full set of QbR questions were enabled. All other responses used the standard form allowing for the upload of the protocol PDF file.

With the latest change, a new question has been added related to the design of your Blood Level Bioequivalence Study. The new question is only presented when “Blood Level Bioequivalence Study” has been selected as the type of protocol you are submitting. The options within the new question are “Crossover (including RSABE analysis) or Parallel Design” and “Alternate Design.” If selecting “Crossover (including RSABE analysis) or Parallel Design” the full set of QbR questions are enabled. If selecting “Alternate Design” the standard form allowing for the upload of the protocol PDF file is enabled.

New Design of your Blood Level Bioequivalence Study Question

The screenshot shows a software interface with a light blue header that reads "Use SI units in any responses where units are requested". Below this is a question: "What type of protocol are you submitting?". A dropdown menu is open, showing "Blood Level Bioequivalence Study" selected. Underneath, a sub-question is displayed: "What is the design of your Blood Level Bioequivalence Study?". A second dropdown menu is open for this question, showing two options: "Crossover (including RSABE analysis) or Parallel Design" and "Alternate Design".