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To: [Patel, Manisha \(manisha.patel@novartis.com\)](#)
Cc: [Riggins, Cindy](#); [narin.ahmed@novartis.com](#)
Subject: BL 125646 Clinical Information Request
Date: Monday, July 17, 2017 7:33:28 PM
Attachments: [image001.png](#)

Good evening,

Please see the information request below and provide a response by noon tomorrow, July 18, 2017. As usual please respond directly to this e-mail and provide the information as an official amendment to the BLA.

Please send us definitions for the following:

- acute renal injury
- acute renal failure
- Dialysis
- Continuous venovenous hemofiltration (CVVH)

Please send a Excel spreadsheet with the unique patient identifiers for all of the subjects on B2202 that fall under these categories.

Please include creatinine levels and duration of the time that subjects had abnormal levels.

Please provide the relative start and stop dates for the dialysis and CVVH as well as the duration.

Please also provide start and stop dates for renal injury and renal failure.

Please confirm receipt of this request.

Thank you,

Erica Giordano

Regulatory Project Manager

Center for Biologics Evaluation and Research

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