

Davidson, Mark

From: Davidson, Mark
Sent: Tuesday, April 11, 2017 3:14 PM
To: Rizwana Sproule
Cc: 'Alex Babayan'
Subject: RE: BLA 125643/0 Rolling Submission: Site Selection Request for Information

Importance: High

Dear Dr. Sproule,

We have the following request for information:

To facilitate the selection of the clinical sites for inspection, submit as a dataset (1 site per row) the following information from the clinical trial ZUMA1. Submit this information as a SAS transport file, and include a define.pdf file.

Please respond by close of business Thursday, April 13, 2017.

- Site number
- Principal investigator
- Location: Address, City, State, Country
- Contact Information: Name, Phone, Fax, Email
- Number of subjects who signed informed consent
- Number of subjects who received leukapheresis
- Number of subjects who received KTE-C19
- Number of subjects who achieved CR or PR, per investigator
- Number of subjects who achieved CR or PR, per central review
- Number of subjects who achieved CR, per investigator
- Number of subjects who achieved CR, per central review
- Number of major protocol violations
- Number of deaths
- Number of subjects who experienced SAEs

Thank You

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