

## Davidson, Mark

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**From:** Davidson, Mark  
**Sent:** Tuesday, April 04, 2017 4:38 PM  
**To:** 'Rizwana Sproule'  
**Cc:** 'Alex Babayan'  
**Subject:** RE: BLA 125643/0 Rolling Submission: Define File Error  
**Attachments:** kte-c19- 101 - Data tabulation data definition, define-1 screenshot..doc; kte-c 19- 101, analysis data definition, define screenshot.doc

**Importance:** High

Dear Dr. Sproule,

The dataset definition file (define-1) does not open definition tables in a user friendly format and we cannot access the definition tables for the study datasets. Please submit the define file as define.pdf or other user friendly define.xml files. The define-1 screenshot displays the error, and the analysis define screenshot displays the correct file. Please provide this file ASAP so that we can go through the data for acceptance and eventually to issue inspections. If you have any questions, please don't hesitate to contact me.

See attached.

Thank You

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