To whom it may concern,

We would like to inform you that the following has been added to the statistical plan of our proposal based upon a request from VIVLI. The purpose of this amendment is to explain our statistical plan to better understand the purpose of our study and how the analysis will be conducted.

The added text: “Data from the clinical trials will be assessed based on the disease type (UC or CD) for patients treated with ustekinumab or vedolizumab and will be stratified into three categories: prior failure of 1 biologic, prior intolerance of 1 biologic, and biologic naive.  Vedolizumab and ustekinumab-treated patients will be analyzed separately to determine if there are differences in patterns of response for biologic failure and intolerant patients for the different biologics.  Clinical response, clinical remission, and mucosal healing will be assessed and compared for each category in both disease types.”

The date of amendment is: Feb 12, 2024

Regards,

Hasan Hamam