

From: Morris, Nevitt  
To: Jim.wang@sparktx.com  
Cc: Morris, Nevitt  
Subject: BLA 125610 Information Request Clinical 9/4/17  
Date: Monday, September 04, 2017 4:13:01 PM  
Attachments: image001.png

Hi Jim:

Could you please respond to the following Information Request (below) as soon as possible:

Clinical Information Request:

In the table below, which assess the T-cell immune response,

For Study 102, the table refers to a "low response", suggesting that the measurement system might be "low", "medium", and "high".

For Study 301, the table refers to a "weak" response and a "moderate" response, suggesting that the measurement system might be "weak", "moderate", and "strong".

For Study 303, the table refers to a "positive" response, suggesting that the measurement system might be "positive" and "negative".

What is the relationship between low and weak and positive? Is there any chance of standardization across these studies, for the purposes of this table?

Tests Study 101 (n=12) Study 102 (n=11) Study 301 (n=21) Study 302 (n=9)

Human PBMC Interferon-. Responses to AAV2 and RPE65 by ELISPOT at BL, Days 14, 30, and 90 No T cell response to AAV capsid and RPE65 Six subjects with low response at single time point Three subjects with weak to moderate response at single time point Five subjects had positive response at single time point

Source: Section 2.7.4.4 Cell-mediated and humoral immune response with modification Please acknowledge receipt of this email Information Request. Thanks Nevitt

Nevitt Morris

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