

Telecon Summary

FDA Participant:

Sudhakar Agnihothram

Moderna Participant:

Michelle Olsen

Date and Time

December 6, 2021 12:15 PM EST

Discussion:

FDA reached out to Moderna to seek an update on Moderna's response to FDA's 11.10.21 comments (attached to this document), related to their pediatric development program. Moderna responded that they plan to provide a response by 12.17.21. Since the materials for the PeRC review of Moderna's agreed iPSP were due on 12.10.21, FDA requested Moderna to provide a high-level response on their pediatric development plans, by 12.8.21.