

Teleconference record for 125426 regarding pediatric study plan timelines:

- After introductions and establishing that the reason for the teleconference was to update FDA on the status of pediatric studies and subjects, FDA reviewed prior communications regarding plans for pediatric clinical trials. We noted that we could not locate timelines for existing and proposed pediatric trials.
- Emergent BioSolutions agreed to submit the estimated timelines and inquired which method was preferred. FDA indicated that a new amendment with the information in the cover letter would be acceptable.
- FDA sought further information on the status of pediatric subjects and studies.
 - Protocol IB1001-01 is ongoing. No pediatric subjects have received modified IB1001. The youngest subject having received mod-IB1001 is 24 years old.
 - Protocol IB1001-02 is ongoing and enrolling subjects in the U.K. and India. Seven subjects have been enrolled between ages 4 and 12 and have received mod-IB1001. No data have yet been submitted to FDA. The data are being collected and cleaned for submission [presumably as an annual report or other regulatory document].
 - Protocol IB1001-03 is still in the development phase. No protocol has been submitted.
 - Protocol IB1001-04 has not been initiated and is on internal hold within the company.

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