Pediatric Study Progress[1]

The following table provides statistics on the progress of studies with a due date of September 27, 2007, or later. Many of these studies are from deferrals granted prior to passage of the FDA Amendments Act (FDAAA). These statistics reflect data collected through December 31, 2023.

CDER Total Number of Studies	**Total**
CDER Total Number of Studies Completed by Due Date[2]	460
CDER Total Number of Studies Pending on Due Date[2]	304
CDER Total Number of Studies that have not Reached Due Date	481
CDER Total Number of Studies with a Due Date of 9/27/07 or Later	1245

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1. In accordance with Section 505B(f)(6)(D) of the Food, Drug, and Cosmetic Act.

2. Please note that all studies deferred under PREA are considered Postmarketing Requirements (PMRs) and are assigned a specific status depending on their progress. The following points discuss how such studies were counted. For a list of PREA PMR Status definitions please scroll down.

a. Any studies that were Released by their due date are not included in any of these statistics.
b. "Number of Studies Completed by Due Date" includes only those studies with a PMR status of Fulfilled or Submitted by the due date. Please note that the Submitted status is retained until the FDA determines whether the requirement has been satisfied. If the data Fulfilled the PMR then the study would remain in the “Number of Studies Completed by Due Date”. If the data had not Fulfilled the PMR and the due date had passed then it would be moved to “Number of Studies Pending on Due Date”.
c. "Number of Studies Pending on Due Date" includes anything that was still Pending, Ongoing, Delayed, or Terminated as of the due date as well as Submitted studies that had not Fulfilled the PMRs (see above) or any studies Released after the due date had passed.

The definition for each PMR status follows:

Pending: The study has not been initiated (i.e., no subjects have been enrolled or animals dosed), but does not meet the criterion for delayed (i.e., the original projected date for initiation of patient accrual or initiation of animal dosing has not passed).

Ongoing: The study is proceeding according to, or is ahead of, the original schedule. The FDA considers a study to be ongoing until a final study report is submitted to the FDA, as long as the activities are proceeding according to the original study schedule. If patient accrual or animal dosing has started but is not complete, and the projected date for completion of that milestone has passed, the study should be categorized as delayed.

Submitted: The applicant has concluded or terminated the study and has submitted a final study report to the FDA, but FDA has not yet notified the applicant in writing that the study commitment has been fulfilled or that the commitment has been released.

Fulfilled: The applicant has submitted the final study report for the commitment, and upon review of the final study report, FDA is satisfied that the applicant has met the terms of the commitment.

Released: FDA has informed the applicant that it has been released from its obligation to conduct the postmarketing study because the study is either no longer feasible or would no longer provide useful information.

Delayed: The progression of the study is behind the original study schedule. Delays can occur in any phase of the study, including patient enrollment, analysis of study results, or submission of the final study

report to the FDA. While the original study schedule — not a revised schedule — serves as the basis for defining a study as delayed, each phase of the study will be considered in its own right. If the applicant has one delayed phase, but gets back on schedule during the next phase, the delayed status will no longer apply.

Terminated: The applicant ended the study before completion, and has not yet submitted a final study report to the FDA.

CDER = Center for Drug Evaluation & Research

For more information on postmarketing requirement and commitment studies and clinical trials that occur after a drug or biological product has been approved by FDA please visit the http://www.accessdata.fda.gov/scripts/cder/pmc/index.cfm.