

Thanks for your patience. Please see the response below, which can be attributed to an FDA spokesperson.

Response

During clinical trials, study sponsors (vaccine manufacturers, clinical investigators, etc.) are required to report serious adverse events to the FDA. This includes unexpected fatal or life-threatening suspected adverse reaction reports, for which sponsors must notify the FDA as soon as possible, but no later than 7 calendar days after the sponsor's initial receipt of the information (see 21 CFR 312.32(c)(1) and 312.32(c)(2), which may be found [here](#)).

For the clinical trials of the Moderna COVID-19 Vaccine that were the basis of the Emergency Use Authorization (EUA), there were no deaths reported in any age group (6 through 23 months of age; 2 through 5 years of age; 6 through 11 years of age; and 12 through 17 years of age). The FDA's Decision Memorandum, which describes the agency's evaluation of the studies including the safety data, is posted on the FDA's [web site](#), document name "r_EUA 27073_Moderna COVID-19 Vaccine_Pediatric EUAs Decision Memorandum.final.pdf".