
42 C.F.R. § 11.60

What requirements apply to the voluntary submission of clinical trial information for clinical trials of FDA-regulated drug products (including biological products) and device products?

(a) If a responsible party voluntarily submits clinical trial information for a clinical trial described in paragraph (a)(1) of this section, the responsible party must meet the conditions specified in paragraph (a)(2) of this section.

(1) The requirements of paragraph (a) of this section apply to a clinical trial that was initiated before January 18, 2017 and has a primary completion date before January 18, 2017, and that is either:

(i) A clinical trial of an FDA-regulated drug product (including a biological product) or device product that is not an applicable clinical trial, or

(ii) An applicable clinical trial that is not otherwise required to submit clinical trial registration information.

(2) If the responsible party for a clinical trial described in paragraph (a)(1) of this section voluntarily submits clinical trial registration information and/or clinical trial results information, the responsible party must comply with the following requirements:

(i) The responsible party must submit the information in paragraphs (b)(2)(i)(A), (B), or (C) of this section for the clinical trial being submitted voluntarily.

(A) If the responsible party voluntarily registers a clinical trial, the responsible party must submit clinical trial registration information specified in section 402(j)(2)(A)(ii) of the Public Health Service Act (42 U.S.C. 282(j)(2)(A)(ii)).

(B) If the responsible party voluntarily submits clinical trial results information for a clinical trial for which the clinical trial registration information specified in section 402(j)(2)(A)(ii) of the Public Health Service Act (42 U.S.C. 282(j)(2)(A)(ii)) has not been submitted, the responsible party must submit the clinical trial results information specified in sections 402(j)(3)(C) and 402(j)(3)(I) of the Public Health Service Act (42 U.S.C. 282(j)(3)(C) and 42 U.S.C. 282(j)(3)(I)).

(C) If the responsible party both voluntarily submits clinical trial registration information and voluntarily submits clinical trial results information, the responsible party must submit both clinical trial registration information specified in section 402(j)(2)(A)(ii) of the Public Health Service Act (42 U.S.C. 282(j)(2)(A)(ii)) and clinical trial results information specified in sections 402(j)(3)(C) and 402(j)(3)(I) of the Public Health Service Act (42 U.S.C. 282(j)(3)(C) and 42 U.S.C. 282(j)(3)(I)).

(ii) If, on or after September 27, 2007, a manufacturer submits an application or premarket notification to FDA for approval, licensure, or clearance of a drug product (including a biological product) or device product under sections 505, 510(k), 515, or 520(m) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355, 360(k), 360e,

360j(m)) or section 351 of the Public Health Service Act (42 U.S.C. 262) for the use studied in the clinical trial submitted under paragraph (a)(1) of this section, the responsible party specified in paragraph (a)(1) of this section must also submit the information specified in paragraph (a)(2)(iii) of this section by the deadline specified in paragraph (a)(2)(iv)(B) of this section for any applicable clinical trial that has not been submitted to *ClinicalTrials.gov* and that meets the following criteria:

(A) The applicable clinical trial is required to be submitted to FDA under sections 505, 510(k), 515, or 520(m) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355, 360(k), 360e, 360j(m)) or section 351 of the Public Health Service Act (42 U.S.C. 262) in an application or premarket notification for approval, licensure, or clearance to market the drug product (including a biological product) or device product for the use studied in the clinical trial specified in paragraph (a)(1) of this section; and

(B) The manufacturer of the drug product (including a biological product) or device product studied in the applicable clinical trial is also the responsible party for the clinical trial specified in paragraph (a)(1) of this section.

(iii) Information to be submitted for clinical trials described in paragraph (a)(2)(ii) of this section:

(A) If the clinical trial information voluntarily submitted for a clinical trial described in paragraph (a)(1) of this section consists only of the clinical trial registration information specified in section 402(j)(2)(A)(ii) of the Public Health Service Act (42 U.S.C. 282(j)(2)(A)(ii)), the information to be submitted in accordance with paragraph (a)(2)(ii) of this section must consist, at minimum, of the clinical trial registration information specified in section 402(j)(2)(A)(ii) of the Public Health Service Act (42 U.S.C. 282(j)(2)(A)(ii)).

(B) If the clinical trial information voluntarily submitted for a clinical trial described by paragraph (a)(1) of this section consists of the clinical trial results information specified in sections 402(j)(3)(C) and 402(j)(3)(I) of the Public Health Service Act (42 U.S.C. 282(j)(3)(C) and 42 U.S.C. 282(j)(3)(I)), the information to be submitted in accordance with paragraph (a)(2)(ii) of this section must consist of the clinical trial results information specified in sections 402(j)(3)(C) and 402(j)(3)(I) of the Public Health Service Act (42 U.S.C. 282(j)(3)(C) and 42 U.S.C. 282(j)(3)(I)).

(C) If the clinical trial information voluntarily submitted for a clinical trial described by paragraph (a)(1) of this section consists of both the clinical trial registration information specified in section 402(j)(2)(A)(ii) of the Public Health Service Act (42 U.S.C. 282(j)(2)(A)(ii)) and the clinical trial results information specified in sections 402(j)(3)(C) and 402(j)(3)(I) of the Public Health Service Act (42 U.S.C. 282(j)(3)(C) and 42 U.S.C. 282(j)(3)(I)), the information to be submitted in accordance with paragraph (a)(2)(ii) of this section must consist of both the clinical trial registration information specified in section 402(j)(2)(A)(ii) of the Public Health Service Act (42 U.S.C. 282(j)(2)(A)(ii)) and the clinical trial results information specified in sections 402(j)(3)(C) and 402(j)(3)(I) of the Public Health Service Act (42 U.S.C. 282(j)(3)(C) and 42 U.S.C. 282(j)(3)(I)).

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