COSMOS
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42 C.F.R. § 11.28

What constitutes clinical trial registration information?

(a) For each applicable clinical trial that must be registered with ClinicalTrials.gov, other than a pediatric postmarket surveillance of a device product that is not a clinical trial, the responsible party must submit the following information:

(1) For such applicable clinical trials that were initiated before January 18, 2017, the responsible party must submit the information specified in section 402(j)(2)(A)(ii) of the Public Health Service Act (42 U.S.C. 282(j)(2)(A)(ii)).

(2) For such applicable clinical trials that are initiated on or after January 18, 2017, the responsible party must submit the data elements listed below:

(i) Descriptive information:

(A) Brief Title;

(B) Official Title;

(C) Brief Summary;

(D) Primary Purpose;

(E) Study Design;

(F) Study Phase, for an applicable drug clinical trial;

(G) Study Type;

(H) Pediatric Postmarket Surveillance of a Device Product, for an applicable device clinical trial that is a Pediatric Postmarket Surveillance of a Device Product;

(I) Primary Disease or Condition Being Studied in the Trial, or the Focus of the Study;

(J) Intervention Name(s), for each intervention studied;

(K) Other Intervention Name(s), for each intervention studied;

(L) Intervention Description, for each intervention studied;

(M) Intervention Type, for each intervention studied;

(N) Studies a U.S. FDA-regulated Device Product;

(O) Studies a U.S. FDA-regulated Drug Product;

(P) Device Product Not Approved or Cleared by U.S. FDA, if any studied intervention is a device product;

(Q) Post Prior to U.S. FDA Approval or Clearance, for an applicable device clinical trial that studies at least one device product not previously approved or cleared by the U.S. FDA;

(R) Product Manufactured in and Exported from the U.S., if the entry for U.S. Food and Drug Administration IND or IDE Number in § 11.28(a)(2)(iv)(C) indicates that there is no IND or IDE for the clinical trial, and the entry(ies) for Facility Information in § 11.28(a)(2)(iii)(C) include no facility locations in the United States or its territories;

(S) Study Start Date;

(T) Primary Completion Date;

(U) Study Completion Date;

(V) Enrollment;

(W) Primary Outcome Measure Information, for each primary outcome measure; and

(X) Secondary Outcome Measure Information, for each secondary outcome measure.

(ii) Recruitment information:

(A) Eligibility Criteria;

(B) Sex/Gender;

(C) Age Limits;

(D) Accepts Healthy Volunteers;

(E) Overall Recruitment Status;

(F) Why Study Stopped;

(G) Individual Site Status; and

(H) Availability of Expanded Access. If expanded access is available for an investigational drug product (including a biological product), an expanded access record must be submitted in accordance with § 11.28(c), unless an expanded access record was submitted previously in accordance with that provision.

(iii) Location and contact information:

(A) Name of the Sponsor;

(B) Responsible Party, by Official Title; and

(C) Facility Information.

(iv) Administrative data:

(A) Unique Protocol Identification Number;

(B) Secondary ID;

(C) U.S. Food and Drug Administration IND or IDE Number;

(D) Human Subjects Protection Review Board Status;

(E) Record Verification Date; and

(F) Responsible Party Contact Information.

(b) Pediatric postmarket surveillance of a device product that is not a clinical trial. For each pediatric postmarket surveillance of a device product that is not a clinical trial, the responsible party must submit the following information: