Recording Regulatory Information - Include 20170413

Complete this section only if you require an XML document to register your trial with ClinicalTrials.gov.

How to Complete the Regulatory Information Section

Select or enter the appropriate information in the text fields and drop-down lists. The following table describes the fields. An asterisk (*) indicates a required field. For a definition of each field, refer to http://prsinfo.clinicaltrials.gov/definitions.html.

Instructions for recording regulatory information

Field Label	Description/Instructions
Studies a U.S. FDA-regulated Drug Product	If the trial studies one or more U.S. FDA-regulated drug or biologic products (a drug subject to section 505 of the Federal Food, Drug, and Cosmetic Act or a biological product subject to section 351 of the Public Health Service Act), select **Yes**. Otherwise, select **No**.
Studies a U.S. FDA-regulated Device Product	If the trial studies one or more U.S. FDA-regulated device products (a device subject to section 510(k), 515, 520(m), or 522 of the Federal Food, Drug, and Cosmetic Act), select **Yes**. Otherwise, select **No**. If you select Yes in this field, the Unapproved/Uncleared Device field and Pediatric Post-market Surveillance field become available.
Unapproved /Uncleared Device	This field is read-only. The default value is No, which indicates the release of trial information on Cancer.gov is not being delayed until after an interventional device has been approved or cleared. You may request a change in the value for this field by submitting a request to the CTRO at ncictro@mail.nih.gov.
Pediatric Post-market Surveillance	If the U.S. FDA has ordered a pediatric post-market surveillance of the device product, select **Yes**. Otherwise, select **No**.
Product Exported from the U.S.	If the product is manufactured in the U.S. or one of its territories and exported for study in a clinical trial in another country, select **Yes**. Otherwise, select **No**.
FDA Regulated Intervention Indicator	If the trial is regulated by the FDA, select **Yes**. (If the trial includes an IND or IDE, you must select **Yes**.) Otherwise, select **No**. If you select Yes in this field, the Section 801 Indicator field becomes available.
Section 801 Indicator	If the FDA-regulated interventional trial is an applicable trial as defined in US Public Law 110-85, Title VIII, Section 801, select **Yes**. Otherwise, select **No**.
Data Monitoring Committee Appointed Indicator	Optionally, if a data monitoring committee has been appointed for this trial, select **Yes**. Otherwise, select **No**. ⓘ This information is required for compliance with the Public Law 110-85 of the Food and Drug Administration Amendment Act of 2007. If you are unsure about how to classify a trial, or what information to provide, contact the FDA's regulatory affairs office.