Trial Summary Report and XML File Data Elements - Include 20170328

The CTRP system captures the trial data you submit, and from them generates two types of trial documents: a Trial Summary Report (TSR), formatted for user consumption; and an XML file formatted for upload to ClinicalTrials.gov. Both documents contain a subset of trial data elements captured in the CTRP. However, the TSR contains more elements than the XML because ClinicalTrials.gov-required fields are different from those in CTRP. Some data that appear in the TSR do not appear in the XML, and vice versa. The documents are described below.

- **Trial Summary Report (TSR)** – Report that presents a summary of key abstracted data from the trial you registered, in an easy-to-read format. The CTRP system sends the TSR as an attachment in an email to the trial submitter/owner with instructions to review the TSR for accuracy and to report any changes to the CTRO staff.

  > When a trial has been amended, the system sends a modified TSR to the submitter that reflects the changes.

- **XML File** – File that contains abstracted data in the format suitable for submission to ClinicalTrials.gov. You may want to make sure the trial record in CTRP has all of the trial attributes required for ClinicalTrials.gov before you use CTRP to generate an XML file from that trial record, to avoid having to make corrections/additions in ClinicalTrials.gov.

The following sections compare the TSR data elements with those in the XML.

For instructions on viewing these trial documents, refer to Viewing Trial Summary Reports and XML Documents.