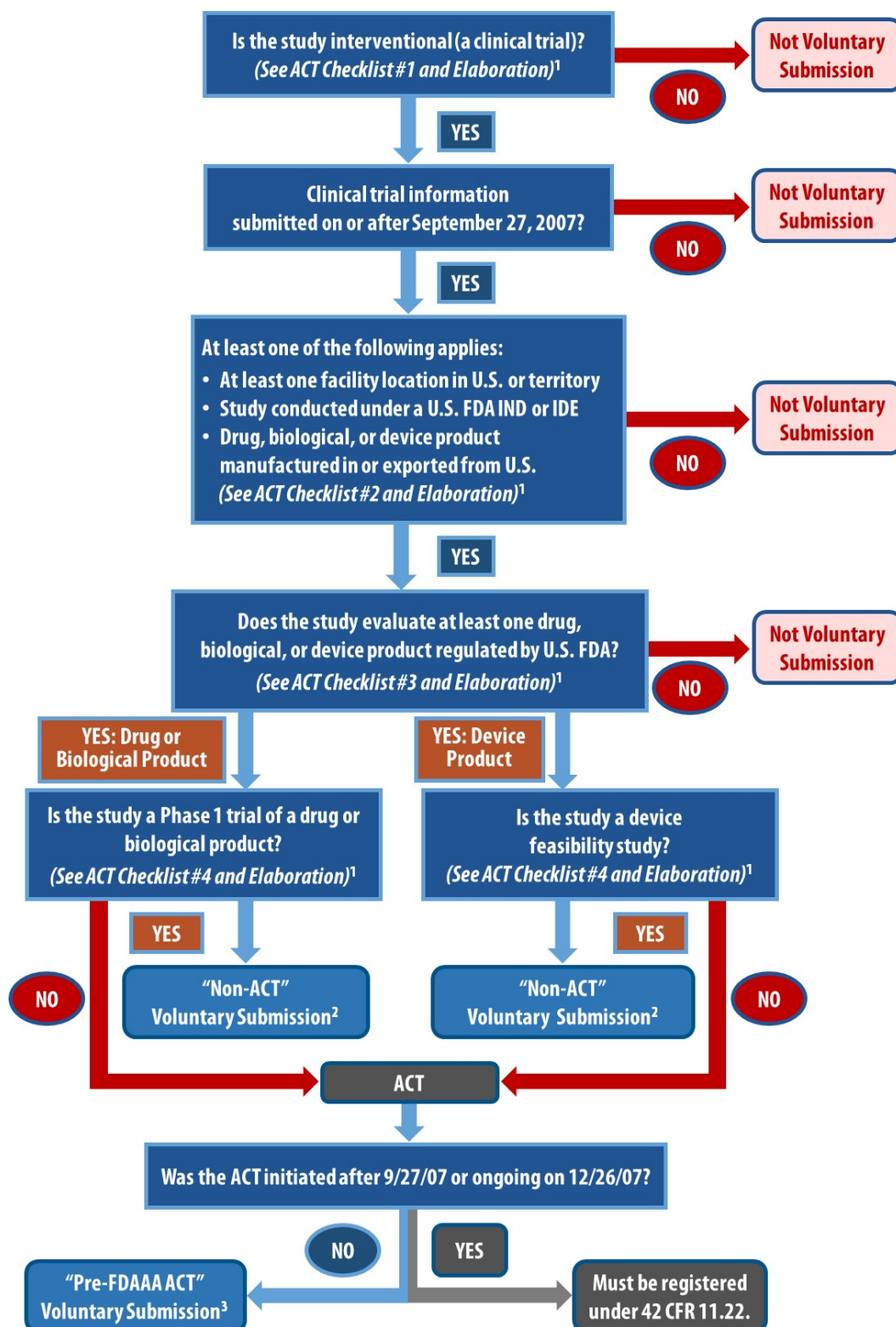


Voluntary Submission Flowchart and Triggered Trials Checklist

Flowchart to Determine Voluntary Submissions Under Section 402(j)(4)(A) of the PHS Act and 42 CFR 11.60*

*This flowchart should not be used to evaluate whether a study is an applicable clinical trial (ACT). See the ACT Checklist and Elaboration¹ to evaluate whether a study is an ACT.



¹ NIH: [Checklist and Elaboration for Evaluating Whether a Clinical Trial or Study is an Applicable Clinical Trial](#) (PDF)

² See 42 CFR 11.60(a)(1)(i), 42 CFR 11.60(b)(1)(i), and 42 CFR 11.60(c)(1)(i).

³ See 42 CFR 11.60(a)(1)(ii), 42 CFR 11.60(b)(1)(ii), and 42 CFR 11.60(c)(1)(ii).

Voluntary Submission Flowchart and Triggered Trials Checklist

Checklist for Determining Whether Information for Triggered Trials Must Be Submitted Under Section 402(j)(4)(A) of the PHS Act and 42 CFR 11.60

(NOT FOR SUBMISSION)*

Instructions: If you are the responsible party and submitted registration or results information on or after September 27, 2007, for a clinical trial of a U.S. FDA-regulated drug, biological, or device product that is a voluntary submission under section 402(j)(4)(A) of the PHS Act and 42 CFR 11.60, then you may use this checklist to determine whether clinical trial information must be submitted for any additional clinical trials (i.e., “triggered trials”). The regulations in 42 CFR 11.60 identify two types of clinical trials for which submission of clinical trial information is considered “voluntary”:

- A clinical trial of a U.S. FDA-regulated drug, biological, or device product that is not an applicable clinical trial (referred to here as a “non-ACT” voluntary submission) (see 42 CFR 11.60(a)(1)(i), 42 CFR 11.60(b)(1)(i), and 42 CFR 11.60(c)(1)(i))
- An applicable clinical trial initiated on or before September 27, 2007, that reached the primary completion date before December 26, 2007 (referred to here as a “pre-FDAAA ACT” voluntary submission) (see 42 CFR 11.60(a)(1)(ii), 42 CFR 11.60(b)(1)(ii), and 42 CFR 11.60(c)(1)(ii))

See the accompanying Flowchart to Determine Voluntary Submissions Under Section 402(j)(4)(A) of the PHS Act and 42 CFR 11.60.

Question		Yes	No
1.	Have you submitted an application or premarket notification to U.S. FDA under section 505, 510(k), 515, or 520(m) of the FD&C Act or section 351 of the PHS Act for the drug, biological, or device product studied in the voluntary submission? • If “No” then Stop. No Triggered Trials.	☐	☐
2.	Is the application or premarket notification for the same use studied in the voluntary submission? • If “No” then Stop. No Triggered Trials.	☐	☐
3.	Are you the manufacturer of the drug, biological, or device product studied in the voluntary submission? • If “No” then Stop. No Triggered Trials.	☐	☐
4.	Was the application or premarket notification submitted on or after September 27, 2007? • If “No” then Stop. No Triggered Trials.	☐	☐
5.	Are there any applicable clinical trials initiated on or before September 27, 2007, that reached the primary completion date before December 26, 2007 (pre-FDAAA ACTs) that are required to be submitted to U.S. FDA in the application or premarket notification? • If “No” then Stop. No Triggered Trials.	☐	☐
6.	Have any of these required pre-FDAAA ACTs not been submitted to ClinicalTrials.gov? • If “No” (i.e., all pre-FDAAA ACTs have been submitted) then Stop. No Triggered Trials. • If “Yes” to all six questions, these pre-FDAAA ACTs are considered triggered trials and must have clinical trial information submitted to ClinicalTrials.gov, as described in section 402(j)(4)(A) of the PHS Act and 42 CFR 11.60.	☐	☐

* The outcome generated by the checklist tool will not be retained by the Agency and will not be binding on either the user or any Government agency in any future actions.