

Regulatory Device field - Include 20170414

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.