

## CTTI Pregnancy Testing in Clinical Trials Project Survey

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## ABSTRACT

The main purpose of pregnancy testing as part of a clinical research protocol is to minimize risk to an embryo or fetus from exposure to potentially harmful study interventions. The specific goal of testing may be to prevent exposure completely (by testing prior to any study interventions), or to minimize the duration of exposure during early pregnancy (by periodic testing during the study).

This survey provided five clinical study scenarios and asked respondents a series of questions about the acceptable risk of an unintended fetal exposure to a drug, the importance of several factors going into clinical study design, and the type of pregnancy testing protocol that you would recommend.

**EXTERNAL LINK** 

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Morse JE, Calvert SB, Jurkowski C, Tassinari M, Sewell CA, Myers ER (2018) Evidence-based pregnancy testing in clinical trials: Recommendations from a multi-stakeholder development process. PLoS ONE 13(9): e0202474. doi: 10.1371/journal.pone.0202474

Appendix S1\_Survey.docx

## Document body

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that, when used consistently and correctly, have a failure rate <1 per 100 woman-years.\u00a0 Examples include male or female
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frequency of testing may result in different negative predictive values in different subject populations.\u00a0 Conversely, in a given
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