



# 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

<https://doi.org/10.1371/journal.pone.0202474>

## THIS DOCUMENT ACCOMPANIES THE FOLLOWING PUBLICATION

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](https://doi.org/10.1371/journal.pone.0202474)



Appendix  
S1\_Survey.docx

## Document body

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Testing Costs

For this scenario, which type of pregnancy test would you recommend using? (Choose 1)

- Serum hCG performed in lab
- Urine hCG performed in lab
- Point of care urine hCG performed by study personnel
- Home test performed by patient

For this scenario, how do you recommend scheduling the pregnancy test(s)? (Choose 1)

- Whenever convenient for subject
- Timed to expected menses
- 9sbjm
- boa0t
- 2f8qv
- 7qpec

Please answer a few final questions about the previous scenario, restated below.

A Phase III study of a new analog of thalidomide (a drug known to be associated with a very high risk of birth defects). Study drug is administered for 12 months. Assume that all subjects are required to use two methods of highly effective contraception.

For this scenario, at which study time points do you recommend a pregnancy test be performed? (Choose 1)

- Before study only
- Before and during study
- Before, during, and after study exposure completed
- The final two questions on this page are only shown if applicable to the answer above.

Prior to study drug administration, when do you recommend testing for pregnancy? (Choose 1)

- At screening visit
- Immediately before administering study drug
- At screening visit and immediately before administering study drug
- 9bggj
- d9htl

How often do you recommend testing for pregnancy during the study?

- Every month
- Every other month
- Every three months
- Other (Please Specify)
- 5usc2

How long after study exposure is completed do you recommend continuing to perform pregnancy testing?

- 1 month
- 2 months
- 3 months
- 6 months
- 12 months
- 6udd3
- 5le23

Scenario: A Phase III study of a new indication for a currently marketed drug administered for 6 months, currently classified as Pregnancy Category C (the relative risks and benefits in humans are unknown, because of positive data in animals only, no human data, or no data at all). Assume subjects are using a highly effective method of contraception as specified by the protocol.

Would you recommend excluding pregnant women from this study?

- Yes





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