

General Considerations for the Clinical Evaluation of Drugs



1977

1993:

Women of child-bearing potential allowed in clinical trials

U.S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
Public Health Service

WOMEN OF CHILDBEARING POTENTIAL

A woman of childbearing potential is defined as a premenopausal female capable of becoming pregnant. This includes women on oral, injectable, or mechanical contraception; women who are single; women whose husbands have been vasectomized or whose husbands have received or are utilizing mechanical contraceptive devices. Women in certain institutions, e.g., prisons, although of childbearing potential, could be considered as not in the appropriate environment to become pregnant during administration of an investigational drug. However, women in mental institutions could become pregnant.

1977:

Women of child-bearing potential banned from FDA clinical trials

In general, women of childbearing potential should be excluded from the earliest dose ranging studies. If adequate information on efficacy and relative safety has been amassed during Phase II, women of childbearing potential may be included in further studies provided Segment II and the female part of Segment I of the FDA Animal Reproduction Guidelines have been completed. All three Segments should be completed before large-scale clinical trials are initiated in women of childbearing potential.

[FDA 1977](#)

