



THE SPECIFICITY OF THE INVOLVEMENT OF PREGNANT WOMEN IN CLINICAL STUDIES: MEDICAL AND BIOETHICAL APPROACH

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Introduction

Clinical trials are a type of research based on new drug and interventional treatment with the analysis of their effects on human health. Clinical trials that include pregnant women have an outstanding interest in the medical and bioethical field.

Purpose

To highlight the medical and bioethical aspects of clinical trials involving pregnant women.

Material and methods

The results of scientific, ethical and bioethical investigations, articles on clinical trials involving pregnant women. The analytical, bioethical and sociological method was applied.

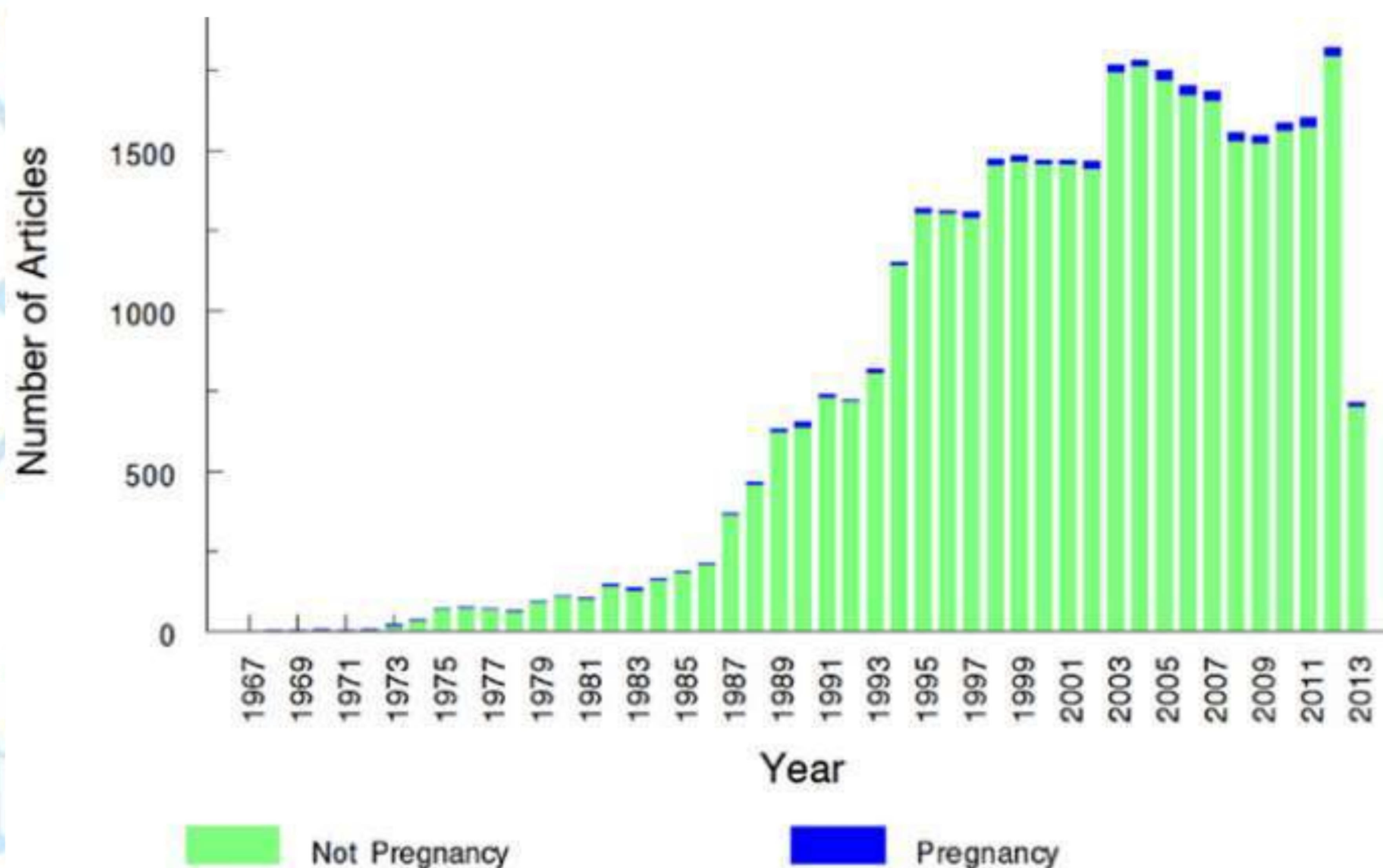


Fig. Nr 1 Number of pregnancy and non-pregnancy pharmacokinetic clinical trials

Results

Pregnancy is not an exclusion criterion from clinical trials unless there is a convincing scientific or ethical reason for it. Research is needed to provide women with effective, safe treatment for the fetus that would not be possible outside of the study. Ethical complexity is reflected in the need to balance the interests of the pregnant woman and the fetus.

Conclusions

The inclusion of pregnant women is guided by the protection of the human being. If the clinical study offers the potential clinical benefit to the pregnant woman, for the fetus the risk must be more than minimal.

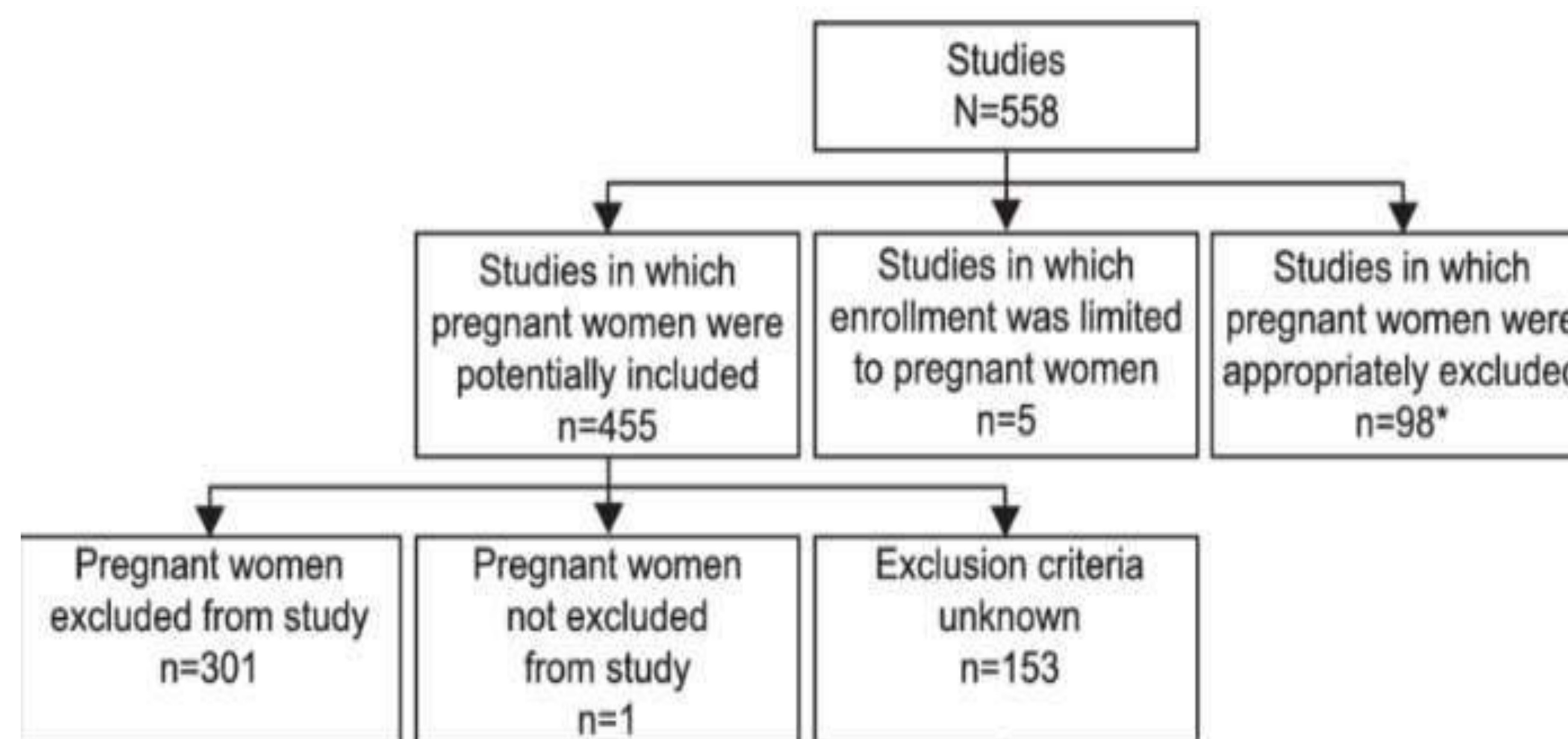


Fig. Nr 2 Number of studies excluding and not excluding pregnant women from participation in industry-sponsored clinical studies.

Country	2007-2011
USA	231
Australia	50
Canada	46
Brazil	30
UK	30
India	30
China	28
Netherland	24
Italy	23
France	18
Spain	17
Germany	14
Japan	10
Denmark	8
Belgium	7
Sweden	5
South Africa	5
Poland	6
Czech	5
Argentina	4
Mexico	3
Hungary	4
Austria	4
Russia	1
Republic of Korea	1

Fig. Nr 3 Clinical Trials in Pregnancy