

# **Propuestas para incrementar la representación de la mujer en los estudios clínicos**

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# Women are underrepresented in clinical trials

## Clinical trial results are not analyzed by gender

- CVD in Europe is responsible for 55% of deaths in women compared to 43% in men;
- Over the past two decades myocardial infarction (MI) has increased in women aged between 35 and 54, whereas it has declined among men from the same age group;
- The 62 randomized clinical trials published between 2006 and mid 2009 enrolled 380,891 participants, 127,716 of them were women (33.5%);
- The percentage of women enrolled in each trial ranges between 15 to 60;
- Only 31/62 trials (50%) reported the analysis of the results by gender



# How to implement European Heart Network Recommendations ?

Barriers to the enrolment of women in clinical trials need to be addressed:

- Survey should be launched to understand existing barriers

**Clinical trials enrolling a significant proportion of women to allow for pre specified gender analysis should be encouraged, especially in the fields of ischemic heart disease, cholesterol-lowering therapy and heart failure:**

- Regulatory agencies in the European Union are urged to adopt strict rules on the inclusion of women in clinical trials and a systematic gender analysis
- Discussion with all stakeholders incl. industry should be launched

**Scientific guidelines should systematically address gender differences:**

- Guidelines implementation program should be in place incl. women patients' education.