





where science and ethics meet

## Statement 1

100 per cent of humankind is affected by pregnancy, but there is almost no guidance on women who become pregnant during a trial.

Most medicines are contraindicated during pregnancy. We have become ultraconservative, and yet 90% of pregnant women actually use medicines. But there are nearly no clinical trials in pregnant women and other ways of systematic data collection about medicines in pregnancy are not established.



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## Statement 2

The different provisions in the upcoming Clinical Trials Regulation encourage the performance of clinical trials in and for pregnant women, however, direct AND group benefit principles are acceptable.

Ethical guidance on management of particular situations and conditions need to be worked out, e.g., concerning

- benefit-risk assessment
- informed consent process
- patient protection
- embryo protection
- use of data

## Statement 3

### Result from EFGCP's Annual Conference 2014:

As part of the responsible transition for a woman who falls pregnant during a study, the EFGCP strongly recommends:

- That she meets the researchers responsible for her care in the study, along with an appropriate counsellor to discuss:
  - Implications for her and her baby,
  - Whether or not she should remain in the study,
  - What further data collection will be done,
  - And future therapeutic management and prenatal care
- That her study medication is unblinded and shared with her unless she takes an informed position not to unblind