

Translated from *Rev Prescrire* September 2013; 33 (359): 647

At least two!

The results of a study are not always confirmed when a similar study is conducted by another team. In basic sciences, this well-known phenomenon means that results are not accepted until they have been reproduced.

In clinical trials, a number of factors can lead to overestimation or underestimation of the benefits and harms of an intervention, including the type of population studied, excluded patients, and concomitant treatments. Drawing conclusions about the efficacy of a treatment on the basis of the results of only one comparative clinical trial, conducted by a single team, means running the risk of seriously misjudging the treatment's harm-benefit balance.

Drug regulatory agencies still seem to be overlooking this principle. This issue contains two examples: *bevacizumab* in relapsed ovarian cancer (page 289) and *rivaroxaban* in the treatment of pulmonary embolism (page 290). Furthermore, in the case of *bevacizumab*, the results of the single trial did not convincingly demonstrate that these drugs provide a benefit to patients. Its serious adverse effects are certain, however, and have been confirmed by successive studies.

There are valid reasons to try to give patients and healthcare professionals rapid access to useful new drugs, especially for serious diseases. But one "positive" trial cannot suffice: in order to protect patients, the drug's harm-benefit balance needs to be established with an acceptable degree of certainty. Authorising drugs on the basis of favourable preliminary results mainly benefits pharmaceutical companies. While patients remain in the dark and take risks that may be unjustified.

Prescrire