

# Most information in drug development is lost

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Lots of potentially useful medical information is getting lost. McGill researchers discovered this when they looked into the lack of reporting of information from "stalled drug" trials in cancer, cardiovascular and neurological diseases.

"Stalled drugs" are drugs that fail to make it to the market either because they prove to be ineffective or unsafe or both. Because only one in ten of the drugs that goes into human testing actually gets licensed, most of the information collected in developing [new drugs](#) is currently being lost. This is despite the fact that this information is critical for effective care, protecting patients, and discovering better drugs.

"We focused on drug trials in these three areas because they are a major

focus for [drug development](#)," says Prof. Jonathan Kimmelman who is Associate Professor of Biomedical Ethics at McGill University and is the lead author on the study that was published today in the *British Medical Journal*. "We expected to see that many of these trials are never published. What surprised us was the magnitude of the data withholding."

Indeed, between 2005 and 2009, the period that the researchers studied, only about 37 per cent of registered trials for "stalled" drug trials were actually published. For the [approved drugs](#) developed in the same period, 75 per cent of the trials were published.

The researchers believe information sharing - even for drugs that stall in development - offers clues about how to deliver care or develop drugs more effectively. Findings from trials of stalled drugs:

1. Allow drug developers to discover what didn't work, and then adjust the compound or method of delivery so that it might work for other conditions. For example, the drug Viagra failed initially as a drug for treatment of angina. We now know it to be a very effective drug for erectile dysfunction.
2. Help us learn about the safety of other approved drugs. Often, trials of experimental drugs generate valuable evidence about the safety of approved drugs - especially if the approved drugs are in the same chemical family.
3. Help drug discoverers learn about the limits of animal models and other experimental techniques. "When a drug works in animal models but not in patients, we have an opportunity to study why our model fell short and to improve it," says Amanda Hakala, a Master's student who is first author on the study.
4. Contain safety and efficacy information that might be useful in other parts of the world. Often, drugs that are considered unsafe and ineffective in one part of the world are approved in another.

"Failure to publish these trials deprives patients in those other jurisdictions of state of the art evidence of safety and efficacy," says Kimmelman.

A further reason to share the information about "stalled" drugs is that many patients who take part in these trials are given either placebos or ineffective or unsafe drugs. "The failure of the drug developers to share their findings runs contrary to the Declaration of Helsinki which lays out clear ethical guidelines for medical research involving human subjects," says Kimmelman. "In our study, we found that over 20,000 patients were involved in "stalled" drug trials that were never reported. That's a lot of people whose altruism is not being honoured."

"There are many reasons that drug developers do not report findings in 'stalled' drug trials. One is an unwillingness to share information with competitors," says Amanda Hakala, the Master's student who is the first author on the study. "However, the value of this lost [information](#) is starting to be recognized." The European Parliament recently passed legislation that requires sponsors to report on "stalled" trials. And the U.S. is considering policies that would encourage limited transparency about stalled [drug trials](#). "Policies like these are no substitute for full publication, but they go a long way to redeeming the sacrifices of the research subjects and advancing the cause of more effective healthcare and better [drug](#) development."

**More information:** To read the full paper in the *British Medical Journal*: [www.bmj.com/content/350/bmj.h1116.full](http://www.bmj.com/content/350/bmj.h1116.full)

Provided by McGill University

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