

A drugs company runs hundreds of tests called clinical trials every year to test how efficient and safe their medicines are. But they aren't required to publish the results of all of them.



UK to Force Drugmakers to Share Info

Britain plans to force pharmaceutical companies to share more information with regulators about clinical trials after an investigation recently concluded that GlaxoSmithKline PLC deliberately withheld information about an antidepressant.

The four-year probe by the Medicines and Healthcare products Regulatory Agency, completed earlier this month, said the British company should have revealed more quickly that Seroxat sometimes increased the suicide risk in teenagers - by more than six times.

But without stronger legislation in place, the MHRA admitted there is no chance of prosecuting the company for what the agency perceives as an ethical lapse. "I remain concerned that GSK could and should have reported this information earlier than they did," MHRA chief executive Kent Woods said in a statement[...]

Because Seroxat was only recommended for adults, GlaxoSmithKline was not required to report on any dangerous side effects it found in adolescents.

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Anti-depressants' 'little effect'

New generation anti-depressants have little clinical benefit for most patients, research suggests.

A University of Hull team concluded the drugs actively help only a small group of the most severely depressed. They reviewed published clinical trial data, and **unpublished** data secured under Freedom of Information legislation.

The researchers found that the drugs did have a positive impact on people with mild depression - but the effect was no bigger than that achieved by giving patients a sugar-coated "dummy" pill.

Lead researcher Professor Irving Kirsch said: "The difference in improvement between patients taking placebos and patients taking anti-depressants is not very great. "This means that depressed people can improve without chemical treatments." Professor Kirsch said the findings called into question the current system of reporting drug trials.

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Peer review is part of how science is quality controlled.

Before a scientist can publish their work other scientists check it. All the scientists will be from the same field of science. These experts should have **no links** to the person who completed the study or anyone else involved in it. Otherwise they might be able to 'do them a favour' and say their work is OK when really it's not.

This process makes sure that what gets published is as **accurate** as it can be. But it can't do much about things that **aren't** published...



Your task.

Get into groups of three.

1. Can you think of three reasons why the scientists hadn't published all of their research on anti-depressants?
2. Find out what a **placebo** is and write a one paragraph explanation.
3. Think about if there could be any publication bias (see below) in the areas the IAS scientists work on. Think of a question to ask them about it.
4. Make a list of three reasons why you might volunteer for a clinical trial. And three reasons why you wouldn't.

A drug's journey...

All medicines go through a tough **testing process** before they can be prescribed. This can take about **10 years**. Only if a drug performs well in one phase will it go to the next one.

The process will start when a scientist or a team of scientists find a **compound** that looks like it could be useful in treating a disease. They will carry out tests. If they are sure that it could be useful as a drug they will start the **preclinical trials**.

Preclinical trials test the drug in **test tubes** and **on animals**. Once scientists think it's safe, and will have the right effect, they start trials on people.

Clinical trials test the drug **on humans** to check whether it is safe and whether it works. These are in three phases with more people in each trial.

If a drug passes this point it will get a licence but will continue being tested to make sure it is safe. Only a few percent of the 'useful compounds' identified at the start of the process will make it this far!!



'**Publication bias**' is a term to describe the fact that some results are more likely to be published than others.

This can be **unintentional** – just because people are more likely to get round to writing up **positive** or **interesting** results. Scientists are people too and can take longer to get round to writing up **boring** or inconclusive results. This is sometimes called the 'file drawer problem'. Or it can be **intentional** – because organizations may not like negative results or want to publicise positive results more.

For agencies like the MHRA to make decisions about drugs, or even for the public to make a decision about something, they need all relevant data. Otherwise it's like trying to make your mind up about something when you only have half the story.

Understanding publication bias

Do you ever **show your parents** your school coursework when it's been marked?

Do you show them **all** your coursework, or only **some**?

If you only show them some, is it **at random**, or are you **more likely** to show them ones where you've got a **good mark**?

Will they get a better idea of **how you're doing at school** from your exam results, or from the individual **bits of coursework** you show them?



Further info

Good drug development information and activities

<http://www.wellcome.ac.uk/Professionalresources/Education-resources/Big-Picture/Drugdevelopment/index.htm>

Seroxat Q + A

<http://news.bbc.co.uk/1/hi/health/7281305.stm>

Anti-depressant study Q + A

<http://news.bbc.co.uk/1/hi/health/7264486.stm>

