

# What is a human drug trial?

A human drug trial is a trial conducted with volunteered patients to evaluate a new drug which may have been discovered. The purpose of the trial is to find new improved methods to treat patients with certain diseases or illnesses. With any new drug there are possible risks as well as benefits. So therefore any new drug has to undergo some procedures such as drug trials where some volunteers take the drug. These drug trials help doctors to determine:

- If the drug is safe and effective,
- If the new drug is better than the current drug available,
- If there are any serious side effects,
- If the drug works on the patient carrying the illness or disease.

## How are drugs licensed?

When a new drug has been discovered it has to be licensed to the public that it can be used effectively and safely to cure any disease or illness. The best way to do this is undergo a human drug trial where the drug goes through some procedures. Human drug trials are conducted in three phases, and each of the phase are designed to find out different specific information. The phases of a human drug trial are:

### Phase 1 – Laboratory Stage

1. The first stage of a human drug trial is that before the drug is tested on humans, or animals, it must be tested on a few human tissue samples in the laboratory to make sure the drug reacts with the cell.
2. If step one's result are positive, it is then moved on to the second step where the drug must be tested on at least two different species of mammals, usually monkeys and rats. This stage of the phase is done to see for rodents and toxicity. Animals and humans have similar organ systems in their body, so therefore if the drug is tested on animals it will give doctors and nurses a better reference of how the drug will react on humans.
3. The third and final step of phases 1 is that the drug must be approved by ethical bodies and most importantly it must be approved by the MHRA (Medicines and Healthcare Products Regulatory Agency). Before phase 2 starts, this whole procedure has to go through a pre-clinical trial just to make sure it is safe.

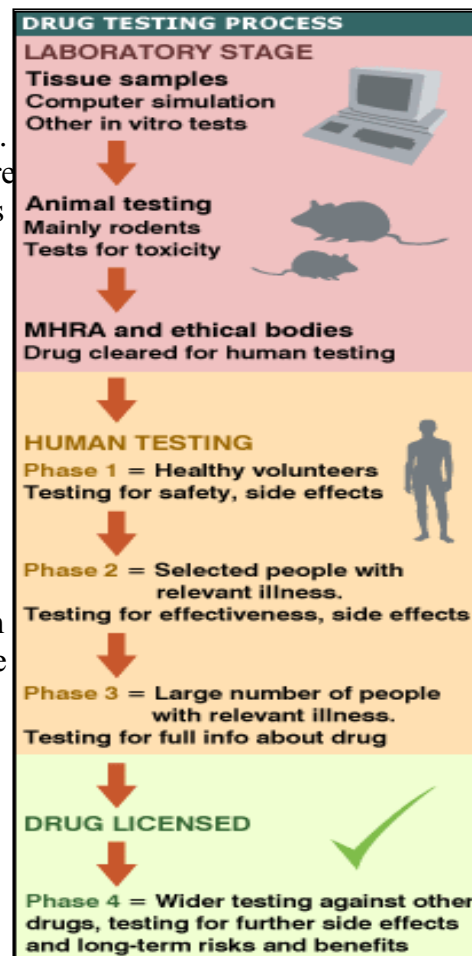


### Phase 2 – Human Testing stage

1. After the laboratory stage is fully securely checked and guaranteed the drug is safe, it is then tested on healthy volunteers who get paid to take the drug. This stage is done to ensure that there are no harmful side effects when the body is working normally. The reason why the drug is tested on healthy volunteers is that if the drug was to be tested on volunteers with illness and there was serious side effect, it might make the patient's conditions worse.

2. After the drug is tested on healthy volunteers and there are no serious side effects, it is then tested on volunteers who are suffering from the illness which the new drug is to cure. This stage of the phase is tried for both safety and effectiveness. Placebos are given to small amount of patients to compare the results with the volunteers whom took the real drug. Placebos are given at all stages of the phases.

3. After the step two of phase 2 is complete and successful that the drug cures the illness that it was designed for, it is then gone ahead to be tested on a large number of people who are suffering from the certain illness or disease. The reason why this stage of the phase is conducted is because to find total specific information about the drug and for further side effects.



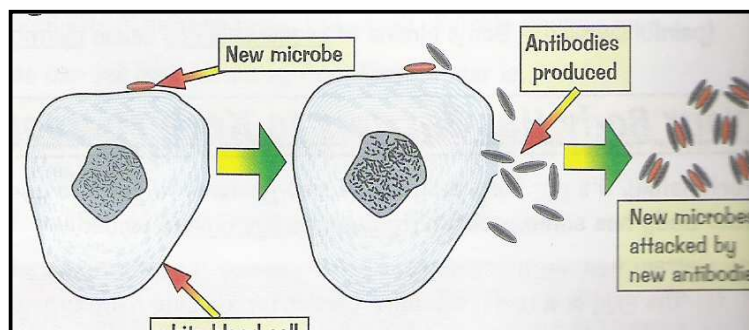
(I got this flow chart from, [www.bbc.co.uk/1/hi/health/4808090.stm](http://www.bbc.co.uk/1/hi/health/4808090.stm))

### Phase 3 – Drug License

1. After phases 1 and 2 are complete and fully 100% successful, it is then given license to be used in patient's world wide.

## The TGN1412

The TGN1412 is in a class of drug known as monoclonal antibodies. Intensive care were said to be critically ill. Another Mubeen Mubarak



two men out of the eight were given a placebo (fake drug), and did not have any effects. The trial was stopped as soon as the six men fell ill.

Ryan Wilson was one of the two men who critically and is still facing recovery in hospital. Ryan Wilson was seriously affected by the drug and still faces the possibility of losing his toes and

## Why should human drug trials continue?

On March 13<sup>th</sup> 2006 the world of drug testing became a controversial issue after what happened in North London at Northwick Park Hospital. Some say that human drug trials should be brought to an end, due to the severe reactions suffered by the six volunteers at Northwick Park Hospital after taking the inflammatory drug. So therefore we can sum up from this that the TGN1412 drug trial was an “exceptional occurrence”.

TeGenero, whose drug was being tested, said the reactions of the men were areas of the body where there were not supposed to go”. Richard Lee who is part of the Association of British Pharmaceutical Industry told BBC News that he “cannot remember anything comparable. So therefore we can sum up from this that there is an extremely low probability of the events at Northwick Park Hospital repeating itself again.

## Why should human drug trials stop?

However despite many researchers saying that the TGN1412 human trial was an “exceptional occurrence”, some critics still say that human drug trials should be brought to an end, considering the TGN1412 drug trial. They say that not only the TGN1412 drug trial went wrong but also the HRT drug trial, as I mentioned before. The HRT drug trial left the volunteers at an increased risk of stroke. However the effects of the HRT drug trial were found at a much later stage compared to the TGN1412 drug trial. Moreover, other drug trials also have gone wrong such as the trial of US swine flu vaccine which killed several volunteers and left many paralysed. Also six years ago at the University of Pennsylvania, a teenager also died due to a gene therapy trial. So therefore we can take into consideration that not only the TGN1412 went wrong but also other drug trials have gone wrong in the past, which raises the issue of human drug trials to be stopped.

## Conclusion

the future of drug trials that lies dim. However I stick with firm belief that human drug trials should still continue, in advantage for the future generation

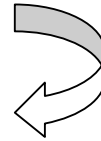
and their health as human drug trials are vital in progressing new drugs to treat diseases and illnesses which many patients around the world are suffering from.

## Bibliography

I used lots of information to put my case study together. I used the following websites, but however I did not use much information from the last website as I thought it was a bit too biased.

- [www.guardian.co.uk/theissues/article/0,,1733551,00.html](http://www.guardian.co.uk/theissues/article/0,,1733551,00.html)
- [www.bbc.co.uk/1/hi/health/4808040.stm](http://www.bbc.co.uk/1/hi/health/4808040.stm)
- [www.bbc.co.uk/1/hi/health/4808090.stm](http://www.bbc.co.uk/1/hi/health/4808090.stm)
- [www.bbc.co.uk/1/hi/health/4813124.stm](http://www.bbc.co.uk/1/hi/health/4813124.stm)
- [www.bbc.co.uk/1/hi/england/london/4808836.stm](http://www.bbc.co.uk/1/hi/england/london/4808836.stm)
- <http://www.scienceblog.com/cms/comment/reply/12447>
- [www.wikipedia.org/wiki/TGN1412](http://www.wikipedia.org/wiki/TGN1412)
- <http://clinicaltrials.gov/ct/info/whatis>
- <http://www.parexel.com/about/company/default.cfm>
- [www.voanews.com/english/archive/2006-5-02-voa54.cfm](http://www.voanews.com/english/archive/2006-5-02-voa54.cfm)

I did not use much information from this website as I thought it was biased



I also used some books to put my case study together. I used:

- CGP GCSE Core Science OCR 21<sup>st</sup> Century (p.40)

Pictures were mostly taken from – [www.google.co.uk/images](http://www.google.co.uk/images)