



how science works

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What is Science Supremo?

Science Supremo is a game-based learning resource that offers young people studying GCSE Science an opportunity to get a feel for what scientists do and to understand the interplay between science and society. It is mapped to learning objectives in the new GCSE curricula (launched in September 2006).

In Science Supremo students take on the role of scientists working in modern drug development. They run a clinical trial of a new, fictional drug for tuberculosis and make choices about how to run the trial and which volunteers to include. Their choices affect the results of the clinical trials, with ratings and statistics affected.

The current version of the game is a fully playable prototype, which can be played in small groups or by individuals and is accompanied by comprehensive teacher support resources, handouts and suggested lesson plans.

Science Supremo has been developed by DESQ Ltd, a learning games development studio www.desq.co.uk and Sheffield Hallam University's Centre for Science Education <http://www.shu.ac.uk/research/cse/>, with support from the Wellcome Trust and NESTA.

Aims

Science Supremo will enable students to answer the questions:

- What does it mean to be a scientist, and what do scientists do?
- How does science interact with and influence society and vice versa?
- How do scientists make ethical choices?

The game aims to:

- Help teachers cover an unfamiliar area of the curriculum in an interesting way, whilst remaining in control of what students do.
- To use computer game mechanisms popular with young people (i.e. management simulation games) for making the high level learning objectives of 'how science works' more accessible to a range of abilities.
- For students to learn about the scientific process experientially, by making life-like decisions and seeing the consequences of their actions.

Learning Outcomes

Learning comes from playing the game, with learners discovering the learning points for themselves by drawing conclusions from their gameplay experience. Learning also comes from drawing on the supplementary worksheets and handouts to inform gameplay.

Students will be able to:	How pupils learn this by playing
1. Understand the role of clinical trials in drug development/medical and scientific research.	By being able to design their own trial and see the consequences
2. Understand the need to include healthy as well as unhealthy participants.	By realising that they cannot tell what the improvement is, without a reference/control.
3. Understand the need for objectivity in the selection of appropriate participants for trials.	By initially using subjective (empathy) criteria, and finding out their conclusions are not accepted for publication.
4. Know the role of a placebo in a drug trial.	This idea developed in post-game discussion from the experience of 2. above
5. Know the implications of participant side affects on the success of your trial.	Discover that too many side effects can cause your trial to be shut down, for ethical reasons.
6. Describe what constitutes a 'balanced trial' normally called a 'double blind, controlled trial'.	This notion developed in discussion, by combination of need for 3) and 4) above
7. Be able to describe why regulations over clinical trials are important and name the body who oversees regulations	After seeing first hand the dangers of bad clinical decisions, easy to lead pupils in discussion to need for regulation.

Curriculum Mapping

Science Supremo is mapped to the '**How Science Works**' objectives within the new Programme of Study.

Applications and implications of science:

- a) the use of contemporary scientific and technological developments and their benefits, drawbacks and risks
- b) how and why decisions about science and technology are made, including those that raise ethical issues.

The game is set within the 'breadth of study':

Organisms and health: human health is affected by a range of environmental and inherited factors, by the use and misuse of drugs and by medical treatments

The game addresses learning objectives in **AQA's Core Science**:

- Many drugs derived from natural substances have been known to indigenous peoples for many years.
- Scientists are developing new drugs. These need to be thoroughly tested.
- When new medical drugs are devised, they have to be extensively tested and trialled before being used. Drugs are tested in the laboratory to find if they are toxic. They are then trialled on human volunteers to discover any side effects.

The game addresses these learning objectives in **OCR 21st Century Core Science**:

Module B2: Keeping healthy

- recall that new drugs are first tested for safety and effectiveness using human cells grown in the laboratory and animals;
- recall that human trials may then be carried out:
 - on healthy volunteers to test for safety;
 - on people with the illness to test for safety and effectiveness.
- describe and explain the use of 'blind' or 'double-blind' human trials in the testing of a new medical treatment;
- understand why placebos are not commonly used in human trials.

Ideas about science: the scientific community

- Scientists report their findings to other scientists at conferences and in special journals. Scientific findings are only accepted once they have been evaluated critically by other scientists.
- In many areas of scientific work, the development and application of scientific knowledge is subject to official regulations and laws.

The game will address this learning objective in **Edexcel Core Science**

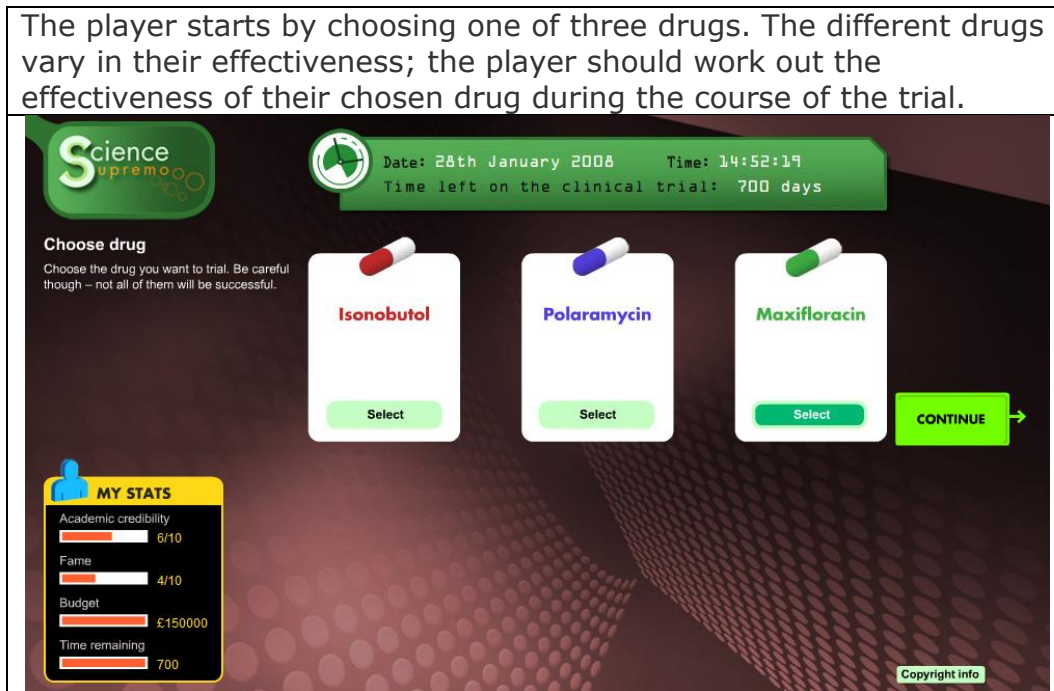
- use secondary data to explore the costs of developing new drugs.

What happens in the game?

The game starts at the beginning of a clinical trial stage in the development of a new drug for tuberculosis. The introduction of a new drug goes through many stages of development and approval. Science Supremo focuses on one of the most important stages; a clinical trial.

The clinical trialling process has been simplified¹ for the purpose of learning about the processes and ethical choices that scientists undertake.

The player starts by choosing one of three drugs. The different drugs vary in their effectiveness; the player should work out the effectiveness of their chosen drug during the course of the trial.



¹ The developers of Science Supremo consulted with the Medical Research Council in the process of developing the title.

The next step is a safety trial; the player chooses whether to include participants from a pool of 12 candidates, whether they are to be given the drug or a placebo, and what dosage to give them.

Science Supremo

Date: 28th January 2008 Time: 15:00:10
Time left on the clinical trial: 700 days

Phase 1: Overview

In order to set up the trial you will need to:

1. Select who you want to include from a pool of 12 volunteers, based upon their individual profiles.
2. Choose whether to administer the new drug or a placebo.
3. If you selected the new drug for the subject, you will then need to decide on whether to administer a high or a low dosage.
4. When you are happy with your selections, click the 'run trial' button and wait for your results to process.

Remember: You can click the 'return to start' button at any stage if you are not confident with your choices.

MY STATS

- Academic credibility: 6/10
- Fame: 4/10
- Budget: £150000
- Time remaining: 700

PHASE 1 TRIAL STATS

Number of subjects included		5
Drug given	New	4
	Placebo	1
Dosage given	Low	2
	High	2

Candidate Profiles:

- Nakato: Not in trial
- Wayland: Not in trial
- Xiang: Not in trial
- Kenneth: In trial (Given new drug, High dosage)
- Diane: Not in trial
- Shannon: Not in trial
- Wilma: Not in trial
- Tom: In trial (Given new drug, High dosage)
- Baljeet: Not in trial
- Maria: In trial (Given placebo)
- Frans: In trial (Given new drug, Low dosage)
- Lesley: In trial (Given new drug, Low dosage)

Buttons: QUIT TRIAL, RETURN TO START, MORE INFO, RUN TRIAL

Copyright info

After receiving the results for Phase 1, the player moves on to the effectiveness trial, again deciding whether to include participants and whether to give them the drug or a placebo. There are 20 candidates available for the effectiveness trial.

Science Supremo

Date: 18th March 2008 Time: 15:04:32
Time left on the clinical trial: 650 days

Phase 2: Overview

In order to set up the trial you will need to:

1. Select who you want to include from a pool of 20 volunteers, based upon their individual profiles.
2. Choose whether to administer the new drug or a placebo.
3. When you are happy with your selections, click the 'run trial' button and wait for your results to process.

Remember: You can click the 'return to start' button at any stage if you are not confident with your choices.

MY STATS

- Academic credibility: 5/10
- Fame: 4/10
- Budget: £146250
- Time remaining: 650

PHASE 2 TRIAL STATS

Number of subjects included		5
Drug given	New	3
	Placebo	2

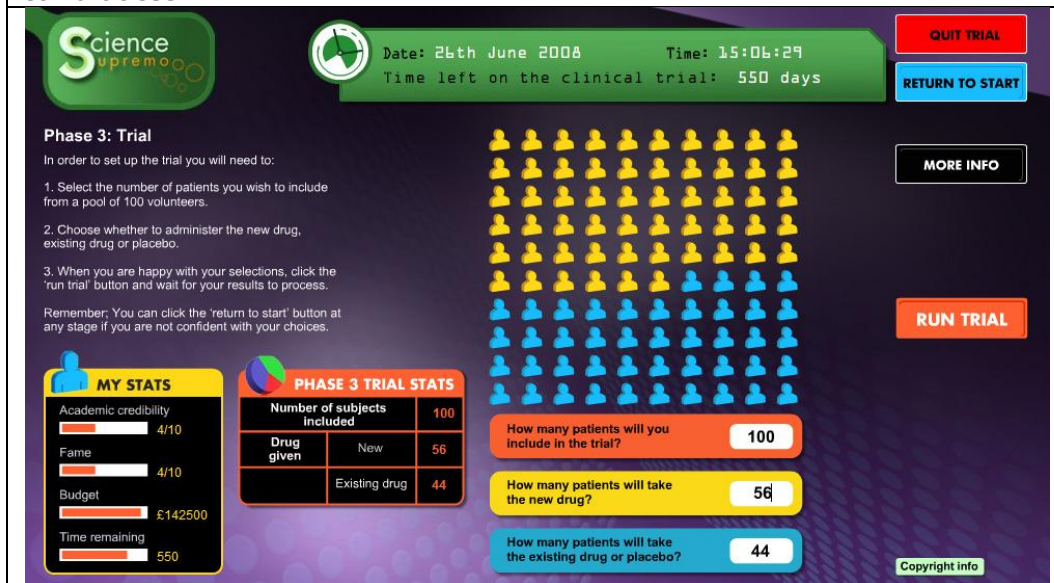
Candidate Profiles:

- Mascotch: Not in trial
- Cliff: Not in trial
- Corbin: In trial (Given new drug)
- Sefu: In trial (Given new drug)
- Jayde: Not in trial
- Tawny: In trial (Given placebo)
- John: Not in trial
- Marilene: In trial (Given placebo)
- Niu: In trial (Given new drug)
- Dan: Not in trial
- Coreen: Not in trial
- Storm: Not in trial

Buttons: QUIT TRIAL, RETURN TO START, MORE INFO, RUN TRIAL

Copyright info

After receiving the results for Phase 3, the player moves on to a large scale effectiveness trial, choosing from a pool of 100 candidates.



Throughout the game, players will be able to see their 'stats' that is their academic credibility rating, fame rating, budget and the time remaining. These stats will run throughout the game and are affected by the decisions the player makes throughout Science Supremo.


In the prototype all players start with the same game status stats, 'brought forward' from the previous stage (not shown in this version). These are:


- Academic credibility: 4/10
- Fame: 4/10
- Budget: £150,000
- Time remaining: 700 days



At the end of the trial, the player will achieve one of three outcomes:

- They fail the trial (because they conducted the trial badly);
- They have run a fair trial, but the drug has failed; or
- They have run a fair trial, and the drug is successful.





Date: 12nd January 2009 Time: 15:13:23
Time left on the clinical trial: 350 days

QUIT TRIAL

RETURN TO START

Phase 3: Final results

Were your results reliable? Consider the following.

- Did too many subjects receive an existing drug or placebo, rather than the one you were supposed to trial? Maybe you didn't select enough subjects for the trial.
- Did you do what you were told? In Phase 3, your company wanted to compare the new drug against an existing drug belonging to a competitor. Did you do that?
- Did you carry forward unreliable or unsuccessful results from a previous phase?

MY STATS

Academic credibility 5/10


Fame 4/10

Budget £108750

Time remaining 350

Any of these might have caused you to run an unreliable trial.

Do you still think you made all the right decisions? If not, then it is strongly recommended that you retake one or all of the trial phases. Or maybe you didn't choose the right drug at the beginning. Were your drug results successful?



MORE INFO

This game currently doesn't take you through the publishing stage. Have a think about what would happen if it did. Do you think that a major science magazine would be interested in publishing your findings?

Copyright info

How to use Science Supremo

Science Supremo is designed to be integrated into lessons but can also be used as an individual learning resource. These supporting resources are designed to help teachers to find the most appropriate way to integrate the game into their teaching and learning.

The supporting resource includes:

- guidance for teachers on using appropriate gameplay strategies as part their lessons (to reflect the diversity of student attainment levels and different levels of access to ICT resources)
- a set of supporting student handouts, designed to ensure reflection and formation of the desired outcomes.

There are two main ways in which the game can be played by students, ensuring the game meets the differentiation needs of classes or groups, as well as teacher confidence in using the game as part of a lesson. These are self directed or directed gameplay.

1. Self-directed gameplay

Let students play the game individually, in pairs or in small groups as a self exploratory project. They play the game as they choose to, developing their own hypotheses and strategies and playing these out. They may repeat the trial as many times as they like, until they run out of time and money; or they can quit and start again from scratch.

This approach might be best suited to more able students who are capable of working independently or with less direction from teachers.

Students are left to decide on their own how they want to play the game and what they want to achieve. For instance, whether to play for academic credibility, fame and notoriety, speed, spending as little as possible, or for a balance. Students may decide to jump in and play the game without a strategy and see how successful they are.

The principle behind this approach is to allow students to experiment and come to their own conclusions as to how to best conduct a clinical trial. How much preparatory information is given about drug trialling and the ethical codes scientists adhere to is up to the teacher.

Teachers might consider supporting this exercise with any of the following:

- Students could be given access to the internet to research aspects of the clinical trialling process or be given any of the

supporting handouts and worksheets, to inform their game choices.

- Students could be asked to write a log of their choices or a diary/blog on their game strategies and to record the impact their choices make on the outcome of the game.
- Teachers could interject at key points (for instance, when students have completed one stage of the clinical trial) and discuss and compare different groups' strategies and results.

Lesson planning for self-directed play

The game has been designed to be integrated into lessons, with teachers facilitating the learning experience, but Science Supremo could be used as the basis for homework or a private study project.

The number of lessons required to deliver the learning outcomes will depend on the attainment level of students, their familiarity and aptitude for management sim-like games and on how teachers organise students into groups.

As a guide, we estimate:

- **It will take a student or small group of students between 15-20 minutes to complete a full clinical trial.**
- **Using self-directed play, teachers will need 1 or 2 lessons of 40-60minutes to achieve the desired learning outcomes.**

In integrating the game into lessons, teachers should consider:

- How much introductory or contextual information to present to students before they play the game.
- How groups of students are organised and how much direction or in-situ guidance they are given as they play the game. (NB, in testing the game, the developers found that students had more meaningful exchanges in pairs or in groups of threes. This will depend on how many computers a cohort of students has access to.
- What research tools students are given access to as they play the game, e.g. access to the internet or accompanying handouts or if they are given any supporting resources at all. The latter approach may produce a less structured session but should create increased learner autonomy and therefore a deeper learning experience.
- How extensive or prescribed to make the writing and recording of students' approaches to the game and the ensuing results.
- After students have played the game, teachers will need to decide how much time to spend on sharing the results and strategies from groups of students and how best to facilitate this.

Tips

- A plenary session could be structured as a 'show and tell' presentation from each of the groups who have played the game. Groups would present their strategy to the whole class and demonstrate the results of their gameplay, reporting their clinical trial findings as scientists might to their peers or colleagues.
- The more freedom students are given to choose their own strategy, or indeed to not choose a strategy at all, creates a more personalised and deeper learning experience. Students tend to then have greater moments of 'eureka' when they discover for themselves the positive impact certain choices they make have on the game's outcomes.

2. Directed gameplay

The teacher can take more control of the game, giving students more direct instructions about what to do in each of the game stages and within a lesson or lessons.

This approach breaks the game down into bite-sized learning points and uses the game more as a teaching aid than as a learner-centred game. Teachers are able to select particular learning points they want to make. In pairs or in small groups, students then play the game following these instructions and review the given strategy as a whole class.

Teachers could also play the game as a whole class activity, using an interactive whiteboard or projector, commenting on actions and game feedback and asking students to suggest different approaches or to attempt to explain results.

Using a more directed approach may reduce the amount of time needed to cover the learning points.

This approach may favour those students who are less able and need more support and structure in their learning.

The principle behind this approach is to give students a more structured learning experience, where the game is played as part of a whole class experience. This might involve a number of groups playing the game using a given strategy and others given a different strategy, with a plenary session to compare results.

Lesson planning for directed gameplay

Science Supremo has been designed to be integrated into lessons, with teachers facilitating the learning experience, but the game could be used as the basis for homework or a private study project.

The number of lessons required to deliver the learning outcomes will depend on the attainment level of students, their familiarity and aptitude for management sim-like games and on how teachers organise students into groups.

As a guide, we estimate:

- **It will take a student or small group of students between 10-15 minutes to complete a full clinical trial and approximately 5 minutes to complete one of the stages.**
- **Using directed gameplay, teachers will need 1 or 2 lessons of 40-60minutes to achieve the desired learning outcomes.**

In integrating the game into lessons, teachers should consider:

- Careful use of the supplementary handouts and worksheets, to support a given learning point or to set the scene for a chosen game strategy. For example, playing the game with or without a placebo to compare results, using handouts to explain the placebo effect.
- How students should record the results of a given strategy and its effects on the game and how to share these with other students. This could be done in groups or as a whole class.

Learning resources

Science Supremo comes with a series of supporting learning resources to help teachers integrate the resources into their schemes of work and to extend the learning that occurs through playing the game.

Learning resources consist of:

- Lesson plans
- Reporting worksheets
- Handouts

Lesson plans

Lesson plans give suggested timings and use of the game and associated worksheets for self-directed and directed gameplay approaches.

Reporting worksheets

Students can record gameplay decisions and reasons using supplementary worksheets.

Handouts

Handouts with accompanying background information can be used as part of lessons or as homework or extended activities.

Each handout covers associated content to support the game stage and is a side of A4 of digestible language with illustrations and an extension activity at the bottom of each.

Handouts provide content and background information for different stages of the game and are designed to give students contextual information to help them make informed decisions in the game as well as to stimulate debate in the classroom.

NB handouts provide supplementary content not embedded into the game itself.

Lesson plan 1

This lesson uses a 'self-directed gameplay' approach, where students set themselves a game strategy and see the results. This lesson may be more suited to higher attainment levels.

Timing: 50-60 minutes

Before you let students play the game:

- Set the context for examining clinical trials by giving them an overview of an infectious disease like tuberculosis. You might like to tell them statistics and ask students what can be done, steering them towards the development and testing of new and more effective drugs.
- You might like to open with a broader discussion by posing a number of fundamental questions such as what would you do to cure tuberculosis? How do you think science makes sure drugs work?

Play the game:

- Students play the game in pairs or threes or in small groups, depending on the number of computers you have. As the game is intended to provoke discussion and dialogue between students, it is not recommended that students play alone.
- Let students play the game under their own steam, with or without a thought-out strategy. Give them access to the internet and/or the associated handouts to help them to make informed decisions in the game.
- Allow them to run as many trials as they like in order to achieve a successful trial. Students may try to purposely make an unsuccessful trial to see what happens. You may decide to let them do this - they will still be learning about the parameters of clinical trials by trying to fail. Alternatively, you may prefer to disallow this.

After playing the game:

- When all groups have played the game and reached the end of a trial, regardless of their results, stop them playing.
- As a whole group, pull up the different groups' results screens on a whiteboard/projector (or circulate around each workstation) and ask them to explain their results and how they thought they came to them. Discuss results/success, and their strategies for playing – what worked/what didn't. It's important to validate player experience and make sure they are thinking about strategies for success and failure.
- Use these discussion points to create generalised meanings, drawing out concepts such as the placebo effect, regulations, double blind controlled trials, etc.

Round-up/plenary

- You might like to discuss as a whole class whether the work of scientists should be focused on curing, treating the symptoms or vaccinating/preventing tuberculosis.
- You might like to use the handouts as further reading, setting the class one of the research tasks as homework.

Lesson plan 2

This lesson uses a 'directed gameplay' approach, where you set strategies for students to play the game. This lesson may be more suited to lower level attainment levels.

Timing: 50-60 minutes

Before you let students play the game:

- Set the context for examining clinical trials by giving them stimulus for an imaginable disease like tuberculosis. You might like to tell them statistics and ask students what can be done, leading them towards the development and testing of drugs.

Play the game and review:

- Students play the game in pairs or threes or in small groups, depending on the number of machines you have. As the game is intended to provoke discussion and dialogue between students, it is not recommended that students play alone.
- Set either the whole class or groups of students with a particular strategy, then let them play that out and ask them to draw conclusions and share them with the whole class.
 - Get players to give everyone only the new drug; then discuss the results.
 - Play the game again, but give volunteers half the drug and half not.
- Compare the results and discuss. Why did one approach work and the other fail? What conditions create a successful trial?

Other possible strategies could be:

- Students could be encouraged to play it either by making conscious reflective choices for the participations (based on, for instance age or gender) or by random scientific/objective responses. Then compare and discuss the results.
- Stimulate a double-blind trial by asking one member to input data selected by other members who do not see the screen/client participants. Other members make random numerical selections and do not know anything about the participants (e.g. number 1 has new drug, number 2 has placebo etc).

Round-up/plenary

- You might like to discuss as a whole class whether the work of scientists should be focused on curing, treating the symptoms or vaccinating/preventing tuberculosis.
- You might like to use the handouts as further reading, setting the class one of the research tasks as homework.

Handouts

#1 What is tuberculosis?

Tuberculosis (TB) is still one of the primary infectious causes of death in adults worldwide. It's a bacterial disease that normally affects the lungs.

²More than 8 million people catch active TB per year, with over 2 million dying from the disease. Since the 1980s, tuberculosis has been on the increase; although the developing world is most at risk, tuberculosis is also on the rise in the developed world.



Symptoms of TB include coughing up blood, chest pain, fever chills, weight loss, and fatigue. It is spread by people with active TB expelling droplets while coughing, sneezing, spitting or speaking.

Tuberculosis is currently treated using combinations of antibiotics, which can carry with them the possibility of dangerous side effects. Drug-resistant TB is also a problem. Preventing the disease through vaccination is important.

Research

- Look up tuberculosis on the internet. Can you find out any more about the symptoms?
- Try to find out what ways you can prevent tuberculosis – don't limit these to drugs.
- The impact of tuberculosis can be more widespread than the health impact on individuals. Try to find out more about the effect TB has on society, economy, and ecology. What else can be affected by a widespread disease such as TB?

Discuss

- Do you think that preventing or curing diseases such as tuberculosis should be a high priority for governments, in this country and abroad?
- Why should scientists in the UK study tuberculosis prevention and cures when the UK has comparatively low levels of the disease?

² Photos on this page courtesy istock / Lisa F. Young and istock / kkgas

#2 Who decides to run a clinical trial?



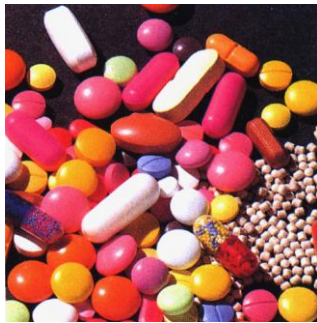
Ideas for clinical trials usually come from researchers. Researchers test new therapies or procedures in the laboratory and in animal studies, and the experimental treatments with the most promising laboratory results are moved into clinical trials. During a trial, more and more

information is gained about a experimental treatment, its risks and how well it may or may not work.

Who sponsors clinical trials?

Clinical trials are sponsored or funded by organisations or individuals such as physicians, medical institutions, foundations, pharmaceutical companies, and voluntary groups, or government agencies such as the Department of Health or the National Health Service. Trials take place in various locations, such as hospitals, universities, doctors' offices, or community clinics.

How are trials made safe?



Designing and running a clinical trial raises many ethical issues. A clinical trial design needs to consider not only what is necessary to determine the safety and effectiveness of the thing being trialled, but also how the safety and human rights of the participants are to be protected. These decisions can be difficult ones for scientists to make. They are under pressure to make sure that the results of the trial are reliable; to ensure that trials

come in under budget; and to ensure that the patients are not mistreated in the course of the trial.

What is a control or control group?

A 'control' or 'control group' is what the trial observations are measured against. In many clinical trials, one group of patients will be given an experimental drug or treatment, while the control group is given either a standard treatment for the illness or a placebo.

Research

- Try to find out a list of organisations or individuals who are involved in sponsoring clinical trials. Find out the reasons why they are involved.
- What ethical issues could be involved in the design of a clinical trial?

Discuss

- Why do you think we need clinical trials?

#3 What is a placebo?



A placebo is an inactive pill, liquid, or powder that has no treatment value. In clinical trials, experimental treatments are often compared with placebos to assess the treatment's effectiveness.

One interesting aspect of placebos is that often people who take placebos show signs of improvement or recovery despite not have taken a drug.

This is known as the 'placebo effect'.

Research

- Use the internet to find out more about the 'placebo effect'. What is it?
- What are the implications of the placebo effect for drug development companies?
- What are the implications of the placebo effect for other health specialists, both 'conventional' (e.g. doctors, physiotherapists) and 'alternative' (e.g. acupuncturists, homeopathists)

Discuss

- Why should someone who is sick – who could, potentially, be cured by the new drug – be given a placebo?
- What do you think the benefits and drawbacks of using a placebo in a clinical trial are?

#4 Who can participate in a clinical trial?



All clinical trials have guidelines about who can participate. Using inclusion/exclusion criteria is an important principle of medical research that helps to produce reliable results. The factors that allow someone to participate in a clinical trial are called 'inclusion criteria' and those that disallow someone from participating are called 'exclusion criteria'. These criteria are based on such factors as age, gender, the type and stage of a disease, previous treatment history, and other medical conditions. Before joining a clinical trial, a participant must qualify for the study.

Some research studies seek participants with illnesses or conditions to be studied in the clinical trial, while others need healthy participants. It is important to note that inclusion and exclusion criteria are not used to reject people personally. Instead, the criteria are used to identify appropriate participants and keep them safe. The criteria help ensure that researchers will be able to answer the questions they plan to study.

Why do people volunteer to take part in clinical trials?

Clinical trials that are well-designed and well-executed are the best approach for eligible participants to:

- Play an active role in their own health care.
- Gain access to new research treatments before they are widely available.
- Obtain expert medical care at leading health care facilities during the trial.
- Help others by contributing to medical research.



Discuss

- Would you take part in a clinical trial? Why / why not?

#5 Single blind / double blind trials

A 'single blind' trial is one in which the administrator knows what the subject has been given, but the subject does not. The subject is therefore prevented from making any assumptions about their symptoms or how they're feeling based on their knowledge of whether they have been given a drug or a placebo. In theory, their reaction to the trial should be more accurate.

A 'double blind' trial is one in which neither the subject nor the administrator knows what the subject has been given. This means that the subject should give a more 'accurate' reaction to the trial, and that the administrator cannot not make any choices – conscious or unconscious – of what the subject should be given based upon their demographic group (age, gender, or race).



Using healthy and sick subjects

One of the issues clinical trial designers and trial administrators have to deal with is whether it is right that an ill subject should be given a placebo or an existing drug, rather than a new drug that could be the best available treatment. This is particularly difficult with trials for life threatening illnesses, such as HIV / AIDS or cancer.

Research

- Do some research to find out: What are the advantages of running a single blind or double blind trial? What could be the disadvantages?
- Find out how ill participants are dealt with in trials in the 'real world'. Are they ever given placebos? Why / why not?

Discuss

- Why should someone who is sick – who could, potentially, be cured by the new drug – be given a placebo or existing drug?
- Why do you think a clinical trial designer would choose to run a single blind or double blind trial, or neither? What do you think they would consider in making that decision?
- Do you think that clinical trials should be used to try to cure individual subjects of illness? Why / why not?

#6 What happens if things go wrong?

Risks to subjects

Any trial that involves experimenting with something new is open to risk. Some of these risks will be known – for instance, certain potential side effects will be known and should be made clear to each subject before the trial starts. However, some will not be known. Each participant runs the risk that they will be open to unwanted – and unknown – side effects by participating in the trial.



Potential for abuse of trial

Any clinical trial involves potential for abuse of that trial by the people that design or run it. They may have a motive for the trial that does not consider the rights of the subjects; or they may make decisions before or during the trial that are biased or unethical based upon their own personal motives or caused by expectation of financial gain.

Normally, clinical trials are overseen by an ethics committee, who determine the ethical parameters of a trial with regard to its human subjects and in order to prevent any abuse in terms of 'creating' a favourable trial result. Any member of an ethics committee, and anyone involved in designing or running a clinical trial, will need to consider these issues.

Research

- Clinical trials have gone wrong and participants have been affected in the past. Do some research on one case where a trial went wrong. Try to find out what happened, why it happened, and what the impact was.
- Find out what measures trial organisers take to ensure that risks are kept to a minimum.
- Find out about how trial organisers ensure that participants are aware of the risk to themselves.

Discuss

- Do you think participants should be compensated for potential risk, for instance, by paying them greater amounts for greater risk?
- Do you think that if the trial is to have great benefit to medical research or development, this justifies any level of risk to the participants?
- Do you think a participant should remain in a trial if they display an adverse reaction to the drug?