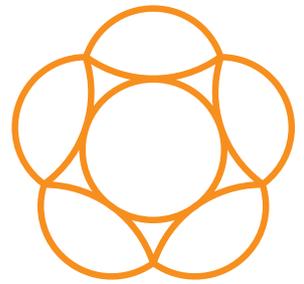




igniting our potential



Centre of the Cell

# Clinical Research Workshop

## Introduction

In these activities, pupils learn about how new medicines are developed – from the initial idea, through the science that turns them into treatments, to the clinical research that tests whether they are safe and effective.

## Curriculum Links

KS4: Science  
AS/A Level: Applied Science, Human Biology

SQA Access, Intermediate and Higher: Biology,  
Biotechnology, Chemistry

## Keywords

Clinical research  
development of medicines  
Phase I

Phase II  
Phase III clinical trials

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## Background Information

The development of a new medicine, from idea to pharmacy shelf, involves both basic science and clinical research.

This workshop takes students through all of the steps that are needed to produce successful new medicines. This includes researching the biology of a disease and how it affects the body. When enough is known about how a disease causes harm, scientists can then develop medicines to intervene. There are many strategies that scientists use when they develop new medicines. Some examples include designing new molecules to block the disease's interaction with cells, or intervening with a patient's own immune defences.

In the first activity, Detecting Cancer, pupils need to design a chemical to detect and treat cancer. They need to consider properties of cancer cells, and how a medicine must work to identify and destroy the cancer cells without causing harm to a patient.

The second activity takes students further along the process of developing a new medicine. Students are asked to put several cards in order, describing the steps from research into the biology of disease through the stages of a clinical trial from start to finish.



# Activities

## Activity 1: Detecting Cancer

This game explores several of the factors researchers need to consider when designing new medicines, and demonstrates how important it is to understand how a medicine affects different parts of a patient's body. Try playing this game several times, trying different options to understand how researchers design medicines and what can go wrong.

### Relevant Links

Find out about the research and development that led to Viagra: <http://resources.schoolscience.co.uk/Pfizer/viagra/index.html>

### Materials Needed

Whiteboard with an internet connection, or a classroom set of computers with an internet connection

To play the game, follow this link:

<http://www.centreofthecell.org/interactives/detectingcancer/index.php>



## Activity 2: How are medicines developed and tested?

There are many stages in the development of new medicines before they are ready for human use. When scientists find molecules that might have the potential to fight disease, they test them in human cells and in animals to determine whether they are effective and safe. Only then are they ready for testing in humans.

New medicines go through a standard set of steps in clinical trials, called Phases, to test for safety and effectiveness. Phase I tests for the most serious side effects. Phase I trials are often done in healthy volunteers. Phase II trials are usually done in volunteers who have the disease the medicine is targeting, and this Phase determines the most effective dose of a medicine, and how long it stays in the body. Phase III trials are larger in scale, and look for rare side effects which may occur in a larger population.

Most clinical trials follow these Phases, but there are some important variations.

Some new medicines, including some cancer treatments, are not tested in healthy volunteers. Several cancer treatments are only tested in terminally ill cancer patient volunteers. This is because these treatments can be toxic to cells. While they might destroy tumours in a cancer patient, these treatments would have side effects that could cause undue harm to healthy volunteers.

In this game, students are asked to design a medicine to treat a new disease, Cellpox. They must put the cards describing the stages in the research and development process for a medicine to treat it, called Poxaway, in the correct order.

### Relevant Links

[Clinical Research Patient's Journey TBC](#)

Find out more about the process of developing new medicines: <http://www.abpischools.org.uk/res/coResourceImport/resources04/manufacturing/index.cfm>  
<http://www.ukcrc.org/PDF/CT%20Booklet%20August%2007%20for%20web.pdf>

### Teacher-led Activity

To be played in small groups of 4-5

### Materials Needed

Cellpox News Flash Cards (one per group) (page 6)

Cellpox Cards (one set per group) (page 9 – 11)

Phase Cards (one set per group) (page 12)

- Give students the Cellpox News Flash and Poxaway cards.
- Can they put the cards in order to create the medicine?
- After the students have put the cards in the correct order, give each group a set of cards marked Phase I, Phase II, and Phase III.
- Explain that new medicines go through a standard set of steps in clinical trials, called Phases, to test for safety and effectiveness. Phase I tests for the most serious side effects, Phase II determines the most effective dose of a medicine, and Phase III looks for rare side effects which may occur in a larger population. Tell the students to put the card labelling these trials with the right trial Phase in the Cellpox Card game.

### Further Questions

- What do the scientists hope to learn by studying people with Cellpox?

*How the disease is spread, how it affects systems in the body, possible targets to stop it.*

- If scientists study Cellpox in people who have it, why do they study it in cells (in vitro) as well?

*By studying the structure of the Cellpox virus, they can understand more about its shape and properties. It is also a cheaper and faster way to test and exclude ideas that don't work.*



- How do scientists find potential molecules to turn into medicines?

*They study how a virus or bacteria behaves, and then look for molecules which have shapes or properties that are likely to interfere with this process.*

- Why do scientists need to test these new molecules in animals if they appear to work in cells (in vitro)?

*Several compounds can affect other organ systems or processes in the body as well as their intended targets. (For an example of this, try playing the Detecting Cancer game again and choosing to make a fat-soluble medicine with a radioactive tracer. While this medicine may work to identify the cancer, it will also leave radioactive traces that may cause damage to the body, because it stays in the body longer.) New medicines need to be tested in animals, with their complex organ systems, to understand what possible side effects could appear, before they are tested in humans.*

- Why is Poxaway tested on healthy volunteers first?

*The Phase I clinical trials are done on healthy volunteers to ensure that there are no major side effects. Once this is established, Phase II clinical trials are conducted on ill volunteers to test for the optimum dose. It is also important to study how much medicine is needed to be effective, and to measure how long the medicine lasts in the body. This is so the medicine can be given in the correct dose at the appropriate intervals. Phase III trials are done on a larger scale to determine whether there are any minor side effects that occur more rarely.*

- Discuss the length of time trials take. Does this leads to decisions on the costs of new medicines?

*Yes—trials are very expensive, but all stages of clinical trials must be completed before medicines are available to prescribe. This ensures that medicines are safe and effective. Also, clinical trials show many medicines to be unsuitable. The time and money spent on these is lost and pharmaceutical companies need to recoup this money. However, because of this cost, there is little incentive for pharmaceutical companies to develop medicines for diseases that affect small numbers of people, or for poor people who cannot afford the medicines.*

## Materials

### Activity 2: How are medicines developed and tested?

Cellpox newsflash card

# BREAKING NEWS

## **CELLPOX**

THERE'S A NEW DISEASE CALLED 'CELLPOX'.  
CELLPOX CAN KILL PEOPLE BECAUSE THERE IS NO MEDICINE  
THAT CAN STOP IT.

PHARMACELL IS A PHARMACEUTICAL COMPANY TRYING TO  
FIND A NEW MEDICINE TO TREAT CELLPOX.

HELP PHARMACELL TO FIND A NEW MEDICINE TO TREAT  
CELLPOX BY PUTTING THE STAGES IN THE CORRECT ORDER.

## Activity 2: How are medicines developed and tested?

### Card Order:

1. To isolate the cause of Cellpox, PharmaCell scientists study people with symptoms of the disease.  
*They discover that Cellpox is caused by a virus, so they can look for ways to fight it.*
2. PharmaCell scientists study people infected with Cellpox to find out how the virus works.  
*Understanding the virus and how it infects people will help the scientists to design a new medicine.*
3. PharmaCell scientists discover how the virus interacts with human cells.  
*Now they can search for a molecule that can block this interaction and stop the Cellpox virus from working.*
4. PharmaCell scientists search databases for molecules that are the right shape to stop the virus working.  
*These molecules will be the likeliest candidates for treating Cellpox.*
5. After searching through thousands of molecules, the PharmaCell scientists have found a promising contender. They call it Poxaway and test live cells infected with Cellpox to see if it kills the Cellpox virus without killing the cells.  
*It's important for Poxaway to destroy Cellpox without killing the cells. This shows that the new medicine is not toxic and may not harm people.*
6. Poxaway is tested on animals.  
*Animals such as mice and rats have similar organ systems as people. Therefore, testing Poxaway on animals helps to ensure that it does not cause harm to other organs.*
7. Poxaway is tested on 30 healthy volunteers. Half of the volunteers receive a placebo whilst the others receive Poxaway. The study takes a few weeks.  
*It's important to find out:*
  - the dose of medicine to use
  - if the new medicine is safe
  - how the volunteers' bodies cope with the medicine**(This card is matched with the Phase I Clinical Trial Card)**
8. Poxaway is tested on hundreds of volunteers infected with Cellpox. The study lasts from three to six months.  
*It's important to find out if:*
  - the medicine stops the Cellpox infection
  - the dosage is correct
  - the medicine is safe to use**(This card is matched with the Phase II Clinical Trial Card)**
9. Poxaway is tested on thousands of volunteers infected with Cellpox. The study lasts from six to twelve months or longer.  
*It's important to find out that:*
  - the medicine stops the Cellpox infection
  - there are no dangerous side effects that occur less frequently**(This card is matched with the Phase III Clinical Trial Card)**
10. PharmaCell are awarded a license to mass-produce Poxaway.  
*There are enough data to show that Poxaway stops Cellpox and it is safe to use. Poxaway is produced and sent to pharmacies in countries around the world.*



To isolate the cause of Cellpox, PharmaCell scientists study people with symptoms of the disease.

They discover that Cellpox is caused by a virus, so they can look for ways to fight it.

Activity 2: How are medicines developed and tested?

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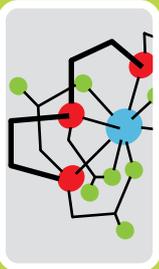


PharmaCell scientists study people infected with Cellpox to find out how the virus works.

Understanding the virus and how it infects people will help the scientists to design a new medicine.

Activity 2: How are medicines developed and tested?

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PharmaCell scientists discover how the virus interacts with human cells.

Now they can search for a molecule that can block this interaction and stop the Cellpox virus from working.

Activity 2: How are medicines developed and tested?

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PharmaCell scientists search databases for molecules that are the right shape to stop the virus working.

These molecules will be the likeliest candidates for treating Cellpox.

Activity 2: How are medicines developed and tested?

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After searching through thousands of molecules, the PharmaCell scientists have found a promising contender. They call it Poxaway and test live cells infected with Cellpox to see if it kills the Cellpox virus without killing the cells.

It's important for Poxaway to destroy Cellpox without killing the cells. This shows that the new medicine is not toxic and may not harm people.

Activity 2: How are medicines developed and tested?

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Poxaway is tested on animals.

Animals such as mice and rats have similar organ systems as people. Therefore, testing Poxaway on animals helps to ensure that it does not cause harm to other organs.

Activity 2: How are medicines developed and tested?

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Poxaway is tested on 30 healthy volunteers. Half of the volunteers receive a placebo whilst the others receive Poxaway. The study takes a few weeks.

It's important to find out:

- the dose of medicine to use
- if the new medicine is safe
- how the volunteers' bodies cope with the medicine

Activity 2: How are medicines developed and tested?

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Poxaway is tested on hundreds of volunteers infected with Cellpox. The study lasts from three to six months.

It's important to find out if:

- the medicine stops the Cellpox infection
- the dosage is correct
- the medicine is safe to use

Activity 2: How are medicines developed and tested?

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Poxaway is tested on thousands of volunteers infected with Cellpox. The study lasts from six to twelve months or longer.

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**PHASE I**  
**Clinical Trial**

**PHASE II**  
**Clinical Trial**

**PHASE III**  
**Clinical Trial**