**Beating bacteria** activit

**Beating bacteria activity (version 2)**

Three years ago research started on chemical compounds to kill severe bacterial infections such as MRSA (*Methicillin Resistant Staphylococcus Aureus*). Over 5000 compounds have been tested so far. The Project Team decided that 52 of these compounds were worth testing further.

The best compound will be used in a clinical trial and be given as tablets to patients who have a severe infection. This experiment will test that the compound is effective at curing the infection. Eventually, if this and subsequent trials are successful, your company will apply to the government for a licence so that the medicine can be sold to the health service, and then prescribed to patients.

As the Project Team you must make a recommendation as to which compound should be used in the clinical trial.

# Activity 1: Finding the best four compounds

The 52 compounds tested were given the codes AA to BZ. The results of the tests are shown in the spreadsheet ‘Beating Bacteria 1’.

The results (*Potency* score) show how good the various compounds are at killing bacteria in a petri dish. The *Side effect* scores were obtained by studying the effects of the compounds on suspensions of isolated human cells in test tubes.

The “*standard”* which is referred to is being used in an experimental trial in a specialist clinic for patients with infections. *The standard* works but there is room for improvement. It is not generally available to doctors and patients.

Carry out the tasks below and use the data on spreadsheet beating bacteria1.xls to work out which 4 of the 52 compounds are the best. Further tests will be done on these compounds before one of them is selected for the clinical trial.

**a.** Look at the data in spreadsheet ‘Beating Bacteria 1’

**Potency**: the number shows how many times better the compound is when compared to the *standard*:

For example, the number for compound AE is 200. This means that compound AE works at 1/200th the concentration of the *standard*; it is 200 times stronger.

**Side effect score**: the number shows how the compound compares with the *standard*. For example:

2.0 means that compound is worse than the standard – twice as bad

0.5 means that compound is better than the standard – twice as good.

You must pick compounds that are:

* Significantly more *potent* (stronger) than the *standard*
* At least 300 times more *selective* (safest and with the least side effects).

Calculate *Selectivity* by dividing *potency* by the *side effect* score. Enter your results in the *Selectivity* column.

**b.** Use the *Data* function on the spreadsheet toolbar to sort the values so that they are in decreasing potency order.

**c.** Create a bar chart using the clustered bar format to show clearly which of the most potent compounds have a *selectivity* of greater than 300.

**d.** Decide which are the 4 best compounds. Write your recommendations on the *Memo* sheetto the Director, Research & Development.

# Activity 2: Selecting the best compound for clinical trials

The 4 best compounds were then tested in a small number of animals to see which had the best “bioavailability”. This is a measure of how much of the compound is taken up from the stomach or small intestine into the blood stream. If a drug is given by mouth it first goes into the stomach and then into the intestine. It is very rare for 100% of the dose to be taken up into the blood stream. Sometimes as little as 10% might be absorbed. The best potential drug has the highest bioavailability.

Put the codes for the 4 best compounds in the table below in order of potency.

|  |  |  |
| --- | --- | --- |
| **Compound** | **Compound code** | **Bioavailability** |
| Most potent |  | 10% |
| 2nd most potent |  | 20% |
| 3rd most potent |  | 55% |
| Least potent |  | 30% |

Decide which compound should be taken on into clinical trials. Write your recommendation on the *Memo* sheet.

# Activity 3: Manufacturing and launching the new antibiotic medicine

Read through the information below.

Decide whether it will be quicker for your company to make the launch stock itself, or to place an order with another UK manufacturer. Put your answer on the *Memo* sheet.

## Part 1: Manufacturing the new antibiotic medicine

The manufacture of the new antibiotic medicine involves three stages:

* buying and receiving the raw materials
* manufacturing the chemical compound from the raw materials
* making up the new antibiotic medicine from all the ingredients (including the chemical compound) and packaging.

The stock needed for the launch is 4 million packs.

The raw materials are readily available from a Japanese supplier. It takes 4 months to get this raw material from the time of placing an order.

1. You could contract out the whole manufacturing process to another UK company. They could deliver the stock 10 months after receiving the raw materials.
2. Alternatively your company could manufacture the new treatment itself. However, you would need to buy a special monitoring device to be used in the chemical manufacturing stage. This device is only available from an American supplier. The monitoring device will take 6 months to arrive from the time of order.

If your company manufactures the new antibiotic medicine, it will take:

2 months (after receiving all the raw materials) to make the chemical compound then 4 months to produce the launch stock

Now decidewhether it will be quicker for your company to make the launch stock itself, or place an order with another manufacturer. Put your answer on the *Memo* sheet.

## Part 2: Launching the new antibiotic medicine onto the market

Decide on the launch date for the new medicine using the information below. Put your answer on the *Memo* sheet.

Before you can launch the new antibiotic medicine you must consider the following stages. These can only happen one after the other.

* Testing in the laboratory should be completed by the end of next year.
* Clinical trials in healthy volunteers and patients suffering from infections (both adults and children) will take four years to complete.
* The treatment must be registered with the authorities in the country where it will be launched first. This will take 1 year.
* As soon as the treatment has been registered, the raw materials will be ordered and the launch stock manufactured. Use your answer from Activity 3 to decide how long this will take.

## Now decide:

When to launch the new antibiotic medicine

What to call it

Put your answers on the *Memo* sheet