Activity 1: Development of a medicine

**Task 1: Stage sequencing**

First, write a number in the order column to sequence the stages involved in designing and testing a new medicine, ready for large scale manufacture and use. Then draw lines to match the descriptions to each stage.

Useful website, showing the full process for the development of a medicine: [www.abpischools.org.uk/topics/making-medicines/creating-a-medicine/](http://www.abpischools.org.uk/topics/making-medicines/creating-a-medicine/)

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| Order | Stage |  | Description |
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|  | NHS approval |  | Small-scale experiments are conducted on promising potential compounds (‘leads’) such as small-scale synthesis and pharmacological screening. Biological testing is initially carried out on cell culture. Promising leads are tested later on animals to look at toxicity. |
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|  | Post-marketing surveillance |  | Licenses are granted when a medicine is proven to be safe and effective, and the manufacturing processes meet quality standards. Once approved, the medicine can be manufactured on a large scale and packaged for distribution. |
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|  | Discovery and research |  | Newly licensed medicines are continuously monitored in phase IV clinical trials (pharmacovigilance). Patient information leaflets (PIL) are supplied with instructions on how to use the medicine and possible side effects. Doctors and the public can notify novel side effects to the Medicines and Healthcare products Regulatory Agency (MHRA) via the Yellow Card Scheme. Significant side effects may lead to the PIL being amended or the medicine being withdrawn from the market. |
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|  | Licensing |  | Knowledge is gathered about the disease, including its causes, symptoms, and potential treatment options. |
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|  | Clinical development |  | Three main stages – Phase 1, 2, and 3 – to study the safety and effectiveness of the medicine and determine the dosage requirements:  Phase 1 – a small number of healthy volunteers  Phase 2 – a larger group of people with the disease  Phase 3 – typically several thousand patients |
|  |  |  |  |
|  | Preclinical development |  | Health Technology Assessment agencies such as NICE (National Institute for Health and Care Excellence) evaluate new treatments and their cost-effectiveness. The NHS is legally obliged to fund medicines recommended by these agencies to ensure equality of treatment options. |

**Task 2: Careers in the pharmaceutical industry**

More than 65% of all medical research and development in the UK is carried out by the pharmaceutical industry ([www.abpi.org.uk/careers/job-roles/](http://www.abpi.org.uk/careers/job-roles/)). Not all jobs in the pharmaceutical industry are related to research and development. There is a collaboration between a vast range of disciplines. The Association of the British Pharmaceutical Industry (ABPI) groups these disciplines into four areas:

* research and development
* manufacturing and supply
* commercial
* support functions.

Your task is to scan the QR codes around the classroom to research the job disciplines associated with each of the four sectors. List the roles included in each, for example, research and development includes archiving tasks.

Share your findings with the rest of the group. Be prepared to be asked about each of the different types of roles.

Useful websites:

[www.abpi.org.uk/careers/working-in-the-industry/](http://www.abpi.org.uk/careers/working-in-the-industry/)

<https://careersinpharmacy.uk/>

<https://www.pfizer.co.uk/science/developing-new-medicines>