Activity 1: Development of a medicine

**Task 1: Stage sequencing** – **answers**

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| Order | Stage | Description |
| 1 | Discovery and research | Knowledge is gathered about the disease, including its causes, symptoms, and potential treatment options. |
| 2 | Preclinical development | 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. |
| 3 | 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 |
| 4 | Licensing | 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 larger scale and packaged for distribution. |
| 5 | NHS approval | 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. |
| 6 | Post-marketing surveillance | 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 MHRA via the Yellow Card Scheme. Significant side effects may lead to the PIL being amended or the medicine being withdrawn from the market. |