The process of discovering, testing, and eventually gaining approval for selling a drug is a long and arduous one. Here, we look at the different stages involved, and the approximate length of time that each stage takes, to eventually arrive at an approved drug that can be given to patients.

<table>
<thead>
<tr>
<th>Stage</th>
<th>Duration</th>
<th>Description</th>
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</thead>
<tbody>
<tr>
<td>Research &amp; Development</td>
<td>3–6 years</td>
<td>Drug development begins long before clinical testing. It starts with the identification of a target for a drug to act on, then the identification of compounds that could potentially hit that target.</td>
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<tr>
<td>Preclinical Studies</td>
<td>1 year</td>
<td>Up to 10,000 compounds considered during screening, but only around 250 will make it to preclinical testing. Efficacy and potential risks are evaluated before human trials can begin.</td>
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<tr>
<td>Clinical Trials</td>
<td>4–7 years</td>
<td>Clinical trials involve human participants. These tests in volunteers provide information on safety and efficacy. Around 70% of drugs succeed in phase 1, 33% in phase 2, and 25–30% in phase 3.</td>
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<tr>
<td>Review &amp; Approval</td>
<td>1–2 years</td>
<td>If a drug is deemed effective in clinical trials, it is submitted to regulating bodies to be approved. It’s estimated that only around 1 in 5000 drug candidates makes it all the way to approval.</td>
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**Target Identification**

What will the drug affect?

Understandings of the causes of diseases or conditions can help researchers know what processes or pathways drugs to treat the condition need to be able to target.

**Compound Screening**

10,000+ compounds

Compounds are screened in laboratory tests for their ability to affect the identified target. They are also screened to check they don’t interfere with other related targets.

**Lead Identification**

Which compounds to test?

Though screening is unlikely to uncover a perfect drug candidate, promising compounds can be identified. The structures of these molecules can be modified to try and improve their activity.

**Required Standards**

Min. 2 mammalian species

Drugs must undergo toxicity testing on at least two mammals (one non-rodent), including at least two administration routes, before they are allowed to proceed to clinical trials in humans.

**Phase 1 Trials**

Usually 20–80 people

The primary goal of phase 1 trials is to determine the drug’s side effects. Additionally, how quickly the drug is metabolised and excreted from the body can be determined during these trials.

**Phase 2 Trials**

Usually 100–300 people

Phase 2 trials help to determine how effective the drug is in patients who have the condition it is trying to treat. Controlled trials compare the effects of the drug to that of a placebo.

**Phase 3 Trials**

Usually 1,000–3,000 people

Gauges efficacy, dosage, and safety in a larger population. Also compares efficacy to existing treatments, as well as interactions with other drugs and effects of different dosages.

**Post-release Monitoring**

Indefinite duration

After a drug is approved and available for use by patients, it is still monitored for any side effects in the general population that may not have occurred in the drug’s clinical trials.