The drug development process: what do pharmaceutical physicians do?

Pharmaceutical medicine is the medical specialty concerned with the discovery, development, evaluation, registration and monitoring of new medicines. Pharmaceutical physicians are involved in every step in the drug development process.

The drug development stages

<table>
<thead>
<tr>
<th>Development time</th>
<th>Phase 1</th>
<th>Phase 2</th>
<th>Phase 3</th>
<th>Regulatory approval</th>
<th>Phase 4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Year 1-4 (including preclinical)</td>
<td>Year 4-7</td>
<td>Year 7-9</td>
<td>Year 9-11</td>
<td>Approved medicine</td>
<td>Ongoing</td>
</tr>
<tr>
<td>Year 11-12</td>
<td>many thousands</td>
<td>Year 11-12</td>
<td>many thousands</td>
<td>Approved medicine</td>
<td>ongoing</td>
</tr>
<tr>
<td>£500 million (including preclinical)</td>
<td>£700 million</td>
<td>£900 million</td>
<td>£1.1 billion</td>
<td>£1.2 billion</td>
<td>£1.2 billion</td>
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<tr>
<td>10-20</td>
<td>5-10</td>
<td>2-5</td>
<td>1-2</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>10-20 subjects in each phase</td>
<td>20 - 80</td>
<td>100–300</td>
<td>1,000–3,000</td>
<td>£500 million (including preclinical)</td>
<td>£700 million</td>
</tr>
<tr>
<td>Candidate molecules</td>
<td>10-20</td>
<td>5-10</td>
<td>2-5</td>
<td>1-2</td>
<td>1</td>
</tr>
</tbody>
</table>

The role of pharmaceutical physicians

Clinical Pharmacologist

Responsible for the design, performance and interpretation of studies focussed particularly on the collection of pharmacokinetic data.

Working as an investigator is probably the role that is closest to clinical medicine. Physicians in this role take medical histories and perform physical examinations, predominantly in healthy volunteers.

Clinical research physician

Responsible for clinical plans, design of phase 2 and 3 clinical trials, safety monitoring and medical governance of new medicines.

Medical Assessor

Works in a regulatory body to approve new trials and to evaluate clinical efficacy and safety of medicines submitted for approval.

Medical Affairs

Work with commercial colleagues to ensure the sales and marketing strategies are based on accurate clinical data and executed in a medically sound and ethical way.

Regulatory Affairs

Ensure the appropriate licensing, marketing and legal compliance of pharmaceutical and medical products in order to control the safety and efficacy of products.

Pharmacovigilance

Analyses data to identify the safety profile of a medicine, including drug reactions, adverse reactions (or side effects), contraindications, warnings, interactions and special populations.

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