U.S. DRUG DEVELOPMENT PROCESS

**Potential New Drugs**

- How does the drug work?
- How can it be delivered in the body?
- Is it safe in animals?

**FDA Investigational New Drug Application**

**Clinical Trial Phases**

<table>
<thead>
<tr>
<th>Phase 1</th>
<th>Several months</th>
<th>Usually healthy volunteers</th>
<th>20–100</th>
<th>~$25 million</th>
<th>Is it safe?</th>
<th>What is the right dose?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phase 2</td>
<td>Several months to 2 years</td>
<td>Volunteers with the disease or condition</td>
<td>100+</td>
<td>~$58 million</td>
<td>Is it safe?</td>
<td>What is the right dose?</td>
</tr>
<tr>
<td>Phase 3</td>
<td>1–4 years</td>
<td>Volunteers with the disease or condition</td>
<td>300–3000</td>
<td>~$255 million</td>
<td>Is it safe?</td>
<td>Is it effective?</td>
</tr>
<tr>
<td>FDA Approval</td>
<td>1–2 years</td>
<td>New Drug Application submitted</td>
<td>Application reviewed</td>
<td>Application approved</td>
<td>Available to public</td>
<td></td>
</tr>
<tr>
<td>Postmarket Testing (Phase 4)</td>
<td>11–14 years</td>
<td>Volunteers with the disease or condition</td>
<td>1000+</td>
<td>~$312 million+</td>
<td>Is it safe?</td>
<td>Are there rare side effects?</td>
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Of 100 drugs that begin clinical trials...

- ~70 move to Phase 2
- ~23 move to Phase 3
- ~6-7 will be approved

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**Clinical Trial Phases**

- **Preclinical Phase**
  - Several years

- **FDA Investigational New Drug Application**

- **Clinical Trial Phases**
  - **Phase 1**
    - Several months
    - Usually healthy volunteers
    - 20–100 individuals
    - Cost: ~$25 million
    - Purpose: Is it safe? What is the right dose?
  - **Phase 2**
    - Several months to 2 years
    - Volunteers with the disease or condition
    - 100+ individuals
    - Cost: ~$58 million
    - Purpose: Is it safe? What is the right dose? Is it effective?
  - **Phase 3**
    - 1–4 years
    - Volunteers with the disease or condition
    - 300–3000 individuals
    - Cost: ~$255 million
    - Purpose: Is it safe? Is it effective? What are the side effects?

- **FDA Approval**
  - 1–2 years
  - New Drug Application submitted
  - Application reviewed
  - Application approved
  - Available to public

- **Postmarket Testing (Phase 4)**
  - 11–14 years
  - Volunteers with the disease or condition
  - 1000+ individuals
  - Cost: ~$312 million+
  - Purpose: Is it safe? Are there rare side effects? How does it compare to other similar drugs?