Cancer Drug Approval Timelines

Updated April 2013
Development Timing by Class

Clinical and Approval Times by Therapeutic Classes, 2002 to 2006

- **CNS**: 9.2 years U.S. Clinical Phase, 1.6 years U.S. Approval Phase (Total 10.6 years)
- **Cancer**: 8.5 years U.S. Clinical Phase, 0.8 years U.S. Approval Phase (Total 9.3 years)
- **Endocrine**: 7.2 years U.S. Clinical Phase, 1.5 years U.S. Approval Phase (Total 8.7 years)
- **Antiinfective**: 6.8 years U.S. Clinical Phase, 1.6 years U.S. Approval Phase (Total 8.4 years)
- **Gastrointestinal**: 6 years U.S. Clinical Phase, 2.3 years U.S. Approval Phase (Total 8.3 years)
- **AIDS Antivirals**: 6 years U.S. Clinical Phase, 0.6 years U.S. Approval Phase (Total 6.6 years)
- **Cardiovascular**: 5.7 years U.S. Clinical Phase, 1.5 years U.S. Approval Phase (Total 7.2 years)
- **Anesthetic/Analgesic**: 4.6 years U.S. Clinical Phase, 2.4 years U.S. Approval Phase (Total 7.0 years)

**Cancer Drug Development**

- Based on two recent analyses, the average development timing for oncology drugs are:

<table>
<thead>
<tr>
<th>Disorder</th>
<th>N</th>
<th>Phase II</th>
<th>Phase III</th>
<th>Approval</th>
<th>Phase I</th>
<th>Phase II</th>
<th>Phase III</th>
<th>Cost ($)</th>
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<tbody>
<tr>
<td>Blood</td>
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<td>60</td>
<td>57</td>
<td>25</td>
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<td>32</td>
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<td>22</td>
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<tr>
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<td>84</td>
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<td>29</td>
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<td>29</td>
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<td>677</td>
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<tr>
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<td>37</td>
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<td>28</td>
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<tr>
<td>HIV/AIDS</td>
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<td>36</td>
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<td>23</td>
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<tr>
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<tr>
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<td>60</td>
<td>40</td>
<td>11</td>
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<td>30</td>
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<th>Phase I</th>
<th>Phase II</th>
<th>Phase III</th>
<th>Cost ($)</th>
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</thead>
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<td>46</td>
<td>25</td>
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<td>44</td>
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<td>37</td>
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<tr>
<td>HIV/AIDS</td>
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<td>56</td>
<td>44</td>
<td>22</td>
<td>22</td>
<td>19</td>
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</tr>
</tbody>
</table>

**All Drugs and Biologics**
- 7.1 years

**Non-Biologic Agents**
- 7.3 years

**Clinical Timing:**
- 6.6 years (79 mos)
- PI to PI: 78%
- PI to PII: 59%
- PII to PIII: 43%
- PI to NDA: 20%
Drug Approval Success Rates

• Overall approval rates by therapeutic class

Approval Success Rates for NCEs by Therapeutic Class

- Anti-infectives: 40.4%
- Oncology/Immunology: 27.2%
- Respiratory: 17.9%
- Cardiovascular: 15.2%
- CNS: 14.4%
- GI/Metabolism: 10.9%

Cancer Trial Attrition Example

- The following graphic presents Deloitte’s example of attrition for cancer products in clinical trials based on their portfolio of companies:
  - Success rates by phase are Phase I: 72.6%; Phase II: 40.3%; Phase III: 66.7%; and Approval: 90.6%; Overall success: 17.7%

Cost per Drug by Therapeutic Area

- Development cost by key therapeutic areas
  - Cancer was not assessed but estimated by Epiphany


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