

Drug Development Cost Per Patient

Traditional FDA Approval vs. Phase 1 Only Pathway

TRADITIONAL PATHWAY

Full FDA Approval

ASSUMPTIONS

STEP 1

Development Cost

\$985,000,000

Median capitalized R&D investment
[1] Wouters et al., JAMA 2020

STEP 2

Time to Approval

12 years

Discovery through clinical trials to patient
[2] Wikipedia, Cost of Drug Development

STEP 3

Post-Approval Patent Life

13 years

20yr base - 12yr dev + 5yr ext (capped 14yr)
[3] Hatch-Waxman Act, 35 U.S.C. §156

STEP 4

Annual Patient Volume

18,600 patients/yr

~20% of Humira's patient volume
[4] AbbVie/Humira prescribing data

ALTERNATIVE PATHWAY

Phase 1 Only

STEP 1

Development Cost

\$6,600,000

Upper range of Phase 1 trial costs
[5] Sertkaya et al., Clinical Trials 2016

STEP 2

Time to Approval

2 years

Phase 1 trial duration + regulatory
[6] ASPE/HHS 2014

STEP 3

Post-Approval Patent Life

18 years

20yr base - 2yr dev (no extension)
[3] Standard patent term, 35 U.S.C. §154

STEP 4

Annual Patient Volume

18,600 patients/yr

~20% of Humira's patient volume
[4] AbbVie/Humira prescribing data

CALCULATION

STEP 5

Total Patients Over Patent Life

241,800 patients

$18,600 \times 13 \text{ years}$

STEP 6

Development Cost Per Patient

\$4,074

$\$985,000,000 \div 241,800$

STEP 7

Add 20% Profit Margin

+ \$815

$\$4,074 \times 0.20$

STEP 5

Total Patients Over Patent Life

334,800 patients

$18,600 \times 18 \text{ years}$

STEP 6

Development Cost Per Patient

\$20

$\$6,600,000 \div 334,800$

STEP 7

Add 20% Profit Margin

+ \$4

$\$20 \times 0.20$

COST PER PATIENT

\$4,889

COST PER PATIENT

\$24

204×

Cost difference per patient treatment

SOURCES

[1] Wouters OJ, McKee M, Luyten J. "Estimated Research and Development Investment Needed to Bring a New Medicine to Market, 2009-2018." JAMA. 2020;323(9):844-853.

[2] Wikipedia. "Cost of drug development." The process from discovery and clinical trials amounts to approximately 12 years from research lab to the patient.

[3] Drug Price Competition and Patent Term Restoration Act (Hatch-Waxman), 35 U.S.C. §156. Maximum extension 5 years; total post-approval patent life capped at 14 years.

[4] AbbVie. "HUMIRA has helped treat more than 1.4 million patients since its introduction in 1997." humira.com

[5] Sertkaya A, Wong HH, Jessup A, Beleche T. "Key cost drivers of pharmaceutical clinical trials in the United States." Clinical Trials. 2016;13(2):117-126. Phase 1 costs: \$1.4M-\$6.6M.

[6] ASPE/HHS. "Examination of Clinical Trial Costs and Barriers for Drug Development." 2014. Phase 1 expected to last approximately one year.