Estimated Cost of Developing a Therapeutic Complex Medical Device in the US

This document presents the abstract of this paper, as published in *JAMA Network Open*. The full text of the article is available at: https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2796179.

Aylin Sertkaya,[1], Rebecca Devries,[1], Amber Jessup[2], and Trinidad Beleche[3]

[1] Eastern Research Group Inc
[2] US Department of Health and Human Services, Office of Inspector General
[3] US Department of Health and Human Services, Office of the Assistant Secretary for Planning and Evaluation

KEY POINTS

Question: What are estimated costs associated with bringing a novel therapeutic complex medical device to market in the US?

Findings: In this economic evaluation study using data from public and proprietary sources, an analytical cost model found that the estimated mean expected capitalized development cost per therapeutic complex medical device was $522 million. The nonclinical development stage accounted for 85% of this cost, whereas the US Food and Drug Administration submission, review and approval stage comprised 0.5%.

Meaning: Results of this economic analysis study provide an estimate of development cost for novel therapeutic complex medical devices using public and proprietary data sources that account for cost of failures and cost of capital.

ABSTRACT

IMPORTANCE: The US medical device market is the world's largest, but estimates of the cost of a medical device to market are not available to help inform policy making and regulatory efforts to enhance device safety and innovation.

OBJECTIVE: To estimate the mean expected capitalized cost of developing a novel therapeutic complex medical device.

DESIGN, SETTING AND PARTICIPANTS: In this economic evaluation, an analytical model of novel therapeutic complex medical device development using data from public and proprietary sources with coverage from 2000 through 2018 was used to estimate the cost, duration, and phase transition success probability associated with each stage of development. Data analysis was completed in September 2021.

EXPOSURES: Conduct of nonclinical and clinical studies; payment of FDA user fees for novel therapeutic complex medical devices.

MAIN OUTCOMES AND MEASURES: Mean development cost (in 2018 US dollars) incurred by developers from FDA-approved novel therapeutic complex medical device, accounting for failures and cost of capital.

RESULTS: In this economic analysis, the mean development cost for a novel therapeutic complex medical device was $54 million (95% CI,, $25 million-$200 million) excluding any post-approval studies that might be required. After accounting for the cost of failed studies and cost of capital, the mean capitalized cost of bringing a novel therapeutic complex medical device to the US market was $522 million (95% CI, $205 million-$3382 million). The key factors associated with this cost were the phase transition probabilities: 46.9% for nonclinical to feasibility study, 48.0% for feasibility to pivotal study, 75.7% pivotal study to FDA premarket approval submission, and 80.5% for FDA premarket approval submission to approval. The nonclinical development stage constituted the largest portion of overall cost at 80.5% with the FDA review stage with the highest phase transition probability accounting for only a small fraction at 0.5%.

CONCLUSION AND RELEVANCE: In this economic evaluation study, the cost of therapeutic complex medical device development from proof of concept through post-approval stages was assessed accounting for the cost of failures and the cost of capital. Existing estimates did not account for all stages of development, capitalization, or failure costs, which this study suggest were substantial.

The estimated mean expected capitalized development cost for therapeutic complex medical devices, counting expenditures on failed products, is $522 million (95% CI: $205 million-$3,382 million) excluding any post-approval studies that may be required in addition. The estimates are based on data from ClinicalTrials.gov, US Food and Drug Administration's (FDA’s) premarket approval and post-approval studies databases, Medidata Solutions, published literature, and interviews with Federal and industry medical device experts and are applicable to those devices approved by FDA between January 2013 and September 2018.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Assistant Secretary for Planning and Evaluation

200 Independence Avenue SW, Mailstop 434E
Washington, D.C. 20201

For more ASPE briefs and other publications, visit:
aspe.hhs.gov/reports

SUGGESTED CITATION
Sertkaya, A., Devries, R., Jessup, A., Beleche, T., Estimated Cost of Developing a Therapeutic Complex Medical Device in the US. JAMA Network Open, 2022; 5(9):e2231609. doi:10.1001/jamanetworkopen.2022.31609.

For general questions or general information about ASPE: aspe.hhs.gov/about