Digital Endpoints ROI Calculator Reference Guide

This reference guide is the official manual for the Digital Endpoints ROI Calculator, a tool developed through DATAcc by DiMe's "Building the Business Case for Digital Endpoints" project in collaboration with Health Advances. It provides you with a description of the methodology, functionality, and step-by-step instructions to effectively leverage the calculator for assessing the financial impact of incorporating digital endpoints in clinical trials.

In this guide, you will find:

- Instructions on how to use the calculator, input data, and interpret the results
- Definitions of inputs and assumptions made to run calculations

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Section 1. About the Digital Endpoints ROI Calculator

Background

Informed by findings from DiMe's partnership with Tufts Center for the Study of Drug Development and pharma and biotech industry leaders, the ROI calculator provides evidence-backed insights into the cost savings and financial benefits of using digital endpoints in clinical trials. These insights highlighted the need for standardized tools to quantify these benefits across the industry.

What does the calculator do?

The calculator estimates the ROI of incorporating digital measures as endpoints in clinical trials based on the impact that the inclusion of digital measures has on the expected net present value (eNPV) of a program. The calculator quantifies the estimated financial impact based on the user's input. The output from the calculator

is an important data point that should be used with other information to guide the decision to include digital measures in clinical development.

Who is the calculator for?

The Digital Endpoints ROI Calculator's primary users are clinical trial sponsors interested in quantifying the financial benefit of incorporating digital measures as endpoints in clinical trials. Teams experienced in incorporating digital endpoints would find value in the calculator's ability to estimate their potential magnitude of impact on the trial. Additionally, the calculator is valuable to teams early in the journey of digital endpoint adoption by helping them evaluate the potential financial impact of incorporating digital endpoints.

Methodology of the Digital Endpoints ROI Calculator

The Digital Endpoints ROI Calculator builds upon the foundational model presented in DiMasi et al., 2024. In collaboration with Health Advances, the model was enhanced by integrating industry benchmark data, enabling the calculator to generate ROI estimates even when specific trial data is unavailable. The resulting calculator ensures broad applicability and ease of use, allowing users to assess the financial impact of digital endpoints using either custom inputs or industry-standard assumptions.

Section 2. Inputs, assumptions, and source data

The Digital Endpoints ROI Calculator requires you to input assumptions to calculate the ROI. The assumptions and their definitions are listed in the table below. If you do not have access to all assumptions listed for your specific program, the calculator provides the option to use pre-populated industry averages on an assumption-by-assumption basis. The pre-populated industry averages are based on analyses of industry-wide databases and publicly available research studies.

Category	Assumption	Definition	Sources for pre-populated industry averages
Revenue forecast	Peak sales (USD)	Estimated revenues in the year the asset reaches peak adoption	DiMasi, et al. (2024). Assessing the net financial benefits of employing digital endpoints in clinical trials. Clinical and Translational Science. Based on annual sales data from Evaluate Pharma. The average is conservative as it's only based on US peak sales data.
	Adoption ramp Curve	The percent of peak adoption achieved by year over the first 7 years after launch	Health Advances analysis based on historic sales data from Evaluate Pharma
	Period of exclusivity	Length of time from drug approval to loss of exclusivity (LOE)	DiMasi, et al (2022). Assessing the financial value of decentralized clinical trials. Therapeutic Innovation and Regulatory Science.
	Years after loss of exclusivity	The percent of pre-LOE revenues maintained after loss of exclusivity by year	Health Advances analysis based on historic sales data from Evaluate Pharma
Cost assumptions	Cost of goods sold (COGS) (as a % of revenue)	Cost for manufacturing the asset once commercially launched (assume manufacturing costs in clinical development are included in R&D costs)	Health Advances analysis of company financials. Value is an average of 35 mid to large-cap biopharmaceutical companies.
	Phase 2: Total cost or cost per patient	Estimated spend on phase 2; can be entered as a total or on a per-patient basis	DiMasi, et al. (2016). Innovation in the pharmaceutical industry: New estimates of R&D costs. Journal of Health Economics.
	Phase 3: Total cost or cost per patient	Estimated spend on phase 3; can be entered as a total or on a per-patient basis	DiMasi, et al. (2016). Innovation in the pharmaceutical industry: New estimates of R&D costs. Journal of Health Economics.
	Phase 4 Cost (as a % of revenue)	Ongoing R&D costs after product launch	Health Advances analysis based on analysis of historic company financials
	Sales & marketing at launch (as a % of peak year revenue)	Includes activities like market development, marketing materials, and the sales team for the asset	Health Advances analysis based on analysis of historic company financials
	Other operating costs at launch	Includes other general and administrative costs associated with supporting the asset	Health Advances analysis based on analysis of historic company financials

	(as a % of peak year revenue)		
	Pre-launch sales & marketing	Sales & marketing costs across the year immediately pre and post-launch, assuming these efforts ramp up before launch in anticipation of commercialization	DiMasi, et al (2022). Assessing the financial value of decentralized clinical trials. Therapeutic Innovation and Regulatory Science.
	Growth after launch	The growth rate applied to the costs from product launch	Health Advances analysis based on a review of historic company financials
	Costs after LOE (as a % of revenue)	The cost, as a percent of revenue, associated with the program after the product loses exclusivity	Health Advances analysis based on a review of historic company financials
Clinical development assumptions	Phase 2: Number of patients	Enrollment target (number of patients) for the study	Health Advances analysis based on Evaluate Pharma
	Phase 2: Time to completion	Total time from first patient enrollment to result	DiMasi, et al. (2016). Innovation in the pharmaceutical industry: New estimates of R&D costs. Journal of Health Economics.
	Phase 3: Number of patients	Enrollment target (number of patients) for the study	Health Advances analysis based on Evaluate Pharma
	Phase 3: Time to completion	Total time from first patient enrollment to result	DiMasi, et al. (2016). Innovation in the pharmaceutical industry: New estimates of R&D costs. Journal of Health Economics.
	Probability of success	Likelihood of the program progressing from phase 2 to phase 3 and from phase 3 to regulatory approval and launch	DiMasi, et al. (2016). Innovation in the pharmaceutical industry: New estimates of R&D costs. Journal of Health Economics.
Other	Tax rate	Tax rate applied to forecasted operating income from the asset	Based on data reported in DiMasi, et al. (2025) in press.
	Cost of capital	The discount rate used to calculate the net present value of future probability-adjusted income	This value will vary over time and by company. We've selected 10% as a round number within the typical range of values seen in pharma and biotech. For additional details, see DiMasi, et al. (2016). Innovation in the pharmaceutical industry: New estimates of R&D costs. Journal of Health Economics

Section 3. Formulas

Expected net present value (eNPV)

What is eNPV?

The net present value (NPV) tells you how much a project is worth today, considering future cash flows (money coming in and going out) adjusted for the time value of money (a dollar today is worth more than a dollar in the future). If NPV is positive, the project is expected to be profitable. If negative, it may not be worth pursuing. However, since future outcomes are uncertain (especially in high-risk industries like drug development), eNPV considers multiple possible scenarios, each weighted by its probability of occurring. It makes an educated guess about the project's financial value by considering different potential futures. eNPV models are commonly used in pharma and clinical trials to assess whether developing a drug is financially viable. Additionally, eNPV models support go/no-go decisions in clinical development and help decision-makers compare risky projects and prioritize investments. This modeling approach enables decision-makers to make data-driven investment choices while accounting for uncertainty.

The Digital Endpoints ROI Calculator leverages the eNPV model presented by DiMasi et al. 2024, which analyzed cash flows associated with new drug development and commercialization. This model measures the increase in eNPV that results from incorporating digital endpoints into the process and helps determine whether incorporating digital endpoints can save money and speed up drug development. Additionally, the model considers several financial and operational aspects of a clinical trial, including cost savings, trial efficiency, probability of success, and market acceleration. It compares traditional trial methods against trials incorporating digital endpoints by estimating the costs of both approaches, projecting potential time savings in different trial phases, and calculating the financial impact of bringing a drug to market sooner. By applying industry benchmark data and financial projections in the model, it estimates the net financial benefit of using digital endpoints. If the model shows a strong positive impact, it suggests that digital endpoints could make drug development more cost-effective. As described in the formula below, the eNPV model incorporates the revenue and costs of a program each year, weighing them by the probability of success and discounting based on the cost of capital.

$$\text{eNPV of a Program}^{*} = \sum_{t=0}^{25} \frac{(\text{Revenue}_t - \text{Costs}_t) * \text{POS}}{(1+\text{Cost of Capital})^t}$$

*The *eNPV calculation applies the same formula for a program with and without digital measures*

POS = Probability of success (likelihood of the program progressing from phase 2 to phase 3, and phase 3 to regulatory approval and launch)

Revenue_t = Peak sales * $\text{Share of peak sales}_t$

Calculated based on a peak sales value. Revenues ramp up to the peak sales value over a specified number of years after launch and then decline to a specified steady state after loss of exclusivity.

Costs_t = COGS_t + $\text{R\&D}_t$ + $\text{Sales \& marketing}_t$ + Other operating_t + Taxes_t

COGS_t = Revenue_t * COGS as a % of Revenue

$\text{R\&D}_t$ = Phase 2 costs_t *(if relevant)* + Phase 3 costs_t + Phase 4 costs_t

- Phase 2/3 costs_t = Phase 2/3 cost per year OR Phase 2/3 number of patients * Phase 2/3 cost per patient per year, costs allocated across years based on the phase 2/3 trial start date and phase 2/3 trial duration *(phase 2 only if relevant)*
- Phase 4 costs_t = Revenue * Phase 4 as a % of revenue

$\text{Sales \& marketing}_t$

- Costs start 2 years before launch and increase to a specified % of peak sales at launch
- After launch, costs grow each year while the product is under exclusivity
- After loss of exclusivity, costs decline to a set % of revenue

$\text{Other operating costs}_t$

- Costs start 2 years before launch and increase to a specified % of peak sales at launch
- After launch, costs grow each year while the product is under exclusivity
- After loss of exclusivity, costs decline to a set % of revenue

Taxes_t = $\text{Operating income}_t$ * Tax rate (if > 0)

- Operating Income = Revenue – COGS – R&D – Sales & marketing – Other operating costs

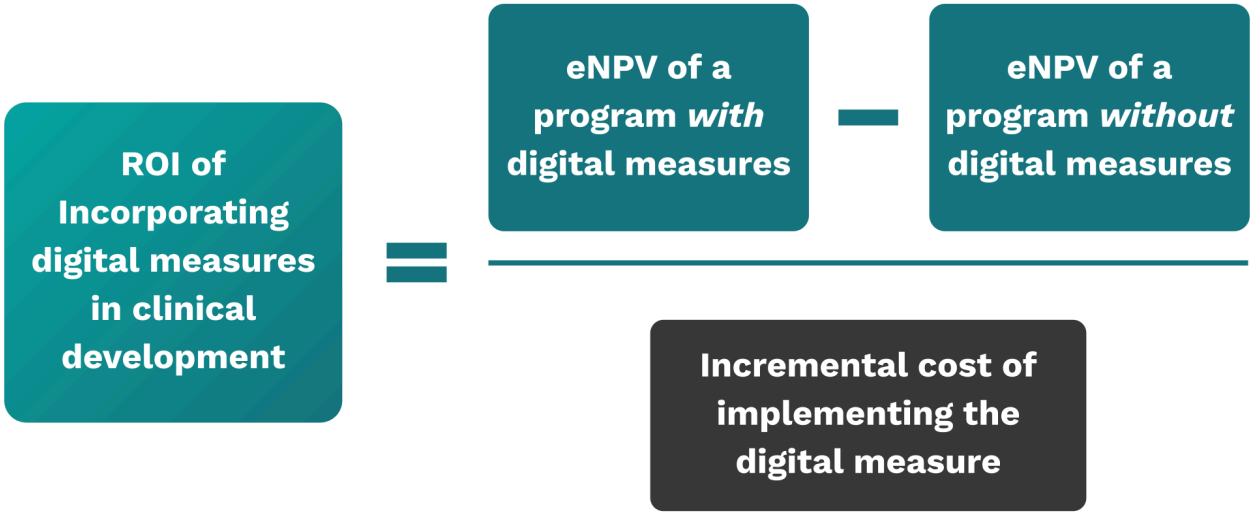
t = Time in years

The calculator assumes the next phase of clinical development starts in year 1. The model uses a 25-year time horizon and includes a terminal value.

Cost of capital = Discount rate used to calculate the net present value of future probability-adjusted income

ROI of incorporating digital measures

The calculator computes ROI as the ratio of the estimated increment in eNPV to the mean digital endpoint implementation cost. Additional investments required to implement digital endpoints include technology costs (devices, software, data storage, etc), operational costs (training site staff and integrating digital tools with existing trial infrastructure, etc), and validation costs. If the result is a positive ROI, it suggests that digital endpoints provide financial value beyond their cost. If the ROI is negative, it indicates that the investment may not be justified based on current conditions.



Section 4. Data privacy, security, and storage

The Digital Endpoints ROI Calculator does not send any data input by a user to a server or other third-party system. Any data you input is processed locally in your browser in a user session, meaning the data is no longer available once the session is closed. No one else can access your data, assuming you access the calculator from a secure system. Users may download their results in PDF format. This functionality is also executed on the user's local system and requires no data transmission to a DiMe server or other third-party system.

By prioritizing data privacy and security, the Digital Endpoints ROI Calculator allows users to confidently assess the financial impact of digital endpoints without risking data exposure.

Section 5. Maintenance and updates

To maintain accuracy and relevance, the calculator is updated annually to:

- Refresh industry benchmark data based on the latest available research and real-world trial insights
- Incorporate new variables as additional data becomes available, improving the depth and precision of ROI estimates
- Enhance functionality and user experience based on industry advancements and user feedback

Any methodological changes to the calculator are documented to ensure transparency in ROI calculations.