



Digital Endpoints Business Case Template

How to use this template to build your business case

The business case template is designed to help you build a compelling case for integrating digital endpoints into clinical trials. It offers a well-organized approach to aligning your proposal with portfolio goals and organizational priorities, ensuring your argument is strategic and data-driven. By leveraging this template, you can clearly communicate the value of digital endpoints to key stakeholders, highlighting their impact on business outcomes.

This document guides you through six sections, prompting you to provide appropriate information to build your business case by communicating:

- ✓ The value proposition of incorporating digital endpoints in clinical trials
- ✓ Required budgeting
- ✓ Projected return on investment (ROI)

[Additional resources](#) to support your business case are available and are referenced throughout this guide.

General tips for using the template

- **Use case studies:** Include relevant examples or pilot results to illustrate the potential benefits of digital endpoints.
- **Customize for your team:** Refine each section with internal stakeholders (e.g., clinical operations and digital health teams).
- **Leverage available tools:** Use the resources linked in this template (such as the [ROI Calculator](#) and [Value Framework](#)) to estimate costs and ROI effectively.

Table of contents



Please note: Not all sections need to be completed, as they may not apply to every use case.

Section 1. Title and executive summary

Section 2. Benefits and value proposition

Section 3. Budget

Section 4. Projected ROI

Section 5. Anticipated challenges

Section 6. Relevant case studies and examples

Your template summary

Section 1. Title and executive summary

Title

Your business case title should be clear, concise, and compelling, capturing the essence of your proposal while being specific enough to convey its focus. By following these steps, your title will set a strong foundation for your business case and immediately communicate its relevance and importance. Follow these guidelines to craft a compelling title:

1. Start with the core objective

What is the primary goal of your business case? (e.g., reducing trial timeline, enabling remote monitoring)

2. Include key elements

Mention relevant components such as the therapeutic area (TA), [concept of interest](#), digital health technologies (DHTs), or digital measures if applicable.

3. Keep it concise and impactful

Aim for 10 words or fewer while ensuring clarity. Avoid jargon or overly complex phrasing.

4. Emphasize value and outcomes

Highlight the impact on clinical trials, patient outcomes, or operational efficiency.

Examples of compelling titles:

- *Leveraging digital endpoints to enhance neurology clinical trials*
- *Scaling wearable-based digital measures for oncology trials*
- *Advancing patient-centric monitoring in cardiology studies with DHTs*

Insert title of your business case:

Executive summary

The purpose of this section is to summarize the proposal concisely, focusing on its value and goals. This section should clearly outline the collaboration structure, the DHTs involved, the digital measures captured, the clinical trial use cases, and the overall value proposition. Completing this section will ensure that the business case effectively communicates the strategic impact of using digital endpoints in clinical trials. Follow these steps to ensure completeness and clarity:

1. Define the team leading the case

Specify the primary team or department responsible for driving the business case (digital health team, clinical development, research and development, etc.).

2. Identify relevant internal collaborators

List internal stakeholders who will contribute to developing and scaling the capabilities (regulatory affairs, clinical operations, IT, etc.).

3. Specify the TA

Indicate the therapeutic area(s) the initiative will support (e.g., neurology, cardiology, oncology).

4. List the DHTs involved

Identify the specific DHTs (e.g., wearables, smartphone-based measures, connected devices).

5. Detail the digital measures captured

Describe the key digital measures these DHTs will generate (e.g., passive gait monitoring, actigraphy-derived sleep patterns, digital cognition assessments).

6. Outline the use cases

Provide the specific clinical trial applications where these measures will be leveraged (e.g., trial 1, trial 2, basket protocol, natural history studies).

7. Summarize the value proposition

Clearly state why this capability is valuable, focusing on aspects such as:

- Improved patient-centricity
- Accelerated decision-making in clinical trials
- Reduction in trial burden and operational efficiencies
- Enhanced regulatory acceptance and alignment with patient outcomes

Insert your executive summary:

Example: The [team leading the case] will collaborate with [any relevant internal teams] to develop and scale a suite of capabilities for [TA] clinical trials. This suite will involve [include DHTs involved], which will provide [specify digital measures] measures that can be applied across [include use case: trial 1, trial 2, basket protocol, etc.]. This capability will [summary of why it's valuable].

Section 2. Benefits and value proposition

The purpose of this section is to clearly articulate **why** investing in digital endpoints is valuable, emphasizing the benefits for clinical trials, patients, and the organization. The benefits maximized will depend on the context of the study/TA and conditions that will allow for optimal incorporation of digital endpoints in your clinical trial. There are multiple potential benefits to incorporating digital endpoints. Reference the [Digital Endpoints Value Framework](#) to identify value drivers that apply to your study or organization’s context.

Tip! Tailor the value proposition to your stakeholders.

Different stakeholders prioritize different benefits. Address how your business case aligns with their goals:



Clinical teams: Focus on data quality, better patient outcomes, and more precise endpoints.

Regulatory & compliance teams: Focus on evolving regulatory expectations and improved data integrity.

Operations & finance teams: Focus on efficiency gains, cost savings, and risk reduction.

List the value drivers relevant to your study:

Example value drivers:

- Shorter trial timeline
- Reduced trial size
- Inform early decision-making due to increased sensitivity
- Enables access to a broader, diverse patient population
- Enables remote/home assessments, reducing clinic visits
- Increased sensitivity and earlier signal detection compared to traditional measures to enable accurate treatment effect detection, detect adverse events, and indicate treatment efficacy

Tip! When identifying value drivers, include tangible metrics from case examples where possible (e.g., "Based on previous studies, 20% faster recruitment during screening due to increased earlier signal detection to identify target population to enable accurate treatment effect detection").



Section 3. Budget

This section will provide a detailed breakdown of costs over the trial's duration and a clear, side-by-side comparison of the financial resources required to implement digital endpoints versus traditional (non-digital) endpoints in your clinical trial. This comparison will help stakeholders assess the cost-effectiveness of adopting digital measures. The budget section should provide a clear and realistic estimate of the financial resources required to implement digital endpoints in your clinical trial.

The following steps will help ensure accuracy and completeness:

1. Identify key cost categories

Break down the budget into logical categories for both **digital** and **non-digital** approaches, such as:

- a. Technology & digital health tools
 - Wearables, sensors, or smartphone apps
 - Licensing fees for DHTs
 - Software platforms for data collection, storage, and analysis
- b. Data management & integration
 - Data processing, analytics, and validation costs
 - System integration with existing clinical trial infrastructure
 - Cloud storage and cybersecurity considerations
- c. Vendor & partnership costs
 - Third-party vendors for device provisioning and support
 - External consulting for regulatory strategy, validation, and implementation
- d. Regulatory & compliance expenses
 - Validation studies to support endpoint qualification
 - Submission preparation and documentation for regulatory agencies
- e. Operational & training costs
 - Investigator/site training on device use and data collection
 - Participant onboarding and support (e.g., helpdesk, troubleshooting)
 - Internal staff time and resource allocation
- f. Other costs (if applicable)
 - Participant incentives (if needed to drive compliance)
 - Long-term maintenance and scalability planning

2. Provide cost estimates and comparisons

For each category, include the following information for digital and non-digital endpoints:

- a. Estimated cost per unit (e.g., per device, per participant, per trial phase)
- b. Total projected costs for the full trial or implementation period
- c. Indicate Capital Expenditures (CapEx) vs. Operating Expenses (OpEx) to separate long-term investments (e.g., platform buildout) from operational costs (e.g., licenses or device maintenance)

3. Calculate a cost difference between digital and non-digital costs

4. Present the budget clearly

Use tables, bullet points, or a structured format to improve readability.

5. Highlight cost-savings

Tip! Use case-specific data or industry averages to estimate costs.



Build your digital endpoint budget

Cost category	Digital endpoint		Non-digital (traditional) endpoint		Total projected cost difference (digital-non-digital)	CapEx/OpEx	Notes
	Estimated cost (per unit)	Total projected cost	Estimated cost (per unit)	Total projected cost			
Total							

Complete your budget summary statement:

Example: Incorporating digital endpoints will reduce the per-participant enrollment costs by [X] or [X%] compared to using non-digital endpoints.

Section 4. Projected ROI

The purpose of this section is to emphasize the value of incorporating digital endpoints. Emphasize the ROI projections of using digital endpoints by including ROI and eNPV data from the [Digital Endpoints ROI Calculator](#) and input them in the table below.

Overall ROI	eNPV with digital measures	eNPV without digital measures

Insert your ROI summary statement:

Example: Incorporating digital endpoints in a [TA] clinical trial is projected to deliver a return on investment of [ROI x] after [X] years.

Section 5. Anticipated challenges

This section identifies potential risks and barriers to implementing digital endpoints and provides strategies to mitigate them. The challenges section demonstrates proactive risk management and strengthens your business case. While acknowledging that challenges exist, it is important to emphasize that they are manageable with proper planning.

Examples of challenges and mitigation strategies

Category	Anticipated challenge	Mitigation strategy
Regulatory acceptance	Lack of precedent for digital endpoint validation	Engage regulators early, leverage prior approvals
Data reliability	Variability in wearable sensor data	Implement validation protocols and quality control
Site adoption	Resistance from investigators	Offer incentives, provide hands-on training
Patient engagement	Low adherence with DHT use	Provide support and troubleshooting
Budget constraints	High initial investment in DHT	Highlight long-term savings, conduct implementation in phases

Challenges and mitigation strategies

Category	Anticipated challenge	Mitigation strategy

Section 6. Relevant case studies and examples

This section demonstrates precedent and credibility by showcasing real-world examples of how digital endpoints have been successfully implemented in clinical trials and provided a quantifiable benefit. By leveraging the [Value of Digital Endpoints: Case Study Catalog](#), you can strengthen your business case with data-driven evidence and industry validation.

Consider the following steps in selecting your case study/example:

1. TA alignment

Look for case studies within the same or similar disease area to strengthen relevance.

2. Similar use case

Identify studies that used comparable digital endpoints, devices, or data collection methods.

- *Example: If wearables are implemented for gait analysis, select studies that apply sensor-based mobility measures.*

3. Regulatory & trial phase

- Prioritize case studies from similar trial phases (e.g., Phase II, III, post-market studies).
- Highlight regulatory approvals or positive interactions to build confidence in the digital endpoints.

4. Demonstrated value

Focus on studies that illustrate measurable benefits, such as:

- Improved data quality
- Reduced trial duration
- Reduced trial costs

Present your case study in the format found on the following page.

Case study name <i>Study name or sponsor</i>	
TA <i>Disease/condition</i>	
Digital endpoints used <i>List sensors, wearables, smartphone-based measures, etc.</i>	
Study objective <i>What was the goal of implementing digital endpoints?</i>	
Key results <i>Summarize outcomes—data quality, efficiency, cost savings, patient compliance, etc.</i>	
Impact & takeaway <i>How does this case study support your business case?</i>	

Summary of case studies: Provide support and credibility to your proposal.

Example: These case examples demonstrate that digital endpoints have provided quantifiable values in [TA] trials, leading to [list the value(s)]. By leveraging these insights, we can confidently apply similar approaches to our clinical trial strategy.

Your template summary

Title of business case:

Executive summary:

Value drivers relevant to study:

Your template summary

Your digital endpoint budget

Cost category	Digital endpoint		Non-digital (traditional) endpoint		Total project cost difference (digital-non-digital)	CapEx/OpEx	Notes
	Estimated cost (per unit)	Total projected cost	Estimated cost (per unit)	Total projected cost			
Total							

Your budget summary statement:

Your template summary

Overall ROI	eNPV with digital measures	eNPV without digital measures

ROI summary statement:

Challenges and mitigation strategies

Category	Anticipated challenge	Mitigation strategy

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Summary of case studies: