



Generating economic evidence  
for digital health solutions

# Executive summary

**Economic evidence is arguably the most crucial type of evidence for digital health innovators.**

This evidence is vital for decision makers to determine whether a digital health solution can be funded through investment, adopted by patients and clinicians, and reimbursed by payors. It is not currently a standard part of evidence generation in digital health. All major health systems are facing the converging pressures of growing demand for healthcare, increased costs and labour shortages. Digital technologies can be part of the solution, but they need to provide value for money to cash-strapped health systems. Innovators must be able to demonstrate this value for money. In a recent survey, 94% of investors reported that showing value for money is either important or very important for the success of digital health companies.

**Evidence standards, including for economic evidence, are becoming clearer across major markets.**

Providers value economic evidence above all else to make purchasing decisions. The most comprehensive guidance has been published in the UK by the National Institute for Clinical Excellence (NICE) as part of the Evidence Standards Framework (ESF).

Digital health solutions are frequently complex and this creates challenges in terms of common evaluation principles that may be used in other healthcare settings. Health economic evaluation has been well established for pharmaceuticals, with clear pathways to support this evaluation. The value of digital health solutions may differ from that of conventional drugs because they may provide a unique combination of advantages that go beyond clinical outcomes.

**Economic evidence is required by different stakeholders across the product lifecycle**

– from early economic modelling to HTA-ready models and business case development. **In an economic evaluation, the study's perspective** is important and should be specified in order to answer the evaluation question for a digital solution. There are several common methodologies that can be used for the economic evaluation of digital health solutions. Ultimately the methodology used will be chosen based on the specific endpoints an innovator is trying to achieve or what a payor may require.

## Key messages

- **Economic evidence is critical for a variety of key stakeholders**, including: investors, payors, healthcare professionals and consumers. The onus is on digital health innovators to show the value for money for their solutions.
- **The reimbursement landscape for digital health solutions is complex and evolving.** Demonstrating value for money is paramount for innovators to ensure that their solution can be reimbursed.
- The Food and Drug Administration (FDA) and Centers for Disease Control and Prevention (CDC) in the United States, the Federal Institute for Drugs and Medical Devices (BfArM) in Germany, and the National Authority for Health (HAS) in France have published **guidance to help innovators compile the evidence required to aid reimbursement.**
- The National Institute for Health and Care Excellence (NICE) in the UK has published further **guidance to advise on economic evaluation.**
- Innovators should ensure that **data is being collected at all stages of digital health solution development**, from concept to post-market to ensure this can support economic evaluations.
- **The value of early modelling is often not considered by digital health companies.** However, it can help them prioritise their evidence generation, secure funding and investment by showing potential cost-effectiveness and help optimise the most effective placement in the pathway/population for the technology.
- **Due to the complexity of digital solutions, it can be difficult to conduct economic evaluations.** Challenges include: lack of comparators, differentiating comparators, population of interest (including channel shifting with the intervention), identifying unintended consequences and organisational impact.
- Economic analysis helps to quantify the **value proposition** of digital solutions, the **value for money** arguments to support pricing and reimbursement decisions, and the **cost implications** of implementing these solutions.
- **Different methodologies can be used to conduct the economic evaluation of digital solutions.** The most commonly used methodologies include cost-effectiveness analysis, cost benefit analysis and cost-comparison analysis.
- **It is prudent to consider whether an economic analysis will still be relevant if there are any post market changes to the solution**, or how potential future post market changes could be incorporated into economic analysis. This is particularly relevant to AI-based digital health solutions that may have algorithms updated after initial deployment.

# Why is economic evidence important?

## **Economic evidence is arguably the most crucial type of evidence for digital health innovators.<sup>1</sup>**

It is vital for decision makers to determine whether a digital health solution can be funded through investment, adopted by patients and clinicians and reimbursed by payors. It is not currently a standard part of evidence generation in digital health.<sup>2</sup>

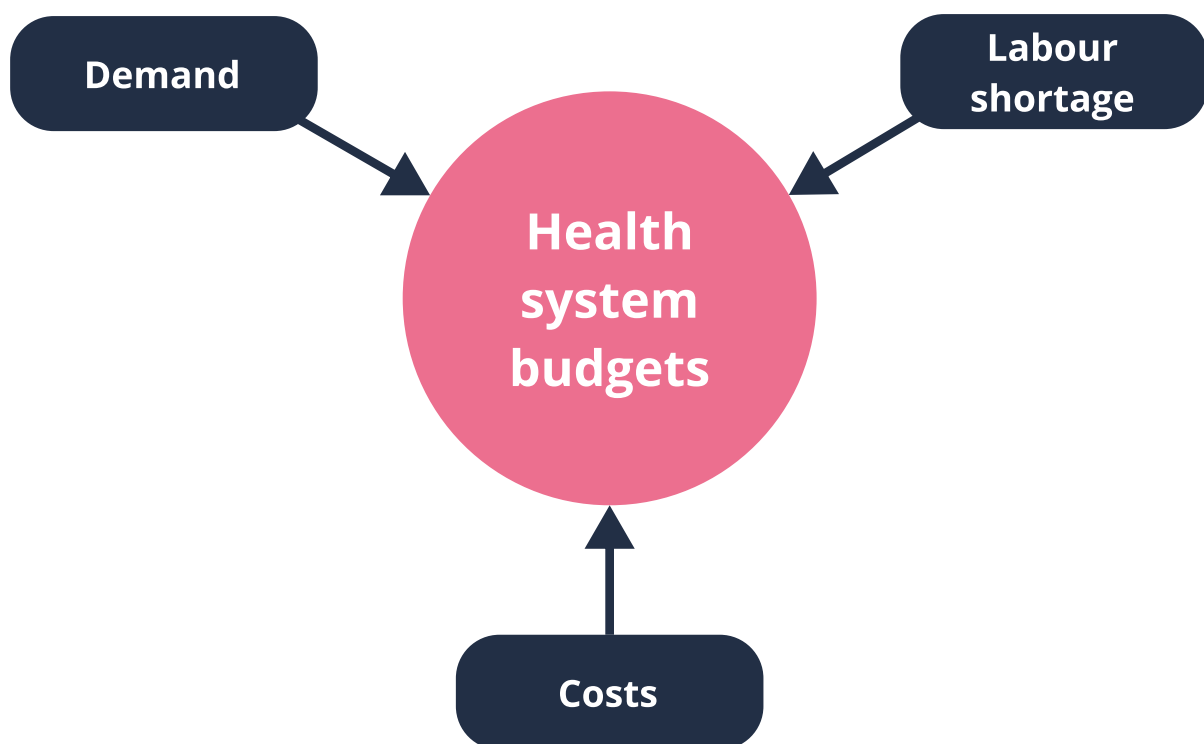
Overall healthcare expenditure and investment in digital health boomed during the Covid-19 pandemic.<sup>3</sup> The sector has since experienced a reset and funds available for investment in digital health have contracted. Money is tighter and this is no surprise to innovators, who have felt the squeeze.

**There is increasing pressure on healthcare budgets, which are declining as a share of GDP for the first time in two decades in major markets such as the US, the UK, Germany and France.<sup>4</sup>** As money has gotten tighter, demonstrating the economic impact of a digital health solution to prospective customers has become increasingly important.



**The trend is here to stay:** all major health systems are facing the converging pressures of growing demand for healthcare, increased costs and labour shortages. Digital health solutions can be part of the solution, but they need to provide value for money to cash-strapped health systems. Innovators must be able to demonstrate value for money.

**Evidence standards, including for economic evidence, are becoming clearer across major markets.** Providers value economic evidence above all else to make purchasing decisions. The most comprehensive guidance has been published in the UK by the National Institute for Clinical Excellence (NICE) as part of the Evidence Standards Framework (ESF).





**United States** <sup>5,6</sup>

In the US healthcare system, there are many possible routes to market for digital products. Customers include Medicare and Medicaid, private insurance providers, healthcare providers (hospital systems, clinics, etc.) and individual consumers. The Centers for Medicare and Medicaid Services (CMS) plays a key role in setting public policy for reimbursement of emerging health technologies provided to patients under the Medicare and Medicaid programmes, but is not allowed to consider economic evidence when making coverage decisions for reimbursement. The main focus is on private insurers that must know there is a ROI for what they spend when committing to digital solutions for patients.



**Germany** <sup>7,8</sup>

Health economics considerations play an important role in the social health insurance system. Germany's Fast Track pathway for digital health applications (DiGA) enables high-quality solutions that meet specific regulatory requirements and evidence standards to be added to a national directory of apps.<sup>7</sup> Once prescribed, these apps are paid for by health insurance providers. To be approved, all products must meet prerequisite standards in several domains including clinical benefit, quality, security and data protection - but not economic evidence. While economic evidence is not required for approval, it will be considered in price negotiations with the social health insurances.



**United Kingdom** <sup>9,10</sup>

In England, the main route to adoption for digital solutions is via integrated care systems (ICSs), the NHS bodies responsible for procurement and delivery of services at a local level. In most cases, there is no direct route to market access at the national level. The NICE ESF for digital health technologies offers guidance to decision-makers on what evidence they should seek when procuring digital tools and the economic evidence required. The tiered structure of the ESF also means higher levels of clinical and cost-effectiveness evidence are required for technologies with greater potential risk to patients. The updated ESF has also considered AI tools specifically, which is not as yet clearly presented in other countries' guidance. The most relevant standards are:

**Describing value:**

Standard 13: Describe the expected health, cost and resource impacts compared with current care or system processes.

**Delivering value:**

Standard 17: Provide a budget impact analysis.

Standard 18: For digital solutions with higher financial risk, provide a cost effectiveness analysis.

NICE has similarly adopted a DiGA approach with the Early Value Assessment and the operating model is around evidence generation.<sup>10</sup>

**Economic evidence is particularly important when it comes to purchasing and payment decisions by customers.** Effectively quantifying the financial impact of a solution, including after adoption, using real world data, can help justify pricing and achieve commercial goals.<sup>11,12</sup> Good decision making with a constrained budget is critical, as funding new innovations, other interventions or

products will likely need to be given up. This means that every decision has a real opportunity cost of lost health within a system and makes it even more crucial that money is being spent on innovations that demonstrate the best value for money.

### Case study: economic evidence in support of commercial goals<sup>13</sup>

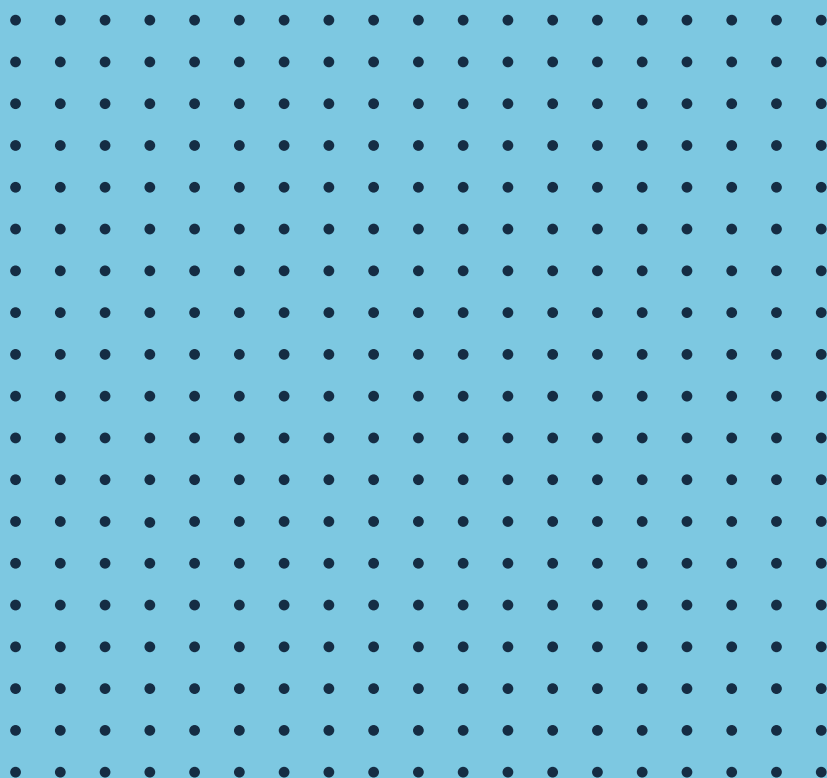
Accurx, a leading primary care triage solution provider, recognised that demonstrating economic impact was a crucial part of securing contracts with their core customer, NHS England. Accurx commissioned a mixed-methods evaluation combining health economics modelling with rich qualitative insights from real-world users. The combined output produced compelling evidence demonstrating the impact the solution had on the health system at practice, ICB and national levels. Alongside high levels of NHS staff and patient satisfaction, the evaluation demonstrated potential savings for England's primary care services of £123 million over five years by reducing phone calls and missed appointments.

**Investors in digital health companies have noticed:** 94% say that demonstrating value for money (framed as return on investment) is critical for the success of digital health companies.<sup>1</sup>

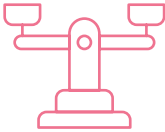
It is not enough to have a solution that can prove health outcomes – the solution also needs to demonstrate value for money to healthcare providers and deliver a clear value proposition. Innovators need to have hard data to substantiate their claims and demonstrate clear, tangible benefits to the healthcare system to ensure both reimbursement for their tech and support scalable adoption.



# What are the challenges in generating economic evidence for digital health solutions?

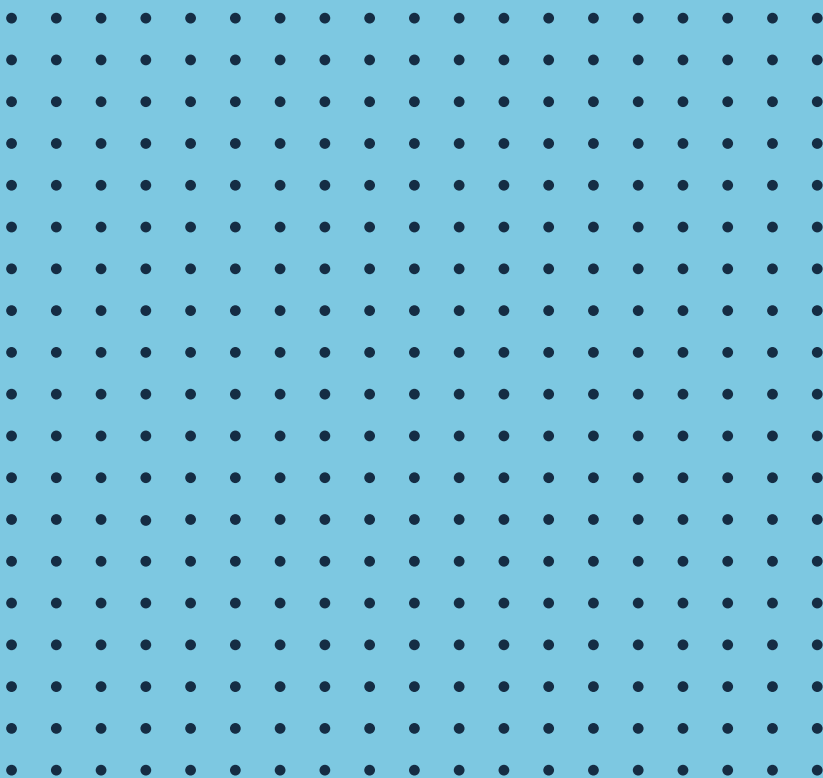


Digital health solutions are frequently complex, creating challenges in terms of common evaluation principles that may be used in other healthcare settings. These challenges are summarised in the following table:

| Challenge associated with economic evidence                                                                                                                                                          | Description of challenge                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|  <p>An unclear, shifting or very heterogeneous population</p>                                                       | <p>While pharmaceuticals have a specific indication, digital solutions often can be used on a <b>broader population</b>. This can make economic modelling more difficult when there is very wide <b>heterogeneity</b> in the population who can benefit from the technology.</p> <p>Sometimes the digital solution actually distorts the population of interest, such as <b>changing access in the pathway</b>, leading to different effectiveness and outcomes across the intervention and comparator. For example, a technology-enabled virtual ward may lead to a milder population than traditional standard of care (care in hospital) due to easier access.</p> |
|  <p>What is the comparator?<br/>What is standard care?<br/>Does this differ by region or healthcare practice?</p> | <p>Digital solutions often involve a <b>combination of alternative treatment options</b>, including both digital and non-digital comparators, with differences in pathways across regional and local healthcare practices.</p> <p>Determining what the appropriate comparators are for digital solutions can be challenging. Unlike pharmaceuticals with well-defined placebos or competing drugs, digital solutions often replace or complement existing technology or pathways, which is highly variable.</p>                                                                                                                                                       |
|  <p>Quality and quantity of economic evidence</p>                                                                 | <p>Pharmaceuticals are typically evaluated through randomised control trials, the gold standard of evidence. However, for some digital solutions randomisation presents a challenge, which together with other limiting factors may make it difficult to conduct RCTs. In this case the best quality evidence should be sought, which may be <b>observational data</b> or <b>real-world evidence</b>.</p>                                                                                                                                                                                                                                                             |

| Challenge associated with economic evidence                                                                                                                 | Description of challenge                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|  <p>The evolving nature of the digital health solution</p>                 | <p>For digital health solutions (and AI-based solutions in particular), the <b>changing nature of the technology</b> (i.e., upgrades and internal learning) can mean that effectiveness may differ from the initial evaluation. For some digital solutions, such as diagnostic platforms operated by clinicians, there may be a <b>'learning curve' effect</b>, as clinicians become experienced with using the technology. Other challenges include treatment waning due to adherence and real world compliance compared with study populations, though this is not a problem isolated to digital solutions.</p>                                                                                                                                     |
|  <p>Which features provide effectiveness?</p>                              | <p>Digital solutions often have <b>multiple components</b> incorporated into the technology. Additional components may cost more than the base package of the technology, yet the impact of the additional component on the effectiveness may be unknown. Articulating and understanding the impact of different features on the overall effectiveness and the value for money of different features can be challenging.</p>                                                                                                                                                                                                                                                                                                                          |
|  <p>Ability of healthcare systems to engage and adopt the technology</p> | <p>The success of digital health solutions depends on the healthcare system's <b>readiness to adopt</b> them. This includes factors like <b>infrastructure, training</b> and <b>changes in clinical pathways</b>. There are also implications for geographic variation and the ability for higher capitated regions to have economies of scale in some areas, for example AI-based pathology readers. Evaluating the organisational impact is crucial for successful implementation, but often overlooked.</p> <p>Furthermore, digital solutions need to be <b>interoperable</b> with other digital systems in the healthcare system. Ensuring connectivity and data exchange can be challenging, and the assessment should consider this aspect.</p> |
|  <p>Capturing the relevant outcomes</p>                                  | <p>Digital health solutions have a wide range of potential impacts, including <b>clinical, organisational, behavioural, and technical outcomes</b>. Some digital solutions are more public health style interventions, while some may be more administrative interventions. Traditional health economic outcomes such as quality-adjusted life years may not adequately capture these multidimensional outcomes.</p>                                                                                                                                                                                                                                                                                                                                  |

# What are the differences in health economic evaluation for digital health solutions, medical devices and drugs?



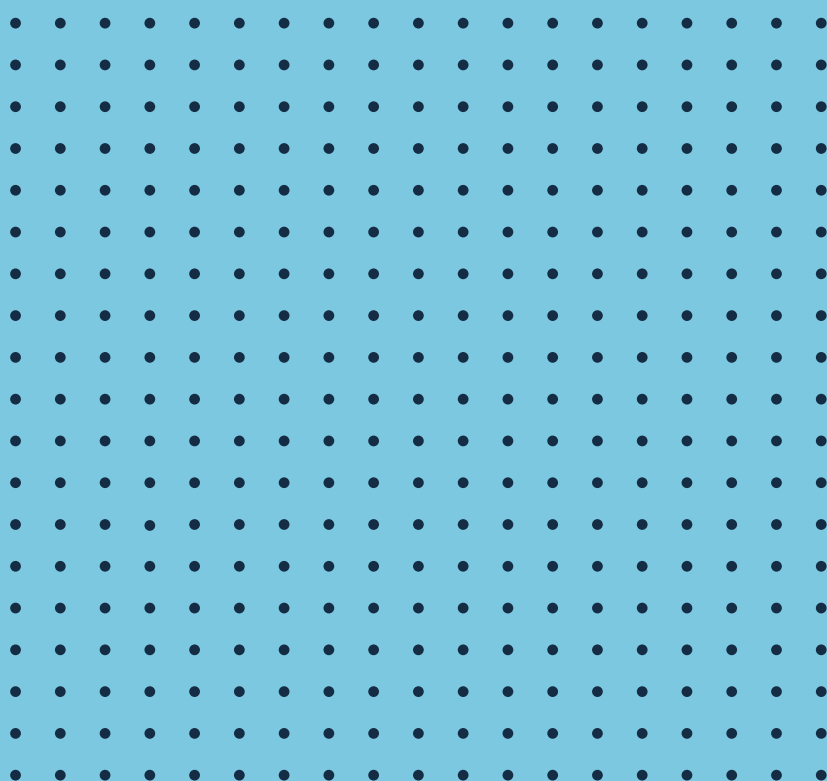
**Health economic evaluation has been well established for pharmaceuticals**, with clear pathways to support this evaluation. The value of digital health solutions may differ from that of conventional drugs because they may provide a unique combination of advantages that go beyond clinical outcomes. While drugs primarily focus on treating medical conditions and symptoms, digital solutions may encompass a broader spectrum of value propositions. However, these features can also make the economic evaluation of digital solutions difficult. Key features to consider as part of developing any economic evaluation are considered below, contrasting the difference with medical devices and digital health solutions.<sup>2,14</sup>

| Features of economic evaluation                                                                                       | Pharmaceuticals                                                                                                                                                                                                                                                                    | Medical Devices                                                                                                                                                                                                                       | Digital health solutions                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
|-----------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <br>Costs                            | <p>Dependent on the perspective. E.g., all costs from an NHS/ PPS perspective (drug costs, hospital appointments, cost of treating adverse events).</p> <p>Cost can usually be estimated quite accurately, as the packet or dose size for the population of interest is known.</p> | <p>Dependent on the perspective. To include costs associated with training and for devices used across multiple individuals.</p> <p>May need to consider implementation costs. Likely to include training but this is not unique.</p> | <p>For digital solutions, there are a range of costing models put together by companies, where in some cases the marginal cost of an additional user may tend to zero.</p> <p>Examples of intervention costs include <b>licence costs, setup costs, cost per person engaged or cost per person activated</b>. It is important to account for all costs, including <b>staff time</b> to operate, engage and set up the solution, and not just company-associated costs.</p>                                                                                                                                 |
| <br>Funding mechanism and audience | <p>Clear. Often national-level decision maker.</p>                                                                                                                                                                                                                                 | <p>Often clear. Either local or national decision maker</p>                                                                                                                                                                           | <p>Less clear. Some solutions involve people using subscription apps on their own devices not funded by the decision maker.</p> <p>Could be funded by either <b>local</b> or <b>national</b> decision makers, including from outside the health sector, e.g., local councils or the education sector if the solution is a public health intervention. In some instances, similar solutions go through different routes of use. E.g., one is used in hospitals through local decision makers, whilst another goes through more formal assessment. This may be directed by individual company decisions.</p> |

| Features of economic evaluation                                                                            | Pharmaceuticals                                                                                            | Medical Devices                                                                                                                                                                                                                                                                                          | Digital health solutions                                                                                                                                                                                                                                                                                                                      |
|------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|  <p>Discounting</p>       | Annual discount applied to health outcomes and costs.                                                      | Annual discount applied to health outcomes and costs.                                                                                                                                                                                                                                                    | Annual discount applied to health outcomes and costs.                                                                                                                                                                                                                                                                                         |
|  <p>Time horizon</p>      | Lifetime horizon often used – long enough to reflect all important differences in costs and outcomes.      | <p>This may just be the length of the procedure (e.g., with a diagnostic device which has no impact on treatment).</p> <p>However, it should still be long enough to reflect all important differences in costs and outcomes.</p> <p>Time horizon required may be shorter for local decision making.</p> | <p><b>Shorter time horizons</b> may be preferred where the long-term impact of the solution is unknown or highly uncertain. However, it should still be long enough to reflect all important differences in costs and outcomes.</p> <p>Time horizon required may be shorter for local decision making.</p>                                    |
|  <p>Health outcomes</p> | Health outcomes are expressed as generic measures of health in the first instance, such as QALYs or DALYs. | Cost-comparison may be of more interest than individual health outcomes (e.g., number of adverse events avoided).                                                                                                                                                                                        | <p><b>Cost-comparison</b> may be of more interest than individual health outcomes (e.g., number of images needed for a result). Equally, cost analysis may be more appropriate where there is no quantifiable clinical outcome.</p> <p>Other factors may be considered for other sectors, e.g., educational attainment or judicial costs.</p> |

Although there are challenges to modelling digital health solutions, these issues are not unique in economic evaluation and have been faced before. The key is recognising these challenges and identifying solutions to support informed decision making.

# How to generate economic evidence for digital health solutions?



**Economic evidence is required by different stakeholders across the product lifecycle** – from early economic modelling to HTA-ready models and business case development. Each of these phases contributes to understanding the value for money of new healthcare innovations, driving price decisions, understanding the required effectiveness, understanding key drivers of the analysis, and supporting future evidence generation. This use of different analyses at different points in the product cycle is highlighted in the figure below.

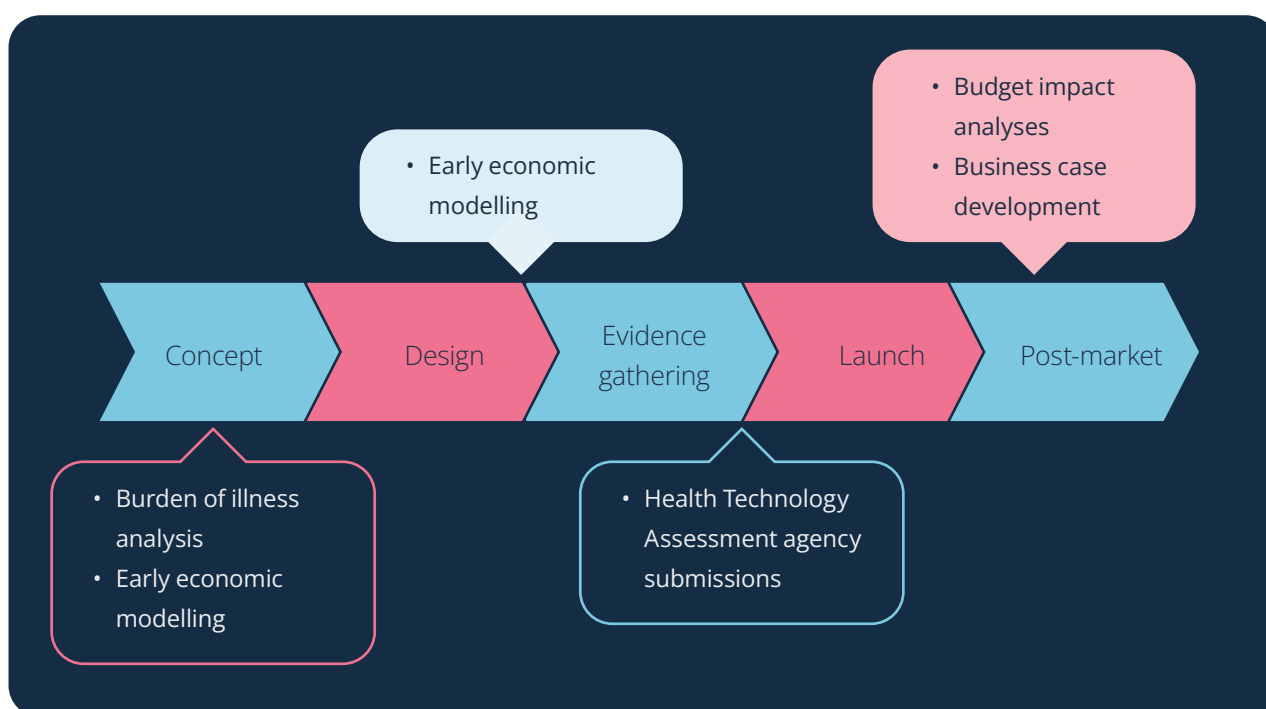


Figure 1. Use of different economic analyses at various stages in the product cycle.

Although not routinely conducted, **early economic evaluation** can be highly useful to support digital solutions along their development pathway. They are a useful tool for providing:

- Ballpark indications of **cost-effectiveness**, including if it is plausible the technology is cost-effective or cost-saving.
- **Pricing indications** on the maximum price a payor may be willing to pay, at different levels of effectiveness for the technology.
- An exploration of the **optimal positioning in the pathway** for the maximum benefit to the healthcare system.
- Greater understanding of what the **key parameters are that drive the cost-effectiveness** of the technology.
- Information for determining and optimising **future evidence generation**.

**In an economic evaluation, the study's perspective** is important and should be specified in order to answer the evaluation question for a digital solution. There are several common methodologies that can be used for economic evaluations of digital solutions. Ultimately the methodology used will be chosen based on the specific endpoints an innovator is trying to achieve or what a payor may require.

**Cost-effectiveness analysis (CEA):** Evaluates the effectiveness of two or more treatments relative to their cost. The aim of the decision maker when assessing a new intervention is to maximise outcomes and minimise opportunity costs. As an example, this methodology can be used to compare different apps used in the management of a specific disease and which one is the most cost-effective based on the same measured health outcome across all the apps.

This methodology is applied when the benefits of a digital solution are mostly health-related and can be captured by a single clinical outcome (e.g., number of relapses).

CEA can help a decision-maker achieve a specific policy objective and often takes the perspective of the payor, health service provider or healthcare system.

**Cost-utility analysis (CUA):** This methodology is a type of CEA in which the (incremental) cost per quality-adjusted life year (QALY), or some other preference-based valuation of health outcome, is estimated. This methodology would be useful for interventions where QALYs are a sensible metric to capture the clinical outcomes, and the opportunity cost of paying for the intervention falls with the healthcare system.

CUA is useful when the health benefits of a digital solution have an impact on both the quantity and quality of life. It is also useful for determining cost-effectiveness when explicit thresholds are used to determine cost-effectiveness. An example of this is the National Institute for Health and Care Excellence using a £20,000 per QALY threshold.<sup>15</sup>

**Cost-comparison analysis (CCA):** This methodology considers a wide range of both health and non-health impacts (consequences or outcomes) for the end user. The outcomes are reported separately, allowing the payor to make a decision based on the effects that are most relevant to them.<sup>16</sup>

CCA can be tailored to identify what costs and effects will be relevant to decision makers. This methodology can consider a range of clinical outcomes, which can be presented to decision makers, rather than focusing on one single outcome.

**Cost-benefit analysis (CBA):** This methodology is a comparison of interventions and their outcomes in which both costs and resulting benefits (health outcomes and others) are expressed in monetary terms. This methodology can help evaluate non-health benefits, and would be conducted for technologies with a clear public health benefit or where the benefits expand beyond health, such as to education or crime.

CBA can determine whether a digital solution is worth the investment when compared to alternative products. This methodology is useful when the non-health benefits are an important component of the comprehensive assessment of using the digital solution.

**Budget impact analysis (BIA):** This methodology is used to estimate the likely change in expenditure to a specific budget holder resulting from a decision to implement a new healthcare intervention or some other change in policy at an aggregate population level.

BIA will help assess the financial impact of a digital solution before implementation. This methodology determines whether a digital solution is affordable and within the payor's budget.

For a more in-depth look at approaches to the economic evaluation of digital health solutions, both the [\*\*World Bank\*\*](#) and the [\*\*Peterson Health Technology Institute\*\*](#) (in collaboration with the Institute for Clinical and Economic Review) in the US have recently published frameworks on the topic.<sup>17,18</sup>



### Get in touch

Together with our partners, Prova Health can offer a comprehensive solution for the economic evaluation of digital health tools to complement our core offering of evidence generation across the product pipeline.

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