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Intermediate

# How to: Develop a Successful Health Technology Assessment Strategy

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In the eighth instalment of our "How to" series, we outline how to build an effective health technology assessment strategy by starting early, collaborating cross-functionally, anticipating local needs, generating strong evidence, engaging stakeholders, and continuously refining the value story.



## What is health technology assessment? (and why it matters)

Health technology assessment (HTA) is a rigorous and multidisciplinary assessment of the value of an intervention for a particular group of patients versus the current standard of care. It typically informs whether – and how – an intervention should be used and funded within a health system, and is expected to be transparent, evidence-based, and accountable.

In practice, HTA brings together clinical effectiveness, economic value, and broader system impact (where relevant) to support payer and policy decisions. Many agencies describe HTA as independent research assessing effectiveness, costs, and wider impact to inform healthcare planning and delivery.

> **[HTA is an] independent research about the effectiveness, costs and broader impact of healthcare (treatments and tests) for those who plan, provide or have care in the NHS**
>
> NICE Glossary

## What "success" looks like in HTA

From the manufacturer's perspective, a successful HTA outcome typically enables positive reimbursement (or a favorable recommendation) in the optimal population and optimal treatment positioning (often as broad as feasible and aligned with the label – though sometimes a targeted subpopulation or later-line positioning is strategically preferable) at a commercially viable price, across priority and other countries.

Two realities influence the definition of success. First, there is no global one-size-fits-all HTA strategy. Some systems focus mainly on clinical benefit; others combine clinical benefit with cost-effectiveness and/or budget impact. Trade-offs are common. Second, HTA is lifecycle-wide, not a one-time "at launch" event. Post-launch reassessments, coverage-with-evidence-development arrangements, and policy changes can all redefine what "good" looks like over time.

## HTA vs Regulatory Approval

Regulators and HTA bodies answer different questions.

**Regulators** – such as the Medicines and Healthcare Products Regulatory Agency (MHRA) – primarily assess whether a medicine is safe and efficacious based on clinical trial data, and whether the benefit–risk profile supports marketing authorization.

*"We rigorously use science and data to inform our decisions, enable medical innovation and to make sure that medicines and healthcare products available in the UK are safe and effective" – MHRA*

**HTA bodies** – such as the National Institute for Health and Care Excellence (NICE) – assess the magnitude of additional benefit and value versus locally relevant alternatives (and often affordability), using the totality of evidence – not just pivotal trials – to inform reimbursement and access decisions. Their decisions are anchored in real-world practice and payer priorities.

*"Evidence-based recommendations for the health and social care sector, developed by independent committees, including professionals and lay members, and consulted on by stakeholders" – which "help practitioners and commissioners get the best care to people, fast, while ensuring value for the taxpayer" – NICE*

# How to develop a successful HTA strategy (the essentials)

The key elements that distinguish strong HTA strategies from reactive, submission-only approaches.

### Start early

Build HTA strategy as early as possible to shape evidence generation and value communication—not just the final dossier. Early planning ensures trials (including population, endpoints, and analyses) are relevant to both payers and regulators, and allows time to design and execute robust evidence plans to support HTA.

### Align cross-functionally

Integrate clinical, biostatistics, regulatory, Real-World Evidence, Health Economics and Outcomes Research, and market access to create an aligned HTA narrative and evidence plan. This holistic approach improves alignment, reduces inefficiencies, supports high-quality evidence generation, consistent positioning, and credible economic models.

### Tailor locally – while managing global spillover

Adapt to differences across HTA bodies (comparators, endpoints, modeling, and evidence thresholds) rather than using a single "one-size-fits-all" approach. At the same time, manage how choices in one market can influence expectations and negotiations in others.

### Define the right decision problem using the PICOs framework (population, intervention, comparator, outcome, study design)

Lock down the population, comparators, outcomes, and perspective that the HTA body is likely to deem appropriate – and identify where your preferred scope may diverge. Address common friction points early, especially comparator relevance to local practice, label-aligned populations vs narrower payer priorities, and endpoint relevance beyond the trial setting.

### Close evidence gaps with fit-for-purpose methods

Go beyond pivotal trial data to address appraisal questions using robust methods (e.g., indirect comparisons, real-world evidence, expert input). Clearly state evidence strengths, justify methods, and proactively address likely critiques to show the evidence is fit for decision-making.

### Ensure the economic model (where needed) captures meaningful differences

Where cost-effectiveness evidence is part of HTA, ensure the economic model structure, assumptions, and time horizon are appropriate to capture meaningful differences in costs and outcomes. Clearly separate the known from assumed, and thoroughly justify assumptions made and explore resulting uncertainty.

### Make uncertainty a strength, not a vulnerability

Identify and quantify key uncertainties across clinical evidence, supplementary analyses, and economic modeling. Use targeted sensitivity and scenario analyses to demonstrate robustness and show decision makers what drives results.

### Keep optimizing as the situation changes

Treat HTA strategy as a living plan that evolves with new evidence, shifting standards of care, competitor entries, guideline changes, and agency precedent. Regularly refresh the value story, model assumptions, and evidence plan so the submission remains aligned to the current landscape.

### Build strategic partnerships early

Engage early with HTA bodies, clinical experts, and patient organizations to validate the decision problem, outcomes that matter, and the real-world care pathway. Pair that with the right external partners that can support you to navigate local HTA nuances, accelerate evidence generation, and translate evidence into a clear, credible value narrative and dossier.

## Key takeaways

Successful HTA strategy is proactive, cross-functional, decision problem-led, and tailored locally, while also being globally coordinated. The strongest teams treat HTA as a lifecycle discipline – starting early, developing cross-functionally, anticipating local decision needs, building the right evidence deliberately, proactively engaging with relevant stakeholders, and continually refining the value story as the market and evidence base evolve.

## About the authors

Have a question for our authors? Use the links below to contact them directly on LinkedIn or by email.




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