eHTA Suitability Checklist

Early health technology assessment (eHTA) uses methods from health economics, epidemiology, and health services research to assess the potential value of health technologies under development for patients, providers, and payers.

This checklist will help you to assess at what stage an eHTA study could help inform your research and development strategy. It involves the following three steps:

- ☑ **Step 1:** Identifying what type of medical product you are developing
- ☑ **Step 2:** Determining its current technology readiness level
- ☑ **Step 3:** Defining eHTA studies that might help inform your strategy to advance your product to the next technology readiness level

Key Terms

Technology platform: An innovative technology and/or scientific process that can be used to create, discover, or optimize therapies, medical devices and/or diagnostic tests for a broad range of diseases.

Medical product: A specific therapy, diagnostic test, or medical device that is aimed at a single disease, or group of diseases sharing a common molecular target, disease process, or treatable symptoms.

Technology Readiness Level (TRL): A broadly used framework for defining the stage of development for a new technology and the associated activities and milestones needed to advance the technology.

☑ Step 1: Identify the type of medical product you are developing

Q1 How would you best describe the technology your team is developing?	If you checked this box...
☐ A technology platform that can be used in a wide range of applications ➤	GO TO Q2
☐ A medical product for a single disease ➤	GO TO Q3
☐ A medical product for a group of related diseases ➤	GO TO Q3
☐ Other ➤	GO TO Q2

Q2 Are you currently developing any medical products (either alone or in partnership) using your technology?

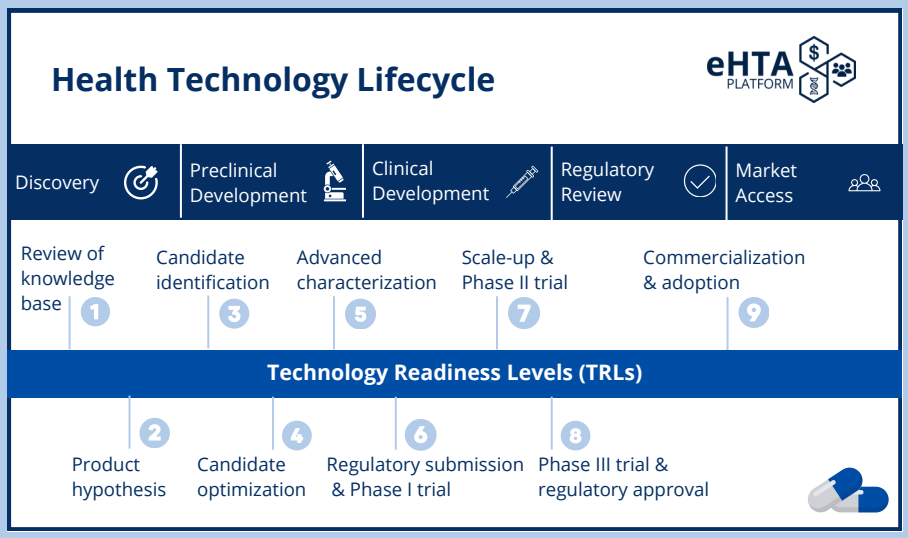
☐ Yes ➤ GO TO Q3 ☐ No ➤ GO TO PAGE 8

Q3 What type of medical product(s) are you currently developing?	If you checked this box...
☐ Pharmaceutical (incl. small molecules, biologics, and gene & cell therapies) ➤	GO TO PAGE 2
☐ Diagnostic or screening test ➤	GO TO PAGE 4
☐ Therapeutic medical device ➤	GO TO PAGE 6
☐ Other ➤	GO TO PAGE 9

eHTA Suitability Checklist

☑ **Step 2:** Determine your **pharmaceutical** product's TRL

An eHTA is most useful in the earlier stages of medical product development. For pharmaceuticals, this usually means somewhere between the late discovery phase and Phase I clinical trials.



The Technology Readiness Level (TRL) framework used by government agencies like Innovation, Science, and Economic Development Canada and the U.S. NIH Centers for Accelerated Innovation, offers guidance regarding the activities and milestones necessary to advance a new technology along the development and commercialization pathway. Determining the current TRL for your medical product will help identify the type of eHTA analysis that would be most useful for you.

Q4 **Based on the information on this page, at what TRL is your drug development program?**

TRL	Key lab-based scientific activities	
1	▶ Review of scientific evidence on target, diseases, and relevant technologies.	☐
2	▶ Pre-clinical studies to validate target. Identifying drug candidates via compound screening or other methods.	☐
3	▶ Evaluate efficacy and toxicity of candidates *in vitro*; Preliminary toxicity studies *in vivo*. Decide on which candidate(s) to advance to next stage of development.	☐
4	▶ Preliminary product profile, including clinically-relevant endpoints and administration. Non-GLP toxicity, pharmacokinetics, and efficacy studies of lead candidate(s) *in vivo.*	☐
5	▶ Full target product profile (TPP) drafted; IND-enabling toxicology studies. Develop scalable GMP-compliant manufacturing strategy.	☐
6	▶ Submit IND application and begin Phase I clinical trial(s).	☐
7	▶ Phase II clinical trial(s); validate and scale GMP manufacturing.	☐
8	▶ Phase III clinical trial(s); submit application for regulatory approval.	☐

If your technology is at a TRL of between 2 and 6, inclusive... ▶ **GO TO PAGE 3**
If your technology is at a TRL of 1, 7 or 8... ▶ **GO TO PAGE 9**

eHTA Suitability Checklist

☑ Step 3: Define eHTA studies to help advance your product to the next TRL

If your **pharmaceutical** product candidate is between **TRLs 2 to 6** eHTA may be able to support its further development.

Early Health Technology Assessment

Discovery | Preclinical Development | Clinical Development

TRL 2 Product ideation → **TRL 3** → **TRL 4** → **TRL 5** → **TRL 6** Phase I trial

Which disease or indication to focus on?

- Unmet medical need
- Competitive pipeline
- Potential cost offsets
- Prevalence in major markets

Which product characteristics to optimize for?

- Efficacy vs. safety
- Mode of administration
- Dosing frequency
- Clinical differentiation

What data to collect in clinical trials for value dossier?

- Quality of life
- Patient-reported outcomes
- Healthcare resource utilization

Types of assessments the eHTA Platform team can perform for specific indications

TRL ➤ 2 - 3	• Characterize disease **epidemiology** • Map out current care patterns • Define unmet need and **competitive landscape**
TRL ➤ 4	• Identify clinically relevant endpoints for impact in clinical practice • Preliminary product profile • Map out **reimbursement** pathway • Estimate economic burden of illness and **treatment costs**
TRL ➤ 5 - 6	• Partner with key opinion leaders to inform clinical trial design • Identify reimbursement value drivers and inform plan for collecting **health economics** and long-term outcomes data • First draft of a full target product profile

WANT MORE INFORMATION? LET'S TALK!

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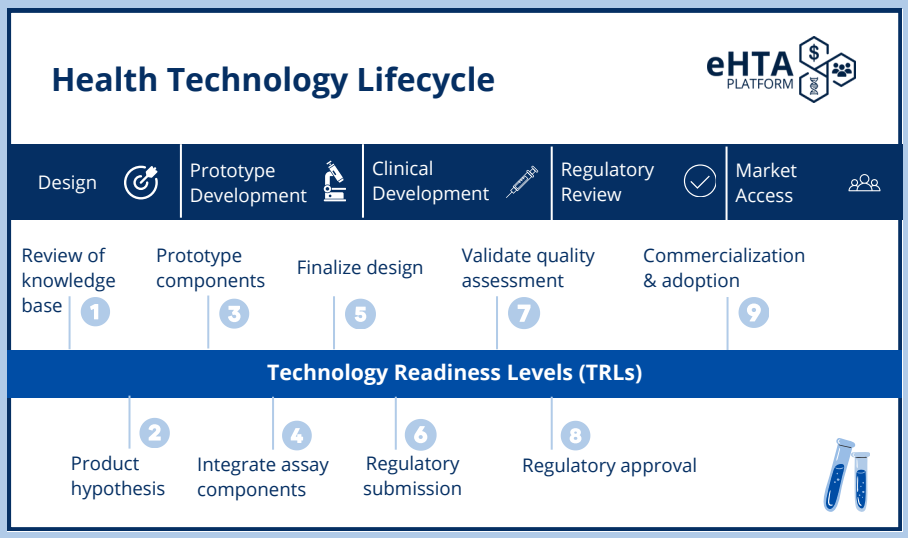
eHTA Suitability Checklist

☑ Step 2: Determine your **diagnostic test**'s TRL

An eHTA is most useful in the earlier stages of medical product development. For diagnostic tests, this usually means somewhere between product ideation and finalizing the design.



The Technology Readiness Level (TRL) framework used by government agencies like Innovation, Science, and Economic Development Canada and the U.S. NIH Centers for Accelerated Innovation, offers guidance regarding the activities and milestones necessary to advance a new technology along the development and commercialization pathway. Determining the current TRL for your medical product will help identify the type of eHTA analysis that would be most useful for you.

Q4 **Based on the information on this page, at what TRL is your diagnostic development program?**

TRL	Key lab-based scientific activities	
1	• Review of scientific evidence on target, diseases, and relevant technologies.	☐
2	• Plan for necessary additional foundational scientific research studies.	☐
3	• Prototype and evaluate assay components and technologies. • Evaluate performance of preliminary assay in simplified model.	☐
4	• Full integration of assay components and technologies. • Evaluate performance using sample type, volume, and components matching intended use. • Identify applicable regulatory pathways for initial target market.	☐
5	• Finalize design and demonstrate performance sufficient to justify regulatory filing. • Develop scalable, regulation-compliant manufacturing strategy. • Design clinical trial, if necessary (e.g., FDA Class III IVD, Premarket Approval required).	☐
6	• Begin regulation-compliant manufacturing. • Submit regulatory package and initiate clinical trial(s), if applicable.	☐
7	• Validate quality assessment process.	☐
8	• Complete clinical trial(s), if applicable, and regulatory approval process.	☐

If your technology is at a TRL level of between 2 and 6, inclusive... **GO TO PAGE 5**
If your technology is at a TRL of 1, 7 or 8... **GO TO PAGE 9**

eHTA Suitability Checklist

☑ **Step 3:** Define eHTA studies to help advance your product to the next TRL

If your **diagnostic** product candidate is between **TRLs 2 to 6** eHTA may be able to support its further development.

Early Health Technology Assessment

Discovery | Preclinical Development | Clinical Development

TRL 2 Product ideation → **TRL 3** → **TRL 4** → **TRL 5** → **TRL 6** Phase I trial

Which disease or indication to focus on?

- Unmet medical need
- Patient & provider preferences
- Potential cost offsets
- Prevalence in major markets

What data to collect in clinical trials for value dossier?

- Clinical outcomes
- Quality of life & cost impacts and offsets
- Comparisons with predicate diagnostic

Which product characteristics to optimize for?

- Sensitivity vs. specificity
- Fit with existing workflows
- Patient convenience
- Value-based price

Types of assessments the eHTA Platform team can perform for specific indications

TRL ➤ 2 - 3	• Characterize disease **epidemiology** • Map out current care patterns and clinical and laboratory wokflows • Define unmet need and **competitive landscape** • Begin collecting user feedback on early prototypes
TRL ➤ 4	• Draft product profile • Estimate **economic burden** of illness and treatment costs • Characterize analytical and clinical utility, cost, and **cost-effectiveness** of predicate diagnostics (if applicable) • **Reimbursement** landscape map for U.S. and other markets
TRL ➤ 5 - 6	• Assess **provider** and **patient preferences** before finalizing design • Partner with key opinion leaders to inform trial design, if applicable • Design data collection strategy for reimbursement dossier • Estimate **budget impact** for key payers in U.S. and other markets

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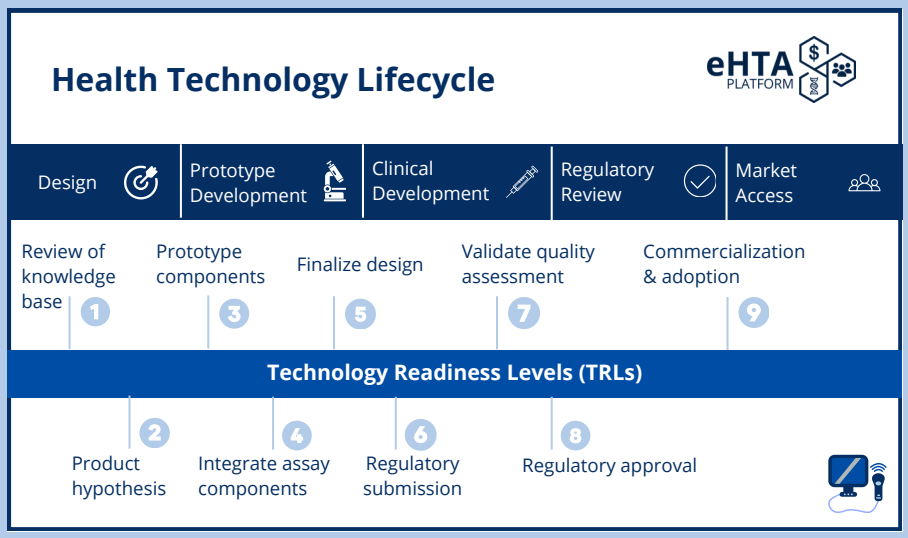
eHTA Suitability Checklist

☑ Step 2: Determine your **therapeutic device**'s TRL

An eHTA is most useful in the earlier stages of medical product development. For therapeutic devices, this usually means somewhere between product ideation and finalizing the design.



The Technology Readiness Level (TRL) framework used by government agencies like Innovation, Science, and Economic Development Canada and the U.S. NIH Centers for Accelerated Innovation, offers guidance regarding the activities and milestones necessary to advance a new technology along the development and commercialization pathway. Determining the current TRL for your medical product will help identify the type of eHTA analysis that would be most useful for you.

Q4 **Based on the information on this page, at what TRL is your therapeutic device development program?**

TRL	Key lab-based scientific activities	
1	• Review of scientific evidence on target, diseases, and relevant technologies.	☐
2	• Plan for necessary additional foundational scientific research studies.	☐
3	• Identify key design features and technology needs through iterative prototyping. • Assess likely efficacy and safety in simplified model(s).	☐
4	• Refine prototype using iterative cycles of user feedback and efficacy testing. • Full integration of device components and technologies. • Define indication and endpoints, and demonstrate efficacy *in vivo*.	☐
5	• Finalize design and demonstrate performance sufficient to justify regulatory filing. • Develop scalable, regulation-compliant manufacturing strategy. • Design clinical trial, if necessary (e.g., FDA Class III device, Premarket Approval required).	☐
6	• Begin regulation-compliant manufacturing. • Submit regulatory package and initiate clinical trial(s), if applicable.	☐
7	• Scale up manufacturing process. • Complete clinical trial(s), if applicable.	☐
8	• Submit full regulatory package.	☐

If your technology is at a TRL level of between 2 and 6, inclusive... ▶ **GO TO PAGE 7**
If your technology is at a TRL of 1, 7 or 8... ▶ **GO TO PAGE 9**

eHTA Suitability Checklist

☑ Step 3: Define eHTA studies to help advance your product to the next TRL

If your **therapeutic device** product candidate is between **TRLs 2 to 6** eHTA may be able to support its further development.

Early Health Technology Assessment

Discovery | Preclinical Development | Clinical Development

TRL 2 Product ideation → **TRL 3** → **TRL 4** → **TRL 5** → **TRL 6** Phase I trial

Which disease or indication to focus on?

- Unmet medical need
- Patient & provider preferences
- Potential cost offsets
- Prevalence in major markets

What data to collect in clinical trials for value dossier?

- Clinical outcomes
- Quality of life & cost impacts and offsets
- Comparisons with predicate device

Which product characteristics to optimize for?

- Sensitivity vs. specificity
- Fit with existing workflows
- Patient convenience
- Value-based price

Types of assessments the eHTA Platform team can perform for specific indications

TRL ➤ 2 - 3	• Characterize disease **epidemiology** • Map out current care patterns and clinical and laboratory wokflows • Define unmet need and **competitive landscape** • Begin collecting user feedback on early prototypes
TRL ➤ 4	• Systematic user feedback research • Estimate **economic burden** of illness and treatment costs • Characterize clinical effectiveness, cost, and **cost-effectiveness** of predicate devices (if applicable) • **Reimbursement** landscape map for U.S. and other markets
TRL ➤ 5 - 6	• Assess **provider and patient preferences** before finalizing design • Partner with key opinion leaders to inform trial design, if applicable • Design data collection strategy for reimbursement dossier • Estimate **budget impact** for key payers in U.S. and other markets

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eHTA Suitability Checklist

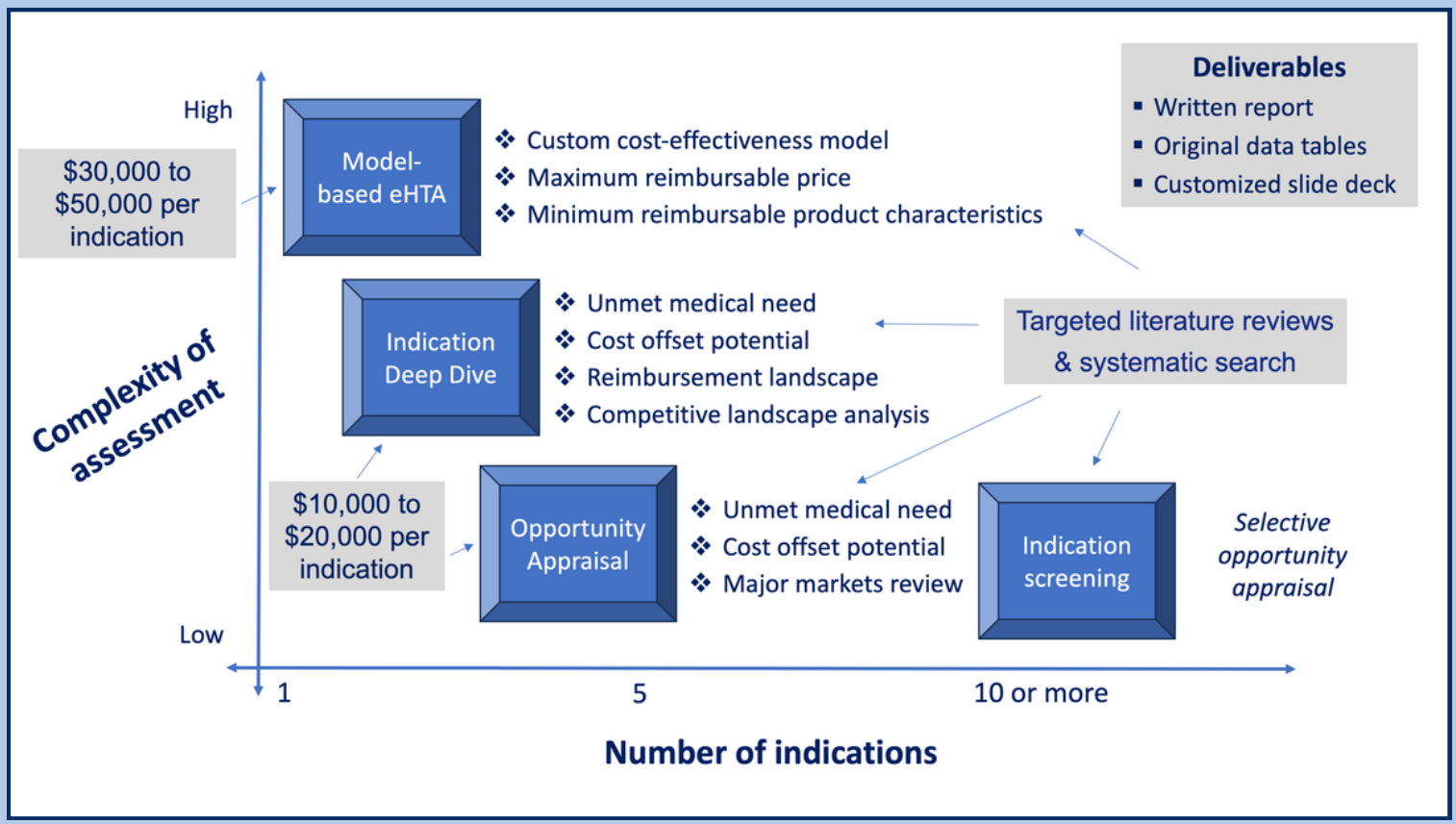
☑ Indication assessment study packages

An **Indication Assessment** can help life science teams to identify which of the indications that their product candidate could be used to address offers the greatest opportunity in which to improve patient outcomes (**clinical headroom**), differentiate the new product from competing technologies, and deliver value for money to health systems and payers (**economic headroom**).

Indication assessments can be performed in many different ways. Some types of studies, like a **Model-based eHTA**, involve the development of a customized cost-effectiveness model and are resource intensive. While they are excellent tools with which to estimate the potential clinical benefit of a new medical product when the pathway through which it impacts patient outcomes is complex (e.g., for new diagnostic tests), building a cost-effectiveness model is not always necessary.

Less complex study types, like an **Indication Deep Dive**, **Opportunity Appraisal**, or **Indication Screening**, can effectively be used to assess the clinical and economic headroom for one or more specific indications in many situations. In addition, they can easily be customized to address life science teams' specific needs.

eHTA Platform Indication Assessment Framework



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eHTA Suitability Checklist

☑ Reach out to us to discuss how eHTA might be able to help you

Not all technologies are at a stage where they can benefit from eHTA. Generally speaking, eHTA can help to inform the development of **medical products to diagnose or treat specific indications**. However, in situations like the ones listed on this page, eHTA may not be a good fit.

Platform technology	**Platform technologies** are often commercialized as laboratory instruments or leveraged to provide a valuable service to industry partners. If you are **not developing a specific medical product** at this time (either alone or in partnership with others), then eHTA is probably not the type of support you need. Instead, you may benefit from more general customer discovery and market research to help you define your commercialization strategy.
Other product type	If you are developing a type of medical product that **doesn't fit** into the three categories listed above (drugs, diagnostics tests, and therapeutic devices), such as an AI algorithm or digital health app, eHTA may be able to help, but we would likely need to develop a customized study plan.
Late-stage product candidate	If your medical product is at **TRL 7 or 8**, traditional health technology assessment is better suited to your needs than eHTA.
Discovery-stage research	If your medical product is at **TRL 1**, or if you plan to develop or co-develop a drug, diagnostic, or therapeutic device **in the future**, it is probably too early to conduct an eHTA study. However, you may find it useful to use this checklist to learn about the type of questions eHTA could help you answer when you do have a product at the TRL 2-6 stage.

If you think we may be able to help your team and would like to discuss your technology with the eHTA Platform, please reach out to us!

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