

Collaboration Guidebook



HealthIL

Digital Health Community



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EUROPE

INTRODUCTION

The gap between demand for healthcare services and the supply of healthcare services has been growing and will continue to grow in the future. This is driven by multiple factors, such as an aging population with complex conditions, workforce constraints, and the need for increasing coverage and access for citizens.

One way to address this increasing gap is to incorporate technological solutions, such as startups, into healthcare systems, as startups and technology have the potential to increase capacity and capability of care. To successfully implement external technological solutions – whether they are startups or established companies – healthcare systems should develop an efficient and replicable methodology for assessing which startups are most relevant.

This guide is intended to offer healthcare systems, of any kind, a high-level framework for assessing external technologies, particularly startups, without the need for a deep understanding of technology. It is intended to be used by any individual within the healthcare organization who is potentially considering some form of collaboration with startups or external technology providers.

We invite you to adjust and adapt this mainframe based on your individual needs or experience, with the hope of creating a unified and efficient methodology for all stakeholders within healthcare organization.

For any questions,
feel free to contact Yoav Fisher at **HealthIL**:
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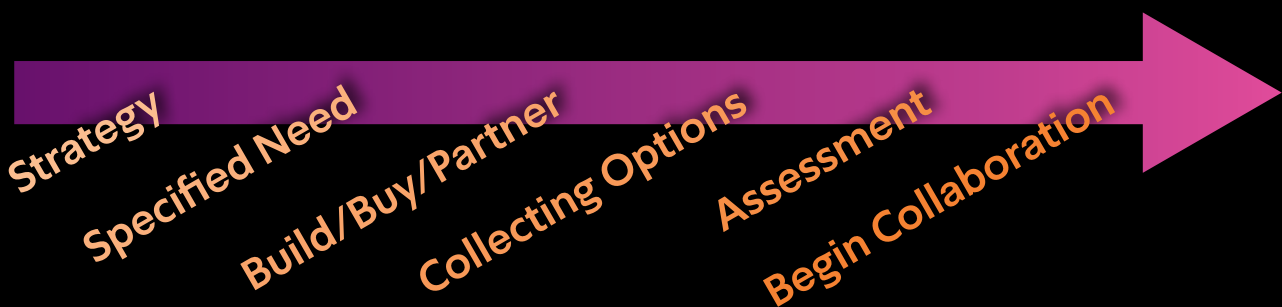
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25 SUMMARY

HOW TO USE THIS GUIDEBOOK

Assessing external startups is part of a larger Open Innovation process, whereby healthcare organizations move from strategy to a defined challenge to finding a suitable solution. The “solution” is the external innovation to be assessed.

Assessment of the external startup happens after the healthcare organization has decided on a specific need or challenge to be addressed that relates to some high-level strategic interest, and after the healthcare organization has decided that collaborating with an external startup is the best pathway.

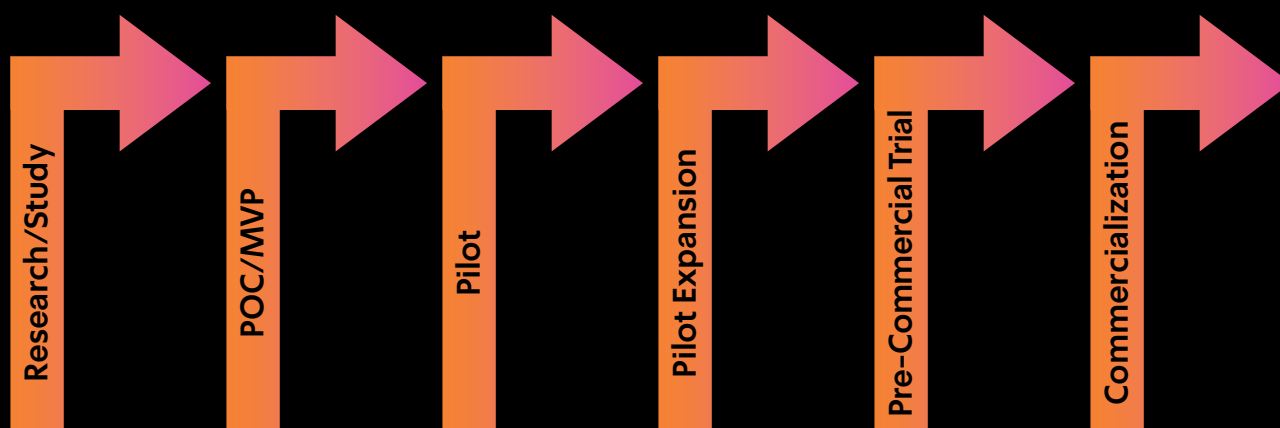


For this purpose of this guide, we will assume that the healthcare organization has isolated a need or challenge related to a larger strategic goal. For example, the need for improved cross-departmental staffing can be defined from the larger strategic goal of reducing staff burnout.

We also assume that the organization has decided to collaborate with external technology – a startup or other provider – to address this need. This is different from buying an off-the-shelf solution or allocating funding to build a customized solution ¹.

¹ The question of Build vs. Buy vs. Collaborate is beyond the scope of this guide, but readers are invited to email HealthIL for further details and support on this topic.

There are numerous pathways to collaborate with external startups or providers, from initial research or observational studies all the way through full commercialization. Even though each pathway has unique nuances, the healthcare organization must decide who to work with in each pathway. This guide is intended to help with that critical step.



“Co-development”, also known as “Design Partnership” or “Joint Venture” is a unique collaboration pathway that requires special consideration and will not be covered as part of this guide. Interested readers are invited to email HealthIL to receive our free guidebook on “Co-Development Best Practices for Healthcare Organizations”.

Each section of this guide contains components that help innovation managers or innovation leaders within healthcare organizations assess startups.

You can think of these components as a “checklist”, and each organization can choose to add to or adjust the questions contained.

There are five main components to review when deciding on a startup:

- 1. GENERAL ASSESSMENTS**
 - a. Patient Factors
 - b. Clinical Factors
 - c. Organizational Factors
 - d. External Factors
 - e. Internal Factors
- 2. LEGAL ASSESSMENT**
- 3. IT ASSESSMENT**
- 4. ECONOMIC ASSESSMENT**
- 5. COLLABORATION PATHWAY**

It is important to include domain experts from within the organization when doing the assessment. For example, if the organization is exploring solutions in the neurological field, the feedback from clinicians, patients, or nurses in the neurological department is relevant. Certain components, specifically Legal and IT considerations, will require involvement from the organization's Legal and IT departments.

It is also possible to use this guide to effectively “rank” options. Healthcare organizations can assess each item on a scale (like one to ten), and then decide which sections are more relevant to effectively create a weighted average and a minimum threshold for consideration.

For more ideas on how to best utilize this guidebook feel free to contact **HealthIL**.

GENERAL ASSESSMENT

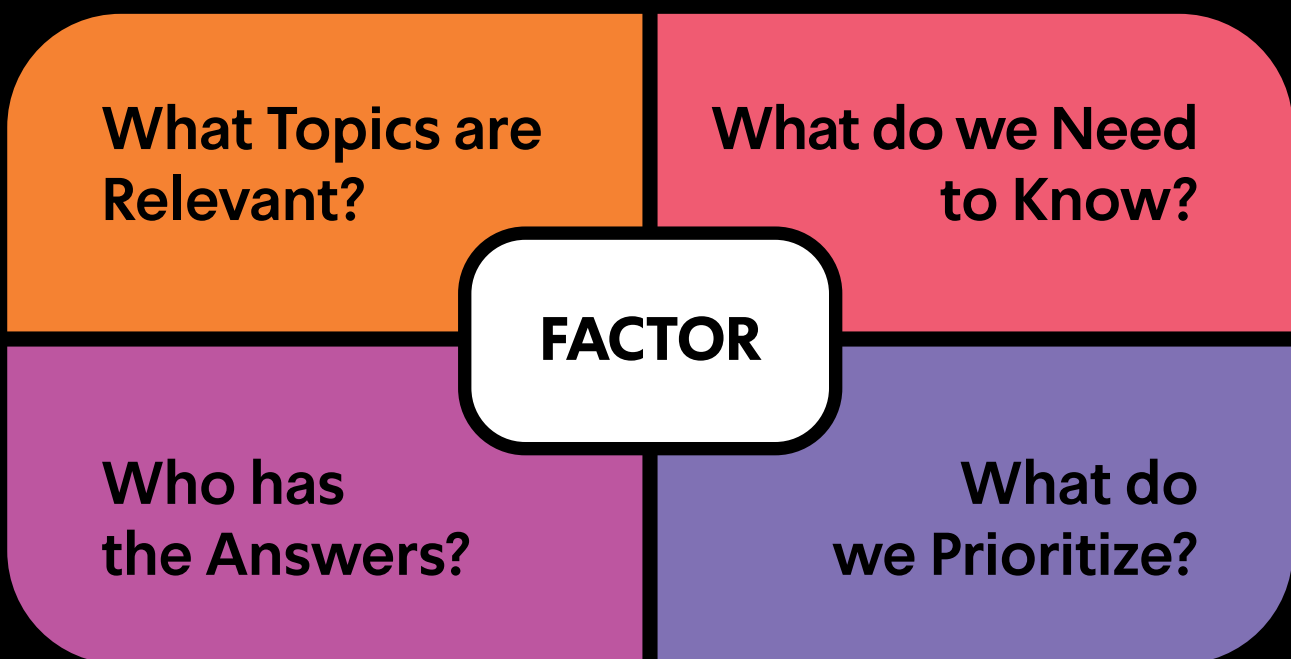
This component is divided into sub-categories, where each category has specific example questions to give innovation managers and innovation leads direction on how to assess the innovation in question.

As stated, it is important to include the feedback and opinions of domain experts and key opinion leaders for each sub-category.

Within the “General” Assessment component we will look at specific factors:

- **PATIENT FACTORS**
- **CLINICAL FACTORS**
- **ORGANIZATIONAL FACTORS**
- **EXTERNAL FACTORS**
- **INFRASTRUCTURE FACTORS**

For each factor there are four main questions that the organization must address:



PATIENT FACTORS

What Topics are Relevant?	What do we need to know?	Who Has the Answers?	What do we Prioritize?
How important is this to our patients?	What is prevalence of condition in Israel/in the organization? Who is the target population/patient of the innovation?		
Number of patients that need this solution?	Is the product intended for widespread use, or only for a subgroup of the target population?		
How quickly will our patients see the impact? (short term impact)	To what extent is the patient expected to adopt the solution? How quickly will patients be able to adopt the solution?		
How impactful will this be to our patients over the long run? (long term impact)	What projected health/care outcomes does this product create?		
Is the product safe?	Will the product endanger patients? Is there a risk of incorrect results/usage? How harmful are incorrect results/usage? Does the product have a process for addressing the possibility of incorrect results/usage?		

While all of these questions pertain to how the startup affects patients, healthcare organizations should be mindful to include multiple perspectives. It is important to include not only the patients, but also their caregivers, families, clinicians, nursing, and more to gain insights.

What to Prioritize is an effective way to create ranking to understand what is most critical for patients. Healthcare organizations can ask stakeholders to give a score – say from one to ten – and then give weights to each line item.

CLINICAL FACTORS

What Topics are Relevant?	What do we need to know?	Who Has the Answers?	What do we Prioritize?
How clinically relevant is the product?	Does the product need clinical validation for the intended use? Is the product supported by clinical research/evidence? Have any previous clinical/academic studies been performed?		
Is there a clinical need?	Does the product address a gap/need in clinical care? Is the gap/need in clinical care broad or narrow? Is the gap/need in clinical care widespread to providers in general?		
Is there regulatory relevancy?	What regulations exist and how relevant are they to the challenge/need of the organization? What does the regulation address?		

It is important to note that many interesting startups actually do not require clinical validation in the “traditional” sense of FDA or CE approval. These startups, which can include things like workflow automation, supply chain, or inventory management, still impact clinicians and clinical workflows.

Therefore, healthcare organization should still explore how the startup affects clinicians and their workflow.

As with Patient Factors, while these questions pertain to how the startup affects clinicians, healthcare organizations should be mindful to include multiple perspectives.

ORGANIZATIONAL FACTORS

What Topics are Relevant?	What do we need to know?	Who Has the Answers?	What do we Prioritize?
How relevant is this to the strategic interest and goals of the organization?	Does this product promote address the strategic aims of the organization? Is the product relevant to the longer term business/operational goals of the organization?		
How impactful will this be to our organization?	How does the product add value to our organization? How does this product affect our ability to deliver care? How will this product affect our existing services? What are the metrics to measure value to our organization?		
How quickly will our organizations see the impact?	How quickly will our organization benefit from using this product? Are we willing to wait?		
How easily can this be integrated into our existing workflows and processes?	How will the innovation fit with existing workflows and processes? Is there a substantial change to existing workflows/processes? Does staff need to be trained? Do existing workflows/processes need to be changed and how so?		

As before, it is important to address these questions from multiple perspectives. For example, the head of a department will probably have a different viewpoint than the CFO of a hospital.

EXTERNAL FACTORS

These questions are to assess qualitative aspects of the startup itself, without relationship to the healthcare organization.

All of these questions fall under two broad categories: Does the startup give significant added value when compared to the current existing practices, and how capable is the team in executing on the vision.

What Topics are Relevant?	What do we need to know?	Who Has the Answers?	What do we Prioritize?
Is the stage relevant?	Does the stage of the product/feature match the desired collaboration? Will the collaboration help move the product/feature forward?		
How Available is the team?	Can the team members commit to collaboration with your organization?		
How strong is the team track record and relevant experience?	Does the team have the necessary background to follow through with the collaboration?		
Does the team have the financial resources to continue?	Do they have the financial means to support the duration of the collaboration? Do they have a plan for securing financing for the collaboration?		
How much competitive advantage does this have as compared to other known alternative innovations?	What are other known innovations and how does this product compare? To what degree is this product better than other innovations and how do you measure the difference?		
How much competitive advantage does this have as compared currently used internal methods?	What is your accepted method used today to address this challenge within the organization and how does the innovation compare? What is the accepted method used in other organizations in Israel and how does this compare? To what degree is this product better than currently used methods and how do you measure the difference?		
What is your overall impression of the product?			

INTERNAL FACTORS

While the “External Factors” pertain just to the startup, these questions are “Internal”, where the healthcare organization must understand their internal capability to work with the startup.

For example, many startups work with healthcare organizations based on access to patient data, and it is important for the healthcare organization to understand if they can provide access to the relevant data before beginning some type of collaboration.

What Topics are Relevant?	What do we need to know?	Who Has the Answers?	What do we Prioritize?
Data access	Does collaboration with the product require access to data? What type of data?		
Data availability	Does the organization have the necessary data? Does the organization need special approval to access the data? Can a workaround be created if the org does not have the data?		
Does any type of collaboration require any additional resources?	Does the collaboration with this product require support from organization staff? Additional hardware? Additional infrastructure? What additional resources are needed to successfully collaborate with the product?		
Is the organization able to supply the additional resources?	Is this product important enough for the organization to allocate additional resources if needed?		
Does the collaboration have an internal “champion”?	Is there someone internally dedicated to being the sponsor for the collaboration?		

It is important to remember to tie this to the defined strategy and specific need or challenge of the organization. Not all needs require access to patient data. Not all needs require AI. And some needs to do even require technology for the solution.

IT ASSESSMENT

IT departments are critical for assessing if a healthcare organization should collaborate with an external startup.

For these items, it is recommended that innovation managers or innovation leads incorporate feedback from IT departments earlier in the assessment process, to reduce the chance that the healthcare organization spends time and effort on a project only to find out later that there is no practical way to collaborate due to IT concerns.

These items do not need to be “ranked” like the items in the General Assessment, but rather innovation managers and innovation leads can work with their IT counterparts to determine if each item “exists”, “does not exist”, is “in process”, or is “not relevant” given the specific use case of the innovation.

As before, additional considerations may be included based on recommendations and experience of the organization and the IT teams.

IT CONSIDERATIONS FOR CLINICAL ASPECTS

Item	Brief Description	Notes & Considerations
Clinical Risk Management Protocol/System	Clinical risk management protocol for product exists based on local guidelines	May or may not be relevant given product and local regulation
Hazard/Safety Plan	Identification of hazards and intended action plan to correct	May include hazard log
Clinical Safety Officer	Naming point of contact for all safety concerns	
Medical Regulation	Any medical regulation (FDA/CE/AMAR) that can support claims	
3rd party interface	Any connection to outside 3rd parties	Must also provide risk management protocol for 3rd parties

IT CONSIDERATIONS FOR DATA

Item	Brief Description	Notes & Considerations
Personal Data Access	Does product have access to patient data	May require Helsinki or Cloud Board
Data protection standards	Assessment of data protection standards (HIPAA/GDPR) – aka de-identification	Depends on Data
Access Controls	Defining who has access and to what degree	
Storage/access locations	Where data is stored and used	May require Helsinki or Cloud Board
3rd party access/storage	Any connection to outside 3rd parties	Must confirm 3rd parties are also compliant
Data Protection Officer	Naming point of contact for all data concerns	
Data Protection Impact Assessment		May or may not be relevant based on product and local regulation

IT CONSIDERATIONS FOR SECURITY

Item	Brief Description	Notes & Considerations
Cyber Security Credentials	Standard cyber security credentials, approvals, or protocols	May or may not be relevant based on product and type of collaboration
Penetration Testing	Evidence of standard penetration tests (OWASP/CVSS)	
Code review	Assessment of any custom code that may pose vulnerabilities	
Authentication review	Multi-factor authentication for access controls	
Load testing	Load testing of product as need be	May be different based on type of product
Logging/reporting protocols	Log-in and usage reporting and monitoring	

IT CONSIDERATIONS FOR INTEROPERABILITY

Item	Brief Description	Notes & Considerations
Communication Protocols	List of all communication protocols (Wifi/Bluetooth/4G/etc..)	Specific Protocols may have additional requirements based on local regulation (example: Wifi)
API interfaces	Exposure to any APIs – internal and external	Must confirm APIs are compliant and safe
System Architecture Review	Assessment of architecture and matching to existing architecture of health org	
API Standards	Confirm standards of APIs (FHIR/HL7/etc..)	
EMR Read/Write standards	Does product interface with internal EMR	Must confirm product conforms to industry and organization standards for secure interoperability
Standards for hardware components	Any wearables or devices that are part of the product?	Must confirm hardware components are compliant and safe

LEGAL ASSESSMENT

All too often healthcare organizations overlook the relevancy of the legal implications of working with an external partner. There are many examples of healthcare organizations who spend the time and effort on finding an external partner, only to discover that there is no way to begin collaboration due to contractual disputes or other legal disagreements or obligations.

Much like IT, Legal counterparts should be looped into the process early, to ensure that collaboration is possible, and that both sides are mutually satisfied with the terms. Also, like IT, the specific details of each item are to be assessed according to “exists”, “does not exist”, is “in process”, or is “not relevant” given the specific use case of the innovation.

Finally, it is not expected that any innovation manager or innovation leader understands the legal nuances of collaboration – that is what lawyers are for – but it is recommended that innovation managers and innovation leaders are at least aware of the legal considerations of collaboration.

GENERAL LEGAL CONSIDERATIONS

- **General Purpose and Objective**

- **Stipulations**

- Prior Agreements

- Prerequisites

- Funding

- Milestones

- Standards

- Boards

- Certifications

- Other

- **Confidentiality**

- 3rd parties

- Scope and Access

- Circumvention

- **IP**

- Ownership

- Titles

- Interests

- Patents

- Trade Secrets

- Copywrites

- Proprietary Know-How

- Inventions

- Other

- **Ownership**

- Data

- Results

- Future work

- **Data**

- Description

- Size/Scope

- Access

- Permissions

- 3rd parties

- **Fees**

- Services

- Rate

- **Future Actions**

- **Termination**

- **Indemnification**

- **Penalties**

- **Liabilities**

- **Compliance**

- **PR / Marketing**

- **Additional Provisions**

- Equipment usage

- Settlement / Disputes

ECONOMIC/FINANCIAL ASSESSMENT

In certain situations, a healthcare organization may want to have an economic or financial stake in the external company in addition to the standard collaboration considerations. This happens when the healthcare organization sees both strategic and economic benefit of the startup and is interested in pursuing some form of remuneration from the collaboration.

There are numerous pathways for building an economic/financial relationship with an external company, and healthcare organizations can choose to consult with financing experts, like venture capital firms, to understand best practices. **HealthIL** can also assist with this process.

ORGANIZATIONAL CONSIDERATIONS FOR ECONOMIC/FINANCIAL STAKE

What Topics are Relevant?	What do we need to know?	Who Has the Answers?	What do we Prioritize?
How viable is the business model?	Does the company understand the economic motivations behind their product? Does the company have strong underlying assumptions about the value-add of their product? Does the company understand the size of the market and the profile of real users/customers?		
How viable is the market and marketing strategy?	Does the company have a clear go-to-market plan? Does the company have a marketing strategy? Does the company have real added value to first customers? Can the company successfully defend their product to customers?		
How strong is the sales potential?	Does the company have a strong monetization strategy? Does their monetization strategy make sense with how the healthcare market works?		
How strong is the exit strategy?	Does the company have an exit strategy? Does the exit strategy make sense for the market, incumbents, and competitors? What is the probability that the company will reach some exit?		

How strong is the funding history?	Has the company successfully raised capital from investors? Are there strategic investors? Has the company raised enough to give them a runway for proposed collaboration? For the long run? What is the probability that the company will be around in the long run?		
How relevant is the track record of the company?	Has the company successfully commercialized within healthcare? Has the company ever worked with another healthcare organization and in what capacity?		
Degree of Economic value to our organization	How is the economic value of the product defined? What are the metrics for assessing economic value? Has the company presented anything to support their claim? What is the likelihood of realizing the economic value?		
How quickly will our organization see the economic value?	How fast until some economic value is realized? What hurdles/gateways to see the economic value? Can the organization wait?		

The two **highlighted** questions should anchor the economic assessment of the company, and the perspective of multiple stakeholders should be included when making assessment.

Should the healthcare organization decide to pursue an additional economic or financial relationship with the startup, there are multiple mechanisms that can be pursued. The specifics of these mechanisms are beyond the scope of this guide, but healthcare organizations are invited to contact HealthII for additional details and best practices on this frequently complex consideration.

LEGAL CONSIDERATIONS FOR ECONOMIC/FINANCIAL STAKE

Should the healthcare organization decide to pursue an economic or financial relationship with the startup, in addition to the collaboration, legal departments must be included to address additional factors:

- **Type of relationship and terms**

- Equity
 - Royalties
 - Licensing
 - Other

- **Exclusivity**

- Activity Restriction**

- Selling / promoting product
 - Working in a specified region
 - Non-solicitation
 - Time frame cap
 - Others

- **Joint Discovery**

- **Patenting**

- **Ownership**

- **Warranties**

- **Dispute Resolution**

- **Termination**

COLLABORATION PATHWAYS

There are many ways to collaborate with a startup, from initial research through full commercial deployment.

For each type of collaboration there are “minimum requirements” that the healthcare organization should be prepared for.

These elements are not part of the assessment, but are included in this guide to give healthcare organizations a high level understanding of what the collaboration will entail.

It is important for the healthcare organization to review these elements and ensure they are able to commit to the collaboration.

Type of Collaboration	Minimum Requirements
Research or Observational Study	•Objective of the collaboration •Size/Scope of the collaboration •Data Access and Management/Capture protocol •Gantt/Timeline •Risk Assessment •Safety Protocol •KPIs •Budget
Proof of Concept or Minimum Viable Product	All above plus: •Defined points of contact •Defined roles and responsibilities •Logistical review •Physical Resource assessment
Pilot	All above plus: •Security Review
Expanded pilot or secondary site	All above plus: •Internal infrastructure & resources assessment •Internal operational assessment
Pre-Commercial Trial	All above plus: •Compliance Review •Economic Impact Assessment (cost-benefit or cost-neutrality)
Commercialization	All above plus: •SLA (Service Level Agreement)

Each collaboration with a startup is unique, and healthcare organizations should feel free to add or adjust these requirements based on how they wish to operate and potential regulatory considerations in their region.

ADDITIONAL CONSIDERATIONS

Some collaborations with startups may involve specific “gateways” that need to be completed. These gateways may include Cloud Board approval, Helsinki board approval, or IRB approval. The gateways vary, or may even be irrelevant, based on the usage of the startup and the need or challenge of the healthcare organization.

A SPECIAL NOTE ON SLAs

An SLA (“Service Level Agreement”) is used when the healthcare organization and the startup form a commercial collaboration.

These situations occur typically when the startup is mature and ready to be deployed within the healthcare organization, and the healthcare organization has agreed to pay for the product or service provided by the startup.

In these situation, there are additional considerations that should be included for this type of collaboration, and healthcare organizations are encouraged to work in conjunction with their legal counterparts to determine if the following “exists”, “does not exist”, is “in process”, or is “not relevant” given the nature of the commercial agreement.

- **Transferability**
- **Usage Definition & Restrictions**
- **Sublicensing**
- **Implementation**
 - Training
 - Onboarding
 - Duration
 - Schedule
 - Costs
 - Milestones
 - Other
- **Testing**
- **Terms**
 - Renewal
 - Payments
 - Non-solicitation
 - Non-compete
 - Non-circumvent
- **Termination**
- **Exclusivity**
- **Standards**
- **Disaster/Hazard Recovery**
- **Insurance**

SUMMARY

Every startup that is building a health-tech solution is trying to save lives and make healthcare more efficient and effective. But for all the good intentions of these startups, there is a difference between good intentions and practical application and usage.

In addition, the proliferation of health-tech, and the rapid increase in possibilities, means healthcare organizations are inundated with potential opportunities.

Finally, most people are not data scientists, and the rapid progress of technological tools like Generative AI means most people are frequently confused.

It is the job of the healthcare organization, or the innovation leader with the healthcare organization, to filter through these options and assess which of these startups has the highest potential to create effective improvements in care that benefit patients, clinicians, and the healthcare organizations themselves.

It is the job of the healthcare organization, or the innovation leader within the healthcare organization, to look beyond fancy technical jargon and focus on the practical usage of the startups.

This guide is meant to assist with this process, giving a replicable and non-technical methodology whereby healthcare organizations can assess which startups are most beneficial to patients, clinicians, and organizations.

We encourage practitioners to work cross-functionally within their organizations to align stakeholders around this methodology, and to build upon this methodology according to their own needs and experience.

About **HealthIL**

HealthIL is an Israeli NGO dedicated to improving healthcare through the successful integration of startups and technology into healthcare systems. **HealthIL** works holistically across all stakeholders in healthcare to understand the needs and challenges of healthcare systems, regulatory constraints, and the potential and relevancy of startups and tech providers.

HealthIL is proud to work in collaboration with healthcare systems and stakeholders from around the globe and share their insights, best practices, and methodologies with the goal of improving healthcare for citizens worldwide.