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Beyond Technical Milestones:
Incorporating Desirability Into Your Medical Innovations

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August 24, 2021

NIH National Heart, Lung, and Blood Institute

Seminar Objectives

- Emphasize the importance of **desirability** for innovation success.
- Highlight techniques to engage the market and incorporate critical stakeholder **insights** early.
- Introduce a framework tool — ICANVAS for medical applications — that can help **guide** your innovation journey from concept to impact.

CATALYZE
Accelerating Translation

Catalyze provides a comprehensive suite of support and services to facilitate the translation of basic heart, lung, blood and sleep discoveries into viable therapeutics, devices and diagnostics ready for human testing.

Funding

Unique funding strategy to leverage federal investment with matching commitments and flexibility to adjust to technical challenges

Individualized Support

Milestone-driven project management and technical support to mitigate technical risk

Coordinated Approach

Seamless continuum of funding programs to advance promising heart, lung, blood and sleep technologies from validation through first-in-human trials

Program Flexibility

Evaluation and oversight to adjust program and projects based on trends, challenges, and to share best practices

For more information email
NHLBI_Catalyze@mail.nih.gov

NIH National Heart, Lung, and Blood Institute

Today's Agenda

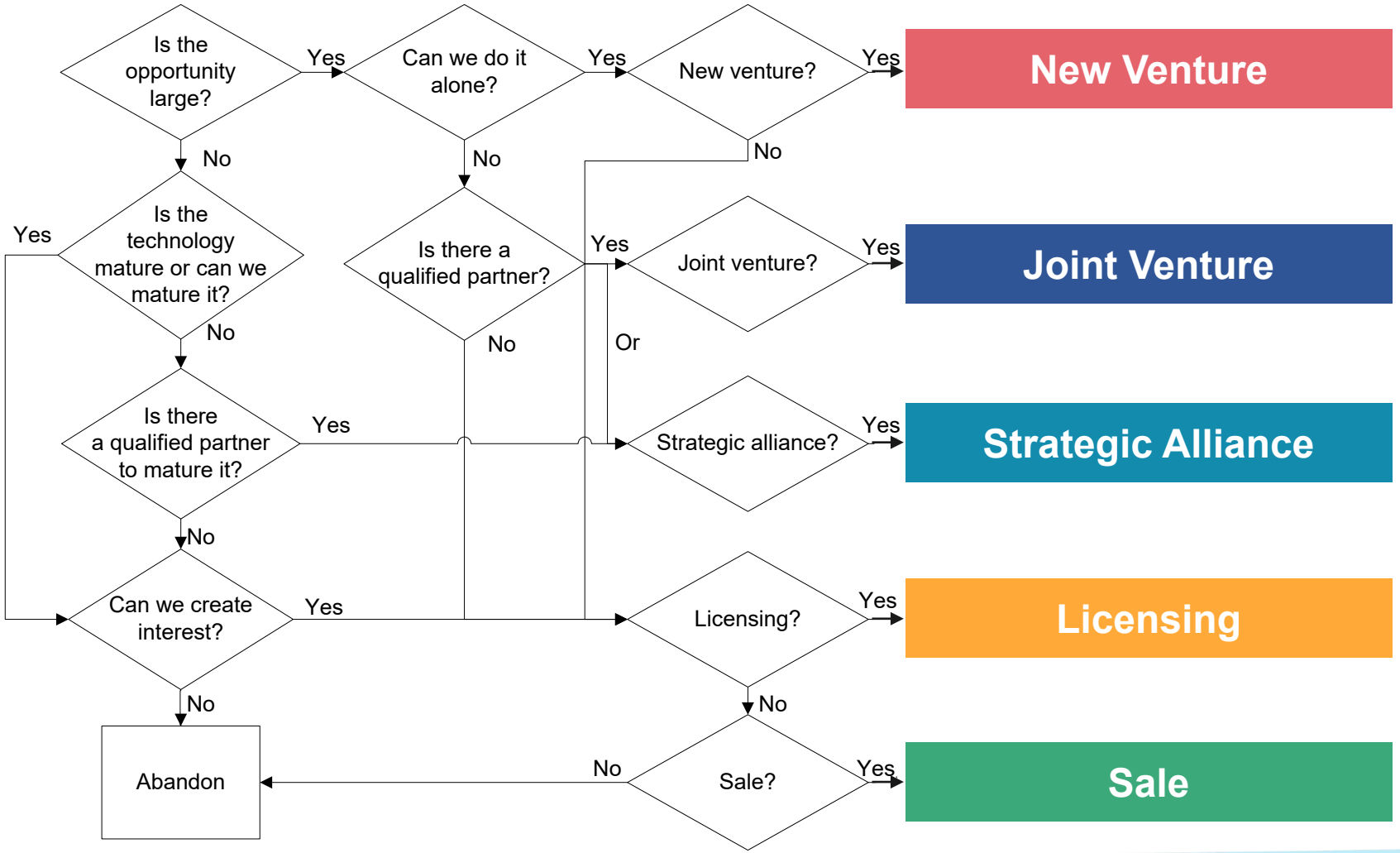
- Why is Desirability important?
- Introduction to ICANVAS
- How to assess Desirability

One way to achieve clinical impact is through commercialization.

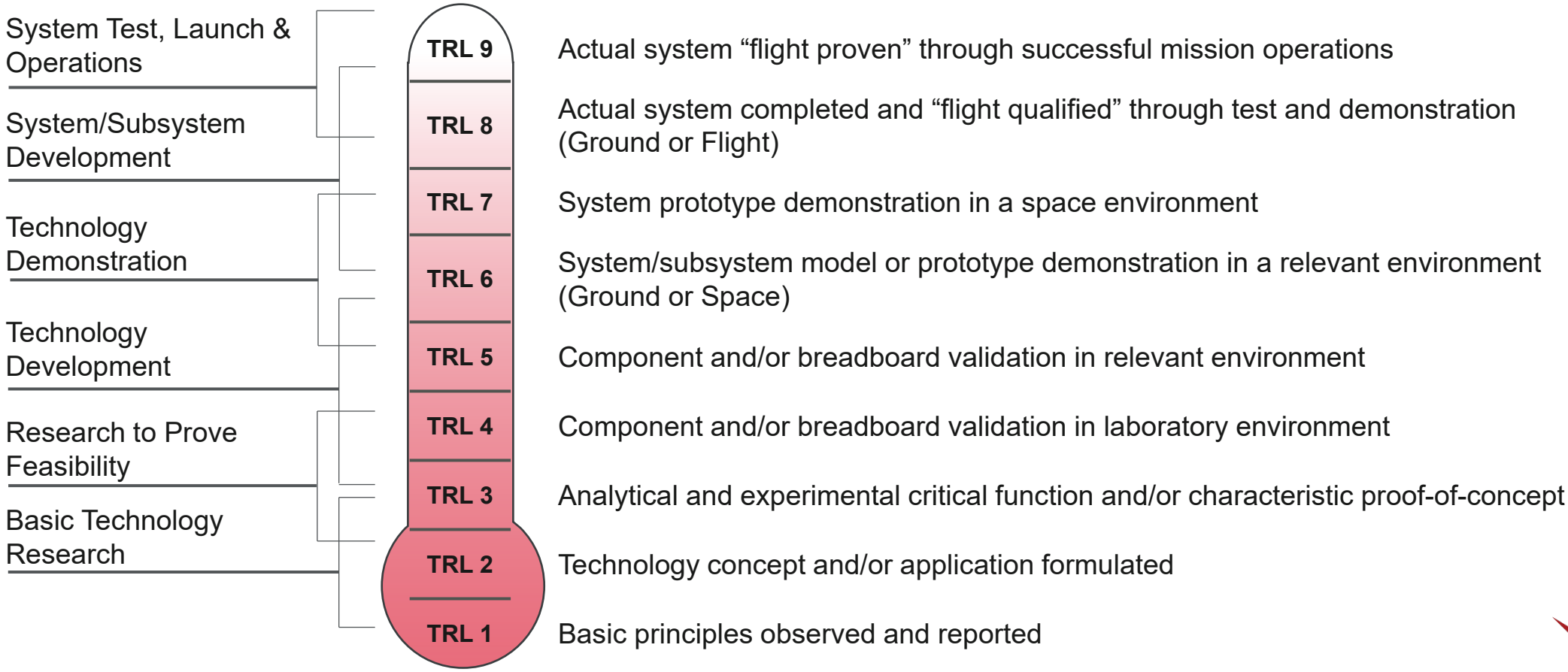
What is commercialization?

- The process of moving new technologies, products, or services into the market.
- A mechanism for moving ideas and innovations from the lab into clinical impact.

There are multiple paths to market.



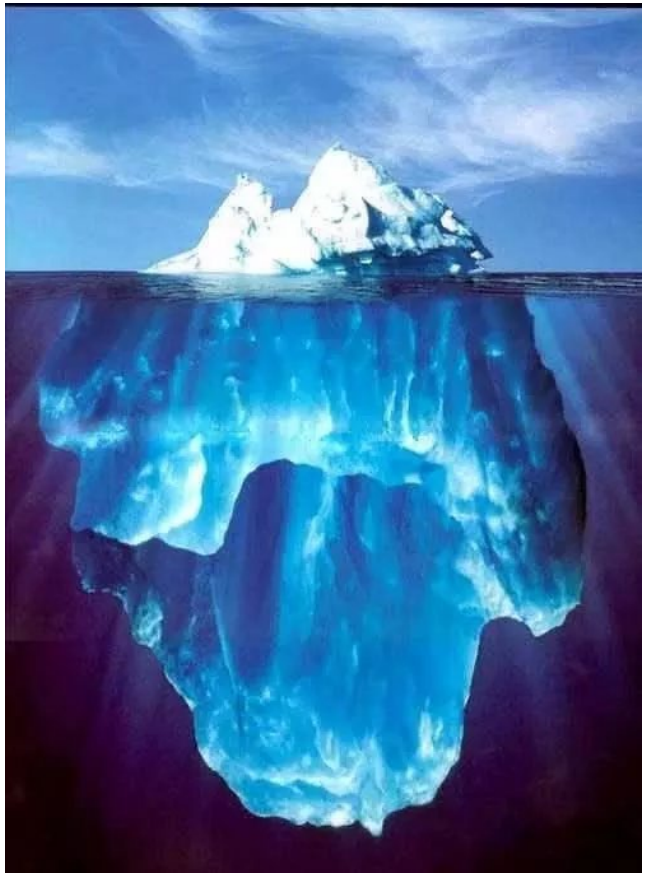
Technology readiness reveals the status of technical milestones.



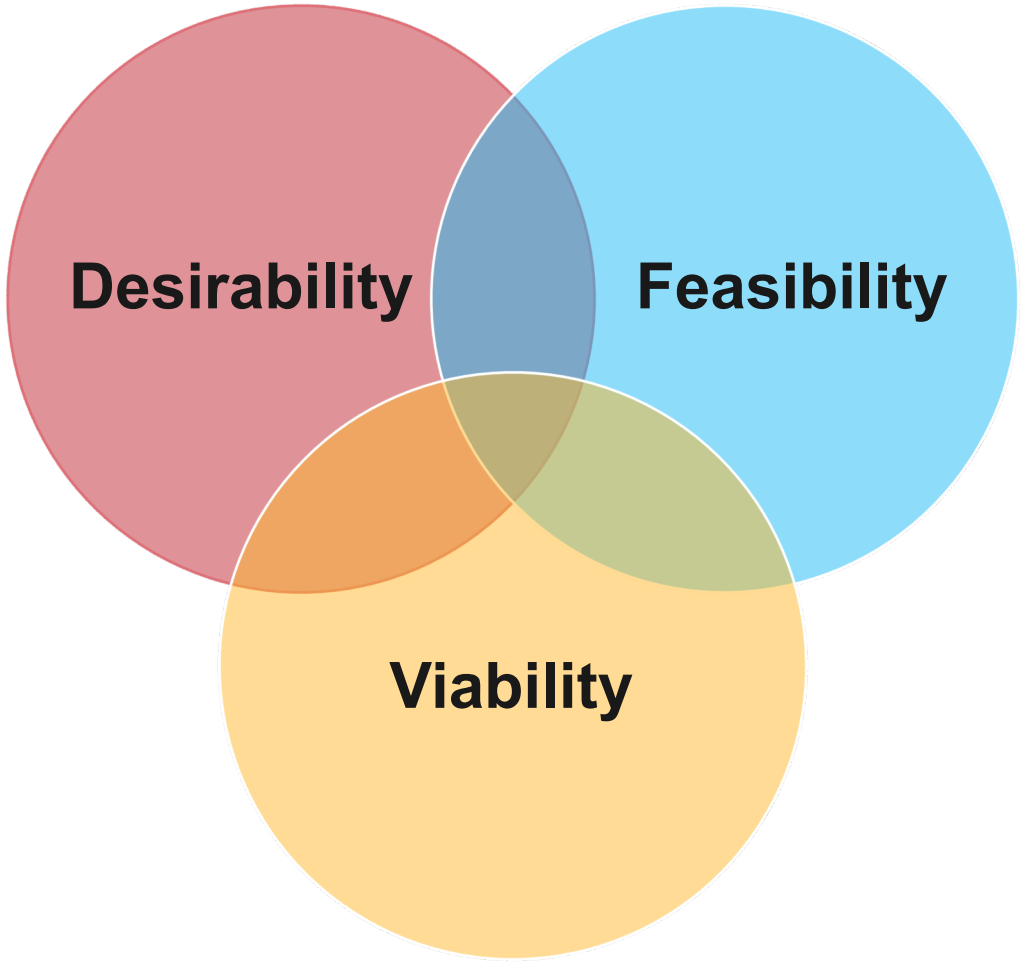
But successful commercialization requires *more* than technology readiness.

Technology Readiness Levels

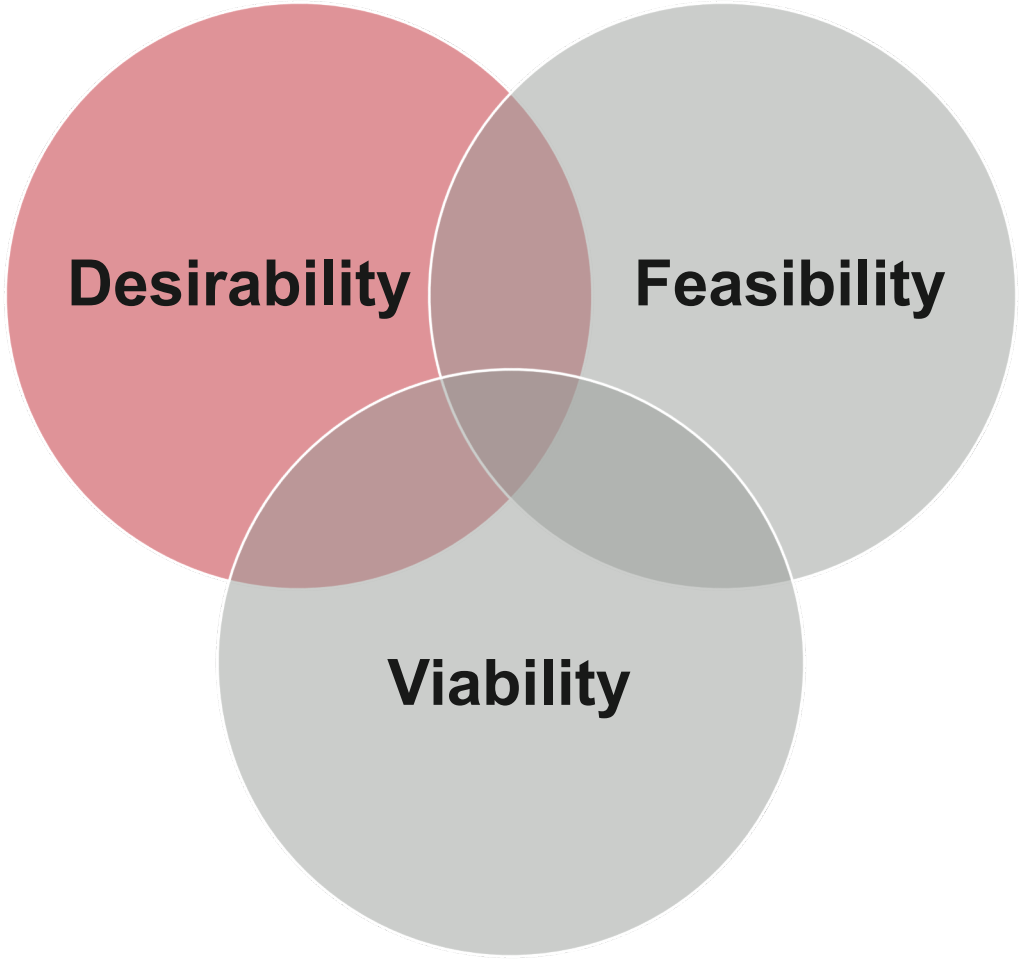
Everything else



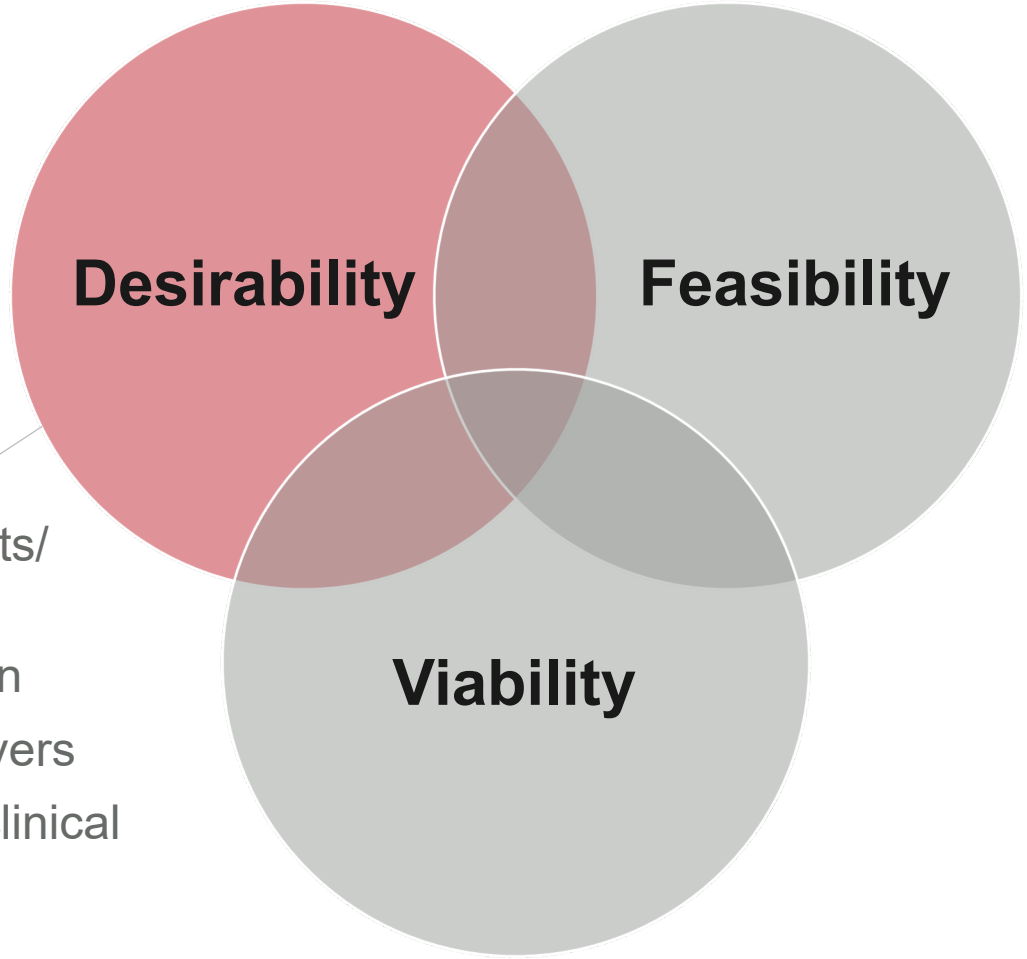
A successful innovation must have all three elements of Desirability, Feasibility, and Viability (DFV).



During this seminar, we will focus primarily on Desirability.



Assessing Desirability helps you identify key stakeholders and understand the potential impact of your innovation on them.



Example Goals:

- Identifying current pain points/ market need
- Testing the value proposition
- Understanding adoption drivers
- Assessing integration with clinical workflow

Users include a variety of medical stakeholders.

Today's Agenda

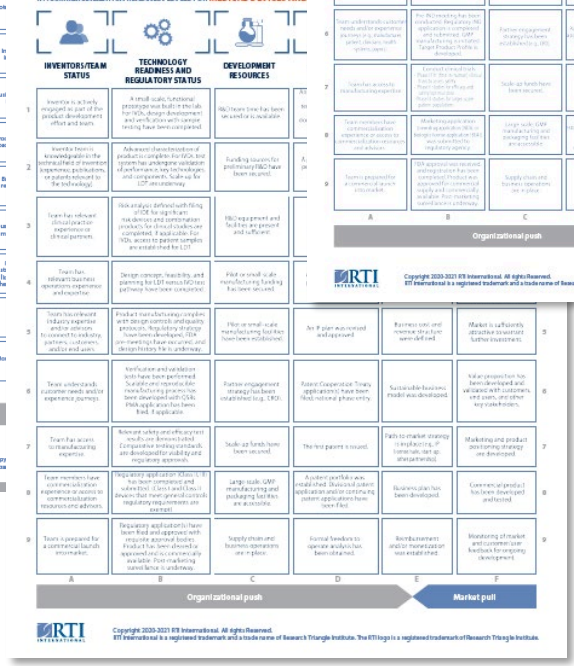
- [x] Why is Desirability important?
- [ ] **Introduction to ICANVAS**
- [ ] How to assess Desirability

Another way to assess commercial readiness is with RTI's ICANVAS®.

ICANVAS® frameworks comprehensively and visually assess and communicate the maturity of technology-based innovations.

Drugs & Biologics

Novel Research Technologies



Medical Devices & In Vitro Diagnostics

ICANVAS® offers six facets of commercial readiness.

TECHNOLOGY READINESS AND REGULATORY STATUS

DEVELOPMENT RESOURCES

INVENTORS / TEAM STATUS

INTELLECTUAL PROPERTY

BUSINESS STRATEGY

MARKET FIT

Market fit is another way to describe *Desirability*.

Technology Readiness & Regulatory Status

TECHNOLOGY READINESS AND REGULATORY STATUS

A small-scale, functional prototype was built in the lab. For IVDs, design development and verification with sample testing have been completed.

Advanced characterization of product is complete. For IVDs, performance, key technologies, and components validation of test system is completed. Scale-up for LDT are underway.

For significant risk devices and combination products, risk analysis for clinical studies is defined with filing of IDE, if applicable. For IVDs, access to patient samples are established for LDT.

Design concept, feasibility, and planning for LDT versus IVD test pathway have been completed.

Manufacturing complies with product design quality controls. Regulatory strategy has been developed, FDA pre-meetings have occurred, and DHF is underway.

Verification and validation tests have been performed. Scalable and reproducible manufacturing process has been developed with QSRs. PMA application has been filed, if applicable.

Relevant safety and efficacy test results are demonstrated. Comparative testing standards are developed for viability and regulatory approvals.

Regulatory application (for Class II or III) has been completed and submitted.

Regulatory application(s) have been filed and approved with requisite approval bodies. Product has been cleared or approved and is commercially available.

Moving from idea to prototype to a regulatory-approved product for clinical use.

Inventors/Team Status

- Inventor is actively engaged as part of the product development effort and team.
- Inventor team is knowledgeable in the technical field of invention.
- Team has relevant clinical practice experience or clinical partners.
- Team has relevant business operations experience and expertise.
- Team has relevant industry expertise or advisors to connect to partners, customers, and/or end users.
- Team understands customer needs and/or experience journeys.
- Team has access to manufacturing expertise.
- Team members have commercialization experience or access to relevant resources and advisors.
- Team is prepared for a commercial launch into market.

Having the right mix of technical, clinical, and industry experienced talent is crucial.

Intellectual Property

- An invention disclosure was submitted to the TTO. Research has been documented but with no public disclosures.
- An invention disclosure was submitted to the TTO. Research has been documented but with no public disclosures.
- A provisional application was filed.
- A full (non-provisional) patent application has been filed.
- An IP plan was revised and approved.
- Patent Cooperation Treaty application(s) have been filed; national phase entry.
- The first patent is issued.
- A patent portfolio strategy was established. Divisional patent and/or continuing patent application(s) were filed.
- Formal freedom to operate analysis has been obtained.

It is important to consider your IP strategy and evaluate the best way to protect a new invention.

Development Resources

DEVELOPMENT RESOURCES

- R&D team time has been secured or is available.
- Funding sources for preliminary R&D have been secured.
- R&D equipment and facilities are present and sufficient.
- Pilot or small-scale manufacturing funding has been secured.
- Pilot or small-scale manufacturing facilities have been established.
- Partner engagement strategy has been established (e.g., CRO).
- Scale-up funds have been secured.
- Large-scale, GMP manufacturing and packaging facilities are accessible.
- Supply chain and business operations are in place.

Without resources for development, a great technology will not make it very far.

Business Strategy

- Problem statement was defined, and potential applications have been identified.
- Initial application was defined.
- Business environment is understood.
- Product development roadmap has been established.
- Business cost and revenue structure were defined.
- Sustainable business model was developed.
- Path-to-market strategy is in place (e.g., IP license/sale, start-up, other partnership).
- Business plan has been developed.
- Reimbursement and/or monetization was established.

A great product, without a sound business strategy, will fail to attract commercial interest.

Market Fit

- Preliminary market information gathered.
- Customers and end users are defined, and their segmentations are understood.
- Competitors and their offerings are identified.
- MVPs were tested with customers or end users, and competitive advantage was confirmed.
- Market is sufficiently attractive to warrant further investment.
- Value proposition has been developed and validated with customers, end users, and other key stakeholders.
- Marketing and product positioning strategy are developed.
- Commercial product has been developed and tested.
- Monitoring of market and customer/user feedback for ongoing development.

Finding product market fit is one of the most challenging aspects of technology commercialization and it is critical for success.

Today, the remainder of the seminar will focus on understanding product market fit.

Market Fit requires an understanding of the external environment.

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Preliminary market information gathered.

Customers and end users are defined, and their segmentations are understood.

Competitors and their offerings are identified.

Market Fit involves developing and vetting your value proposition with key stakeholders.

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MVPs were tested with customers or end users, and competitive advantage was confirmed.

Market is sufficiently attractive to warrant further investment.

Value proposition has been developed and validated with customers, end users, and other key stakeholders.

Market Fit also involves developing and executing on a strategy to capture your market.

MARKET FIT

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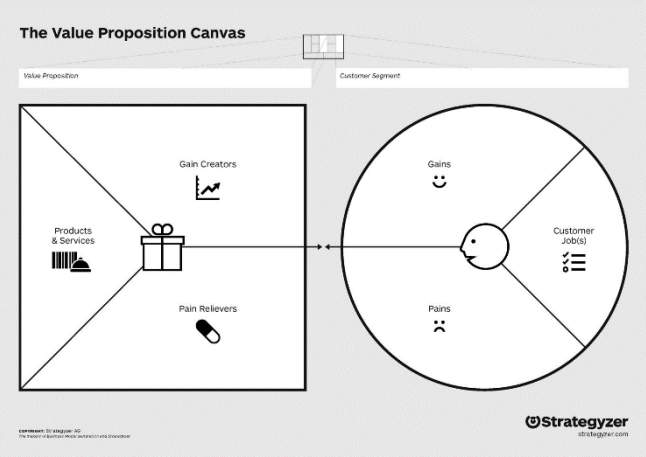
Monitoring of market and customer/user feedback for ongoing development.

Today's Agenda

- [x] Why is Desirability important?
- [x] Introduction to ICANVAS
- [ ] **How to assess Desirability**

Product market fit begins with a **value proposition.**

A **value proposition** describes the value that a product or service offering provides to your customer.



Use a template to begin drafting your value proposition.

Our _____
Product or service

help(s) _____
Customer/End user

who want(s) to _____
Customer/End user jobs to be done

by _____ _____
Verb (e.g., reducing, avoiding) a customer/end user pain

and _____ _____
Verb (e.g., increasing, enabling) a customer/end user gain

(unlike _____**).**
Current situation or solution

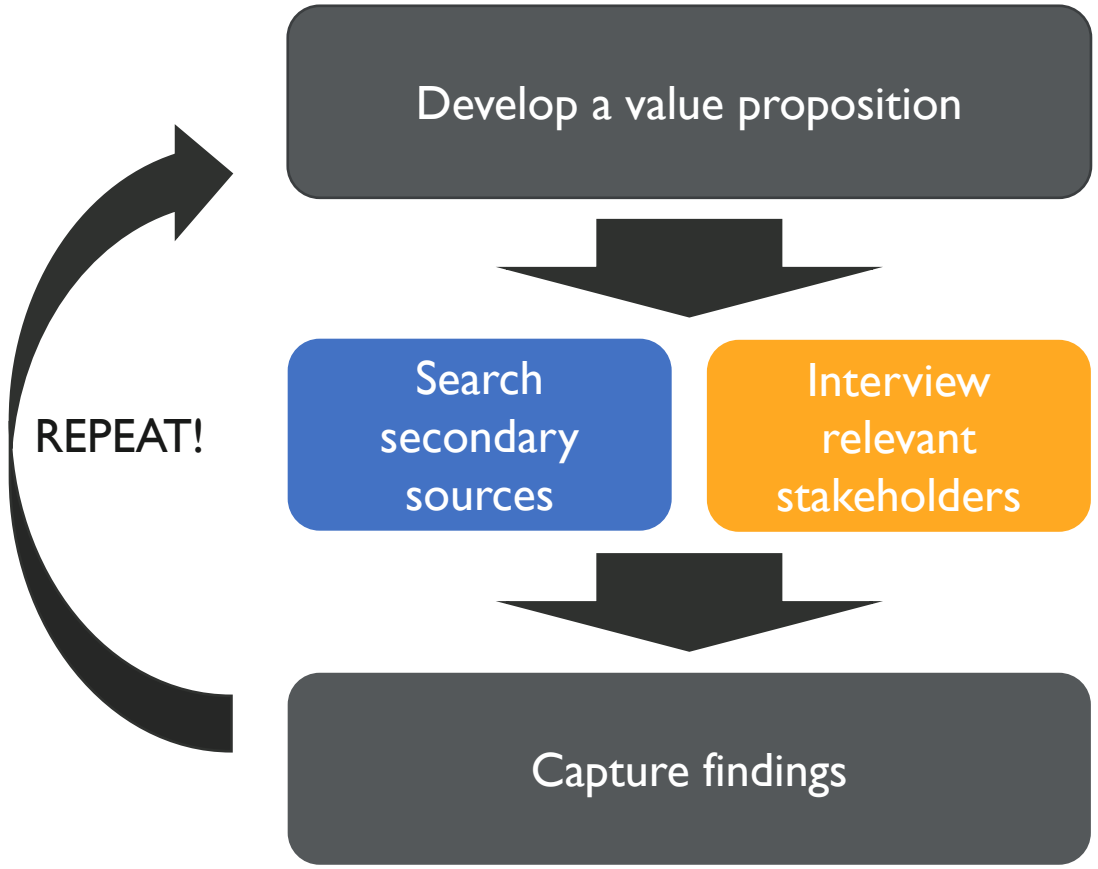
Convey value to your end user.

We help X do Y by doing Z.

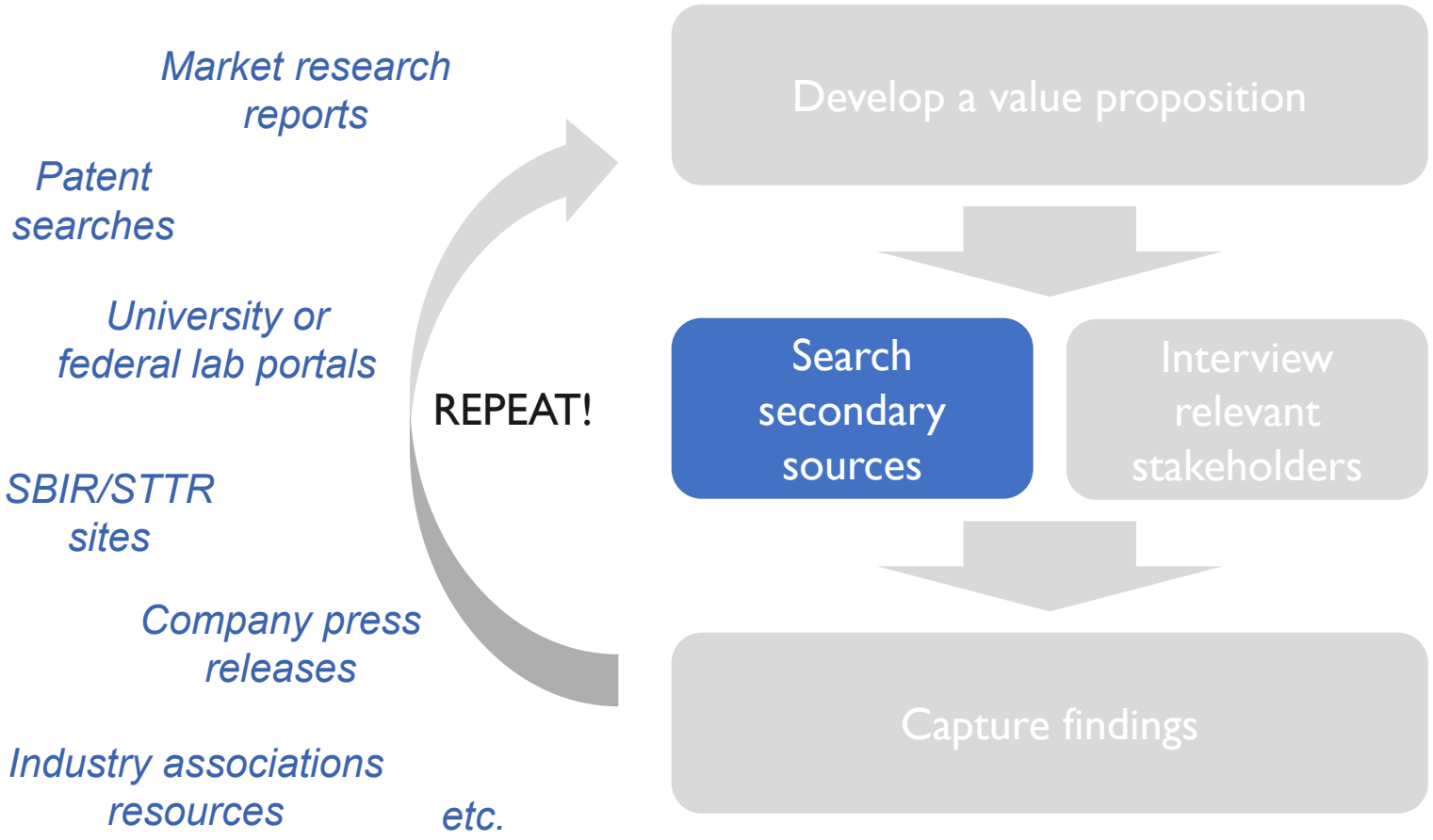
Example:

We help patients and their caregivers obtain the proper treatment faster by better monitoring symptoms and identifying anomalies sooner.

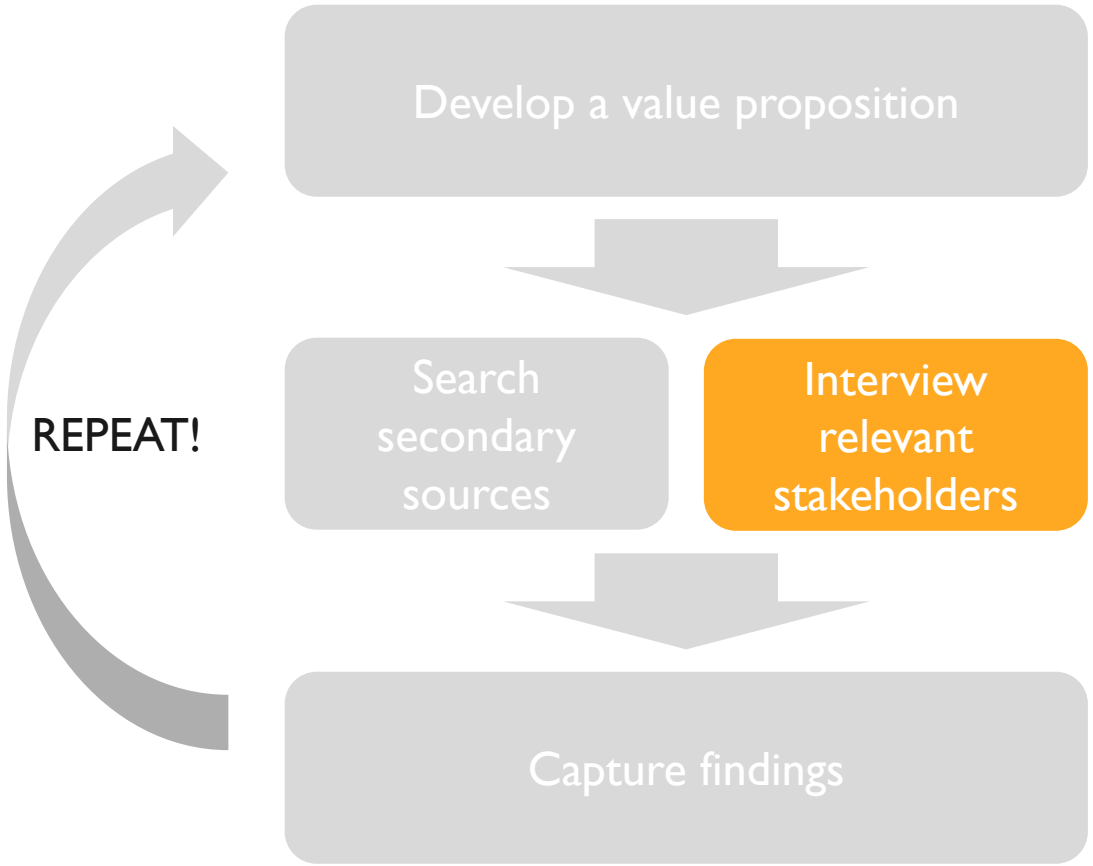
Developing a value proposition is an iterative process.



Look broadly for **secondary research** to lay a foundation for your understanding.



Speaking with other experts will affirm or change your value positioning.



Key opinion leaders

Clinician champions

Nurses

Technicians

New technology committees

Patients & caregivers

Hospital administrators

Payors

etc.

Why do primary research?

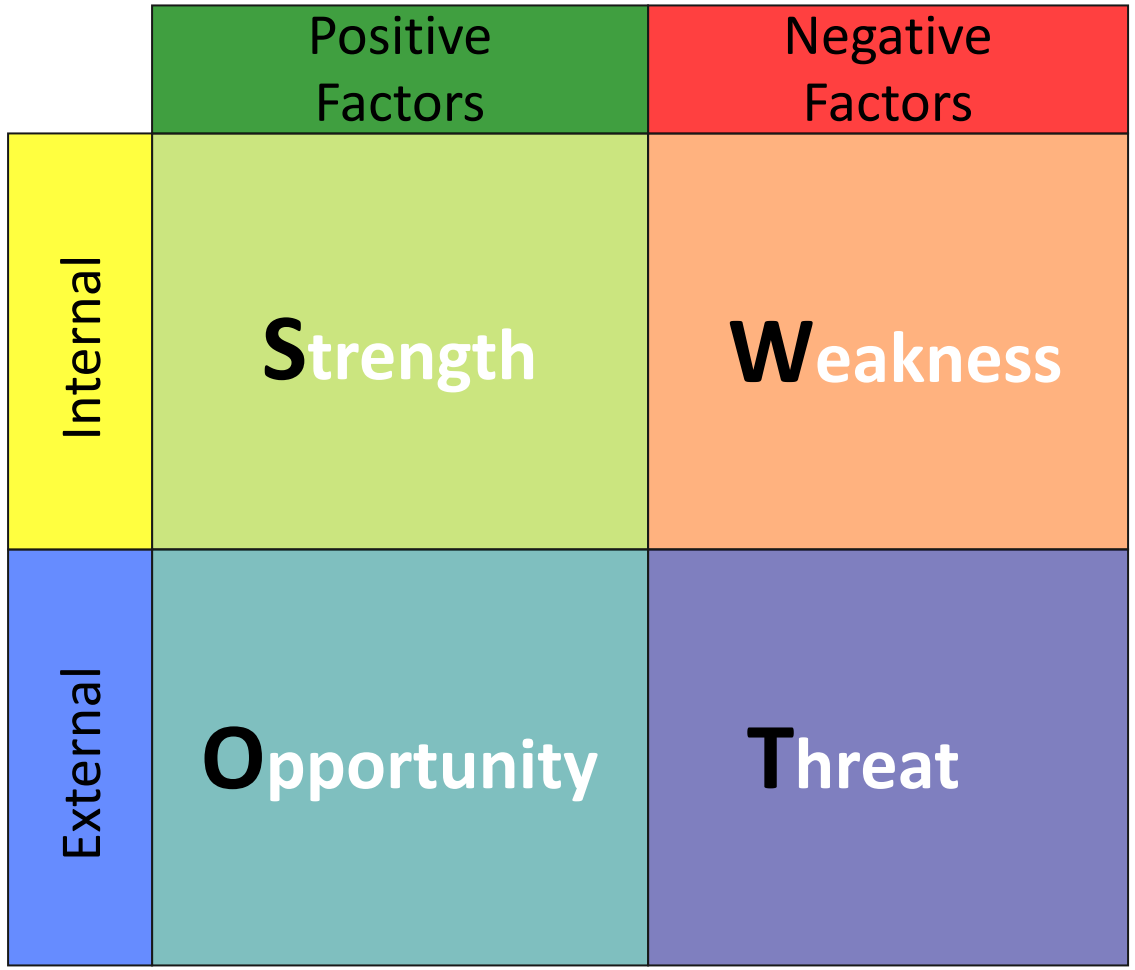
Primary research lets you:

- Leverage expertise and perspective beyond your own team's.
- Verify and validate your research and analysis.
- Get up-to-date and specific insights not available in secondary sources.
- Tap into networks of other key stakeholders.
- Confirm or challenge your hypotheses.

Consider how to phrase questions to illicit the feedback that you seek on your innovation.

- What is the current standard of care and clinical workflows related to…? Are the current tools and processes adequate? What are the gaps and challenges?
- Would an innovation that … add value for you?
- Do the benefits sound interesting? If so, of what value to what applications and markets? Is it evolutionary or revolutionary (compete or dominate)?
- What are the competing products? How does the asset compare?
- What are the barriers to entry?
- Who are the leaders in this space?
- Would your organization have interest in this technology? Why or why not?
- Whom else should we speak with? Whom shouldn't we speak with?

Capture and analyze your feedback and findings.

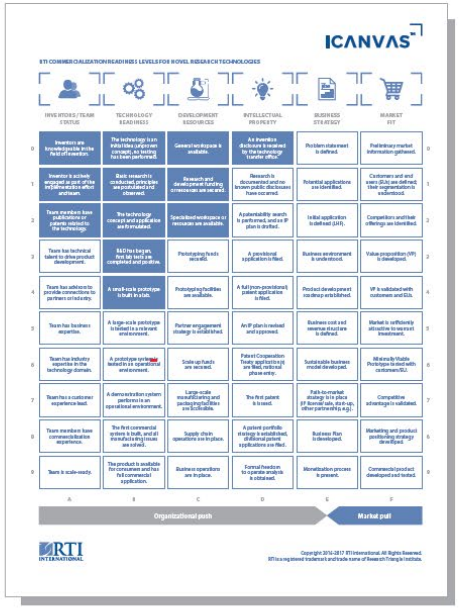


SWOT ANALYSIS

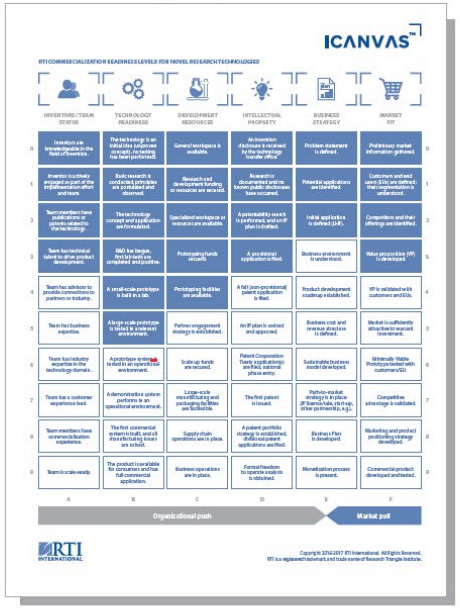
- A framework for analyzing asset potential.
- Helpful to identify the internal and external factors that are both favorable, and unfavorable to the various market opportunities.

Using ICANVAS to assess your innovation can influence your team's strategy and next steps.

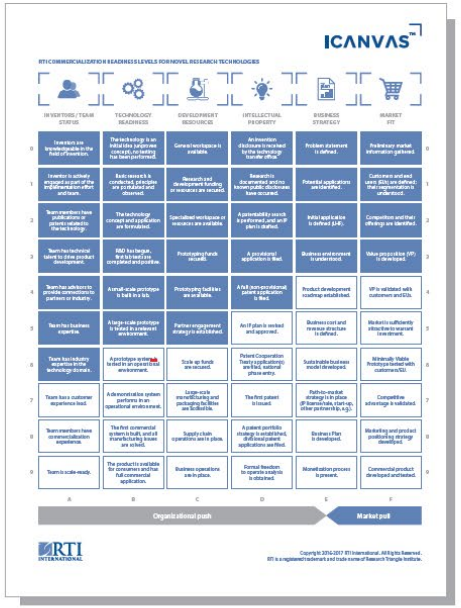
New Academic Invention Disclosure



Early Testing of an Invention

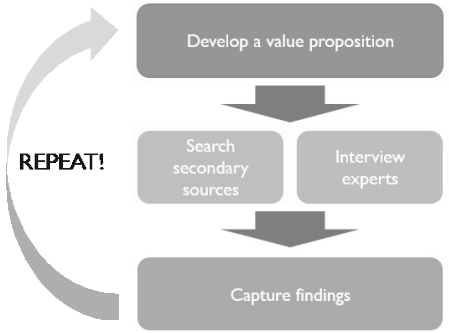


Pre-funding Startup



ICANVAS case examples

Remember these Dos and Don’ts.



Do

- ✓ Develop a draft value proposition.
- ✓ Consider secondary resources to build your hypotheses.
- ✓ Speak with relevant stakeholders outside of your immediate network.
- ✓ Capture and analyze your findings.
- ✓ Consider enlisting help from internal and/or external partners.

Don’t

- ✗ Be afraid to change your value proposition based on the feedback you receive.
- ✗ Stop at secondary research.
- ✗ Disclose confidential information without the proper intellectual property protection.
- ✗ Assume market needs will not change.
- ✗ Underestimate the value of an unbiased assessment.

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Would you like more information about assessing Desirability or about ICANVAS?

Contact the Catalyze Coordinating Center at: catalyze_mail@rti.org