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HOW CLINICAL RATIONALE FITS IN EVALUATION STRATEGY

Technology Product Development often begins with identification of a clinical problem or need at an individual or local level. For example, a family member or provider experiences a problem which sparks an idea for a new solution.

This provides the rationale for the problem in one specific context. In order to justify development of a product, the problem must be experienced by a larger group of people. Therefore, the first evaluation activity is to assess whether there is a problem on a broader scale.

This work will inform the Need and Opportunity Analysis and the evaluation activities broadly. In particular, information about the population and settings in which this problem is a high priority will guide sampling and testing environments.

An overview of the Evaluation Strategy steps is provided below in Table 1:

For each of the evaluation steps, identify the tests, what tools are necessary, and what outcomes must be measured:

The Question: What is the question I need to answer to evaluate the technology at this stage of development?

The Test/Procedure: What test can be devised to answer the question? How would the test be structured? What tools, skills and facilities will be needed? Who would conduct the test? What is the target population? Where will the test be conducted?

Prototype Needed: The evaluation steps go hand-in-hand with technology development steps. In planning evaluation activities, the innovator will need to consider timing of technology development milestones.

Outcomes: What outcomes will be measured and how? How will success or failure be determined? The feedback will provide an early opportunity for the team to 'pivot', i.e., make changes to the product before development begins.

The Center for the Translation of Rehabilitation Engineering Advances and Technology

TREAT is part of the National Institutes of Health (NIH) Medical Rehabilitation Research Resource Network (MR3). Funding is provided by the National Center for Medical Rehabilitation Research (NCMRR) in the Eunice Kennedy Shriver National Institute of Child Health & Human Development (NICHD) through awards R24HD065703 and P2CHD086841.

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Evaluation Strategy	Potential Approaches	Necessary Version of Product	Outcome
1. Validate Societal Problem	Literature search and synthesis	None	Go/no-go decision
2. Validate the Customer Need	One-on-one interviews with customers	None	Go/no-go decision, initial market requirements
3. Validate Concept	Focus groups, interviews with customers	Concept	Revised market requirements
4. Validate Solution	Focus groups, interviews, surveys	Rough mockup	Yes/No Answer
		Beta prototype	Revised market requirements
		Pre-production model	Revised product requirements
5. Validate the Business Model	One-on-one interviews with customers	None	Draft business model List of outcomes required
6. Component Testing	Laboratory tests to meet requirements	Pre-production model	Study reports, documentation of properties & function
7. Safety and Usability Testing	Feasibility, safety, and usability testing in laboratory or ideal setting	Pre-production model	Study reports, documentation of confirming safety & usability
8. Clinical/Comparative Effectiveness Research	Clinical research	Final production model	Evidence of effectiveness in real-world settings

Table 1: Overview of the evaluation steps to be conducted for product development.

VALIDATING THE SOCIETAL NEED

While the Customer Need will officially be done through Customer Discovery Interviews, it is important for the innovator to have a broad understanding of the challenges patients face, if they are clinically relevant and if a technology can be developed, from the perspective of scientific evidence and the policy and funding priorities of provider, policy, or advocacy groups. Understanding and communicating what is known about the problem or what has been established as priorities at the community or societal level can be a powerful advantage in the journey toward commercialization. Preliminary interviews may be conducted, as necessary, to confirm and/or include additional stakeholder perspectives to ensure an adequate sample of the market has been captured. However, the main method to employ at this stage is a thorough literature search.

LITERATURE SEARCHES

Where to start? First consider the tools: databases are sources of material (e.g. Medline, CINAHL, etc.) and the search engines that help you find the material (e.g. Google Scholar, PubMed, Ovid, CINAHL). Important information can also be accessed from national organizations, which may involve searching websites. If the topic is a major national priority, start by searching within websites of major organizations, for example, a center within the National Institutes of Health or a foundation. If it is a clinical issue, look for clinical practice guidelines that cover the topic.

Either way, consider the question the innovator is attempting to answer, and where best to search for it. PubMed, Ovid, and Google Scholar will be useful if attempting to find research articles. There are many resources for learning how to search the medical/rehabilitation literature, and a few good ones are provided below. If you have access to a librarian, by all means engage help! Here are a few basics to start in the direction of an informal search.

Write questions down in complete sentences. For example, “How many older people fall?” or “How often do older adults

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fall?” Identify the main concepts involved in the question, for example, older adults, falls/falling, balance, prevalence, etc. Search those terms or look for major subject headings that relate to those terms (see tutorial links below). Results from searches can be collected in the Literature Review Worksheet, and for evaluation purposes, collecting information based on the four categories as seen in Table 2 below may be useful.

Evaluation Strategy	The Question(s)	The Test/ Procedure	Prototype Needed	The Outcome
1. Validate the Societal Need	Is there evidence of need from the perspective of advocacy, provider, or research groups?	Literature search and synthesis	No	Yes or no answer A written summary of the specific evidence about prevalence, incidence, individual or societal impact, research or clinical priorities, guidelines or standards. Appropriate for the Significance section of a grant application or an Executive Summary

Table 2: Questions to keep in mind while conducting Step 1 of the Evaluation Strategy.

LITERATURE SEARCH RESOURCES

- [PubMed Tutorial](#)
- [Yale Library of Medicine Ovid Tutorial](#)
- [Google Scholar Tips](#)
- [Dartmouth Biomedical Libraries](#)
- [National Guidelines Clearinghouse](#)

ADDITIONAL RESOURCES

REHABILITATION RESOURCES

[University of Buffalo Department of Rehabilitation Science](#)

[Administration for Community Living](#)

[National Rehabilitation Information Center REHAB DATA](#)

[National Rehabilitation Information Center National Institute on Disability, Independent Living, and Rehabilitation Research \(NIDILRR\) Database](#)

[Cochrane Review Database](#)

[National Center for Medical Rehabilitation Research \(NCMRR\)](#)

[NIH RePORTER](#)

[Center for Scientific Review](#)

STATISTICS ON DISABILITY

[Fostering Independence, Participation, and Healthy Aging Through Technology - Workshop Summary](#)

[Institute of Medicine Disability Committee Reports published by National Academies Press](#)

[Disability Statistics & Articles - Annual Disability Statistics Report](#)

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MR3 NETWORK MEMBERS

Members: (Including TREAT!)

- [Rehabilitation Research Resource to Enhance Clinical Trials \(REACT\)](#)
- [Alliance for Regenerative Rehabilitation Research & Training \(AR3T\)](#)
- [National Center for Simulation in Rehabilitation Research \(NCSRR\)](#)
- [The National Center of Neuromodulation for Rehabilitation \(NC NM4R\)](#)
- [Center for Large Data Research and Data Sharing in Rehabilitation \(CLDR\)](#)

STANDARDS AND GUIDANCE DOCUMENTS

[International Organization for Standardization \(ISO\)](#)

[Federal Communications Commission \(FCC\)](#)

[Association for the Advancement of Medical Instrumentation \(AAMI\)](#)

[American National Standards Institute \(ANSI\)](#)

[American Society of Mechanical Engineers \(ASME\)](#)

[American Heart Association](#)

[American Academy of Neurology](#)

[FDA Guidance Documents](#)

SEARCH ENGINES

[PubMed - National Center for Biotechnology Information](#)

[IEEE Xplore Digital Library](#)

[The Voices of Healthcare - Medline](#)

[Ovid](#)

[Google Scholar](#)