



OBJECTIVES

- Establish that the problem is very important to the people who will use, buy, pay or in other ways influence the adoption of a new technology
- Create a clear argument supported by objective evidence



OUTCOMES

- A convincing Rationale formatted based on the particular purpose and audience intended (e.g. to support a grant application, business plan, or marketing materials)
- Understanding of guidelines or consensus documents by Key Opinion Leaders



NEXT STEPS

- Determine if clinical need is aligned with market opportunity
- Determine if clinical need has a feasible technology solution
- Ensure the technology solution is not impeded by Intellectual Property
- Determine if Customers want the technology



RELEVANT RESOURCES



[PubMed](#)

Medical Literature Database



[Ovid](#)

Literature Search Engine



[National Guideline Clearinghouse](#)

Source of Clinical Practice Guidelines



[American Heart Association](#)

Source of Clinical Practice Guidelines



[American Academy of Neurology](#)

Source of Clinical Practice Guidelines



[Medline](#)

Medical Literature Database

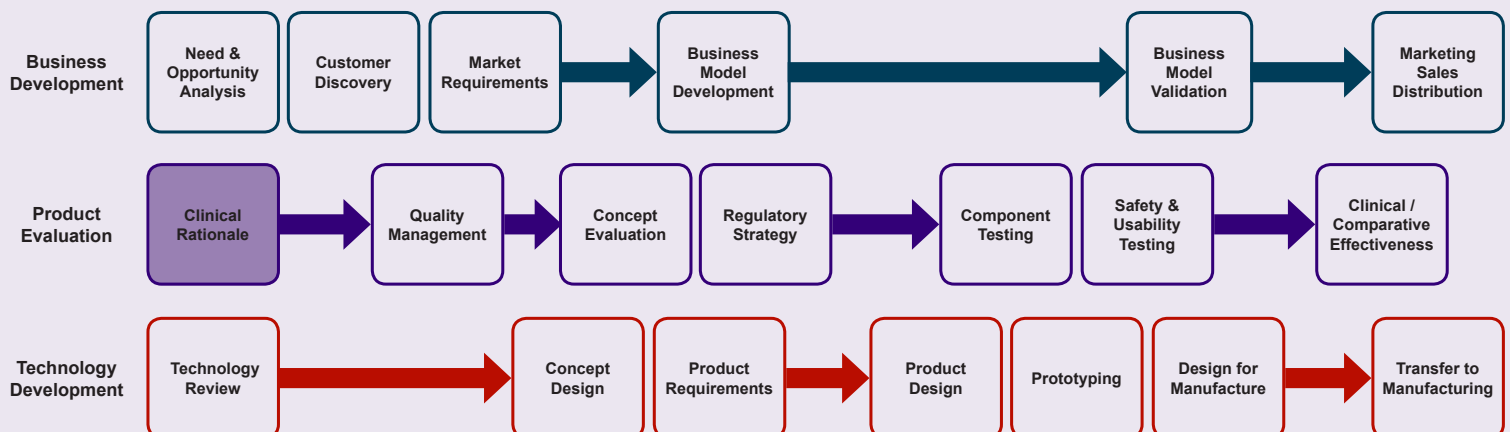


Clinical Rationale Literature Search



Technology Review Supplemental Reading

COMMERCIALIZATION METHODOLOGY



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 (NCMR) in the Eunice Kennedy Shriver National Institute of Child Health & Human Development (NICHD) through awards R24HD065703 and P2CHD086841.

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APPROACH

1. We strongly recommend beginning by creating a bullet outline of the key elements as described below
2. After drafting and refining these bullets, expand them into three concise paragraphs with supporting evidence and references as appropriate.

NOTE: Use the Clinical Rationale Literature Search Worksheet to record important information found throughout the research stage - for more information about literature searches and relevant links see the Clinical Rationale Supplemental Reading

KEY ELEMENTS

The Problem

- Does the technology solve an important problem that the key stakeholders care deeply about?
 - Estimate the incidence and/or prevalence of the problem, number of people affected, new cases per year, and the magnitude of the impacts on groups or society, and the number of people in your specific user/buyer groups.
- What is currently known about the problem: provide a series of statements that provide objective evidence of the importance of the problem to the major stakeholders
 - Describe the impact on the lives of the people affected.
 - Identify whether there are organizations for which this problem is a priority, whether there are clinical practice guidelines or other standards that apply to the problem.
 - Summarize existing practices and solutions, and specific persistent needs or problems identified.
 - **Important sources:** opinion pieces from stakeholder groups, policies, standards, and published evidence of need and impact on people and society.

The Story:

- The Innovator/ The company's overall goal/mission.
 - How was the problem identified?
 - Why develop this technology?
- The solution: How and/or why will it solve the problem, and for whom?

The Payoff:

- When the technology is developed and on the market, will people buy, use, recommend, or provide reimbursement for it?
 - Summarize the results of any published research and results from preliminary Customer Discovery (focus groups, interviews and surveys) that validate the need, and interest in purchase and use of the solution.
- When the technology is developed and on the market:
 - What changes in function or activity or other key outcomes will the users experience?
 - What relevant outcomes will clinicians experience?
 - What costs will payers/society experience?
 - Summarize the literature and personal research to support important outcomes of use of the technology. If the research has not been completed, provide a central hypothesis, and related research to support the likely outcomes.