Clinical Literature Evaluations to Support Medical Device Marketing

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Uses of Clinical Literature Evaluations

Comprehensive evaluations of the clinical and technical literature serve a variety of purposes for medical device companies. Literature evaluations are frequently used in the following ways:

- To support design of clinical investigations (e.g. to understand expected outcomes and results for historical controls).
- To support regulatory approvals and ongoing regulatory requirements (e.g. literature route to CE mark).
- To develop a product’s value proposition. By better understanding the product’s economic and quality of life benefits, this work can be used for supporting pricing decisions.
- To provide support for reimbursement (e.g. supporting payment rates for procedures/products). Typically, efficacy and cost-effectiveness of a product are the key parameters.
- To support product marketing claims or to refute competitor marketing claims (e.g. to support claims around safety and efficacy of the product).

Key Steps of a Literature Evaluation to Support Marketing Claims

Proving the value of medical technologies is increasingly important for gaining market acceptance and for convincing hospitals, group purchasing organizations, and doctors to purchase a product. Literature evaluations are typically designed around addressing both the key strengths of the product and the perceived weaknesses or deficiencies of the product. Below, we have outlined the key steps of a literature evaluation to support (or refute) marketing claims.

- **Design a plan for the literature search.** Decide ahead of time on a purpose and key objectives. Be clear on the questions the literature search is designed to answer. (e.g. safety, efficacy, cost-effectiveness). Have an idea of how the data will be used, although this could change, depending on the results of the literature review.
- **Design a search strategy with key words and exclusion criteria.** This step may take several iterations to get an appropriate number of targeted papers. Too broad of a search will yield off-topic publications, while too narrow of a search will exclude important publications.
- **Perform the literature search.** PubMed/Medline are freely available resources that provide coverage of >80-90% of clinical literature. In some cases, these databases may be adequate. However, including other resources in the search (e.g. Google Scholar, Scopus, Biosis) will ensure
better coverage so that the review does not miss crucial information. (Keep in mind that EMA regulations require multiple databases be searched for regulatory literature reviews.)

- **Exclude articles with duplicate information or patient datasets.** If there are multiple papers with the same authors, keep in mind that there could be overlap.

- **Grade the articles based on quality of the data.** There are no hard and fast rules for this step: quality of the data found in the published literature may vary depending on how long the device has been on the market, how widespread the device is used, or how controversial the device or procedure. In general, it is preferable to include articles with more patients and with well-designed studies (e.g. randomized, controlled trials preferred over single-arm studies).

- **Select articles for further review.** Article selection is based on the grading of the articles and pre-determined inclusion and exclusion criteria.

- **Read and summarize the full-text of each selected article.** Clearly understand the patient populations, author definitions of success or failure, and endpoints.

- **Prepare tables to consolidate and compare the data.** Make sure that data comparisons are made on an apples-to-apples basis, by clearly understanding the authors’ definitions. For example, the authors may use different criteria to define an adverse event, so it is important to note any differences in criteria.

- **Prepare a written report of the literature evaluation.** This report should contain the following information:
  - Objectives/ purpose
  - Literature search methodology
  - Summary of the articles, including devices used, patient populations, clinical indications etc.
  - Summary of key metrics (e.g. safety, efficacy, cost-effectiveness).
  - Identify the key limitations of the studies and any differences in definitions or methodologies between studies
  - Overall summary of results and conclusions.

- **Decide on next steps for presenting the data to the target audience.** After the literature evaluation is complete, the plan for data presentation can be finalized. Approaches for presenting the data may include the following
  - Publication in a peer-reviewed journal
  - Publication as less formal white paper in a non-peer reviewed publication
  - Creation of marketing presentations, including marketing collateral/ advertisements, slide presentations, or information on company website. Keep in mind that any marketing collateral must be in compliance with regulatory requirements. It is always appropriate for legal council to review materials before dissemination.

### Next Steps/ Further Work

Depending on the results of the literature evaluation, it could make sense to perform further analysis in order to flesh out a value proposition or to answer questions not addressed in the literature. There are several avenues for further data analysis:
Cost effectiveness modeling. Development of a clinical or economic cost-benefit model may be possible based on the clinical literature. For example, the literature may have sufficient data on the cost-effectiveness of similar diagnostic tests, but not on a specific (possibly improved) diagnostic test. In this case, it might be possible to gain a better understanding the value proposition of a new product based on its specific parameters (e.g. specificity, sensitivity) through modeling. Key parameters to calculate may include:

- Cost savings
- Cost per life year gained
- Avoidance of treatment costs
- Profit margin/ revenue gained from new test compared to other tests or devices.

Analysis of primary health databases, including private insurance, Medicare/ Medicaid, health outcomes databases, and systematic chart reviews. Analysis of primary data might be necessary in cases where there is no published evidence to support an assumed benefit of a product. For example, a new diagnostic test is thought to enable early detection of disease, which leads to fewer surgeries down the line. Longitudinal health claims data can be an important source of data to follow patients over time and to determine if this assumed benefit is real.

Validation of assumptions through primary research interviews. Interviews of Key Opinion Leaders (KOLs) can be important to validate assumptions about patient treatment and work-flow. For example, if a particular device is believed to save surgeons time during a procedure, KOL interviews and surveys can be an important source of data to estimate the time savings and importance of this time savings to the surgeon.

In conclusion, there is no set method for performing a clinical literature evaluation to support marketing claims. Each project requires a clear purpose and plan that may need to be modified, depending on the quality and results of the literature search. However, there are some general guidelines to follow in performing the literature evaluation. In addition, there are other avenues of obtaining data to support marketing claims, outside of the clinical literature; these can be expensive and time-consuming, but ultimately worthwhile.
About the Analyst

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Roz Sweeney, Ph.D., advises medical technology clients on new market opportunities, reimbursement, and regulatory issues. Before joining Nerac, Dr. Sweeney was an associate with Mitchell Madison Group, a global management consulting firm focusing on cost reduction for clients in healthcare, high tech manufacturing, and financial services. She also worked in healthcare equities research at Royal Bank of Canada, Capital Markets, covering small and mid-cap biotech companies. Dr. Sweeney has an academic background in cell and molecular biology (Ph.D. University of Texas) and was a postdoctoral fellow at California Institute of Technology, where she conducted research in nanoparticle-based drug delivery systems.

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