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Why Publish Scientific Data?

The case for publishing your medical device data

The importance of publishing your data

Publishing your medical device data after you've introduced a new medical technology is now more important than ever. It's *critical* to the health of patients, *indispensable* as a source of great information for medical clinicians and, above all, *invaluable* to the growth of your medical device business.

While there is, and always has been, a strong emphasis on and necessity for publishing data in the pharmaceutical industry, medical device manufacturers, by contrast, are not required by regulatory bodies to publish their clinical data.[1] Consequently, many medical device manufacturers often lack the necessary publication resources to publish proficiently in comparison to their counterparts in pharmaceuticals.[2]

As a result, potentially harmful situations can develop. For example, not publishing your medical device data may cause harm to patients, waste device manufacturers' limited resources, lead to unnecessary duplication of research, and contribute to the loss of scientific integrity.[3]

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Clinical benefits

There are a number of significant clinical benefits associated with the publication of medical device data. In a survey of Canadian clinicians, researchers found that clinicians who practice evidence-based medicine frequently utilize scientific publications for guidance and are likely to have authored publications.[4] Engaging clinician authors and supporting a robust publication plan fosters clinical practices guided by peer-reviewed literature.[4]

Specifically, the *lack* of clinical data can affect medical practice and patients' access to optimal health care technologies, which may result in the following:

- Clinicians lack the support to make evidence-based care decisions[1] needed to tailor health care for optimal patient outcomes
- Insurance reimbursements are questioned or denied when evidence of efficacy is lacking[1]
- Hospital review committees look to non-clinical sources to guide their evaluation of "product use and equivalencies, cost comparisons, and evaluation of patient outcomes"[1]

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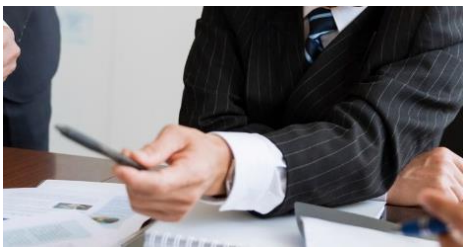
The significance of published evidence



In a recent survey of leading US insurers, 44% of respondents expect there will be a higher level of evidence required to approve new medical technology over the next three years.[5] In insurers' evidence review processes for new technologies, key approval requirements are:

- Demonstrated cost effectiveness
- An improvement over current care standards, supported by measured outcomes.[5]

The significance of published evidence to the continued success of an approved technology is illustrated by the rise in use of cochlear implants vs hearing aids, although digital technology had offered smaller, more flexible devices.[6] Strong clinical research programs combined with targeted, strategic publication plans implemented by the cochlear implant industry resulted in two times more publications in peer-reviewed journals over a decade, essentially creating the evidence to support the use of cochlear implants in appropriate patients.[6]

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Publication planning: an unmet need

Pharmaceutical companies have a history of publication planning and processes to support drug therapies, whereas medical device, biotechnology and diagnostic companies have only recently begun to consider publication planning for their products.

Survey results presented at the 7th Annual Meeting of the International Society for Medical Publication Professionals (ISMPP) indicate that publication planning remains an "unmet need" for many device manufacturers:

- 50% responded that publication planning is important
- Only 38% indicated they have a publication policy in place
- Only 21% responded that their company employs publication planning staff

In contrast, 89% of pharmaceutical industry respondents indicated that they have publication planning resources in place.[2]

Progressive device manufacturers should similarly bolster their publication planning resources to meet the impending stricter evidence requirements.

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Your solution

MedVal is at your service to customize and deliver an effective and comprehensive publication plan to match your needs and achieve your data publication objectives, whether for a single device or for multiple products or indications, all while upholding the highest industry standards.

To learn more, please visit the MedVal website.
Or, for additional inquiries and information, please contact:

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