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...Another Resource

Evidence-Based Medicine (EBM) is neither a "cure-all" nor a replacement for traditional clinical process. This module examines the limitations of traditional clinical models, and how the addition of EBM to the practitioner's toolkit results in an enhanced treatment algorithm. EBM enables each physician to leverage the synergy of clinical research & expertise and patient-centric decision-making in order to improve clinical outcomes.

The five steps in the process of EBM will be examined in some detail. This includes how physicians...

- construct productive questions based on clinical needs
- research the answers using evidence-based techniques
- evaluate the validity and clinical importance of findings
- determine when evidence merits introduction into clinical practice, and
- evaluate clinical outcomes where EBM has been applied.

The Module also explores how to leverage EBM results in future discussions with healthcare practitioners (HCPs). Understanding the EBM process will not only help you appreciate how a prescriber may view the approved reprints you carry, but also how to position them more effectively in the clinical process.

This last issue - EBM and healthcare practitioners looks at regulatory requirements in the application of EBM in clinical practice, the role of EBM in interactions between pharmaceutical representatives and prescribers... and a few challenges associated with the adoption of evidence-based medicine in clinical practice.

MODULE OVERVIEW

Turning ideas into in[ter]vention...

Similar to the way a physician uses evidence-based medicine to answer patient-focused clinical questions, clinical trials are designed to answer questions about new medical techniques or therapy.[5 6]

While the main goal of pharmaceutical research and investigation is to generate new knowledge about a potential intervention, it also serves to provide regulatory authorities with the information required to determine whether a therapy or procedure is safe and effective... so that new treatments can be developed - then made available to patients.[7]

Most clinical trials start in a laboratory where researchers explore potential interventions. Very few initial investigations yield favorable results, but those that do show promise - and that find a sponsor - advance into the clinical trial process.[8]

Pharmaceutical research and investigation is conducted in a series of sequential steps or 'phases' starting with small trials that investigate basic issues such as the safety of an agent in a few healthy volunteers. If earlier steps are successful, the drug is evaluated in progressively larger numbers of patients and trials that compare its effectiveness to a currently accepted standard of care and/or placebo given to one or more control groups. [9]

All trials follow stringent clinical processes with built-in safeguards for the patients, [10] and are carefully monitored every step of the way. At the same time, researchers report results at medical conventions, in peer-reviewed journals, and to various government and regulatory agencies. [11] These same results are studied to assess the safety, efficacy, and quality of an agent before a new therapy is approved for sale in Canada to treat or prevent diseases or their symptoms. [12] [13]

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From the perspective of evidence-based medicine, how a clinical trial (a.k.a. "study") is designed is never as important as how research results are applied. Nevertheless, pharmaceutical professionals must be familiar with the elements of clinical trial design engineered into each trial's protocol, and how they support the products they are authorized to promote - as well as other in- and out-of-class agents.

Within 2 general classes, each type of trial has unique characteristics that differentiate it from other trial designs; differences that determine the relative validity of its outcomes. This validity is positioned in a hierarchy of 'levels of evidence', a classification structure that helps physicians evaluate a trial's findings and compare them to trials supporting alternate therapeutic options when making treatment decisions.

Similarly, it is important to recognize the most appropriate types of trials to provide the best evidence in response to specific clinical questions from the 4 main categories of patient management: etiology, diagnosis, treatment, and prognosis.

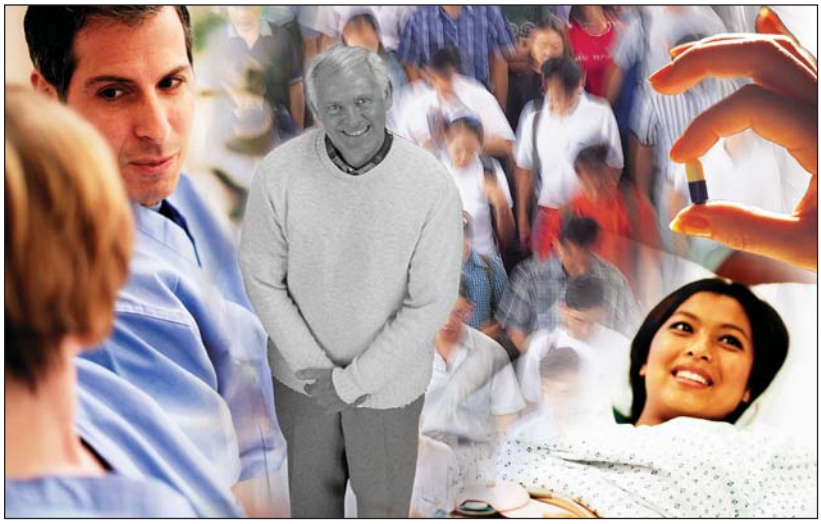
The last Section in this Module will take a closer look at the category of therapeutic trial design in comparing pharmaceutical agents and evaluating efficacy - a common and frequent discussion between pharmaceutical professionals and healthcare practitioners.

MODULE OVERVIEW

Module 1 explained the role of EBM in clinical practice, Module 2 examined the clinical research process, and Module 3 looked at the tools used by researchers to conduct a valid trial. This Module addresses the outcome of those processes and tools: The Clinical Reprint - the formal report of the trial.

Clinical reprints play a pivotal role in the success of each sales call. The clinical reprint is the core of all approved sales material carried by pharmaceutical professionals - the source upon which all detail and visual-aids are designed. The approved clinical reprints pharmaceutical professionals carry are often the same ones submitted to the regulatory bodies for the drug's approval... and are the foundation for the product's monograph.

In effect, a pharmaceutical professional must sell the features and associated benefits of the underlying clinical trial data of their products.[1] In-depth knowledge of all clinical reprints in each drug class enables you to quickly 'connect' patient and treatment issues raised by healthcare providers, with the solid empirical support required in evidence-based medicine today.



Of equal importance is that healthcare practitioners expect pharmaceutical professionals to provide fresh insight into patient and disease management. Following initial trials that support approval or subsequent new drug indications, new clinical trials and support data are often infrequent. Sales professionals must 'dig deeper' into clinical trial publications to bring new strategies and discussion to each call with the same reprints they often have been carrying for years.

This module will dissect the standard clinical reprint format so that you can quickly and effectively:

- Navigate all sections of your clinical reprints
- Identify issues of interest to health care practitioners that can be linked to information in your clinical reprints
- Use your clinical reprints to answer clinical questions with trial-based evidence
- Uncover 'clinical pearls' that can bring new focus to sales call strategy and clinical discussions

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The previous Module explored the anatomy of clinical trial articles so that pharmaceutical professionals can quickly and effortlessly navigate any reprint to find relevant and meaningful information to enhance discussions with healthcare practitioners.

It is essential that the investigators conducting clinical research; reviewers and editors selecting trial reports for medical journals; and physicians reading the medical literature all be familiar with the fundamentals of clinical research and the interpretation of the results. But as discussed at the outset of this program, clinicians constantly face the challenge of accessing, reviewing, understanding and evaluating the results of the large body of research published monthly in peer-reviewed journals.

As a result, pharmaceutical professionals must be able to bring to the attention of prescribers the key trial data of greatest value in making clinical decisions. But prior to presenting or questioning specific trial results in discussions with physicians, pharmaceutical professionals must also be able to accurately interpret that data. This requires understanding trial strengths and weaknesses - and therefore validity - to be able to appreciate what value the results can have in the management of patients.

NOTE

This symbol in the call-out box is used to indicate "Rep's Perspective".

This module will focus predominantly on the third step in the Evidence-Based Medicine Process: answering the fundamental questions that every healthcare practitioner will ask:

1. Are the results valid, fair and accurate?

2. What exactly are the results, and are they important?

3. Do the results apply to patients, and how can they benefit?

Every pharmaceutical professional knows that the results from two different trials cannot be compared. However, the strength of the trial designs, the legitimacy of the data and the validity of the results can be.

NOTE

"The profession will be best served by an interprovincial effort to provide timely evidence-based guidelines for prescribing... the partnership of drug manufacturers should be seen as an essential asset rather than an obstacle to progress."

Stuart M. MacLeod
MD, PhD, FRCPC

MODULE OVERVIEW

The previous 5 Modules have provided a framework for evidence-based medicine; the clinical trial process and design that are the genesis for all clinical reprints; an in-depth analysis of the reprint structure and content; and how that content can be interpreted to evaluate the evidence presented.

Having gone 'full circle', the logical conclusion to this program is how the wealth of medical evidence in each clinical reprint is best presented in discussion with healthcare practitioners to assist them in making effective, evidence-based, patient centric treatment decisions.

In as much as healthcare practitioners employ clinical expertise, evidence-based medicine and patient needs to make sound treatment decisions... pharmaceutical professionals depend on their field experience, interpretation of evidence-based medicine and understanding of physician/patient needs to effectively achieve the same endpoint.

NOTE

This symbol in the call-out box is used to indicate "Rep's Perspective".

This Module will examine opportunities for integrating the tenets of evidence-based medicine, and the data in your clinical reprints, into your relationship with healthcare practitioners - within a generic model of a typical sales call.

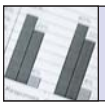
1. Pre-call planning

2. Opening the call

3. Demonstrating value

4. Managing issues, concerns and objectives

5. Closing the call



6. Post-call activities

Pharmaceutical sales force employees use a specialized selling model unique to their corporate character, product lines, disease state expertise and the segment of the healthcare market they serve. However, every pharmaceutical professional will recognize where the elements of the 'standard' model presented in this Module fits into their own selling style.