

CLINICAL DATA: WHY, WHAT, HOW

GETTING YOUR CLINICAL STRATEGY RIGHT

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**WHY DO WE NEED CLINICAL
DATA?**

- **Regulatory authority requirements**
- **Reimbursement clinical data expectations**
- **Evidence-based medicine**
- **Patients are well informed**
- **Importantly – it makes good business sense**

Article, “Compliance Is Not Enough: The Benefits of Advanced Quality System Practices”, MD&DI magazine, May, 2004, survey undertaken by Pittiglio Rabin Todd & McGrath (PRTM) in September 2003

- 300 individuals surveyed (45% senior management), representing 260 FDA-regulated medical device companies
- Those companies with the best performance in FDA inspections are the ones whose quality practices go beyond merely complying with the regulations
- “Advanced performers” aim for excellence in quality throughout their companies &, therefore, they need not worry about achieving baseline regulatory compliance
- Their overall focus on quality automatically builds compliant practices as an inherent part of their organisations
- In addition, they realise benefits beyond traditional quality measures

**WHY IS CLINICAL DATA AN
ONGOING ISSUE/PROBLEM?**

- **Evolving regulatory requirements**

From the TGA guidance document & website...

The TGA requires that manufacturers of all classifications of medical devices have clinical evidence.

Manufacturers must:

- demonstrate compliance with Essential Principle 14 relating to clinical evidence*
- compile clinical data*
- arrange for a signed and dated clinical evaluation report to be prepared by an expert.*

EU report produced by the Medical Devices Expert Group in
June 2002...

Feedback during discussions indicated that there were shortcomings in the implementation of the Directives' provisions on clinical data. Manufacturers do not always have clinical data available, including for Class I devices. Furthermore, Notified Bodies would not verify sufficiently the adequacy of clinical data provided with respect to characteristics and performances of the device. Finally, concerns have been raised that the wording of the Directive can lead to doubts on interpretation.

Article October 30, 2008, “Regulatory Alert: New Challenges in Clinical Data Evaluation for Medical Device Manufacturers” ...

The amendments to Council Directive 93/42/EEC relating to clinical data...come into force on 21 March, 2010.

One of the significant implications for medical device manufacturers is that clinical data must now be used not only as the basis for the evaluation of adverse effects but also for the evaluation of the acceptability of the benefit/risk ratio (referred to in Section 6 of Annex I). The clinical evaluation should take account of any relevant harmonised standards, and follow a defined and methodologically-sound procedure.

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- **The need for clinical data to support reimbursement & evidence-based medicine is often overlooked or an afterthought**

Comments by Don St. Pierre, Associate Director, Policy & Operations, Center for Devices & Radiologic Health's (CDRH) Office of In Vitro Diagnostic Device Evaluation & Safety (OVID) in an article by Holland Johnson, Managing Editor, Diagnostics & Imaging Week, "St. Pierre: FDA goal is to bring new products to market", May 14, 2009...

...his organization is often unfairly looked at as the boogeyman by the industry, when in fact FDA is only a "first step" in the process of getting a product to market. "The products still have to demonstrate their use in the clinical practice and if they do, hopefully they'll get reimbursed better."

Article December 10, 2008, "Payback Time" ...

These lists are making reimbursement an increasingly complex issue as they vary by country, between public and private healthcare providers, between hospital and outpatient care and, in some countries, even by geographical region. It is therefore becoming imperative for manufacturers to have a thorough understanding of reimbursement issues in order to gain or maintain market share.

Those developing new medical devices need to be especially aware of how they are going to achieve reimbursement as early as possible. Not doing one's homework could mean that it takes years even after CE marking to receive any money from product sales.

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- **Time & cost for clinical trials is underestimated**

Article December 8, 2007, “Uncovering the Best Practices in Completing Studies On-Time & On-Budget, Securing Regulatory Approval, and Opportunities in Working with Venture Capital Teams to Secure Funding” ...

It is a known fact to both device executives as well as venture capital firms that clinical research is the most expensive stage of a medical device companies' growth and development.

During this stage, organizations are often burning through enormous amounts of funding, and in the end, find themselves short of the capital required to finish their studies and secure regulatory approval.

These clinical studies are often delayed due to shortfalls in subject recruitment, proper site management, as well as not meeting difficult protocols after CE marking to receive any money from product sales.

HOW TO GET YOUR CLINICAL STRATEGY RIGHT

- **Plan, plan, plan...early, early, early**
- **Decide what the clinical data is to be used for...& design a protocol to suit (endpoints, country-specific requirements, etc.)**
- **Time...resources...expertise...costs**
- **Investigator/site selection is CRUCIAL**
- **Keep clinical data collection going post-market**

THANK YOU!

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