



## Pre-marketing product evaluation, June 2009

### Introduction

Creating awareness in the market for a new medical device with a goal to shorten time-to-market is a challenge for every company. Setting-up a product evaluation in one or more clinical centres is one of the options available and discussed here.

What is the main difference between a "product evaluation" and a clinical trial? Which specific criteria are innovative products evaluated on? "How can one motivate a hospital to start an evaluation? What is the value of a product evaluation as a marketing tool? The answer to these and more questions can be found in this article on pre-marketing product evaluation.



### Product evaluation versus clinical trial

First of all we have to distinguish between a "product evaluation" and a "clinical trial". The differences lie mainly in the objectives, number of patients and time needed to complete the project. A clinical trial is a more scientific approach to statistically prove the clinical- and economical efficacy. A product evaluation is carried out by a hospital using the medical device while evaluating it with the intention of future purchase.

### Criteria for evaluation of a medical device

The product evaluation is based on objective criteria, specific to the medical device's function and use. Criteria used to evaluate products include important aspects such as:

- performance,
- ease of use,
- safety,
- efficiency,
- cost,
- compatibility with other medical devices,
- efficacy,
- quality,
- standardization.

Ideally the experience of the users will be registered according to an agreed upon protocol over a period of 2-3 month with a relevant number of patients. At the end of the evaluation period the hospital will – in a format agreed with the manufacturer of the medical device – put together an abstract and summary of its findings.



### **Package to motivate hospitals to start a product evaluation**

To create interest with the hospital – preferably a leading clinical centre - it is self-understanding the “product evaluation package” should be attractive enough to motivate and convince a potential candidate hospital to perform an evaluation. It speaks for itself that the centre will need to have a genuine clinical interest in the first place. Given a clinical interest, the points to consider among other are:

- complete trial unit (incl. consumables for the evaluation period) made available;
- clinical training for users;
- 24/7 support and contact during evaluation period;
- possible compensation for efforts of hospital/ specialist being =>
  - cost,
  - compatibility with other medical devices,

### **Objective to start a product evaluation**

The main objective of a product evaluation is to have a reference from a hospital, possibly a centre with above average credentials in the care area of your medical device. This reference can be used to create awareness, acceptance and credibility in the specific country. Possibly even as a reference for other countries in Europe. In most of the cases the product evaluation will be set-up together with the chosen partner/ distributor responsible for the country. However, given certain circumstances, it can be considered setting up a trial prior to having a local distributor. The trial can then also be used in the process of searching & selecting the perfect distributor.

MedSupport Europe has experience in organizing and managing product evaluations in conjunction with business development. Please contact us and we will be happy to discuss your needs and views.

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