

Worksheet: Regulatory and Reimbursement

This worksheet is meant to help you organize develop a strategy for obtaining regulatory approvals and appropriate reimbursement for your medical technology. This is often accomplished by a well-designed clinical trial.

Make sure to look at the example materials in this section of the CD for a sample clinical trial design.

- 1. FDA Regulations: Is your medical technology regulated by the FDA? If so, what is the category of medical product and type of approval that will be required? Typically, drugs and pharmaceuticals require the most stringent approval process (a New Drug Approval, or NDA). Devices may require one of two general approval processes -- Pre-Market Approval (PMA) or 510(k). Drug / device combination products may require some combination of these approvals. Review the video materials in this section to determine which regulatory process you will need to follow.**
- 2. What is the clinical indication for which you will attempt to market your device? Your stated clinical indication must be proven to be accurate through clinical trials; therefore, it may be wise to initially seek an indication that is easier to prove through a clinical trial. See the example materials for more information.**
- 3. What number of patients and duration of trial will you need to prove safety and efficacy to the FDA for your chosen indication? What criteria will you use to screen patients as candidates for your therapy?**
- 4. Does a reimbursement code currently exist that could be used for your medical product? If so, is the reimbursed amount sufficient to cover the cost of your product?**
- 5. If adequate reimbursement is not currently available, will your clinical trial show that your therapy, if reimbursed, would be cost-effective or cost-neutral compared with current therapies? If not, is there a compelling mortality benefit or other argument for reimbursement?**