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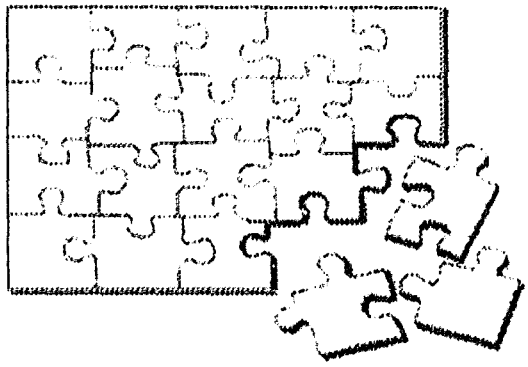
A Strategy for Integrating Regulatory, Reimbursement and Outcomes Research Functions for Effective Market Introduction of Medical Devices in the USA.



Overview

Achieving rapid market penetration and fair pricing for innovative medical technology in today's cost- conscious U.S. healthcare environment necessitates a strategic approach to product development. While Food & Drug Administration (FDA) approval is adequate to establish product safety, healthcare coverage decisions made by payers such as Health Care Finance Administration (HCFA) or managed care plans are increasingly based on evidence of clinical effectiveness and improved patient outcome not to mention value and cost of delivery.

To successfully introduce a device into the US market, manufacturers must identify ways to coordinate the 'Regulatory', 'Reimbursement' and 'Outcomes Research' functions of their operations to maximise the effectiveness of the various "independent" efforts. The strategy discussed in this report deals with the product development cycle in three phases and describes how various activities can be made mutually reinforcing in both a particular phase and over the course of the product development cycle.

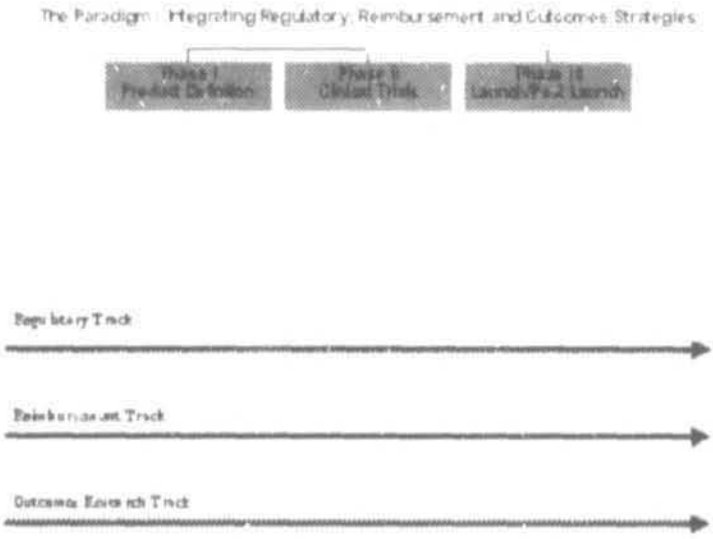
The product development strategy identifies the key relationship between 'Regulatory', 'Reimbursement' and 'Outcome Research' activities and the integration necessary between these functions to achieve any measure of sustained success in the marketplace. For example, Reimbursement planning analysis may reveal that key third-party payers are more likely to cover a certain new procedure *if* there is strong evidence showing favourable impact on the disability. The Outcomes Research function identifies methodologies for establishing that evidence while Regulatory determines how best to incorporate the requisite data gathering in the clinical trials programme.

The Three Phases:

Phase I: Product definition and pre-clinical development deals with
a) Product Definition, Market Assessment and Regulatory Routes;
b) Assessing Reimbursement potential and
c) Creating evidence of 'Value'.

Phase II: Clinical Studies describes
a)Clinical tasks and submissions;
b) Evaluation of funding and reimbursement and
c) Developing Economic and Quality of Life data

Phase III: Launch/Post Launch reviews
a) Regulatory approval and post market developments;
b) Coverage and coding and
c) effective means of communicating product value.



Phase I: Product Definition and Pre-Clinical Development

Regulatory Track:

The regulatory assessment is the logical starting point when looking to deliver a new product into the market and it can be broken down into 4 sections.

- Product Definition
- Market Assessment
- Disease Model
- Regulatory Route

Product Definition begins to address the competitive issues of the product depending on wether it represents a new core competency/product or a new generation of existing product (ie is this a new breakthrough or a platform development?.) The definition should include an assessment of possible additional features and future design qualifications but, most importantly, it should define the user environment for the product (ie Outpatient, Hospital, Home, Surgery, etc.)

Defining the product is critical at this stage as therapeutic devices follow a very different track of regulatory approach than diagnostic devices. Also, it may save considerable time (and money) to look at the failure/risk analysis of the product even at this early stage of planning.

Market Assessment is critical at this early juncture because it will determine, right from the outset, where the company can go with the product and will be a key reference through every stage of product development. The starting point in the assessment phase is in defining the user (or customer) ie Doctor, Hospital, Patient - as well as the scope of the market. Market Assessment should also cover the issues of intended use, labelling and selling strategy - this may seem like putting the cart before the horse but it will a) flag problems throughout the product development process and b) as the product changes, it will enable the company to develop an ongoing data model which will prove its value many times over before the product launch. It is advisable to get hold of currents products being used to treat the disability (not just the literature) and comparing them to the new device to obtain a benchmark for positioning the device.

The ***Disease Model*** should determine if this is a replacement therapy or a duplicative treatment and, given that the FDA will eventually require this information, it is well worth talking to the core contact at the FDA at this point to determine the level of detail required. Communications with the FDA should be established early and used often - this will assist in validating the product strategy, developing milestones and identifying problems before they become insurmountable or time critical. The more dialogue with the FDA at this early stage, the better the chance of success.

The ***Regulatory Route*** must also be part of this early planning process. Product classification & codes for Medical devices in the

USA are easily obtained (they can be found on the internet) and will be needed when preparing the regulatory submission. All experimental devices fall under an FDA Category A classification while everything else comes under Category B. Establishing this classification will determine the appropriate regulatory approval path for the device.

Reimbursement Track:

Reimbursement Assessment should deal with the following issues:

- Who will eventually pay for the product? (eg Medicare/Medicaid/HMO/PPO/Patient)
- Where are the sites of service? (eg Clinic, Hospital, Surgery, Home)
- What is the frequency of service? (ie is treatment ongoing on a regular basis; is it irregular or performed once?)
- What are the current payer coverage policies and will the device be covered? - Manufacturers must be fully cognizant of coverage availability (be it HMO/PPO or HCFA) .
- Can the product pass utilization review and if the product/procedure is elective will it be covered by the payer?
- What are the associated costs of using the product?
- Is reimbursement adequate to justify widespread use or will the payer insist on product/procedure being used only in certain locations? (eg hospitals but not clinics)
- Are there existing product codes that can be used for reimbursement? - this will be covered in detail in ***Phase III***..
- What is the cost savings potential compared to existing products/procedures?
- What are the anticipated health care policy changes? The US Healthcare Budget 2000 is already available and one of the significant line items is the Outpatient Reform section which will significantly impact hospital revenues by implementing a fixed prospective payment system (PPS) for all outpatient care. Manufacturers need to understand this legislation ***now*** and the impact it will have on US healthcare. Also, companies need to follow the ongoing round of hospital consolidations and HMO/PPO partnerships.
- What are the impacts of outcomes evaluation and practice guidelines? It will be worth the time to work with a healthcare association dealing with the relevant disease area to establish guidelines and the need for the device. Too often in the U.S., coverage policies spell out brand devices by name to be used in treatment, therefore, it is important to protect the device/product from de facto exclusion..

In terms of the strategic plan for the device, the reimbursement assessment will:

- Define procedure, patient population and setting
- Ascertain payer mix
- Examine existing coverage policies
- Determine need for national or local coverage
- Determine coding needs
- Develop a reimbursement budget

Outcomes Research Track:

Initially, Outcomes Research focuses on one simple message - ***it's the value of the product not the price*** that will determine success or failure. ***Value*** is not always covered during product development but it ***must be part of the equation***. Changes in health status dramatically effects health care resources in the U.S.A. and the manufacturer needs to prove that the product brings ***Value*** to the market, to the patient/community and provide evidence to support reimbursement claims. The Value equations looks something like:

Cost (new) - Cost Offsets

Improvement in Health or

Cost (new) - Cost (usual care) =Net cost/net effect

Effect (new) - Effect (usual care)

=Value for money spent!!!

Or, in broad terms, ***Price is what they pay/Value is what they get.***

It is essential to analyze the market ***before*** product development and to ascertain impact on the usual care pattern of any new product.

- Review the literature on treatments and clinical outcomes (there is no sense trying to survive in a vacuum)
- Analyze existing data bases - there are many available and while the good ones may cost a little more, they do track everything
- Track complication rates, patient returns, product problems
- Conduct focus groups
- Construct simple models on patient types/cost types/ care by region/outcomes - these models are vital to the product development cycle as they will be the platform to communicate ***Value*** to the payer ***and*** models are flexible to market changes and influences and can offer a very flexible means of simulating different scenarios; identifying cost drivers; designing clinical protocols and target pricing.

Phase II: Clinical Studies

Regulatory Track:

The regulatory clinical tasks in this phase can be divided into:

- Trial Types
- Protocol Design
- Statistical Considerations
- Trial Logistics
- Submission Documentation

Trial Types covers the areas of product safety, efficacy & equivalence; defines the body/organ treatment focus; identifies the key physicians for product usage. It is also worthwhile, at this point, to start utilizing some of the data gathered during phase 1, particularly if it relates to cost benefits, hospital use and length of stay. Look at what other products (if any) will be needed to augment the treatment/procedure, include them in the model and weave in the payer mix and reimbursement information.

Protocol Design is where the regulatory input positions the product/device in relation to current medical practice and established treatments; Covers the development of objective measurements - not just limited to therapeutic interventions but length of treatment, coding, assessments, time spent instructing physicians on the device etc; Deals with identification and communication with independent testing labs (CRO's) to undertake trials; Develop a schedule of regular reviews with advisory physicians and, last but not least, develops the case report form and review procedures for the device (this is essential for outcome measurements) to provide early indications of how cost effective the product will be long term and how it will improve health ***Value*** of the device/procedure. Great care is needed in developing the questions posed in the case report form to get the answers needed for approval, reimbursement and product marketability.

Statistical Consideration is the effective development of analytical procedures to use the data from clinical trials and current studies on treatments/other solutions. It is important to ensure that the sample size is compatible with the product and, it is at this point, that the case report form will reap dividends.

Trial Logistics must focus on the hands-on details of the clinical trials - How many sites?; What are the site qualifications and do they fit the product needs?; How will the trials be managed?; What will be the preliminary timeline?; What cost data or measurement will result for use in the product development model? The important message at this stage is to ***'do it right the first time!'*** Having to repeat the clinical trial process will severely impact the development cycle, not only by inflating costs but by losing competitive edge in the marketplace. Remember, strong market research at the beginning can dramatically improve return on investment.

It is never too early in the regulatory phase do start compiling the Submission Documents needed for future stages. Now is the time to begin dealing with design descriptions; performance data; equivalence comparisons; product labelling and advertising and performance standard compliance.

Reimbursement Track:

Reimbursement during clinical studies is becoming more important to device companies during this phase of product development. The company must decide how clinical trials will be funded viz: a) paying all costs themselves b) cost sharing with a strategic partner or c) obtaining reimbursement during testing. If a company decides it wants to see a revenue stream during testing then it is essential to pick the right payers and evaluate funding/reimbursement requirements. The device manufacturer must develop information on who is paying, how much are they paying and why; It is vital to educate the payers through a constant supply of information releases and direct interactions; Manufacturers must also be prepared to assist providers with authorization of device usage and provide assistance to providers if claims are denied.

Through changes in the US Healthcare program, it is possible to obtain Medicare funding during clinical trials provided the device is not experimental/investigational (Category A or Class III). For Category B devices, HCFA will ***consider*** coverage if the device meets the following criteria:

- It is Safe & Effective - has the device been accepted by the medical community and is it effective based on literature, database assessment etc
- 't is a true Category B device (non experimental/investigational)
- ost effective. Here the following criteria may be applied

i) It is less costly but as effective as alternatives

ii) It is less effective and less costly than alternatives but viable for certain patients

iii)It is more effective and more costly than alternatives but benefits outweigh costs

It is appropriate for the Medicare patient population

Outcomes Studies Track:

Outcomes studies in Phase I determined "what data do we want to collect". In Phase II, the Outcomes Studies focus becomes "how will we collect it. There are two data paths to track - a) the Economic - to determine the cost effect of all medical and non-medical resources resulting from clinical trials and b) Quality of Life - to assess health Impact of the intervention on patient and family.

Economics: What to Measure and the Sources available

- Resources/costs of intervention (ie device cost; procedure cost; OR/recovery room cost)
- Resources/costs of care (ie consultation; length of hospital stay; treatment of complications)
- Resources/costs outside of the system (ie productivity costs; caregiver costs)

Remember to include costs of providers time on the procedure as well as time spent in training provider to correctly use device.

- Use case report forms for information on procedure time/recovery time; concomitant procedures/other medications used and adverse events.
- Use billing/administrative data for length of stay; other proc dures performed and ancillary costs (drugs, supplies etc). Access to administrative data is getting more restrictive due to patient confidentiality requirements and it is important to obtain patient releases for each procedure.

Quality of Life: What to measure and the Sources available

- Pain & distress
- Disease specific symptoms
- Ability to function following procedure
- General well being
- Death rates

Measurement should be against baseline health status and patients receiving alternative treatments. The patient is the only source of quality of life data and there must be ongoing dialog with patients through interviews (pre and post procedure), patient diaries and ongoing surveys.

Phase III: Launch/post launch:

Regulatory Track:

In Phase III of the product development, regulatory functions can be divided into the following:

- Product Modifications
- Additional Product Claims
- Labelling and Advertising

- Post Market Study

Product Modifications: Clinical trials may lead to manufacturing/packaging changes or even next generation product improvements. All design & manufacture changes arising from clinical trials must be reported to the FDA.

Additional Product Claims: All new marketing claims must be supported by hard data evidence which may lead to further notifications to the FDA. "Off label" use (product being used for a different application or in a way not originally intended) can indicate new product development opportunities which need to be investigated.

Labelling and Advertising are obvious, but there are elements in launch materials which are often forgotten - a well trained sales force is vital to the market success of the device and all aspects of its uses, the regulatory requirements and the reimbursement process for the device must be understood by all employees in the field.

Post Market Study deals with the long term health implications on patients. T he providers and payers will require continuing proof from the manufacturer of the effectiveness of the device. This burden of proof may seem onerous but as the product develops through future generations or as the life cycle of the product grows, there will be a need to ensure that coverage for the device will continue.

Reimbursement Track:

Phase III reimbursement can be summed up as:

- Coverage
- Coding
- Payment

Coverage: Payer advocacy swings into high gear and payer should be bombarded with clinical benefits information; FDA Status reports; Clinical group reports; Outcome reports; Quality of life data; Patient survey reports; Peer review journal articles; Full clinical studies etc. The manufacturer needs to keep proving the case for the device and providing hard data to maintain coverage payment. Also, providers may need assistance to obtain reimbursement and the manufacturer should be ready to provide that assistance through guidelines, 'hot lines' and by ensuring the sales force are trained to deal with reimbursement issues.

Coding: Physician codes for devices fall into 2 categories - CPT Codes which are used for both diagnostics and procedures determine costs for physician services and ICD-9-CM Codes are used to report the procedure to the payer who will rule on payment based on these codes. Note that it can take 2 - 3 years to obtain a CPT Code and manufacturers should look to work with relevant associations and societies to get CPT endorsement through the American Medical Association. ICD-9-CM codes are established by HCFA and are used by hospitals as well as physicians. Hospitals also use the HCFA governed HCPCS codes for durable medical equipment and supplies for outpatient use. HCPCS codes are set annually by April 1st for following year (codes for 2000 were established by April 1st 1999) and there will be no further review of codes until April 1st 2000. The HCPCS codes are also used in home health care/nursing services.

Payment: Remember that payment rates can change as device data changes so it is important to keep re-presenting data to payers over the life of the product.

Outcomes Studies Track:

Communicate the value of the device to maximize commercial success. Use favourable coverage policies; reimbursement levels; clinical and patient acceptance to get the point across to decision makers (HCFA, HMO's etc). Provide evidence of value and effectiveness to clinicians through peer review articles, published extracts, user friendly models and promotional materials. Remember, providers and payers are making decisions based on hard, credible evidence but the manufacturer has control of producing the evidence to demonstrate the value of the device/product.

Conclusion:

The need for a systematic and sustained communications process between the 'Regulatory', 'Reimbursement' and 'Outcomes Research' functions during the product development cycle of any medical device should be obvious to all manufacturers. When entering into export markets, it must be remembered that each country addresses the health care needs of its population differently and has unique issues that can affect the marketing of medical devices. Government policies on health care spending in both industrialized and emerging nations change continuously and there can never be 'too much' knowledge when dealing

with this rapidly evolving sector.

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