

## RCRI/d-TARGET – Partnering for Global Success

In the current business environment, speed, responsiveness, flexibility and geographic reach are the key determinants of success. RCRI has enjoyed a successful, ongoing alliance with our Swiss-based partner, d-TARGET to offer specialized consulting services to the medical products industry in the areas of global clinical trial design and management, regulatory affairs, quality assurance and health outcomes research.

Understanding the need for bringing products to market faster in an ever changing regulatory environment, the alliance was developed to provide increased global access in support of successful market introduction.

In this issue, we are pleased to feature an article by Danielle Giroud, President of d-TARGET, on the opportunities (and headaches) when conducting clinical trials in Europe.

Also, we would like to congratulate d-TARGET on the launch of their web based Regulatory Intelligence Centre ([www.ric.d-target.com](http://www.ric.d-target.com)), a highly informative e-database for EU regulatory information on clinical investigations. Subscribers of the centre are provided with immediate and easy access to up-to-date regulatory information from EU countries, enabling them to make efficient decisions in clinical trial design strategy. Having this knowledge available on one site and making it easily accessible can significantly reduce time to market through improved efficiency of clinical research activities.

If you are planning to attend the RAPS Annual Conference in Washington DC, please visit the d-TARGET booth (#323) to learn more about the Regulatory Information Center or contact Danielle directly at [dgiroud@d-target.com](mailto:dgiroud@d-target.com)

## RCRI, d-TARGET and KJ International at RAPS in Washington



Attendees at the **RAPS Annual Conference in Washington October 10-13** are invited to visit RCRI and our partners d-TARGET and KJ International.

d-TARGET is a leading European clinical research organization specializing in medical devices and in-vitro diagnostics. Founded in 1997, d-TARGET offers full support and management of clinical investigations, including pre- and post- marketing trials as well as in European regulatory matters including CE marking. For more information about d-TARGET's services, visit their Web site at [www.d-target.com](http://www.d-target.com).

KJI is a full-service translation firm bringing together state-of-the-art technology and business-savvy language consultants to help clients of all sizes communicate effectively across language and cultural barriers. With clients in medical, software, industrial manufacturing, legal and scientific sectors, KJI helps clients navigate cultural differences, regulatory requirements and international law. Capabilities include print, graphic design and layout, web translation and localization, conversational and group interpretation, voice-overs, and more. For more information on KJI, please visit [www.kjinternational.com](http://www.kjinternational.com).

*For further information on upcoming events, contact RCRI at 952-746-8080, email: [info@rcri-inc.com](mailto:info@rcri-inc.com) or visit our website at [www.rcri-inc.com](http://www.rcri-inc.com).*

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# Strategic Market Segmentation

While executives in the medical device industry often advocate being market oriented and customer focused, we have found that few companies (large or small) use market segmentation to its maximum potential. Against the backdrop of an evermore demanding marketplace and many advances in strategic marketing planning technology, a majority of medical device companies still base their product development and commercialisation plans on cursory, incomplete, or intuitive marketing analysis with the resultant marketing strategy, missing fundamental opportunities and delivering incomplete or inappropriate strategies.

Such a lack of rigour may be explained by a number of factors: need to reduce time to market, reducing levels of expertise in marketing, a less than optimal medical marketing interface, and the poor or ineffective leverage of information. Used effectively, strategic market segmentation can provide a point of consensus for all stakeholders and a more robust foundation for creating advantage(s) that will lead to increasing sales and improving overall marketing performance. Strategic market segmentation is necessary to provide a commercial orientation to product development right from the earliest stages of the development process. It leads to creative advantage, and improved resource allocation and decision making because it enables the company to be customer-facing and to reflect this in the approach to development and marketing of the device.

## Is There a Need to Reassess Current Practice?

In the relentless search for the necessary critical mass to ensure survival and the next blockbuster, the last 10 years have seen significant consolidation within the medical device industry with most sources expecting more in the future. The last decade has also seen a radical change in the research and development strategy followed in the industry. The key aspects of this shift in strategy reported by the top industry executives who contributed to this article are summarised as:

- the number of research and development (R&D) collaborations will increase
- risk sharing for the launch of products will be extended to interchanging products to streamline the companies' indication areas
- small and medium-sized companies that do not have the critical mass to regularly develop new products will be faced with the need either to merge or to build up collaborations beyond their country borders to reduce their cost burden
- everything will be organised around being market driven. The key drivers will be the need to reduce R&D spend, shorten the time for a device to reach the clinic, and thus to launch an increased number of high-value products in terms of duration of peak sales.

In order to enhance commercial success, there needs to be an increased emphasis in the use of strategic segmentation from the earliest stages of the development process. The need for clearly differentiated products meeting customer need is and probably always has been accepted. Diminishing returns from the development and marketing of me-too devices has forced companies to re-engineer their research focus.

Given that market segmentation is the starting point of the marketing process, and that one of the most important advantages of good segmentation is competitive advantage ie differentiation, the following hypothesis is postulated.

- Historically, the industry has been able to sell poorly differentiated products. This will become increasingly difficult to do, as healthcare systems are cash-constrained. Tough choices need to be made. Only those devices that can demonstrate value over and above that offered by existing treatments are likely to have a role to play. In the new millennium, innovation requires the application of strategic market segmentation. If, in the rush to get a device to the market, the needs of different patient populations and the physicians serving these populations are ignored (ie strategic market segmentation), then this might have several implications. It could mean that:
  - a promising candidate won't get to market because the design of the clinical trial program failed to identify the discrete population in which it might have demonstrated value
  - the potential value of the device is never fully realised because
    - (i) it gets to market without the data and evidence that it needs to compete in all market segments
    - (ii) the design of the clinical trials resulted in an 'undifferentiated' market offering
    - (iii) the marketing program is not tailored to the different needs of the segments.

## What Is Meant by Strategic Market Segmentation?

A range of definitions can be found in the major marketing texts but have at their core one crucial element of segmentation: an examination of customer needs and/or requirements. This focus on needs is crucial to the understanding of segmentation. Strategic marketing theory has provided an abundance of literature on pioneering advantages under high uncertainty. Pioneering advantages occur primarily during the initial stages of the product life cycle and generate a substantial amount of company profit. These profits result from early market share gains that make it difficult for competitors to catch up during later stages of the product life cycle.

Specifically the segmentation process:

- *can be used to ensure an appropriate focus of research activities* as it provides a framework for opportunity identification and an understanding of the product profile that will be required to take advantage of the opportunity.
- *can be used to facilitate candidate selection* as the product profile (ie one that will satisfy customer needs and requirements) is crucial to decision making at this stage; it needs to be robustly evaluated and market segmentation facilitates this.
- *is required to support the decision to commit to product:* a rigorous assessment of the opportunities and threats and potential sales that will be achieved given a target profile is required before a company makes the substantial investment commit to product.
- *is required to support the decision to launch:* given the target product profile, the launch plans and associated resource commitments and sales forecasts need to be deemed acceptable before a commitment to launch the product is made.

## Strategic Market Segmentation

**Conclusion** The industry needs to have the right data for the right population to support the positioning of the product. In conflict with this goal, is the eagerness to shorten time to develop and win approval from the FDA (or equivalent) for new products; this is why companies devote the vast majority of their spending to product innovation. In our view, strategic segmentation offers a different and not mutually exclusive route to the required innovation. Investing strategically to create the blockbuster that each company is striving to achieve means bringing marketing expenditure into the R&D phase. It also requires that the goals of these two departments be closely aligned. Strategic segmentation is a very powerful vehicle for ensuring that everyone in the organisation is building their understanding of the customer on the same ground; the company is a customer-facing organisation; irrespective of teams and/or departments, contact and communication with the customer is always appropriate. Finally, once in the market, successful new products are two-edged swords. On the one hand, they create new markets, attract buyers willing to pay premium prices and enable the company to generate significant profits. On the other, the better and the more successful the product, the more competitors strive to imitate it. Here, strategic segmentation provides a company with the knowledge to put strategies in place to defend the business against competition while continuing to grow the business. In conclusion, the decision to undertake a market segmentation study even under circumstances of high uncertainty we believe is crucial. *John Lambert, RCRI Inc*

## Conducting Clinical Investigations with Medical Devices in Europe, a headache or opportunity?

Prospective clinical investigations are a significant investment within the development plan of a medical device product. Therefore careful planning to optimize use of the outcome of the clinical investigations is essential. More and more companies adapt the approach of conducting global clinical investigations and use the data for global market access. However the differences in regulations does not make it easy for the clinical and regulatory specialists.

Europe, with the ever growing number of member states, represents a real challenge to the medical device manufacturers. However the great market perspectives usually make the challenge worthwhile. Although data collected outside the EU, provided comparable medical practice can be demonstrated, are acceptable as part of the CE mark dossier, they usually are not sufficient for a successful marketing support. Frequently there is a need to complete such data by extensive marketing trials in order to generate profitable sales.

There are significant differences in regulatory and ethics systems from one country to another which makes the start of a clinical investigation in some cases a burdensome exercise. Taking into account that such regulations tend to change quite frequently over time, companies who frequently conduct multi-center/multi-national trials in Europe are confronted with repeated research of the regulations in order to ensure continuous compliance.

All investigations conducted with non-CE marked devices, and most of the clinical investigations with CE-marked device, necessitate an approval of the ethics committee prior to starting the enrollment of patients. Ethics committee systems vary from one country to another and are covered in a centralized manner in some countries and local manner in other countries. Likewise some countries, in an attempt to simplify the regulations, initiated a centralized ethics committee procedure, which unfortunately is only partially implemented due to local additional regulations, which still continue to reinforce the need of a local ethics committee (a classic example is Germany).

Submissions are usually required to be performed in the local language, which provides an additional challenge for any manufacturer. Prior to initiating the process of the ethics committee submissions, clinical trial insurance needs to be set up. National laws from most countries specify the need for country specific insurance coverage requirements. It is essential that manufacturers work very closely with their insurance company to obtain certificates in a timely manner.

Competent Authorities, per device directives, require that all clinical investigations with non-CE marked products are notified prior to the start of the clinical investigations. Some countries may require a simple notification without necessitating further delay for the start of the investigations, other countries are requiring a 60 day review period. As per medical device directives, if a Competent Authority has not provided a negative reply, a trial can start.

In addition to the above, compliance with the national data protection regulations is needed. US manufacturers need to take into account that the HIPPPAA regulations do not have any validity in the EU but that national laws have specific requirements to be included in the informed consent and taken into account for further data handling.

Despite the fact that the setup of the clinical investigations in Europe may be a burden, it remains an interesting opportunity. The increased market size combined with the potential of usually earlier start possible than with the FDA IDE process, make Europe a significantly attractive place to conduct clinical investigations with medical devices. Compliance can be obtained to use data under an IDE, which is important to take into account in a global strategy.

To overcome the waste of time in finding out and continuously updating the different national regulations for trials with non-CE and CE marked products, manufacturers could greatly benefit from a centralized information tool, which provides an overview of the implementation rules for clinical investigations. Such tool has now been created by d-TARGET, called the REGULATORY INTELLIGENCE CENTER [www.ric.d-target.com](http://www.ric.d-target.com) which is web-based, continuously updated with summaries, in English, of the requirements for each EU country. Easily accessed, it will help the regulatory and clinical professionals overcome the regulatory challenges of starting a multinational clinical investigation by ensuring compliance and making a faster way to the opportunities of the EU market. *Danielle Giroud, President of d-TARGET can be contacted at [dgiroud@d-target.com](mailto:dgiroud@d-target.com)*

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**Oct 10 - 13**

**Medical Alley Conference**

**Nov 17 St. Paul**

## Contact Information

Your comments, questions and general feedback are very important to us. Please address comments to us at the above location or send email to [info@rcri-inc.com](mailto:info@rcri-inc.com).

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