AN OVERVIEW OF
MEDICAL DEVICES STUDIES
Outsourcing Trends & Regulatory Landscape in Europe and Latin America

MARKET & LANDSCAPE

With the technological advancements and increasing patients worldwide, the Medical Device Industry is expected to grow at an annual rate of 4%, and to reach USD $440 billion by 2018*. The aging population and other lifestyle conditions will give a new focus to the cardiac, respiratory and neurologic diseases, especially with patients above 65 years old.

Due to increasing cost pressure, medical device companies are moving from fixed costs to a more flexible model, by outsourcing studies services and staffing, which is changing the medical device CRO market.

Medical devices companies are now, more than ever, interested in investing in clinical studies for the development and launch of their products with an improved value proposition to the market. Observational studies are being used as an efficient process to collect post-marketing data related to the use of the devices. Some of the reasons to choose an outsourcing option is the utilization of operational resources non-existent in house, product access to new markets and compliance with regional and specific regulatory requirements.

This industry is turning to CROs to deliver a personalized package of services for medical devices studies, as they have being demonstrating various benefits for market access and reimbursement.

THE OPPORTUNITY OF OUTSOURCING

In the drug development process, safety for medical devices is imperative. To get the marketing approval and launch their products to the market, devices companies must submit their products to clinical evaluation and regulatory review.
As adaptive trials are more flexible and provide a constant monitoring, they are gaining focus in the medical device industry. A 45% reduction of the outsourced costs may be achieved though the implementation of an adaptive trial design*.

The majority of the services outsourced by device companies to CROs include services such as clinical development, investigator recruitment, biostatistics, site management and data management, with activities signed on project-by-project analysis.

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**Some benefits from outsourcing to a CRO are to avoid costs from employment, CROs operational and financial flexibility through various outsourcing approaches and their regulatory expertise to execute complex and specific regional device trials**

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The market is dominated by specialty and niche CROs, with an equal presence of mid-size CROs comprising to 32% of the total market. Device companies prefer to engage with specialty CROs at a preference level of 38%, rather than generalized top CROs*.

CROs are turning their focus to the medical devices products, as many companies in this industry need support regarding product development and market access. CROs are therefore providing a solution for efficient clinical trial outsourcing and offering device companies with the possibility to maintain a lean in-house staff. There is also a growing number of small medical devices companies needing to use external resources to conduct product development functions including clinical trials.

**Outsourcing to CROs allow medical device companies reduce their product development cost by 10% to 30%*, shifting their focus exclusively on core R&D and sales investments.**

The outsourcing of clinical studies, clinical trials and observational studies, is attractive to medical device companies due to the financial and operational flexibility in the process of efficiently bringing devices to market, as well as the ability to access external expertise and dealing with different regulatory environments worldwide.

**REGULATORY ENVIRONMENT IN EUROPE**

On June 2016 the European Union published the latest status of the regulations regarding medical devices. According to this, the MDR will be in general applicable three years after its entry into force (Art. 97 para. 2), while a five-year period is proposed for the Regulation on in vitro diagnostic medical devices (Art. 90 para. 2).

Find next some important information related with this new regulation:
1. Device companies need to conduct clinical performance studies and provide evidence of safety and performance proportionate with the risk associated with the device. They will also be required to collect post-market clinical data as part of the ongoing assessment of potential safety risks.

2. Device companies will be required to have available within their organization one person responsible for regulatory compliance with expertise in the field. The organization must document the specific qualifications of this individual relative to the required tasks.

3. Device companies will have to fit their products with a unique device identification to allow the identification and facilitate the traceability, other than custom-made and investigational devices ("Eudamed").

4. Notified bodies must notify the competent authorities of certificates they have granted to class III devices and class IIb active devices intended to administer and/or remove a medicinal product. A competent authority and the Commission may then apply further procedures.

5. Notified bodies will have the right and duty to carry out unannounced on-site audits and to conduct physical or laboratory tests on medical devices to ensure compliance by manufacturers after receipt of the original certification.

6. The EU Commission will be able to publish common specifications which shall then be taken into account by device companies and notified bodies. These shall exist in parallel to the harmonized standards. Devices in conformity with the common specifications are presumed to be in conformity with the requirements of the regulation.
REGULATORY ENVIRONMENT IN LATIN AMERICA

An exponential growth in clinical research activities in emerging regions such as Latin America is being noticed due to local low costs, population characterization and regional regulatory expertise. The device industry is expected to increase the studies being conducted in emerging markets; as so, device companies are anticipated to hire more staff through outsourcing.

Many Latin American countries have already developed a regulatory system for devices, mainly, Argentina, Brazil, Bolivia, Colombia, Costa Rica, Cuba, El Salvador, Ecuador, Mexico, Panama, Puerto Rico, Uruguay and Venezuela.

PAHO – Pan American Health Organization – has as main goal the creation and strengthening of systems for medical device regulation in the Latin America region.

MERCOSUL: Argentina, Brazil, Paraguay, Uruguay, Venezuela and Bolivia has a regulation - MERCOSUR/GMC/RES. No 40/00 Technical Regulation for medical device registration

Most countries follow ICH Guidance and elements from EU/USA systems.

Mexico & Brazil

Mexico is the second largest country in Latin America and a good first option for market entry in Latin America. The country is member of the North American Free Trade Association (NAFTA) and has a friendlier regulatory climate, without the import duties (for American and Canadian companies) which other latin american countries have.

Brazil is the largest economy in Latin America and is also a key market for medical device products. It has the 6th largest GDP in the world and a $4 billion medical device industry. On the other hand, Brazil imposes high taxes on imports compared to other countries. Products imported from MERCOSUL countries (Argentina, Bolivia, Brazil, Paraguay, Uruguay, and Venezuela) are generally without duties as part of the free trade agreements.

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Latin America is known for its surgical and non-surgical aesthetics and ophthalmology markets. Brazil and Mexico have two of the largest aesthetic markets in the world, and vision correction is another driving factor in Latin America.
Here are some tips related with product launch for medical devices in Latin America:

1. **REGULATORY CLEARANCE**
   Pursue regulatory clearance with urgency. Seek approval in Latin America as soon as UE or FDA clearance is obtained in order to maximize future options. Delay registering in Latin America can be a costly as the region has a complex regulatory process.

2. **RISK CLASSIFICATION**
   The approval process depends on the risk classification of the product. Each national agency has guidelines that define risk based on the technology and the regulatory process. However, the guidelines are similar to those in other countries.

3. **LOCAL REPRESENTATIVE**
   Most countries requires a local establishment for medical device commercialization, with the presence of a license holder or local representative. In-country establishment with at least operating license and Technical Responsible Professional.

4. **SCRUTINY MECHANISM**
   Notified bodies must notify the competent authorities of certificates they have granted to class III devices and class IIb active devices intended to administer/remove a medicinal product. A competent authority and the Commission may then apply further procedures.

5. **PRODUCT REGISTRATION**
   Letter of Authorization (LoA) seals this partnership and is mandatory requirement for product registration.

6. **LANGUAGE**
   Brazil and Argentina accept studies, validations and literature in English. In Mexico all documents need to be in local language (Spanish).
EUROTRIALS EXPERTISE IN MEDICAL DEVICES

Eurotrials addresses all steps of a medical device regulatory strategy and clinical development, including services like clinical trials monitoring, regulatory submissions, preparation of technical dossiers, post market surveillance and consultancy for new markets entry.

Our multidisciplinary team is prepared to manage complex medical devices and diagnostics clinical studies, from the strategical consulting to the market access guidance. Present in Europe and Latin America, Eurotrials has in consideration the several differences in the regulatory landscape of distinct regions. As there is a difference between a medical device study and a pharmaceutical study, it is important to have the right professionals working in your project, bringing the necessary expertise and generating the best outcomes for its success.

Experience in Medical Devices clinical trials, namely with ISO 1450.

A team of experts in Medical devices, which will guarantee your product is brought to the market safely, effectively and efficiently.

Relationships with clinical research sites experienced in medical device studies.

Strong local expertise in Europe and Latin America, allowing for the best trial strategy and design, allowing cost-effective decisions.

Ideal data management tools to ensure the successful execution of all the data collection and management, providing accurate metrics and restricting risks.

Dedicated multidisciplinary team for regulatory and clinical development strategy.

ABOUT EUROTRIALS

Eurotrials is a full-service CRO with strong local expertise in Europe and Latin America. The company has been validated by international biopharmaceutical companies, has several master agreements and is ISO- 9001 certified. With more than 20 years of experience, Eurotrials has offices in Argentina, Brazil, Chile, Mexico, Peru, Portugal, Spain and France, covering over 15 countries in both regions. Eurotrials provides an extensive array of services from early- to late-stage research as well as product support in accordance with global and specific regional requirements.

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