TALENT SOURCE LIFE SCIENCES
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ARTICLE

A CRA Perspective:

The Difference between Medical Device Studies and Pharmaceutical Studies

Experts Providing Experts

TalentSource Life Sciences is the dedicated flexible resourcing business unit within CROMSOURCE - a business started over 25 years ago when CROMSOURCE first entered the resourcing market.

The Difference between Medical Device Studies and Pharmaceutical Studies

In my role with TalentSource Life Science, I was working as a CRA at a large pharmaceutical Company working solely on medical device trials. My previous experience with device studies was limited to working as a scientist on a small study involving cold sore patches, so this was my first experience of monitoring a device study.

Device studies and pharmaceutical studies are very similar. They both involve the exposure of a specifically selected population to an experimental entity, according to an ethically approved protocol or clinical investigational plan. Data are collected according to the protocol, safety issues are reported and conclusions are drawn based on this data. As a CRA, your role remains the same – ensuring sites have the suitable experience, resources and training to perform the studies, ensuring the correct data are being collected according to the protocol and that its integrity is maintained, making sure the safety and well-being of the subjects are protected throughout, and ensuring the necessary ethical and regulatory approvals are in place. Of course this is the role of a CRA in its most basic form.

So what are the differences? Let's start with the regulations. Devices and pharmaceutical studies are both conducted in accordance with ICH GCP guidelines and the principles outlined in the Declaration of Helsinki. In addition, they each have their own specific guidelines.

The main guidelines are detailed below:

REGULATIONS COMPARISON

Medical Device	Pharmaceutical
Medical Device Directive 93/42/EC (MDR 2017/745)	Clinical Trials Directive 2001/20/EC
ISO14155 2011	GCP Directive 2005/28/EC
ICH GCP E6	ICH GCP E6
Declaration of Helsinki	Declaration of Helsinki
Meddev 2.7/3, 2.12/2, 2.12/8	

Pharmaceutical studies differ amongst themselves: therapeutic area, phase, and route of administration and each add their own level of complexity affecting the study design. For me, it was interesting to learn a new set of regulations and expand my knowledge base and experience outside of the realm of pharmaceuticals.

Next, you must evaluate the difference in the design of pharmaceutical and device studies. Pharmaceutical studies are split into phases (I, II, III and IV) whereas device studies tend to be split simply between pre- and post- CE mark. By their very nature it is often difficult to use placebos when working with devices, likewise blinding of both the study team and patients can be difficult, if not impossible. Both of these impact the trial design.

What impact did these differences make to me as a CRA?

On a day-to-day basis it did not feel very different to working on pharmaceutical trials. I was working on studies which involved the implantation of bioresorbable stents in patients with angina. The most significant and interesting difference for me didn't have to do with the regulations and study design, but the expertise required to implant these devices successfully. Of course, in pharmaceutical studies, understanding the pharmacology and toxicology of the study drug is paramount, however, in this study there was a practical element to implanting a novel device which requires specific skill and practice. This meant a higher level of sponsor involvement than I had encountered before and in the training and signing off the investigators implanting the device. As a CRA it meant attending the first 'case' at each site to support the team to observe the percutaneous intervention (PCI) from the Cath Lab, to make sure the relevant data was collected in the correct order and to ensure the site had everything they needed. (It was incredibly interesting to be involved in this study). Once the device is implanted the patient becomes part of the follow-up group only. There is no on-going dosing schedule as you would see in a pharmaceutical study.

There are other subtle differences including the requirements for safety reporting, for example, which specify three days rather than 24 hours from point-of awareness to reporting SAEs. These small, but important, differences need to be known to ensure you can do your job properly. In essence, if you enjoy the challenge of working on pharmaceutical studies you can transfer this knowledge and have a fulfilling role working on medical device studies. After all, it's important to keep learning new things and challenging yourself.

About the Author

The Author is a Senior CRA who joined the industry in 2008 and has worked in CRA roles on both pharmaceutical and medical device projects.

ABOUT US

About TalentSource Life Sciences

TalentSource Life Sciences is the division of CROMSOURCE, dedicated to providing our clients with a variety of flexible resourcing models.

Established over 25 years ago when the staffing division, formerly MSOURCE, entered the market, TalentSource supplies flexible, tailor-made resource teams, management and processes for any clinical/medical devices study, as well as in a number of other related industry functions. Our flexible resourcing solutions include staff augmentation/insourcing, full functional resourcing solutions (FSP) and bespoke hybrid delivery models – whatever is required, we can tailor our support to client needs.

The most valuable assets in clinical research are well-qualified, experienced and expert resources and we appreciate that the Life Science Industry is looking for every viable option that will identify true professionals. That's why we invest heavily in training and development to ensure our resources are learning all the time and always up-to-date with regulations.

About CROMSOURCE

CROMSOURCE is a highly qualified ISO-certified international provider of outsourced services to the pharmaceutical, biotechnology and medical device industries, specialized in clinical development and staffing solutions.

Operating through offices across all regions of Europe and North America, CROMSOURCE delivers a comprehensive breadth of services. We seamlessly move biopharmaceutical products from first in human conducted in our exceptional early phase unit through all subsequent phase of pre- and post-approval research internationally.

Our pharmaceutical and medical device experts oversee projects through regulatory strategy and submission to pilot and pivotal clinical investigations in Europe and North America.

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