How Medical Affairs might help in patient recruitment: a closer look at the new role of an Investigator Science Liaison

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Experiences gathered by the pharma industry while running clinical trials over the years, coupled with feedback coming from clinical investigators, resulted in the rise of a new role within Medical Affairs departments - the Investigator Science Liaison.

Managing the increasing complexity of Clinical Trials

Nowadays, it is rather difficult to run a clinical trial. The use of the Investigators Satisfaction Index, helped identify key issues clinical investigators face today. It turns out it is becoming a challenge for the investigators to thoroughly understand the complexities of study protocols. Those are a reflection of complicated therapy regimes and the emergence of sophisticated guidelines for the treatment of most clinical conditions. Narrow patient populations are also targeted in modern clinical trials, which is another aspect that adds to the increasing complexity of their design. These issues make it harder to recruit new patients which often leads to trials being terminated.

It turns out that, during an ongoing trial, investigators are looking for better education about their role in relation to the study protocol and also for a higher level of scientific discussion they can have with their supporting pharma partners. If these are not being provided, investigators can quickly lose interest in the trial which will result in a lower number of recruited patients. It is important to remember that clinical investigators have a lot on their plate as they are often involved with several trials running simultaneously. On top of that they deal with their day to day clinical duties. Then there is the issue of how the study protocol corresponds to real world medical practice. The reality is that every clinical site is different, even if the study protocol assumes it's not. One thing is certain - the clinical investigator should not be left alone to deal with the complexities of a clinical trial as this might jeopardise the whole trial.

Under recruitment in clinical trials: economic burden and missed opportunities for patients

There is a large problem with under recruitment within clinical trials. Figures show that 80% of trials fail to meet their initial recruitment targets and that successful completion of as much as 45% of trials is delayed. This means that almost one in two trials will most likely be completed late this year. At present times almost one in five trials is terminated before reaching its completion date due to an insufficient number of participants. As one can

imagine, this cannot be without consequence for the sponsors. It has been calculated that one day of delay in running a clinical trial can cost anywhere from $600,000 up to $8 mln. With such high costs of running clinical trials, it has become crucial for companies to deliver trials within a set timeframe and an approved budget. This is, without a doubt, the biggest obstacle for companies running clinical trials today.

Once a trial is delayed problems do not end with additional costs for the company. Late regulatory approval for the product, its delayed launch date and all lost revenue can cause a real headache, especially when direct competitors are present on the market. Currently, there is a narrow window of opportunity for a new product so its delayed arrival may cause the company to come to a daunting conclusion that their product is no longer needed.

It is also important to remember that under recruitment in clinical trials has the potential to strip patients of their chance to receive experimental treatment. There are numerous medical conditions for which there are no treatment options, therefore every successfully completed trial brings new hope to patients in their battle with the disease.

Tackling under recruitment: can Medical Affairs contribute?

To face the demanding reality of modern clinical trials a new role has emerged within medical affairs – the Investigator Science Liaison (ISL). Medical Science Liaisons (MSLs) have been around for quite a while now and most of us are familiar with their input in clinical trials. It may be confusing at first to distinguish ISLs from MSLs, but there are major differences separating the two roles. ISLs begin their interaction with investigators at an earlier stage compared to MSLs. It is usually as early as phase 2 of the clinical trial when ISLs step in to assist the investigator. MSLs, on the other hand, start work when data from phase 3 trials is available. Throughout a clinical trial, ISLs have the opportunity to work closer with the investigator than MSLs do. ISLs look out for any challenges investigators face during a trial. Once a problem is identified, they gather such information and present it to the company. This allows the CRO or pharmaceutical company to come up with solutions that help investigators and in turn improve recruitment.

Additionally, ISLs make sure investigators feel comfortable with the protocol and understand the study objectives well. They also work between monitors and investigators to improve their communication. Any issues reported by clinical monitors can be dealt with on the spot by ISLs which allows for quicker problem solving and better communication in the study team. The input of ISLs does not end here.

After a trial is completed ISLs bring back expertise on real world practice to the company. This information can become invaluable when the company sets to create new protocols for future studies. ISLs also help maintain an investigators scientific interest in the trial. As a result, strong relationships are built with leading experts which can prove to be beneficial in later stages of drug development.

Taking into account the wide scope of responsibilities ISLs carry and the impact or their work, it is safe to say that they help tackle the problem of under recruitment within clinical trials

and serve as a true bridge between the domain of R&D and marketing within pharma companies.