Investigator Initiated Studies – Industry or Investigator – "Who Wins?"

To the Editor:

After careful reading, the communication between the investigators who published their work in July's issue of Pain Physician (1), as part of an Investigator-Initiated Study and company Nervomatrix Ltd. who funded this study (2), and their response to the company's comments (3), the remaining question is "Who wins?".

Investigator-Initiated Studies (IISs) should be of mutual interest for both investigators and industry funders.

Usually, companies have the interest to fund these studies as part of post-marketing research that could help them proving the efficacy and/or safety of their medication or device. Their expectations are to prove that their medication or device provides good results, that it is safe, to acquire an idea for potential new indication, or upgrade the features of the medical device. However, as the actual name says these studies should be initiated by investigators, and not solicited by companies. The companies should not be involved in any data analysis nor should it limit publication of the research if it does not speak in favor of their product/device.

According to Code of Federal Regulations 21 CFR 312.3 "Sponsor means a person who takes responsibility for and initiates a clinical investigation" (4) and in the case of IISs, investigators are serving as both sponsor and investigator and they should take full responsibility for the study design, conduct, analysis and interpretation of the results. On the other hand, I can understand the frustration from the industry that funds the research in hopes of getting more favorable results.

It is clear that sometimes, the industry and investigators have different expectations from IISs. However, to answer the question from my title, I believe that both the industry and investigators should be the winners, because even negative results could help the industry to adjust the approach or to give different, more detailed instructions when training physicians or patients. Negative results from small IISs could help change something in their strategy and prevent therapy failure in everyday practice.

Since clinical trials sponsored by companies are sometimes written with strict inclusion and exclusion criteria, it happens that "in the real world", when a medication or device gets used by patients, the results turn out to be different, and that is the reason why IISs should be encouraged.

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