Understanding of clinical investigator about the serious adverse event reporting and its complexity in Latin America

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In Latin America, different efforts are being made to increase clinical studies, working on the speed of evaluation and approval of these. Likewise the need for new drugs and medical devices and its offer to improvements in healthcare. Clinical research is undertaken to elucidate product benefits, but also to identify potential harms. The report of Adverse event (AE) and serious AE (SAE) bring crucial information in drug and device development.

Unfortunately, there is an increasing of requirements from health authority that trigger in requirements by the sponsors to the research centers, leading to a decrease in the uptake of have a robust training and capacity building program which is strengthening the focus on patient. Therefore, it is essential that both researchers and coordinators genuinely understand the impact of the information contained in the reports and the value of quality in their evaluation.

The value proposal launched with this initiative is aimed that academics from different universities work virtually with the industry, in order to strengthen research centers selection during the feasibility process, also, do a reengineering on training of the research team focus on the observation of patient beyond of physical or laboratory tests.

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