

ScienceMedia's Training Significantly Reduces Unplanned Protocol Deviations in Decentralized Trials

SAN DIEGO, CA. (07-06-2021) Recent guidance by the FDA and EMA (E6 (R2) Good Clinical Practice) emphasizes the need for education and training of all constituents in a clinical trial to reduce unwanted protocol deviations and improve overall quality in clinical trial operations. In accordance, ScienceMedia's SMi Trial prevents unexpected protocol deviations in decentralized trials with their just-in-time educational content, protocol-specific curriculum, and powerful comprehension checks along the way.

ScienceMedia's Chief Strategy Officer, David Turner, shares that: "With billions of dollars at stake and a timeline of ten-plus years, drug development is very complex and often daunting. Add to that the shift to decentralized trials because of the pandemic, and things just got more interesting. Education and training have never been more important when setting up a clinical trial or clinical study. With the additional moving parts, technology, and people involved, education and training are paramount to de-risk trials and studies from the beginning. The days of training Pl's with a 160 slide PowerPoint presentation in a large room in Boca Raton, Florida are over."

The NIH reports that deviations from the approved protocol are common and have been noted in routine management and research settings at differing frequencies. These deviations in a study could be due to the participant, the sponsor, or the investigational team. Compliance by a participant to an advised medication regimen is also known as medication adherence. It is dependent on a variety of factors, including the disease, efficacy of the medicine, age, and mental attitude of the patient. Some of these deviations could be avoided by properly counseling the participants, whereas some are unavoidable. Deviations caused by investigational staff often result from poor training and can be prevented.

Turner continues: "Building education and training into the operational plan instead of bolting it on afterward is more important than ever. Even more important than delivering effective educational content is ensuring that the content is consumed and retained by all constituents of a clinical trial. SMi Trial^D's curriculum and analytics technology ensure that everyone involved is fully educated on their aspect of the clinical trial, resulting in fewer unwanted protocol deviations."

Whether you are considering hiring a CRO or are already in site startup mode, it is time to rethink your approach to protocol training and education and call ScienceMedia at 858-263-1666 or request a demonstration at: sciencemedia.com/decentralized.

About ScienceMedia

For over 25 years, <u>ScienceMedia</u> has been at the forefront of delivering innovative multimedia elearning solutions to improve clinical competency. <u>SMi Trial</u> for site-based trials and <u>SMi Trial</u> for decentralized trials mitigate clinical risk and decrease trial cost by optimizing study compliance

throughout the lifetime of your clinical trial. <u>SMi Source™</u> is a mobile-enabled, cloud-based science education library that provides 16,000+ microlearning topics and 400+ complete courses covering a vast catalog of disease and therapeutic areas. For ongoing insight about proven clinical trial performance solutions for decentralized and hybrid trials, follow ScienceMedia via <u>LinkedIn</u> or our <u>blog</u>.

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