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Rethinking training and operational approaches with investigative sites

Adam Chasse
OnPoint CRO, USA

Clinical research is critically important to develop new treatments and substantial regulations help to protect patient safety and data integrity. However, poor patient recruitment continues to increase clinical study costs and timelines. In the United States, the pharma/CRO industry has reacted by developing tactics to engage patients directly and "match" them with "qualified" investigators (i.e., physicians with a successful track record in clinical research), yet macro-level data do not suggest this has had positive impact. To fix the problem, industry must acknowledge and address the shortage of physicians willing/able to become involved with clinical research (and the business-related reasons for this) and that the "matchmaking" approach incorrectly assumes patients will be enthusiastic about seeing doctors other than their own. Boosting patient participation in studies; means increasing the number of physicians willing to serve as investigators. The industry can no longer depend on a free market approach in which the best potential research sites voluntarily invest in the infrastructure necessary to be successful, because quite simply, the benefits of doing so are uncertain and not enough to offset the many other regulatory and resource demands in today's healthcare environment. This session will explore barriers to physician and patient participation in clinical research, the strengths and weaknesses of today's normative approaches to investigator training/selection and potential solutions that the pharma/CRO industry must consider.

adam.chasse@onpointcro.com

Efficacy and safety of iota-carrageenan nasal spray versus placebo in early treatment of the common cold in adults: The ICICC trial

Stephan Koelsch
Boehringer Ingelheim Pharma GmbH & Co. KG, Germany

Iota-carrageenan (I-C) is active against respiratory viruses *in vitro* and was effective as nasal spray in three clinical trials with common cold patients. To further investigate I C, a fourth randomized, placebo-controlled, double-blind clinical trial was conducted in 200 adult patients with self-diagnosed colds that were confirmed by baseline symptom scores. Respiratory viruses were quantified at baseline and on treatment day 3 or 4. Primary endpoint was the mean total symptom score of 8 cold symptoms on Days 2 to 4. The primary endpoint did not demonstrate a statistically significant difference between I-C and placebo but showed a trend towards I-C benefit. Exploratory analyses indicated significant reduction of cold symptoms in the I-C group and also substantiated I-C's activity against rhinovirus. To observe trends rather than statistically significant outcomes obviously was based on an unexpected low power of the trial. In particular, the proportion of virus-positive patients was smaller than anticipated. Only 23.6% had rhinovirus in contrast to 50-90% in other studies. This low frequency of rhinovirus-positive patients in the ICICC study demonstrates that there may often be a trade-off when the standard design for cold studies is used. When a controlled study tries to recruit patients at the earliest stages of a cold, patients may incorrectly believe they are coming down with a cold, prior to full blown cold symptoms. Hence, the peculiarities of the ICICC study may trigger a discussion among the scientific community about more suitable study designs to investigate common cold treatments.

stephan.koelsch@boehringer-ingelheim.com