NEWS RELEASE

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FOR IMMEDIATE RELEASE
January 29, 2015

Investigator Training Efficiencies Highlighted in New CTTI GCP Recommendations

DURHAM, NC – The Clinical Trials Transformation Initiative (CTTI) has announced recommendations to streamline Good Clinical Practice (GCP) training of investigators who participate in clinical trials. GCP is an international standard for the design, conduct, performance, monitoring, auditing, recording, analyses, and reporting of clinical trials.

According to CTTI's executive director, Pamela Tenaerts, M.D., MBA, "Sponsors generally require clinical investigators to complete GCP training prior to participating in each clinical trial. This requirement can result in investigators who participate in multiple clinical trials receiving redundant GCP training numerous times within a single year."

"CTTI's recommendations to eliminate redundant training and for sponsors to accept one another's training would reduce unnecessary burden on sites and signify a major landmark for U.S.-based clinical research sites," said Christine Pierre, president, Society for Clinical Research Sites (SCRS). "The Society for Clinical Research Sites is proud to have participated in this important initiative to maximize efficiency in GCP training."

The recommendations, presented in a public webinar hosted by SCRS, focus on four components of GCP training: minimum essential elements, training frequency, training format, and evidence of completion. Adaptability is encouraged as appropriate; for example, the frequency of training should be sufficiently flexible to accommodate different experience levels, gaps in training, etc., and should not be the same course every time.

The recommendations were developed by a multi-stakeholder project team that considered the results of a literature review and analysis of some common GCP training programs, as well as discussions with experts on challenges regarding GCP training and possible solutions. The team expects to publish the complete details of the project in a peer-reviewed publication later this year.

CTTI was established by Duke University and the FDA as a public-private partnership in 2007, and now comprises more than 60 member organizations working to identify

and promote practices that will increase the quality and efficiency of clinical trials. More information about CTTI and its projects is available at www.ctti-clinicaltrials.org.

SCRS was founded in 2012 in response to the growing need for a trade organization representative of the needs of clinical research sites globally. SCRS's mission is to unify the voice of the global clinical research site community for greater site sustainability.

Financial support for the work was provided by a grant from the FDA awarded to Duke University for CTTI, as well as pooled CTTI member funds and in-kind contributions.

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