

FOR IMMEDIATE RELEASE

Tufts Center for the Study of Drug Development Establishes Workload and Utilization Benchmarks for Global Clinical Research Associates

BOSTON – Jan. 17, 2012 – The Tufts Center for the Study of Drug Development today announced that it has established the first global benchmark for clinical research associate (CRA) workload and utilization, giving managers insights into improving CRA effectiveness and efficiency.

CRAs are based in the field and they are responsible for overseeing and closely monitoring clinical studies conducted by research centers.

“Over the past 15 years, demands on study monitors have intensified as clinical trial volume and complexity have increased. Yet, drug development managers haven’t had benchmarked global metrics to assess their CRA field force capacity and utilization,” said Ken Getz, Tufts CSDD senior research fellow and assistant professor at Tufts University, who conducted the study.

According to Tufts CSDD, CRAs worldwide spent approximately 20% of their time traveling and devoted 41% of their time at clinical trial sites. Getz noted that prior to the study the research-based drug industry widely believed that CRAs spent 60% of their time on-site.

In addition, the study found that CRA workload and time allocation varies widely by geographic region with U.S.-based study monitors spending more time traveling and on-site than their counterparts elsewhere. European study monitors spend relatively more time performing off-site monitoring and administrative tasks.

According to Tufts CSDD, there are 20,000 – 23,000 CRAs supporting clinical research studies worldwide.

“CRAs play an integral role in the drug development process as they are the people who ensure the safety of trial participants, the quality of clinical data, and the compliance by investigative site staff with the study protocol,” said Getz. “Knowing how much time CRAs spend on specific tasks gives managers and regulators a way to refine practices and policies aimed at enhancing CRA effectiveness and efficiency.”

The Tufts CSDD study, reported in the January/February *Tufts CSDD Impact Report*, released today, also found that:

- For Phase I studies, CRAs on average conduct 3.8 investigative site visits each month.
- For Phase II-III studies, CRAs on average conduct 7.9 investigative site visits each month.
- CRAs overall have an average of 6.3 years on the job and expect to remain in their position for another 3 years, with both metrics varying widely by region.

About the Tufts Center for the Study of Drug Development

The Tufts Center for the Study of Drug Development (<http://csdd.tufts.edu>) at Tufts University provides strategic information to help drug developers, regulators, and policy makers improve the quality and efficiency of pharmaceutical development, review, and utilization. Tufts CSDD, based in Boston, conducts a wide range of in-depth analyses on pharmaceutical issues and hosts symposia, workshops, and public forums, and publishes *Tufts CSDD Impact Reports*, a bi-monthly newsletter providing analysis and insight into critical drug development issues.

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