Study monitor workload high & varied with wide disparity by global region

Assessment sets global benchmark for CRA workload and utilization

- Clinical research associates (CRAs) worldwide devote 41% of their time at clinical trial sites, with those based in Europe spending 30% fewer hours on-site than CRAs in North America.
- Sponsor CRAs spend more time than their counterparts at contract research organizations (CROs) conducting on-site monitoring visits, monitoring trials off-site, and handling administrative tasks.
- Half (53%) of CRAs overall rate their work life as good or excellent; those based in Latin America gave the lowest ratings.
- 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.

Demands on clinical research associates, known as CRAs or study monitors, have grown dramatically over the past 15 years in tandem with the increasing volume of trials, global dispersion of research activity, and rising complexity of study protocols. Until now, the absence of industry benchmarks for CRA workload and utilization has hindered managers and regulators from refining practices and policies aimed at enhancing CRA effectiveness and efficiency. To address this need, Tufts CSDD conducted a quantitative assessment of the global study monitor landscape to derive baseline metrics of CRA workload and utilization, findings of which are summarized in this report.

As the research-based pharmaceutical and biopharmaceutical industry continues to grapple with ways to lower the costs and time required to conduct clinical trials, better informed CRA management will help ensure data quality and integrity, safe and ethical treatment of study volunteers, protocol adherence, and improved site performance.