Regulatory compliance an increasing burden on sites

Increased staff time, materials, storage eroding site operating profit

As the biopharmaceutical industry strives to reduce its R&D costs and shorten timelines, it must face the fact that today's successful drug development plans often require more clinical studies than they did a dozen years ago.

Often that translates to more complex clinical trials for investigative sites, requiring pre-screening of larger patient pools, more personalized data and time-consuming and complex regulatory compliance. Site noncompliance with Good Clinical Practices (GCP) has been rising; many sites have said the regulatory burden continues to increase as study timelines continue to slip.

But unlike the pharmaceutical industry, many sites continue to operate as a cottage industry, lacking the cohesiveness and financial resources to improve efficiency and flexibility.

While there is wide agreement that the regulatory compliance burden for sites is high, few initiatives have been launched in the industry and little to no data exists to quantify this regulatory compliance burden on sites.

But a new CenterWatch survey, sponsored by Complion, sheds some light for the first time on how, and how well, sites manage regulatory compliance.

Complion, a Cleveland-based software development firm for sites and site networks that creates software for electronically recording essential clinical trial regulatory documentation, recently surveyed 164 site personnel. The results have been released in 2014 Regulatory Compliance Practices.

Regulatory staffing

	Overall	Independent	AMCs	Community Hospitals
Median number of staff involved with regulatory compliance tasks	2	2	3	3
Median number of studies for which staff are managing regulatory compliance	6.0	6.6	3.3	6.7

Source: CenterWatch-Complion study, 2015; N= 164 investigative sites

Respondents included independent research centers (10% of the total sample size), sites affiliated with Academic Medical Centers (35%), private practice sites (23%), sites affiliated with community hospitals (27%) and other sites (5%). More than half of the survey respondents were Study Coordinators/study nurses, while 20% were Principal Investigators. Other respondents included regulatory specialists, administrators and managers.

Time required

The survey found Study Coordinators and nurses, often the primary managers of regulatory compliance for sites, juggle a significant amount of work when factoring in all of their responsibilities. Interestingly, the survey found staff time for most regulatory tasks did not differ significantly across the different site types.

"We were specifically interested in a range of things, from staffing requirements to managing site regulatory compliance, the formats used in storage and exchange of regulatory documents, the costs related to maintaining compliance, plus the inefficiencies that are a burden on sites," said Rick Arlow, CEO of Complion. "What stood out is that over a two-month clinical trial period, one-third of the time is spent on regulatory tasks, and the rest was on routine information maintenance. So we see big opportunities for improvement with a streamlined process in which some clerical tasks don't need to exist."

Still, that is a disproportionately large amount of time spent on regulatory compliance, which leaves less time for activities such as patient recruitment. For a typical clinical study, site staffs spend a median 34 hours on clerical activities, 36 hours on regulatory work and 44 hours on sponsor/CRO-related activities.

Of that median 114-hour per week total of regulatory, clerical and spon-