

# The Clinical Trials Landscape

ASSOCIATION OF ACADEMIC HEALTH CENTERS

Clinical trials activity varies widely, as does availability of information



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Given the growth and expansion of clinical trials at many academic health centers, data on the volume, scope, and finances of clinical trials operations is of interest when examining research, compliance, or financial administrative infrastructure within the academic health center enterprise.

Members of the Forum on Regulation of the Association of Academic Health Centers (AAHC), the chief compliance officers at the 100 AAHC member institutions, were asked about these issues for FY 2006 in a questionnaire in May and June 2007. Findings from the 21 responses to the questionnaire provide a snapshot of clinical trial activities and changing structures at academic health centers, and suggest several issues for further assessment.

## FINDINGS

The number of active clinical trials per institution varies widely, as do the types and scope of trials being conducted. Eight of the 21 institutions conducted between 101 and 500 trials in 2006, five institutions conducted 1,001-2,500 trials, and five conducted more than 2,500 trials. Only one institution reported conducting fewer than 100 clinical trials, and two reported conducting 501-1,000 trials.

Great variability was reported on the number of different clinical sites at which institutions conducted trials as well. One respondent reported conducting clinical trials at only one site (the major teaching hospital) and one respondent reported conducting trials at 16 owned or affiliated sites. All other answers were scattered throughout that range, with the exception of one outlier, who reported 55 sites.

The time required to achieve operational readiness (i.e., the completion of budget development, IRB approval, and signing of the clinical trial agreement) is often a critical factor in contracting for clinical trials. This timeframe was more constant across responding institutions; 13 of the 21 institutions cited a 3-6 month timeframe between the initiation of study design and

operational readiness. The remaining responses were split evenly, with four institutions reporting a timeframe of fewer than two months and four institutions citing 7-10 months. No institution reported a timeframe of greater than 10 months.

Reported revenue from clinical trials in FY2006 varied between \$2.4 million and \$25 million, with a median of \$13 million. However, 10 respondents—nearly half of the sample—did not know the revenue or did not respond to the question, indicating that such information may not be available to compliance officers or may only be known to finance or research administrators. It appears that many institutions may lack a central databank for such information.

Clinical trials may represent only a small portion of an institution's total research awards. However, the percentage is nevertheless a vital interest when considering the imperative of academic health centers to stimulate the development of lifesaving medical treatments and cures, as well as the magnitude of associated compliance and administrative infrastructure necessary to sustain clinical trial operations. Ten respondents reported the percentage of the academic health center's total research awards dedicated to clinical trials in FY2006. Seven of the responding institutions cited percentages between two and eight percent, while the other three responses fell between 20 and 22 percent. The remaining 11 respondents did not provide answers or declared the figure to be unavailable at this time.

The industry-sponsored indirect cost recovery rate for clinical trials was consistent across responding academic health centers. Nineteen respondents reported a rate between 20 and 29 percent; one respondent reported 54 percent; and one did not respond. Three-quarters of respondents reported a rate of 25 or 26 percent.

In contrast, clinical trial fees charged by institutions varied. With regard to clinical trial administration fees, only six of 21 respondents reported charging a separate fee to the industry sponsor for clinical trial administration, with an additional two declaring that their institution will begin to do so in fall 2007. Fees varied widely, with answers including: \$1,000; \$1,500-\$2,000; \$2,000-\$3,000; \$2,000-\$5,000; \$3,000; \$3,500-\$17,000; and "varies." In addition, nearly all respondents—17 out of 21—reported that the academic health center charges an IRB fee.

## CONCLUSION

The responses to the questionnaire reveal that a good deal of critical information about clinical trial operations is not known or not readily available to chief compliance officers, even though such information may increase understanding of institutional resources, enhance job performance, and ensure increased efficiencies in clinical trial administration. Such data may be housed in multiple offices of the university, and central data repositories for clinical trial administration do not appear to exist at most responding institutions at this time.

Due to the critical need to continually improve the efficiency and effectiveness of clinical trial administration, more work is needed to build central data repositories as well as to expand information exchange and communication regarding clinical trials in academic health centers.



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