

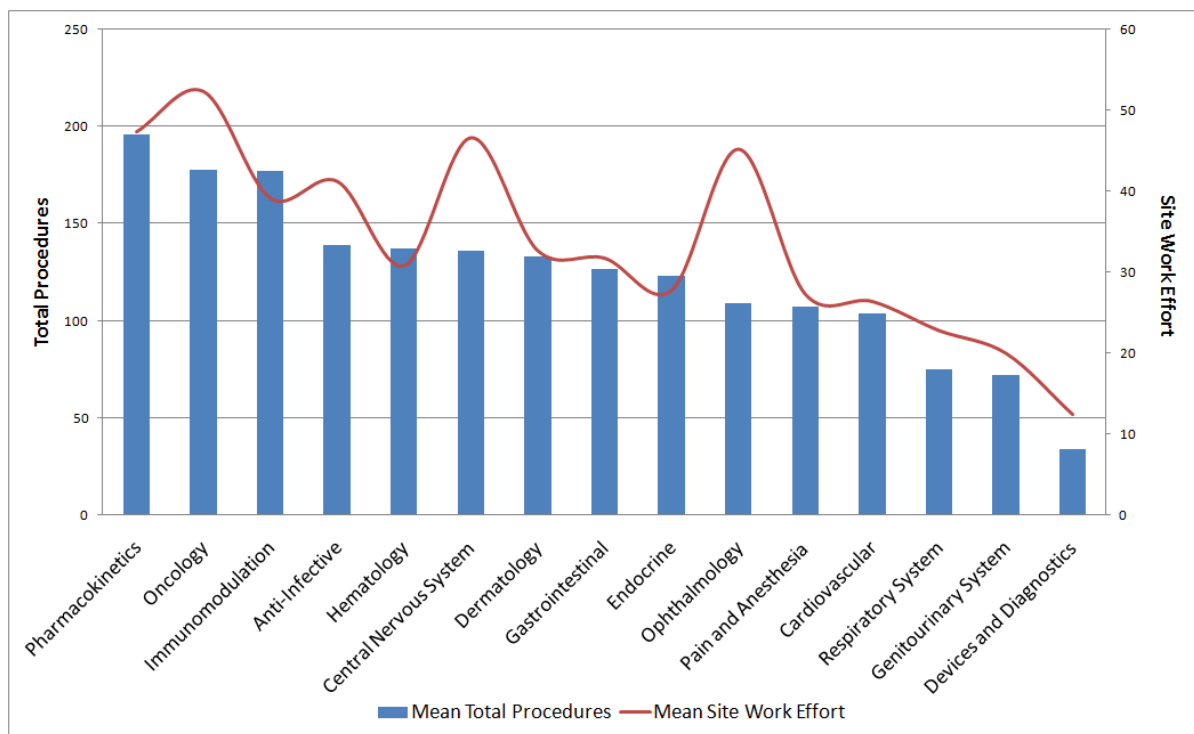
## Spotlight on Research Fees: Protocol Complexity

By Rafael A Campo

Protocol designs have become more complex. Not only has the total number of clinical procedures increased, but the relative effort necessary to execute the average procedure has also increased.<sup>1</sup> In the past, the best measure of protocol complexity was the total number of clinical procedures performed during the study.<sup>2</sup> This measure of complexity is no longer adequate. A new measure of complexity, termed Site Work Effort (SWE), takes into account the effort put forth by the physician and subject to complete each clinical procedure (Work Effort Units (WEU)).<sup>1,3</sup> Certain therapeutic areas are more affected than others by WEU. For example, although total procedure counts for Anti-Infective, Hematology and CNS trials are very similar, SWE is much higher for CNS and Anti-Infective than Hematology. The same difference can be seen with Ophthalmology versus Pain & Anesthesia.

### Total Clinical Procedures versus Site Work Effort (SWE)

(Worldwide, All Phases, All Therapeutic Areas, Industry-Sponsored)



Pharmaceutical and Biotechnology Studies, 2003-2007)<sup>4</sup>

## **Notes & References**

1. Getz K et al. Protocol Design Change and its Impact on Study Conduct Performance. American Journal of Therapeutics, Volume 15, No. 5, September/October 2008, pp 450–7.
2. Total Procedures: The number of unique procedures multiplied by their frequency during the duration of a protocol.
3. Site Work Effort (SWE): The product of Work Effort Units (WEUs) per unique procedure multiplied by the frequency that the procedure was conducted over the duration of a protocol.
4. Source: Medidata Grants Manager™, the PICAS® database

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