

BOTTOM LINE



Regular staff workload assessments help to ensure balance, optimize efficiencies, and improve retention.



Accurate workload measurement accounts for trial complexity.



The ASCO Clinical Trial Workload Assessment Tool assesses workload on a per protocol basis.

Management of a clinical research program is becoming increasingly challenging due to myriad of factors, including regulatory and administrative burdens and fewer available - yet more complex - trials. Site resources are often limited, so investigators and program managers must be able to use their staff as effectively and efficiently as possible. Workload assessments can compete with other important clinical trial management tasks, such as maintaining data quality, complying with protocols, meeting program accrual goals, and keeping within budget. To help ease this administration burden associated with clinical trial-associated workload, the American Society of Clinical Oncology Research Community Forum created the [ASCO Clinical Trial Workload Assessment Tool](#).¹

KEY CONSIDERATIONS, TIPS, AND BEST PRACTICES



Regular assessments are necessary to determine each staff member's clinical trial associated workload and the complexity of work they are able to manage. The resulting information can help a research program establish their own benchmarks, monitor trends and shifts, justify current staffing and the need to hire additional staff, assist with budget planning, provide metrics for staff performance, ensure workload balance, and ultimately improve staff satisfaction, potentially reducing staff burnout and turnover.¹

Measuring Workload

To effectively measure staff workload, consider the following best practices:

- ❑ Assess Complexity of Trial – Clinical trial associated workload cannot be measured solely by the number of patients enrolled and observed. Measurement of workload based on trial complexity scoring or trial-specific effort more accurately represents actual workload.¹ The [ASCO Clinical Trial Workload Assessment Tool](#) uses a 4 point protocol acuity rating scale, which distinguishes trials on a continuum from less complex trials (i.e., observational/registry trials) to very complex trials (i.e., multiple drug regimens and high degree of toxicity potential).
- ❑ Assess Balance of Workload – A regular assessment of workload across staff members enables research managers to ensure workload balance, optimize efficiencies, and improve staff satisfaction and retention.
- ❑ The [ASCO Clinical Trial Workload Assessment Tool](#) is designed to help research sites assess staff workload based on the complexity of research protocols and the number of patients assigned to staff. It can be used for the following key elements of assessing and managing clinical trial associated workload:
 - Assess staff workload on a per protocol basis,
 - Compare and redistribute research staff workload,
 - Identify staff-related accrual issues and opportunities for improvement,
 - Provide productivity data for annual staff performance review,
 - Re-evaluate current processes for improvements in efficiencies, and/or
 - Assess staffing needs and justify budget for staffing (for grant and/or institutional justification).

REFERENCES

1. Good MJ, Hurley P, Woo KM, et al. [Assessing Clinical Trial–Associated Workload in Community-Based Research Programs using the ASCO Clinical Trial Workload Assessment Tool](#). *J Oncol Pract* 12(5):e536-e547, 2016.

OTHER RESOURCES

- American Society of Clinical Oncology Research Community Forum. [ASCO Clinical Trial Workload Assessment Tool](#). Alexandria, VA; 2014.
- Good MJ, Lubejko B, Humphries K, et al. [Measuring Clinical Trial–Associated Workload in a Community Clinical Oncology Program](#). *J Oncol Pract* 9(4):211-215, 2013.
- Smuck B, Bettello P, Berghout K, et al. [Ontario Protocol Assessment Level: Clinical Trial Complexity Rating Tool for Workload Planning in Oncology Trials](#). *J Oncol Pract* 7(2):80-84, 2011.
- Fowler DR and Thomas CJ. Protocol acuity scoring as a rational approach to clinical research management. *Research Practitioner* 4(2):64-71, 2003.
- National Cancer Institute. [Assessing Clinical Trial Associated Workload \[Webinar\]](#). 2018.
- National Cancer Institute. [NCI Trial Complexity Elements & Scoring Model](#). 2016. *Note: link is to an automatically downloaded PowerPoint presentation.*
- James P, Bebee P, Beekman L, et al. [Creating an effort tracking tool to improve therapeutic cancer clinical trials workload management and budgeting](#). *J Natl Compr Canc Netw*, 9(11), 1228-1233, 2011.
- Kee AN. [Investigator responsibilities for clinical research studies: Proper staffing can ensure an investigator is compliant](#). *J Med Pract Manag* 26(4):245-247, 2011.



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