

# Staff Effort Estimate Calculator: A Successful Multisite Program Budget and Staffing Tool

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# Background

A successful multisite program requires an accurate estimate of staff effort in order to sufficiently support funding proposals. The program must define how its operations integrate and differentiate from existing clinical trial office operations. We developed a budget estimate tool to provide funding proposal justification and assist in projecting multisite program staffing needs. Here, we detail how our multisite operational plan and staff effort estimate calculator have become invaluable tools for the MCW Cancer Center Clinical Trials Office Multisite Program.

### Goals

- Completed multisite program operations plan and staff effort estimate calculator
- Received funder feedback about multisite budget
- Obtained approved multisite budget proposal(s)
- Gained approval for staff hiring requests from human resources

### Methods

- Define multisite program structure and staff roles in an operational plan
- Develop Excel-based multisite budget estimator
- Utilize estimator for multisite funding proposals and staff hiring decisions

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**Download calculator (Excel)** 

www.mcw.box.com/v/MCWcalculator

### Acknowledgements

# Results

The MCW Multisite Program operations plan and staff effort estimate calculator (Excel-based) were created in 2017. After implementation, all eight multisite funding proposals with an approved letter of intent (LOI) and completed funder fair market value (FMV) analysis obtained multisite budget approval, totaling over \$9.7 million (\$1.4 million dedicated to multisite), although a few are still pending review. Funder feedback required only minor clarifications. These were addressed by sharing details from the estimator. The MCW Department of Human Resources approved two program staff positions using data generated from the estimate calculator. In addition, the tool served as an important source in the administrative decision to pause acceptance of new multisite studies during the height of the COVID-19 pandemic.

### Conclusions

The staff effort estimate calculator was successfully utilized to obtain funding for multisite program studies and to justify the need for new staff positions.

The calculator allows for constant refinement based on team feedback (e.g., perceived effort), the impact of process changes, and experience (e.g., external site declining participation or slower than anticipated accrual rates). It is crucial that study-related data input into the estimator (e.g., accrual goals from statisticians, estimated time to enrollment completion, duration of patient treatment and follow-up) is accurate. These elements have greater impact on the budget than the specific estimated effort assigned to various tasks. After initial implementation of the estimator, we discovered that scrutiny of this sensitive study-related data input was possible through directed questions to the study PI and statistician, in addition to applying more liberal time windows (e.g., average treatment or follow-up duration).

By calculating the full-time equivalent (FTE) numbers of active and pending multisite studies, along with the categories of tasks assigned to various positions, we have been able to assess current and future staffing needs. One current limitation is validation of estimated effort to actual effort. This is a future goal, which may be accomplished through the use of our actual effort-tracking billing system, whereby staff enter their daily effort according to the tasks on which they worked. We can then correlate that effort with the various categories of the estimator.

	Effort Budget C			Time to complete enrollment (with other											
tudy		Sites (including MCW)	X	sites)  Time for patient to complete treatment	X yrs										
rotocol used		Accrual goal (per stats)	x	(full tx length of 1 patient)	Xmo/yr (Xcyo	cles) for X sub	jects, X m	o/yr maintena	nce for ~X subjects						
		Total time to budget (years based on E2-E4)	x	Time for patient to complete follow up (max length of follow up)	X yr (FU data	a after tx, un	til progres	sion or anothe	r therapy)						
						Hourly Rate	ENTER		Multiplied per X	Multiplied					
Effort Tracking Category	General Category	Specific Category	Specific Category 2	Specific Category 3	Hours per	Hours per staff	Hours	Hours/cost per	number or frequency of anticipated	per X	Multiplied per X number of	Multiplied per X number of staff	number of	Total hours over entire	Study Cost
cutegory ▼	▼	~	₩1	<b>▼</b> ↑	paue ▼	mem	pc. ▼	tasiy ou	instances (total or	site	ye ars	membe	patients	stud	_
Development	Funder LOI and approval process management							128	1		1			128	#VALUE!
Site Startup	Protocol development (multisite)		Initial					128	1		1			128 96	#VALUE!
	Data forms development		Amendments					16	1		6			1	#VALUE!
	(multisite specific)  IND Management	Start Up	Initial  Amendments  Cross reference request from funder					1	1					32 16 1	#VALUE! #VALUE!
	IND Management	Start Up	IND application (multisite support) IND forms (1572, etc.) from sites					12 32	1 1					12 32	#VALUE! #VALUE!
			Logisitics set up with drug manufacturer and admin systems (shared folder, funder portal)					8	1					8	#VALUE!
	Site feasibility	CDA Site Feasibility Form	Sites Submission				1	8	1 1	3				2	#VALUE! #VALUE!
		Site reasisting roun	Review/acceptance				1		1	3				2	#VALUE!
		Site Qualification Review	Travel (if applicable, onsite)	Flight (round trip)				\$657.47	0	3		2			\$0.00
			Communications and review (onsite or offsite)	Hotel (per night)			8	\$286.64	0 1	3 3		2		24	\$0.00 #VALUE!
	Regulatory documents		Follow up	Follow up letter			1		1	3				3	#VALUE!
	(consent, protocol, ancillary documents, amendments,														
	approval letters, site SOPs, training and delegation log,														
	financial disclosures, etc.)	Start Up	Documents sent to sites  Documents collected (e.g., LCF, IAA, etc.)	Preparation and Submission Collection			128 128		1	3 3				384 384	#VALUE!
				Filing and submission/follow-up with regulatory agencies			8		1	3				24	#VALUE!
	Activation	Activation Letter Review	Review of all necessary requirements Confirmation with administrative staff	Administrative sign off			64 1		1	4 3				256 3	#VALUE! #VALUE!
	Regulatory documents			Activation Letter			1		1	3				3	#VALUE!
	(consent, protocol, ancillary documents, amendments,														
Regulatory	approval letters, site SOPs, training and delegation log,		Document changes (general trial amendments, staff												
	financial disclosures, etc.)	Maintenance	changes, and/or site specific changes/requests)	Preparation and submission Review and negotiation of changes			32 32		1	3	5			480 480	#VALUE!
				Filing and submitting to regulatory agencies (e.g., sIRB and to local site IRBs)			8		1	3	5			120	#VALUE!
Study Oversight			Special circumstances requiring additional monitoring (e.g. first patient after SIV, SAE, site	,											
	Staff management	Staff management	deficiencies, etc.)				1		1	3	6			18	#VALUE!
	IND Management	Maintenance	External Safety Letters	Review/signoff of sponsor PI (if actionable)				1	2		6			12	#VALUE!
				Report to participating sites (if actionable)				1	2	3	6			36	#VALUE!
				Sponsor follow up with regulatory agencies (if actionable)				1	2	3	6			36	#VALUE!
			Internal Safety Reports (SAEs and AESIs)	Review from Multisite Team/Site Report to drug manufacturer				4	10 10		6			240 60	#VALUE!
				Review/signoff of sponsor PI Report to FDA/sIRB/DSMC				2	10		6			120	#VALUE! #VALUE!
				Report to participating sites				1	1	4	6			24	#VALUE!
				Follow up report to FDA/sIRB/DSMC/sites/funder/etc.				1	1		6			6	#VALUE!
			Amendments Findings from other studies review/signoff	1 org sindy osmer stees rained a cie.				16 1	1		6			96 6	#VALUE!
			Increase in rate review/signoff  Annual report					1 4	1		6			6 24	#VALUE!
	Study progress tracking	Study updates	Screening log collection Site/study accrual rate/goals				0.25		1 4	3	6			4.5 72	#VALUE!
			Low accrual actions Newsletter				1	1	2	3	6			3 12	#VALUE!
		Suspension Closure	Report to participating sites  Report to participating sites	Report to participating sites Report to participating sites				8 2	1					8 2	#VALUE!
Education	Education	OnCore	Recorded study specific OnCore training	Set up with study team				16	1					16	#VALUE!
				Performance time and maintenance				2	1					2	#VALUE!
			Updates, individual follow up, and staff change training			2			10					20	#VALUE!
		Misc	Additional ad hoc training (as needed, e.g. SAEs, specific issues, fixes, etc.)			_	64		10	4				256	#VALUE!
		SIV Closeout procedures	Recorded SIV	Set up with study team			8	32	1	3				32	#VALUE! #VALUE!
Monitoring Visit	Lligh rick		Travel - if MCW performed vs. contracted partner (if utilized, e.g. CTSI, CRO, etc.)	Flight (round trip)				\$657.47	0	3	6				\$0.00
Staff Management	High risk	Onsite (if applicable)	Onsite review time	Hotel (per night)			16	\$286.64	0	3	6			0	\$0.00 \$0.00 #VALUE!
			Follow up	Follow up letter/actions  Corrective action plan collection and review			1 1		0	3	6			0	#VALUE! #VALUE!
		Remote	Routine remote call/WebEx and outstanding data reports	Preparation			8		4	4	5			640	#VALUE!
		nanote	ιεμυτιδ	Preparation  Performance time  Follow up			0.5 8		4 4	4 4	5			40	#VALUE! #VALUE!
		Data	Data and source verification	Eligibility/baseline Consent and reconsent	8 2		J			-			60 60	480 120	#VALUE! #VALUE!
				Key data points  Data lock (site prep, data lock)	8			40	2				60	480	#VALUE! #VALUE!
		Staff management	Staff accounts/onboarding/maintanence Shared folder management			2			2 2	3		4 4		48	#VALUE! #VALUE!
			Staff regulatory items (Human Subjects Protection												T. L. C.
			training, CAP/CLIA, staff contacts, CV, licenses, etc.)			0.25			4	3		30		90	#VALUE!
Eligibility		Central eligibility review prior to enrollment	Review/signoffs		2								60	120	#VALUE!
Meetings		Meetings	With Study PI and Protocol Team  Internal Multisite Team					1	26 52		3			78 156	#VALUE!
													TOTAL Direct Indirect Cost	6823.5	#VALUE!
													I I I I I I I I I I I I I I I I I I I		VALUE:

Figure 1: Multisite Effort Budget Calculator (example only, actual hours/FTE differs from this screenshot)