Benchmarks for statistical effort on clinical trials

Described are global expected % effort of faculty and staff on clinical trial applications*. Very general examples are provided below. The underlying assumption is a team approach with constant interaction. *The overarching principle that guides the requested effort is the complexity of the design, data structure and analyses.* Note, these do not include effort for database development which would increase the level of requested effort.

Large scale clinical trials (e.g., multi-site RCTs):
The biostatistics effort would be for all the usual activities on a clinical trial: assist in preparing the grant; develop the protocol; assist with CRF endpoint capture; collaborate with programmers to set up the trial database; monitor the trial for accrual, adverse events, data acquisition; conduct interim analyses; prepare DSMB reports; final analyses; and manuscript preparation. An additional fee of $5,000 should be budgeted for preparation of de-identified datasets for sharing, as per NIH sharing guidelines (multiple versions potentially required with extensive supporting documentation).

R01 type	General design & analysis structure		Faculty effort/yr	Staff effort/yr
	Basic 2 arm, single site, simple endpoint	No interim, only final analysis	10-15%	10-20%
		Interim monitoring & analyses	15-20%	20-30%
	+multi-site	No interim, only final analysis	10-20%	15-25%
		Interim monitoring & analyses	15-25%	20-35%
	Complex/adaptive designs	Constant monitoring, interim & final analyses	20-30%	30-50%

Smaller scale IITs (e.g., early phase I/II):
The biostatistics effort would be for all the usual activities on a clinical trial: assist in preparing the LOI & develop the protocol; grant; assist with CRF endpoint definitions; collaborate with programmers to set up the trial database; monitor the trial for accrual, adverse events, data acquisition; conduct interim analyses; prepare monitoring reports; final analyses; and manuscript preparation.

R21, in-house or pharma	General design & analysis structure		Faculty effort/yr	Staff effort/yr
	Multi-dose level phase I	Basic CRM design	5-10%	10-20%
		Innovative/drug combinations	10-20%	15-25%
	Basic single arm phase II design	Fixed or staged	5-10%	10-15%
	Multi-arm randomized phase II; multi-site	Futility/interim analyses	10-15%	15-20%

** Based upon supporting information from UVA, Medical University of South Carolina, Ohio State University, University of Minnesota, Wake Forest University, Duke University, University of Pittsburgh, 'Ten Essential Practices for Developing or Reforming a Biostatistics Core for a NCI Designated Cancer Center',(JNCI Cancer Spectrum, Volume 2, Issue 1, January 2018*