

Task	Unit	# of Units	Hrs per unit	Total Cost (\$)
Pre-study planning and development of tracking systems	per study	1	643	\$ 137,848
Project specific training	per study	1	961	\$ 192,385
Produce/critique protocol, CRF and informed consent	per study	1	372	\$ 64,372
Regulatory Submissions	per IND/CTX/CTA compile	6	60	\$ 132,830
Site start-up	per site	59	57	\$ 498,255
Pre-study visits	per pre-study visit	53	16	\$ 103,822
Site initiation visits	per site initiation visit	59	23	\$ 168,597
Investigator meeting preparation and attendance	per investigator meeting	3	485	\$ 253,249
Client interactions	per month	16	102	\$ 425,200
Project management	per month	16	440	\$ 1,571,408
Project close-out activities	per study	1	149	\$ 14,078
On-site monitoring visits	per on-site monitoring visit	295	17	\$ 624,091
Close-out visits	per close-out visit	59	18	\$ 130,244
Site management	per site per month	441	8	\$ 456,688
Drug supply start-up and management	per month	16	0	\$ 579
Safety management	per month	8	34	\$ 67,611
Data review, coding and query resolution	per page	0	0	\$ 25,898
<b>Clinical Fees</b>				\$ 2,839,060
<b>Feasibility costs</b>				\$ 38,000
<b>24 Hour Medical Cover</b>				\$ 24,830
<b>0.8% Accompanied field visits</b>				\$ 38,482
<b>Project Management/Site Management</b>				\$ 2,028,096
<b>Sub Total</b>				\$ 4,968,468
<b>OOPs</b>				\$ 826,835
<b>Grand Total</b>				\$ 5,795,303

## EXAMPLE

### Operational and administrative costs of a PHASE II trial across 65+ different clinical sites and 12+ countries

Total outside US clinical trial costs: **US\$ 5,795,303**

Weighted VAT and associated tax rate across 12+ countries and 65+ sites (re: per site/ per country budget) **17.91%**

Maximum VAT and associated taxes **US\$ 1,037,939**