

How Much is Your IND Going to Cost?

Michelle Higgin, Ph.D.
Principal, PharmaDirections, Inc.

Drug development budgeting (over)simplified.

Easy: Its **\$3M** for a basic chronic, orally administered small molecule program using rats and dogs as the toxicology species and assuming *no existing staff* of toxicologists, process chemists, formulators and regulators just waiting for something to do. However, few programs actually meet these basic criteria, and many factors will impact this number, up and down. They include:

Factor	Cost (\$\$)	Comment
Need to use non-human primates (monkeys)		Add ~\$250K
Formulation is IV		Add \$150-\$250 for sterile manufacturing
API is commercially available with a DMF		Subtract \$300 – \$500K
Inhalation program	 	Keep on adding ...
Sweat equity		If you have the diverse technical competence and can do the management, go for it and save as much as 400K
Acute administration only		Save \$100K or so.
Oncology indication		No <u>genotox</u> or safety pharmacology studies needed. Save \$200K
Therapeutic biologic		CMC costs go way up. Add \$500K
Peptide	-----	Add for CMC work but save on DMPK, break even.
	 	API costs are extremely variable. estimate –get a quote!
		toxicology program \$1.5M

but that is all it is. A good budget effectively. One use something unexpected recent in the budget so you other activities.