

2. Clinical Trials

Clinical trials are the result of promising new biotech and biomedical research. Once a new drug has been developed and tested on animals, the next step is clinical trials. Phase I clinical trials are conducted to confirm that a drug is not harmful. Phase II clinical trials measure the drug's effectiveness, while Phase III clinical trials further confirm a drug's efficacy, compare it to alternate treatments, and evaluate side effects.

a) Representative Operation – Clinical Trials Management

The representative operation modeled is a clinical trials management firm. As illustrated in Exhibit 3.50, this operation is characterized by:

- A leased office/laboratory facility. (Because the representative operation is a management firm, hospital/clinical operations and related costs are not included in the operational model.)
- A workforce consisting primarily of clinical trial administrators
- Activities that mostly represent tax-eligible R&D activities

The business is assumed to operate as a stand-alone profit center.

b) International Results

International results are illustrated in Exhibit 3.51. These results reflect the combined impact of 27 location-sensitive cost components applied to the modeled operation. Detailed results, by key cost component, are presented in Exhibit 3.52.

c) Selected Cities

Exhibit 3.53 profiles results for selected cities, by country, from among the 102 cities featured in this report. Results for all other featured cities can be found in Chapter 4, Exhibit 4.10.

EXHIBIT 3.50 – CLINICAL TRIALS	
Clinical Trials Management – Summary of Operating Parameters	
Facilities Requirements	
Class A office space leased	10,000 ft ² (929 m ²)
Other Initial Investment Requirements	
Office equipment – US \$'000	\$150
R&D equipment – US \$'000	–
Inventory – US \$'000	–
Equity financing - % of project costs	85%
Workforce	
Management	3
Sales and administration	9
Dedicated product development	38
Unskilled laborers	0
Other	–
Total employees	50
Energy Requirements	
Electricity monthly consumption/peak demand	50,000 kWh and 195 kW
Other Annual Operating Characteristics	
Sales at full production – US \$'000	\$5,900
Operating costs - % of sales	5%
Investment in tax-eligible R&D - % of sales	60%

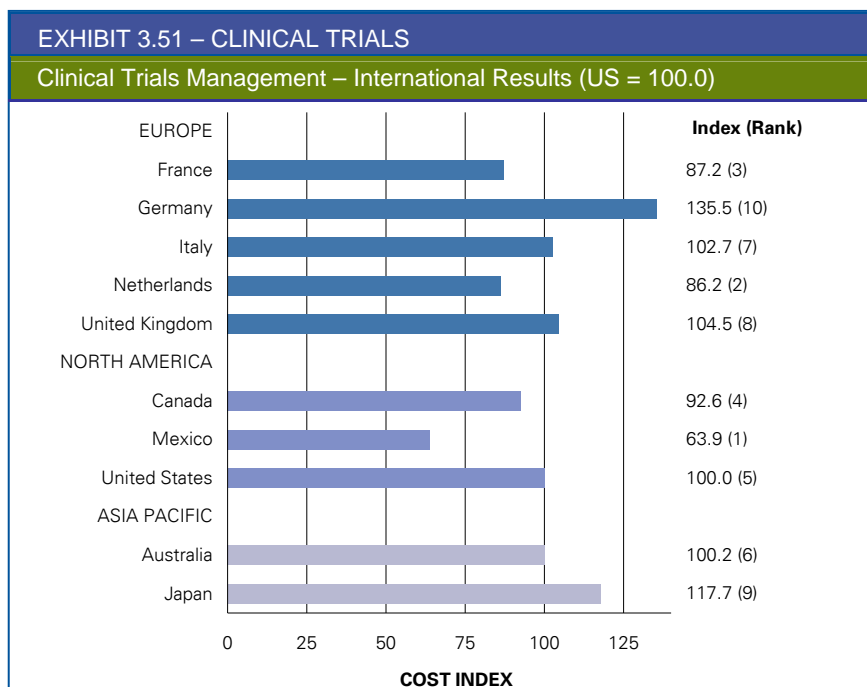


EXHIBIT 3.52 – CLINICAL TRIALS

Clinical Trials Management – Costs, by Major Component, US \$'000

	Europe					North America			Asia Pacific	
	France	Germany	Italy	Netherlands	UK	Canada	Mexico	US	Australia	Japan
Revenues	4,990	4,990	4,990	4,990	4,990	4,990	4,990	4,990	4,990	4,990
Costs										
- Salaries & Wages	2,537	3,854	2,494	3,269	3,268	3,122	1,528	2,941	2,923	3,317
- Statutory Plans	1,106	611	818	396	395	193	206	250	371	324
- Other Benefits	481	775	711	996	890	594	325	658	658	911
- Total Labor & Benefits	4,124	5,240	4,024	4,660	4,554	3,908	2,058	3,849	3,952	4,552
- Facility Lease	238	200	144	205	357	291	185	227	345	374
- Transportation	-	-	-	-	-	-	-	-	-	-
- Utilities	55	87	106	64	65	55	102	50	72	81
- Interest & Depreciation	47	463	13	(100)	50	(58)	(469)	(3)	(5)	145
- Non-income Taxes	10	-	53	3	-	20	17	25	-	8
- Location-insensitive Costs	250	250	250	250	250	250	250	250	250	250
Profit Before Income Tax	266	(1,250)	399	1,356	(285)	525	2,846	593	377	(419)
- Income Taxes ¹	(708)	-	139	(1,110)	(463)	(199)	798	208	-	13
Effective Rate	(265.8%)	n/a	34.9%	n/a	n/a	(38.0%)	28.0%	35.2%	n/a	n/a
After-tax Profit	974	(1,250)	260	1,018	178	724	2,048	384	377	(432)
Total Annual Costs	4,016	6,240	4,730	3,972	4,812	4,266	2,942	4,606	4,613	5,422
Index (US=100.0)	87.2	135.5	102.7	86.2	104.5	92.6	63.9	100.0	100.2	117.7
Rank	3	10	7	2	8	4	1	5	6	9

¹ Income taxes may be either positive or negative, irrespective of whether profit before income tax is positive or negative, due to the impact of specific expense deduction rules, minimum taxes, and refundable income tax credits. Effective tax rates are not shown where results are not meaningful because of low profitability.

EXHIBIT 3.53– CLINICAL TRIALS

Clinical Trials Management – Results for Selected Cities, by Country

Country	City	Index	Rank Among 102 Cities	Country	City	Index	Rank Among 102 Cities
France	Paris	96.0	35	Canada	Halifax	77.5	11
	Toulouse	82.2	13		Montreal	85.0	15
Germany	Erlangen	133.8	100	Toronto	100.5	60	
	Frankfurt	147.0	102	Vancouver	106.3	80	
Italy	Livorno	102.6	69	Mexico	Guadalajara	67.7	4
	Vicenza	102.1	65		Monterrey	71.9	5
Netherlands	Utrecht	86.2	16	United States	Boston	112.1	89
United Kingdom	London	138.4	101		Indianapolis	103.3	71
	Plymouth	99.5	53		Minneapolis	106.3	81
Australia	Adelaide	94.4	28		New York City	122.3	98
	Sydney	106.8	82		North Virginia (Metro DC)	103.8	73
Japan	Fukuoka	116.2	92		Philadelphia	105.4	76
					Providence	102.3	66
					San Diego	105.8	77
			Trenton	114.5	90		