

How to budget a clinical trial

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Budget

Recently sitting in a coffee house talking casually about a possible future clinical trial:

a colleague from our hospital took out her phone, punched in a few numbers and said: “monitoring for this trial will cost about €35.000,-”

Can it be that easy?



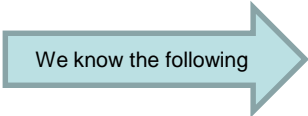
Steps of action

1. Know your key assumptions – create a rough estimate
2. Build a more detailed budget

Key assumptions

- Study phase and type, Indication

We know the following



Patient numbers required
Investigational product /Placebo
Patient abundance (length of recruitment)

Site selection
Monitoring
Insurance
Drug management
Pharmacovigilance
Data management

Key assumptions

- Study protocol (draft/synopsis)

We know the following

Number of patients needed

Number of sites needed

Trial length (end points, accrual rate)

Screening failure rate

Schedule of events

Types of assessment (eg. ECG special report)

Types of procedures

Departmental involvement (specialist)

Sample collection

Translational/exploratory research

Fixed costs



Site costs (start-up fees, overhead)

EC/CA fees

Admin fees (Study Coordination)

Budget

What funding are we using in AGO-Austria?



“Pure
academic“



“Non-
commercial“



Pharma

What funding is possible or necessary?



**“Pure
academic”**

- No funding; all in-kind services



**“Non-
commercial”**

- (limited) budget from pharma or public sources, some in-kind services, SOC, special rates at the sites, major contribution from AGO-trial center



Pharma

- Major contribution or completely funded by Pharma; contract research



Rough estimate



ORACLE
HEALTH SCIENCES

Creating An Accurate
Clinical Trial Budget in
Under 10 Minutes

Kate Shelton
Senior Sales Consultant

Is the trial feasible?

YES!

The trial is going to happen!

From rough estimate to detailed budget



Building the budget

All the before mentioned key aspects need to be put into the calculation.

- Needs to be somewhat flexible
- If not in the budget, sponsor is not obligated to pay
- Must cover all costs
- There are many variables to consider.

Building the budget

SOPs, Worksheets

Depending on the trial type and involvement

Conduct / administrative

- Roles and responsibilities
- Hourly calculation
- Budget worksheet with Modules

Site / patient fee

- Schedule of events

Building the budget

Conduct / administrative – WORKSHEET 1

- Roles and responsibilities - who is responsible for what

ROLES AND RESPONSIBILITIES CHECKLIST						
	Note details of roles and responsibilities for 3 rd party are recorded for information purposes only. 3 rd party is not party to agreement. [This can be deleted where not applicable e.g. no 3 rd parties involved.]	Leading Group / Sponsor	Group	Group Clinical Centres	Monitoring CRO*	eCRF CRO*
<i>Mark appropriate Boxes with an "X" Underlined "X" stands for: Information only</i>						
1	PROTOCOL, Country/ Group Specific Appendices					
1.	Protocol preparation					
2.	Protocol review	X				
3.	Protocol printing					
4.	Protocol distribution to the groups					
5.	Preparation of country/group specific appendices					
6.	Protocol distribution to clinical centres					
7.	Protocol country/group specific appendix distribution to clinical centres					
2	PROTOCOL AMENDMENTS					
1.	Amendment preparation					
2.	Amendment review					
3.	Amendment printing					

Building the budget

Conduct / administrative – WORKSHEET 2

- Possible to calculate approximate hourly costs for limited work loads

		<i>Resource Type</i>	<i>Hourly Rate (EURO)</i>	<i>BUDGETED Units</i>	<i>Cost (EURO)</i>
1. Trial design & preparation / Study protocol					
1.	Protocol preparation	PI	10,00 €	40,0	400,00 €
		PM	10,00 €	40,0	400,00 €
2.	Protocol review	PI	10,00 €	10,0	100,00 €
		PM	10,00 €	10,0	100,00 €
3.	Protocol printing	Sekr	10,00 €	2,0	20,00 €
4.	Protocol distribution to groups	PM	10,00 €	0,5	5,00 €
5.	Preparation of country/group specific appendices	PI	10,00 €	5,0	50,00 €
		PM	10,00 €	5,0	50,00 €
6.	Protocol distribution to clinical centers	PM	10,00 €	0,5	5,00 €
7.	Protocol country/group specific appendix distribution to clinical centers	PM	10,00 €	0,5	5,00 €
AMENDEMENTS					
1.	Amendment preparation	PI	10,00 €	10	100,00 €
		PM	10,00 €	10	100,00 €
2.	Amendment review	PI	10,00 €	3	30,00 €
		PM	10,00 €	3	30,00 €
3.	Amendment printing	Sekr	10,00 €	3	30,00 €
				Total	1.425,00 €

Building the budget

Conduct / administrative

- Hourly costs / Admin staff costs ✓
- Budget worksheet w/modules

Site / patient fee

- Schedule of events

Building the budget: worksheet 3

MODULE 1 Preparation and Conduct of Clinical Trial						
total	Recruitment			Follow-Up		
	Year 1	Year 2	Year 3	Year 4	Year 5	
Hourly calculation according to RR	€ 169.000,00	€ 47.000,00	€ 25.000,00	€ 25.000,00	€ 47.000,00	
Budget and Contract Negotiation	€ 7.500,00	€ 7.500,00				
Protocol Development / Amendments	€ 3.500,00	€ 2.500,00		€ 1.000,00		
ICF/IRIS Development /Amendments	€ 2.000,00	€ 1.500,00		€ 500,00		
Development & Shipment of Investigator Site File**	€ 1.250,00	€ 1.250,00				
Preparation and Maintenance of TMF (material, working hours)**	€ 9.300,00	€ 2.500,00	€ 1.700,00	€ 1.700,00	€ 1.700,00	
Central histopathological review	€ 9.000,00	€ 3.000,00	€ 3.000,00	€ 3.000,00		
Shipping costs tumor slides/blocks**	€ 47.925,00	€ 15.975,00	€ 15.975,00	€ 15.975,00		
Shipping Questionnaires (if not on-line only)**	€ 6.750,00	€ 2.250,00	€ 2.250,00	€ 2.250,00		
Shipping costs lab/TR **	€ 180.000,00	€ 60.000,00	€ 60.000,00	€ 60.000,00		
Materials TR, Shipment	€ 7.500,00	€ 2.500,00	€ 2.500,00			
	€ 443.725,00	€ 145.975,00	€ 110.425,00	€ 111.925,00	€ 26.700,00	€ 48.700,00
						MODULE 1
						€ 443.725,00
MODULE 2 Monitoring						
total	Recruitment			Follow-Up		
	Year 1	Year 2	Year 3	Year 4	Year 5	
Preparation and Updating of Monitoring Plan	€ 2.100,00	€ 2.100,00				
Site Initiation Visits	€ 11.000,00	€ 11.000,00				
On-Site Monitoring Visits	€ 90.000,00	€ 20.000,00	€ 20.000,00	€ 20.000,00	€ 15.000,00	€ 15.000,00
Remote Monitoring Visits	€ 50.000,00	€ 10.000,00	€ 10.000,00	€ 10.000,00	€ 10.000,00	€ 10.000,00
Close-Out Visits	€ 11.000,00					€ 11.000,00
Monitor Training	€ 2.000,00	€ 2.000,00				
Audit Preparation and Attendance	€ 2.000,00	€ 2.000,00				
Preparation and Conduct of Monitoring - Mgmt	€ 15.000,00	€ 5.000,00	€ 2.000,00	€ 2.000,00	€ 3.000,00	€ 3.000,00
	€ 183.100,00	€ 52.100,00	€ 32.000,00	€ 32.000,00	€ 28.000,00	€ 39.000,00
						MODULE 2
						€ 183.100,00
MODULE 3 Meetings						
total	Recruitment			Follow-Up		
	Year 1	Year 2	Year 3	Year 4	Year 5	
Telephone Conferences**	€ 4.501,00	€ 2.500,00	€ 500,00	€ 501,00	€ 500,00	
Preparation of Investigator Meeting**	€ 3.200,00	€ 3.200,00				
DSMC Meetings**	€ 10.000,00	€ 5.000,00		€ 5.000,00		
	€ 17.701,00	€ 10.700,00	€ 500,00	€ 501,00	€ 5.000,00	€ 500,00
						MODULE 3
						€ 17.701,00
MODULE 4 Fees and Payments						
total	Recruitment			Follow-Up		
	Year 1	Year 2	Year 3	Year 4	Year 5	
Set-up-fee Site, Pharmacy, Laboratory	€ 120.000,00	€ 120.000,00				
ENGOT Fee	€ 10.000,00	€ 10.000,00				
Fees for Competent Authority	€ 7.500,00	€ 7.500,00				
Fees to Ethic Committees and Local Authorities	€ 14.000,00	€ 10.000,00	€ 1.000,00	€ 1.000,00	€ 1.000,00	€ 1.000,00
Fees for DSUR/ES**	€ 5.000,00	€ 1.000,00	€ 1.000,00	€ 1.000,00	€ 1.000,00	€ 1.000,00
Patient Insurance	€ 225.000,00	€ 75.000,00	€ 75.000,00	€ 75.000,00		
Central histopathological review	€ -					
Shipping costs tumor slides/blocks**	€ 47.925,00	€ 15.975,00	€ 15.975,00	€ 15.975,00		
Shipping Questionnaires (if not on-line only)**	€ 6.750,00	€ 2.250,00	€ 2.250,00	€ 2.250,00		
Shipping costs lab/TR **	€ 180.000,00	€ 60.000,00	€ 60.000,00	€ 60.000,00		
Materials TR, Shipment	€ -					
	€ 616.175,00	€ 301.725,00	€ 155.225,00	€ 155.225,00	€ 2.000,00	€ 2.000,00
						MODULE 4
						€ 616.175,00
MODULE 5 Data management, IT and Pharmacovigilance						
total	Recruitment			Follow-Up		
	Year 1	Year 2	Year 3	Year 4	Year 5	
Data management	€ 400.000,00	€ 75.000,00	€ 75.000,00	€ 75.000,00	€ 100.000,00	
eCRF development and support	€ 390.000,00	€ 150.000,00	€ 60.000,00	€ 60.000,00	€ 60.000,00	€ 60.000,00
User und Data administration	€ 296.800,00	€ 240.000,00	€ 14.200,00	€ 14.200,00	€ 14.200,00	€ 14.200,00
Pharmacovigilance	€ 120.000,00	€ 24.000,00	€ 24.000,00	€ 24.000,00	€ 24.000,00	€ 24.000,00
	€ 1.206.800,00	€ 489.000,00	€ 173.200,00	€ 173.200,00	€ 173.200,00	€ 198.200,00
						MODULE 5
						€ 1.206.800,00

Modules:

- Preparation and conduct of the clinical trial
- Fees (start-up per site, ENGOT, etc.) and Payments
- Monitoring
- Drug management
- Data management
- IT
- Pharmacovigilance
- Meetings
-

Building the budget: worksheet

Conduct / administrative

Preparation and Conduct of Clinical Trial

	total	allocation				
		Recruitment			Follow-Up	
		Year 1	Year 2	Year 3	Year 4	Year 5
Hourly calculation according to RR	€ 169.000,00	€ 47.000,00	€ 25.000,00	€ 25.000,00	€ 25.000,00	€ 47.000,00
Preparation and Maintenance of TMF (material, working hours)	€ 9.300,00	€ 2.500,00	€ 1.700,00	€ 1.700,00	€ 1.700,00	€ 1.700,00
Development & Shipment of Investigator Site File	€ 1.250,00	€ 1.250,00				
Budget and Contract Negotiation; legal fee	€ 7.500,00	€ 7.500,00				
Central histopathological review	€ 9.000,00	€ 3.000,00	€ 3.000,00	€ 3.000,00		
Shipping costs tumor slides/blocks	€ 47.925,00	€ 15.975,00	€ 15.975,00	€ 15.975,00		
Shipping Questionnaires	€ 6.750,00	€ 2.250,00	€ 2.250,00	€ 2.250,00		
Shipping costs lab/TR	€ 180.000,00	€ 60.000,00	€ 60.000,00	€ 60.000,00		
Materials TR, Shipment	€ 7.500,00	€ 2.500,00	€ 2.500,00	€ 2.500,00		
	€ 438.225,00	€ 141.975,00	€ 110.425,00	€ 110.425,00	€ 26.700,00	€ 48.700,00

Building the budget

Conduct / administrative

- Hourly costs / Admin staff costs
- Budget worksheet w/modules



Site / patient fee

- Schedule of events

Building the budget

Site payment / Patient fee

Do not forget start-up fee, storage fee, laboratory

AND

Calculate like if all patients would complete all cycles.

Buffer for....

Consider hidden/unexpected costs

- Delayed start
- Increased salaries and operating costs over time
- Travel
- Unscheduled visits
- overhead-costs of sites
- Additional study materials (e.g.: kits, printing)
- Audits
- Amendments
- Insurance
- Software license fees
- Storage fees
-

What if ...

This is what your budget shows

but

this is what you have...



Where to reduce costs?

In a non-commercial trial you can consider to ...

- Standard of care
- in-kind contribution
- Outsource tasks to pharma:
 - IMP management/shipment
 - Printing /Shipping / Study materials
- In-house/remote monitoring instead of CRO
- Open source data system
- Site selection – negotiations with sites
- Meetings in combination with other meetings
- Share tasks with participating sites/groups

Some costs are independent of pharma financed or non-commercial trial and always need to be calculated for!

Take home message

The devil is in the detail – know your trial!



With SOPs, worksheets - > One size fits most

And ...

NO monitoring was not covered with €35.000,-

Thank you!