

REDEFINING ANTIBODY THERAPIES



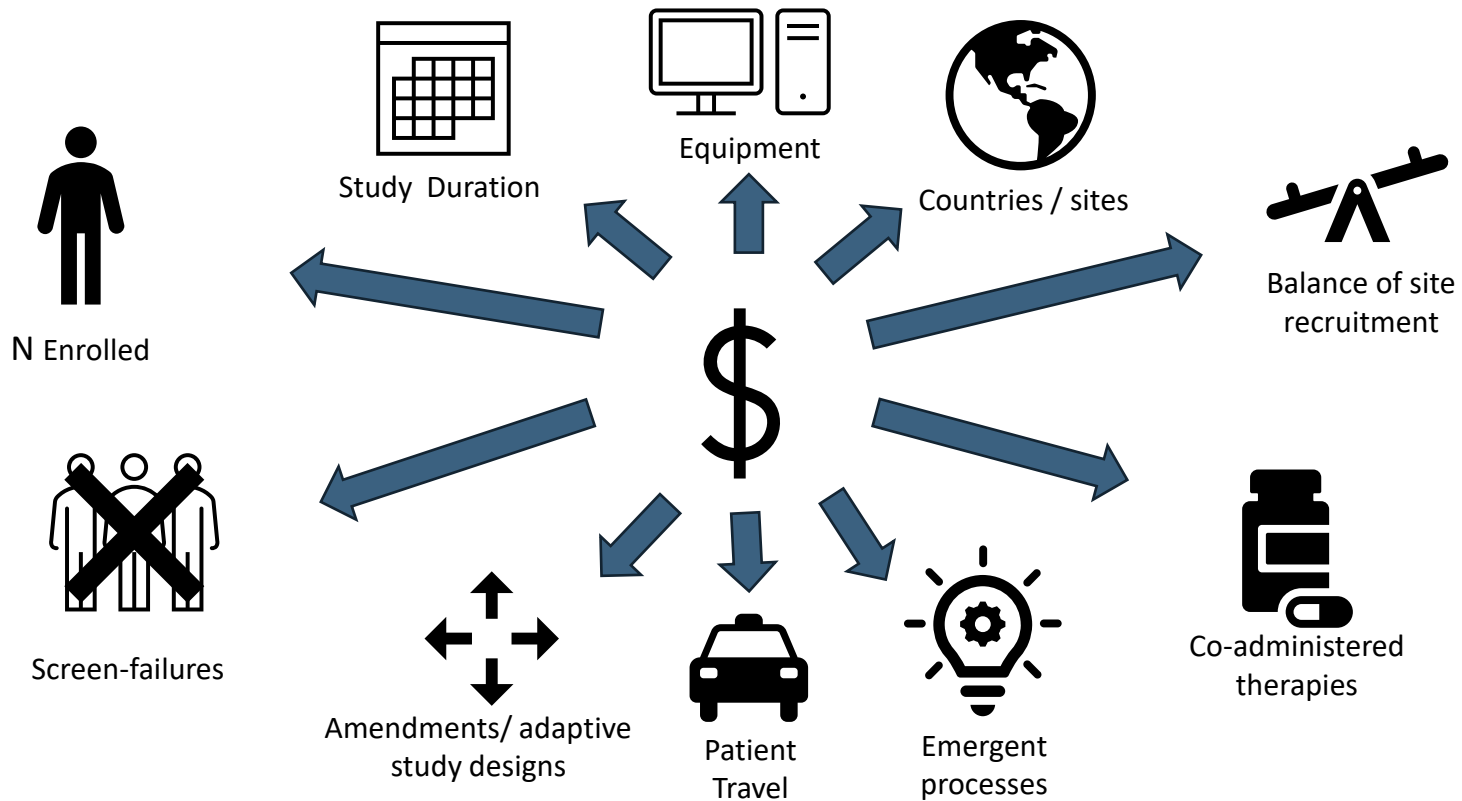
Taming the Beast, Effective Financial Management of Clinical Trials

Wednesday 30th October 2024

Objectives

- **Building a cost-effective study framework**
- **Navigating financial aspects of the vendor selection process**
- **Effective strategies for forecasting and management the clinical trials budget**

Many Clinical Trial Uncertainties with Financial Impact



Building a Cost-Effective Study Framework

Leverage Efficiencies

- Consider full-service provider
 - Technical Expertise vs efficiencies
- Consider developing preferred supplier network
 - Leverage discounts
 - Leverage development of templates and template processes
- Consolidate activities
- Consider in-house resourcing vs outsourcing
- Geographical footprint of study
 - Study sites
 - Location of project management team
- Scrutinise effectiveness of study processes
 - Advertising

Vendor Contracting

Financial Considerations

- Milestones vs Monthly vs Pro-rata
- Clear assumptions
- Management of Pass-Through fees
- Management of Investigator Grant
- Process for Out-of-Scope activities
 - Notification where proposed activities have a cost implication
- Understand estimates for:
 - Extended timeframe
 - Protocol amendment
 - Additional fees as per-unit items

Effective Management of the Clinical Trial Budget

Budget

- Contractual commitments
- Contingency planning
- Year on year
- Process for budget requests
- Cyclical budgeting process

Spend

- Sign-off process
- Governance
- Invoice tracking
- Accruals

Forecasting

- Timespan
- Financial modelling:
 - Investigator Fees
 - Pass-through costs
 - Scenario planning

Effective Management of the Clinical Trial Budget

Budgeting

- Building the budget
 - Experience with similar programmes
 - Vendor estimates
 - Refine with vendor finalised budgets
- Spread per year based on activities
- Build in:
 - Contingency amounts in line with company approach
 - Estimates for potential additional activities, eg:
 - 1-2 protocol amendments
 - Interim Investigator Meeting
 - 1-2 months additional recruitment timeframe
 - Adding additional sites

CDR-Life

Item	Activity Description	Amount CHF
CRO		10,600,000
Direct fees	Milestones	5,800,000
	Contract Signature	2,000,000
	First country submission (IRB or EC)	100,000
	First site initiated	100,000
	First participant enrolled	100,000
	First patient primary endpoint completed	100,000
	All sites initiated	100,000
	50% patient enrolled	100,000
	Draft of SAP Delivered	100,000
	100% patients enrolled	100,000
	50% Patients QC Clean	100,000
	Last Patient QC Clean	100,000
	Database Lock	100,000
	First draft CSR	100,000
	CSR Delivered	100,000
	Other	2,500,000
	Monthly fee	2,500,000
Pass-throughs		700,000
	Labs	200,000
	Software fees	500,000
Investigator fees		4,000,000
Regulatory fees		100,000

Jan-24	Feb-24	Mar-24	Apr-24	May-24	Jun-24	Jul-24	Aug-24	Sep-24	Oct-24	Nov-24	Dec-24	XXX
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Forecast YE 2024	FY to date	YTD 2024	Forecast YE 2025	Forecast YE 2026	Forecast YE 2027
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1,200,000	700,000	500,000	600,000	600,000	100,000
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120,000	70,000	50,000	40,000	20,000	-
120,000	70,000	50,000	130,000	50,000	-
460,000	200,000	260,000	2,000,000	1,540,000	-
70,000	70,000	-	30,000	-	-

CDR-Life

Effective Management of the Clinical Trial Budget

Forecasting

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	50% patient enrolled	100,000															-	-	-	100,000	-	-
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	Other	2,500,000	-	-	-	-	-	-	-	-	-	-	-	-	-	-		-				
	Monthly fee	2,500,000	100,000	100,000	100,000	100,000	100,000	100,000	100,000	100,000	100,000	100,000	100,000	100,000			1,200,000	700,000	500,000	600,000	600,000	100,000
Pass-throughs		700,000	-	-	-	-	-	-	-	-	-	-	-	-	-		-					
	Labs	200,000	10,000	10,000	10,000	10,000	10,000	10,000	10,000	10,000	10,000	10,000	10,000	10,000			120,000	70,000	50,000	40,000	20,000	-
	Software fees	500,000	10,000	10,000	10,000	10,000	10,000	10,000	10,000	10,000	10,000	10,000	10,000	10,000			120,000	70,000	50,000	130,000	50,000	-
Investigator fees		4,000,000	-	-	10,000	50,000	50,000	50,000	50,000	50,000	50,000	50,000	50,000	50,000			460,000	200,000	260,000	2,000,000	1,540,000	-
Regulatory fees		100,000	-	-	10,000	-	60,000	-	-	-	-	-	-	-	-	-	70,000	70,000	-	30,000	-	-

Effective Management of the Clinical Trial Budget

Forecasting

- Forecasting tools:
 - Site per-patient budgets: model out recruitment scenarios skewed to different regions
 - Extending recruitment timelines
- Regular review and update
 - Quarterly
 - End of Year

Clinical Trial Budget Management

Wrap Up

- Get comfortable with uncertainty
- Cannot be 100% accurate
- Get organised
- Use your vendors
- Understand assumptions
- Models provide understanding of financial risk

