

Example of costing of Clinical Trial Budget*

*Costs estimation for Phase 1 study with 20 subjects

Workstream	Low Estimate (€)	High Estimate (€)	Notes
1. Study Design & Protocol	€60,000	€130,000	Protocol, amendments, adaptive statistics, expert board
Protocol writing and amendments	€20,000	€40,000	
Statistical plan (small-N, Bayesian)	€15,000	€35,000	3+3, Package Bayesian Optimal (BOIN)
Clinical genomic development plan (WGS integration)	€10,000	€25,000	
Scientific committee / rare disease expert board	€15,000	€30,000	
2. Regulatory Affairs	€85,000	€160,000	ANSM, CPP, EMA orphan designation, genomic compliance
ANSM authorization application	€15,000	€25,000	
Ethics committee (CPP) submission and FUP	€15,000	€25,000	
Orphan drug designation application (EMA)	€20,000	€35,000	
Genomic regulatory advice (CNIL, Bioethics Law, WGS consent)	€15,000	€35,000	
Amendments	€10,000	€20,000	
SAE, DSUR/DSUSC, SUSAR management	€10,000	€20,000	

3. Project Management	€122,500	€222,000	Senior CPM, genomics/biobank coordination, TMF
Sr Clin PM	€80,000	€130,000	Capped at 15% for all sub activities
Genomics/biobank coordinator	€25,000	€50,000	
Investigator meetings, reporting	€10,000	€32,000	
TMF/ eTMF	€7,500	€10,000	Cost depends on #nb of patients
4. Investigator Sites (CRMR)	€45,000	€105,000	Site start-up and per-patient fees
Site start-up fee (2–3 centers)	€10,000	€30,000	
Per-patient fees (investigator physician, research nurse, visits)	€15,000	€30,000	Screening and follow-up visits (4–8 visits per patient in Phase 1)
Site Closing	€10,000	€15,000	
Logistics for serial biological sampling (PK, PD, biomarkers)	€10,000	€30,000	
5. Patient Recruitment & Retention	€80,000	€165,000	Registries, patient associations, travel reimbursement
Patient identification through registries (BNDMR, Orphanet, FSMR networks)	€10,000	€20,000	use PPIE network/ ERN
Patient advocacy outreach and awareness	€10,000	€20,000	use PPIE network/ ERN
Reimbursement of patient expenses (travel, lodging, lost income)	€25,000	€60,000	Cost depends on #nb of patients
Remote follow-up tools (ePRO, teleconsultations)	€15,000	€35,000	
Management of dropouts / non-evaluable patients	€20,000	€30,000	Cost depends on #nb of patients
6. Genomics Component	€240,000	€440,000	WGS/WES, bioinformatics, Long DNA sequence reading...

WGS sequencing (20 singleton patients)	€40,000	€55,000	Cost depends on #nb of patients
Trio sequencing (patient + parents) if inherited disease	€80,000	€120,000	Cost depends on #nb of patients
Complementary WES (targeted panels, RNA-seq)	€20,000	€30,000	Cost depends on #nb of patients
Library preparation & biobanking (DNA/RNA extraction, QC, long-term storage)	€20,000	€40,000	Cost depends on #nb of patients
Bioinformatics (analysis pipeline, alignment, variant annotation)	€25,000	€60,000	Cost depends on #nb of patients
Clinical interpretation of variants (clinical genomicist, molecular tumor/genomics board)	€20,000	€50,000	Cost depends on #nb of patients
Data infrastructure (secure genomic storage, GDPR-compliant, HDS-certified)	€15,000	€25,000	
Complementary functional biomarkers (proteomics, transcriptomics, metabolomics)	€20,000	€60,000	Cost depends on #nb of patients
7. Clinical Data Management	€85,000	€135,000	EDC, CRFs, data integration
EDC system (license and setup)	€25,000	€40,000	
Data management (CRF design, cleaning, queries)	€25,000	€45,000	Cost depends on #nb of patients
Integration of clinical and genomic data	€20,000	€30,000	Cost depends on #nb of patients
Regulatory archiving (minimum 15 years)	€15,000	€20,000	
8. Monitoring & Pharmacovigilance	€97,000	€155,000	CRA monitoring, PV, DSMB
Clinical research associate (CRA) monitoring visits	€42,000	€75,000	8 visits per site: 21 visits (2 000 € per visit)
Centralized/ Remote RBM	€20,000	€30,000	Cost depends on #nb of patients
Pharmacovigilance (SAE, SUSAR, annual DSUR)	€20,000	€30,000	Cost depends on #nb of patients
Independent DSMB	€15,000	€20,000	

9. IMP / Experimental Therapy	€135,000	€265,000	GMP manufacturing, distribution, insurance
GMP manufacturing or supply	€80,000	€140,000	Complex biologics are much more expensive than repurposed drugs
Storage and distribution (hospital pharmacy, cold chain?)	€30,000	€70,000	
Clinical trial insurance	€15,000	€35,000	
IMP traceability system	€10,000	€20,000	
10. Statistics & Publication	€57,500	€90,000	Final analysis, CSR, publications
Final statistical analysis (mixed models, survival, Bayesian methods)	€20,000	€35,000	
Clinical Study Report (CSR) CDISC	€20,000	€30,000	
Integration of genomic findings into the report	€7,500	€10,000	
Open-access publication and conferences	€10,000	€15,000	
11. Institutional Overheads	€132,675	€373,400	15–20% institutional overhead
Sub TOTAL	€884,500	€1,867,000	
TOTAL	€1,017,175	€2,240,400	
Cost per Patient	€44,225	€93,350	