Julius Clinical

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DETAILED BUDGET BREAKDOWN FOR THE CONDUCT OF VASCO STUDY

VASCO study: A population-based prospective cohort study on vaccine effectiveness of COVID-19 vaccines in the Netherlands

Total costs	Budget	
Total Service fee	€	
Total Pass through costs	€	
TOTAL	€	5.1.2b
Assumed inflation rate included in services fees	2.5% on annual base	
Total costs per subject (Includes PTC)	€	
Total hours per subject	2,41	

General assumptions	
Number of subjects	50.000
Countries	Netherlands
Estimated Timelines	Study start — 15 January 2021
	First Subject Enrolled — 15 March 2021
	Last Subject Enrolled — Depending on Vaccination scheme
	End of Follow-up — Q2 2026
	Study end — Q3 2026

Timelines mentioned depend on actual vaccination strategy.

Service fees				Comments
PROJECT MANAGEMENT				
Project Management				
Project management - Set up phase	2 Month(s)	220	€	Includes involvement of CSO, PD and Sr PM for set-up of the project
Project management - Recruitment phase * * Lenght of recruitment phase will depend om role out of vaccination strategy	4 Month(s)	537 Hrs/unit	€ 5.1.2b	Includes involvement of CSO, PD and Sr PM for management of the project; PM, CTA, PCL for recruitment efforts and follow-up with subjects; CTA for support of fingerprick logistics
Project management - Follow up phase	60 Month(s)	220	€	Includes involvement of CSO, PD and Sr PM for management of the project; PM and CTA for tracking retention and initiating additional efforts like involvement of GP networks for identification of specific populations

Per Patient Activities

Activity	Units	Rate		Ref	Notes
Patient contact during Recruitment	25.000 Participants	0,25	€		Assumes 15 minutes per patient, contact by PCL for compliance follow-up
Patient contact during Follow-up	250.000 Participants	0,25	€		Assumes 15 minutes per patient per year, contact by PCL for compliance follow-up
Patient contact (helpdesk) during study	50.000 Participants	0,25 Hrs/unit	€		Incoming calls from participants. Assumes 1 call per subject of 15 minutes for the study duration
Follow up on missing Fingerpricks	16.667 Participants	0,5	€	5.1.2b	Assumes 30% of subjects need follow-up by PCL and 30 minutes per follow-up action
Trigger Fingerprick kit shipment	50.000 Participants	0,04 Hrs/unit	€		Assumes 2.5 minutes per subject (= 3 fingerpricks) for tracking of when to send out fingerprick kits
Support GPs with outreach to participants	15 GPs	15,00 Hrs/unit	€		
GP Contracts	15 Contracts	8,00 Hrs/unit	€		

SCIENTIFIC SERVICES
Protocol writing

Activity	Units	Rate		Ref	Notes
Input in and review of protocol	1 Protocol(s)	60	€		Project Director input in protocol
Review and statistical input in protocol	1 Protocol(s)	60 Hrs/unit	€		Head of Data Science input on statistics and sample size collection

ICF writing

Review of Informed Consent Form	1 ICF(s)	8 Hrs/unit	€		

Statistical programming & writing

Activity	Units	Rate		Ref	Notes
Statistical CRF review	1 CRF	20,0 Hrs/unit	€		
SAP & TLF specifications (first year plans)	1 Set-up	80,0 Hrs/unit	€		
Monthly data reports	60 Months	6 Hrs/unit	€	5.1.2b	
Complex data derivations and documentation	1 Set-up	80 Hrs/unit	€		Assumes non CDISC
TLF programming	60 TLFs	4 Hrs/unit	€		
TLF and data derivation validation	1 Validation	80 Hrs/unit	€		
Data and TLF reviews (key analysis timepoints)	1 Review(s)	120 Hrs/unit	€		
Support for report writing	5 Years	16 Hrs/unit	€		
Oversight Head of Data Science	1 Oversight	420 Hrs/unit	€		

REGULATORY MANAGEMENT
Initial submissions preparation & conduct

Initial submissions preparation & conduct Central Ethics	1 Submis.	80 Hrs/unit	€

DATA MANAGEMENT
Set up Data management & EDC

Platform Set-up	1 DB Set-up	320 Hrs/unit	€
Database changes	4 DB Changes	160 Hrs/unit	€
Data Management Plans	5 Plans	40 Hrs/unit	€
Helpdesk	60 Months	32 Hrs/unit	€
Reporting	60 Months	32 Hrs/unit	€
Data Monitoring - Surveys	60 Months	48 Hrs/unit	€
Data monitoring eCRF	60 Months	32 Hrs/unit	€
Database lock	1 DB Lock	240 Hrs/unit	€
Oversight Ass Director Data Management	1 Oversight	560 Hrs/unit	€

IT Set up of Platform

Platform qualification and validation	1 Platform	160 Hrs/unit	€
Functional platform management	64 Months	17 Hrs/unit	€
Platform and mobile app support	64 Months	34 Hrs/unit	€
Reporting and Integration	1 Set-up	160 Hrs/unit	€
User management	64 Months	9 Hrs/unit	€
Training	1 Training	160 Hrs/unit	€
Dashboard for status reporting	1 Dashboard	480 Hrs/unit	€

5.1.2b

Pass Through costs							
METC review fee	1 Submission		Euro/unit	€			
Send recruitment letters	50.000 Letters		Euro/unit	€		Assumes letter only, single prined A4	
Send quarterly Newsletters	600.000 Letters		Euro/unit	€			
Distribution Fingerprick kits	150.000 Kits		Euro/unit	€		Assumes distribution only (sample kits + return envelopes supplied by RIVM)	
Link2Trials Media campaing Start-up	1 Set-up	5.1.2b	Euro/unit	€	5.1.2b		
Link2Trials Media campaing Execution	1 Execution		Euro/unit	€			
GP letters to additional cohort subjects	4.500 Letters		Euro/unit	€			
GP Fee	15 GPs		Euro/unit	€			
Digital Platform/app	1 Vendor		Euro/unit	€			

The values described in the budget proposal is understood to be in Euro and are indicative of 2021 pricing. This proposal is valid for a period of six (6) months from the date of this proposal.The budget described in this overview provides a general, rounded overview of costs. Sponsor audits, formal budget and contract considerations such as payment schedule, VAT, and currency exchange consequences are not included and shall be included at a later stage during the final agreement between the parties.