

Date: 26-Feb-2021 Version: 2.0

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		€	5.1.2b	
	TOTAL	€		
Assumed inflation rate included in services fees		2.5% on an	nual base	
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Total costs per subject (service fees only)		€	5.1.2b	
	General assumptions			
Number of subjects		50,0	00	
Countries		Nether	lands	
	T	Study start	15 January 2021	
		First Subject Enrolled	15 March 2021	
Estimated Timelines			epending on Vaccination	
Estimated Timelines		Last Subject Enrolled	scheme	
		End of Follow-up	Q2 2026	
		Study end	Q3 2026	
	Service fees			
PROJECT MANAGEMENT Project Management				
Project management - Set up phase	2 Month(s)	193	€	
Project management - Recruitment phase *	4 Month(s)	495	€ 540	
* Lenght of recruitment phase will depend om re		Hrs/unit	5.1.2b	
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Project management - Follow up phase	60 Month(s)	234	€	
Per Patient Activities				
Patient contact during Recruitment	5,000 Participants	0.25	€	
Patient contact during Follow-up	50.000 Participants	0.25	5.1.2b	
	30,000 1 at 00,001	0.23		
Patient contact during Follow-up	50,000 Participants	0.25	€	

cludes involvement of CSO, PD and Sr PM for set-up of the project

Includes involvement of CSO, PD and Sr PM for management of the project; Head of Data Science and Associate Director Data Management oversight; CTA for admin support and fingerprick logistics

Includes involvement of CSO, PD and Sr PM for management of the project; Head of Data Science and Associate Director Data Management oversight; CTA for admin support

Assumes 15 minutes per patient, contact by PCL for 10% of subjects

Assumes 15 minutes per patient, contact by PCL for compliance follow-up

Process received ICFs	55,000 ICFs	0.08	€	Assumes 5 minutes per ICF
Follow-up incomplete ICFs	5,000 ICFs	0.35 Hrs/unit	€	Assumes 10% of ICFs need follow-up and 20 minutes per ICF
Patient contact (helpdesk) during study	50,000 Participants	0.25	5.1.2b €	Incoming calls from participants. Assumes 1 call per subject of 15 minutes for the study duration
Follow up on missing Fingerpricks	16,667 Participants	0.25	€	Assumes 10% of subjects need follow-up by PCL and 15 minutes per follow-up action. Total of 4 fingerpricks per subject
Trigger Fingerprick kit shipment	50,000 Participants	0.02 Hrs/unit	€	Assumes 1.3 minutes per subject (= 4 fingerpricks) for tracking of when to send out fingerprick kits
GP to GP management	4 Months	27.50 Hrs/unit	€ 5.1.2b	Interaction with GPs to get commitment for database search
Support GPs with outreach to participants	100 GPs	15.00 Hrs/unit	€	SupportGPswithdatabasesearchforsubjectswithmedicalindication
GP Contracts	100 Contracts	8.00 Hrs/unit	€	
SCIENTIFIC SERVICES Protocol writing				
Input in and review of protocol	1 Protocol(s)	40 Hrs/unit	€ 5.1.2b	Project Director input in protocol
Review and statistical input in protocol	1 Protocol(s)	40	€ 5.1.20	Head of Data Science input on statistics and sample size collection
ICF writing				
Review of Informed Consent Form	1 ICF(s)	8 Hrs/unit	€ 5.1.2b	
REGULATORY MANAGEMENT Initial submissions preparation & conduct				
Initial submissions preparation & conduct	1 Submis.	80 Hrs/unit	€ 5.1.2b	
DATA MANAGEMENT Set up Data management & EDC				
Platform Set-up	1 DB Set-up	320 Hrs/unit	€	
Database changes	5 DB Changes	80 Hrs/unit	€	
Data Management Plans	5 Plans	24 Hrs/unit	€	
Helpdesk	60 Months	16 Hrs/unit	€ 5.1.2b	
Reporting	60 Months	24 Hrs/unit	€ 3.1.20	
Data Monitoring - Surveys	60 Months	32 Hrs/unit	€	
Data monitoring eCRF	60 Months	24 Hrs/unit	€	
Database lock	1 DB Lock	240 Hrs/unit	€	

IT Set up of Platform

Platform qualification and validation	1 Platform	160 Hrs/unit	€	
Functional platform management	64 Months	12 Hrs/unit	€	
Platform and mobile app support	64 Months	34 Hrs/unit	€	5.1.2b
Reporting and Integration	1 Set-up	160 Hrs/unit	€	
User management	64 Months	6 Hrs/unit	€	

METC review fee	1 Submission	Euro/unit	€
Send invitation letters	250,000 Letters	uro/unit	€
Return envelopes ICFs	55,000 Letters	Euro/unit	€
Distribution Fingerprick kits	200,000 Kits	5.1.2b Euro/unit	€ 5.1.2
GP letters to additional cohort subjects	16,000 Letters	uro/unit	€
GP Fee	100 GPs	Euro/unit	€
Digital Platform/app	1 Vendor	Euro/unit	€

Assumes letter only, single prined A4

Assumes distribution only (sample kits + return envelopes supplied by RIVM)

Assumes 50% GPs will send email and 50% will need send invitation letter