



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	€
<b>TOTAL</b>	€ <b>5.1.2b</b>
Assumed inflation rate included in services fees	2.5% on annual base
Total costs per subject (service fees only)	€ <b>5.1.2b</b>

General assumptions	
Number of subjects	50,000
Countries	Netherlands
Estimated Timelines	Study start: 15 January 2021
	First Subject Enrolled: 15 March 2021
	Depending on Vaccination scheme
	Last Subject Enrolled
	End of Follow-up: Q2 2026
Study end	Q3 2026

*Timelines mentioned depend on actual vaccination strategy.*

**Service fees**

PROJECT MANAGEMENT

**Project Management**

Project management - Set up phase	2 Month(s)	193	€	5.1.2b
Project management - Recruitment phase *	4 Month(s)	495 Hrs/unit	€	
* Length of recruitment phase will depend on role out of vaccination strategy				
Project management - Follow up phase	60 Month(s)	234	€	

Includes 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

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**Per Patient Activities**

Patient contact during Recruitment	5,000 Participants	0.25	€	5.1.2b
Patient contact during Follow-up	50,000 Participants	0.25	€	

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	€	5.1.2b
Follow-up incomplete ICFs	5,000 ICFs	0.35 Hrs/unit	€	
Patient contact (helpdesk) during study	50,000 Participants	0.25	€	
Follow up on missing Fingerpricks	16,667 Participants	0.25	€	
Trigger Fingerprick kit shipment	50,000 Participants	0.02 Hrs/unit	€	5.1.2b
GP to GP management	4 Months	27.50 Hrs/unit	€	
Support GPs with outreach to participants	100 GPs	15.00 Hrs/unit	€	
GP Contracts	100 Contracts	8.00 Hrs/unit	€	

Assumes 5 minutes per ICF

Assumes 10% of ICFs need follow-up and 20 minutes per ICF

Incoming calls from participants.  
Assumes 1 call per subject of 15 minutes for the study duration

Assumes 10% of subjects need follow-up by PCL and 15 minutes per follow-up action.  
Total of 4 fingerpricks per subject

Assumes 1.3 minutes per subject (= 4 fingerpricks) for tracking of when to send out fingerprick kits

Interaction with GPs to get commitment for database search

Support GPs with database search for subjects with medical indication

SCIENTIFIC SERVICES

**Protocol writing**

Input in and review of protocol	1 Protocol(s)	40 Hrs/unit	€	5.1.2b
Review and statistical input in protocol	1 Protocol(s)	40	€	

Project Director input in protocol

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
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REGULATORY MANAGEMENT

**Initial submissions preparation & conduct**

Initial submissions preparation & conduct	1 Submis.	80 Hrs/unit	€	5.1.2b
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DATA MANAGEMENT

**Set up Data management & EDC**

Platform Set-up	1 DB Set-up	320 Hrs/unit	€	5.1.2b
Database changes	5 DB Changes	80 Hrs/unit	€	
Data Management Plans	5 Plans	24 Hrs/unit	€	
Helpdesk	60 Months	16 Hrs/unit	€	
Reporting	60 Months	24 Hrs/unit	€	
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	€	5.1.2b
Functional platform management	64 Months	12 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	6 Hrs/unit	€	

Pass Through costs					
METC review fee	1 Submission		Euro/unit	€	5.1.2b
Send invitation letters	250,000 Letters		Euro/unit	€	
Return envelopes ICFs	55,000 Letters		Euro/unit	€	
Distribution Fingerprick kits	200,000 Kits	5.1.2b	Euro/unit	€	
GP letters to additional cohort subjects	16,000 Letters		Euro/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