



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

General assumptions	
Number of subjects	50,000
Countries	Netherlands
Estimated Timelines	Study start: 15 January 2021
	First Subject Enrolled: 15 March 2021
	Least 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

PROJECT MANAGEMENT

Project Management

Project management - Set up phase	2 Month(s)	193	€	5.1.2b	Includes involvement of CSO, PD and Sr PM for set-up of the project
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 management of the project; Head of Data Science and Associate Director Data Management oversight; CTA for admin support

Per Patient Activities

Patient contact during Recruitment	5,000 Participants	0.25	€	5.1.2b	Assumes 15 minutes per patient, contact by PCL for 10% of subjects
Patient contact during Follow-up	50,000 Participants	0.25	€		

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.	30 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	5.1.2b Euro/unit	€	5.1.2b
Send invitation letters	250,000 Letters	5.1.2b Euro/unit	€	
Return envelopes ICFs	55,000 Letters	5.1.2b Euro/unit	€	
Distribution Fingerprint kits	200,000 Kits	5.1.2b Euro/unit	€	
GP letters to additional cohort subjects	15,000 Letters	5.1.2b Euro/unit	€	
GP Fee	100 GPs	5.1.2b Euro/unit	€	
Digital Platform/app	1 Vendor	5.1.2b Euro/unit	€	

Assumes letter only, single printed A4

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

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