

		Date: 8-Feb-2021 Version: 1,0		
DETAILED BUDGET BREAKDOWN FOR THE CONDUCT OF VASCO STUDY				
<i>VASCO study: A population-based prospective cohort study on vaccine effectiveness of COVID-19 vaccines in the Netherlands</i>				
Total costs		Budget		
Total Service fee	€		5.1.2b	
Total Pass through costs	€			
TOTAL	€			
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 <small>Timelines mentioned depend on actual vaccination strategy.</small>		
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 *	4 Month(s)	537 Hrs/unit	€	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
<small>* Length of recruitment phase will depend on role out of vaccination strategy</small>				
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				5.1.2b	
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	€		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					
Input in and review of protocol	1 Protocol(s)	60 Hrs/unit	€	Project Director input in protocol	
Review and statistical input in protocol	1 Protocol(s)	60	€	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					
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 printed 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 RVM)
Link2Trials Media campaign Start-up	1 Set-up	5.1.2b	Euro/unit	€	5.1.2b
Link2Trials Media campaign 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 payments schedule, VAT, and currency exchange consequences are not included and shall be included at a later stage during the final agreement between the parties.