3. *Work order*

Multicentre, randomised, double-blind, parallel, placebo-controlled study evaluating the efficacy and safety of early self-treatment of influenza and influenza-like illness with oral antibodies to TLR3 FYW peptide (TAO1).

Please find below the different modules of the Price offer:

MODULE 1:	MEDICAL WRITING
MODULE 2:	EC & CA SUBMISSION
MODULE 3:	SMO - Investigators Network
MODULE 4:	INVESTIGATOR'S MEETINGS
MODULE 5:	INVESTIGATOR'S FEES
MODULE 6:	SUBJECTS COMPENSATION
MODULE 13:	INTEGRATED e-PLATFORM
MODULE 7:	MONITORING
MODULE 8:	DATA MANAGEMENT
MODULE 9:	BIOSTATISTICS
MODULE 10:	SAFETY
MODULE 11:	PROJECT MANAGEMENT

MEDICAL WRITING		
Task	Detail	Price (€)
Clinical Study Protocol (English)	First draft	3.300
	Second draft	1.650
	Final version	825
IB (Investigator's Brochure) (update)	First draft	990
	Final version	495
IMPD (Investigational Medicinal Product Dossier) (update)	First draft	990
	Final version	495
Informed Consent Form (ICF) in French	First draft	1.100
	Second draft	550
	Final version	225
Translation of the ICF in Dutch	Finalversion	880
Case report form (engl) and diary card (french)	First draft	3.300
	Second draft	1.650

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	Final version	825
Translation of the diary card in Dutch	Final version	880
Clinical Study Report including medical review and QC	First draft	3.000
	Second draft	1.500
	Final version	750
Total		**23.405**

EC & CA SUBMISSION		
Task	Unit Price €	Price (€)
Belgium		
FAMHP (Competent Authority) electronic dossier preparation (#1)	€ 1.200,00	1.200
ECPSO (Central Ethics Committee) electronic & paper dossiers preparation (#1)	€ 1.700,00	1.700
Insurance contract finalization		220
Answers to FAMHP & ECPSO Questions		560
Translation of Documents	at cost	
Transportation of submission files to E.C.		150
Amendment Submission (per unit)		560
France		
Document redaction		2.000
Submission & follow-up		2.000
Total		**8.390**

SMO - Investigators Network		
Task	Unit Price €	Price (€)
1. Feasibility		
In dept feasability		2.000
2. Selection & Recruitment		
Selection and recruitment of 50 investigators, list and CV edition		
providing of investigators trained to GCPs		
Investigators agreement management	300€/inv	15.000
3. Project Implementation		1.200
Sites validation by study nurses visit		
Workload, calendar, tracability & reporting definition		
3. Project follow-up		
Recruitment optimisation, logistics & network management		

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Follow-up of the inclusions and patients visits (SN & IC)preventive & corrective actions by medical manager			
Medical coordination	Medical director		3.500
	Investigators Coordinators		11.136
Study coordination (visit regisration, study central file management, specification follow-up)			42.000
Study nurses			16.584
Total			**91.420**

INVESTIGATOR'S MEETINGS			
Task	Units	Unit Price €	Price (€)
Budget per participant		115€/participant	8.050
Meeting organization	3	€ 400,00	1.200
Meeting participation	4	€ 400,00	1.600
Total			**10.850**

INVESTIGATOR'S FEES			
Task		Unit Price €	Price (€)
Number of Investigators	GP:60		
Budget by Subject	V1: 200€ (300 patients) V2: 200€ (300 patients) V3: 75€ (60 patients)	300 patients Budget by patient: 475€	
Total fees			124.500
Management of investigator's fee (8%)			9.960
Total			**134.460**

SUBJECTS COMPENSATION			
Task		Unit Price €	Price (€)
Subjects Compensation	300 patients	€ 25,00	15.000
Management of subject indemnisation (8%)			1.200
Total			**16.200**

INTEGRATED e-PLATFORM		
Task	Unit Price €	Price (€)
eCRF and e-Platform development costs		44.768

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Monthly e-Platform, database hosting and maintenance costs	650/month	3.250
Participation in investigator meetings	€ 1.350,00	
N Unique page	€ 10,00	
Additional user configuration sessions	50/user	
Additional unique page development (from 11th)	2200/page	
Helpdesk & Support	90/h	
Total		**48.018**

MONITORING				
Task		Units	Unit Price €/day	Price (€)
Set up of the study				
Review of study documentation (protocol, ICF, CRF,...)				
set up of study files	8 days	8	480	3.840
Investigators agreements management				0
Investigators meetings (2 CRA) + preparation	2 days	4	480	1.920
Site Selection visit (Belgium) **Visit preparation** Meeting & preparation of the visit **On site visit** Evaluation of the Investigator's qualifications, the team's availability, the site's material & equipment Study document review &regulatory/financial aspects negotiation **Administration tasks** Selection visit report writing, Post selection visit mail, Phone call, final decision about the site selection	CRA (BE,FR): 1,5 day/visit travel time included			0
Site initiation visit (Belgium) *This visit will take place if the investigator didn't participate to the Investigators meeting **Visit preparation** Meeting & preparation of the visit & the study material (presentation of study documents, study files, IMPs, **On site visit** Regulatory & finical aspects finalization, Review of the study documents, study procedures, IMPs management, CRF presentation **Administration tasks** Initiation visit report writing, Post initiation visit mail, Phone call, documentation of the potential issues before the study start	CRA (BE,FR): 1,5 day/visit travel time included	20	720	14.400

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Site Monitoring visit (Belgium & France) **Visit preparation** Meeting & preparation of the visit according the last visit report (queries) **On site visit** Data verification (CRF & diary, investigator site file, IMPs accountability & storage, queries resolution)) **Administration tasks** Monitoring visit report writing, Post monitoring visit mail, Phone call, documentation of the potential issues before the study start	1 visits/sites - 50 sites in BE,FR (1,5 days/visit travel time included)	50	720	36.000
Site close-out visit (Belgium & France) **Visit preparation** Meeting & preparation of the visit according the last visit report (queries). **On site visit** Data & queries verification, check of investigator site file, final IMPs accountability, final queries resolution, randomization envelopes) **Administration tasks** Close-out visit report writing, Post close-out visit mail, Phone call, documentation of the potential issues before the study start	1 visits/sites - 50 sites in BE,FR (1,5 days/visit travel time included)	50	720	36.000
Global administration				
Site management (Contact with sites for recruitment and samples logistics)	0,5h phone contact/site/month - 5 months	50	30	7.500
CRA office administration	2 days/month - 7months	14	480	6.720
Archiving	TBD			
Total estimated budget				**106.380**

FIRST-LINE DATA MANAGEMENT		
Task		Price (€)
Training for 2 persons		600
Data Validation Plan		2.400
Database monitoring (4h per week during 20 weeks or 5 months): Regular examination of the database (on a weekly basis) Generation of queries to the investigators	4h/week x 20 weeks x 72 €/h	5.760

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Verification and validation of the answers to queries Alert to the CRA when a major issue is detected for a given investigator Alert to EDC department when a recurrent issue encountered with data entry in the eCRF by the investigator		
Interaction with the monitoring department for resolving special queries		1.000
Pre-analysis meeting (discussion of the patient status : ITT or PP)		1.500
Database lock (SPSS) after introduction of elimination codes		250
Total		**12.510**

BIOSTATISTICS		
Task	Detail	Price (€)
Study Analysis Plan (SAP)	First draft	2.880
	Second draft	1.440
	Final version	720
Randomization list		550
Preparation and validation of statistical analysis programs (IBM SPSS Statistics)		3.300
Statistical report according to the SAP	First draft	3.300
	Second draft	1.650
	Final version	825
Total		**14.665**

SAFETY		
Task	Unit Price €	Price (€)
Setup costs Set-up includes all start-up activities: writing of a SOP approved by CRO/sponsor, creation of the files Initial meeting with CRO/sponsor, investigator, data management if deemed necessary and maintenance of the files	3.000	3.000
Monthly fee for availablity (including BU)	400/month	2.400
Expedited reporting (SUSAR) to FAMHP	3	TBD
Expedited reporting (SUSAR) to ECPSO	400	TBD
SAE initial and FU reports (average 2 FUs) CIOMS I report including causality and expectedness assessment in close collaboration with CRA and investigator, writing of a medically-sound narrative. Collection of the clinically relevant concomitant medications	50/case	TBD
MedDRA coding all AEs/ case (optional)	50/case	TBD
Total		**5.400**

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PROJECT MANAGEMENT			
Task	Units	Time(h)/Unit	Price (€)
Project Team Coordination	18	8	11.520
CRA Visit Administration	77	2	12.320
Project Teleconferences	4	1	320
Accompanied Site Visit/ Travel	7	4	2.240
Accompanied Site Visit/ On-Site	7	4	2.240
Accompanied Site Visit/ Administration	7	4	2.240
Client Meetings	2	3	480
Update project tracking	18	1	1.440
Invoicing Administration	18	1	1.440
Additional meetings	In Belgium: 110 €/h door to door + 30 € for travel expenses		
	In Europe (except Belgium): 1500 €/day + travel expenses (passthrough)		
Total			**34.880**

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Total costs:		Budget (€)
MODULE 1:	MEDICAL WRITING	€ 23.405,00
MODULE 2:	EC & CA SUBMISSION	€ 8.390,00
MODULE 3:	SMO - Investigators Network	€ 91.420,00
MODULE 4:	INVESTIGATOR'S MEETINGS	€ 10.850,00
MODULE 5:	INVESTIGATORS FEES MANAGEMENT	€ 9.960,00
MODULE 6:	SUBJECT COMPENSATION MANAGEMENT	€ 1.200,00
MODULE 13:	INTEGRATED e-PLATFORM	€ 48.018,00
MODULE 7:	MONITORING	€ 106.380,00
MODULE 8:	DATA MANAGEMENT	€ 12.510,00
MODULE 9:	BIOSTATISTICS	€ 14.665,00
MODULE 10:	SAFETY	€ 5.400,00
MODULE 11:	PROJECT MANAGEMENT	€ 34.880,00
Total		€ 367.078,00

	Budget (€)
INVESTIGATORS FEES	€ 124.500,00
SUBJECTS COMPENSATION	€ 15.000,00
Total	€ 139.500,00

	Budget (€)
Total Study	€ 506.578,00

Remark: In order to control the budget, the offer includes 50 investigators sites recruiting each 6 patients.
It's impossible to assess in advance the extent of the epidemic 2015-2016.
The number of sites could be revised upwards, but this must be decided before the start of the trial.

GENERAL EXPENSES (estimation)		
Task	Comments	Price (€)
FAMHP & ECPSO evaluation fees		5.000
Transportation of submission files to FAMHP & ECPSO		150
Copies, stationary, paper, toner, etc.		1000
Travel (meetings, site visits)	0.4€/km	5.000
Parking, lunch (site visits > 4hrs/day)	Receipts	750
Phone calls	Monthly forfeit (18 months)	100
Transportation of study files for archiving to sponsor		500
Total		**12.500**

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