IMMERSE minutes
10/6/21
medX

Present

WP1	Inez Germeys Martine van Nierop
WP2	Jörg Ottenbacher Simon Krause
WP3	Thomas Ganslandt
WP4	
WP5	
WP6	Luca Marelli
WP7	Uli Reininghaus Anita Schick
WP8	

1. **Changes to original quote (see below)**

-Module 1: review validation
medX will help with all ethical/legal requirements.

-Module 1: templates
We won't include the templates, except for the CIP (800 euros)

-Module 2: planning of clinical investigation / statistics
We won't need

-Module 3a: monitoring
We'll keep. This counts as a monocentroc study as all data will be digital and in 1 place. They will organize online meeting(s) for the other sites for monitoring

-Module 3b: data management
We'll keep. Is now a different system (https://maganamed.com/modules) so price will change a bit.

-Module 3b: statistics
We won't need

-Module 3b: data base system
Thomas will contact Daniela with additional questions, so this remains open for now.

-Module 3c: Clinical Investigation report
We'll keep. medX will need our stats to be able to do this.

Actions

Who	**What**	**When**
Thomas	Contact Daniela about database system	
Martine	Organize financial side, based on final quote	

medXteam GmbH - Saarlandstraße 40 - 67434 Neustadt an der Weinstraße

KU Leuven
Leuven Research and Development
Waaistraat 6 – bus 5105
3000 Leuven
Belgium

Quote-No.	AN-1047
Date	17.12.2020
Ihre Kundennummer	1043
Your VAT No.	BE0419052173
Your contact	Daniela Penn

Quote AN-1047

Dear Mrs van Nierop
thank you for your inquiry. We would be pleased to submit you the desired quote:

Background
The movisens GmbHwants to conduct an implementing study (other clinical investigation) with a prototype of a medical app to support physiotherapy. IN this case and in particular, monitoring is required. However, all other parts of a clinical investigation shall alsp be offered with this quote (planning, data management, etc.).
In order to support you with this other clinical investigation, you consider the support of myself and my team, for which we thank you very much.
This quote is intended to give you an overview of the necessary work and thus of the possible costs.

Quote module 1: Review/validation of study documents
The goal of this module is to first provide you with templates and then validate the documents you have compiled yourself for the clinical investigation with your medical device, so that these comply with legal requirements such as the Medical Devices Regulation 745/2017 (MDR) as well as with the relevant standards and recommendations such as ISO 14155. This includes the following Documents:
- Clinical Investigation Plan (CIP) including synopsis.
- Patient information and consent form
- Clinical Investigator's Manual

For the validation, I propose an hourly quota of 16 hours. Costs for the templates:
Protocol: € 1,200.-, the patient information and consent form and the clinical investigator's manual investigator's manual are 800.- € each.

Quote module 2: Planning of your clinical investigation
The goal of this module is to create the clinical investigation planning with your medical device that complies with legal requirements such as the Medical Device Directive/EU Regulation 2017/745 (MDR) as well as the as well as the requirements of relevant standards and recommendations such as ISO 14155.

This include the following steps:
- Statistical calculation of the sample size
- Compilation of the clinical investigation plan based on the calculated sample size
- Compilation of the registration documentation (incl. patient information, informed consent form, investigator's brochure, etc.)
- Submission of the documents to BOB and EC

For this I propose a contingent of 75 hours (approx. 9 days) as well as a flat rate for the statistics of 3.200 €.
Optionally, we also offer a GCP-MPG training course for investigators on request. This will be charged billed separately.

Quote module 3: Conduct of the clinical investigation

The regulations oblige manufacturers to conduct their business in a regulatory and ethical manner in accordance with MDR, ISO 14155, Good Clinical Practice (GCP) and the Helsinki Declaration. As CRO we take over all activities regarding data management, statistical analysis and assessment, monitoring and we prepare the clinical investigation report as well as any required interim reports. The aim of this module is therefore to conduct the clinical investigation with your medical device for you in such a way that it complies with the legal requirements such as the Medical Device Directive (MDR) as well as the specifications of relevant standards and recommendations such as ISO 14155. This includes the following components:

3a. Monitoring (remote monitoring and on site) (remote via the system and 2 monitoring appointments (per video session) including planning and execution for a monocentric study: 10 days

3b. Data management:

- Compilation of the CRF mapping and template for data extraction from the database
- Compilation of the statistical analysis plan (SAP)
- Database development, input and editing
- Clarification of the validity rules of the data
- Training for database entry and data maintenance
- Standard controls for data integration
- Statistical data analysis/assessment

10 days and

Flat rate of 6.400 € for the compilation, setup and adaptation of the database system)

Flat rate for statistics: 6.300 € 3rd

3c. Compilation of the clinical investigation report (final report of the clinical trial): 6,75 days

For this purpose, I suggest an hourly rate of 214 hours/investigation site (26.75 days) in total plus the above- mentioned flat rates.

For each additional investigation site, 4 additional days for monitoring will be added, which will increase the costs by 4,800 €/further site.

Cost calculation

The daily rate of me and my colleagues is 1,200 EUR. The hourly rate is 150 EUR. Altogether the costs for the quote modules as well as the quote result as listed below.

Pos.	Description	Amount	Single rate	Total
1.	**Module 1: Review/Validation**	16,00h	150,00 EUR	2.400,00 EUR
2.	**Module 1: Templates**	Flat rate	2.800,00 EUR	2.800,00 EUR
3.	**Module 2: Planning of the clinical investigation**	75,00 h	150,00 EUR	11.250,00 EUR
4.	**Module 2: Statistics**	Flat rate	3.200,00 EUR	3.200,00 EUR
5.	**Module 3a: Monitoring**	80,00 h	150,00 EUR	12.000,00 EUR
6.	**Module 3b: Data management**	80,00 h	150,00 EUR	12.000,00 EUR
7.	**Module 3b: Statistics**	Flat rate	6.300,00 EUR	6.300,00 EUR
8.	**Module 3b: Data base system**	Flat rate	6.500,00 EUR	6.500,00 EUR
9.	**Module 3c: Clinical investigation report**	54,00 h	150,00 EUR	8.100,00 EUR
	Total net			64.550,00 EUR

The quote modules can also be ordered individually. All prices are subject to the applicable value added tax.

Performance period

We can immediately start with this project.

Further agreements

Satisfaction Guarantee

Our satisfaction guarantee: If you are not completely satisfied with our service, no costs will be incurred. Please let us know by the day after next, for example after submitting a document.

On the other hand, if you were absolutely happy with our support (for which we will do everything possible), I would be very happy to receive a "testimonial", e.g., on our Google website, expressing in your words how you found our help. Would that be possible?

Intellectual property

Also, because we may not have signed a non-disclosure agreement yet, I am very keen on the following: It is a matter of course for us to keep all documents you send us secret, and under no circumstances to pass them on to third parties or to use the concepts contained therein in any way ourselves.

In the same way, we would like to make sure that the documents we create are not passed on as blueprints to other companies (not affiliated with you) or even offered as products. As simple

as some things look, there are years of work and experience involved. Of course, you can develop these documents as you wish, use them for all your projects and make them available to authorities and notified bodies.

We also kindly ask you not to pass on this quote.

Your participation

In order for us to support you successfully and to lead the project to success as planned, we need your support. Therefore, we are dependent on you

- provide us with the required documents completely and as early as possible,
- take over the tasks you are assigned according to the project plan and our agreements
- evaluate our work results immediately and inform us if you still have any wishes,
- inform us without further delay if a date cannot be kept,
- give us the name of your project manager who is authorized to make decisions and, if applicable, other contact persons, inform us about changes of these persons and
- respond to our emails within two working days.

Of course, we adhere to this agreement in exactly the same way.

Archiving of study documents

After completion of the clinical investigation, we hand over the Trial Master File (TMF) with all study-relevant documents for archiving.

Costs and terms of payment

We are at your disposal at the agreed hourly rates. You can also order them in "quarter hour units".
If we travel within the scope of the joint project, the following costs will be incurred:

- Travel expenses: If we travel by car, we charge 0.30 EUR per kilometer driven. The costs for international travel and/or flights will be agreed with you in advance.
- Accommodation: Flat rate 120 EUR
- Travel time: We would like to charge one third of the travel time for trips of more than one hour per way.

Invoices will be issued at the end of each month for the hours worked and we kindly ask you to settle them within two weeks without deductions.

Cancellation clause

It is not unusual to have to change priorities or deal with unplanned constraints during the course of a project. We know that. Therefore, we offer to cancel, shorten or postpone already agreed dates up to four weeks in advance free of charge. This concerns appointments with you or with us as well as appointments where we have reserved time for you, e.g., for the compilation or review of documents.

In case of shorter-term cancellations or postponements we would like to charge the following

cancellation fees:

Period: Cancellation fee

More than four weeks: Free of charge

Two to four weeks: 20%.

One to two weeks: 40%.

Less than one week: 60%.

For special cases, such as illness, we have so far always found a solution.

Binding period of the quote

We are bound by this quote until 2021-02-28.

I would be very pleased if you are interested in my quote. If you have any questions, you can reach me as always fastest by email (daniela.penn@medxteam.de).

This quote was created electronically and is valid without signature.