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**Request for proposal**

This form is meant to help our clients or potential clients identifying their needs. It is not a binding contract. Revision costs-estimates are always possible while the project process is being discussed and refined.

How to go about this request for proposal?

Proposals can be made is several steps, should you not be ready providing us with the full project outline. We can get started with the initial strategy setup and then redefine the scope for future quotations.

If you do not exactly know the number of patients/centers involved in a clinical investigation, please provide us with your best estimate, as costs are usually proportional to the number of patients or centers involved. If you are at an early stage where you do not know at all how many patients will be involved, then let us know as many details of your device as possible so we can provide you with an early assumption.

If you are planning a marketing study, please accurately review the dates as to when you may need data for abstracts, conference presentations because these may require an interim analysis. From experience, we know that these data cut-off dates, if not accurately planned, can influence the budget significantly.

Please feel free to advise us on the different study scenarios you think may be appropriate (e.g., 20 or 50 patients, 1 or 3 sites). We can provide you with a range of quotations for the different scenarios in order to help you plan your budget as accurately as possible.

Please also indicate to us the extent of your future clinical evaluation needs. This information is kept strictly confidential, but this information may help us better streamline your budgets.

If you have any questions answering this questionnaire, please do not hesitate to contact Danielle Giroud at Tel + 41 21 349 9636 or e-mail to [dgiroud@md-clinicals.com](mailto:dgiroud@md-clinicals.com)

Thank you for your interest in our clinical investigation services!

Danielle Giroud

CEO

MD-CLINICALS SA

# Company Details

|  |  |
| --- | --- |
| Company name |  |
| Company address |  |
| Contact phone number |  |
| Email Address |  |
| Contact name and title |  |
| Product name |  |
| Intended use/patient indication |  |
| Date of request |  |

# Regulatory and clinical strategy support

|  |  |
| --- | --- |
|  | Setup regulatory strategy EU, US, China, global |
|  | Assist with CE marking process |
|  | Writing of Essential requirements overview |
|  | Setup of Risk analysis |
|  | Assist/coordinate IDE application |
|  | Assist/coordinate 510(k) application |
|  | Assist/coordinate PMA application |
|  | Assist with China market access process |
|  | Assist with ASEAN market access |
| Please specify the primary target countries: | |
|  | |
|  | Clinical strategy setup pre-market |
|  | Clinical strategy setup post-marketing |
|  | Assist with clinical evaluation report |
| Please specify: | |
|  | Initial report |
|  | Update/review existing report |
|  | Adapt EU report to Chinese requirements |

Clinical research services

## Description of the clinical investigation

|  |  |
| --- | --- |
|  | Study intended to support CE marking |
|  | Study under an IDE application |
|  | Study intended to support Chinese market access |
|  | Study included to support other market access |
| Please specify: | |
|  | Marketing study |
|  | Other, please specify: |

If you have ticked off ‘Marketing study’ please provide us with the dates (if possible) you will want to have the data reviewed i.e., for conference presentations, abstract or interim publications. This information will be used to estimate the frequency and number of monitoring visit needed.

|  |  |  |  |
| --- | --- | --- | --- |
| Date by which data report is needed | | Reason for data compilation | |
|  |  | |
|  |  | |
|  |  | |

Total number of patients (including control subjects if applicable):

Participating centers (if available, a list of centers may be attached in lieu of filling out the below table) Please note location is important to estimate travel and translation requirements.

|  |  |  |
| --- | --- | --- |
| Country | Number of centers | City location of centers |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |

|  |  |
| --- | --- |
| Tentative start date of patient enrolment |  |
| Estimated patient enrolment duration (months) |  |
| Estimated follow up time including treatment (months) |  |
| Please specify follow up frequency  (e.g., 1month, 3 months, etc) |  |

## Pre-study tasks

|  |  |
| --- | --- |
|  | Clinical Investigation plan writing |
|  | Clinical Investigation plan review |
|  | Statistical analysis plan/statistical sample size calculation and writing stats section in clinical investigation plan |
|  | Case Report Form design |
|  | Case Report Form review |
|  | Informed consent writing (English master) |
|  | Investigator brochure writing |
|  | Investigator brochure review |
|  | Investigator selection |
|  | Pre-study assessment visit |
|  | Translation of documents |
|  | Investigator agreement writing |
|  | Investigator budget preparation and negotiation |
|  | EC submissions |
|  | Competent Authority notifications |
|  | Project guidelines including annotated Case Report Form |
|  | Setup and management of study master files |
|  | Setup investigator files |
|  | Setup of centralised laboratory activities |
|  | Setup of Safety Boards (DSMB, CEC) including writing of charters |

## Study Management tasks

|  |  |
| --- | --- |
|  | Study initiation visit |
|  | Train investigation site personnel on use of device |
|  | Standard monitoring visits |
| If yes, how many per site and indicate frequency: | |
|  | Monitoring of centralised laboratory |
| If yes indicate frequency: | |
|  | Process and track investigator payments |
|  | Vigilance reporting |
|  | Management of CEC |
|  | Management of DSMB |

## Data management tasks

Data handling:

|  |  |
| --- | --- |
|  | Paper case report forms |
|  | Electronic data capturing system |

MD-CLINICALS works with both paper and electronic case report forms. The current systems available do not make it worth using the paper case report form as these are no longer cost effective compared to electronic case report forms. Nevertheless, if our clients prefer the paper format, we are more than happy to go with their preference.

|  |  |
| --- | --- |
|  | Data base design (including data management plan) |
|  | Statistical analysis |

If yes indicate the number of interim analyses you wish to perform:

## Post study tasks

|  |  |
| --- | --- |
|  | Study close down visit |
|  | Final report writing |
|  | Final report review |

## Other services

|  |  |
| --- | --- |
|  | Independent audit of study sites |
| If yes, please indicated number of sites to be audited: | |
|  | Setup of investigator meeting |
| If yes, how many meetings do you anticipate; | |
|  | Attending investigator meetings by Project Manager |
|  | Attending investigator meetings by monitors |
|  | Client meeting, if yes provide preferred frequency: |
|  | Periodic reporting to client |
| If yes indicate frequency: | |
|  | Setup and Management of study coordinators (Asia specific mostly) |
|  | Other services (please specify hereunder) |
| 1. | |
| 2. | |
| 3. | |

# Other non-clinical research services

|  |  |
| --- | --- |
|  | Marketing research |
|  | Setup distribution services |
|  | Research and compilation of Reimbursement file |

# Project description

## Device classification

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Europe | | USA | | China | |
|  | Class I |  | Class I |  | Class I |
|  | Class II a |  | Class II |  | Class II |
|  | Class II b |  | Class III |  | Class III |
|  | Class III |  | Non-significant risk  Significant risk |  | New material in China? |

## Study design

|  |  |
| --- | --- |
|  | Open non-comparative study |
|  | Randomized controlled study |
| If yes, how many control groups: | |
|  | Randomized controlled blinded study |

# Confidentiality

# MD-CLINICALS ensures that the information provided in this request for a tender is kept strictly confidential and proprietary to the requester. A standard confidentiality agreement may also be signed at your request, please send us your standard confidentiality agreement or request one MD-CLINICALS’s standard confidentiality agreement.

We thank you for your time and efforts in completing this form.

Danielle Giroud

CEO

MD-CLINICALS SA