



International country feasibility for the implementation of a Covid-19 Vaccine Trial

This document is a questions catalog which should help you to prepare for answering the online feasibility on our website: <https://exomgroup.com/survey/>.

Section 1: Company Information

- Company Name
- Contact Person
- Telephone
- Contact E-Mail
- Company Website

Section 2: Country Information

- Which country are you located in?
- Which official language(s) should be considered for the preparation of the participant's informed consent form?
- Are you covering any additional countries?

Section 3: Clinical Site related Information

- What potential sites in the metropolitan areas could actively participate to the study? *(please indicate the names of the sites and the city they are located in)*
- How many participants do you expect **each site** to recruit **per month**?
- Which sites are already involved in competitive vaccine trials?
- Please indicate a leading site (investigator) who could act as Study National Coordinator
- Please indicate the expected investigator fee per study (EUR or USD)
- Please indicate the cost of a molecular diagnostic Covid-19 test (EUR or USD)
- Please indicate the cost of a serological test (EUR or USD)
- Should participants be compensated and reimbursed for any possible related costs? If yes, how much should the fee be?



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Section 4: Regulatory related Information

- Are there any specific documents to be provided or procedure to be followed, for getting approval of a Covid-19 trial in your country?
- Please indicate the documents required for CA and ECs study approval
- How long does it take to get a Covid-19 vaccine trial approved by the Regulatory Authority (CA)?
- How long does it take to get a Covid-19 vaccine trial approved by the local Ethics Committee(s)?
- Should SAE and SUSAR be expedite reported to the local health authority?
- Which type of documents are required for importing the vaccine doses into your country?

Section 5: Vaccine supply importation and distribution

- Can you identify a drug warehouse where to store the vaccine at -80°C ?
- If you already have a warehouse in mind, please indicate here.
- Can you organize the distribution of vaccine vials from the country depot to clinical sites at -80°C controlled temperature?

Section 6: CRO Services Information

- What do you charge for the submission to the Regulatory Authority? (EUR or USD)
- What do you charge for the submission to each Ethics Committee? (EUR or USD)
- What do you charge for the negotiation and finalization of the financial agreements with sites per site? (EUR or USD)
- What do you charge for each site monitoring visit, considering the locations of the identified potential sites, travel cost included?
- What is your monthly fee for site management per site?
- What is your price for the participation in trainings related to Exom Groups Genius SUITE and SOP-System? (EUR or USD; # of Participants and duration)



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Section 7: Other Information

- Do you have any further comments?
- Please feel free to upload any supportive materials here. However, the questions should be answered using this online form. (Only PDF, DOC, DOCX, PNG, JPG, JPEG, GIF files are supported.)