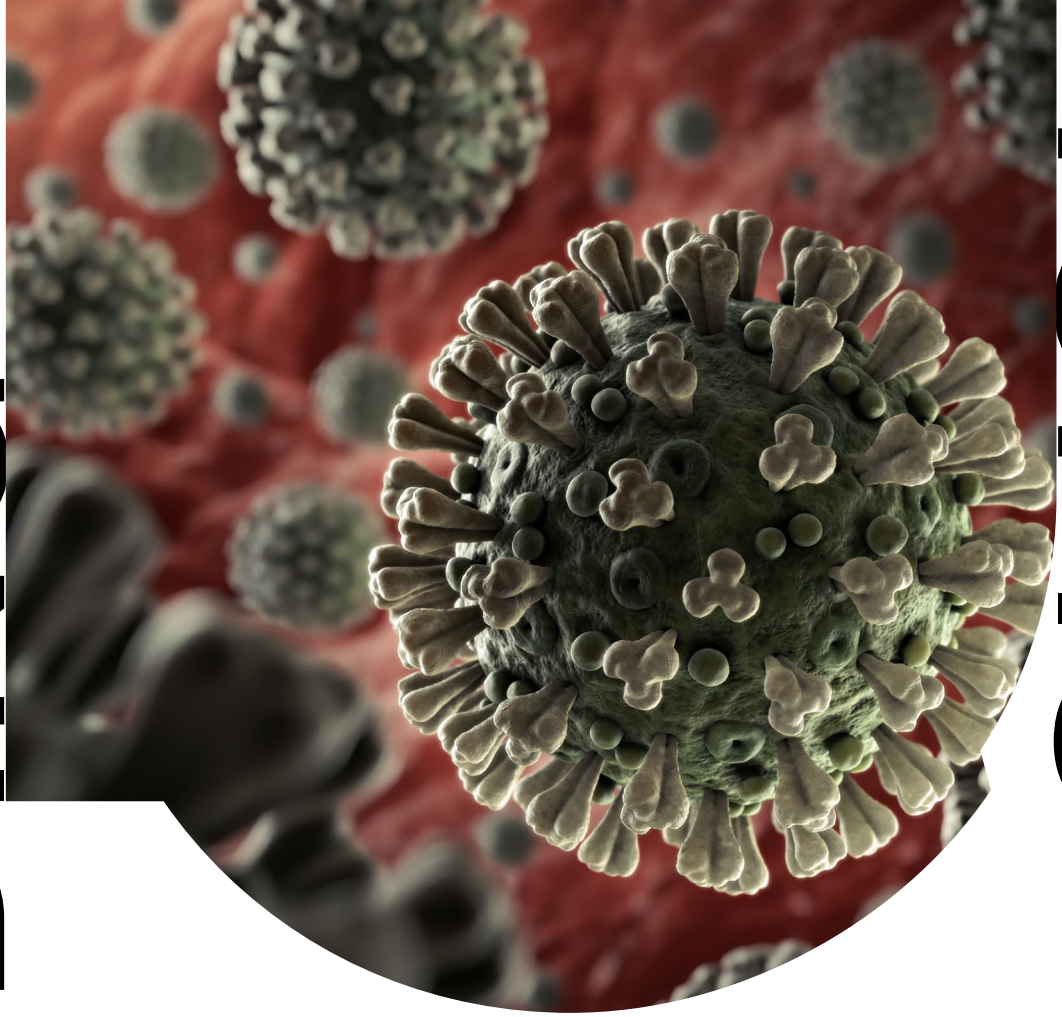
TRENDING TOPIC



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HEALTHCARE, LIFE SCIENCES & PHARMACEUTICALS

Coronavirus: Changes to clinical trials

INFARMED has published a set of exceptional measures – which will remain in force during the period of risk to public health – to be adopted by sponsors, clinical trial sites, and research teams, to guarantee the safety, protection and rights of clinical trial subjects".

PLMJ

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It has also defined INFARMED's evaluation of trials intended to treat or prevent the new Coronavirus disease (SARS-CoV-2) as a priority. Applicants must submit trial results through the RNEC (National Registry for Clinical Studies) and clearly identify in the subject that it is in the context of the COVID-19 disease. Applicants must also send an email to INFARMED (ensaios.clinicos@infarmed.pt) and CEIC (National Ethics Committee for Clinical Research) (ceic@ceic.pt).

On 4 February 2020, the European Medicines Agency (EMA) asked all those developing medicinal products or vaccines that can be used to treat or prevent the new Coronavirus, SARS-CoV-2, to contact the EMA to discuss the best strategy to develop drugs in order to obtain reliable information quickly about how a drug or vaccine works, and about its safety.

"Priority is given to INFARMED's evaluation of clinical trials intended to treat or prevent the new Coronavirus disease (SARS-CoV-2)."

To encourage this cooperation, on 13 March 2020, the EMA communicated the exemption from the payment of fees for any request for scientific advice from any entity that is to develop treatment therapies or vaccines for SARS-CoV-2. In this type of service, the EMA guarantees informal preliminary advice on the development of medicines. At the same time, it will also identify the products with the greatest potential that could benefit from accelerated scientific advice.

In relation to ongoing clinical trials, INFARMED recommends implementing the following measures:

- The suspension of recruitment whenever this would entail an additional risk of infection by SARS-CoV-2 for the subjects to be recruited and the immediate interruption of the trial treatment when the safety of the trial subjects is at risk.
- The assessment of the need to review the visiting arrangements in order to *(i)* adjust the frequency of visits during the period considered necessary and *(ii)* adjust the level of information collected on each visit. The possibility to carry out visits remotely (electronically) when the subject agrees to this, and only the information strictly necessary for the visit in question should be collected and recorded.
- The assessment of the need to review the monitoring arrangements, with the possible *(i)* postponement of in-person monitoring visits; *(ii)* implementation of centralised monitoring visits, and *(iii)* reduction of monitoring activities to what is possible to do remotely.
- In light of the current exceptional circumstances and provided certain requirements are met, it is still possible to dispense investigational medicinal products directly at the homes of the trial subjects. Alternatively, if the authorities require the intervention of a health professional and it is not possible to for them to ensure this can be done safely at the home of the trial subject, the subject may be transferred to another clinical trial site. If a transfer to another clinical trial site is not possible, the research centre must be closed.
- Any transfer between clinical trial sites must be done in compliance with the General Data Protection Regulation's Good Clinical Practice (GCP) and with the other ethical requirements or the transfer of documents between health care institutions.

INFARMED also recommends:

- The submission of documentation to INFARMED by email - ensaios.clinicos@infarmed.pt, and this is compulsory for all cases submitted to the RNEC.

- The guarantee of a reserve stock of the investigational medicinal product (of at least three months). If it is not possible to guarantee the reserve stock of the investigational medicinal product, it is necessary to check whether it is *(i)* possible to suspend the recruitment of trial subjects, and *(ii)* necessary to suspend the clinical trial, in accordance with how critical the trial subject's condition is, the therapeutic indications, and the risks of discontinuation.

- The guarantee of a reserve stock of non investigational medicinal products (NIMPs) or medical devices necessary to administer or handle the investigational medicinal products, for a minimum period of three months, if they are not part of the Strategic Stockpile of Medicines.

- The communication of any deviation from the protocol in the Sponsor Quality Management System.

The implementation of the above recommendations can be immediate, without the need for prior notification or approval of any substantial change, except when recruitment is suspended or the trial treatment is suspended.

The decision on the measures to be adopted must be preceded by a risk assessment of the specific case. This is carried out by the sponsor and the investigator, and it focuses, in particular, on the epidemiological risk associated with the trial and with the site where it is carried out.

"The implementation of the recommendations can be immediate, without the need for prior notification or approval of any substantial change, except when recruitment is suspended or the trial treatment is suspended."

If they conclude that, to protect the trial subjects, it is necessary to adopt some of the INFARMED recommendations in contradiction with the provisions of the protocol and the pre-defined procedures for the study, the sponsor must notify INFARMED, no more than 4 months after the pandemic crisis, with a report that systematically documents: *(i)* the set of measures implemented, *(ii)* the deviations produced, *(iii)* the assessment of the implementation of these measures, and *(iv)* the impact on the study after the end of the outbreak. ■

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