Since January 2020 Elsevier has created a COVID-19 resource centre with free information in English and Mandarin on the novel coronavirus COVID-19. The COVID-19 resource centre is hosted on Elsevier Connect, the company's public news and information website.

the Birmingham Environment for Academic Research local Cloud.[10]

UKCCMP delivers meaningful real-time data to all UK cancer centres and clinicians to allow more personalised approaches to individual patient care and inform clinical decision making. This initiative will improve cancer care in the UK and beyond at this time of unprecedented global turmoil and reliance on health-care resources.

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See Online for appendix

Members of the UK Coronavirus Cancer Monitoring Project team are listed in the appendix (p 1).

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Recommendations from national regulatory agencies for ongoing cancer trials during the COVID-19 pandemic

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Clinical research has transformed cancer care and is often integrated seamlessly into routine oncology clinics, offering eligible patients additional treatment options or lines of therapy. Typically, and particularly for diseases with poor prognoses or when trials entail biomarker-directed personalised treatment, clinical trial enrolment can be preferred (by both doctors and patients) over standard care.[1]

However, many barriers already preclude patients' participation in clinical trials, with only a small proportion enrolled in interventional trials.[2] The coronavirus disease 2019 (COVID-19) pandemic presents an additional major barrier to patients' enrolment and ongoing participation in clinical trials. Institutions are adapting their oncology practice, considering alternative treatment strategies to appropriately balance risks and benefits, despite the absolute individual risk increases from COVID-19 for patients being currently unknown.[3]

The US Food and Drug Administration (FDA) and other international bodies have released guidance for sponsors and study sites to ensure the safety of trial participants while maintaining compliance with Good Clinical Practice and minimising risks to study integrity. This guidance is summarised in the panel.[4–10]

Although this guidance is very welcome and helpful, specific considerations must be made for each trial, in view of the wide variety of study types, relative complexities, and perceived risks and benefits. Many study sites and sponsors have already stopped study enrolment, and it is not clear when these studies will reopen because of the probable prolonged effects of the COVID-19 pandemic. For patients on study treatment, the difficult decision to stop or carry on with the investigational medical product or other study treatments should be discussed between

***Panel*: Summary of guidance from national regulatory agencies for clinical trials during the COVID-19 pandemic**

FDA (USA; April 2, 2020)[4]

- Sponsors should make a list of contingency measures and record participants who are affected by the study's interruption because of COVID-19 in a specific study document or section of the study
- Establish procedures to describe approaches to protect study participants and manage study conduct during a possible disruption to the study as a result of COVID-19 control measures at study sites
- Consider optimising use of central and remote monitoring programmes to maintain supervision of clinical sites if needed
- The future of ongoing studies should be decided by consultation with sponsors, investigators, and IRBs or IECs
- Alternative safety assessments should be implemented if needed (eg, telephone medical review or virtual visit)
- Consultation with the appropriate review division is recommended regarding protocol modifications for the collection of efficacy endpoints, including, for example, virtual assessments and assessment delays
- Additional safety monitoring (including potential withdrawal of treatment) might be needed when a patient's access to the IMP or study site is lost
- Changes implemented in new or existing processes will vary according to the protocol and the local situation
- Changes to a protocol are generally not implemented before review and approval by the IRB or IEC and, in some cases, by the FDA
- Prioritise patients' safety
- Inform patients about changes to the study that might affect them

Instituto Nacional de Vigilancia de Medicamentos y Alimentos (Colombia; March 17, 2020)[5]

- When doing risk assessments, prioritise the most important aspects of the protocol and ascertain how these will be done
- Periodically assess patients' ongoing participation in the study by weighing up risks and benefits
- Consider remote follow-up visits (and monitoring) or visit delays, when visits to the study centre are not absolutely necessary
- Sponsors or clinical research organisations should provide safe transport and protection to minimise the risk of infection for study participants when attendance at the study centre is required
- Recruitment to continue according to the specific measures and restrictions of local government

NoMA (Norway; March 19, 2020)[6]

- Changes and new safety measures can be taken as soon as possible, even before NoMA approval
- Source data verification, when necessary, can be done remotely but should resume on sites once the situation returns to normal
- Take precautions about infection control
- Telemedicine use is necessary, when medically justifiable
- Study drugs can be delivered to patients but must be received directly by the patient themselves (ie, not sent by post), and drugs must not be sent directly by the sponsor
- When necessary, study-related assessments can be done by non-study personnel and at different sites, if considered acceptable by the PI, patient, and trial team

MHRA (UK; March 24, 2020)[7]

- Teleconferences and videoconferences are encouraged to maintain trial oversight; remote monitoring is acceptable, assuming patient confidentiality can be ensured
- Avoid extra burden on clinical staff because of increased pressure
- Inform MHRA if there is a direct participant safety issue or drug supply issue in halted trials
- Amendment must be sought if changes are made to protect participants' safety when restarting a halted trial
- Reduction in participant visits because of COVID-19 will not need a substantial protocol amendment, but appropriate documentation of rationale and risk assessment must be done
- Telephone calls are acceptable to replace visits in person, when possible
- Delivery of IMP to a patient's home is acceptable without needing an amendment notification; confirmation by telephone call can be used instead of a delivery signature

BDA (Bulgaria; March 18, 2020)[8]

- Sponsors and PIs should collaborate to decide which study visits can be done remotely (eg, by telephone) and which can be delayed or cancelled, applying a risk-based approach (including a study amendment) when necessary
- Patients can be transferred to another study centre should this be necessary to provide continuous treatment
- New trials shall not begin
- The sponsor should consider closing a study centre, and how to do so safely, if it is not possible for the centre to continue their involvement, and the BDA should be informed about how this is done
- A risk assessment should be undertaken to ascertain if patients' recruitment should be suspended

State Institute for Drug Control (Czech Republic; March 20, 2020)[9]

- Always ascertain the infection and quarantine status of the participant and their household by telephone
- Exchange patient's physical follow-up visits with telephone calls when possible, and provide patients with appropriate personal protective equipment when study visits are required

(Continues on next page)

(Panel continued from previous page)

- Study drugs can be couriered to patients from the trial site, or to a pre-agreed family member, and delivery should be confirmed by telephone and recorded
- Laboratory tests can be done at the patient's home, or the examination can be booked in advance at the study centre

European Medicines Agency (Europe; March 27, 2020)[10]

- Specific national legislation and guidance must be taken into account
- Sponsors should consider a risk assessment to modify ongoing trials and consider measures such as converting physical visits to remote visits, postponing or cancelling visits, halting or suspending recruitment to trials, and closing trial sites
- Consider transfer of participants to alternative study sites, and doing study assessments (eg, laboratory tests and imaging) at other centres, when necessary, to ensure participant safety
- Submit a substantial amendment application if changes are likely to affect the safety or wellbeing of the participants or the scientific value of the trial
- Risk assessments by the sponsor should be ongoing and documented
- Implement measures that prioritise patient's safety and data validity
- When consent needs to be reobtained from patients for studies, visits to centres solely for documentation of consent should be avoided; consent can be obtained using other means (eg, verbally over the telephone or by video-call with email confirmation)

Dates provided are the dates of the last update to guidance. COVID-19=coronavirus disease 2019. FDA=Food and Drug Administration. IRB=institutional review board. IEC=independent ethics committee. IMP=investigational medicinal product. NoMA=Norwegian Medicines Agency. PI=principal investigator. MHRA=Medicines and Healthcare products Regulatory Agency. BDA=Bulgarian Drug Agency.

sponsors and study sites, but most importantly between the investigator and patient.

Substantial uncertainty remains about which interventions or treatments might increase the risk for contracting COVID-19 or for COVID-19-related morbidity or mortality. Presumably, immunosuppressive regimens and drugs with a higher risk for drug-related lung injury present the biggest risk to patients. Careful consideration of additional COVID-19-associated risks of continuing these agents should be balanced against the potential issues with stopping or delaying treatment that might extend life, help with or delay symptoms, or reduce the risk for disease-related complications.

We encourage all sponsors and regulatory authorities to permit rational changes to study assessments and interventions that allow individualisation of these complex decisions, putting the patient first while continuing to optimise safety and endpoint assessment. We hope that risk mitigation and easing of previously inflexible rules, which will put the patient at the centre of clinical research, will continue long into the future.

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