NHS
Research and
Development Forum

COVID19: Impact on Clinical Research
For the Department of Health & Social Care

General picture to date (12th March 2020)

The following contains examples, insights and information from a cross-section of organisations whose members form the NHS R&D Forum working groups. Please note the examples below are therefore a general picture and are not necessarily reflective of activity across the UK.

- Organisations are holding regular meetings to take decisions around and HRA their research portfolios and are writing Organisational guidance for their research staff. This Organisational guidance is being continually updated and we have a number of examples to share via our resources exchange.

- Organisations are reporting a general slow down in recruitment and study visits with patients not wanting to attend hospital, GP practices or have extra visits etc.

- Some Oganisations are already suspending study recruitment and this could be either as a site or as a Sponsor. For example due to a particularly vulnerable patient population a site has suspended recruitment to a study but the study itself is remaining open.

- Some sites are not taking on any new studies and are risk assessing their portfolios to decide which might be closed or halted temporarily to ease capacity. Some plan this.

- Some Organisations have cancelled visitors who are external and not patients or relatives. This prevents study monitors, Clinical Research Associates and external researchers etc. visiting, cancelling on site study monitoring, site initiation visits and pre-study visits for example. We are aware that cCOG are tracking this situation to help inform their plans for oversight.

- Many organisations have formally agreed that research staff may be deployed to clinical areas to support within their clinical competence and are preparing them to do so, with fit testing of equipment etc. Some are releasing research space.

- Sponsors and sites are working with their Chief and Principal Investigators to **risk assess** their study portfolios for the following and to put mitigating strategies in place:

  a) The safety of study participants who are continuing on the study protocol. This might include the risk of more frequent trips to hospital/GP surgery or particular areas within the hospital plus the risk of taking the study intervention itself should they contract COVID19.

  b) The safety of study participants if the study has to be halted or is unable to be delivered because research staff are not available due to sickness or deployment to the clinical setting. This might be assessed specifically in order to re-deploy staff.

  c) The risk to the organisation and to important research data if the existing portfolio of research can't be delivered because research staff are off sick or working in a clinical setting.

  d) The risk to researchers, monitors and staff who might be visiting sites that have a higher chance of infection

  e) The risk to other organisations from materials/bloods etc. that might be infected with Corona Virus

  - Sponsors and sites are reviewing their study portfolios on a regular basis to agree which studies are then priority for continuing support and which may need to be halted temporarily or otherwise. Some organisations have agreed a series of criteria or levels upon which to make this decision and example of these can be provided.

- Some have reported evidence that clinical researchers are keen to prioritise their clinical standard patient care commitments at this time of public health emergency

- Organisations are informing Sponsors when they are halting a study and drawing on the Force Majeure clause in their research, research funding or clinical trial agreements.

- In Primary Care there is a sense that if practices are being advised not to bring in individuals for routine health checks (to be confirmed) they are likely to be applying the same principles to research visits. There is some concern that communication with GP practices and research support teams is going to be more challenging that for Trusts and that this is likely to vary within a given area.

- Planning for taking part in pandemic research is underway where it is possible to do so.

  "We are involved in local Trust planning regarding COVID19 19 and the implications of the PHE on continuation of research are being actively assessed by Trust Leadership teams. Practically this is with regards to prioritising studies, releasing research staff to support clinical staff and/or releasing research space to the Trust to manage patients, protocol deviations/USMs in case of a lockdown, mitigation strategies on a study basis, considering if any amendments would be required, research team numbers/ delegation and who to contact if the PI is unavailable"

Co-ordinated Guidance

The following have been highlighted as requiring further co-ordinate guidance, position or support. We recognise this landscape is changing on a daily basis:

- There is some evidence of uncertainty from research teams and sponsors as to how participants already enrolled in studies can best be supported to continue along protocol pathways and have

continued access to investigational products and treatments should there be a public health emergency.

- Clear guidance on how to manage study deviations in this context would be welcome and we note the new MHRA and HRA guidance issued at the time of writing. Clarity on the regulatory implications for amending how studies can be run to enable participants to continue on study in a safer or self isolating location e.g. remote consultations and posting drug. For example when is an activity a deviation and when is an amendment required

- How to manage temporary suspension of studies from the regulatory perspective. Clarification from the MHRA regarding whether temporary halt of trial notifications are required if sites stop recruitment (not just Sponsors).

- A fast track process for the approval of amendments to studies to enable more flexible recruitment, recruitment from home etc., and whether there maybe some flexibility in the 15-days to notify of amendments and halts given that sites may be short staffed.

- A position statement that NIHR CRN staff should prepare to support clinical care and outreach safety visits for active participants and that RTT penalties will not be applied.

- Guidance on suitable platforms for remote working and consultation with participants from a confidentiality and GDPR perspective.

- NIHR accept that studies will be delayed then we will need 'no cost extensions' but where staff have been employed as practitioners/researchers on fixed term contracts their contracts will need extending and there will be a cost.

- Clarity on whether the advice for research patients should still be to contact 111 if they have the COVID19 symptoms. For patients in cancer CTIMPS some organisations are advising that the trial

participants first contact the study team so that the patient can be advised if they need to call 111. If patients who are advised to call 111 and then are asked to self isolate or be swabbed then this needs to be recorded as an SAE.

- Any general guidance at all on how studies might best be prioritised in the national interest? We realize this is extremely difficult.

- Advice to ensure that there remains capacity and capability to deliver the COVID19 studies if clinical research staff have been deployed to clinical areas and support for boards to realize the importance of these studies as priority. This may not be in place immediately.

Impact and issues:

- We anticipate there is a risk of considerable impact on research as the public health emergency escalates with some level of impact on all aspects of research and research data.

- The sharing of practical solutions to enable data to be collected and verified at home are urgently required to ensure that the data already collected is not lost. A flexible regulatory landscape to enable this would be welcomed.

- Given the short-term nature of research training there is a also a possibly very real impact on people's careers as their studies are de-prioritized by sites (PHDs etc)

- A coordinated approach or position for solving contractual, financial and resourcing issues and threats might be beneficial.