NRS Strategic Restart Advisory Group

12th November 2020 Minutes

Attendance List

Prof David Crossman	Chief Scientist
Euan Dick	Head Of Chief Scientist Office
Dr Alan McNair	Senior Research Manager
Gordon Watt	CSO/ NRS Funding, Ethics and Intellectual Property
Dr Charles Weller	General Manger of Central Management Team
Tom Baggaley	AMRC
Prof Patrick Mark	NRS Speciality Group Lead for Renal
Prof Jurgen Schwarze	NRS Clinical Research Champion for Children
Clare Orange	NRS Biorepositories
Ben Chui	Cancer Research UK
Dr Helen Bodmer	MRC/UKRI
Dr Andrew Keen	NHS Innovation
Dr Sheuli Porkess	ABPI
Dr Andrew Fowlie	NHS Innovation

Apologies: Prof Tim Walsh, Prof Maggie Cruickshank, Prof Julie Brittenden, Prof Jacob George, Raymond Hamill, Carol Porteous, Marion O'Neill, Prof John Cleland, Prof Andrew Gumley, Prof David Cameron

1. Welcome (Prof David Crossman)

Prof David Crossman welcomed everyone to the fifth Restart Advisory Board meeting and progressed through the actions from the previous meeting below.

Can CMT review the metrics associated with the NRS activity paper and work out a method to highlight follow up activity at the next meeting The NRS Activity Paper was circulated to members. This includes data on follow-up and will be discussed under agenda item 4.

R&D directors should communicate with medical directors in the event of it being difficult to identify which clinical services would remain open in subsequent covid waves. Ongoing

Dr Alan McNair to request if he can share the response to the NIHR Restart Issues paper from the NIHR Implementation board with this group. Agreement from William van't Hoff to share paper with this group. Circulated to members as Clinical Restart Analysis pdf and will be discussed under agenda item 5.

Dr Andrew Fowlie to follow up with the group on the outcome of working with NHS colleagues to assess where the lack of solutions are to restart research. Meeting between CMT, Alan McNair, Andrew Fowlie, Andrew Keen and Billy Hislop (Head of software procurement for NHS Scotland) to discuss these issues.

Dawn Williamson and Johnathan Berg to liaise with NRS PCC to confirm with boards that they should complete one risk assessment per board which will allow all musketeers studies in their board area to restart. Completed

2. AMRC Impact of Covid (Aisling Burnand and Tom Baggaley)

Tom Baggaley presented details on the importance of funding from AMRC members and the positive impact this has had mainly on patient research and investment in early researcher careers. The impact of Covid is anticipated to cause a projected decrease of 41% of available research funding equating to £252 - 368 million in the coming year with an estimated 4.5 years for charity research spend to recover.

AMRC are calling on the government to set up a life sciences charity partnership fund. This would ensure the UK maintain their current high position in the life sciences sector. The co-investment scheme would be a match funding proposal over the next three years and will require £310 million to fund the projected shortfall. Over 30 pharma and bio-industy companies have backed the proposal. The concern is that if the shortfall in funding is allowed to occur then the diversity of research may flounder and will take longer to recover.

AMRC has built on the campaign to highlight the further economic benefits to the UK not just including the obvious patient and researcher benefits. The funding is anticipated to be confirmed on the 25th November by the cabinet secretary.

To continue the awareness of the subject, AMRC, CRUK and the BHF have a paper published in the lancet on the requirement of the support needed for UK Charities.
https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(20)32397-7/fulltext AMRC will continue to raise awareness through current affairs activity.

If the bid is not successful, each of the charities will have their own planned approach. Many of which are already in the public domain. Lockdown is a continuation of the problem where charity shops have been forced to close and face to face funding ventures are unable to happen.
Prof David Crossman: If the bid is successful how will AMRC allocate the funding?
Aisling Burnand: AMRC have put together a criteria and a formula to allow fair funding distribution across all research charities. Charities will submit what they intend to focus on in the next year and will be requested to report back on the outcomes they have achieved. The funding delivery mechanism is yet to be confirmed but likely to be a research council or government body.
Prof David Crossman: Could CSO view the proposed allocations if the bid is successful? CSO would also be willing to extend help for financial distribution in Scotland. In addition perhaps the R&D directors could help identify studies which can come to conclusion without the requirement for additional funding?

Action: Raise with the R&D Directors if it is possible to have a review process which can identify studies that can come to conclusions of the study early. These studies could be closed and allow additional funding to be recuperated?

3. NRS Activity Report (Ian Anderson)

Ian Anderson narrated around the presented NRS Activity Report and reminded everyone that the baseline was taken in July. There has been some different statuses implemented which will provide more clarity on study sites which were in follow up and those which were active and still recruiting when they went to suspension. The data is still provisional as these new statues were only rolled out on 21st Oct and may still fluctuate as they are corrected.

Dr Sheuli Porkess: Suggested that it might be useful to keep in mind that although some studies may appear non covid related in their suspension it could be because of backlogs in the system due to covid i.e clinical services such as scans. Also to begin looking at different statuses which might need to reflect Brexit issues (after 31st Dec) which could be disruption in trial supplies. Could the colouring be reversed to show that a reduction in numbers is a positive not a negative and therefore should potentially be green rather than red?

Prof Paddy Mark: was keen to highlight that while PIs would be keen to restart and open their studies, but are concentrating their efforts into Covid studies as a means to an end. Dr Charles Weller: also highlighted that in this second wave very little studies would be restarting and that recruitment would remain low into those studies which were open.

Prof David Crossman: Raised if there were any issues with the data being presented on the website it might help disperse some myths about research activities. Dr Sheuli Porkes if the intention is to publicise the data, may need to highlight that there are slight differences between NIHR and NRS data where Active means with and without associated recruitment compared to NIHR CPMS data.

Ian Anderson added that it was Difficult to follow up on high versus low intensity of studies and how many live patients are in follow up. Dr Sheuli Porkess it might be useful to know why follow up is suspended and why this is different to suspended recruitment. Is there a way of identifying this? Prof Jürgen Schwarze : Would it be possible to view the trend of data over years for paediatrics? Is there a way to use this data to provide credit associated with in follow up studies as this is an intensive and overlooked issue across NRS. Prof David Crossman: More understanding around numbers in follow up and build on the data if possible and Ian Anderson to discuss with Dr Sheuli Porkess offline to identify what would be beneficial to understand.

Action: Ian Anderson to review new suspended status which would take into consideration Brexit issues. Review the colouring code used to highlight the shift of study sites restarting.

Action: Ian Anderson review if publishing the NRS Activity papers on the website would be feasible?

Action: Ian Anderson to discuss with Dr Sheuli Porkess on the details which would make follow up information more valuable to the group.

3. NIHR Implementation Board Response to NIHR Issues Paper and building resilience into research going forward?

This paper was circulated to the group and represents the response from the NIHR Implementation Board to the NIHR Restart Issues paper which originated from the NIHR Restart Advisory Board. There is a high degree of commonality between NIHR and NRS issues with specific reference to the 13 action points into 5 key areas. Dr Alan McNair welcomed a view from the restart advisory board, however was willing for CSO to

draft their own responses on behalf of the Advisory Board but would welcome other views to incorporate feedback. Dr Sheuli Porkess wrote the original restart document at the end of summer where covid incidence was lower. The responses from the Implementation group have come during the second wave where it is more evident that we should consider shifting restart into resilience. The three key action areas which could be reviewed and actioned on at this point are:

1. Embedding research into clinical care to prevent the competing nature of resource
2. Shifting to more virtual research landscape
3. Involving sponsors to incorporate resilience as listed above into funding bids

The aim to have a system where any patients approaching the NHS is also offered a clinical trial will only be realised if we identify and work to correct some of the issues above.

Prof David Crossman: We need to look at patient groups and raising awareness as it is difficult for individual organisations to do this. This would be a requirement of a strong patient group to drive this forward and raise this issue with a need to draw patient groups into the availability of trials. However, there is a need to have system which is ready for it, which is where NRS comes in. The biggest regret would be not to learn from the pandemic and make the changes required to install more resilience in the system.

Prof Paddy Mark highlighted that the general NHS is struggling with the capacity to fulfil routine clinical services and guarantee a safe environment for patients. There has to be better control within the system for example routine screening before we can proceed fully and engage in restart. Although there is optimism in vaccine cover and faster screening technologies in the future there should be a recognition that the NHS is in a very difficult situation at present.

Action Dr Alan McNair will write and circulate a CSO response to the NIHR Implementation paper.

Action: Could Carol Porteous report on the work which goes on within PPI which helps to drive awareness to the general public on clinical trial availability?

4. AOB

The Biorepositories of NHS Tayside and NHS Grampian have raised issues with obtaining donated tissue. The health boards are looking into having same day consent and clinical teams are unhappy that patients may not have the time to read PIS and that face to face consent is an issue. NHS GGC has various methods of remote consent and Clare Orange will present some of these workings with the group initially.

Next meeting scheduled 17th Dec 1030-12noon