NRS Strategic Restart Advisory Group

23rd February 2021 Minutes

Attendance List

Prof David Crossman	Chief Scientist
Euan Dick	Head Of Chief Scientist Office
Dr Alan McNair	Senior Research Manager
Ian Anderson	Information Manager
Dr Charles Weller	General Manger of Central Management Team
Prof David Cameron	NRS Clinical Champion for Cancer
Tom Baggaley	AMRC
Prof Patrick Mark	NRS Speciality Group Lead for Renal
Prof Jürgen Schwarze	NRS Clinical Champion for Children
Clare Orange	NRS Biorepositories
Raymond Hamil	R&D Manager for NHS Lanarkshire and representation for DG
Ben Chui	Cancer Research UK
Prof John Cleland	CTU Director for Greater Glasgow and Clyde
Dr Andrew Keen	NHS Innovation
Dr Sheuli Porkess	ABPI
Dr Andrew Fowlie	NHS Innovation, CSO
Dr Andrew Keen	NHS Innovation, NHS Grampian
Prof Andrew Gumley	NRS Clinical Research Champion for Mental Health
Carol Porteous	PPI
Prof Julie Brittenden	R&D Director for Greater Glasgow and Clyde
Prof Maggie Cruickshank	R&D Director for Grampian
Dr Helen Bodmer	UKRI/MRC
Carol Porteous	PPI Representative
Prof Tim Walsh	R&D Director for NHS Lothian
Prof Jacob George	R&D Director for NHS Tayside

1. Welcome (Prof David Crossman)

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

Action Dawn Williamson: Circulate the levelling up agenda (20.01.20) and DHSC Pillars (22.01.21). Completed.

Action: Andrew Fowlie to provide a paper on the stakeholders who have been selected to be involved in the software and data task and finish group at next meeting. Ongoing.

Action Ian Anderson: to re-send suspended status to all boards to ensure they are being interpreted correctly and are reflective of the actual reality of the situation. Agenda Item#3

Action Ian Anderson: Identify a list of studies which have not recruited since the pandemic began with reference to those studies with statuses of "suspended" and "active" categorised by speciality and health board. Agenda Item#3

Action Dr Alan McNair: Set up a virtual clinical lead network meeting with R&D directors to focus on discussion topics such as identifying reasons to lack of recruitment on "active" studies and identifying studies which may not mobilise from "Covid-Suspended" to "Active". Meeting held on February with joint Network and SG leads with R&D Directors. Will follow up once minutes are done.

Action Dr Alan McNair: Dr Alan McNair will write and circulate a CSO specific response to the NIHR Implementation paper on barriers to research. Circulated to group on 22nd Feb.

Action CSO Task the group into sub groups to provide a summary of key steps that is within the power of CSO to take forward with regards to implementing resilience. Agenda Item#6

Action CSO: Identify if representatives from Information governance should be considered for membership of this group.

2. AMRC Update on Life Charity Partnership Fund - Tom Baggaley

Tom Baggaley provided an update that the likelihood of any level of government based funding was low. The Life Charity partnership fund is now no longer an option. Outcomes of the spending review in 2020 are looking at a limited settlement for a limited number of charities for 21/22 which is far less than they were hoping for. AMRC are continuing to engage with UK Government and have a scheduled meeting with Matt Hancock.

Prof David Crossman: Is the projected loss still expected and if there is no additional funding is there a sectorial approach or will it be left to charities to find funding.

Tom Baggaley: Whilst the loss of funding hasn't been quite as bad for some funders, the loss and impact is still significant. The next steps for AMRC is how to represent members on this issue. Another assessment of how much this is likely to cost the sector and from there pull members together and look ahead to another spending review.

Helen Bodmer: UKRI/MRC are still awaiting allocations which are expected to be flat also.

3. NRS Activity Paper - Ian Anderson

Data presented is from 2nd Feb. 18% of non-commercial studies are still currently "Covid suspended" which is a 27% reduction since last report. Similar news on commercial studies where 11% commercial studies which is a decrease in 40% since last report.

IA presented on additional data which reviewed studies which have recruited in the last 6 months. This correlated to 30% for studies and 25% in view of study sites.

Those specialty areas which have recruited to non covid studies during the past 6 months are those where patients which are embedded in the clinical care pathway i.e. critical care, stroke, cardiology and surgery. Caveat to consider is that some specialties outside of these may also still be heavily invested still on covid related work.

Studies are currently re-opening even if the recruitment has not returned. It should be noted that even though non covid recruitment has not returned the highly successful volume of covid recruitment far exceeds previous recruitment levels from previous years for this period.

Prof David Crossman: raised a query of the data where Cancer was recruiting 26% of non covid patients which is lower in comparison to other specialities. Does this elude to Cancer services closed or temporally suspended? The R&D Directors commented that Cancer has lower recruitment targets due to stratified approaches. Only Cancer studies which haven't opened are those which haven't opened due to Sponsor request. R&D are continually re-opening studies. Dr Charles Weller: Highlighted that we don't have a base line for this data under normal circumstances so might be that such a percentage of the NRS portfolio is normal for Cancer.

Prof David Crossman: While we proceed through JCVI cohorts should we have patients with co-mobirdy conditions return to trials and acute hospital locations for trials. Do we expect that patients will return to CRF with vaccine deployment on the horizon for many? Prof John Cleland: Long covid studies may take up a considerable capacity and there might still not be flex in the system to continue normal non covid activity given also the follow up required for covid related work including vaccines. Also there could be the requirement for boosters in autumn which could further defer patient's confidence in returning to acute hospital locations for research. Dr Alan McNair: Highlighted that the patient attitude survey last year which showed fairly robust confidence in returning to trials and wondered if there was scope to extend this. Carol Porteous: Happy to support the feedback on this question through some national PPI workshops which are upcoming. Also will discuss with Ellen Drost on revisiting the patient survey for a revised response.

A paper from Ian Anderson was provided to the group on the board challenges on reopening. Large majority appears to be sponsor delays and lack of patients returning. Other issues are priority 3 studies (non-covid) are not reopening, PI not having the capacity to deal with non covid research. Prof Julie Brittenden suggested repeating this exercise in May which might provide a better picture. This scoping exercise was performed during the height of the second wave. Maybe useful to re-ask boards again in a few months. Prof Maggie Cruickshank: Grampian does a lot of studies in surgery particularly in gynaecology and clinical services are still suspended in this area so accumulating a lot of recruits but with no open trials.

Action: Carol Porteous to speak with Ellen Drost to revisit and look again at evaluating patient confidence in returning to research particularly now vaccine deployment is being rolled out and on the horizon for many.

Action: Ian Anderson to revisit the request of board challenges on reopening in early May.

4. Restart, Resilience and Growth - Dr Sheuli Porkess

The RRG programme is a UK cross sector wide look at how to rebuild, restart, recover and add in resilience to the clinical sector. The RRG is split into three meeting panels with all devolved nation involvement. RRG Oversight board meets with representation from Prof David Crossman, RRG Programme board has met every two weeks and has Euan Dick representing and finally the RRG Advisory Group has Scottish representation of Joanne Rodger (CSO) and Steve McSwiggan (NHS Lothian, CRF manager) involved. The RRG programme board are looking for immediate short time actions to be circulated by 31st March. There

will be a four nation ministerial meeting to move the RRG plan to progress through four distinct national systems.

The deep dives of discussion are:

- UK vision of Clinical research currently out for consultation
- Workforce actions from the Industry/Government group and recommendations for workforce planning for future
- Risks around restart from a commercial perspective. ABPI members not being able to plan restart or complete existing studies.

UK commercial colleagues are having difficulties explaining to their global counterparts the unknown expected restart and thus completion of studies. This unknown is driving a worrying potential of commercial companies pulling out of UK which will also reduce commercial UK headcount. The aim is to identify how we enable flexibility to deliver the study when some or the majority sites are unable to open. Commercial companies are also receiving messaging around the exclusion of all non UPH studies. Commercial companies are concerned that their studies will be permanently shelfed as long as the UPH prioritisation exists. There is ongoing work to help commercial companies provide a response and work with sites to identify ways in which to re-open.

Ian Anderson and Dr Charles Weller highlighted that there is a potential scope to deliver a record breaking order book value based on the high per patient fee protocols currently awarded to NRS for 2021. Feasibilities are continuing to come in and have actually seen an increase in 3-4%. Prof John Cleland: Some studies have not stopped recruiting and it will be concerning if UK cannot return to normal.

Prof Paddy Mark: NHS still have huge volume of nursing staff on sick and whom are burnt out. Local investigators are still struggling with the resilience to restart normal routine clinics let alone research.

Dr Sheuli Porkess: Commercial companies feel if they aren't part of the recovery they are far down the priority list due to the prioritisation. Companies are identifying a lot of study sites which are keen to restart but do not have workforce or clinical service to perform the studies. Prof Julie Brittenden: The most successful specialities were those which were embedded within the service. Prof David Cameron: Why are we sending out the message on prioritisation to a possibility of losing studies? Dr Alan McNair: CSO has aligned with the UK wide prioritisation matrix. High up on the list are those which are non covid studies and three messages on this have been communicated to the NRS Community. A further communication to the community could be sent out if this would prove useful. Euan Dick: CSO message is clear but there are difficult and practical constraints within different boards which leads to the heterogeneity observed of study restart. Discuss with boards that key messaging to commercial companies should not be that only UPH studies can take place. Dr Sheuli Porkess: Important to communicate the actual barriers of sites unable to take part in commercial studies. Commercial companies may be able to help.

Prof Tim Walsh: Destructive issues were the drop everything studies to make way for SIREN and vaccine studies and potentially begin to look into Covid as a business as usual. Until this message is clear with the potential removal of the prioritisation matrix there will still be issues with restarting non Covid studies. Prof David Cameron: A drop everything study is still heterogeneous across the boards. Prof Julie Brittenden: Prioritisation has been helpful but could we agree a date when the prioritisation schedule could be removed. In time this message could impact the regrowth of portfolio. Raymond Hamil: Would suggest linking the Route map out of lockdown to the prioritisation matrix. It's uncertain when Scotland commercial studies can reopen however this links directly to clinical services which links to the route map out of

lockdown which is government driven. Dr Helen Bodmer: Changing prioritisation is useful but should do with a UK wide position rather than individual nations of the UK. Prof David Crossman: Linking to route maps is useful discussion to have. Euan Dick: CSO would like to ensure there are clear messaging and clear that the boards have the executive decision on how to proceed with opening studies. Could raise the issue of when it is expected to at the RRG board meeting. Sheuli Porkess agreed to take this to the RRG programme board. Dr Alan McNair: Could useful to also raise the prospect of UPH long Covid studies. Prof David Crossman: If there are large commercial studies which are more beneficial to patients than others and if we could nationally prioritise opening these?

Action: CSO to review potential NRS messaging around request to open as much of the NRS portfolio where possible and not to the exclusion of non covid trials where it is feasible to open even if it is not a UPH study.

Action: Euan Dick and Sheuli Porkess to raise with RRG programme board on an indication when the prioritisation matrix might be removed especially with the flurry of many new Long Covid studies which will be potentially badged as UPH.

5. Creation of Sub Groups to help implement resilience - Prof David Crossman

The formation of sub groups will be expected to help move the NRS portfolio from recovery to resilience. Andrew Fowlie has provided some work on Software and the data task and finish group and will be able to report back. Looking for an additional sub set of members to contribute to a sub group theme and help to set time lines and key outputs. CSO looking for action points which can be verified and discussed by this group which would help secure potential resource required. For example, NHS Research Scotland portfolio has a 30% cancer portfolio and there is a very active cancer resilience group with a sub group reviewing equity of cancer trials. What are the key aspects to discuss to help move the agenda onto resilience? Prof David Cameron: Cancer are reviewing the lessons learnt and now reviewing equity of access which is easier as cancer care is embedded in clinical care. If there were any calls for individuals looking to join the sub group they are more than welcome.

Prof David Crossman How to make commercial studies more resilient with regard to the prioritisation issues raised in section 4. Would it benefit to have a lessons learnt? Prof Julie Brittenden: look at not just commercial but tall those studies invested in patient care.

Dr Charles Weller looking to reconvene commercial manager meetings and it might be useful to involve them in the queries raised in section 4 and how to make progress.

Dr Sheuli Porkess suggested the industry partnership forum. Dr Charles Weller would like commercial managers and the IPF to feed into commercial managers meeting will discuss with key colleagues in CSO.

Prof Jurgen Schwarze: worth reviewing remote working as a regular conduct of studies i.e. remote consent, monitoring, SIV etc. This will open access to trials who are unable to travel and sending out IMP to home residences etc. Prof David Crossman: This would be part of the data and software group led by Andrew Fowlie and Prof David Cameron is also reviewing this in his sub group with regard to the equity of trials.

Prof David Cameron: Could there be lessons where we do not have to shut down research in its entirety again which are not necessary related to Covid. So we understand what we didn't need to do. When research is challenged is there a guidance document which could support boards and networks? Dr Alan

McNair is there scope for key international learnings could be identified through ABPI interactions contacts members. Prof David Crossman: CSO could request ICJU to provide covid data.

Prof Crossman indicated that the NHS digital and data group will be one subgroup which will be led by Andrew Fowlie. In addition taking some of this information should be projected to four nation discussions. Euan Dick: Key outputs from the resilience sub groups could be with reference to producing a resilience document suggested by Prof David Cameron and from Prof Julie Brittenden on how we learn from the pandemic. This could also help progress our agenda as a one Scotland approach. Dr Charles Weller: Planning for the next emergency, would do well to take some learnings and experiences from pandemic protocols such as ISARICH. Protocols such as these can provide the invaluable. Raymond Hamill: Should be careful to consider the membership of those groups and ensure that those groups of people who are required to practically make changes are involved in the discussions not just dictated at by higher board or policy members.

The sub groups to be formed from this group will be:

- NHS Data and Digital - applications through the life cycle of clinical trials to increase resilience
- Lessons learned - how to avoid shut down in the event of future pandemics or subsequent waves of the current pandemic.

The Sub group of Data and Digital and Trial managers will be able to review on lessons learned. CSO will work on a four nation's basis to gather intelligence from ICJU and will take forward with NIHR and Sheuli and Euan through RRG.

Action: CSO to review learnings from the ICJU and four nation working on lessons learned to feed into NRS Restart sub groups.

6. AOB

Ben Chui: CRUK will be publishing a report on how COVID-19 has demonstrated how foundational the NHS is to UK medical research, and we now faced with an unprecedented opportunity to learn from the pandemic and expand the NHS's capacity to consistently and quickly deliver research that will accelerate the UK's recovery from COVID-19 and build a world-leading environment for clinical trials. This will be circulated in due course from this meeting.

Next meeting scheduled 26th April 2021