NRS Strategic Restart Advisory Group

9th September 2020 Minutes

Attendance List

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
Dr Ewan Dougall	Central Management Team
Ian Anderson	Central Management Team
Prof Julie Brittenden	R&D Director NHS Greater Glasgow and Clyde
Prof Tim Walsh	R&D Director, NHS Lothian
Prof Maggie Cruickshank	R&D Director, NHS Grampian
Prof Jacob George	R&D Director, NHS Tayside
Raymond Hamill	R&D Director, NHS Lanarkshire
Prof Patrick Mark	NRS Speciality Group Lead for Renal
Prof Jurgen Schwarze	NRS Clinical Research Champion for Children
Prof David Cameron	NRS Clinical Research Champion for Cancer
Prof Andrew Gumley	NRS Clinical Research Champion for Mental Health
Prof John Cleland	Director of CTU Greater Glasgow and Clyde
Clare Orange	NRS Biorepositories
Marion O'Neill	Head of External Affairs Cancer Research UK
Dr Helen Bodmer	MRC/UKRI
Dr Mehwaesh Islam	AMRC
Dr Andrew Keen	NHS Innovation
Dr Charlie Mayor	NRS Safe Havens
Dr Aisling Burnand	AMRC
Carol Porteous	PPI / PE
Dr Sheuli Porkess	ABPI

Guest Speakers: Dr Ellen Drost, Primary Care Network Manager.

Apologies: Prof David Crossman

1. Welcome (Dr Euan Dick)

In the absence of Prof David Crossman, Dr Euan Dick, Head of CSO welcomed everyone to the fourth Strategic Restart Advisory Board. Euan Dick progressed through the actions from the previous meeting below.

2. Actions (Dr Euan Dick)

Action: Raymond Hamill to provide feedback on the high number of suspended studies amongst the Dunfermline Group (DG) Boards. Is this a sponsor or site issue to re-open? With regard to NHS Lanarkshire and other DG boards, the delay is not sponsor related but an issue with the reopening of clinical services. All of DG research is dependent on existing clinical services which up until now has been a slow process to restarting. As clinical services reopens this is correlating with the number of research studies now also restarting.

Action: Prof Maggie Cruickshank provide a report on what second lockdown means and the impact to research. Although the public guidance was amended it didn't change for the health board and allowed us to recruit again to Covid studies. The amendment in guidance didn't impact the health boards ability to continue with research.

Action: Any data which would help underpin the understanding issues with site or sponsor. Will be picked up under Item 5.

Action: Prof David Crossman and Dr Alan McNair to further investigate the overall book value of commercial activity. Will be covered in item 5 How steps might be considered to support trial activity through the recruitment of clinical support workers and to raise any pertinent points at a future meeting of the cross-UK working group. **Dr Alan McNair** responded, this was originally raised by the group to help support and increase patient recruitment in trials by having access to a graduate level group of trainees. CSO do not feel that this is required at present after canvasing opinion but will revisit with R&D boards and Networks across NRS and action as required. The group, **Prof John Cleland**, **Prof Paddy Mark** consequently noted that it was not necessary graduates that provided the most support but school leavers also which could be trained to be phlebotomists and that their contributions greatly relieved pressure within trials. In addition this can help boost and shape careers of a young workforce. **Raymond Hamil** also commented that such resource would have a massive advantage in the SIREN study and that NHS Lanarkshire are considering HCSW roles for SIREN.
Action: Marion O'Neill to share the CRUK report with the group. Has been circulated.

Action: David Cameron to send around SACT agreement. Has been circulated.

Short life working group to assess the issue of remote consent. Will be picked up on item 7 of the agenda.

Provide data around lost space to identify if this is an issue that requires further investigation. Will be picked up in Item 6 of Agenda.

3. Activity Report (Ian Anderson)

Non-commercial continues to display a reduction in studies with the current status of "suspended". There has been a drop in 10% of studies in "suspended" status since the last report was noted. At this present rate to reopen the non commercial portfolio to pre pandemic level would take around 96 days. This is a considerable drop in days from the previous report due to restart beginning to accelerate.

In comparison 7% of commercial studies have been removed from "Suspended" status from the last report and at the current rate to reopen all studies to pre pandemic level looking at 133 days.

The report followed the similar format as previous reports but now attributes recruitment to vaccine trials as new data. Also non Covid recruitment to non-commercial studies appears slow but understandable given

that studies are now only opening. This will provide a useful tool to identify barriers to recruitment after studies are open.

Dr Sheuli Porkess requested if there was any insight into why there would be an obvious difference in rates to reopen to pre pandemic portfolio levels between commercial and non commercial and if so ABPI would be happy to lend support. **Raymond Hamil** and **Prof Maggie Cruickshank** commented that perhaps there might be less complex trials for non-commercial than commercial, thus easier to open. **Prof John Cleland** suggested there could also have been disruption to IMP supply during Covid. **Prof Maggie Cruickshank** and **Prof Julie Brittenden** also commented that commercial studies were slower to adapt to remote monitoring and other complexities but is improving.

Prof Paddy Mark raised concerns regarding lack of potential recruitment to non covid and non cancer studies. CRF research resources are still heavily involved in performing follow up to vaccine studies. Clinics are not yet functioning to capacity and thus reduction in patients to recruit. Should observe that even though studies are open, recruitment will be very slow for a variety of complex reasons.

Marion ONeill commented that the workload for follow up was stable throughout lockdown and if there was an expectation to see an increase in follow up workload. **Ian Anderson** said we can only capture what the status of the project is at a time point rather than the workload associated. **Marion ONeill** also highlighted that we are being reactive to the data but may need to consider longer term that this will impact on research capacity. Should begin to start planning forward to understand in the potential chance we do not see the portfolio returning i.e. Is there anything proactive we could we be doing to look into the data.

4. Commercial Revenue Overview and Commercial Declines (Dr Charles Weller)

Dr Charles Weller narrated the paper drafted by Dr Ewan Dougall looking at commercial feasibilities and orderbook value.

Feasibility approaches reduced during the early stages of the pandemic, increased strongly during the summer, before falling back to normal levels. Projected yearly figures are similar to previous years.

Order book figures track the total number of contract signed and their financial worth. Normal value averages approximately £5 million of new contracts signed per quarter: this reduced to around £2 million in Q1 20/21 during lockdown but early data suggests that sites are now beginning to pick up new contracts and total value is returning to previous levels.

Although it is not simple to look at the actual cost recovery associated with studies across time, a Nominal Commercial Income Projection (NCIP) has been developed which uses patient recruitment information combined with per patient fee values provides to estimate consequent income.
This suggests that although orderbook value from new contracts is returning to normal levels, there is a shortfall in overall financial recovery due to a lack of recovering recruitment and associated income.

Aisling Burnand suggested that since clinical services are not yet well established, absence of a patient's usual Health Care Professional may mean fewer suggestions of participating in research are made. **Prof John Cleland** suggested that NRS could use PICS and SHARE. **Prof Paddy Mark** also agreed that there is a requirement to remember how we recruited to studies pre pandemic and may find that these are still suitable in current climate. **Prof John Cleland** suggested that we should target studies which could recruit to studies which are embedded in clinical practice. **Alan McNair** advised that this suggestion was subject of a

paper at a previous meeting where networks and specialty groups reviewed their portfolio of studies to ascertain priority based on studies embedded in care.

5. Barriers to Restart with Site and Sponsor Specific Issues (Gordon Watt)

This item will be a standing agenda item provided to the group. The tracker is compiled with input from members of Restart Operations group. It is used as an ongoing monitoring tool which will identify new issues through progression of restart. The tracker provides information on issue type and current actions. Gordon Watt narrated through the paper supplied to the group.
Raymond Hamill highlighted that the group aims to identify common issues across the boards and put in place a process where boards can share working SOPs or Work Instructions. This will hopefully ease the bottlenecks of administrative workload and share best practice across NRS.

6. Barriers to restart through space issues identified (Dr Alan McNair)

This paper was submitted as an action from a previous meeting on the 5th August. The Restart Operations group were asked if they could comment on space which was lost due to covid and yet to be returned.

Six of the Dumfermline Group boards and one of the main larger boards provided a response. The comments from all are presented maintaining anonymity within the paper shared with the group. The comments presented in the paper demonstrate that there has been a loss of space during the peak of the pandemic but during the current recovery phase it is apparent that some of this space has not yet been returned or has no intention of being returned.

Prof Paddy Mark mentioned that CRF facilities are welcome but clinic space to recruit patients have been lost due to social distancing. Recognising that this is an issue with no real solution. With this note it is challenging to recruit patients unless studies are embedded in clinical care. **Raymond Hamill** highlighted that CMO letters would work to place pressure on the clinical services to provide space for research. CMO support for the SIREN study has provided the availability to access two clinic rooms for 1 year and without a letter from CMO this would not be available. **Marion O'Neill** advised that Cancer has been identified as a clinical priority through Scottish Government and agreed that we need to push trials to the forefront of medical care. Many of the trials are linked to Cancer, of those a suggestion could be that we use the Cancer policy team to use as a directive with health boards that reports back on specific criteria. Also agreed that a push from Scottish Government to highlight the importance of research would help. **Raymond Hamill** also confirmed that prior to the Scottish Government Cancer Plan there were very little Cancer trials outside main centers, now with the appropriate steer this has changed research dramatically.

Action: CSO to identify if this might be raised within the four nations to provide a UK government steer on the importance of research and if not review other approaches within Scottish Government.

7. Remote Consent (Charles Weller)

Paper was circulated on remote access and restart. Dr Charles Weller narrated through the paper provided. Related issues although distinct with regards to policies also involved:

- SIV monitoring and Site Set up
- Remote Patient Consent
- Remote Monitoring by sponsor

Many boards have already developed policies to deal with these issues and few of these policies have already been circulated through the Restart Operations Group to share best practice.

The main way to support remote monitoring across NRS as a whole could be to either:

- Define a standard approach to remote consent on each of the afore mentioned issues and deliver across NRS Or
- Allow boards to pick up on the best practice allowing them to address internal board issues which might relate to NHS board policies

In the case of the latter NRS could look at supporting and addressing the inconsistencies where remote monitoring becomes an issue across multisite locations.

Prof Tim Walsh suggested that remote SIV and Site set up was less an issue for sponsors. Are Scottish ethics committee noting remote consent, would be useful to note their stance on this? **Prof Julie Brittenden**: Recognises that there is a lot of best practice sharing. Some studies have now remote consent built in but none, as aware, are in CTIMPs. Could we get a unified ethics approach to remote consent? **Raymond Hamill** Innovation are also looking at remote consent could Andrew Fowlie provide feedback which may help health boards to share best practice with? **Prof Julie Brittenden**: GGC shared a pilot being run on remote consent within Innovation which was circulated at a previous meeting using a remote consent platform called "e-consent" **Prof Tim Walsh** with regard to the patient group in AWI, Scotland has massive gaps compared to England to consent. Perhaps a new way of looking at remote consent could benefit this patient group? **Prof Jacob George**: BHF funded TIME trial all runs on remote consent (online) and there is president here to pull from that experience amongst others.

Action: Gordon Watt to identify if Ethics committees are aware of the increased amount of remote consent submissions and if there is a unified approach to approving across NRS.

Action: Andrew Fowlie to provide any update to remote consent within Innovation.

8. Patient Confidence in returning to Research (Dr Ellen Drost)

The NRS Networks generated a questionnaire to assess patience confidence to return to research within hospital settings which has been in circulation since August. Originally the survey was sent to PPI groups from the Networks who were a population already aware of clinical research. However since then an effort has been made to circulate this more widely across the general public. The survey results were last presented to this group on 5th August and since then a further 165 responses have been received. The general public have been targeted through friends and family of Networks, published on the CSO and NRS webpages and there is a hope to have a mailing list out to 1000 SHARE participants.

Aisling Burnand commented that this data was important to help underpin the challenges and barriers associated with patients returning to trials. **Marion O'Neill** commented there were similarities in results between this and the Cancer survey. Patient confidence can be easily installed by the simplicity of being transparent with mitigating risk i.e such as PPE for both NHS and patients. There should be an aim to help manage the expectation of a patient prior to entering a clinic during Covid. Going forward it would be helpful to also involve patients in the solutions to any barriers. There will be a new Cancer Clinical Resilience Group which will be supported by Scottish government where it is expected a sub group of this will focus purely on Cancer Clinical trials which will help to build on patient feedback and patient facing resources to

identify what it is like to engage in trials. Some of the feedbacks from this survey would help address some of the questions for this group. **Prof John Cleland** suggested increasing the sampling frame by extending to Primary Care. **Dr Ellen Drost** suggest to mail out from GP practices would need funding. **Prof John Cleland** suggests that CSO could potentially fund this if you pick different socioeconomic areas you could target many new points of view from general public.

Next meeting scheduled 8th Oct 2020 3pm - 430pm