NRS Strategic Restart Advisory Group

5th August 2020 Minutes

Attendance List

Prof David Crossman	Chair / Chief Scientist
Euan Dick	Head Of Chief Scientist
Dr Alan McNair	Senior Research Manager
Gordon Watt	CSO/ NRS Funding, Ethics and Intellectual Property
Dr Roma Armstrong	R&D Director NHS Greater Glasgow and Clyde
Carol Porteous	PPI /PE
Prof Tim Walsh	R&D Director, NHS Lothian
Prof Maggie Cruickshank	R&D Director, NHS Grampian
Prof David Cameron	NRS Clinical Research Champion for Cancer
Prof Adam Hill	NHS Education Scotland
Prof Andrew Gumley	NRS Clinical Research Champion for Mental Health
Prof John Cleland	Director of CTU Greater Glasgow and Clyde
Dr Helen Bodmer	MRC/UKRI
Dr Aisling Burnand	AMRC
Carol Porteous	PPI / PE
Dr Bryan Deane	ABPI
Marion O'Neill	CRUK

Apologies: Prof Jurgen Schwarze, Prof Julie Brittenden, Prof Jacob George, Prof Patrick Mark, Clare Orange, Dr Andrew Keen, Andrew Fowlie.

Welcome (Prof David Crossman)

The Chief Scientist, Prof David Crossman welcomed everyone to the third of the Strategic Advisory Restart meetings.
The minute was passed as finalised and will appear on the NRS webpages here.

Activity Report (Dr Alan McNair)

The data is represented from the local portfolio management system, ReDA, which is used by all R&D offices across Scotland to help track governance approvals and activities. It is useful to note that the unit of this report is based on **study sites not studies**.

The data presented in the paper demonstrates two data cuts which are 20 days apart (9th July and 29th July) to identify the differences in the number of sites leaving suspended in the three different classes of suspended (highlighted below).

- COVID-19 New Recruit Suspended – studies which were suspended to enrolling new recruits only

- Pre-Approval suspended – Studies which had been suspended prior to being awarded management approval
- Suspended – studies which were closed in their entirety due to routine course of events

The main focus of the paper presents a decrease in the number of study sites across Scotland which are leaving suspended. As a crude measure the data indicates that at the current rate of studies re-opening to a similar portfolio activity of pre Covid will take 300 days for non-commercial and 215 days for commercial.

Section 6 highlighted the stark reality of the recruitment between non covid and covid studies across NRS. With recruitment numbers considerably higher than the average recruitment figures of previous non covid recruitment.

Prof David Crossman: Commented that the larger boards, NHS Lothian, NHS Grampian, NHS Tayside, NHS Glasgow and NHS Ayrshire and Arran have the smallest number of pre-approved suspended and suspended studies in comparison to the other smaller Dunfermline group boards. As an example Lanarkshire has 48% of its current portfolio as pre-approved or suspended for commercial and non-commercial combined. **Dr Alan McNair** highlighted that certainly with the smaller boards they rely on clinical space which isn't actually open as yet and is tightly entwined with routine clinical care. **Prof David Crossman**: Is there a metric we can use to continually monitor and identify if the smaller boards are requiring support with this?

Prof John Cleland: Highlighted that some study sponsors are slow to provide approval and some sites are slow to re-open given the issues surrounding local policy. **Dr Roma Armstrong** highlighted that in Glasgow they have focussed on opening their own sponsored studies. GGC highlighted that hosted study sites will not open unless they can prove they have sponsor approval and studies which do open are slow to recruit. Suggestion that in time we may also be focusing on recruitment to studies of those that have managed to restart to identify the issues with actual recruitment. **Prof John Cleland** highlighted that studies will be catching up with follow up rather than recruiting to existing trials. **Prof Maggie Cruickshank:** highlighted NHS Grampian is in local lockdown and that restriction to hospitals and travel within a 5 mile radius will impact restart to clinical services and research again. **Prof David Crossman** mentioned it would be useful for feedback on how this was managed by NHS Grampian for the next meeting so that others may be able to learn lessons and help implement a strategy for managing local lockdowns. **Prof David Cameron** highlighted the difference between CTIMP and Non CTIMP trials and is it the CTIMP that are particularly affected to suspended to new recruits. There is a need to understand if the issue is sponsor or site related. **Prof Tim Walsh**: highlighted where NHS Lothian/University of Edinburgh are sponsor they have a clear pathway to reopening. Real differences between commercial and non-commercial studies. I.e. with commercial monitoring, sponsors are slow to change practice and agree to remote monitoring. **Dr Bryan Deane** huge variation between commercial sponsors, HRA are flexible can do remote monitoring for some studies.

Action: Raymond Hamill to provide feedback on the high number of suspended studies amongst the Dunfermline Group Boards. Is this a sponsor or site issue to re-open?

Action: Prof Maggie Cruickshank provide a report on what second lockdown means and the impact to research.

Action: Any data which would help underpin the understanding issues with site or sponsor.

Commercial Feasibility (Ewan Dougall)

Highlighted the increase in non covid related feasibilities predominantly from NIHR with the biggest number of feasibilities in the speciality area of Cancer. The feasibilities have increased considerably from the same time frame from the previous year.

Dr Dougall highlighted that many boards are declining commercial studies due to issues already with restart and some PI are reluctant to take on more studies in case of subsequent waves. **Dr Bryan Deane** highlighted that ABPI's impression is that new feasibilities are still not being accepted by some sites. He is happy to provide data on feasibility requests at a later date if required.

Prof Tim Walsh studies requiring CRF support particularly with Vaccine studies, UPH follow up and restart provides issues with being able to support further new commercial work. **Dr Roma Armstrong** Glasgow CRF feel they need to honour existing commitments rather than take on more. **Prof David Cameron** agreed on **Dr Armstrong** and **Prof Walsh** point.

Prof John Cleland should we identify the national budget of the income generated for commercial trials as now is time to invest if faced with unemployment. Recruitment of clinical support workers who can be school leavers have shown to provide much needed support. **Prof David Cameron** have hired Biomedical Scientist graduates to take consent under SOPs and this has boosted the research community by identifying those individuals rather than moving research nurse staff around. **Prof Andrew Gumley** highlighted that recruitment often falls to nurses and that the role of a clinical support worker could make a real difference to mental health research for both commercial and non-commercial. **Dr Roma Armstrong** consider ways of capturing consent remotely. Cannot rely on going back to old model. How we provide information to patients and plan remote pre consent visits and remote consent thereafter, reducing the risk of attending hospital. Ethics are supportive of both remote and verbal consent. **Prof Tim Walsh** highlighted the importance that all NHS boards should review remote consent collaboratively as the project of implementing remote consent at NHS board level will be difficult and time consuming.

Action: Prof David Crossman and Dr Alan McNair to further investigate the overall book value of commercial activity and 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.

Assessing Patience Confidence Returning to Research

A survey monkey was sent to PPI groups across the networks from the work performed by the network managers with specific work by Pamela Dicks (Children's Network) and Ellen Drost (Primary Care). https://www.surveymonkey.co.uk/r/KZ2566Y

The results of the patient responses were highlighted and presented by Carol Porteous. PPI main issues were communications with researcher's i.e. not being sent reading material with no discussion or support on information received. How patients interpret the risk being mitigated and what they expect to see at hospital i.e should everyone within a hospital setting be wearing masks and will they be expected to share a waiting room with others. Of the PPI panel 50% felt they were surprised not all hospital staff were wearing masks.

Prof Crossman perhaps we need to communicate with patients to provide an expectation of returning to hospital. **Aisling Burnand** where sites were proactive to show patients what to expect and thus upping

communications has been greatly received. **Marion O'Neill** Cancer specific survey assessed ~1800 patients about access to treatment and services which are cancer specific. Most patients were able to access treatment and research in similar areas. Main concerns were about catching and being seriously ill with Covid, many cancer patients are in a high shielding group. Mitigation strategies and offering a safe environment and how to protect covid free zones i.e. regular testing for staff and patients.

Action: Marion O'Neill to share the CRUK report with the group.

Prof John Cleland requested if the survey could be placed in the public domain and potentially add important themed questions. Can we boost this survey to more patients might provide a better overall picture. **Dr Roma Armstrong** indicated that clear communication from hospital to patients is to reduce footfall in hospital and then conflicting research advice is to attend. Need to work on communication strategy.

Prof David Crossman: Collective view on what it is we want to communicate. Research is still important even under extreme conditions. Important to leave the survey open and collect this information as opinions may change during the progress of the pandemic.

Barriers to Restart by Restart Operations Group (Gordon Watt)

Paper was presented with the key issues from the Restart Operations group.

Prof David Crossman suggested gathering more data with specific issues to space which was research based and then removed and repurposed during Covid. Shared learning and mitigating risk by remote consents and have a task and finish group.
Dr Roma Armstrong An innovation study has been piloting consent electronically and providing information and follow up to ask questions remotely. There is also a difference when recruiting vulnerable patients and those who have guardians and are expected to consent for them. **Prof David Cameron** a standard agreed form for remote consent inform for SACT has been implemented. This can be shared to the group. **Prof Tim Walsh** we need to use this opportunity to have a system for informed consent across NRS. **Dr Bryan Deane** it would be useful and advantageous to broaden consent to monitoring. The UK are slower to restart than other countries and anything that can be helped to speed up restart should be done. **Prof Andrew Gumley** a move towards accessing consent remotely is advantageous but mindful we have significant digital inequalities and those people may have multi morbidity and chronic illness. We need to ensure that those patients are still incorporated either at board or study level.

Action: Prof David Cameron to send around SACT agreement

Action: Short life working group to assess the issue of remote consent

Action: Provide data around lost research space to identify if this is an issue that requires further investigation

NRS Network Portfolio Analysis (Alan McNair / Dawn Williamson)

Previous action from meeting to identify and stratify the existing portfolio of studies into studies which are already embedded in clinical care and those which do not require face to face contact.

Prof David Crossman highlighted that we need clinical services to resume to allow those studies which are embedded to open. **Prof David Cameron**, Cancer are reducing face to face interaction as much as possible and face many barriers similar to other specialties where clinical services are unable to provide scans at the same throughput as pre-pandemic. So remote consent is a big thing for Cancer also.

Prof Andrew Gumley reflecting on the strengths of the Cancer networks, other networks could strive towards having a greater number embedded in care. How do we support those studies which are not embedded in care?

Conclusions

Distinguishing between sponsor and site issues and helping Dunfermline Group, non-nodal boards to progress to Active and understand specific blocks.

Issue on commercial feasibilities collecting data on declines and reasons.

Patient survey, keeping the survey open and collecting data on an ongoing basis with a clear steer to communicate and engage with patients and what it means to participate. Identifying how much of our current portfolio can be embedded in clinical care. What does it mean to participate in non covid research and can we embed as much of this in clinical care?

An audit to evaluate the research space which has been lost which is currently preventing restart happening.

Next meeting will be on 9th September 1530 - 1700