NRS Strategic Restart Advisory Group

13th July 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 Charles Weller	General Manger of 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 Jürgen Schwarze	NRS Clinical Research Champion for Children
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
Dr Charlie Mayor	NRS Safe Havens
Carol Porteous	PPI / PE
Dr Sheuli Porkess	ABPI

Apologies: Prof Patrick Mark (partial meeting), Marion O'Neill, Clare Orange, Dr Andrew Keen

Welcome (Prof David Crossman)

The Chief Scientist, Prof David Crossman welcomed everyone to the second of the Strategic Advisory Restart meetings. The task of today's meeting was to identify a framework for prioritisation.

Activity Report (Charles Weller)

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**.

When the pandemic occurred a number of flags were inserted into the system to be able to track the sites which were suspended during the pandemic.

- 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 portfolio in this report is represented by those number/percent of sites which are in follow up, actively recruiting and those which are suspended with the associated reasons noted above. The portfolio can be categorised into non-commercial, commercial, specialty, health board location, study type and trial phase.

The data also tracks recruitment on a monthly basis but there is a slight lag on collating this data into the system. The recruitment data does not include covid activity and as a result demonstrates the reality of how non-covid research has been affected with regards to recruitment.

Prof David Crossman: Requested additional information to be overlaid on the recruitment to highlight covid activity to ensure that resource to recruitment in covid trials would not saturate the ability to proceed with non-covid trials. **Prof Julie Brittenden** highlighted that recruitment is only part of the picture as GGC has manged to increase recruitment considerably compared to the same time frame as the previous year. Utilising recruitment as a metric of capacity and resource is a metric and does not take into consideration the workload involved in follow up of these studies.

Action: CW to demonstrate the next data report with Covid recruitment added

Prof David Cameron: Requested how do we communicate to commercial companies that we are open for business. With the issue that commercial companies might have already been shying away from research in the UK due to Brexit it is important to advertise positivity that Scotland is open to do commercial research.

Prof John Cleland: Commented that we should identify where the commercial stumbling blocks actually are. Some commercial companies have suspended the study where some local sites have issues with being able to opening the study. It is not always R&D who are the resistance to opening studies back up many issues surround capacity and safety of re-opening trials.

Gordon Watt: Highlighted that the operations restart group have reviewed the stumbling blocks with particular reference to local issues of clinical services and how social distancing will affect capacity of patient numbers to studies.

Prof David Crossman: Requested if the Operations group could draft a paper which would highlight what is preventing NRS being business as usual. Therefore we can highlight what can be corrected and what is t out of NRS control.

Prof Patrick Mark: The charity sector has indicated that some studies should not open until the risk of second and additional waves of the pandemic has passed even those which are low risk studies. This is different to studies which have started and have to suspend and where the staff are paid on the grants.

Role of the funder when studies can start and stop

Prof John Cleland: Grants which would have been funded have been delayed to the funding round in October. Funders are now looking for covid mitigation strategies to reduce face to face visits and request hospital visits. Pharmacy flexibility would aid in helping IMP be home delivered - i.e. hospital collection rather than home delivery.

Aisling Burnand: The overall message from the charity sector is that trials which can should restart where appropriate but there is a potential delay to those which have not yet started to safeguard funding in the event of further waves which could cause suspension. Challenge is also ensuring recruitment to studies is happening and not just sitting with studies which are open.

Lack of routine clinical services places additional pressure to study sites reopening. Furthermore should we begin to address if we have enough capacity to prioritise vaccine studies?

Dr Helen Bodmer: For un-costed extension there is an expectation that these will be granted. If you have a grant and you can complete the grant within the timeframe you can continue and do not need approval from funder but should have approval from the sponsor. For amending the milestones within the grant you would need to agree with MRC. For costed extensions the expectation is that you would use the UKRI process that has been devolved to the universities or research organisation. The complication is that this applies to grants which finish before April 2021 - the realisation is that clinical trials may be disrupted for much longer. MRC haven't asked anyone to stop.

Dr Sheuli Porkess: Industry position is to restart unless you hear otherwise. How do you get the communication across to say open for research? On site monitoring is practical demonstration that clinical research is open.

Prof John Cleland:

- Permissions - Have you approval to restart
- Capacity - can you deliver
- Confidence - mostly by patients returning to trials

Research teams may need to work closer to the clinical teams to recruit within clinical visits rather than add additional visits. Suggestion that NHS staff help to deliver vaccine studies?

Prof Adam Hill: Highlighted many issues surrounding restart of non COVID research- patients are concerned about returning to hospital because of the fear of contracting COVID 19. There are issues with research staff being able to do certain investigations, such as spirometry, endoscopic procedures etc. There are also issues with participants retrieving supplies from pharmacy, some of the issues due to fear of the participant coming into hospital. There are staffing issues as research staff are being prioritised for COVID research. There are regulatory issues with delays in processing through ethics, R+D and sponsors.

Study Prioritisation (paper submitted on Deep Dive study prioritisation)

The paper submitted to the group ahead of the meeting focuses on three principals on

- Study viability
- Safety
- Capacity and site readiness

Prof David Crossman: suggested the ROG group to report on what the issues are in these categorisations based on the discussion points made so far in the meeting. Can we make general statements on which studies can go ahead and which cannot based on safety?

Action: GW to provide a paper on issues of restart from ROG

Prof Cleland: Could we provide staff with weekly covid tests and advertise they are negative by the badging them to reassure patients?
Prof Julie Brittenden: Health boards are tied to local policies on safety constrains. Raised the issue of shielding and high risk groups. Cancer and children's patients are protected because they are off the acute sites. GGC are looking at having sites off acute sites where feasible. More difficult to restart studies for those studies for patients who are shielding.
Prof David Cameron: Cancer studies are embedded in routine care. Can we review which studies are already embedded in routine care and use the visits that are occurring already and follow up on remotely.
Prof David Crossman: Testing of asymptotic healthcare workers is not currently the reason to test. This would be changing policy of the health board and may not be something NRS will be able to mandate.
Dr Alan McNair: Recognising those studies which are embedded in routine care and those which can be followed up remotely could be actionable. These could be identified and prioritised studies.
Prof Tim Walsh: Ensure PI feels enable to push to restart within the restart framework. Difficult to micromanage which studies should and should not re-open at NHS Lothian R&D, hence the delegation of responsibility has been pushed back out to the PI to make the decision. Remote consultation on clinical care and do we need to involve ethics and involve remote participation in research? This was identified as an enabler to research.
Raymond Hamill: Looked at classifying studies by clinic embedded or home visits which will ease up studies which can restart. Studies such as children's, stroke and pregnancy studies are easier to restart as embedded in clinic care already. Hospital management may also be nervous restarting but may ease up as they see more successful studies open.
Prof Maggie Cruickshank: local boards are working on safety mobilisation plans. Grampian is all one large campus. Non commercial studies have put in many mitigations. Commercial studies haven't taken such an imaginative approach.

Carol Porteous: PPI has existing structures which have continued throughout the pandemic and would be happy to take forward any key messages for the group.

Aisling Burnand: Presented on behalf of CRUK the concerns over prioritisation where some early phase trials maybe deprioritised compared to late phase trials to recover research engagement metrics, non-commercial studies might be deprioritised to commercial in order to recover lost income. Implementation of prioritisation may be inconsistent perhaps portly communicated by researchers and not with the needs of patients. The prioritisation should be based on patient focusing. Without a trial patients could come to harm. PPI will be essential when addressing concerns for restart. Circulation of the paper will be sent out to this group.

Action: AB to circulate paper from CRUK with group

Prof Andrew Gumley: Clinicians are important in the re-organisation of services during the covid pandemic and they are still transitioning back to frontline care. Clinician's priorities for reinstating services and then researchers after that. Communicating the importance of research to patients but also to provide researchers with confidence to restart. There is a role of Networks and PPI. How do we get the PPI strategy right?

Dr Helen Bodmer: Early stage studies are almost unfeasible to do remotely. There is a hope that these would not be prioritised out because they are more risky. Instead how do we mitigate this risk to be able to deliver given the complexity on management?

Study Viability

Review of the issue of study viability and what this means and how to measure.

Prof John Cleland: Many studies could be informative even if the power of recruits is not met. Therefore if the study won't meet target you can modify by suspending recruitment and still report the outcome. Studies which maintain integrity but with smaller numbers are still valuable. Co-author of a paper with FDA reps advocated that some studies should be curtailed in this way. Will investigate if this paper can be shared.

Dr Helen Bodmer: PI and sponsor need to review protocol carefully and determine the viability and then come to UKRI/MRC. No plans to reassess all trials. Requires to be on a case by case basis. Speak with the appropriate program manager. But no plans to reassess everything.

Prof Jurgen Schwartz: Patient acceptance is very much part of the viability. Assessing the patient's opinion on continuing in a study if means making hospital visits.

Prof Julie Brittenden: Sponsor completed RA checklist and restarted all CTIMPs with exception of a few complex shielded studies.

Conclusions

Discussion originally focused with the aid of the activity paper the capacity to support non-Covid research in addition to initiating vaccine trials. CSO realise that non-covid capacity needs to be evaluated especially if expected vaccine patient populations are realised.
Raised capacity and site readiness issues alongside local practicalities i.e. radiology, staff, pharmacy and issues on patient confidence. Discussion then led to safety. Emerged there are studies which are embedded in clinical routine care which could sit in the top end of prioritisation and networks and specialty groups could review their portfolios to see the proportion of studies which could be prioritised in this way.

Action: AMc to request Networks and Speciality groups to prioritise portfolio based on embedded clinical care.

There appears a need to review practice such as performing investigations in covid free locations i.e. cancer hospitals, non-acute locations or by home visits. These off acute sites could be prioritised. Still an ongoing issue with shielding patients should we prioritise or deprioritise encouraged by PPI to view opinion. Researcher confidence in being able to execute the study is highly important but we should also engage with PI to see which ones should not be restarted.

Early patient engagement, ensuring the PI understands the patient's willingness to continue participating and building this into a priority.
Study viability - where does the ownership of assessment sit. Funders could drive but PI and Sponsor require to approve. Funders could trigger the viability as a question which could then be examined locally.

Alan McNair - The prioritisation suggestions by this group will be used to enhance support for decision making by the boards not to mandate.

Next meeting will be on 5th August 1530 - 1700