NRS Strategic Restart Advisory Group

30th June 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 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
Carol Porteous	PPI / PE
Dr Sheuli Porkess	ABPI

Welcome (Prof David Crossman)

The Chief Scientist, Prof David Crossman welcomed everyone to the first Strategic Restart Advisory Group. This group will link with NIHR Restart Advisory Group and the NRS Restart Operations group (ROG) chaired by Gordon Watt, CSO.
Prof Crossman explained that the role of this group is to provide advice, guidance and support to restart the diverse portfolio of studies across Scotland.

Orientation and Background (Alan McNair)

The ToR was circulated ahead of this meeting.

CSO and the devolved nations were involved in drafting the guiding principles which CSO later published https://www.cso.scot.nhs.uk/cso-statement-on-the-restart-framework/. CSO set up the ROG with immediate response to address the issues of restart.
AMc requests that this group bring their expertise, experience of restart, priorities and concerns to build an agenda which will feed into the ROG so that the groups can be aligned to function in the most efficient and productive manner.

Points raised:

- Marion O'Neill – raised issue of lessons learned around Covid 19. Concerns on how to mitigate the effort of restarting in further potential covid peaks.

Restart Operations Group Role and Activity (Gordon Watt)

The ROG met initially on 28th May with their own ToR which will be circulated. The aim of the group is to provide a forum to agree national approaches, focus on resuming research activity, integrating Covid and non covid studies onto the portfolio, sharing best practice and aligning process. Next stage is to plan and develop for a variety of different scenarios as the progress of the pandemic continues and the impact on clinical research. In addition searching for lessons learned and how to mitigate restart if local or national spikes occur once more.

Common themes emerged to date:

- Pressure on clinical physical space due to social distancing
- Lack of restart process alignment where a study is multisite across health boards
- Proportionality of risk assessments and how this leads to prioritisation as outlined in restart framework
- Research space lost to clinical frontline and not yet reclaimed back
- Research staff deployed to frontline and not yet released back

Actions:
Circulate ROG ToR (DW)
Circulate ROG Minutes (DW)

Activity Report (Charles Weller)

Report was circulated to demonstrate the number of studies which were suspended during the peak of the pandemic. Studies were closed based on the following definitions:

- COVID-19 New Recruit Suspended – studies which were suspended to enrolling new recruits only
- COVID-19 Suspended – Studies which had not been awarded management approval
- Suspended – studies which were closed in their entirety due to routine course of events

The data was caveated around the fact that resources from R&D boards were directed to frontline which left a skeleton staff to keep data as up to date as required.

Requested Data:

- Tracking suspension over time i.e. monitoring the change in suspension status to active or closed
- Breaking down by trial phase
- Normalise the data so they are comparative across specialties rather than displaying total numbers

- Following up on trials which have been suspended after almost complete recruitment but now have major impact to follow up
- Cancer trials be broken down by Pediatrics and Adult
- The breakdown i.e. specialty, phase of trials that remained active

Other data related queries:

Are we getting patients back into research– is there a measure to demonstrate this over time?

How do we capture studies which drop out due to lack of study viability i.e. no extended funding?

Lessons learned, is there a way to share learning on why studies remained open? I.e. remote visits and home delivery of IMP?

Agenda Setting (Prof Crossman)

Prof Crossman asked for insight into how R&D directors were managing restart locally.

Prof Brittenden (GGC)

- 25th May GGC wrote and requested to researchers if they had capacity to restart and directed them to RA checklist
- Sponsor and hosted studies are treated differently (70% hosted with ~1000 studies on portfolio in GGC)
- Twice weekly meetings to review RA checklist – to date 130 studies restarted in line with NIHR framework.
- CRF are still heavily involved in Covid studies. Along with Covid both Cancer and Paediatric studies are prioritised.
- Realisation that recruitment will be slower and reduced.
- Sponsors reviews are slightly different close working with Robertson centre and CTUs. Discussions on study viability and resources with trial steering committees.

Prof Cruickshank (NHS Grampian)

- RA assessment form so researchers can apply to restart
- Reliant on NHS remobilisation plans to re-opening clinical services to help research restart
- Financial pressures due to number of staff deployed to frontline duties and further exasperated by suspension of commercial studies where NHS Grampian continues to fund salaries.

Prof George (NHS Tayside)

- RA checklist available for local PI/CI
- Broad categories of safety and capacity are appreciated on the NIHR framework but would welcome a view on how to objectively prioritise studies within these prioritisation levels.

Marion O'Neill: There is an importance of objectively assessing and balancing certain types of trials and ensuring they are not disproportionately deprioritised or prevented from restarting. Early phase and non-commercial trials have increased vulnerability. Perhaps introduction of a scoring matrix?

Prof Walsh (NHS Lothian)

- Continued proposals for new Covid research continues at ~10-15 studies per week. Many which are declined but there is a committee established to review. Realisation that anything that is taken on will be immediate priority.

- Governance teams have an amendments backlog.
- All staff are remote working as NHS Lothian have University accommodation which has provided its own challenges.

Raymond Hamill

- Clinical services need to restart fully to allow Dunfermline Group access to implement research as the boards have no access clinical research spaces such as CRF.

Cost extensions

Prof David Crossman: Raised the issue that priority should be considered to studies which are almost complete otherwise there has been an exposure of patients to unnecessary risk and effort. Suggestion of having a generalisable principal to complete studies which are close to completion? Prof David Crossman was happy to take opinion.

Prof John Cleland CTU representation: CTUs continued to operate throughout the pandemic; only a few staff were furloughed. CTU budgets for trials are relatively fixed and so there will be a definite shortfall in funding if studies need to be extended. One suggestion to conserve and ensure efficient use of existing funds would be to close trials that were either no longer viable or had already acquired sufficient data to be informative (likely effect-size, neutrality, already positive). CTUs and trialists should be encouraged to explore the conditional power of their studies, through blinded analyses by their IDMC and independent statistician. Trials that were unlikely to achieve their primary endpoint or had already done so might be closed. Steer from CSO to propose this nationally could help.

Prof David Crossman: Raised that these were good points and accepted that this was a useful steer.

Marion O'Neill CRUK: From the perspective of CRUK which is largely based on fundraising and presents its own issue on shortfalls of funds, have not issued any statement of extensions as yet though have categorised their issues of concern into following:

- Impact on existing and immediate studies
- Future innovation and treatment research – what funding will be available
- Projections for the research workforce

Most of CRUK's research funding goes to multi-year projects, so the number that need to consider extensions *now* are limited.

Dr Helen Bodmer UKRI MRC: UKRI has implemented cost extensions on a pro rata allocation to universities and IROs on basis of grants which are due to complete in April 2021. Main objective is for research organisations to prioritise within that. MRC will be publishing some guidance. Meanwhile information can be found here: https://www.ukri.org/files/funding/coa-master-policy-final/

Dr Sheuli Porkess ABPI - From a UK picture funding from industry should be considered extended unless informed otherwise. Industry wish onsite monitoring but limited with local safety constraints. Resource is limited in terms of Pharmacy, radiology etc. PPE and Covid testing are also recognised cost issues.

Charity funding extensions requires case by case review and happy to feed back on this from the NIHR group.

Prof David Cameron Cancer Research Champion: In the Cancer service recovery plans with reference to cancer surgical studies a set of guidelines has been developed on how to prioritise between surgical groups of patients at either board or regional level. This model is awaiting input from the UK Colleges of Surgeons. This crosses specialities, could this be modelled from the service world into the research arena?

Prof Crossman: Suggested that this might mean studies would miss resuming where they could because the model was approving restart on a national basis rather than locally.

Prioritisation

Prof Crossman advised prioritisation should be at board level and would prefer not to have Scotland specific set of prioritisations. Requesting input from Glasgow and Lothian.

Prof Brittenden (GGC) : Boards need to be allowed to develop their own priorities to help monitor consistency with their dedicated committee review panel within the board.

Prof Walsh (Lothian): Over 1000 studies so cannot review all studies individually so restart approval has been pushed back out to PI/CI to confirm state of readiness. Following on from Prof Cameron's suggestion, there is merit in the potential of NRS Networks and Speciality groups reviewing their portfolio to identify which studies, given the constraints, should be opened first.

Closing Actions and Comments

Prof Crossman concluded that the group would do well to help agree some collective criteria to apply at board level with regards to patient safety and finance issues to reflect the medical value of research trials. Help create a list of generalisable principals for Scotland to work with and meeting with new data and comments and looking to create prioritisation criteria.

Finally the closing statement was how to communicate with patients? With all the effort into restart we need to communicate with patients to ensure they feel safe enough to engage with research again.

Next meeting scheduled 13th July 2020 9am - 1030am