Cancer Trials Resilience Sub Group Minutes

20th November 1100 - 1200hrs

Attendance List

Prof David Cameron	NRS Clinical Research Champion for Cancer
Dr Alan McNair	Senior Research Manager
Dr Charles Weller	General Manger of Central Management Team
Ian Anderson	Information and Quality Manager, Central Management Team
Dr Kirsty Shearer	NRS Cancer Network Manager for the North
Dr Ben Chui	Cancer Research UK
Joy Dawson	Research Governance Manager, NHS Borders
Laura Rooney	CRUK Senior Research Nurse, Beatson WoSCC
Emma Kinloch	NCRI Consumer Lead
Joe Woollcott	Brain Tumour Research
Tracy McEleney	Clinical Trial Service Manager Public Health Scotland
Jeff Evans	Director Glasgow Experimental Cancer Medicine Centres
Stefan Symeonides	Director Edinburgh Experimental Cancer Medicine Centres
Rachel Reel	Senior Policy Officer, Cancer Policy, Scottish Government
Denise Calder	Cancer Services Manager, NHS Lothian
Anthony Chalmers	Chair of Clinical Oncology, Wolfson Wohl Cancer Research Centre, University of Glasgow
Gregor McNie	Team Lead, Cancer Policy, Scottish Government

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

Apologies: Prof Maggie Cruickshank, Carol Porteous, Sarah McDonald, Milind Ronghe, Ghulam Nabi.

1. Welcome (Prof David Cameron)

Prof David Cameron welcomed everyone to the first Cancer Trials Resilience meeting.

2. NRS Activity Report - Ian Anderson

Ian Anderson provided an overview of the NRS data paper and informed the group of the different terminologies used to describe Covid suspended and active studies. The data is split into non-commercial and commercial. The overall direction is that studies are re-opening after initial shutdown due to the pandemic. Recruitment to Cancer demonstrates a downward trend of recruitment year on year but this is likely due to precision medicine. Data was also provided on order book value, demonstrating study sites are opening but recruitment is yet to follow on. A reduction in cancer recruitment is due to the issues that most studies were placed in “new recruit suspension” due to Covid but that the recruitment has not yet recovered.

Joy Dawson: Reasons for commercial studies being suspended? Jeff Evans: Some suspensions have continued due to sponsors mandating onsite monitoring. Glasgow has lacked the technical ability to comply with sponsor requests to remote monitoring thereby some studies have remained closed. However most of these have now opened since August. Can the data highlight the lag in new studies receiving approval as this area is now suffering from longer and more significant delays than pre Covid. Ian Anderson : The data can be identified in lag terms from commercial studies but not non-commercial and can be reviewed for next meeting. Denise Calder: Can there be additional granularity on site performance and what the issues are commercial versus non-commercial to help understand the difficulties. I.e. accessing onsite monitoring for Glasgow has been problematic but not for Lothian. NHS Lothian currently have 110 cancer trials open and running with 4 sponsored trials still suspended. Ian Anderson: The group would need to commission boards to identify the specific issues with individual suspended studies as this is not captured on the database for reporting. Kirsty Shearer: NHS Grampian and Tayside have been efficient in reopening studies though Highland are slower but it is found to be harder in smaller boards due to resource and capacity issues. Jeff Evans: Glasgow have allowed onsite monitoring since Augusts but sponsors are still concerned with this. Joy Dawson: NHS Borders had less Covid prevalence and have brought back resource to Cancer studies quicker. David Cameron highlighted that SACT was working on remote consent and requested the group's comments around online consent and monitoring for trials. Also given that patients would normally have been invited to consent to a trial as part of routine care. Jeff Evans: For molecular profiling and access to tissue Glasgow have been using the "attend anywhere" app has been allowed to be used for online consent. Laura Rooney also highlighted that sponsors have been amenable to protocol amendments to allow them to perform online consent. Jeff Evans: ATIMPS are particularly challenging. Patient travel and available accommodation is an issue for those to take part in experimental early phase trials. Further complicated by Covid tests and finding accommodation prior to hospital treatment.

David Cameron highlighted the resources to run trials where other efforts have been re-directed elsewhere. For phase 1 trials which utilise a lot of NHS clinical resources in terms of scans etc. these were increasingly difficult during the summer months with staff re-deployed but this now appears to be returning to normal. Denise Calder: resource issues in NHS Lothian are more due to the expansion of the cancer portfolio, 94% increase from 2019 to 2020 with particularly reference to issues with recruitment to pharmacology posts. Covid may have exasperated the issues but these were already present in the system. Stefan Symeonides: There is a benefit in teaming up with boards to share best practice and to help us to do this we would need the breakdown on site locations and board suspended studies. Joy Dawson: NHS Borders were limited with clinic space due to social distancing requirements and any academic researchers which may have been on furlough are now returning. Joy will look to identify issues with the remainder of the Dumfermline board R&D managers.

Jeff Evans highlighted that Cancer has been a victim of success in some instances where commercial studies offer per patient recruitment fee which is able to resource financially the nursing and cancer infrastructure but with studies being suspended and now reduced in recruitment and there is an expectation that the financial reserves to pump prime this business model may soon be an issue in the coming year. Would CSO or CRUK have any suggestions on how to mitigate such a risk? Alan McNair: CSO meet on a weekly basis with R&D managers with the NRS data and monitor the progression of per patient fee. Charles Weller highlighted there are processes available to recover commercial funds from health board recovery plans. Charles would recommend to contact your health board finance team.

Action: Ian Anderson to highlight if there is a way to review significant delays to new studies requiring approval for non commercial and commercial studies.

Action: Ian Anderson to highlight the study sites status of suspension and recruitment.

Action: Joy Dawson to contact DG boards to identify any other issues to restarting Cancer trials that are not resource issues.

3. Scottish Government Cancer Recovery Plan Gregor McNie

National cancer recovery plan will be submitted to cabinet sectary with publication expected shortly. The plan is focussed on diagnostic treatment phases of the pathways where these pressures are significant.

There is a reference to trials within the plans i.e. commitment to produce a radiotherapy plan and helping to embed trials into routine care. The other reference is to this group to establish actions and solutions where required. Financial support is expected.

Alan McNair this group will produce minutes which can publicise on NRS webpages. Is there a feed of the outputs of this group to the National Cancer Recovery Group which David Cameron also sits on? Gregor McNie: This group is a sub group of the Cancer Recovery Group and minutes and actions of this group will be fed to the National Cancer Recovery Group.

Denise Calder: Raised awareness of highlighting the positive impact of clinical trials while supporting the delivery of the National Cancer Recovery Plan. Many trials help to ease the pressured system of the NHS yet the first thing to suffer in times of NHS clinical pressure is clinical trials. Denise hopes to raise the benefits of clinical trial awareness through NHS Lothian and would be useful to do this on a national level if possible. In addition is there a funding stream for supporting studies such as research optimisation which would not otherwise be supported by commercial funds. Gregor McNie: highly supportive of communication on key messaging. SG can provide communications and weekly contact with chief executives to support this national messaging. Following on PHS published data suggesting higher levels of Cancer diagnosis that previous years and that for many, treatment will only be available through clinical trials. Jeff Evans: Early phase trials are the standard of care treatment.

Action: Gregor McNie to work alongside Denise Calder on capturing the key messaging around benefits of trials and ensure these are passed through SG and publicised effectively.

4. Assessing Patient Confidence in Returning to Hospital - Dr Ellen Drost

Networks managers wished to canvas public opinion on returning to hospital setting for clinical trials. The network managers submitted the 10 question survey to friends and family and network PPI groups. The group canvased is not specific to a Cancer patient population.

Ellen narrated through the survey response which was submitted as a paper to the group ahead of the meeting. With the overall consensus that people would agree a return to research and were more comforted if healthcare and patients both wore PPE and if a list of mitigated risks were provided ahead of their visit. Laura Rooney: There is a level of anxiousness around patients attending bone marrow clinics and the staff are mitigating risks as appropriate and to make patients feel safe but unaware of any national process of advertising this. Jeff Evans: Increase and completion of more EOIs than before for early phase trials more than ever. Scotland is open for business. Kirsty Shearer: Confirmed feasibilities has increased. Denise Calder: Would be useful to canvas the opinions of a cancer patient population in such a survey to identify patient sub groups i.e. blood cancer patients accessing care in a tier 4 area. Anthony Chalmers: Unware of reluctance to attend radiotherapy trials.

5. Agenda Setting and For Future Meetings and ToR - Prof David Cameron

This group will feed into the National Cancer Recovery Group. The aim is to safely and appropriately avoid any further shutdowns to trials. An update of the ToR should reflect shared learning. Alan McNair: reflecting resilience into the ToR and Cancer Recovery Plan would also be priority. Can members of the group please suggest any comments they would like reflected in the ToR by email. Stefan Symeonides: Cancer trials should stand as a priority in R&D process of restart, highlighting that these are standard of care and extend life. Joy Dawson: CSO prioritisation framework highlights that majority of Cancer trials are level 2 in priority next to UPH Covid studies for restarting.

Membership was hoped to represent a broad selection of stakeholders across NRS. Alan McNair suggested ABPI to represent commercial trials. Suggestion of diagnostics also NCRG does have diagnostic and who would able to represent diagnostics across NRS in Cancer trials. Relook at surgery representation. Pharmacy, ABPI, Surgery and Pediatric trials for broader representation.

Action: Alan McNair to revise the ToR to incorporate shared learning and resilience. Review the membership list to incorporate representation from ABPI, Diagnostics, Surgery, Pediatrics and Pharmacy representation.

6. AOB

The meeting frequency is set to be every three weeks with a 90 min meeting agenda. The meetings are expected to be required for a period of around six months but this time period can be reviewed appropriately as and when required.

Next meeting scheduled 14th December 1500- 1630hrs