



Project Protocol

Background

The **UK Coronavirus cancer monitoring project (UKCCMP)** is a national scheme which will pioneer the use of a clinician-led reporting project to enable tracking of cancer patients who have tested positive for COVID-19 across the United Kingdom. This project will enable direct real-time daily updates back to individual Cancer Centres. This new tool will provide insight of high clinical utility to facilitate key decision makers. It will also enable national monitoring of the COVID-19 impact on cancer patients and cancer centres.

Aim

To track cases and outcomes of cancer patients affected by COVID-19 infection.

Project design

1. All centres that care for patients with active cancer are invited to participate in UKCCMP. A network of centres has been pre-identified but if additional centres are interested they will complete an expression of interest form.
2. To access the submission of interest form click 'Submit' on the www.UKcoronaviruscancermonitoring.com website and download it.
3. Once complete it should be emailed to Reportingnetworklead@ukcoronaviruscancermonitoring.com whereupon you will be sent an invitation letter, protocol and a centre activation form.
4. Each trust/hospital will identify a lead clinician (can be a consultant or registrar). They are termed the UK Coronavirus Monitoring project emergency response reporting individual (ERRI).
5. The ERRI will form a reporting group known as the local emergency response reporting group (LERRG) which can have as many individuals as felt to be necessary to sustain the project throughout the pandemic and may include nurses and or data managers in addition to clinicians.
6. The LERRG with oversight from the ERRI will be responsible for reporting patients with cancer to the UK Coronavirus Cancer Monitoring Project.
7. The individual at each centre should liaise with the Trust's clinical lead to gain approval for this process (an invite letter is provided). If committee approval is needed this should be requested from the relevant individual. A request for expedited approval could be made given the unprecedented nature of the pandemic and the urgent need for national information.

8. Once approval is complete this is logged by completion of the Centre Activation Form which should then be emailed to h.curley@bham.ac.uk, copied to Reportingnetworklead@ukcoronaviruscancermonitoring.com and case inputting can commence. Following completion of the Centre Activation Form the UKCCMP will assume local approval will be gained.
9. An initial invitation email will be received by the ERRI with an activation link to RedCap.
10. Activation of the link will generate a username and password.
11. A LERRG personnel log and a centre patient log should be downloaded from www.UKcoronaviruscancermonitoring.com
12. Following this registration then the ERRI will be provided with a centre username and password that all individuals of the LERRG will use. Only that centre will be able to see the forms generated in that centre.
13. Summary of the project steps can be found in Appendix A.

Case Definition

The case definition is any patient who meets both of the following criteria

- Has an active cancer diagnosis
- Has tested positive for coronavirus (COVID 19) since January 31st 2020

Active Cancer is defined as:

- Any patient with metastatic disease (Irrespective of status including those on treatment/ Watch and Wait / Best Supportive Care)
- Any patient with cancer on active treatment in any setting
- Those treated within the past 12 months with either surgery, Systemic anticancer therapies (SACT) and/or radiotherapy in the curative/radical/adjuvant/neoadjuvant setting.

Cases should be retrospectively added to the database when they have tested positive between the 31st January 2020 and the date of centre activation.

Case Identification

There are a number of strategies to identify a cancer patient with COVID19. These strategies include liaising with inpatient clinical teams, acute oncology admission teams, allied health specialities or diagnostic test facilities. The relative utility of these approaches are likely to vary by centre to centre. In order to ensure rapid dissemination of information of new cases, each ERRI is encouraged to identify the most effective means in their local trust to achieve efficient case finding.

Case Logging

1. Once a new case of COVID-19 in a cancer patient is identified, the reporting individual from the LERRG should go to the following webpage:- <https://itm-redcap.bham.ac.uk>.
2. Please login using the username and password provided to the centre you are reporting on behalf of (By default three logins will be made for each site. Centre_user_1, centre_user_2, centre_user3. Only one person should use a login

username and password at a time. Centre_user_1 account should be held by the main person responsible for reporting as this account only will have the necessary privileges to generate reports).

3. The ERRI ultimately responsible for ensuring that one entry per new case is entered.
4. Study IDs will be automatically assigned and will consist of a centre code and a participant code. Please ensure you add this study code to the patient record and the centre patient log so that you can easily update the record of a patient that you have already registered on the system.
5. The ERRI should also maintain a spreadsheet to be kept on the Trust server that links the study ID to the patient ID, in case further clarification of data is required. All documents related to the study that contains patient identifiable information will be destroyed on completion of the study in line with Trust policy on managing confidential waste.
6. The form (Appendix B) is separated into 3 sections: Registration, Management and Outcomes:
 - a. The Registration data is information regarding patient, their cancer diagnosis and treatment and the date of their COVID-19 positive status. Data fields can be viewed in Appendix B.
 - b. The management data pertains to the management of their viral infection
 - c. The outcome data pertains to their outcome: Long term admission (>2 months), Discharge or Death. If the outcome is death the cause of death must also be completed.
7. The form can be reopened multiple times and remains active until the site completes the outcome data. The outcome data should be completed as soon as possible.
8. To increase efficiency of reporting, case logging is only required for each new case. If there are no new cases, no reporting is required.
9. If an individual is logging data for multiple sites they will need to use the appropriate site login to see each centres data
10. Local processes are outline in Appendix C

A document outlining the upload steps in more detail is available on the www.UKcoronaviruscancermonitoring.com website.

Data Platform

All data is collected on a central REDCap data platform hosted by The Institute of Translational Medicine, University of Birmingham. Each centre has a unique site code, individual username and password to the site. Inputting sites cannot see each other's data forms.

Statistical Analysis

This project is supported by continuous bioinformatics support via the University of Birmingham. An interactive map of cases will be visible on www.UKcoronaviruscancermonitoring.com and updated on a daily basis. More in-depth data will be concatenated on a weekly basis and distributed to the UKCCMP distribution list. They will then subsequently be made available on the website.

Ethics and Approvals

It has been confirmed with The Director of Approvals, NHS Health Research Authority that the project falls under the remit of Public Health Surveillance and therefore does not require further ethical review or approval by the HRA (letter available at www.UKcoronaviruscancermonitoring.com). All data is de-identified at source with location level data blinded to the level of City/Town. The submission of the Centre Activation Form will be taken as confirmation that all required local approvals are in place (including Caldicott approval where deemed necessary by your Centre).

Project Personnel

The project is being co-led by Prof Gary Middleton (University Hospitals Birmingham), Prof Rachel Kerr (Oxford University Hospitals) and Dr Lennard Lee, with scientific supported provided by Dr Claire Palles (University of Birmingham), Dr Roland Arnold (University of Birmingham), Dr Jean-Baptiste Cazier (University of Birmingham) and Dr Shivan Sivakumar (University of Oxford).

Project leads:

Project Clinical and National Support (Dr Daniel Hughes, Guy's and St Thomas' NHS Foundation Trust),

Project Clinical Outreach and Scotland (Dr Karin Purshouse, Edinburgh Cancer Centre)

Project Ethics and Regulatory Affairs (Dr Vinton Cheng, Leeds),

Project Clinical Informatics (Dr Helen Curley, Dr Archana Sharma-Oates, University of Birmingham),

Project Reporting Network (Dr Anna Olsson-Brown, Clatterbridge Cancer Center and NOTCH),

Project Data processing and Intelligence (Dr Alvin Lee, UCLH),

Project Media and Comms (Mr Ashley Smith and Ms Naomi Longsworth).

It is important to note that whilst there is nominal leadership, this project actually is being created by and for the entire oncology community in the UK to enable cancer care to those who need it where clinically necessary.

Authorship Statement

Papers will be authored by the project steering committee. Each centre contributing will then be credited on any publication as they are in any multi-centre oncology project. Individuals making a significant contribution to the project will be invited to join the steering committee and afforded co-authorship.

Endorsement

This project has the support and backing of the Cancer Alliance, The Association of Cancer Physicians (ACP) , Royal College of Radiologists (RCR), Cancer Research UK (CRUK), The UK Chemotherapy Board and The National Oncology Trainees Collaborative for Healthcare Research (NOTCH)

Appendix A



*Forms emailed to Reportingnetworklead@ukcoronaviruscancermonitoring.com

**Forms emailed to h.curley@bham.ac.uk and copied to Reportingnetworklead@ukcoronaviruscancermonitoring.com

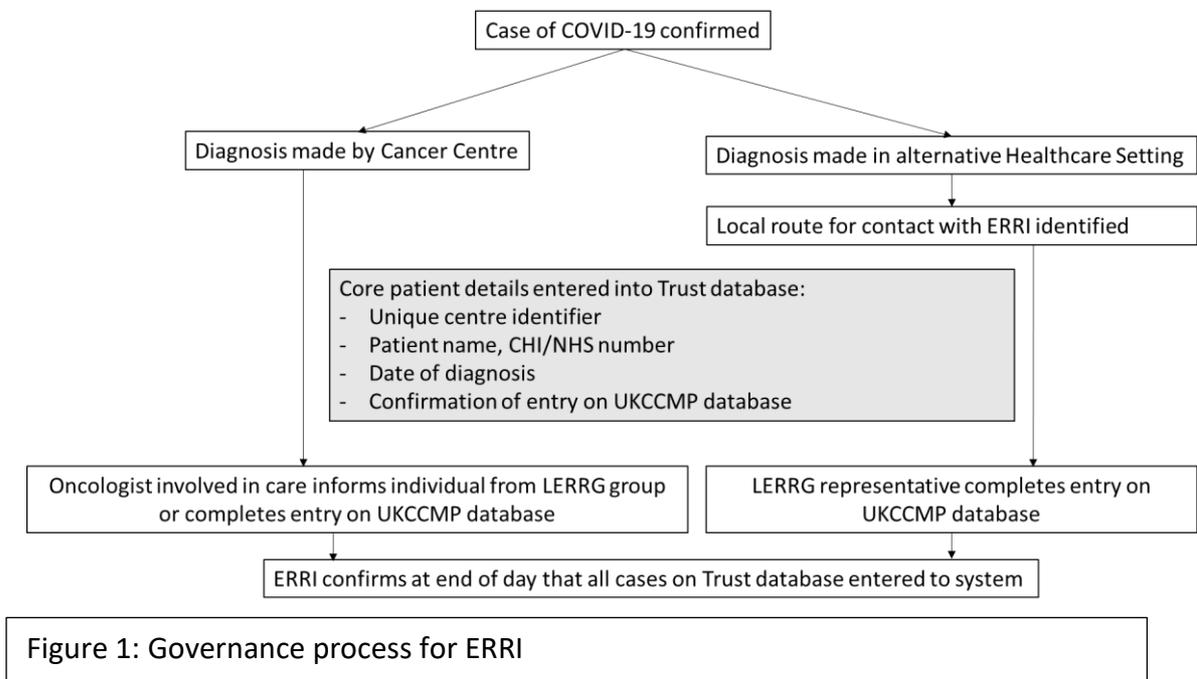
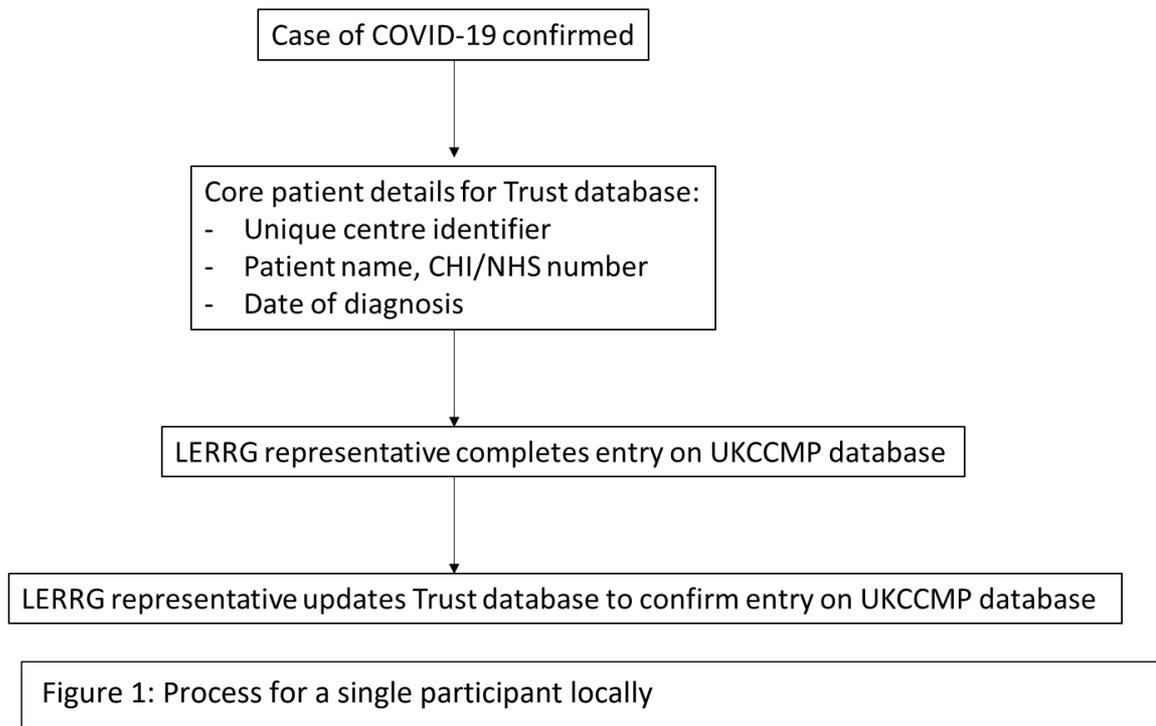
*** Documents downloadable from www.UKcoronaviruscancermonitoring.com

Appendix B

Data Fields with the Data Collection Tool:

| Data Fields with the Data Collection Tool | |
|---|---|
| Patient Registration | Completing Centre Coronavirus positivity data (date, method of confirmation, test number) Presenting Symptoms of Coronavirus Coronavirus severity score (as per WHO) Patient's gender identity Patient's Ethnicity Age of patient at diagnosis of infection Cancer Type Stage Treatment intent Line of treatment Cancer treatment(s) within in 4 weeks of infection Comorbidities |
| Patient Management | Patient admitted to hospital Supportive treatment for Coronavirus |
| Patient Outcome | Patient Outcome Date of Patient outcome |

Appendix C



Appendix D

Expression of interest form

| | |
|---|--|
| Name of Trust/Hospital/Centre | |
| Type of institution | Stand alone cancer centre Hospital Network including a standalone centre Hospital network with an integrated cancer centre University Hospital District General Hospital |
| Emergency response reporting individual (ERRI) | |
| ERRI contact details (email and telephone number) | |

Appendix E

Centre Activation Form

| | |
|---|--|
| Name of Trust/Hospital/Centre | |
| Emergency response reporting individual (ERRI) | |
| ERRI contact details (email and telephone number) | |
| Project Approval Date | |
| Name of Medical Director | |
| Local emergency response reporting group (LERRG) members if known | |