Privacy Notice for the Stereotactic Ablative Radiotherapy (SABR) CtE

SABR is a specialized radiotherapy treatment planning technique that delivers a high dose of radiation to the target, resulting in a high biologically effective dose (BED) to the tumour while minimizing the dose received by surrounding normal tissues.

This study has been commissioned by the National Institute for Health and Care Excellence (NICE) to support NHS England's Commissioning through Evaluation (CtE) programme. The programme funds a limited number of patients to access medical treatments and technologies not routinely commissioned within the NHS. The role of King's Technology Evaluation Center (KiTEC) is to support the work of the programmes of NICE and NHS England, such as this CtE programme.

The SABR study looks at determining whether the benefits of SABR can be translated into an overall survival benefit for patients with oligometastic cancer, cancer that has recurred in a site treated previously with radiotherapy, and patients with hepatocellular carcinoma, across 17 NHS trusts in the UK.

King's College London/(KiTEC) and University Hospitals Birmingham NHS Foundation Trust (UHB NHSFT) are running the evaluation collaboratively.

Data Controller: King's College London / KiTEC – London, SE1 3QD

Data Protection Officer: Paul Labbett – 020 7848 8184, paul.labbett@kcl.ac.uk

Data Processor: University Hospitals Birmingham NHS Foundation Trust – Birmingham, B15 1JD (UHB NHSFT)

Data Protection Officer: Berit Reglar – 0121 371 4324, berit.reglar@uhb.nhs.uk

For clinical matters, please contact your hospital's clinical SABR team.

If you would like to discuss anything else relating to the SABR evaluation please contact:
Kasia Dylinska, SABR Project Manager
Kasia.Dylinska@kcl.ac.uk
Telephone: 020 7848 9526

Supervisory Authority:
King's College London (KCL)
Strand
London
WC2R 2LS
020 7836 5454
ICO Registration Number: Z7915194

Lawful Basis:
Article 6(1) (e): processing is necessary for the performance of a task carried out in the public interest or in the exercise of official authority vested in the controller
The lawful basis for data processing under Article 6, for this project, is public task and consent.

As per Article 9, special category data collected includes: ethnic group and health. The condition applicable, as listed in Article 9(2) (j): processing is necessary for archiving purposes in the public interest, scientific, or historical research purposes in accordance with Article 89(1) based on Union or Member State law which shall be proportionate to the aim pursued, respect the essence of the right to data protection and provide for suitable and specific measures to safeguard the fundamental rights and the interests of the data subject.

In order to send out the consent form and collect patient information the study needs to access personal data. This privacy notice explains what personal data we are processing and why.

Where we collect information about participants

Participation in the study will be kept confidential. Ethical and legal practice will be followed and all information about you will be handled in confidence.

We collect information about participants in two ways:

- When participants give information to us **DIRECTLY**

A member of the clinical team directly involved with the patient's care will explain the rationale of the study to the participants. This could be a clinician, a nurse or a radiographer. Trial specific Patient information Sheets (PIS) will be given to all potential recruits to the study. These will be backed up by a discussion with the clinician and other members involved with the patient's clinical care. All patients will be seen again at least 24 hours after their initial discussion before written consent is taken. Patients who agree for their identifiable data to be analysed by KiTEC will have written consent taken at a subsequent visit. Patients may also receive consent forms via post if they need to be re-consented or if they have been treated multiple times and are not due back in clinic for follow-ups any time soon.

- When participants give information to us I**NDIRECTLY**

For the longitudinal study, recruited patients are required to give their informed consent for the local research teams at recruiting hospitals to collect and record their clinical and treatment data into a database specifically holding SABR data. The data processor, UHB NHSFT, will be linking patient level data from the Hospital Episode Statistics (HES) and Office of National Statistics (ONS) datasets, disseminated by

NHS Digital, to the SABR database to capture accurate mortality data and other diagnoses or procedures patients may have had at other departments. NHS Digital disseminates HES data, which contains the details of all patient admissions, A&E attendances, and outpatient appointments at NHS hospitals in England. NHS Digital also disseminates ONS data, which contains the date of deaths for patients, required for the study. In order for the data processor to collect non-anonymized patient data (NHS number as a minimum), access to non-anonymized HES/ONS patient records is needed. Data will be sent securely.

What personal data will be collected and how will it be used

This study aims to collect information about clinical outcomes in patients who are treated using SABR, to then compare with historical data for similar populations.

More specifically the following questionnaires will be collected as part of the SABR CtE project:

1. Clinical assessment baseline and follow-up (at 4-6 weeks, 6-12-18 and 24 months post treatment)
2. Treatment toxicity using the Toxicity Common Terminology Criteria for Adverse Events (CTCAE v4)
3. Quality of life (EQ5D)
4. Pain score
5. Patient experience survey
6. Radiotherapy treatment planning data

Identifiable data about patient treatment will be collected and entered electronically at the NHS trust the patient was seen at/recruited at. The data will then be sent securely to a database designed for the specific purpose of this evaluation, which will be established by the database provider UHB NHSFT. The database can only be accessed within the NHS by the named clinicians involved in the project. Each participating NHS trust will be able to access the data about its own patients in identifiable format. All access to patient data will be managed whilst adhering to strict protocols. Identifiable patient data from this database will be transferred for analysis at KiTEC and UHB NHSFT.

At KiTEC and UHB NHSFT, all patient information will be stored on password protected computers and will only be accessible to the named individuals on the team who will be carrying out analysis of your data. When the results of the study are reported, individuals who have taken part will not be identified in any way.

All data processing will take place in line with the requirements of the data protection legislation.

How can participants opt out of the study?

Participants who decide not to participate in the study are free to decline or withdraw at any time, without giving a reason. This does not affect the standard of care you receive.

Participants can withdraw or opt out of the study even after completing their consent form by contacting their NHS Radiotherapy Center where treatment is provided to them. Participants have the right to erasure, also known as the right to be forgotten. The following contact details can be used to withdraw, opt out, or be forgotten:

University Hospitals Birmingham NHSFT
Yardley Court, 3rd floor, Informatics Dept
11-13 Frederick Road, Edgbaston
Birmingham
B15 1JD
STAAR@uhb.nhs.uk

Reporting plans

The end of study will be marked by the final report submission of the complete analysis to NICE and NHSE. The results from both surveys will be made available to patients, their partners/spouses/carers, the funders, NHS, social care, voluntary sector organisations and other researchers through public and professional reporting.

The data analysis will consist of: a statistical analysis, health economic analysis, comparators & model time horizons, transition probabilities, utilities and costs, and a cost-effectiveness analysis. KiTEC will be interested in aggregated data and therefore, no identifiable data will be required.

Reported results will not contain any patient identifiable data.

Data will be retained until 30/06/2021. Patient recruitment is due to end in mid-2018, which means that the end of the two year follow-up for patients who are recruited at the end of the study will be mid-2020 and the data for this time period would be unlikely to be available until late 2020. We are requesting an additional 6-9 months after this data would become available. This additional time to retain the data will allow for any queries which may come back from NSH England and/or NICE to be resolved and will allow for additional time to ensure that publications are finalized.

What if there is a problem?

If you have a concern about any aspect of this study, there are a number of point of sources you can speak to, including: clinicians and researchers at your NHS trust, the Project Manager- Kasia Dylinska, Kasia.Dylinska@kcl.ac.uk, 020 7848 9526
or by post:

School of Biomedical Engineering & Imaging Sciences
5th Floor, Becket House
1 Lambeth Palace Road
London
SE1 7EU

If you remain unhappy and wish to complain formally, you can do this through your local hospital's Patients Advice and Liaison Service (PALS). Please contact your hospital for the contact details to their PALS department.

NHS Trusts involved in the SABR study

- Clatterbridge Cancer Centre
- Royal Marsden Hospital
- Mount Vernon Cancer Centre
- Newcastle-Northern Centre for Cancer Care
- Guy's and St Thomas' NHSFT
- St Bartholomew's Hospital
- Leeds Teaching Hospitals NHS Trust
- Oxford-Churchill Hospital
- Sheffield-Weston Park Hospital
- University Hospitals Bristol NHSFT
- Leicester Royal Infirmary
- Christie NHSFT
- Nottingham University Hospitals NHS Trust
- Middlesbrough/South Tees NHSFT
- Guildford/Royal Surrey county Hospital
- UHB Foundation Trust
- University College London Hospital