Oxford University Hospitals
NHS Foundation Trust

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PARTICIPANT INFORMATION SHEET

AI-REACT STUDY

A sub study of the STEDI: Simulation Training for Emergency Department Imaging;

University of Oxford Central University Research Ethics Committee Reference R80145/RE001

Background

qER 2.0 EU is an FDA cleared and CE marked AI tool for interpretation of non-contrast CT head scans which can detect, classify and localise intracranial haemorrhage, mass effect, infarct, midline shift, atrophy and fractures in non-contrast Head-CT scans. A priority status is assigned if any one of the target abnormalities is detected by the software, and the user will be able to view a single summary slice listing all the target abnormalities found by qER on the CT scan followed by all slices in scan with the overlay of above abnormalities localization. Alternately, if none of the target abnormalities are detected, the output will indicate that the software has analysed the image and identified no critical findings. qER reports are intended to support certified radiologists and/or licensed medical practitioners for clinical decision making. It is a support tool when used with original scans can assist the clinician to improve efficiency, accuracy, and turnaround time in reading head CTs. It is not to be used to provide medical advice, determine a treatment plan, or recommend a course of action to the patient. As such its potential impact on the diagnostic accuracy of radiologist and Emergency Department clinicians has yet to be fully evaluated in the UK.

What is the purpose of the study?

The purpose is to compare the impact of using a tool that implements artificial intelligence in the detection of abnormalities in non-contrasted head CT scans versus the implementation of e-Learning in the main trial.

Why have I been invited?

We are aiming to recruit 30 participants from Emergency Departments across the Thames Valley. You have been invited to participate in this study because you are an Emergency Department clinician in one of the five participating Trusts in the Thames Valley

Do I have to take part?

No, you do not have to participate in the study. This completely voluntary, and you can change your mind at any time.

What will happen to me if I decide to take part?

If you decide to take part in the STEDI – AI-REACT study, you will be offered the chance to discuss the study with the Principal Investigator who will be able to answer any questions you may have pertaining to the study. If you are still happy to participate you will be asked to sign a consent form online provided by

the Principal Investigator, giving permission for the use of your pseudonymised information to be stored and used for the study.

If you are part of the 30 participants recruited as part of the AI-REACT study, your main activities will be as it follows:

1. Reading phase 1: You will be asked to complete an online baseline assessment of CT interpretation accuracy, which includes reading 150 non-contrasted CT heads using a pre-designed platform for this purpose. You will have the link to the platform through an email that will be sent to the account that you provided us in your acceptance email.

2. Reading phase 2: You will perform the reading of 150 non-contrasted CT head one more time, but this time with access to the output of an AI-enhanced image analysis algorithm (qER 2.0 EU). Again, you will use the pre-designed platform to report your findings. You will have the link to the platform through an email that will be sent to the account that you provided us in your acceptance email.

3. You will have to answer a qualitative survey before the first reading phase, and one more after the second reading phase, which will aim to obtain feedback and comments on your project experience and monitor any changes during the study .

4. Having completed both reading phases plus the qualitative surveys, the research team that has invited you to the project will carry out the analysis and processing of the information obtained, to finally generate and communicate the conclusion obtained.

What should I consider?

You will not be able to participate in the STEDI - AI-REACT study if you have previously undergone CT Head scan reporting training, worked as a registrar in Radiology or Neurosurgery, or have worked less than four months in the Emergency Department.
The total time required to participate in this study is estimated at 10-12 hours over 3 months

Are there any possible disadvantages or risks from taking part?

There are no anticipated risks to taking part in the study.
We would expect the time taken to complete the surveys and review the scans to take roughly 10-12 hours of your time over a three month period.

What are the possible benefits of taking part?

By taking part in the STEDI - AI-REACT study you will gain experience and training in reporting CT Head scans.

Will my taking part in the study be kept confidential?

All information provided to the study team at Oxford will be anonymised before transfer, and only the lead at your hospital will be able to link your details to the study number you will be allocated.

All anonymous information will be stored securely on Oxford University Hospitals NHS Foundation Trust servers, and access limited to specific individuals. Study data will be stored for seven years after the study finishes,and will then be securely disposed of.

Responsible members of the Oxford University Hospitals NHS Foundation Trust may be given access to data for monitoring and/or audit of the study to ensure that the research is complying with applicable regulations.

Will I be reimbursed for taking part?

Yes, there is a compensatory payment of £500 for completing the study, including all assessments and training

What will happen to my data?

- We will be using information from the assessments and forms you complete in order to undertake this study. You will be assigned an individual study ID, and your personal details (e.g. name) will be held on a separate list which links them to the ID – this list will only be available to your local study PI, and will not be seen by the central Oxford team analysing the data. Research is a task that we perform in the public interest. Oxford University Hospitals NHS Foundation Trust, as sponsor, is the data controller. This means that we, as Oxford University Hospitals NHS Foundation Trust researchers, are responsible for looking after your information and using it properly. We will store the anonymised research data and any research documents with personal information, such as consent forms, securely at the Oxford University Hospitals NHS Foundation Trust for 7 years after the end of the study. Data will be emailed from sites in a password-protected file once the study has closed.
- Your local NHS Trust study team will keep identifiable information such as your name and contact details from this study for a maximum of one year after the study has finished. A copy of your consent form will also be held.
- Your rights to access, change, or move your personal information may be limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. Further information about your rights with respect to your personal data is available at https://www.ouh.nhs.uk/privacy/default.aspx
- *You can find out more about how we use your information by contacting the Chief Investigator Dr Alex Novak via his email address alex.novak@ouh.nhs.uk*

What will happen if I don't want to carry on with the study?

- Participation is voluntary and participants may change their minds at any stage.
- If you decide to withdraw from, or stop participating in the STEDI study, information already collected will be used in the analysis
- So that we can learn for future studies, we may ask if you would be happy to provide us with a reason as to why you have chosen to withdraw. You are not obliged to give a reason.

What will happen to the results of this study?

The results of the study will be shared in journal articles and conference presentations/posters.

How have patients and the public been involved in this study?

This study was developed in conjunction with member of the AcuteCare Public and Patient Involvement group. The study has also been sponsored by Oxford University Hospitals NHS Foundation Trust

Who is organising and funding the study?

The STEDI study is organised by a group of clinicians working in Emergency Medicine and radiology at the Oxford University Hospitals NHS Foundation Trust, with the help of RAIQC, and is funded by a grant from the Small Business Research Initiative (SBRI)

Who has reviewed the study?

All research involving staff in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect participants' interests. This study has been reviewed and given favourable opinion by a subcommittee of the University of Oxford Central University Research Ethics Committee (CUREC).

What if there is a problem?

if you wish to complain, or have any concerns about any aspect of the way you have been approached or treated during the course of this study, you should contact <name of investigator><contact details (phone number & email)

There are no special compensation arrangements. Oxford University Hospitals NHS Foundation Trust will provide indemnity for this study. If you are harmed due to someone's negligence, then you may have grounds for legal action but you may have to pay for it.

NHS bodies are legally liable for the negligent acts and omissions of their employees. If you are harmed whilst taking part in a clinical trial as a result of negligence on the part of a member of the study team this liability cover would apply.

Non-negligent harm is not covered by the NHS indemnity scheme. The Oxford University Hospitals NHS Foundation Trust, therefore, cannot agree in advance to pay compensation in these circumstances. In exceptional circumstances an ex-gratia payment may be offered.

Further information and contact details:

For further information about the study, please contact the local investigator at your site:
Dr……..
Telephone number: ……
Email:……

If your questions are not adequately resolved, please contact the Chief Investigator, Dr Alex Novak
Phone: 07944 653970
Email: alex.novak@ouh.nhs.uk
Thank you for considering taking part.