

IBM Watson Health Imaging Clinical Review Support Tool Study

IRAS Project ID 278884

USING ARTIFICIAL INTELLIGENCE IN THE IMAGING DEPARTMENT AT SANDWELL AND WEST BIRMINGHAM.

Summary Participant Information Sheet

This information is also available in audio and large print on request.

What we are doing?

In the Imaging Department at Sandwell and West Birmingham NHS Trust (SWB), thousands of patients have X-rays and medical scans taken on a daily basis. We create high quality digital pictures from these X-rays and scans.

These pictures are interpreted by our specialist doctors in the imaging department who diagnose and create reports. These reports are sent to your GP or to the hospital doctor who requested the X-Ray or medical scan.

We, a global company called IBM Watson Health, with several locations in the UK, have approached SWB to support their research as a Sponsor using new software which uses something called Artificial Intelligence.

Artificial Intelligence is used to make sense of a variety of data automatically provided to it. Its use is wide-spread in areas like autonomous vehicles, managing preferences in online retail, social media, speech recognition in banking, image recognition in security monitoring, and the provision of insurance services.

In healthcare, artificial intelligence technology is used to help doctors to provide high quality diagnoses and plan treatments for certain conditions. In the future, its use will become standard across the NHS.

In this research study, we will use information from your digital pictures that SWB collects as part of routine X-Ray or medical scans within their imaging department. We will only use information that we need for the research study. Everyone involved in this study will keep your information safe and secure and we will follow privacy rules.

If you are due to attend an appointment at SWB, we would like to use your digital picture and your previous three years' worth of digital pictures to be included in this research. We would use up to three years' worth of digital pictures because this is usually how far back our specialist doctors review X-rays and medical scans. We will select the types of digital pictures that we provide to the Artificial Intelligence system.

IBM Watson Health Imaging
V6.0, 31 July 2020

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Sandwell & West Birmingham NHS Trust Imaging Group

The selection of these types of digital pictures:

- Does not affect your appointment time or your X-ray or medical scan
- Does not affect how soon the report is sent back to your GP or hospital doctor.
- Does not affect your original pictures which are kept separately and securely on our computer system according to NHS Records standards.

Why we are doing it?

Our specialist doctors in Imaging need to look at a growing amount of these types of digital pictures every day.

We are using the Artificial Intelligence system:

- To think about our digital pictures and flag its findings to our specialist doctors
- Our specialist doctors use their own clinical judgement with support from the AI findings to report your digital pictures more efficiently.
- To see how well it performs when looking at these types of digital pictures. The information SWB collect will show whether it is making a difference to your health.
- To maintain the quality of the reporting. We do this by collecting information from lots of participants, the researchers at SWB can use statistics to work out how well artificial intelligence is supporting our specialist doctors.
- To support the training our future specialist doctors.

How will we use information about you?

We will need to use information from your digital pictures for this research project. This information will include your:

- forename
- surname
- date of birth
- gender and title
- as well as your hospital and NHS Number.

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.

We will keep all information about you safe and secure. We use a secured link to send the de-identified digital pictures and their de-identified reports directly to the Artificial Intelligence system based at a UK data centre in London. No de-identified pictures or reports leave the UK London data centre, and after three months they are securely deleted.

The Artificial Intelligence uses software designed by IBM Watson Health to think about these types of digital pictures, compare the findings in the reports, and tell our specialist doctors what they find.

Our specialist doctors then use this information to support the quality of the reports that they create. If the artificial intelligence technology flags a potential missed finding, and our specialist doctors diagnose and confirm this, then our radiology managers will notify your referring doctor. This is the same process that our specialist doctors and radiology managers follow even if we did not use artificial intelligence.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study. The accompanying information sheet from the Health Research Authority tells you more about this.

Artificial Intelligence

This technology is a set of computer instructions called Artificial Intelligence.

Artificial Intelligence is used to make sense of a variety and large volume of clinical information more quickly than a human.

This research focuses on both chest and abdomen X-ray or medical scans. In the future, we intend to use artificial intelligence to support our patients with prostate and breast disease.

What are your choices about how your information is used?

SWB would automatically enroll you into this research when you attend your appointment for a chest or abdomen X-ray or medical scan.

Only healthcare professionals who are directly involved in your care will be able to access your full patient record.

You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.

If you choose not to take part in the research, that is fine.

If you do not wish SWB to use your data for this research, then there will be no impact on your clinical care. You will continue to have your X-ray or medical scan as normal.

If you wish to OPT-OUT, please use the tear-off slip at the end of this document and leave it our X-ray reception.

As the Sponsor, IBM Watson Health is legally responsible in ensuring the research is designed, managed and conducted correctly and safely.

IBM Watson Health has agreed to share responsibility with SWB for ensuring all the data collected for the research is handled properly. Both IBM and SWB are therefore joint data controllers who have a legal responsibility to ensure our patients' data is handled securely and is protected at all times.

The selected digital pictures provided to the Artificial Intelligence system:

- Do not contain any personal identifiable information about you. SWB will only share information which is linked to your clinical record. Any information shared in relation to your digital picture and your clinical record will be de-identified.
- Are stored for a period of three months after which they are securely and permanently deleted.
- Are not used for any other purpose than that for this research either by SWB or IBM Watson Health.

There are several ways that your privacy is protected:

- Your original digital pictures will be stored securely on our hospital systems as part of your medical records.
- A member of the research team will remove details that can identify a person before sending the selected data to the Artificial Intelligence system.
- We implement robust IT security which involves a secure link to the London data centre and secured environment there.
- We have followed the Information Commissioner's Office guidelines to make sure we protect your picture and reports during this research

You can find out more about how we use your information:

- In the accompanying information sheet from the Health Research Authority or at www.hra.nhs.uk/information-about-patients/
- our leaflet available from <https://www.hra.nhs.uk/patientdataandresearch/>
- by sending an email to the Sponsor's Data Protection Officer
Carl Kraenzel
pooter@us.ibm.com
- by sending an email to one of the researchers listed below

Dr Bahadar Bhatia
Principal Investigator, Principal Medical Physicist. Imaging Group, Sandwell & West
Birmingham NHS Trust
bahadar.bhatia@nhs.net

or

Dr Sarah Yusuf
Co-Investigator, Consultant Radiologist and Group Director, Imaging Group,
Sandwell & West Birmingham Hospitals NHS Trust
sarah.yusuf@nhs.net

- by accessing the hospital website: <https://www.swbh.nhs.uk/services/research-and-development/>

Patient Advisory Liaison Service (PALS).

If you have any concerns regarding the care you have received, or as an initial point of contact if you have a complaint, please contact the Patient Advisory Liaison Service (PALS).

The Patient Advice and Liaison Service (PALS) is a service that offers support, information and assistance to patients, relatives and visitors. They can also provide help and advice if you have a concern or complaint that staff have not been able to resolve for you.

The Patient Advice and Liaison Service may be contacted by

Phone: 0121 507 6440, 4080, 5892 10am – 4pm, Monday – Friday

Email: swbh.complaints@nhs.net

You can get independent advice to assist raising your complaint from:

Voiceability Advocacy Service

0121 303 1234

www.voiceability.org

Advocacy services offer a free, impartial and independent service for people who wish to make a formal complaint about the NHS.

If you are not happy with the response we provide to you, you can tell us why and explain what else you want us to do. If, once we have done all we can and you are still unhappy, you can complain to the Parliamentary Health Service Ombudsman at:

Parliamentary Health Service Ombudsman
Millbank Tower, Millbank, London SW1P 4QP

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Telephone: 0345 015 4033
Email: phso.enquiries@ombudsman.org.uk
Website: www.ombudsman.org.uk

Who has reviewed the study?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests.

This study has undergone independent external review as part of the national Integrated Research Application System through the NHS Health Research Authority

Approvals Officer, Health Research Authority,

Telephone: 0207 104 8085
Email: Londonsoutheast.rec@hra.nhs.uk

What is the research timescale and when will results be available?

The research will be conducted over three months at Sandwell & West Birmingham NHS Trust.

Research results will be presented and published during the course of the study and will be made available on the hospital website within a year of completion.

Thank You

We gratefully acknowledge your support in participating in this research study.

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If you wish to OPT-OUT please tear off this slip and leave it at X-ray reception. Thank you for reading this information leaflet and letting us know.

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I[Enter Name]

RXK.....[Hospital number from the appointment letter]

Do not wish SWB to use my data for this research.

.....[Enter Date]

.....[Enter signature]