AGILE Trial Data Privacy Notice

Version 4.0, 12 February 2025

Document Summary

Section 1 - Background

The University of Liverpool, the trial Sponsor, is required to inform people about the ways in which their personal information is used.

Section 2 - The AGILE Trial

The AGILE Trial is a clinical trial investigating potential treatments for COVID-19. Each drug is evaluated in a separate Drug Specific Trial (CST), meaning that we can look at lots of different treatments, at different doses at the same time.

Section 3 – Data Controller

The Data Controllers decide how your personal information is processed.

Section 4 - What rights do I have when it comes to my data?

There are legal details contained in General Data Protection Regulation (GDPR) and Data Protection Act 2018 that allow trial sites (hospitals running the trial) to use your personal information without your consent. Your rights are listed in this section.

Section 5 - How we use personal data to recruit new participants and check their eligibility

To be able to identify and contact potential participants, trial sites can gain access to personal information from specific organisations that collect data about people who have been diagnosed with COVID-19, without the person's consent.

Section 6 - Data Processors

Trial sites contact potential participants to invite them to take part in the trial. The outcome of this is logged on a securely stored tracker document.

Section 7 - How we use personal data when you consent to participate in AGILE

Participants are given a Trial ID to ensure that they can't be directly identified by the data collected. Hospital notes may be accessed where required.

Section 8 - Our legal basis for processing personal data

Personal data and special category personal data are processed for the AGILE Trial. The lawful basis for processing under UK GDPR and the Data Protection Act 2018 that apply are listed in this section.

Section 9 - Changes to this Privacy Notice

The Data Privacy Notice may be updated in the future.

For further information on each section, please see the following pages.

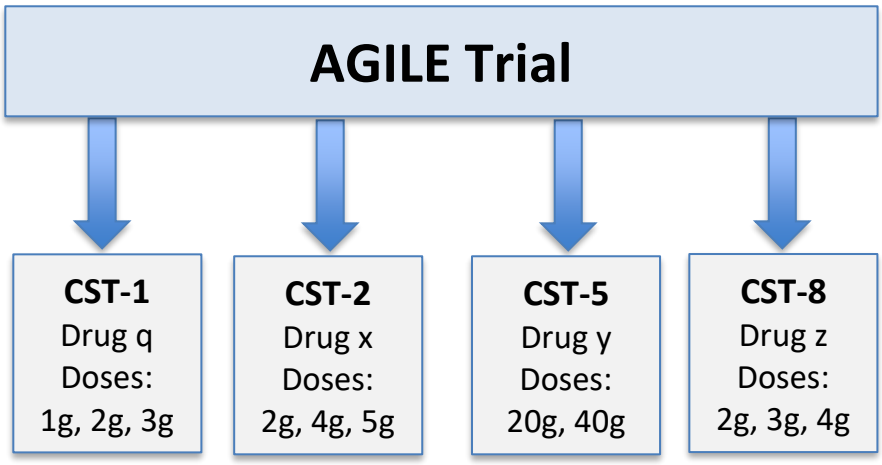
Section 1 - Background

The University of Liverpool, the trial's Sponsor, is required to inform people about the ways in which we use their personal information. We need to tell you about the types of personal information we collect, the purposes we use it for, the legal reasons contained in the General Data Protection Regulation (GDPR) and Data Protection Act 2018 which allows us to use it in these ways, how long we retain the information for and how you can exercise your rights.

This requirement applies when dealing with "personal data". If data is considered personal then the UK GDPR places specific legal obligations on the controller of that data. If data is not personal (i.e. if it never related to a person or if it has since been anonymised) then the GDPR does not apply.

Section 2 - The AGILE Trial

The AGILE Trial is a University of Liverpool sponsored clinical trial that is investigating potential treatments for COVID-19. It is a phase I/IIa platform trial for the rapid evaluation of drugs for COVID-19 treatment, where each drug is evaluated in a separate Drug Specific Trial (CST). This means that we are able to look at a lot of different treatments, at different doses, at the same time. The aim is for important evidence about these treatments to be gained that can help to prevent illness and improve outcomes for people diagnosed with COVID-19.



(exact CST numbers, drugs and doses are not real, used for diagram example only)

To be able to run the AGILE Trial effectively, the trial processes data on 2 groups of people:

1) Adults who have tested positive for COVID-19

2) Adult participants who have provided their explicit informed consent to take part in the trial.

Access to patient data is vital for this trial and we implement high security and governance standards to ensure patient confidentiality within our trial. We obtain appropriate ethical and legal approvals for all research and ensure that it is strictly in the public interest when we use personal information. We do this by following the UK Policy Framework for Health and Social Care Research.

In this privacy notice, we will explain how personal data is accessed, processed and for what purposes.

Section 3 - Data Controller

The Data Controllers are specified for each AGILE CST and include the University of Liverpool (role: Sponsor for all CSTs) and Liverpool University Hospitals NHS Foundation Trust (role: Lead NHS Site). This means that they will decide how your personal information, as a participant in the trial, is created, collected, used, shared, archived and deleted (processed).

Section 4 - What rights do I have when it comes to my data?

Early in the COVID-19 pandemic, 'Control of Patient Information (COPI) notices' set aside the common law duty of confidentiality for a wide range of data sharing for public health, planning and research purposes where they support the response to COVID-19 (referred to as a 'COVID-19 purpose'). They apply to confidential patient information which is defined in legislation and encompasses health records, or information derived from them, which enables the identification of an individual. This meant, that the AGILE trial sites were able to process confidential patient information without consent, in order to contact people who have tested positive for COVID-19 and ask if they would be interested in participating in the AGILE Trial. The COPI notices expired on 30-JUN-2022 and the Confidentiality Advisory Group has provided a recommendation of support to the Health Research Authority to transfer the lawful basis for processing confidential patient information without consent to Regulation 5 of the Health Service (control of Patient Information Regulations 2022) for the AGILE Trial. This is so that AGILE trial sites can receive confidential patient information held by other organisations responsible for the data (see Section 5) to contact people who have tested positive for COVID-19 and ask if they would be interested in participating in the AGILE Trial. Please see Sections 5 and 6, which describe what personal data is requested and how it is accessed, used and stored.

Under the UK General Data Protection Regulation, you may have the following rights with regards to your personal data:

- The Right to subject access – you have the right to see a copy of the personal data that the University holds about you and find out what it is used for.
- The Right to rectification – you have the right to ask the University to correct or remove any inaccurate data that we hold about you.
- The Right to erasure (right to be forgotten) you have the right to ask the University to remove data that we hold about you.
- The Right to restriction – you have the right to ask for your information to be restricted (locked down) on University systems.
- The Right to data portability – you have the right to ask for your data to be transferred back to you or to a new provider at your request.
- The Right to object – you have the right to ask the University to stop using your personal data,to stop sending you marketing information, or complain about how your data is used.
- The Right to prevent automated decision making – you have the right to ask the University to stop using your data to make automated decisions about you or to stop profiling your behaviour (where applicable).

Please note that not all rights apply in all situations. To find out more about your rights under the UK GDPR, please visit the Information Commissioner's website.

Section 5 - How we use personal data to recruit new participants and check their eligibility

To be able to identify people who have tested positive for COVID-19 and ask if they would be interested in participating in the AGILE Trial, the University of Liverpool has sought permission for trial sites to gain access to patient confidential data that the following organisations collect about people who have been diagnosed with COVID-19:

- General practice surgeries
- Local and supra-regional testing laboratories (Pillar 1 and 2)
- Local Clinical Commissioning Groups (CCGs)
- Local Public Health and local authority testing facilities
- Local Public Health Authorities
- UKHSA System

Trial sites request data from these organisations to contact as many people as possible to ask them if they would like to participate in the AGILE Trial. The data we request from these organisations is special category personal data. This is because it includes information that can directly identify a person, and sensitive information about their health. The maximum data we will request is: name, date of birth/age, gender, number of days of COVID-19 symptoms, date of COVID-19 test and telephone number of adults who were recently diagnosed, however sometimes less data is requested.

DATA FROM LOCAL AUTHORITIES

Special category personal data including name, date of birth/age, gender, telephone number, date of positive COVID-19 test and number of days of COVID-19 symptoms, is requested by trial sites from the local authorities named above including local GP practice surgeries. These data are provided at varying frequencies (e.g. daily, weekly, ad hoc as patients present) and is transferred via either encrypted email or encrypted documents to research staff employed by the trial sites (see Section 6). Once the data has been processed (see Section 6) the encrypted email/document is deleted from the electronic system.

Up to 30th June 2022, under the COPI notice trial sites also processed the following data received from local authorities to support participant recruitment: NHS number, postcode, email, test type, local hospital number, location of individual (in hospital, outpatient), date test received at lab, date test authorised, lab number. These data points have not been processed since the COPI notice expired on 30th June 2022.

DATA FROM UKHSA

The trial also processes data on adults diagnosed with COVID-19 from the UK Health Security Agency (UKHSA), an executive agency of the Department for Health and Social Care. As part of its role in the nation's health security and the government's response to the pandemic, the UKHSA has a statutory responsibility to collect data about every diagnosis of COVID-19. This information is obtained from the laboratories that test for COVID-19. To support the recruitment of new participants into the AGILE Trial, UKHSA provide secure access to lists of people who have had a recent test confirming diagnosis of COVID-19. This is made available on a daily basis. The lists include the name, date of birth/age, gender, telephone number, date of test of people who tested positive for COVID-19 and symptoms that were reported less than 5 days ago. Research staff who are employed by the trial sites (see Section 5) are provided access to

this data for a time-limited period using a secure connection to UKHSA systems. For each trial site, the data is restricted to people who are in the geographical area of the NHS trial site (this is usually your local NHS Trust (NHS hospital(s)) or a tertiary centre (specialist hospital) that has a Clinical Research Facility), they can be invited to attend the same trial site in person. For the UKHSA system, the daily cases will be removed from the view of the site trial team after 24 hours, and a new list of 50 cases is provided per day.

DATA FROM NHS DIGITAL

Information about you and your health is recorded when you receive health care or social care, to help with your care and treatment. This is called your medical records. These records can be held by your local hospital and NHS Digital – which is an organisation that has the official role as the safe haven for patient data in England.

To support the recruitment of new participants into the AGILE Trial, the trial team may apply to NHS Digital to provide secure access to lists of people who have had a recent test confirming diagnosis of COVID-19. The access will be via a secure portal for authorised trial staff for a temporary basis.

Using the data from the sources listed above, the trial sites will contact individuals by telephone to provide them with information about the trial, invite them to attend to learn more about the trial and seek their consent. The trial site will make three attempts to contact a person; in instances where the individual is reinfected with COVID-19, the site contact tracker will be checked and another three attempts to contact should not be undertaken. You can read more about this process in Section 5.

When a site receives their first list from an organisation, prior to using the data they will ensure that the sender organisation invokes the National Data Opt-Out. GPs and sites will check their records for opt-out prior to contacting a patient. If a potential patient has 'opted out' they should not be on the list provided by the organisation or contacted by site.

Section 6 - Data Processors

Should the trial site (hospital running the trial) contact you, they will explain the trial and you will have the opportunity to ask any questions. Taking part in the trial is entirely voluntary. If you wish to attend the trial site to learn more and give consent to take part in the trial, the trial

site will collect and securely store your initials, year of birth, gender, telephone number, outcome of contact on a secure tracker document.

If you state that you do not wish to take part in the trial and request that this data is not stored, all data will be removed and a 'D' entered into the site screening tracker. By not storing the data, you may be contacted in the future about the study (e.g. if you are re-infected and on a COVID-19 list provided to the site) as there will be no data to show that you have been contacted previously.

If you do not wish to take part in the trial, you can't be contacted or are not eligible, the trial site will collect and securely store your initials, year of birth, gender and outcome of contact.

Not taking part will not affect the standard of care you receive.

You will not be contacted by the trial site again.

These details will be stored for a maximum of either 25 or 30 years, depending on the type of trial, in case it needs to be checked, as per Good Clinical Practice (GCP) Guidance. Data storage time will be detailed in the Participant Information Sheet for each trial.

Section 7 - How we use personal data when you consent to participate in AGILE

When a trial consent form is signed by a participant, it is stored securely at the trial site and in some cases, transferred securely to the company running the trial for checks.

Data is collected during the trial by the trial site as outlined in the trial Patient Information Sheet. You are given a Trial ID to ensure that you can't be directly identified by the data entered onto the secure data collection database.

Hospital notes may be accessed by the following individuals or groups as per GCP Guidance: hospital medical staff, individuals from University of Liverpool, individuals from company running the trial, regulatory authorities, NHS Trusts, authorised individuals from the funding organisation or drug provider.

The data that can't directly identify you may be shared and stored securely with:

- The organisation running the trial

- The trial funder or drug provider
- Third party individuals e.g. questionnaire provider
- External companies (only for specific purposes and following instruction)
- Other researchers

This data may be shared with the above individuals or groups for the following reasons:

- Safety reporting
- Analysis of trial results
- Sample analysis
- Oversight of product provided e.g. questionnaire
- If required to comply with a legal obligation or to protect rights, property and safety
- To conduct health and care research.

This may mean that this data is securely transferred abroad, if required.

Section 8 - Our legal basis for processing personal data

For this trial, we process personal data and special category personal data. The lawful basis for processing under UK GDPR and the Data Protection Act 2018 that apply are:

- UK GDPR Article 6(1)(e) 'processing is necessary for the performance of a task carried out in the public interest'
- UK GDPR Article 9(2)(i) 'processing is necessary for reasons of public interest in the area of public health, such as protecting against serious cross-border threats to health'
- UK GDPR Article 9(2)(h) 'processing is necessary for the provision of health or social care or treatment or the management of health or social care systems and services'
- UK GDPR Article 9(2)(g) 'substantial public interest'
- UK GDPR Article 9(2)(j) 'Archiving, research and statistics'
- Data Protection Act Schedule 1 Part 1 (2) 'health or social care purposes'
- Data Protection Act Schedule 1 Part 1 (3) 'public health'
- Data Protection Act Schedule 1 Part 1 (4) 'research'
- Data Protection Act Schedule 1 Part 2 (6) 'substantial public interest'

For further information about the lawful basis under GDPR, please visit the Information Commissioner's Office website (see Section 4).

To request a copy of your data, ask questions about how it is used or if you are unhappy about how your data is being used, please contact:

University of Liverpool Data Protection Officer

(all CSTs)

- Email: legal@liverpool.ac.uk

- Post: Legal & Governance, University of Liverpool, Foundation Building, 765 Brownlow Hill, Liverpool, L69 7ZX

Or

Liverpool University Hospitals NHS Foundation Trust Data Protection Officer

(all CSTs)

- Email: DPO@liverpoolft.nhs.uk

- Post: Data Protection Officer, Liverpool University Hospitals NHS Foundation Trust, 2nd Floor, Aintree Lodge, Lower Lane, Liverpool, L9 7AL

You also have the right to complain to the Information Commissioner's Office using the following details:

- **The Information Commissioner's Office, Wycliffe House, Water Lane, Wilmslow, Cheshire SK9 5AF**

- Telephone: 08456 30 60 60 or 01625 54 57 45

- Website: www.ico.org.uk

Section 9 - Changes to this Privacy Notice

We reserve the right to update this privacy notice at any time, and we will provide you with a new privacy notice when we make any substantial updates. We may also notify you in other ways from time to time about the processing of your personal information.