



SANAD II Coordinating Centre
The University of Liverpool
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A study of Standard and New Antiepileptic Drugs – SANAD-II
Electronic Data Opt-out Letter v1.0 27/11/2017

Re: Your participation in SANAD II and your electronic medical record

Thank you for your participation in SANAD II.

One of the objectives of SANAD II is to see whether the newer treatments represent good value for money for the NHS. To do that we will need to collect information about your hospital admissions and other uses of the NHS. The best way to do that is to access the information about you stored on NHS computer systems. The purpose of this letter is to explain this in more detail and to check that you do not object to data about you being used in this way.

When you attend hospital, information regarding this is recorded on NHS computers forming your electronic medical record. These records are stored securely and shared between a number of organisations to inform your care and the wider functions of the NHS. In SANAD II we will use data from your hospital electronic medical records alongside information from the questionnaires you fill in.

For Patients in England

We will retrieve information from your electronic medical records about your hospital care (Hospital Episode Statistics) and other uses of the NHS from NHS Digital (<https://digital.nhs.uk/>) who collects this information on behalf of the NHS.

To retrieve information from your electronic medical records, information to identify you, including your name, date of birth, NHS Number and the date you entered the SANAD II study, will be securely transferred from the SANAD II study team at the University of Liverpool to NHS Digital. Information about your hospital care will be securely transferred from NHS Digital to University of Liverpool and the Health Economics team at University of Bangor.

For Patients in Wales

We will retrieve information from your electronic medical records from **The Secure Anonymised Information Linkage (SAIL) Databank** (www.saildatabank.com) – an organisation based in Swansea University and funded by the Welsh government to make hospital electronic medical records accessible for research. SAIL holds information from electronic medical records provided by the **NHS Wales Informatics Service** (www.wales.nhs.uk/nwis), who record information about your hospital care on behalf of the NHS.

To allow the SANAD II study team at the University of Liverpool to obtain information from electronic medical records in identifiable form for this study, your name, date of birth, NHS Number and SANAD II Study Number will be securely transferred to **The NHS Wales Informatics Service** who then transfer your *SAIL Code Number* and the *SANAD II Study Number* to SAIL. This allows SAIL to securely transfer your electronic medical records to the SANAD II study team at the University of Liverpool and the Health Economics team at the University of Bangor, identified by SANAD II Study Number, without knowing the identity of individuals.

For All Patients

We will extract information only once. We will obtain information only for the time that you are in the study, and the 6 months prior.

Your electronic medical records will be stored on secure University of Liverpool computer servers, which meet NHS data security standards.

The SANAD II study team at the University of Liverpool will receive the electronic medical records and then link all the information collected about you for the SANAD II study. The SANAD II study team at the University of Liverpool will remove your identifying details before sharing the information with the members of the study team who will be conducting the analysis.

Data protection and security is of paramount importance and all information collected about you during this study will be used in accordance with the Data Protection Act 1998. Personally identifiable information collected for this study will be deleted at the end of the trial archiving period, which is for a maximum of 15 years from the official End of Trial. All of the organisations involved in this study have established systems in place for securely retrieving and transferring information from electronic medical records for research. If you wish to opt out of having your electronic medical records accessed for SANAD II, please complete and return the form on the next page and return it to the SANAD II study team in the enclosed pre-paid envelope. We will begin requesting data from NHS Digital within 4 weeks of the date of this letter if we haven't received a completed opt-out form from you. However, if you wish to opt-out at any point in the future you may do so by

contacting us – we will then immediately stop any further requests for your data, or any further processing of your data.

Contact Details

For additional information, please use the details on page 1 of this letter.

Yours sincerely,

A handwritten signature in black ink on a light blue background. The signature reads "Tony Marson" in a cursive style. The "T" is large and stylized, with a long horizontal stroke that extends to the right. The "M" is also large and stylized, with a long horizontal stroke that extends to the right. The "arson" is written in a smaller, more standard cursive script.

Tony Marson,
SANAD II Chief Investigator

