To be printed on hospital headed paper

PARENTS / GUARDIANS PATIENT INFORMATION SHEET

Title of Project:
A*STAR: The UK-Irish Atopic eczema Systemic TherApy Register

What is the purpose of the study?

The purpose of the research study is to collect information from adult and paediatric patients with eczema, starting certain treatments, such as ciclosporin, methotrexate, azathioprine, or novel treatments, such as biologics and so-called 'small molecules'. These medicines are referred to as 'systemic immuno-modulators' throughout this patient information leaflet. As eczema is often a long-term condition, it is important to establish how well these medicines work with regard to improvement in disease severity, quality of life and also safety, especially when these medicines are used for longer periods of time.

All medicines prescribed for eczema in UK and Ireland have already undergone careful testing in clinical trials before being approved for use. However, as clinical trials are run for a relatively short period of time (on average up to a year), have limited numbers of participants compared with those which will be ultimately treated with the medicine and may exclude patients with additional diseases (co-morbidities), the picture we get from clinical trials is not complete.

The UK-Irish A*STAR project will therefore fill this gap in knowledge and collect information (data) on patients treated with systemic immuno-modulators attending regular dermatology clinics. Patients who have other health problems but nevertheless start one of these medications will also be included, making the results more representative of the "real world" use of these medicines. Rates of medical side effects will be compared between medications, and the results will then be used to provide clinicians and patients with a better picture of any potential increased risk of these therapies.

Additionally, this study will look into the 'real life' cost of treating eczema, examining how much these therapies cost in the long term, compared to how well they work.

Participants will be asked to provide a blood sample to help us better understand how eczema develops and why some therapies work better in some people, or cause more side effects in others. However, this is optional and study participants do not have to provide a sample if they do not wish to.

We plan to run this study for at least 3 years, but we may continue beyond that if we obtain further funds. The study is funded by the British Skin Foundation (the UK's main charity that supports skin disease research) and conducted in collaboration with the British Association of Dermatologists (BAD).

Why has my child been invited and what their contribution means?

Your child* has been invited to participate as he/she is about to start a systemic immunomodulatory therapy for eczema. By participating, he/she will help us build up the amount of data available for analysis.

** Refers to the child for whom you have parental responsibility*

Does he/she have to take part?

Your child does not have to take part; participation is entirely voluntary and her/his clinical care will not be affected regardless of the decision. If you both decide to take part, you can keep this sheet and you will be asked to sign a consent form, and your child will be asked to sign an assent form (age-dependant). By signing these forms, you both will be confirming your willingness to take part.

What are the risks of taking part?

The study will run alongside the routine clinical care at the hospital; it will not influence this process at all. Therefore, there are no foreseeable additional medical risks associated with participating in this study.

We will ask participants to donate one blood sample, which will be collected alongside other safety blood samples taken during routine clinical procedures. During the collection of the blood samples participants may experience discomfort and there is a risk of bleeding and bruising around the puncture site but this is very rarely serious.

What are the benefits of taking part?

Although there are no additional clinical benefits from participation in the study, the information obtained from this study will help the study team to better understand eczema and to ultimately develop more targeted and effective treatments for future patients.

Will the research influence the treatment the participant receives?

The research does not alter the treatment that your child will receive. The specialist will start and stop treatments as determined by the clinical condition.

What will happen if I take part?

The participation will involve the following:

(i) Completion of questionnaires and other survey forms about their health. You will most likely be expected to assist your child on the completion of these questionnaires. Some of the questions may be of a sensitive or personal nature; they are not required to answer all of the questions. It should take about 10-15 min to complete these.

Research shows that people with eczema were more likely to have asthma attacks and persistent asthma than people without eczema. If your child is older than 12 years old and has been diagnosed with asthma by a doctor, we would like you to complete an additional questionnaire.

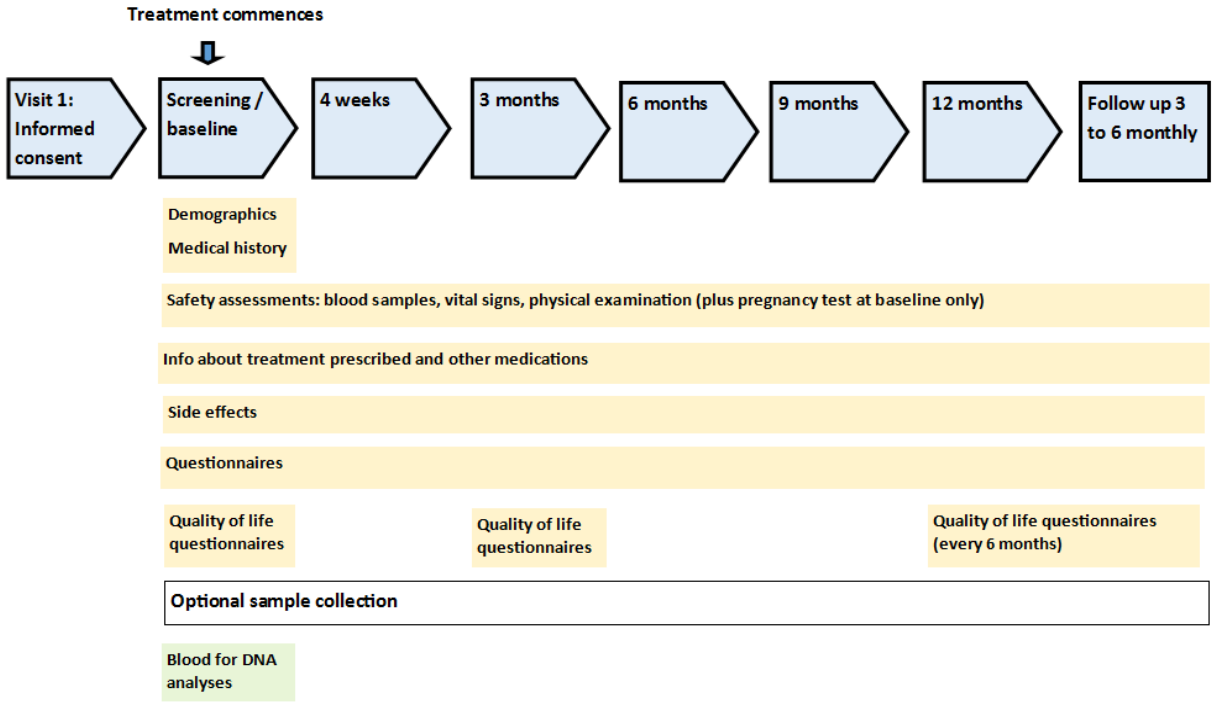
(ii) Agreement of the specialist to provide information of relevance to this study from the hospital medical records to the UK-Irish A*STAR study team at the St John's Institute of Dermatology, Guy's and St Thomas' NHS Foundation Trust and King's College London. This will be information regarding the medical history, the treatments your child is receiving, assessments of the skin, details of any illnesses they may have and body measurements including height and weight.

(iii) Attendance of study specific visits for as long as you both wish, but for at least 12 months in six different appointments. Study visits will happen at the same frequency as would be required for standard care. On these occasions, the doctors will collect some clinical information about the progress, the side effects your child may be experiencing and other medications he/she may be taking. Data from the usual assessments they normally have in clinic, such as blood samples or physical examination will also be collected for the study.

(iv) At initial visit a one off optional blood sample to look at the genes (DNA) will be collected. We will collect this via a blood sample alongside other standard safety blood samples. The volume of blood collected will depend on the age and weight of your child.

We would like to collect this data about your child for at least 12 months, but much longer if possible and if you agree for us to do this. Your child will be able to withdraw from the study at any time without any impact on medical care.

Below is a chart that shows each of the study visits and what samples we would ask him/her to donate at each visit:



In the event that new discoveries are made, or new aspects of the medicines under investigation need to be explored, the researchers are requesting permission to contact you and your child again. If we do so, we would then seek your consent again to collect further information, clinical assessments or samples (e.g. blood) depending on the research question. This is an optional request and if you don't wish to give consent to be contacted, it will not impact the participation in this study.

What will happen to the research blood sample?

We will analyse your child's DNA to understand why some people are more likely to suffer from eczema and why some respond better or worse to a specific treatment; we will **not** use the DNA to look at the risk of developing any other diseases.

The samples will be labelled by the local hospital staff, who will protect the personal details, then sent to the designated laboratory by special post analysed and stored securely in accordance with the Human Tissue Act and according to national Research Governance guidelines. Only staff members involved in this project will have access to these samples; none of the researchers testing these samples will have access to the personal details other than the initials. We plan to store the biological samples for the duration of this study; afterwards we plan to store anonymously any remaining samples for future research into skin disease. In the consent form you will be asked if you are happy to give permission for the storage and analyses of your child's samples in future studies, not covered by the present research proposal; such studies will have had to be approved by a Research Ethics Committee. If you do not consent to this point, the samples will be discarded at the end of this study.

What will happen to my data?

All the data will be stored in accordance with the Data Protection Act 1998 and the International Conference on Harmonization for Good Clinical Practice. Once you provide consent, your child's data will be held on a secure confidential database for the purpose of this study, to which only the Chief Investigator and approved delegated members of the study team will have access (at King's college London and Guy's and St Thomas' NHS Foundation Trust). This information will be entered into the database by the dermatology team following the hospital appointments. Your child's details on this database will be anonymized. Information will be sent using a secure network, and the data will be stored on a secure server.

Some of your child's personal identifiable data will be collected (name, date of birth, national healthcare number) for the sole purpose to be shared with national providers of healthcare data. This will be used to obtain information such as any hospital admissions your child has had, details if they are registered as having cancer, or in the event of death. This will enable these organizations to provide information about these events which may not have been reported via their dermatology team, and will give us a more complete picture of the child's health experiences. There are different data providers in each area of the country, and a summary will be provided on the appendix of this information sheet, however this list may change over time. A complete and up to date list of the national data providers linked with A*STAR will be maintained on the study website.

There are many collaborators on this research. By signing the consent form you are agreeing that your child's anonymized study data can be shared with research collaborators and industry partners, who may be located outside of the country or region in which you live. The study data will always be kept confidential, secure and anonymized and used only for the purposes of research for this study. Research data will be stored for 5 years following study end and subsequently securely destroyed.

How will the data be kept secure and confidential?

The UK-Irish A*STAR project at The St John's Institute of Dermatology, Guy's and St Thomas' Hospital NHS Foundation Trust and King's College London will ensure that the data is processed fairly and lawfully in accordance with the Data Protection Act 1998. We have a number of rigorous procedures in place to protect personal data and keep it secure as follows:

- Computer security is in place to block unauthorised access to the computers/systems that hold personal information. Personal identifiable data will be held in an encrypted format at the local investigator's office, and later transferred to Guy's and St Thomas' Hospital/King's College London. Encryption allows information to be stored in a secure manner making it accessible to the research team (named by the study's Principal Investigator or Chief Investigator) only with the use of a username and password. Identifiable data will not be shared with any other parties other than for the purpose of linkage with healthcare providers.

- If the data is provided as part of a larger dataset to researchers outside of the UK-Irish A*STAR team, information that could identify your child will not be provided.

Should you want to complain about the way we are handling the data, you can contact the Information Commissioner's Office (ICO) in the UK, or the Data Protection Commissioner in Ireland, via their websites.

Involvement of Third Parties

We plan to conduct this study in collaboration with other centers (clinicians and researchers of other Dermatology Departments). It is also possible that pharmaceutical companies might invest in the study in the future. Study results may be shared with these collaborators, but your child will not be identified. You may obtain further information about all study collaborators via our website. There is a possibility that anonymised medical information may be sent outside of the UK or Ireland for analyses. By signing this consent you are agreeing to this transfer.

The hospital medical records will state that your child's data is in this Register. By signing the consent form, you are allowing the dermatology team to permit these records to be viewed by the A*STAR team at The St John's Institute of Dermatology, Guy's and St Thomas' NHS Foundation Trust London/King's College London, or possibly agencies such as authorised members of the Research Ethics Committee or the Hospital Trust. This is for the purpose of checking that the data is correct or checking that the study is being carried out properly.

What if there is any problem? [Sites to include specific details]

If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions [Principal Investigator name: _____, telephone number: _____, email address:_____]. If you remain unhappy and you wish to complain formally, you can do this through your hospital's Patient Advisory Liaison Service (PALS) at NHS hospitals (in the UK), or the Complaints Officer at HSE hospitals (in the Republic of Ireland). The PALS /CO offices are based in _____, with phone number: _____, and email address:_____.

In the event that something does go wrong and your child is harmed during the research you may have grounds for legal action for compensation against your treating Hospital, Guy's and St Thomas' NHS Foundation Trust London, and/or King's College London, but you may have to pay your legal costs. The normal National Health Service or Health Service Executive complaints mechanisms will still be available (if appropriate).

How do we withdraw from the study if we want to?

Participants and parents/guardians are asked to discuss any concerns they might have with their dermatology team.

You can withdraw from the study at any time after giving your signed consent by contacting your child's local dermatology research team. You will be given a withdrawal form where you can state both your will. Unless you tell us otherwise in the form, we will keep all the samples and clinical information that we have obtained up until the point of withdrawal, and we will not collect any further information or samples. If you decide to withdraw from the study, your child's standard of care will not be compromised in any way.

Who has reviewed the study?

Before any research study can go ahead, it has to be checked by a Research Ethics Committee and the Health Research Authority (HRA) to make sure that the research is fair and transparent. The Wales Research Ethics Committee has reviewed and approved this study. The Research & Development team at the hospital where the study is taking place must also approve the study.

Who is organising the study?

The study is being co-ordinated and sponsored by The St John's Institute of Dermatology at Guy's & St Thomas' NHS Foundation Trust and King's College London. The researchers at Guy's and St Thomas' NHS Foundation Trust are Dr Carsten Flohr and Prof. Catherine Smith, Consultant Dermatologists. If you have any concerns about any aspect of this study, you should speak to your researcher who will do their best to answer your questions. If they are unable to resolve your concern or you wish to make a complaint regarding the study, please contact the *Research Practice Governance Co-ordinator / Chief Investigator / Complaints Officer* and follow the complaints procedure.

Where can you see further study information and results?

You can find further information about this study online: http://astar-register.org. Regular updates and results of the research will be uploaded on this portal.

Any study results or published reports using the data will be anonymised prior to publication, so that it is not be possible to identify participants.

Study results will also be published in medical journals, as well as disseminated through the information channels of the British Association of Dermatologists and eczema patient organisations. These will also be available to your consultant whom you can contact for further information.

Local contact name and phone number	

Appendix 1 – Summary of Linkage Organisations

A summary of the national providers of healthcare data A*STAR links to is outlined below. The amount of personal data given to each of these providers will be the minimum possible, and this will vary depending on the region and the organisation requirements. The data returned to the study from every provider will be pseudo-anonymised using the study ID.

This information is accurate at the time this consent form was approved for use. An up-to-date summary is available at the study website.

England

Linkage Type	Data Provider
Cancer Registration Data (Malignancy)	NHS Digital on behalf of Public Health England (PHE)
Civil Registration Data (Mortality)	Sourced from civil registration data and provided by NHS Digital on behalf of the Office for National Statistics
Inpatient Admission	NHS Digital (Hospital Episode Statistics)

Scotland

Linkage Type	Data Provider
Malignancy	National Health Service Central Register (NHSCR)
Mortality	National Health Service Central Register (NHSCR)
Inpatient Admission	National Services Scotland (NSS)

Wales

Linkage Type	Data Provider
Cancer Registration Data	NHS Digital on behalf of Public Health Wales
Civil Registration Data	Sourced from civil registration data and provided by NHS Digital on behalf of the Office for National Statistics
Inpatient Admission	NHS Wales Informatics Service (Patient Episode Database for Wales)

Northern Ireland

Linkage Type	Data Provider
Malignancy	Northern Ireland Cancer Registry (NICR)
Mortality	Health and Social Care Business Services Organisation (BSO)

Republic of Ireland

Linkage Type	Data Provider
Malignancy	National Cancer Registry Ireland (NCRI)
Mortality	National Cancer Registry Ireland (NCRI)
Inpatient Admission	Hospital In Patient Enquiry (HIPE)

PARENTS/GUARDIAN'S CONSENT FORM

Title of Project:
A*STAR: The UK-Irish Atopic eczema Systemic TherApy Register

Please initial box

1.	I confirm that I have read and understood the information sheet dated _____ (version ___) for the above study and have had the opportunity to ask questions.	☐
2.	I understand that my child's participation is voluntary and that we are free to withdraw at any time without giving a reason, and without their medical care or legal rights being affected.	☐
3.	I understand and agree that my child's identifiable details (name, date of birth and national healthcare number) may be shared with national providers of healthcare data for the purpose of linking to information held about any hospital admissions they have had, details if they are registered as having cancer or, in the event of their death.	☐
4.	I agree for my child to complete questionnaires and other survey forms about their health relevant to this Study.	☐
5.	I agree that my child's specialist Dr_____may provide the researchers with information from my child's Health Records that is relevant to this Study.	☐
6.	I agree to my child's information, from which they can be identified, being held by the research Team at The St John's Institute of Dermatology, Guy's and St Thomas' Hospital NHS Foundation Trust together with data collected during the study.	☐
7.	I understand that relevant sections of my child's medical notes and data collected during the study may be looked at by individuals from Guy's and St Thomas' Hospital NHS Foundation Trust, their representatives/agents, the regulatory authorities and individuals from the Hospital. I give permission for these individuals to have access to my child's records which will include identifiable information.	☐
8.	I understand that some data, which will not contain information that could identify my child, may be transferred out of the UK/Republic or Ireland	☐
9.	I agree for my child to take part in this study	☐

Please initial 'Yes' or 'No' to the following optional sections:

		Yes	No
10.	I agree for my child to provide samples for genetic (DNA) analyses.	☐	☐
11.	I agree for any remaining DNA samples at the end of this study to be stored in Research Tissue Banks and used in future studies in skin disease following the necessary Ethical approvals.	☐	☐
12.	I agree to be contacted in the future for the purpose of requesting consent from myself and assent/consent from my child for further clinical investigation and biological samples from him/her.	☐	☐

_____

Name of patient

_____	_____	_____
Name of person with parental responsibility for the patient	*Date*	*Signature*
_____	_____	_____
Name of Person taking consent	*Date*	*Signature*
_____	_____	_____
Name of witness (if applicable)	*Date*	*Signature*

1 copy for patient; 1 copy for researcher; 1 copy to be kept with hospital notes