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| **Study Title** | A-STAR: The UK-Irish **A**topic eczema **S**ystemic **T**her**A**py **R**egister |
| **(Co-)Sponsor(s):** | King’s College London and Guy’s and St Thomas’ NHS Foundation Trust |
| **IRAS Number:** | 237309 |
| **Site Name / Code:** |  |
| **Principal Investigator:** |  |

**Source Document Location List**

| **Data Item**  (Please add any study-specific items as needed) | **Source Document and Location** | **Items Marked 🗸**  **MUST be Documented in Patient Notes** |
| --- | --- | --- |
| Evidence of study participation (i.e. dated statement referring to above protocol confirming consent taken to participate in study, documentation of consent process and enrolment). |  |  |
| Eligibility criteria (i.e. evidence subject meets all criteria). |  |  |
| Study visit dates. |  |  |
| Subject screening /enrolment number. |  |  |
| Demographic data. |  |  |
| Past medical history. |  |  |
| Concomitant medication. |  |  |
| Vital signs / physical examination. |  |  |
| Adverse Events and Serious Adverse Events. |  |  |
| Systemic therapy initiation date. |  |  |

| **Data Item**  (Please add any study-specific items as needed) | **Source Document and Location** | **Items Marked 🗸**  **MUST be Documented in Patient Notes** |
| --- | --- | --- |
| Laboratory reports. |  |  |
| Patient Information Sheet and Informed Consent Forms. |  |  |
| Participant questionnaires. |  |  |
| Sample logs. |  |  |
| Withdrawal dates and reason. |  |  |
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| **I, Principal Investigator, confirm that the above data items will be recorded as indicated.** | |
| **Signed** |  |
| **Dated** |  |