## BADBIR Data access applications

## Frequently asked questions:

**Who can apply to use the BADBIR data?**

We welcome applications from all members of the British Association of Dermatologists.

The application form asks if you are a member of BAD because this helps with internal audits of membership activity.

**How do I apply to use the BADBIR data?**

There is a two-stage process for applying to use the BADBIR data.

1. In the first instance, we encourage you to submit an informal enquiry describing your data request to Zin Mon Research Manager (research@bad.org.uk). Please include the following information:

- About you as the applicant (clinical/academic)
- A very brief outline of your research question
- Whether you have funding/applying for funding/have plans to apply for funding
- Whether you plan to do the analysis yourself or would need analytical support from the BADBIR team.

2. The BADBIR team will assess your enquiry and inform you whether to move to the next step, which involves submitting the data access application form for discussion at the next steering committee meeting.

If the Committee has approved your application, it will then be taken forward. The next steps will involve approval from the relevant pharma companies, signing of data sharing agreements and release of data.

The Steering Committee meets three times a year, usually in February, June and October. We request that you submit your data access application form at least **4 weeks** ahead of the Committee meeting.

**How can I prepare my research question?**

We encourage our members who are interested in accessing the BADBIR dataset to review the following resources which will help you develop your research question. **The BADBIR active research questions** (these are questions that the Committee has already approved and assigned to a group for analyses/publication and will avoid duplication), the **Protocol**, the **data dictionary**, **the data access application form**, **BADBIR publications policy** and the list of **BADBIR publications**.

**Listed here are a few bullet points to help frame your research question and answer questions about the analysis plan in the application form (Q 4.5)**:

**Think of the type of research project:**

- Descriptive ☐
  *i.e., describe the occurrence or trend of disease without causal inference, e.g., do people on ustekinumab have a higher BMI than other people in BADBIR?*
- Causal ☐
  *i.e., show that x leads to y, e.g., does being on infliximab lead to a higher risk of getting serious infections in people with severe psoriasis?*
- Prediction ☐
  *i.e., predict a current (diagnostic) or future (prognostic) outcome, e.g., can clinical variables discriminate those who go on to develop psoriatic arthritis despite being on systemic therapy?*
- Other ☐

*e.g., health economics*

**Indicate the research analysis project design:**

- Cohort study ☐
- Case-Control study ☐
- Cross-sectional study ☐
- Case series ☐
- Other ☐

**Please indicate the following: intervention(s), comparator group, and outcome:**
**Intervention:** *e.g., registrants starting ixekizumab (Taltz)*
**Comparator:** *e.g., registrants starting guselkumab (Tremfya)*
**Outcome:** Please check the data dictionary to ensure that your outcome of interest is reliably captured within the BADBIR dataset

Please consider how potential confounding and missing data will be handled.

**List any other eligibility criteria for the research project**

**What format will the data be provided in?**

The BADBIR team at the University of Manchester will prepare all data extracts. Conventionally these are prepared as one file per table (see Data Dictionary). A basic tab-separated variable format is used to facilitate upload into the preferred statistical analysis software of the applicant.

**How will we assess your application?**

The BADBIR data access process is designed to ensure that BADBIR data is used to address research questions that fall within the ethically approved over-arching aims of BADBIR, using robust analytical approaches with requisite funding.

Each application will therefore be assessed by the Steering Committee against the ethically approved aims of BADBIR, the strength of the proposed analytical approaches and the funding available.

**How long will it take before I receive the data?**

We advise that you allow around six months from your application until the data is received. This allows time for the stages of approval and signing of agreements that will be needed. As part of this, the BADBIR team at the University of Manchester commit to supply a data extract within six weeks of agreements being signed.

**Do I have to be an experienced researcher?**

You do not have to be an experienced researcher to use the BADBIR data but knowing your research experience will help the BADBIR steering committee assess the application and the amount of support that may be required to progress the submission.

**What does it cost to use the BADBIR data?**

Anyone who is a member of British Association of Dermatologists (BAD) an request to access the BADBIR dataset for analysis free-of-charge. For other requests, there will be a charge on a case-by-case basis. This is mainly to cover the time our operational team require to prepare the data set to provide the data to you.

**Why does the application form want details about working with a commercial organisation?**

If you have received funding or sponsorship for this study from a commercial organisation then this will need to be declared. This is important because BADBIR has existing contractual obligations with the pharmaceutical companies who provide funding to cover the operational costs of collecting data sets. In return, BADBIR provides pharmacovigilance reports to the pharmaceutical companies. Currently, we are unable to give data access requests to any commercial organisation who is not part of BADBIR or employed by a pharmaceutical company.

**Do I need to discuss my research study within my local trust/institution?**

We advise that you discuss your study locally before making an application, otherwise this may add extra time getting permission or contracts signed especially as your Trust or University will need to receive the anonymised data sets. Moreover, once the study has been approved by the Committee, your local Research and Development (R&D) department will need to sign the data sharing agreement.

**Does it matter if I have used BADBIR data before?**

There is no limit to the number of times you can apply to use the BADBIR data, but we do ask you for details of the previous studies so that all data use is carefully recorded and cross referenced.

**Is it necessary to include patients and/or user groups in the planning of my research project?**

This is something that we encourage and the importance of having public/patient involvement in the planning of research is recognised by the Health Research Authority

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| (HRA) and the National Institute for Health and Care Research. The inclusion of the public in research planning adds a vital perspective for the relevance of research questions asked and dissemination of findings. For further information: https://www.hra.nhs.uk/planning-and-improving-research/best-practice/public-involvement/ |
| **Is your project a multinational cohort study requiring data aggregation?**<br><br>We ask this because it is important to know about the flow of data that may be required for the overall study, for example a study that receives data from multiple psoriasis registers for a pooled analysis or if the data flows from one institution to another. The BAD and University of Manchester are joint data custodians so it is important to indicate if you plan to send aggregated data outside your own institution. |