

#### THE UNIVERSITY OF MANCHESTER

#### PARTICULARS OF APPOINTMENT

## **FACULTY OF BIOLOGY, MEDICINE & HEALTH**

## **SCHOOL OF BIOLOGICAL SCIENCES**

#### DIVISION OF MUSCULOSKELETAL AND DERMATOLOGICAL SCIENCES

## **RESEARCH ASSOCIATE**

**VACANCY REF: BMH-015555** 

Salary: Grade 6, £32,816 to £40,322 per annum

Hours: 2 full time posts

Duration: Fixed term, each post 12 months

Location: Oxford Road, Manchester

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# Enquiries about the vacancy, shortlisting and interviews:

Post 1:

Name: Professor Kimme Hyrich, Director Email: <a href="mailto:kimme.hyrich@manchester.ac.uk">kimme.hyrich@manchester.ac.uk</a>

Post 2:

Name: Professor Chris Giffiths OBE

Email: <u>Christopher.griffiths@manchester.ac.uk</u>

## **Background**

## **Biologic Studies Group - Director: Professor Kimme Hyrich**

The <u>Biologic Studies Group</u> (BSG) is part of the Division of Musculoskeletal and Dermatological Sciences at The University of Manchester. The Group collects and studies long-term post-marketing safety data for biologic, biosimilar and other new targeted therapies in the treatment of musculoskeletal and dermatological conditions both in adults and children. BSG has over 20 years' experience of hosting some of the largest real-world biologic observational studies in the world.

The Group draws on state-of-the-art epidemiology and statistical methods expertise and has strong international links and collaborations with similar studies across Europe and further afield. The Biologic Studies Group are experts in the field of pharmacovigilance monitoring and comply with global regulatory requirements for drug safety monitoring. The current programme of work includes:

 British Society for Rheumatology Biologics Register for Rheumatoid Arthritis (BSRBR-RA)



- British Association of Dermatologists Biologics and Immunomodulators Register (BADBIR)
- Biologics in Children with Rheumatic Diseases (BCRD)
- British Society for Paediatric & Adolescent Rheumatology Etanercept Cohort Study (BSPAR-ETN)
- British Isles Lupus Assessment Group Biologics Register (BILAG BR)

The group has published over 80 original scientific articles in high impact journals addressing areas of treatment effectiveness and safety. It remains unknown whether longer term exposure to conventional and/or biologic agents increases the risk of co-morbidities. Conversely, it could be hypothesised that these therapies may reduce disease activity and hence the risk of comorbidities. The BSG data will offer the challenge of using advanced statistical methods to analyse repeated measures, allow for confounding by indication and adjusting for missing data. The group is also looking to expand its data capture through linkage of the datasets to other validated healthcare data resources, such as those held by NHS Digital including Hospital Episode Statistics (HES) data.

## The Faculty of Biology, Medicine and Health (FBMH)

The Faculty of Biology, Medicine and Health was created on 1 August 2016 when the Faculty of Life Sciences and the Faculty of Medical and Human Sciences were brought together in a new, integrated structure to deliver a truly translational approach to the life sciences, ensuring smooth research pathways - from pure discovery science through to clinical application and patient care.

With a total annual income of over £300 million, and over 3,000 members of staff, the new Faculty is comparable in size to a medium-sized UK university. Thirty undergraduate and 90 postgraduate programmes will offer our 11,000 students opportunities to develop the skills and knowledge they need for a successful career.

The Faculty's matrix structure will facilitate interdisciplinary working and enable us to learn from each other and share best practice; and our eight, strategic Research Domains will help to articulate our research strengths, drive large-scale, collaborative research activities and strengthen relationships with our research and healthcare partners.

The integration of discovery biology, clinical application and patient care within a single Faculty, particularly in a region with notable health inequality, provides us with a real opportunity to have a very significant and positive impact on people's lives.



## **Our Strategic Partnerships**

The new Faculty has a number of key strategic partnerships that underpin its ambitions to develop ground-breaking research.

Working alongside six local NHS Trusts, the Faculty isa key member of the <u>Manchester</u> <u>Academic Health Science Centre (MAHSC)</u> - a federation of equal partners that unites leading healthcare providers with world-class academics and researchers. It aims to be a global centre for the delivery of applied health research and education and provide leadership for our local and regional health systems.

It also plays a leading role in <u>Health Innovation Manchester (HInM)</u>, which was launched in September 2015, as part of the UK Government's decision to devolve health and social care responsibilities to Greater Manchester. HInM offers a unique opportunity to bring together health and social care, academic and life science related business resources across the region to deliver an innovative health ecosystem that can help accelerate innovation into our local health and social care systems, enhance our global scientific standing and act as a magnet for inward investment.

Key partnerships in the charitable sector include Cancer Research UK; Diabetes UK; and the Wellcome Trust; and the Faculty will also have research and funding links to a number of commercial organisations including Unilever, AstraZeneca, GlaxoSmithKline and Boots, who will help us to bring new drugs and products to the market.

#### **Working for the University of Manchester**

The University of Manchester strives to make our community a welcoming, caring and enthusiastic one, fuelling ambition with opportunities and support to help us all achieve our personal and professional goals.

Our diverse job opportunities include an attractive <u>benefits package</u> with family-friendly policies that provide for flexible working. We care deeply about career and personal development, offering a structured induction programme for new staff, an annual performance and development review, staff training for all career stages and mentoring opportunities to support your career development.

We have a genuine commitment to <u>equality of opportunity</u> for our staff and students, and are proud to employ a workforce that reflects the diverse community we serve.



As a global institution, situated at the heart of a lively, <u>culturally diverse city</u>, we welcome applicants of all nationalities. To help international job applicants plan for life in the UK, we have put together some useful <u>information on passports and visas</u>, travel to the UK, accommodation and a number of other practical considerations.

#### Post 1: BSRBR-RA Research Associate

The BSRBR-RA was set up in 2001 as a collaboration between academia (The University of Manchester), a charity (the British Society for Rheumatology) and a number of pharmaceutical companies to monitor the long-term safety of the then new biologic drugs that were available in the NHS for treatment of rheumatoid arthritis. Since then, different targeted drugs have been developed and approved for use in the UK and these have been added to the study. Today we now monitor over 17 drugs from 10 pharmaceutical companies, who use the BSRBR-RA as part of their regulatory commitments to the European Medicines Agency and the US Food and Drug Administration and there are over 25,000 participants in the study. Data is also linked with national healthcare databases in the UK.

#### Role of The BSRBR-RA Research Associate

You will have good organisational skills and be able to work both independently and as part of a team. You will be able to demonstrate a flexible approach to work and be able to meet strict deadlines using initiative and judgement to prioritise competing demands. In addition, to a rolling programme of research, the post will also be key in generating reports for the scientific steering committee as well as the pharmaceutical companies who financially contribute to the resources. You will have excellent oral and written communication skills and experience giving presentations to small and medium size audiences. You will also have some experience in the supervision of others, including in teaching and training.

Initially, you will develop a key understanding of the structure of the BSRBR-RA data and the Manchester Template used to generate reports for the funders. You will already have training in epidemiology and/or medical statistics and will be able to make a major contribution to this important area whilst extending your own experience, research skills and building your CV. It will also provide an opportunity to extend epidemiological methodology through the combined use of traditional and newer health informatics.

You will apply appropriate statistical techniques to analyse the data in line with the publication plan including developing an understanding of the limitations of the dataset and appropriate statistical / epidemiological techniques to address these. You will be responsible for consulting



with the funders regarding bespoke analyses of their datasets and provide guidance on plans or proposals submitted for review. You will also be expected to conduct data analysis on behalf of the BSR Registers Committee and data monitoring committee (DMC) as well as the Chief Investigator. The primary analysis will be done using STATA. It is expected that you will develop the skills to prepare the dataset(s) for analysis including data cleaning, outcome verification, undertake descriptive statistics and regression modelling, disseminate research findings at seminars and conferences, and prepare papers for publication in peer reviewed journals. It is also expected that you will provide support for students and researchers accessing the BSRBR-RA dataset.

## **Key Responsibilities**

## **Teaching and Learning Support**

- Supervise and assist study staff / students / external researchers working on the data.
- Ensure that all researchers with approval to access BSRBR-RA data fulfil the governance requirements prior to receiving a dataset.

## **Research and Scholarship**

- Understanding of the techniques developed to produce the Manchester Template (a series
  of complex STATA files used to produce crude incidence rates of events) from the BSRBRRA data to provide reports for stakeholders according to contractual requirements.
- Develop testable hypotheses from the data.
- Undertake detailed statistical analyses to address these hypotheses / research questions.
- Investigate the validity of the outcome data used.
- Address regulatory (industry / European Medicines Agency / DMC) requests for potential safety concerns.

#### Communication

- Develop a key understanding of the structure of the BSRBR-RA data and be able to translate this in lay terms to BSRBR-RA members / committees / key stakeholders.
- Prepare and deliver reports for presentation at both national and international meetings, and for publication.

## **Liaison and Networking**

- Liaise with the BSRBR-RA management team.
- Consult with funders regarding analysis of their data.



#### **Teamwork**

- To join a growing team of analysts/epidemiologists and statisticians working within the Biologic Studies Group, including regular attendance at analysis meetings across the studies to keep up to date with issues affecting all biologic registers within the Faculty.
- Assist the database manager in extracting relevant data for a research question from the database into a statistical package which can be used for data analysis by other researchers.

## Initiative, Problem-solving and Decision-making

- Identify potentially unmet needs in the data.
- Develop a full understanding of the complex needs of all BSRBR-RA stakeholders including post-marketing surveillance methodology, publication and third party data access policy.

## **Planning and Managing Resources**

- Co-ordinate the regular BSRBR-RA analysis meetings.
- Actively participate in and facilitate in-house meetings.
- Organise local meetings and produce relevant documentation.
- Demonstrate effective time management and ability to work to strict deadlines.
- Demonstrate the ability to work independently and seek out support from relevant individuals to help inform project work

#### **Expertise**

- Review the current literature and undertake systematic reviews and/or meta-analyses where appropriate for publication and presentation.
- Experience of working with confidential data.
- Ensure an understanding of the limitations of the dataset and learn statistical / epidemiological methods to address these limitations, e.g. how to account for bias as a result of missing data.
- Provide analytical advice to researchers who have BSRBR-RA projects approved by the Steering Committee to ensure outputs using BSRBR-RA data are of the highest quality.
- Responsibility for reviewing abstracts / manuscripts arising from BSRBR-RA data (researchers and funders) and advise oversight committees as appropriate.
- Assist in defining future analyses.

#### **Training**

Although a certain level of analytical experience is expected, you will receive training for all aspects of the work in the form of short courses as well as in-house programmes to fill gaps in



knowledge. Training will include the use of statistical software, writing and presentation skills. You will also be expected to contribute at multi-disciplinary meetings. There is a monthly educational session and a weekly seminar series.

## Social Responsibility (All Staff)

You will be expected to display commitment to the University's third strategic goal of social responsibility, where the aim is to make a positive contribution to society through our full range of teaching, research, engagement and operational activities:

- Promote social responsibility
- Contribute to the delivery of the social responsibility agenda and Centre strategic aims

## **Person Specification**

## Essential Skills, Knowledge and Experience Assessed by

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PhD in epidemiology, medical statistics or related discipline (or with relevant experience)	CV
Excellent IT skills (Microsoft Office)	CV; application form
Proven track record in data analysis and in particular working with longitudinal data	CV; application form
Previous experience of using STATA, M-Plus, R or SAS software, or other appropriate statistical software packages	CV; application form
Demonstrate an understanding of epidemiological methods	CV; application form
Experience of working with confidential data	Application form
The ability to use initiative and judgment to predict problems, plan appropriate changes and provide recommendations to improve current procedures with the help of the study team	Application form; interview
Experience of systematic literature searching, scientific writing, preparing research presentations and reports	CV; application form
Fluent in English (oral and written)	Application form; interview
Demonstrate effective time management and ability to work to strict deadlines	Application form; interview
Be able to demonstrate good interpersonal and good organizational skills	Application form; interview



Be able to demonstrate excellent communication skills (verbal and written) including presentations to audiences of academics, health professionals and lay people at national or international meetings	Application form; interview
Good critical and innovative thinking skills	Interview
Demonstrate a flexible and responsive attitude to a dynamic and fast moving workplace	Application form; interview
The ability to work independently in a flexible manner with attention to detail and to high standards of accuracy with a methodical and conscientious approach to work	Application form; interview
Ability to plan and organize your own workload and work to strict deadlines but also able to liaise and co-ordinate activities with other members of the team within a multidisciplinary environment	Application form; interview
Willingness to travel in both the UK and abroad, to meet project requirements	Application form
Demonstrate an enthusiasm for research	Application form; interview

## Desirable Skills, Knowledge and Experience

## Assessed by

Understanding of Good Clinical Practice and research ethics requirements / processes	CV; application form
Experience of undertaking applied health-related or medical research	CV; application form
An interest in rheumatological research	Application form; interview
Experience of working as part of a research team on a study.	Application form, interview

## Post 2: BADBIR Research Associate

## **Background**

# The British Association of Dermatologists Biologics and Immunomodulators Register (BADBIR) Chief investigator: Professor Christopher Griffiths

The BADBIR is large, world-leading, long-term pharmacovigilance register of psoriasis patients receiving biologic, small molecule or conventional systemic therapies. It is recruiting from 165 dermatology centres in the UK and Republic of Ireland and has been hosted at the University of



Manchester for 12 years (from 2007). Currently over 17,000 patients are being followed in BADBIR. Any pharmaceutical company with new therapies which are licensed in the UK for the treatment of moderate-severe psoriasis are encouraged, by the regulators, to participate in the register for the purposes of long-term monitoring in routine clinical care. The BADBIR data are the property of the British Association of Dermatologists and the registry is indirectly funded by pharmaceutical companies (currently AbbVie, Amgen, Almirall, Celgene, Eli Lilly, Hexal AG, Janssen, Novartis, Samsung Bioepis and UCB). Funding is in place to sustain the study until at least 2023 and negotiations continue with Marketing Authorisation Holders for new drugs in this disease area. The BADBIR is a web-based system with ongoing recruitment and follow-up. To date, 18 original scientific articles have been published using BADBIR data.

#### **Role of The BADBIR Research Associate**

You will have good organisational skills and be able to work both independently and as part of a team. You will be able to demonstrate a flexible approach to work and be able to meet strict deadlines using initiative and judgement to prioritise competing demands. In addition, to a rolling programme of research, the post will also be key in generating reports for the scientific steering committee as well as the pharmaceutical companies who financially contribute to the resources. You will have excellent oral and written communication skills.

Initially, you will develop a key understanding of the structure of the BADBIR data and the Manchester Template used to generate reports for the funders. You will have training in epidemiology and/or medical statistics and will be able to make a major contribution to this important area whilst extending your own experience, research skills and building your CV. It will also provide an opportunity to extend epidemiological methodology through the combined use of traditional and newer health informatics.

You will apply appropriate statistical techniques to analyse the data in line with the publication plan including developing an understanding of the limitations of the dataset and appropriate statistical / epidemiological techniques to address these. You will be responsible for consulting with the funders regarding bespoke analyses of their datasets and provide guidance on plans or proposals submitted for review. You will also be expected to conduct data analysis on behalf of the BADBIR steering committee and data monitoring committee (DMC). The primary analysis will be done using STATA. It is expected that you will develop the skills to prepare the dataset(s) for analysis including data cleaning, outcome verification, undertake descriptive statistics and regression modelling, disseminate research findings at seminars and conferences, and prepare papers for publication in peer reviewed journals. It is also expected that you will provide support



for students and researchers accessing the BADBIR dataset, such as those working for the Psoriasis Stratification to Optimise Relevant Therapy consortium (PSORT; <a href="http://www.psort.org.uk/">http://www.psort.org.uk/</a>).

## **Key Responsibilities**

## **Teaching and Learning Support**

- supervise and assist study staff / students / external researchers (e.g. PSORT) working on the data;
- ensure that all researchers with approval to access BADBIR data fulfil the governance requirements prior to receiving a dataset;

## **Research and Scholarship**

- understanding of the techniques developed to produce the Manchester Template (a series of complex STATA files used to produce crude incidence rates of events) from the BADBIR data to provide reports for stakeholders;
- develop testable hypotheses from the data;
- undertake detailed statistical analyses to address these hypotheses / research questions;
- investigate the validity of the outcome data used;
- address regulatory (industry / European Medicines Agency / DMC) requests for potential safety concerns;

## Communication

- develop a key understanding of the structure of the BADBIR data and be able to translate this in lay terms to BADBIR members / committees / key stakeholders;
- prepare reports for presentation at both national and international meetings, and for publication;

## **Liaison and Networking**

- liaise with the BADBIR management team;
- consult with funders regarding analysis of their data;

## **Teamwork**

 to join a growing team of analysts/epidemiologists and statisticians working within the Biologic Studies Group, including regular attendance at analysis meetings across the studies to keep up to date with issues affecting all biologic registers within the Faculty;



 assist the database manager in extracting relevant data for a research question from the database into a statistical package which can be used for data analysis by other researchers;

## Initiative, Problem-Solving and Decision-Making

- identify potentially unmet needs in the data;
- develop a full understanding of the complex needs of all BADBIR stakeholders including post-marketing surveillance methodology, publication and third party data access policy;

## **Planning and Managing Resources**

- co-ordinate the regular BADBIR analysis meetings;
- actively participate in and facilitate in-house meetings;
- organise local meetings and produce relevant documentation;
- demonstrate effective time management and ability to work to strict deadlines;

## **Expertise**

- review the current literature and undertake systematic reviews and/or meta-analyses where appropriate for publication and presentation;
- experience of working with confidential data;
- ensure an understanding of the limitations of the dataset and learn statistical / epidemiological methods to address these limitations, e.g. how to account for bias as a result of missing data;
- provide analytical advice to researchers who have BADBIR projects approved by the
   Steering Committee to ensure outputs using BADBIR data are of the highest quality;
- responsibility for reviewing abstracts / manuscripts arising from BADBIR data (researchers and funders) and advise BADBIR committees as appropriate;
- assist in defining future analyses.

#### Training

You will receive training for all aspects of the work in the form of short courses as well as inhouse programmes. Training will include the use of statistical software, writing and presentation skills. You will also be expected to contribute at multi-disciplinary meetings. There is a monthly educational session and a weekly seminar series.



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## **Person Specification**

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Proven track record in data analysis and in particular working with longitudinal data	CV; application form
Previous experience of using STATA, M-Plus, R or SAS software, or other appropriate statistical software packages	CV; application form
Demonstrate an understanding of epidemiological methods	CV; application form
Experience of working with confidential data	Application form
The ability to use initiative and judgment to predict problems, plan appropriate changes and provide recommendations to improve current procedures with the help of the study team	Application form; interview
Experience of systematic literature searching, scientific writing, preparing research presentations and reports	CV; application form
Fluent in English (oral and written)	Application form; interview
Demonstrate effective time management and ability to work to strict deadlines	Application form; interview
Be able to demonstrate good interpersonal and good organizational skills	Application form; interview
Be able to demonstrate excellent communication skills (verbal and written) including presentations to audiences of academics, health professionals and lay people at national or international meetings	Application form; interview
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Demonstrate a flexible and responsive attitude to a dynamic and fast moving workplace	Application form; interview
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Ability to plan and organize your own workload and work to strict deadlines but also able to liaise and co-ordinate activities with other members of the team within a multidisciplinary environment	Application form; interview
Willingness to travel in both the UK and abroad, to meet project requirements	Application form
Demonstrate an enthusiasm for research	Application form; interview

# Desirable Skills, Knowledge and Experience

# Assessed by

Understanding of Good Clinical Practice and research ethics requirements / processes	CV; application form
Experience of undertaking applied health-related or medical research	CV; application form
An interest in dermatological research	Application form; interview