

# The Bio-Hermes Biomarker Data Challenge 2024 and beyond



## Background

**Biomarkers for dementia:** Making an accurate diagnosis of the dementia syndrome, and making useful predictions about future dementia risk, are notoriously difficult. Nevertheless, these are the issues that face clinicians and the public every day. New advances in our understanding of the biology of dementia show that brain changes can occur years or decades before any memory and thinking issues are noticed. This recognition of dementia as a long-term brain disease opens exciting possibilities for prevention and early treatment, but also makes the assessment process even more complex.

An increasing number of tests are available that can detect the earliest changes of dementia. Such tests include measurements of spinal fluid or blood, brain scans, detailed memory tests and many others. These dementia biomarkers could potentially transform diagnosis, prognosis, and treatment, but to date they are not routinely used in UK clinical services. Many questions remain around the utility of biomarkers when used in isolation or together.

**Data driven dementia research:** The value of data from clinical research is increasingly recognized and data from a single dementia study has the potential to answer a multitude of differing research questions. Advances in computational power, combined with new methods in analysis, allow teams to make use of research data in ways that would not have been possible previously. Given the potential importance of individual participant data, historically research centers that generated large clinical datasets would keep control of this resource, sharing data only with team members or select groups of collaborators. This created a system that favored certain research institutions, but did not benefit the broader research community, or people living with dementia. The landscape is thankfully changing and moves towards greater open access to data are welcome. However, progress in many areas has been slow. New ideas and infrastructures are required to connect the teams with the most exciting ideas to the most appropriate datasets that can answer their questions.

**A dementia dataset for all of Scotland:** At the 2023 St. Andrew's Summer Brain Health Summit, The Global Alzheimer's Platform (GAP) Foundation presented their study portfolio, with projects assessing potential dementia biomarkers in large and geographically diverse populations. These offer a powerful data resource that could help answer the important questions in biomarker research.

GAP have always worked closely with Scotland and recognize that Scottish dementia researchers have the infrastructures, skills and the passion required to deliver world changing science. As a product of the St. Andrew's Summit, GAP is providing the Scottish dementia researcher community with accelerated access to the full data from their Bio-Hermes biomarker study (<https://clinicaltrials.gov/study/NCT04733989>). This is a uniquely rich dataset, with multimodal data on cutting edge biomarkers. This exclusive access to the dataset is until 2025, at which point the data will become freely available through the Alzheimer's Disease Data Initiative (ADDI).

An exciting resource in its own right, the Bio-Hermes dataset has also provided the catalyst for a project that is uniting the Scottish dementia research community, offering a platform for new ideas, and creating a legacy of collaboration and early career researcher development – the Bio-Hermes Biomarker Data Challenge.

## 2. The Bio-Hermes Biomarker Data Challenge

In partnership with GAP, we have formed a Scottish collaborative group, bringing together academic centers of excellence (University of Glasgow, University of St Andrews) and national research partners including the Scottish Brain Health Alliance for Research Challenges (ARC - <https://www.brainhealtharc.com>), the Scottish Dementia Research Consortium (SDRC - <https://www.sdrc.scot/>) and the Scottish Imaging Network: A Platform for Scientific Excellence (SINAPSE - <https://www.sinapse.ac.uk/>). The Universities and Societies provided initial in-kind support, which our collaboration has been able to supplement through securing 'start-up' funding from the Scottish Funding Council, and Race Against Dementia.

Working in our new collaborative group, and using our extensive networks, we will run a national, open competition for research teams to apply to work with the Bio-Hermes data. Our vision is an end-to-end solution, where the minimum that is required is for a team to have an exciting hypothesis that they wish to test with the data. Our collaborative group will facilitate all other aspects of the process, including data access, ensuring appropriate data governance and ethical approval, assisting with data management, analysis, and facilitating dissemination.

The Bio-Hermes Biomarker Data Challenge represents a new approach to research, that is fully open, truly collaborative and encourages new ideas. We anticipate that the Data Challenge will act as a pathfinder project, establishing a process for future national data sharing schemes. We are aware of other dementia datasets that will be made available soon, and we would hope that a Data Challenge, similar to that proposed here, becomes a regular fixture in the research calendar and could be added and made interoperable with the Bio-Hermes data set within the ADDI environment.

The immediate benefit of the Challenge will be a series of data and calendar driven projects answering important questions regarding biomarkers. These questions will be developed using a 'bottom up' approach, including researchers from across the research ecosystem. We will actively encourage applications to access the data from teams that have not previously worked in the dementia space. By ensuring that data access, governance and ethics are handled centrally, and by offering support with analysis and dissemination, we have created a platform where all that a team needs to bring is an exciting research question. This approach will generate new ideas and the projects will likely inform biomarker clinical practice and policy.

A positive indirect outcome of the challenge is strengthening connections across the Scottish dementia research community and supporting early career researchers. Highlighting the research capacity within Scotland, an important legacy of the challenge will be in creating new teams and bringing new researchers into the dementia space.

Our Biomarker data challenge proposal comes at an opportune time. The UK NHS is looking for data to inform the implementation of blood-based dementia assessment at scale. A major UK cohort is planned to collect data on the most promising biomarkers and to then model potential clinical effectiveness and economic implications. The Bio-Hermes dataset is an ideal platform for initial analyses that can directly inform these projects.

### 3. Partners

The Bio-Hermes Biomarker Data Challenge is truly cross-institute, cross-discipline and cross-sector. We anticipate working with all Scottish Universities, but there are certain key partners that will be at the core of the collective.



The Brain Health ARC is a national research pooling initiative. The ARC's remit is to increase research capacity in Scotland. The Data Challenge is an ideal platform for the ARC to support the Scottish dementia research community and the ARC team are providing infrastructural and project management support.



The Scottish Dementia Research Consortium (SDRC) is the research focussed arm of Alzheimer Scotland. The SDRC now has over 1000 members including academics, clinicians and people with lived experience of dementia. The group will advise on interpretation, dissemination and knowledge transfer.



The Universities of St Andrews & Glasgow have an international track record in both dementia and data research. Recognising the importance of the Challenge, they are providing in-kind staff, consumables and infrastructural support.



The Scottish Imaging Network – A Platform for Scientific Excellence (SINAPSE) brings together academics, clinicians and other working in the imaging space. They will help with promoting the Challenge and advising on neuroimaging aspects.



Race Against Dementia are one of the major funders of dementia research in the UK. Their remit surrounds supporting high-risk, high gain projects. They have provided short term resource to support hiring dedicated data scientists to assist with the Challenge.



The Alzheimer's Disease Data Initiative ADDI envision a future where open data and global collaborations power the end of Alzheimer's disease and related dementias. ADDI are hosting the data and providing the secure environment for analyses.



The Global Alzheimer's Platform Foundation (GAP) and their network of over 100 research partners support trials and studies in diverse populations, recognising that research can offer hope to people living with dementia. GAP conducted the Bio-Hermes study and are sharing their data with the Scottish collective before it becomes open access.

## Bio-Hermes Data Challenge Team

### University of Glasgow

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### SINAPSE, SDRC, Brain Health ARC

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#### **4. Bio-Hermes Biomarker Data Challenge - Process**

We have plans for an official launch, in-person kick-off meeting and multi-platform communications strategy to ensure maximal visibility of the Challenge. Here we benefit from the extensive and diverse networks of our various project partners.

Following the launch in February, applicants will have a time-limited period to submit applications, using our online portal. We have created a concise application form that contains the necessary information to guide project assessment and can be completed in full within the short time windows suggested.

We are offering differing tiers of application. Where the applicant teams have sufficient data science and analytical expertise, the application will be for access to data only.

Unique to our challenge is the option to apply for both data access and in-house support from our team. To encourage applications from the broadest spread of teams and backgrounds, we are offering an end-to-end solution with support at all stages of the research journey. The support we offer as needed will include support in designing the question, support with analysis and interpretation, support in communication of results including drafting manuscripts. Where an idea is interesting, but not suited to the Bio-Hermes data-set, we will signpost to other data resources.

The Challenge will endeavor to support as many applications as possible. However, the in-house data scientist resource is limited. For applicants wishing our support, submissions will be graded by an expert panel. Projects that create new collaboration, consider equality, diversity, inclusion, and support early career researchers will be prioritized. The highest ranked applications will have access to the support of our team of data scientists, project managers and senior dementia researchers. As resourcing grows, The Challenge team will be able to support additional projects in this category.

We anticipate that the first results of analyses should be available within one year of launch and we plan an in-person results showcase event for 2025. We will encourage presentation at scientific meetings and publication in peer reviewed scientific journals and will support both as needed. The SFC Brain Health ARC will support dissemination activities to interested academics and the lay public via social media and newsletter updates throughout the duration of the Biomarkers Challenge Project. All contributing partners will be recognized in the authorship of published papers/conference platforms.

## **5. Data governance and approvals**

We believe we have a novel plan for management of data that allows for secure, comprehensive access with the minimal need for input from applicant teams. This ensures that the applicant teams can focus on the science. Our approach to data management and data governance is informed by discussions with various stakeholders including the Data Protection Office (University of Glasgow), Research Support (University of Glasgow), Research Ethics Committee (University of Glasgow), and the Local Privacy Advisory Committee (NHS Greater Glasgow and Clyde).

The Bio-Hermes datafiles will be stored on the Alzheimer's Disease Data Initiative (ADDI) servers. Access to data will be exclusively through the ADDI workbench platform. This is a secure environment suitable for access by external parties and designed as an end user platform for dementia data projects. No data will leave the secure environment. Our approach of using an existing and approved data access platform substantially reduces costs and time associated with data transfer and storage. Final approval of data outputs will include the Biomarker challenge team, the study sponsor (GAP Innovations) and the study Principal Investigator (Diana R Kerwin MD).

Ethical approval for the work has been provided by the University of Glasgow. We have a single generic approval in place and project titles will be added as required. Before access is given, applicant teams will sign an agreement around use of the data. In addition to ethical approvals, the Challenge and its partners have agreed on a Data Protection Impact Assessment (DPIA), and Memorandum of Understanding and Non-Disclosure Agreement that additional partners will be able to adopt with a minimum expenditure of time.

## 6. Timelines

<b>Time</b>	<b>Action</b>
<b>July 2023</b>	<b>Meeting with Global Alzheimer's Platform, offer of access to Bio-Hermes data</b>
<b>Aug 2023</b>	<b>Project team assembled</b>
<b>Sep 2023</b>	<b>Funding application submitted</b>
<b>Nov 2023</b>	<b>Standard Operating Procedure, Memorandum of Understanding, Non-Disclosure agreed by all parties</b>
<b>Dec 2023</b>	<b>Protocol finalized</b>
<b>Dec 2023</b>	<b>Ethics and data governance approvals</b>
<b>Jan 2024</b>	<b>Recruitment for Challenge specific staff</b>
<b>Feb 2024</b>	<b>Promotion / Applications for Biomarker Challenge Opened Including 'launch' at Biomarkers meeting</b>
<b>March 2024</b>	<b>Applications scored / successful applicants notified</b>
<b>April 2024</b>	<b>Successful applicants commence their projects/database interrogation</b>
<b>Jan 2025</b>	<b>Initial Results</b>
<b>Summer 2025</b>	<b>Dissemination Meeting</b>
<b>Summer 2025</b>	<b>Bio-Hermes dataset becomes freely available world wide</b>
<b>?Summer 2025</b>	<b>? Launch of the next data challenge</b>