GloBE-Reg Management Protocol

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The GloBE-Reg Registry

The Data Access Policy (DAP) covers the process that will be followed for using the registry as well as requesting access to the data from the Registry platform.

Name of system: The GloBE-Reg Registry (The Registry)

Governance & Committees

1. **The Registry Steering Committee**
   This committee will provide the project with over
   Faisal Ahmed, Glasgow, UK (Lead, Project Management Group)
   Natasha Appelman-Dijkstra, Leiden, Netherlands (Endo-ERN)
   Tania Bachega Sao Paulo, Brazil (Latin American Society for Pediatric Endocrinology)
   Maria Craig, Sydney, Australia (Australasian Paediatric Endocrine Group)
   Abdelhadi Habib, Al-Madinah, Saudi Arabia (Arab Society for Pediatric Endocrinology and Diabetes)
   Reiko Horikawa, Tokyo, Japan (Japanese Society for Pediatric Endocrinology)
   Yazid Jalaludin, Kuala Lumpur, Malaysia (Asia Pacific Paediatric Endocrine Society
   Agnès Linglart, Paris, France (European Society for Paediatric Endocrinology)
   Xiaoping Luo, Wuhan, China (Chinese Society of Pediatric Endocrinology)
   Yuen-Sum Man, Novo Nordisk
   Ryan Miller, Baltimore, USA (Pediatric Endocrine Society)
   Krystina Hickman, Glasgow, UK (Project Manager)

2. **Data Access Committee**
   Faisal Ahmed, Glasgow, UK (Lead, Project Management Group)
   Krystina Hickman, Glasgow, UK (Project Manager)
   Annalisa Deodati, Rome, Italy
   Asma Deeb, Abu Dhabi, UAE
   Yazid Jalaludin, Kuala Lumpur, Malaysia
   Clinical Scientist – to be appointed
   John Waller, Novo Nordisk
   Julia von Schnurbein, Ulm, Germany
   S Ching Chen, Glasgow, UK
   Data Scientist – to be appointed
   Patient Representative – to be appointed

3. **Project Management Group**
   Faisal Ahmed, Glasgow, UK (Lead, Project Management Group)
   Krystina Hickman, Glasgow, UK (Project Manager)
   Jillian Bryce, Glasgow, UK (Project Manager)
   Ching Chen (Senior Research Fellow)
   Chris Smythe (Database Developer)
   Xanthippi Tseretopoulou, Glasgow, UK
   Data Scientist – to be appointed
   Fatma Ashraf, Glasgow, UK (Registries Assistant)

4. **The Utility Of The Registry**
   It is expected that the Registry will mainly perform Secondary Research on the data that shall be collected during routine clinical care as described in the participant information sheet and within the

conditions of its ethics approval. It is anticipated that, in time, these data will be used for the following purposes by a wide range of stakeholders.

a. Provide a source population for the conduct of clinical trials
b. Provide the patient with details of their condition
c. Provide information on specific interventions related to defined patient groups
d. Provide for the follow-up of small patient populations.
e. Life-cycle assessment of the effectiveness and safety of interventions and medicinal products
f. Provide robust data on disease epidemiology, patients' characteristics and current standard of care
g. Provide source population data that can be linked to other datasets on specific outcomes
h. Provide data to industry, regulators and other trialists to facilitate the design of pragmatic trials for rare conditions as well as for conducting post-authorisation studies
i. Enable linkages to other rare disease registries approved by the Data Access Committee.

5. Role Based Access Rules

The following broad groups of stakeholders will require access to the data:-

- Patient participants	This group will have access to their own individual data.
- Clinical contributors	This group will have access to all the cases at their centre. They will also be able to provide access to other members of their clinical team.
- Project Management Group	Will have access to all the data.
- Investigators	Will be provided data following approval by the DAC

6. Ownership Of Data

- The patient participant and/or the legal guardians, in case the patient participant is under the age of 16, is/are the primary owner(s) of the data, and will grant each of the users and the University of Glasgow a nonexclusive licence to use such data for research purposes.
- The Office for Rare Conditions at the University of Glasgow is the owner of the database platform.
- The institution of the clinician participant who has entered the data is the owner of the aggregated data of that patient participant.
- When processed, the data become research data and are then the intellectual property of the investigator.
- The Office for Rare Conditions at the University of Glasgow and its principal investigator, Professor Faisal Ahmed, the principal investigator of the Globe-Reg project is the custodian of the data and is responsible for the protection of the data, its storage, use and access.

7. Anticipated Data Analysis

- The data in the Registry shall undergo annual analysis by the Project Management Team to provide progress reports to the Steering Committee. This analysis will focus on overall data accrual, content, quality, and headline descriptions of care. This analysis will not require approval from the Data Access Committee.
- Investigators from any background can request data. This includes academic and healthcare institutions, government and public health organisations, patient organisations and the pharmaceutical industry as well as members of the Globe-Reg consortium.

8. Process For Seeking Access To Data

- Access to the data shall follow the path outlined in Data Flow Within the Registry.
- The investigator shall need to complete the Data Request Form and the Data Sharing Agreement
- The completed forms shall be submitted to the Project Management Team who will check their completeness and forward to the Data Access Committee
- The Data Access Committee shall provide their feedback using the Feedback Form
- The whole Process for seeking access is summarised in Data Access Process.

- In case the contents of a new application overlap with an existing active application, the investigators of the two applications will be jointly advised by the Data Access Committee to discuss the overlap. As a condition of data provision, study groups that perform overlapping projects of the same class of drugs will be asked to present their project at the drug specific scientific study groups committee

9. Dissemination Of Data Analysis Activity

- All approved requests for data analysis shall be posted on the Globe-Reg website.
- Six monthly reports of all such 'research activity' will be obtained from investigators and a lay summary shall be posted on the website.
- Acknowledgements and attribution of any publications should follow the conditions in Section 6.2 of the Data Sharing Agreement

10. The Remit Of The Data Access Committee

a. **Purpose**

- The overall aim of the DAC is to promote the wider use of the data that are being collected in the Registry through a transparent and simple approach ensuring the long-term sustainability of the registry platform.
- The DAC should advise on the maintenance of the highest levels of custodianship of the data.
- Whilst it should have a good knowledge of ethics and data protection, it should not act as another 'research ethics committee' which is a responsibility that rests at the level of the data controllers.

b. **Tasks**

The DAC will review all new applications, existing projects, end of project reports and any other outputs.

Specific tasks include:-

- check that the proposed work complies with the terms and conditions of the ethics approval provided to the Registry project
- look for evidence that the third party who is requesting the data is appropriately qualified for use of the data
- advise on improving the scientific content and feasibility of the projects and any overlaps with ongoing projects
- advise on the dissemination and publication plans
- ensure that the effort of all those involved is appropriately acknowledged
- provide feedback to the requestor
- review and advise on the governance processes within the DAC

c. **Conditions**

All members of the DAC shall

- serve a 4-year term renewable for another 1 yr
- communicate to the Project Management Group through the Chair of the DAC who will represent the DAC in the Steering Committee
- complete a declaration of interests form
- declare any specific conflicts when reviewing an application
- complete a confidentiality and non-disclosure form
- treat all data requests confidentially
- aim to respond to all data requests promptly
- be familiar with the Data Access Policy and ethics approval of the GloBE-Reg project

c. **Further Reading**

Cheah PY, Piasecki J. Data Access Committees. BMC Med Ethics **21,** 12 (2020).