PURPLE TRANSLATIONAL PLATFORM

PANCREATIC CANCER: UNDERSTANDING ROUTINE PRACTICE & LIFTING END RESULTS

WEHI brighter together

PURPLE REGISTRY: DATA ACCESS REQUESTS

INTRODUCTION

The **PURPLE Translational Registry** is one of the Clinical Data Registries managed by the Gibbs Laboratory at the Walter & Eliza Hall Institute (WEHI). The PURPLE Registry collects real world pancreatic ductal adenocarcinoma (PDAC) data on patients receiving cancer care at sites across Australia, New Zealand and Singapore. Full pathway of care data is collected including presenting symptoms, method of diagnosis, treatments received and outcomes.

The ability to **access and share registry data for research is pivotal** to the registry objectives, creating a (inter)national resource for ongoing clinically relevant research. Equally important, the policy and process for data sharing must be consistent, transparent and aligned with the ethical, regulatory, and contractual parameters of the study. All research projects using PURPLE registry data require both Steering Committee Approval and Site Data Custodian Approval.

APPROVAL TO ACCESS DATA IS A TWO-STEP PROCESS:

1) PURPLE Steering Committee Approval – to ensure research project proposals for data usage have scientific merit, are feasible and aligned with the study objectives.

2) Data Access Requests– to request approval for use of individual site data from local site data custodians (GUARD Access Request system) and to agree to BioGrid Australia's terms and conditions of data access (via BioGrid) once Steering Committee Approval has been achieved.

PREPARING YOUR RESEARCH PROPOSAL FOR THE PURPLE STEERING COMMITTEE

- Project proposals are completed on the **PURPLE Data Request Form** by researchers.
- Please ensure you have the following information to complete your application.

1) **Project details**
    a. Name and detailed description of your project or research
    b. Principal Investigator of this research project – Name, Phone, Email, Institution
    c. Prime Contact for the study – Name, Phone, Email, Institution
    d. Institution and Department from where the project is being run.
    e. Sources of funding
    f. If the project is commercial: Commercial purpose and commercial lead.
2) **The science of your project**

a. Description of the science of your research project, including your hypotheses, objectives, study design and feasibility and potential sample where required. You can enter this information into the form or attach documents to the application.
b. Description of how you plan to translate your findings into clinical care, education and training.
c. Provide sufficient information about the science of your research.

3) **Project Ethics Approval**
Provide evidence of the ethical approval for your project. If your project does not have prior ethical approval your project will undergo a scientific evaluation by two members of the Expert Scientific Review Panel overseen by Melbourne Health and ethical review by the Melbourne Health Human Research Ethics Committee.
4) **The data required**
Specify the contributing sites you would like to request data from or select all sites.
5) **The people involved in the project**
Nomination of all people involved in the project, including authors and any other people who will have access to data. You will require the Name, Phone and Email of each person.
6) Security and Archiving
7) Description of the security and archiving arrangements for downloaded data.

BioGrid Australia System

BioGrid Australia developed the PURPLE Registry database and is the data linkage platform that allows data querying and analysis, linkage with other databases and a system to manage approval of data access requests.

The PURPLE Project team will submit your application once approved by the PURPLE Steering committee.

After Submitting

The Principal Investigator (PI) for the project will receive an email confirming the application has been submitted and all listed investigators will receive an email asking them to review and agree to BioGrid Australia's Terms and Conditions of Data Access.

Once all investigators have agreed to these terms and conditions, your application is then sent to the participating site **data custodian(s)** for their review. Data custodians are the nominated person at each site (usually the Site PI) who approve use of their data for research projects.

Once all data custodians have approved access to their data for your project, BioGrid will review whether your project has current ethical approval. If not, your project will be scientifically evaluated then submitted for ethical review to the Melbourne Health Human Research Ethics Committee which provides ethical oversight for projects without ethical approval in the BioGrid Access Request System.

After Approval

A WEHI Data Analyst can access and perform analyses of project data on your behalf. This may include survival, p-values, regression, and multivariate. Alternatively, this may be just in the form of a de-identified data spreadsheet on which you can perform your own analysis.

Please contact our Data Analyst to discuss on purplepancreas@wehi.edu.au