DMP title

Project Name CHARACTERIZATION OF THE EARLY IMMUNE EVENTS UNDERLYING FOOD-INDUCED ABDOMINAL PAIN - DMP title

Project Identifier G077222N

Principal Investigator / Researcher Guy Boeckxstaens

Project Data Contact Hind Hussein, +3216194692, hind.hussein@kuleuven.be

Description Irritable bowel syndrome (IBS) is a prevalent gastrointestinal disorder characterized by chronic discomfort and abdominal pain associated with altered defecation in the absence of an organic cause. Abdominal pain is a hallmark of IBS and results from the mast cell-mediated sensitization of afferent nerves, leading to aberrant intestinal pain perception. Recently, we provided evidence that a local immune response against dietary antigens underlies the development of abdominal pain in IBS. However, the mechanisms and the dynamics leading to this immune response remain unknown. We hypothesize that early signals produced by the epithelium in response to IBS triggers, like infectious gastroenteritis or psychological stress, initiate a local pro-Th2 immune environment in the intestine. This ultimately induces a local type 2 immune response to food antigens and food-induced abdominal pain. In the present project, we aim to unravel the immune mechanisms that cause the loss of tolerance to dietary antigens and lead to pain in IBS, in response to infection or psychological stress, in order to ultimately improve clinical management of the disease. The outcome of this project will be important to uncover the immune dynamics underlying the initiation of IBS and will ultimately lead to more efficient treatment strategies for IBS.

Institution KU Leuven

1. General Information

Name applicant

Guy Boeckxstaens (Supervisor, spokesman)

Hind Hussein (Co-supervisor)

Javier Aguilera-Lizarraga (Co-supervisor)

FWO Project Number & Title

G077222N

Characterization of the early immune events underlying food-induced abdominal pain

Affiliation

- KU Leuven

2. Data description

Will you generate/collect new data and/or make use of existing data?

- Generate new data

Describe in detail the origin, type and format of the data (per dataset) and its (estimated) volume. This may be easiest in a table (see example) or as a data flow and per WP or objective of the project. If you reuse existing data, specify the source of these data. Distinguish data types (the kind of content) from data formats (the technical format).

Type of data	Format	Volume	Creation method
Observational numeric data on human and murine samples	.sav, .csv, .mdb, .xlsx	10 Gb	RNA sequencing, flow cytometry, qPCR, ELISA, VMR
Graphical data	.pzfx, .pdf, .jpeg	200 Mb	RNA sequencing, qPCR, ELISA, VMR
Observational data from patient files	.sav, .csv	500 Mb	Questionnaire-based data
Single cell proteomic data on human and murine samples	.fcs, .pdf, .wsp, .jo, .exdat, .txt	300 Gb	Flow cytometry data
High resolution images	.gif, .jpeg, .tiff, .cloupe, .json	200 Gb	HCR-seqFISH (spatial transcriptomics), immunofluorescence
Text notes	.doc, .sav, .pdf	1 Gb	Experimental protocols, quantitative observations
Omics datasets	.loom, .h5ad	100 Gb	RNA sequencing data
Manuscripts	.doc, .docx, .pdf	1 Gb	Article and literature reviews
Presentations	.ppt	5 Gb	Experimental layout

3. Legal and ethical issues

Will you use personal data? If so, shortly describe the kind of personal data you will use. Add the reference to your file in KU Leuven's Register of Data Processing for Research and Public Service Purposes (PRET application). Be aware that registering the fact that you process personal data is a legal obligation.

- Yes

Privacy Registry Reference: B32220 1941517
We will use patient samples/information (biopsies, faeces, blood, questionnaires). The information is coded, i.e. each patient or healthy volunteer receives a unique code in order to pseudonimize the collected information. The questionnaires will collect information on demographics, previous history, psychological factors, and symptoms. The strategy to guarantee the privacy of individuals that consented to participate in the study has been approved by the Ethical Committee of UZ Leuven.

Are there any ethical issues concerning the creation and/or use of the data (e.g. experiments on humans or animals, dual use)? If so, add the reference to the formal approval by the relevant ethical review committee(s)

- Yes

We will collect disease-related information using validated questionnaires (see above) and collect rectal biopsies and blood samples.
Ethical approval has been obtained on December 20th 2019, reference number S62059 of the Medical Ethics Committee University
Hospitals Leuven.

Does your work possibly result in research data with potential for tech transfer and valorisation? Will IP restrictions be claimed for the data you created? If so, for what data and which restrictions will be asserted?

- Yes

This project can result in the discovery of novel pathways / targets / molecules involved in abdominal pain. We will contact the IP cell of KU Leuven at LRD once this info is collected and prior to publication to patent discoveries in order to valorize this know how.

Do existing 3rd party agreements restrict dissemination or exploitation of the data

you (re)use? If so, to what data do they relate and what restrictions are in place?

- No

4. Documentation and metadata

What documentation will be provided to enable reuse of the data collected/generated in this project?

Each experiment is registered in the lab journal of the scientist performing the respective experiment. Standard operation procedures (SOPs) have been written for all the techniques used in the lab. Data obtained from a study protocol / series of experiments will be stored in a folder that also contains a readme.txt file explaining the design/protocol, results and labels used in the data analysis file, and a reference to the lab journal of that particular experiment. Also the method of analysis will be described. The information provided will allow another researcher to follow all steps in the data processing.

Will a metadata standard be used? If so, describe in detail which standard will be used. If no, state in detail which metadata will be created to make the data easy/easier to find and reuse.

- Yes

Metadata will be created for the transcriptomics using the Dublin core (http://www.dcc.ac.uk/resources/metadata-standards/dublin-core).

Flow cytometry metadata will be generated as part of the Flow Cytometry Standard data file, according to the ISAC standards (https://isac-net.org/page/Data-Standards).
Microscopic metadata will be generated using the OME-TIFF or OXE-XML standard (www.fairsharing.org).
Other metastandard are not available yet (http://www.dcc.ac.uk/resources/metadata-standardsOR http://rd-alliance.github.io/metadatadirectory/standards/OR https://fairsharing.org/).
In these cases, metadata will be included in the read-me file, including description of equipment and settings used and experimental conditions.

5. Data storage and backup during the FWO project

Where will the data be stored?

Data will be stored on servers centrally managed by ICTS KU Leuven and with back-up capacities (KU Leuven enterprise box,
Largevolume-storage).
The scRNAseq data are stored by the lab of Prof. Thierry Voet at the VSC (Flemish Supercomputer Centre) and the server of UZ Leuven.
Physical (tissue) human samples will be stored at -20 or -80°C in freezers purchased by the PIs and located at the biobank of UZ Leuven.

How is backup of the data provided?

We will use the back-up facilities of the KU Leuven ICTS with automatic daily back-up procedures.

Is there currently sufficient storage & backup capacity during the project? If yes, specify concisely. If no or insufficient storage or backup capacities are available then explain how this will be taken care of.

- Yes

So far, there is enough storage room. If the capacity foreseen by KU Leuven is exceeded, extra storage capacity will be requested at the ICT department of KU Leuven.
Expected maximum volume: 5 TB.
Physical samples will be stored at the UZ Leuven biobank. If needed, extra freezers will be purchased.

What are the expected costs for data storage and back up during the project? How will these costs be covered?

The extra costs approximate 160 euro per TB/year (per blocks of 5 TB). The costs will be paid from this project.
The freezers to store tissue samples are purchased by the different PIs and located in the UZ Leuven biobank at no cost. The costs of a -80°C freezer is around 3000-5000 euro.

Data security: how will you ensure that the data are securely stored and not accessed

Data security: how will you ensure that the data are securely stored and not accessed or modified by unauthorized persons?

Data files are stored on the J drive of KU Leuven which is protected via a central login for KUL personnel. Identity of included patients is encoded, i.e. a unique number (hospital patient number) coupled to a unique CRF (case report form) number.
The file containing the link between the CRF number and the patient's identity is saved in a dedicated folder on the J drive which is only accessible by the PI and trial nurse via an entrance code. In case data are stored on managed laptops, the hard drive is encrypted.

6. Data preservation after the FWO project

Which data will be retained for the expected 5 year period after the end of the project? In case only a selection of the data can/will be preserved, clearly state the reasons for this (legal or contractual restrictions, physical preservation issues, ...).

All data will be retained during 5 years following the end of the project.
Pseudonomized data and physical data will also be stored for longer than 5 years.
Permission is requested in the informed consents.

Where will the data be archived (= stored for the longer term)?

Server of KU Leuven (see above)
Data will be archived after 5 years on the K drive of KU Leuven devoted for longterm storage. Permission to access the K drive is limited to the PI and only for read-only use. Archived data may no longer be modified.

What are the expected costs for data preservation during the retention period of 5 years? How will the costs be covered?

The estimated amount of data (scRNAseq data excluded) can be stored on the K drive, KU Leuven ICTS. If needed, an upgrade will be requested at 156,60 euro/TB/year. The expected maximum data volume of 5 TB will cost a total of 4000€ for 5 years (5 x160 euro/yr x 5 years). The costs will be paid from the current project.

7. Data sharing and reuse

Are there any factors restricting or preventing the sharing of (some of) the data (e.g. as defined in an agreement with a 3rd party, legal restrictions)?

- Yes. Specify:

With respect to patient data and physical samples: patient privacy is respected (see above) and permission to share data / samples is obtained in the informed consents.

Which data will be made available after the end of the project?

Data that are not under IP.

Where/how will the data be made available for reuse?

- Other (specify):

Data will be shared within the research unit.
Data under IP will not be shared with peers. Sequencing data will be uploaded to an open access repository and shared upon request. The data will be protected by creative commons.
Data without sharing restrictions will be shared through peer reviewed publications.

When will the data be made available?

- Upon publication of the research results

The data will be made available after publications via the required link in the publication or upon request.

Who will be able to access the data and under what conditions?

Data will be shared within the research unit.
Data under IP will not be shared with peers. Sequencing data will be uploaded in an open access repository and shared upon request. The data will be protected by creative commons.
Data without sharing restrictions will be shared through peer reviewed publications.

What are the expected costs for data sharing? How will the costs be covered?

Peers can use the data at no cost under the condition of co-authorship. Commercial organizations will have to pay a fee that will be determined by LRD-KU Leuven.

8. Responsibilities

Who will be responsible for data documentation & metadata?

G. Boeckxstaens

Who will be responsible for data storage & back up during the project?

A person within the lab will be responsible for the data storage.

Who will be responsible for ensuring data preservation and reuse ?

G. Boeckxstaens

Who bears the end responsibility for updating & implementing this DMP?

The PI bears the end responsibility of updating & implementing this DMP.