D6.2 – Development and update of the Data Management Plan 1

WP6

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Reviewer	Date	Reviewer Name (Short Organisation Name)
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Legal disclaimer

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ABBREVIATIONS

Abbreviation	Definition
CA	Consortium Agreement
CD	Crohn's disease
DMP	Data Management Plan
EEAB	External Expert Advisory Board
GA	Grant Agreement
GDPR	General Data Protection Regulation
HADEA	European Health and Digital Executive Agency
IBD	Inflammatory bowel disease
KPIs	Key Performance Indicators
NAS	Network-Attached Storage
NDAs	Non-Disclosure Agreements
RIA	Research and Innovation Actions
WP	Work Package
FAIR	Findable, Accessible, Interoperable and Re-usable

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About the project

GlycanTrigger is a project funded by the European Union, within the Horizon Europe Research and Innovation Actions (RIA). The long-term goal of GlycanTrigger is to unlock a new checkpoint that regulates health to chronic inflammation transition by proposing mucosa glycans modifications as a master switch towards the early perturbation of host-microbial interactions and the consequent activation of both innate and humoral immune systems. Ultimately, we want to intercept or revert this master switch and thereby exploit/analyse whether this constitutes an opportunity to prevent the development of chronic inflammation in at-risk individuals.

Chronic inflammation is the underlying cause of numerous diseases, including Crohn's disease (CD), which may have a preclinical phase with immunological changes occurring before symptoms manifest. To improve disease prediction and prevention, our innovative approach seeks to understand the health-to-intestinal inflammation transition using CD as a disease model. The GlycanTrigger project will investigate when, why and how changes in glycosylation at the surface of the gut mucosa, constitute an early trigger of the health-to-inflammation transition. We will address how changes in glycosylation of the gut mucosa act as a primary event that dysregulates not only local mechanisms, but also systemic mechanisms associated with health to inflammation transition. Although high-risk/high-gain, our project is based on appropriate and long-standing expertise and fundamental biological principles that the consortium has helped establish and is thus likely to lead to (i) breakthrough biomedical concepts in the driving factors that trigger the health-to-chronic inflammation transition and to (ii) novel predictive tools for early detection of at-risk individuals to develop chronic inflammation, as well as to (iii) a novel intervention strategy that will be tested for disease prevention. In the longer term, the results of GlycanTrigger will improve health literacy through better-informed management of health status, diet and lifestyle to maintain a healthy gut.

Our strategy for understanding the transition from health to gut inflammation is comprehensive and includes the impact of mucosa glycans on local and systemic mechanisms.

Partners:

Short name	Legal name
I3S (Coordinator)	I3S - INSTITUTO DE INVESTIGACAO E INOVACAO EM SAUDE DA UNIVERSIDADE DO PORTO (Portugal)
LUMC	ACADEMISCH ZIEKENHUIS LEIDEN (The Netherlands)
SORBONNE	SORBONNE UNIVERSITÉ (France)
CHARITE	CHARITE - UNIVERSITAETSMEDIZIN BERLIN (Germany)
GLSMED LH	GLSMED LEARNING HEALTH SA (Portugal)
MOUNT SINAI	ICAHN SCHOOL OF MEDICINE AT MOUNT SINAI (USA)
EFCCA	EUROPEAN FEDERATION OF CROHN'S AND ULCERATIVE COLITIS ASSOCIATIONS (Belgium)
SPI	SOCIEDADE PORTUGUESA DE INOVACÃO CONSULTADORIA EMPRESARIAL E FOMENTO DA INOVACÃO SA (Portugal)
LUD	LUDGER LIMITED (United Kingdom)

Executive Summary

This deliverable is the initial version of the Data Management Plan (DMP) of the GlycanTrigger project. It provides an overview of the data that is expected to be generated throughout the project and how this data will be stored, curated and made available following the General Data Protection Regulation (GDPR), Open Science and FAIR (Findable, Accessible, Interoperable and Re-usable) principles, in a manner that is as open as possible and as closed as necessary.

A detailed description of the data collected and processed for each work package (WP), including data collection, documentation, metadata generation, and data assessment mechanisms, is provided. Tools for data storage and methodologies for ensuring data security are also presented. All partners involved in research activities were asked to provide detailed information about the data generated and how it will be stored during the execution of the project as reported in the Data Summary.

Since this is an initial version of the DMP, the datasets described at this stage represent an early reflection on the data that we foresee to collect or generate throughout GlycanTrigger project. The DMP will be a living document that will be updated as the project progresses. It will be periodically reviewed, evaluated, and assessed during the lifetime of GlycanTrigger. i3S will act as the DMP manager with the overall responsibility of ensuring that the DMP is correctly implemented, carrying out periodic reviews. This version was implemented based on the recommendations of the i3S unit for “Responsible Conduct in Research”, as well as of the Data Protection Unit of i3S and following examples provided by the European Commission (EC).

Chapter 1

Data Summary

1. Data Summary

To achieve its objectives, the GlycanTrigger project activities will generate data in a broad range of technical/scientific methodologies, workshops/courses and dissemination activities. Research data will be generated by all the involved project partners.

Hereby, we present tables containing information on the contents and the collection/generation of data provided by each WP leader. At this preliminary stage of the project's development, only general specifications and structures of the metadata to be generated are considered.

WP 1- Mapping the gut mucosa glycome in health-to-inflammation transition **Lead Beneficiary: LUMC**	
What is the purpose of the data collection/generation and its relation to the objectives of the project?	This WP will generate data related with the structural characterization of the gut glycome composition as well as the glyco-immune transcriptomic profile from health to gut inflammation transition.
What types and formats of data will the project generate/collect?	• Raw data from the following methods: -Mass spectrometry imaging (.imzML;.ibd; .ome; .tiff) -Liquid chromatography-tandem mass spectrometry in negative ion mode (.mzXML) -Mass Cytometry Imaging (CyTOF) (.mcd; .txt) -Spatial transcriptomics (.csv) -Tissue (immune)histochemistry (.tiff; .jpeg) -quantitative PCR analysis (.csv) • Statistical analysis (to be determined) • Documents (.docx; .pptx; .pdf) and images (.png; .tiff; .jpeg)
Will you re-use any existing data and how?	To be determined.
What is the origin of the data?	Data will be generated from the analysis of samples derived from patients with CD and healthy controls.
What is the expected size of the data?	>1 TB
To whom might it be useful ('data utility')?	The data may be useful for some partners of the GlycanTrigger consortium and for the scientific community in general.

WP 2 - Understanding the biological impact of changes in gut glycome in microbial and immunological dynamics **Lead Beneficiary: SORBONNE**	
What is the purpose of the data collection/generation and its relation to the objectives of the project?	This WP will generate data from the analysis of how the mucosa glycosylation signature in CD patients changes the composition and function of the microbiome. In addition, the impact of the gut glycome in metabolomics and immunological dynamics associated with gut inflammation will be analyzed.
What types and formats of data will the project generate/collect?	• Raw data from the following methods: -shotgun metagenomics sequencing (to be determined) -LC-MS for metabolomics (to be determined) -FACS (.FCS) • Statistical analysis (to be determined) • Documents (.docx; .pptx; .pdf) and images (.png; .tiff; .jpeg)
Will you re-use any existing data and how?	To be determined.
What is the origin of the data?	Data will be generated from the analysis of human and mouse tissue and stool samples.
What is the expected size of the data?	>1 TB
To whom might it be useful ('data utility')?	The data may be useful for some partners of the GlycanTrigger consortium and for the scientific community in general.

WP 3 - Unravelling the cellular and molecular mechanisms of how changes in gut glycosylation activate innate and humoral immune responses **Lead Beneficiary: i3S**	
What is the purpose of the data collection/generation and its relation to the objectives of the project?	This WP will generate different types of data from the analysis of the impact of changes in gut glycosylation in the cellular and molecular mechanisms associated with the activation of both innate and humoral immune responses.
What types and formats of data will the project generate/collect?	• Raw data from the following methods: -Cytometric bead array (.FCS) -FACS (.FCS) -ELISA (.csv) -nano LC-ESI-MS (to be determined) -Single cell sorting (.FCS) -BCR sequencing (to be determined) • Statistical analysis (.xlsx; .cvs;.PZF) • Documents (.docx; .pptx; .pdf) and images (.png; .tiff; .jpeg) • Educational data will essentially consist of: -Presentation slides (.ppt or .pdf) -Seminar video recordings (.mp4) -Scientific posters (.ppt or .pdf) -Scientific handbooks (.pdf or paper) -Publications (.pdf)
Will you re-use any existing data and how?	Data from literature, public databases, and from GlycanTrigger partners.
What is the origin of the data?	The data will be collected/generated in the laboratory from the measurements of the samples from different animal models developed in the context of this project, as well as from serum samples derived from patients with CD and healthy controls.
What is the expected size of the data?	• Raw data <1Tb • Statistical analysis <1Gb • Documents and images <1Tb
To whom might it be useful ('data utility')?	The data will be important for some partners of the GlycanTrigger consortium such as the coordinator (i3S) and participant partners (LUMC, Charité, GLSMED LH, Mount Sinai, LUD) and useful for the scientific community in general.

WP 4 - Therapeutic efficacy of glyco-metabolic remodeling in preventing health-to-inflammation transition: the proof of concept **Lead Beneficiary: GLSMED LH**	
What is the purpose of the data collection/generation and its relation to the objectives of the project?	Data will be collected on the effects (clinical, endoscopic and immunological) of glycan supplementation both in mouse models and in humans.
What types and formats of data will the project generate/collect?	• Raw data from the following methods: -Lectin histochemistry (.tiff; .jpeg) -FACS (.FCS) -shotgun metagenomics sequencing (to be determined) -LC-MS for metabolomics (to be determined) -CBA (.FCS) -ELISA (.csv) • Patient data: demographics, sex/gender and disease related information such as disease location, phenotype, duration, prior medications, reason for surgery, and smoking status (.docx) • Patient data on clinical (Harvey-Bradshaw index - HBI; endoscopic postoperative recurrence rate – POR (defined by the Rutgeerts score) and biochemical parameters (Calprotectin; CRP, Hemoglobin) • Data from informed consent forms (.docx; .pdf) • Data from clinical questionnaires (.docx) • Statistical analysis (to be determined) • Documents (.docx; .pptx; .pdf) and images (.png; .tiff; .jpeg)
Will you re-use any existing data and how?	All data will be collected prospectively.
What is the origin of the data?	Data will be collected prospectively from patients.
What is the expected size of the data?	Data on approximately 60 patients (30 with glycan supplementation) will be collected.
To whom might it be useful ('data utility')?	The data will be important for all consortium partners.

WP 5 - Dissemination, exploitation and communication **Lead Beneficiary: SPI**	
What is the purpose of the data collection/generation and its relation to the objectives of the project?	The datasets of WP5 will contain information related to the project dissemination and exploitation.
What types and formats of data will the project generate/collect?	• Template and reporting documents (docx; .pptx; .xlsx) • Visual materials and Images/Photographs (.png; .tiff; .jpeg) • Video and podcast recordings (.mp4) • Press-releases (.pdf) • Newsletters (.html)
Will you re-use any existing data and how?	Data from literature and public databases to produce informative and educational communication content, and from GlycanTrigger partners to communicate and disseminate the project activities.
What is the origin of the data?	Data will be collected throughout the lifecycle of the project.
What is the expected size of the data?	<1Tb
To whom might it be useful ('data utility')?	Partners and all target groups of the project.

WP 6 - Project management **Lead Beneficiary: i3S**	
What is the purpose of the data collection/generation and its relation to the objectives of the project?	The data collected in WP6 contains information related to the project management and coordination.
What types and formats of data will the project generate/collect?	• Detailed consortium contact information (.xlsx) • Photographs/images (.png; .tiff; .jpeg) will be collected and processed in accordance with the EU General Data Protection Regulation (GDPR). Non-Disclosure Agreements (NDAs) will be used to protect confidential information from unauthorized disclosure. Consent forms will be obtained from individuals whose personal data will be used in the project, including photographs/images, to ensure informed consent and compliance with data protection regulations (.docx; .pdf) • A dataset containing the identified risks from the beginning of the project accompanied with the mitigation plans (.docx), as already detailed in D6.1 Risk Assessment Analysis • Financial information of each partner of the consortium will be included in a dataset (.xlsx)
Will you re-use any existing data and how?	The re-use of any existing data shall be limited to the project consortium members and the European Commission's Services.
What is the origin of the data?	Data will be collected throughout the lifecycle of the project.
What is the expected size of the data?	<1Tb
To whom might it be useful ('data utility')?	All partners and the European Commission.

Chapter 2

FAIR data

2. FAIR data

2.1 Making data findable, including provisions for metadata

The data of GlycanTrigger will comply with the FAIR data principles: data that is Findable, Accessible, Interoperable and Reusable. In this section, the guiding principles and high-level practices for promoting data FAIRness are outlined.

To condense, organize and make data practical and understandable, only final, or nearly final clean and organized data will be made openly available following FAIR. Data that is in the process of being created or refers to ongoing work (draft manuscripts, reports, and raw data or processed data) will be made available to other members of the project members through the collaborative workspace platform of GlycanTrigger.

The Glycan Trigger project is committed to the following underlying principles to facilitate the discoverability, accessibility, dissemination and reusability of the project data:

- Persistent identifiers will be assigned to the shared data and included in its metadata, so to make data findable;
- Detailed documentation on the datasets will be provided, with metadata being based on standard vocabulary(ies), whenever possible, making data accessible;
- Standardized methodologies and metadata content will be aimed, in order to make data interoperable;
- The relevant data collected in the course of the project, except sensitive and personal data, will be made openly available, with respect to possible embargo periods, through data repositories and with suitable licenses, thus making data re-usable.

When disclosing product information before publication, external researchers or collaborators will be requested to sign Non-Disclosure Agreements (NDAs) to maintain intellectual property protected.

Data documentation within GlycanTrigger will include:

- A description of the data itself: the overview of the files generated from a specific dataset will be included in a readme file, with the data format, the software used to read the data, and a description of the codes and variables used and their significance.
- A description of the data collection process and the tools used: this will include instruments such as codebooks, lab journals, logbooks, diaries, questionnaires, and manuals.

- A description of the changes of the dataset over time: a so-called historical report of the wanderings and processing of the research data in time is necessary to understand the origin of the data.
- As a convention, in GlycanTrigger, the following file name structure will be adopted: (research output) context_ yyyy.mm.dd_creator initials_version.extension

Technical metadata created will be automatically generated by the equipment used. This is based on the date/time and specifications of the captured data.

For glycomics and glycotranscriptomics/genetic data, we will follow the requirements given by EGA (European Genome-phenome Archive). Common field-specific standard formats will be used, such as mzXML, mzML, imzML and fastq. Field-specific guidelines, such as the MIRAGE standard (Minimum Information Required About a Glycomics Experiment), will provide guidance as to the completeness of metadata.

For proteomics raw data, supporting information and/or documentation will be provided according to the standards of the data repository, for example, MassIVE (https://massive.ucsd.edu/ProteoSAFe/static/massive.jsp?redirect=auth).

Additionally, we will provide extensive protocols in the form of peer-reviewed publications, such as research articles, protocols or data descriptors. These will contain the following information: a DOI, essential protocols or references to publicly available versions, processed data, figures, and a final pdf version of the manuscript.

2.2 Making data accessible

Specifically, processed and curated scientific data such as manuscripts, protocols, reviews and book chapters will be made available, after clearance for public dissemination, by publishing this data in golden open access journals/books. When this is not possible, we will use green open access. If necessary, we will use Sherpa/Romeo (https://v2.sherpa.ac.uk/romeo/) to check if the selected publisher allows self-archiving and corresponding embargo periods.

For green open access, we will use Open Science repositories. In detail:

- Manuscripts, reviews, reports and book chapters will be deposited in the institutional repository available at the University of Porto (https://repositorio-aberto.up.pt/) or in preprint servers such as bioRxivs (https://www.biorxiv.org/) or MedRxiv (https://www.medrxiv.org/).
- Raw and processed scientific data used to produce curated scientific data but not included in the final publications will be made available in Zenodo or in available public databases (e.g. plasmid

sequences will be deposited in addgene - https://www.addgene.org/). The corresponding DOI or accession code will be cited with the published peer-reviewed scientific data. All raw and processed data files will contain a detailed description of how the data is organized and how it was processed.

- Educational and Scientific content, when relevant, will be made available in Zenodo.

The i3S data repository (Network-attached storage – NAS) will be used as online storage during the whole project lifecycle. This allows data to be available when needed online or via VPN when researchers are working off-site. Folders allocated to GlycanTrigger within the i3S institutional drive (NAS) will be only accessed by team members working on the project, to ensure security. This access is allowed only after authentication.

2.3 Making data interoperable

To make data interoperable all data will be written or spoken (videos) in the English language. We will use file formats compliant with available open software applications. The international system of units (SI) will be adopted for all scientific data produced within the Glycan Trigger project.

All data shall be provided in standard and open formats that adhere to both commercial and open software protocols. The primary objective is to promote seamless exchange of data between researchers and institutions.

2.4 Increase data re-use

To optimize metadata descriptions and promote the reuse of data, a standard vocabulary will be employed for metadata description purposes. Additionally, the clarification of licensing information will be included to enhance the potential for data reuse.

Data will be accessible in accordance with Open Licenses to prevent potential issues related to intellectual property rights or access. Once the data is publicly accessible, it will remain so.

Each partner is responsible for ensuring the quality of their respective data. The General Assembly will collaborate closely with the coordinator and the Exploitation and Innovation Managers to provide the necessary tools for dataset description and identification, as well as metafile preparation.

Chapter 3

Other research outputs

3. Other research outputs

In GlycanTrigger, we envision to develop intellectual property and patents related to compositions for a novel nutritional product for personalized prevention of IBD, and corresponding methods of production; as well as a new biomarker and testing method for a non-invasive predictive in vitro diagnostic tool for IBD. We will work with the Knowledge Transfer Office at i3S to conduct diligence, prepare and file such patent applications, as well as to explore commercialization opportunities with corresponding target industries.

Furthermore, we plan to disseminate the project results and outcomes to the wider public through various outreach activities such as lectures, speaking engagements, conferences, interviews and social media campaigns. We will also produce non-technical summaries of the project outcomes and make them available on our project website and social networks of GlycanTrigger. These outputs will maximize the impact and value of our research and ensure that it reaches the widest possible audience.

Chapter 4

Allocation of resources

4. Allocation of resources

There are no immediate costs anticipated to preserve datasets. Publication costs under the Open Science policy are included in the budget of the project. i3S, the project's coordinator, will be responsible for the data management.

Chapter 5

Data security

5. Data security

Data will be stored and shared within the private collaborative platform. Access to this platform will be restricted through the use of unique usernames and passwords, limited to authorized users. Initially, only the consortium partners and project managers will be granted access to the cloud storage facility where datasets and metadata will be filed. However, the management of stored data may be adjusted in accordance with the inputs provided by the General Assembly.

At i3S, backups are the responsibility of the i3S IT department. Data is protected by an access list and password. i3S has a Data Protection Unit that will provide support to this project, when applicable. The coordinating and partner institutions are responsible for ensuring that backups are performed on a regular basis.

Chapter 6

Ethical aspects

6. Ethical aspects

The GlycanTrigger members will comply with the ethical principles underlining responsible research: the Charter of Fundamental Rights of the EU, Directives of the European Parliament and Council Directive stating the actions related to good practices, and to Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions. The consortium partners will comply with the ethical guidelines as laid down by The National Committees for Research Ethics and the EU guidelines for research proposals.

Compliance with the EU GDPR will be secured with the help of i3S and the dedicated Data Protection Officers (DPOs) from the coordinator and partner institutes. Protection and confidentiality of personal data will be guaranteed, as regulated by the different Hospitals and respective countries' laws, as well as with EU legislation. All the Information regarding the patient samples will be treated as strictly confidential and pseudonymisation at the source will be required. Procedures to ensure protection and confidentiality of specific GDPR-compliant model documents will be provided by the project coordinator to support the exchange of data between GlycanTrigger partners and the analysis of pools of data from different countries.

All ethical issues related to animal experimentation will be addressed by the i3S and Charité animal ethical committee and authorizations will be obtained from the National Veterinary Authorities. Ethical issues related to pilot clinical trial (WP4) will be managed by LUZ Hospital (GLSMED LH). All the study reporting obligations will be assumed by GLSMED LH (LUZ Hospital).

GlycanTrigger will receive samples (paraffin samples and fresh-frozen tissue samples from CD and HC individuals) and the corresponding clinical/pathological data from the USA. The same confidentiality safeguards will be required as stated above: pseudonymisation at the source and strict confidentiality of all the information regarding the patient samples. These safeguards will be clearly stated in the Material and Data Transfer Agreements.

The danger of fraud or falsification of scientific material will be minimised by open and transparent work standards, following the principles of Open Science. No regulated procedures will be started without the approval of the appropriate ethical committees for animal or human research, as required by law. The documents needed for ethical authorization for the use of animals, human samples and the conduction of the clinical study (including patients informed consent and information sheets) will be sent to the EU, prior to the commencement of the relevant parts of the research. Human tissues and blood samples: All samples (paraffin/fresh biopsies, stools and blood) will be collected after written informed consents (obtained by physicians), according to Directives 2004/23/EC and 2001/83/EC.

Chapter 7

Other issues

7. Other issues

GlycanTrigger has a beneficiary from the US and an associated partner from the UK. The consortium is committed to not transferring any personal data and/or material from or to the EU before obtaining the relevant authorisations. Data protection will be safeguarded by clear observance of the European norms and guidelines as stated in Data and Material Transfer Agreements.

Chapter 8

Conclusion

8. Conclusion

The initial version of the DMP for the GlycanTrigger project sets the groundwork for efficient and responsible data management practices. It outlines the data expected to be generated, storage protocols, and adherence to GDPR, Open Science, and FAIR principles. This DMP will evolve as the project progresses, ensuring continuous updates and compliance. i3S will oversee its implementation, periodically reviewing and evaluating its effectiveness. The DMP aligns with the recommendations of the EC and the Data Protection Unit of i3S, demonstrating our commitment to responsible research and data protection.

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