D6.1 – Risk assessment analysis

WP6

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Task Leader (Name and Short Org. Name)	**Salomé Pinho (i3S)**
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V.2	15-03-2023	Salomé Pinho/Vanda Pinto	Detailed description of risk analysis
V.3	22-03-2023	Salomé Pinho/Vanda Pinto	Removal of confidential information

DOCUMENT REVIEW

Reviewer	Date	Reviewer Name (Short Organisation Name)
V.1	28-02-2023	Catarina Neves
V.2	21-03-2023	Raquel Almeida

Legal disclaimer

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ABBREVIATIONS

Abbreviation	Definition
CA	Consortium Agreement
CD	Crohn's disease
DL	Deliverable leader
EEAB	External Expert Advisory Board
GA	Grant Agreement
HADEA	European Health and Digital Executive Agency
IBD	Inflammatory bowel disease
RIA	Research and Innovation Actions
WP	Work Package

Table of contents

Index of figures

Index of tables

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 life-style 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

The GlycanTrigger risk assessment analysis corresponds to Deliverable 6.1 and is part of WP6 Project Management. It aims to establish standardised quality control procedures and risk mitigation strategies to ensure the successful execution of project activities. The plan was developed based on the GlycanTrigger Consortium Agreement (CA) and Grant Agreement (GA). Quality assessment by the management team will enable a close follow-up of the work plan, leading to timely identification of problems, allowing prompt decision-making and thorough risk review.

The first section of the document outlines the roles and responsibilities of the various parties involved in the project and details project meetings and communication procedures. The second section focuses on quality assurance measures for deliverables, periodic reports, and activities. Finally, the last section identifies potential risks to project success and provides corresponding strategies or actions to minimize or eliminate such risks.

Chapter 1

Introduction

1. Introduction

1.1 Purpose of the document

This document outlines the policies and procedures to conduct adequate quality control and risk assessment, in order to ensure that quality standards are met, and risks mitigated accordingly during the GlycanTrigger project. Risk management is an ongoing process throughout the project's life cycle, and includes planning, identification, analysis, monitoring, and control. The goal of the risk management plan is to minimize the likelihood and impact of negative events while maximizing positive events. Clear communication and transparency between the Coordinator, the work package (WP) leaders, and project members is crucial to avoid problems and conflicts.

1.2 Intended readership

This deliverable is intended for public dissemination and can be accessed by any interested reader. It will be useful for all members of the public, as well as members of the Consortium and the European Commission, who can use it as a reference for tracking the project's progress.

Chapter 2

Roles and Responsibilities

2. Roles and Responsibilities

This section explains the GlycanTrigger management structure and management procedures, as well as the roles and responsibilities of the individuals within the project related to quality control and risk management.

2.1 Governance Structure

The organisational structure of the GlycanTrigger Consortium comprises the **General Assembly**, the **Steering Committee** and the **Coordinator**.

2.1.1 General Assembly

As depicted in Figure 1, the **General Assembly**, which comprises a representative from each Party, is the project's highest decision-making body. Its primary responsibility is to make strategic decisions about the project's direction and the responsibilities of the Consortium members. The decision-making process will follow the guidelines set out in section 6 of the CA, which includes the following key points:

- The Coordinator will chair all meetings of the General Assembly, unless decided otherwise in a General Assembly meeting.
- Decisions made by the General Assembly will be determined through a voting procedure, with each member having one vote.
- Decisions will be made through seeking consensus based on a simple majority. All decisions will require a quorum of at least two-thirds of its members to be considered valid.
- If the quorum is not met, the chairperson will schedule another meeting within 15 calendar days.
- In the event that the quorum is not met in the subsequent meeting, the chairperson will call for an extraordinary meeting. If fewer members than the required quorum are present or represented, this meeting will still be authorized to make decisions.
- External Expert Advisory Board (EEAB) members may attend General Assembly meetings if invited, but they do not have voting rights.

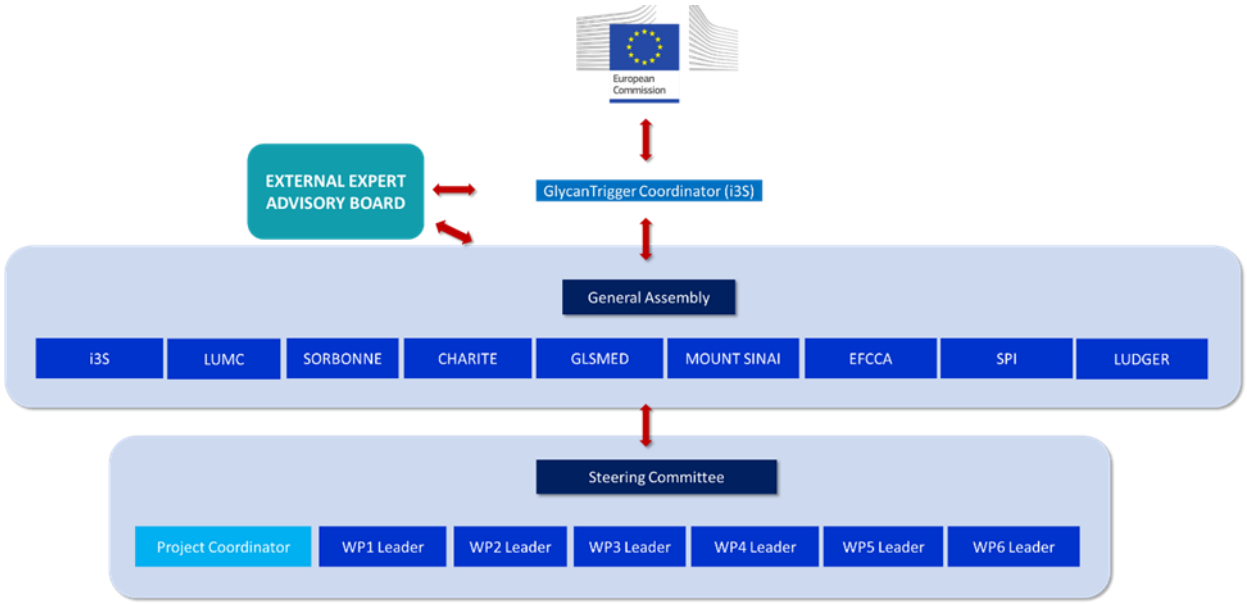

Figure 1. The management structure of GlycanTrigger, which comprises three distinct elements: the General Assembly, the Steering Committee, and the External Expert Advisory Board.

2.1.2 Steering Committee

The Steering Committee of the project consists of the six WP Leaders and the Coordinator, and it will monitor the project, prepare the meetings, propose decisions, and prepare the agenda of the General Assembly. Additionally, the Steering Committee will collect and examine information at least every six months on the progress of the project and, if necessary, propose modifications of the initial plan to the General Assembly.

The primary function of the Steering Committee is to ensure that the project objectives are achieved by coordinating collaboration and integration between WPs. This role includes management of quality assurance, milestone reviews, risk mitigation and contingency actions, and ethics issues. The Steering Committee will inform the General Assembly about any risks and problems which it cannot resolve through consensus and will suggest resolution and/or contingency actions.

In summary, the Steering Committee:

- Oversees the daily operations and execution of the GlycanTrigger project.
- Reports to and is accountable to the General Assembly, which serves as the governing body.
- Supports the Coordinator in preparing meetings and deliverables.

2.1.3 Coordinator

The Coordinator (i3S) is the intermediary between the Consortium Partners and the European Commission. Salomé Pinho, as the Project Coordinator, has been assigned the task of overseeing and coordinating all the activities of the GlycanTrigger project, which includes general monitoring and supervision as indicated in section 6.4 of the CA. The Project Coordinator is responsible for collecting and reviewing reports and other deliverables from the Parties. Additionally, the Project Coordinator is responsible for preparing the agenda of the General Assembly meetings (with the assistance of the Steering Committee), the minutes of the meetings, and for monitoring the implementation of the decisions taken at the meetings.

2.2 Work Package Leaders

The WP leaders are responsible for coordinating, planning, monitoring, and controlling tasks in their respective WP. They need to ensure timely and quality delivery of deliverables, keep the Steering Committee and Coordinator informed of all technical results, risks, and concerns, and develop the execution plan. The WP leader also arranges meetings, coordinates with task leaders and members, reports progress, logs major decisions, and highlights any unacceptable contributions.

Table 1 indicates the six WPs and the organizations or institutions responsible for leading and coordinating each WP.

Table 1. GlycanTrigger work packages and lead beneficiaries.

Work Package	Lead Beneficiary
WP1	LUMC
WP2	SORBONNE
WP3	i3S
WP4	GLSMED LH
WP5	SPI
WP6	i3S

2.3 Project Management (WP6)

WP6 is the WP dedicated to the GlycanTrigger project management and will ensure the effective execution of the project and the timely conclusion of deliverables. Additionally, it aims to conduct adequate quality control and risk assessment in order to ensure that quality standards are met, and risks mitigated. Salomé Pinho is the leader of this WP and will have the support of the Project Management team at i3S. The team comprises several members and departments at i3S, including the:

- Project Manager
- Project Management Advisor
- Financial Manager
- Knowledge Transfer Office (responsible for intellectual property rights and licensing)
- Unit for Responsible Conduct in Research (which supports the i3S community in the implementation of international codes of conduct and best international practices in research ethics and integrity)
- Data Protection Office (which ensures compliance with personal data protection legislation)

2.4 The External Expert Advisory Board

The EEAB will be appointed and steered by the General Assembly and will be responsible for providing external advice and strategic inputs. The members of the EEAB will provide wise advice on the major fields of action of GlycanTrigger, namely on inflammatory bowel disease (IBD) prediction and prevention, as well as in glycobiology. Industry advisors may also be involved in the EEAB committee. The EEAB can provide valuable input in identifying potential risks associated with the project, taking into account their expertise and experience. They can analyse the project proposal, identify potential risks, and suggest mitigation measures.

2.5 Project Meetings and Communication Procedures

The General Assembly meetings will be held annually while the Steering Committee meetings will occur at least twice a year. Depending on the need and the relevance, these meetings may be held in-person or by tele- or videoconference, or other (tele)communication means.

The planning and organization of the meetings will follow the regulations outlined in point 6.2 of the CA, which specifies that the chairperson must provide notice of the meeting as soon as possible, and at least 45 calendar days before an ordinary General Assembly meeting and 14 calendar days before an ordinary Steering Committee meeting. The chairperson must also prepare and distribute a written agenda to all members at least 21 calendar days before the General Assembly meeting or 7 calendar days before a

Steering Committee meeting. All members are expected to attend the meetings, but if that is not possible, they may appoint a substitute or proxy to attend and vote. The chairperson must prepare written minutes of the meeting within 10 calendar days and send them to all members for review. If no member raises an objection within 15 days of receipt, the minutes will be considered accepted and binding.

Chapter 3

Project Quality Management

3. Project Quality Management

Project quality management and risk assessment are closely linked, as quality management processes can help to identify, assess, and mitigate risks that may impact project outcomes.

3.1 General Practices

- The project's documentation will be stored in the collaborative workspace platform of GlycanTrigger.
- A quality review process for the project's deliverables and periodic reports has been established (refer to Sections 3.2 and 3.3 for details).
- The Project Management team at i3S, which has extensive experience in coordinating and managing EU projects, will provide support for financial management.
- All management reports and deliverables will adhere to a uniform format and design.

3.2 Quality Assurance of the Deliverables

The Project Coordinator is responsible for ensuring that project deliverables and periodic reports are submitted on time in the SygMa Platform.

Deliverables and periodic reports are crucial components of the project, providing information on project progress and results. The WP leaders and other project partners may contribute to the preparation of the deliverables, and their inputs may be necessary for meeting the quality standards and deadlines specified in the GA. To ensure that all deliverables meet high-quality standards, we will follow a systematic process (Figure 2) for their production, revision, and submission.

The Coordinator or WP leader will assign a specific GlycanTrigger member, the deliverable leader (DL), to draft the deliverable within the corresponding WP no later than 12 weeks before the submission deadline. The DL will be responsible for creating the initial version of the deliverable, which will then be shared via email with the WP members, WP leaders, and the Coordinator for feedback and revisions at least 6 weeks prior to the deadline.

Once the initial revisions are completed, a revised version (second draft) will be produced and provided to the Coordinator for a thorough quality control check no later than 3 weeks before the submission deadline. The Coordinator will ensure that the deliverable is correctly formatted and consistent with other documentation. The third and final draft, which will be available to all project members on the collaborative workspace platform, will be submitted 1 week prior to the official deadline to the SygMa Platform. Partners will also be notified by email that the final version has been uploaded.

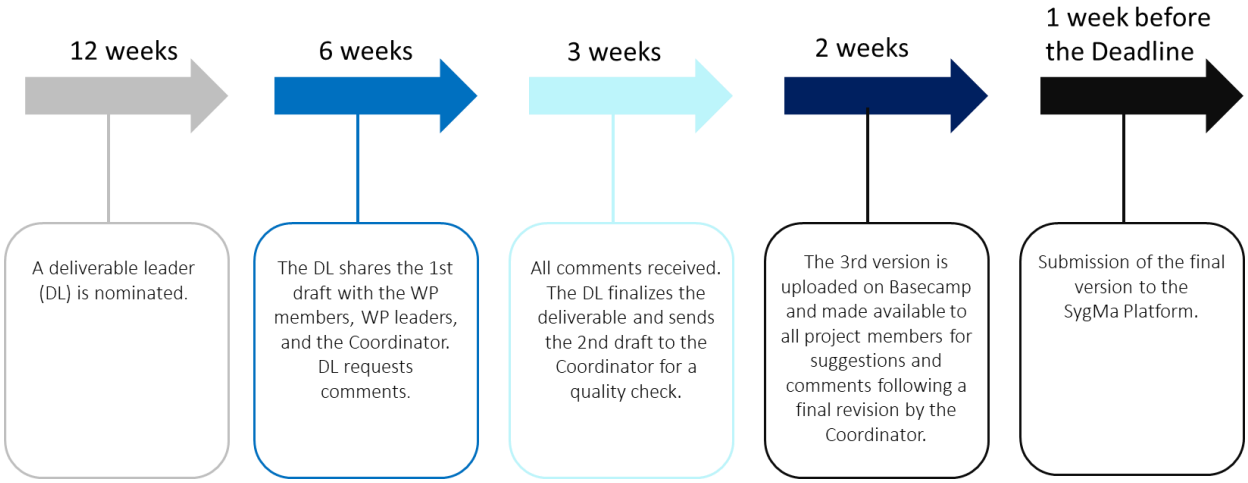

Figure 2. The GlycanTrigger deliverable workflow.

As per the CA, the Coordinator may submit the other Parties' project deliverables and all other documents required by the GA to the SygMa Platform in order to ensure timely submission of the deliverable/report accordingly with the deadline.

3.3 Quality Assurance of Periodic Reports

Periodic reports play a crucial role in monitoring the progress of GlycanTrigger. Each periodic report includes both a technical and a financial section.

To support the preparation of the periodic report for submission, the Coordinator will start the preparation of the report in advance in order to gather input from the WP leaders. The internal reports will consist of two main sections. The first section will provide technical information on the progress of the project, including deliverables, milestones, key performance indicators, exploitation and dissemination of results, as well as communication activities. The second section corresponds to the financial report and will document any significant deviations from the initial financial plan. After each internal report is produced, it will be shared with all GlycanTrigger members for feedback and revisions. The Coordinator will then create a final revised version of the periodic report that will be submitted to the European Commission.

3.4 Quality Control of GlycanTrigger Dissemination Activities

In order to monitor the impact of GlycanTrigger, a set of project objectives and specific Key Performance Indicators (KPIs) have been developed. These KPIs will be continuously monitored throughout the project and reported in the internal periodic reports. The KPIs will also be described in the periodic reports that are to be submitted to the European Commission, as part of the technical information section.

Chapter 4

Risk Management Action Plan

4. Risk Management Action Plan

The GlycanTrigger risk management plan comprises several critical steps that are crucial for effectively mitigating potential risks. These steps include identifying risks, analysing them in depth, devising response plans, and monitoring and controlling the risks over time (Figure 3).

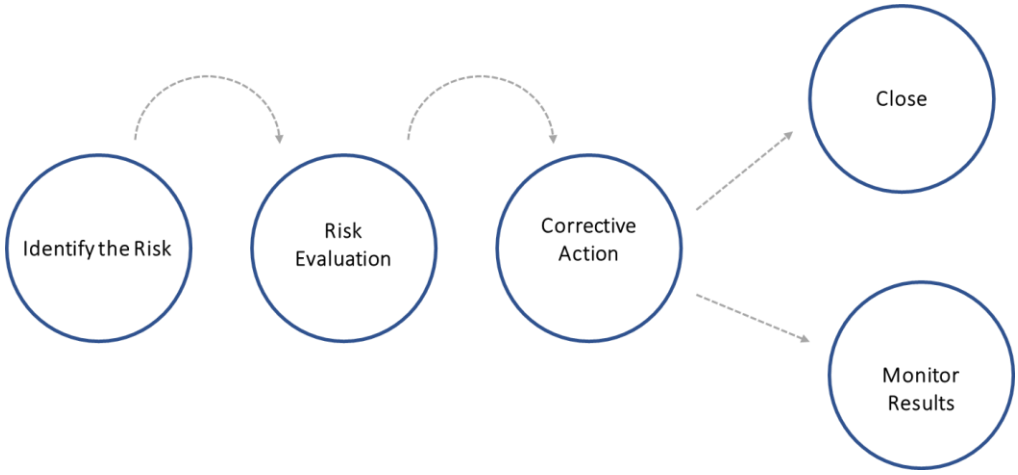

Figure 3. Schematic representation of the GlycanTrigger risk management process.

4.1 Risk Identification

WP leaders will monitor their specific WP's risks and report to the Steering Committee for risk mitigation measures and contingency plans. Risks will be evaluated and managed in internal periodic reports with a **Risk Management Log** that monitors changes in risk probability and impact as indicated below (**Annex I**). The EEAB can provide feedback on progress reports for strategy adjustments, and the Steering Committee will decide how to handle significant delays by reallocating resources, identifying alternative options or reaching proposed goals to avoid progress delays.

The potential risks will be analysed during the entire life cycle of GlycanTrigger using various tools and techniques, which include examining the status of deliverables, analysing WP schedules and scopes, and ensuring regular communication between WP leaders.

4.2 Risk Analysis

After identifying and documenting a risk or group of risks, a thorough assessment will be conducted of the likelihood of the risk materializing and the potential impact it could have. To estimate the likelihood of a risk occurring and the potential impact or consequence, a risk matrix will be employed.

The matrix has a scale of likelihood and impact. Likelihood is classified as "Low-1," "Medium-2," or "High-3," while impact will be rated as "Low-1," "Moderate-3," or "High-3." Each combination of likelihood and impact corresponds to a different level of risk. Cells coloured green indicate low-level risks (risk level <=2), yellow indicate medium-level risks (risk levels 3-4) and red indicates high-level risks (risk level >=6).

The Coordinator will document potential risks in a **Risk Management Log** (**Annex I**), which will be available to all team members via the collaborative workspace platform for each WP. The log will include details such as the risk's number, description, relevant WP, changes in the risk probability and impact and register risk status (P-predicted, M-mitigated, R-resolved). The Coordinator, working with the leaders of each WP, will assess the likelihood of each risk becoming a problem.

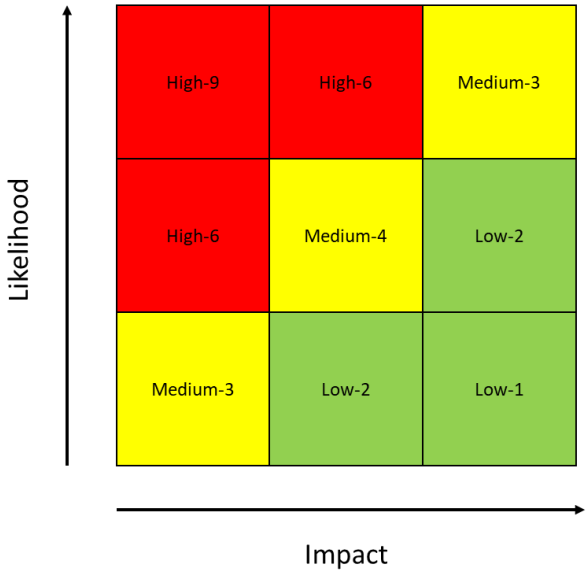

Figure 4. The risk matrix.

4.3 Risk Control

All WP leaders in the GlycanTrigger project are responsible for keeping the Coordinator updated on the status and effectiveness of each risk mitigation plan. The Risk Management Log will be continually updated and reviewed. Any new risks identified by each WP leader will be analysed and added to the register.

4.3.1 Risk-Mitigation Measures

Different strategies will be employed depending on the category of the risk. For high, and medium level risks, the team will use mitigation as a strategy, which involves reducing the probability and/or the impact of the risk to an acceptable level. Taking proactive measures against a risk is often more effective than attempting to address it once it becomes a serious issue.

For low-priority risks, the preferred strategy will be acceptance. Risk acceptance can be passive or active, with the latter involving the development of a cost and/or schedule revision to accommodate the risk. Regardless of the approach, risks will be monitored to ensure that they do not escalate into significant issues.

Each WP leader is responsible for implementing risk mitigation measures related to their specific WP. If a mitigation action proves ineffective or does not resolve the risk, the risk exposure will be re-evaluated and highlighted by the Coordinator for further action. A risk is considered closed when risk mitigation measures have been implemented and the new exposure risk is determined to be low using the risk matrix.

4.4 The Risk Management Log

Several risks were identified in the GA. These critical risks, which were identified at the proposal stage, refer to potential events or situations that could significantly impede the successful completion of the project objectives, and that require special attention and proactive risk management strategies to prevent or mitigate their impact. Based on these risks, a **Risk Management Log** (**Annex I**) will be set up and shared with the Consortium partners. The Log will be available in the collaborative workspace platform and updated at least at the end of each reporting period. As indicated previously, the table will be used to monitor any changes in the risk level and register risk status (P-predicted, M mitigated, R-resolved).

Chapter 5

Conclusion

5. Conclusion

This document outlines the internal procedures that will be implemented to effectively manage the risks associated with the GlycanTrigger project and ensure that it achieves all its proposed objectives within the established time limits. Specifically, D6.1 details the risk management plan for the entire duration of the project. The Risk Management Log will be continually reviewed and updated as necessary throughout the project's lifetime. The processes outlined in this plan have been designed in accordance with the guidelines outlined in the CA and the GA (number 101093997) for GlycanTrigger.

Annex 1- Risk Management Log

Risk Number	Description of Risk	Work Package Concerned	Likelihood (L)	Impact (I)	Risk (L*I)	Level	Status[a]	Proposed risk-mitigation measures

[a]P-predicted; M-mitigated; R-resolved


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