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GLIOMATCH

Project No. 101136670

The malignant Glioma immuno-oncology matchmaker: towards data-driven precision medicine using spatially resolved radio-multiomics

Deliverable 7.6
First policy brief

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Revision history

Author(s)	Description	Date
SPACETIME	First version shared to all projects	24 February 2025
SPACETIME / all U-THI-Clust projects	Incorporated feedback from U-THI-Clust	17 March 2025
Juan Ventura (GLIOMATCH, CPE)	Final content revision	26 March 2025

Contents

Projects

Short name	Short description
ARTURO	ARTURO ethically tackles the lack of experimental approaches to address the role of microbiota in human cancers by using an innovative state-of-the-art 3D tumour-on-chip model, as part of the emerging field of Micro-Physiological Systems.
GLIOMATCH	GLIOMATCH will improve the clinical outcome of malignant brain tumours in adults and children with tailored immunotherapy treatments using spatially resolved radio-multiomics.
HIT-GLIO	HIT-GLIO targets tumour-host interactions in paediatric malignant gliomas to reinvigorate immunity and improve radio- and immunotherapy efficacy.
MULTIR	MULTIR aimsto revolutionise our understanding of tumour-host interactions in melanoma, lung and bladder cancer.
SPACETIME	SPACETIME addresses the spatial analysis of cancer evolution in the tumour immune microenvironment.
THRIVE	THRIVE aims to improve the outcome of paediatric and adult liver cancer patients by understanding at-risk populations, tumour-host molecular interactions, developing biomarkers for current therapies and identifying novel treatments to overcome resistance.

Abbreviations

Abbreviation	Term
D	Deliverable
DMP	Data Management Plan
EHDS	European Health Data Space
EU	European Union
GDPR	General Data Protection Regulation
HaDEA	European Health and Digital Executive Agency
IARC	International Agency for Research on Cancer
JCA	Joint Controllership Agreement
MDTA	Material and Data Transfer Agreement
MTA	Material Transfer Agreement
U-THI-Clust	Understanding (tumour-host) interactions Cluster

Executive summary

This deliverable outlines key policy recommendations to address administrative and regulatory challenges in Cancer Mission Cluster projects. To streamline General Data Protection Regulation (GDPR) compliance in Material and Data Transfer Agreements (MDTAs), we propose standardised templates, EU-level legal support, and research-specific guidelines to reduce administrative burdens. Additionally, improving guidance on deliverables and adjusting the timing of the Common Chapter in the Data Management Plan (DMP) would enhance efficiency and prevent unnecessary delays. Implementing these measures would foster a more supportive research environment, enabling smoother collaboration and accelerating scientific progress.

1 Introduction

The implementation of large-scale, multi-partner research projects within the Cancer Mission's Clusters faces significant logistical and regulatory challenges, particularly concerning **General Data Protection Regulation (GDPR) compliance** in Material and Data Transfer Agreements (MDTAs) and the administrative requirements of common cluster deliverables. While these projects aim to facilitate collaboration and accelerate scientific progress, complex legal frameworks, inconsistent regulations across EU countries, and heavy administrative burdens often create obstacles that slow down research and complicate data sharing.

Navigating GDPR requirements remains one of the most pressing issues, as national variations in interpretation, unclear liability frameworks, and limited institutional expertise hinder the efficient exchange of research materials and patient data. At the same time, **managing cluster deliverables** presents additional challenges, particularly when guidance is unclear or requirements, such as the early inclusion of the Common Chapter in the Data Management Plan (DMP), are not well-aligned with project timelines. When expectations are not clearly defined, this creates an unnecessary administrative burden on the Understanding (Tumour-Host) Interactions Cluster (U-THI-Clust) projects.

Addressing these challenges is essential to ensuring the success of Cancer Mission projects, enabling smoother collaboration, and reducing delays caused by bureaucratic hurdles.

2 Challenges MT(D)As and Personal Data Sharing (GDPR)

Navigating the complexities of the GDPR in the context of Material Transfer Agreements (MTAs) and Material and MTDAs presents a significant challenge, particularly for large-scale, multi-partner projects across EU countries. These legal and administrative barriers can hinder collaboration, delay research progress, and increase the administrative burden on consortia.

To facilitate smoother collaboration and ensure compliance with GDPR, the U-THI-Clust projects propose specific recommendations in this document.

2.1 Key challenges

Establishing GDPR-compliant MTAs and MTDAs in multi-partner EU projects comes with significant legal and administrative hurdles. Below are some of the key challenges identified by the U-THI-Clust that must be addressed to streamline these processes.

- **Legal complexity:** Differing national interpretations and implementations of GDPR create inconsistencies in data-sharing agreements.
- **Time-consuming negotiations:** Developing individual agreements for each partner leads to delays in research activities.
- **Lack of standardized guidance:** The absence of uniform, research-specific GDPR guidelines complicates compliance efforts.
- **Diverging institutional policies:** Universities, hospitals, and private companies often have varying internal policies and legal requirements, further complicating alignment.
- **Unclear liability frameworks:** Uncertainty regarding legal responsibilities in case of GDPR breaches can discourage data sharing.
- **Limited expertise among researchers:** Many researchers lack in-depth knowledge of GDPR compliance requirements, leading to reliance on administrative and legal teams, which can slow down progress.
- **Limited (legal) capacity in academic institutions:** Many academic institutions face challenges in managing multiple projects simultaneously, with insufficient legal personnel to support the growing demands of complex agreements, further slowing down progress.

2.2 Solutions within the U-THI-Clust projects

In response to the challenges posed by GDPR in MDTAs, the U-THI-Clust projects have implemented several solutions to streamline the process and ensure compliance. These solutions were shared across the cluster to help the U-THI-Clust projects overcome similar issues.

- **Engagement of Specialized Legal Expertise.** Some projects within the U-THI-Clust included law firms (TimeLex) as partners within the initial consortium, recognizing their expertise in European data-sharing legislation and patient-related transfer agreements. Their involvement ensured compliance with legal requirements and helped expedite the drafting of our agreements.
- **Pairwise MTAs.** Some U-THI-Clust projects adopted pairwise MTAs to simplify negotiations and create tailored agreements between specific partners. This strategy reduced the complexity of multi-party agreements and allowed us to address individual partner needs more effectively. This is only effective in smaller consortia, or uncomplicated data sharing.
- **Joint Controllership Agreement (JCA) Implementation.** Alongside Consortium Agreement, some projects implemented a JCA. This agreement clearly defined the roles and responsibilities of each partner in terms of data management and GDPR compliance, ensuring that all parties understood their obligations.
- **Synthetic data generation.** Another solution to overcome challenges posed by GDPR in MDTAs has been implemented within MULTIR project. The pipeline is tested in high- dimensional molecular (omics) and clinical data and is based on statistical foundation (Gaussian copulas). Gaussian copulas generated synthetic datasets by maintaining the statistical properties of real data without exposing individual patient information. This approach, anchored in a multivariate distribution framework, effectively captures the underlying dependency structures, enabling the generation of synthetic data without containing real individuals' information. Unlike anonymization techniques, which can sometimes be reversed, copula-based synthetic data does not have a direct, one-to-one correspondence to real individuals. Following this principle, MULTIR has developed a pipeline enabling the accurate reproduction and preservation of correlations between variables within large matrices of more than 21,600 variables. The approach allows to mimic well characterised large molecular datasets and reproduce realistic patterns that retain association with clinical, demographic and molecular information without the risk of exposing patients' identities. The method is under consideration for publication. A preprint has been already posted on medrXiv[1].

2.3 EU-Led Solutions

While we have implemented several solutions within our projects to address the challenges of GDPR compliance in MDTAs, we recognize that these solutions, while helpful, are neither ideal nor sustainable in the long term. For instance, relying on specialized legal teams within the consortium is not a scalable approach and it often comes too late, as many projects do not anticipate these issues in advance. When such challenges arise, projects typically lack the legal partners or resources to navigate these complexities effectively.
Similarly, while pairwise MTAs and JCAs have eased some administrative burdens, they still require significant time and resources that may not be feasible as project progresses. These and other issues have also been highlighted in a recent Nature Medicine article *(Legido-Quigley et al., 2025)*[2]*,* which elaborates on how inconsistent GDPR applications across EU member states remain a major barrier to health data sharing, slowing down precision medicine research. **This underscores the urgent need for standardized GDPR guidelines and legal support at the EU level, aligning with the challenges we have identified within the Cancer Mission U-THI-Clust.**

[1] https://www.medrxiv.org/content/10.1101/2024.10.30.24316342v1

[2] https://pubmed.ncbi.nlm.nih.gov/39825150/

To ensure that future projects thrive without encountering the same bottlenecks, we must advocate for changes at the EU policy level:

- **Develop standardised, GDPR-compliant templates:** Provide or promote the use of official, pre-approved templates for MTAs and MTDAs that comply with GDPR and account for academic/non-academic collaborations. These templates should: i) Define roles (data controller vs. processor); ii) Include provisions for data minimisation, (double)pseudonymisation, or anonymisation; iii) Offer clear guidance on cross-border data transfers (within and outside the EU).
- **Appoint an EU liaison or officer for data transfer issues:** Designate an EU-level officer or liaison to provide expert guidance and support for projects dealing with GDPR-related data transfer challenges. Another option would be to facilitate access to legal experts who can offer advice on complex GDPR issues. Additionally, the forthcoming European Health Data Space (EHDS) initiative presents a unique opportunity to unify data-sharing regulations across EU countries. By integrating EHDS into GDPR compliance frameworks, projects like those in the Cancer Mission Cluster could benefit from clearer legal interpretations, streamlined administrative processes, and improved access to research data across borders. EHDS could serve as a key mechanism for reducing regulatory fragmentation and ensuring that research projects comply with GDPR while maintaining efficiency.
- **Create research-specific GDPR guidelines:** Publish sector-specific guidelines tailored to biomedical and health research under GDPR. This could include: i) Clear definitions of “scientific research” as a legal basis; ii) Examples of lawful processing mechanisms, iii) Simplified consent requirements for secondary data use.
- **Simplify processes for pseudonymised or anonymised data:** Establish simplified regulatory processes for the sharing of (double) pseudonymised or anonymised data to reduce administrative burdens while maintaining data protection would be exempted. One option could be to create fast-tracked approvals where (double)pseudonymised or anonymised data would be exempted from certain administrative steps like individual consent or legal reviews. Another would be to provide EU-Wide Certification, where a standardised certification for (double)pseudonymisation and anonymisation techniques would be introduced to ensure that data meets privacy protection standards. Finally, cross-border sharing guidelines could be developed that would clarify when pseudonymised or anonymised data can be shared across borders with fewer regulatory requirements, promoting broader use in research. In addition to regulatory measures, adopting privacy-preserving technologies could further streamline GDPR compliance in MDTAs. Recent discussions on precision health data-sharing suggest that encryption, pseudonymisation, and blockchain-based AI systems could be leveraged to ensure data security while reducing administrative burdens (Legido-Quigley et al., 2025, see 2.3). Implementing these technical solutions, alongside legal standardisation, would enhance data-sharing efficiency without compromising data protection.
- **Organise educational initiatives:** The EU could organise webinars, e-learning courses, and workshops focused on GDPR compliance, cross-border data sharing, and best practices in data anonymisation and pseudonymisation. Such initiatives would create platforms for legal experts, researchers, and data protection officers to exchange insights, discuss regulatory updates, and enhance collaborative efforts in tackling GDPR challenges.

3 Feedback on the Cancer Mission Implementation

Navigating the complexities of the General Data Protection Regulation (GDPR) in the context of Material Transfer Agreements (MTAs) and Material and Data Transfer Agreements (MTDAs) presents a significant challenge, particularly for large-scale, multi-partner projects across EU countries. These legal and administrative barriers can hinder collaboration, delay research progress, and increase the administrative burden on consortia.

To facilitate smoother collaboration and ensure compliance with GDPR, the U-THI-Clust projects propose specific recommendations in this document. After working on the Cancer Mission‘s Cluster during our first year, we have encountered two logistical challenges that, if addressed, could improve the efficiency and feasibility of project implementation for future initiatives within the Cancer Mission.

3.1 Improved Guidance on Deliverables

One of the challenges we found was the lack of clear guidance on common deliverables. While flexibility in execution is valuable, more precise expectations from the EU on the format, scope, and level of detail required for deliverables would be beneficial. This would not only help the projects help avoiding unnecessary revisions, but also ensure consistency across different clusters. We recommend that the EU provide a standardized guidance document or template for the common deliverables, outlining key requirements and best practices. Additionally, offering early-stage consultations or infosessions on deliverable expectations could further enhance clarity.

3.2 Revising the Timing of the Common Chapter in the Data Management Plan (DMP)

Another challenge we encountered was the requirement to include the Common Chapter in the first version of the Data Management Plan (GLIOMATCH D8.2) which must be submitted within the first six months of the projects. The first version of the DMP already demands substantial time and effort from project partners, and adding the Common Chapter at this stage places an undue burden on consortia.

We recommend decoupling the Common Chapter from the initial DMP submission and instead making it a separate deliverable at a later stage. Alternatively, the Common Chapter could be integrated into an updated version of the DMP once projects have progressed and collaboration within the cluster is more established. This would ensure a more comprehensive and well-aligned Common Chapter without delaying or complicating the early phases of project execution.

4 Conclusions

Streamlining GDPR compliance in M(D)TAs is essential for efficient multi-partner research. While short-term solutions have helped the U-THI-Clust, a long-term, EU-level approach is needed. Standardized templates, dedicated EU legal support, and clear research-specific GDPR guidelines are initiatives that could reduce administrative burdens for the Cancer Mission projects, enabling researchers to focus on scientific progress rather than compliance hurdles. Simplifying processes for pseudonymized data would further enhance collaboration while ensuring privacy protection.

Similarly, improving the logistics of the Cancer Mission Cluster projects would enhance efficiency. Clearer guidance on common deliverables and better timing for the Common Chapter in the DMP would prevent unnecessary revisions and administrative strain. Decoupling the Common Chapter from the initial DMP submission or making it a separate deliverable would allow projects to focus on early-stage implementation without delays.

By addressing these challenges, the EU can foster a more supportive research environment, allowing projects to maximize impact while ensuring compliance and operational efficiency.

The policy brief recommendations will be updated annually following each U-THI Cluster meeting, incorporating any new challenges identified during project implementation.