

D6.4 – Data Management Plan

Version 1.0

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HISTORY OF CHANGES			
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Project Information

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1. Project Data

1.1 Introduction

The Data Management Plan (DMP) is the Deliverable 6.4 (D6.4) from the TRIP project, funded by the EU's Horizon Programme, under grant agreement number 999999. This deliverable introduces the initial version of the DMP. The DMP describes the framework in which the TRIP consortium will manage datasets that will emerge from the project, and how archiving and reuse of data collected within the project will be done. The DMP will ensure that TRIP datasets will be findable, accessible, interoperable, and reusable (FAIR) for other potential users, in accordance with the Horizon 2020 Open Research Data pilot. Also, the TRIP DMP follows the structure of the Horizon 2020 DMP template.

1.2 Project background

Pancreatico-biliary cancers are a leading healthcare concern and their burden is increasing in many EU countries, but especially in Central and Eastern Europe. TRIP project is designed to support trainees and early stage researchers at UMFCD to gain first-hand knowledge and experience in the field of early diagnosis and therapy of pancreatico-biliary cancers, in order to provide personalized care to oncologic patients. This will be supported by workshops, webinars and summer schools. Also, the project aims at introducing innovative services for patients such as a high-risk clinic for pancreatic diseases and an algorithm for pancreatic cancer screening.

1.3 Data Management Plan objectives

This document is the initial TRIP Data Management Plan. The DMP is intended to be a living document where information will be continuously added and revised as the implementation progresses.

The DMP outlines the main objectives of the project – improving knowledge and expertise for early diagnosis and minimally invasive therapy of bilio-pancreatic cancers, and developing a high-risk clinic and pancreatic cancer screening programme.

It also indicates how data will be collected, which methodology and standards will be applied, whether data will be shared/made open access and also how data will be curated and preserved during the project. It provides the approach that the TRIP project will adopt with respect to the management and protection of data. Legal and ethical issues related to the project's collecting and/or processing of personal data are identified and practically considered.

1.4 Data Summary

1.4.1 The purpose of the data generation and collection in TRIP

The aim of the data generation and collection in TRIP is to develop a high-risk clinic for pancreatic cancer, including patients with pancreatic cystic lesions, and a pilot programme for pancreatic cancer screening. A screening algorithm for pancreatic cancer will be proposed

for UMFC and its affiliated hospitals, based on population-specific data and available infrastructure.

1.4.2 The relation to the objectives of the project

Data generation and collection will support the main objectives of the project – improving knowledge and expertise for early diagnosis and minimally invasive therapy of bilio-pancreatic cancers, and developing a high-risk clinic and pancreatic cancer screening programme.

1.4.3 The types and formats of data generated/collected and re-used

Several types of data will be generated/collected and re-used in fulfilling the project objectives – personal data of participants who will take part in training programmes (workshops, webinars, summer schools), and demographic, clinical, laboratory and imaging data from patients recruited for pancreatic cancer screening programme, high-risk clinic and pancreatic organoids cultures.

Data formats include documents, spreadsheets and presentations in software such as MS Office (doc, docx, xls, xlsx, ppt, pptx, etc.), photos (png, jpg, jpeg) and videos (avi, mpg, DICOM).

1.4.4 Expected size of the data that you intend to generate or re-use?

While most data will be text, considering that we will also generate and collect photo and video-data, we estimate the need for hundreds of gigabytes – few terabytes.

1.4.5 Origin/provenance of the data, either generated or re-used

Regarding the provenance of data, on one hand we will have personal data of participants to training activities, collected by sign-up sheets, and on the other hand, there will be patient data, collected from medical charts and medical equipment.

1.4.6 Re-use any existing data and purpose of re-use

The TRIP project aims at developing new patient-oriented healthcare facilities such as the high-risk clinic and the pancreatic cancer screening program. Some existing data that may be re-used consists of data from medical charts and previous examinations results to dynamically evaluate the disease evolution.

1.4.7 To whom might your data be useful ('data utility'), outside your project

The data obtained during the TRIP project might be useful for local healthcare regulatory organizations to increase the knowledge regarding the national pancreatic cancer epidemiology and disease burden. Nonetheless, data generated from TRIP could be compared to similar data before TRIP to evaluate the real-world role in terms of cost-efficiency, morbidity, and mortality of these new healthcare facilities.

2. FAIR data

Information presented in this section relies on Horizon 2020 template for FAIR data.

2.1. Making data accessible

Patient data collected and stored during the project will be deposited in Zenodo, a trusted repository funded by EC. Access to TRIP data in Zenodo repository will be restricted to project partners. For research purposes, access to data might be granted to third parties on request, at the decision of the project coordinator. A digital object identifier (DOI) will be automatically assigned to all Zenodo files in the TRIP project. Data will be published using standard file formats (doc, xls, jpg, DICOM). Data will be accessed using standard software available in medical and research institutions. Open TRIP results that will be deposited in repositories of scientific publishers or other research repositories will be at least identifiable and locatable by means of a persistent Uniform Resource Locator (URL). Scientific publications will be assigned a unique identifier like DOI, URL, Publisher Item Identifier (PII) or International Standard Serial Number (ISSN).

Personal data gathered during the project will not be made publicly accessible as it will be stored on local servers of UMFCDC.

Files generated throughout the project (deliverables, minutes, other documents) will have a standard format (TRIP_[short name partner]_[date]_[xxx], where xxx is a short description of the file).

2.2 Making data interoperable

In the TRIP project we will use standard file formats as mentioned above. Each dataset will have standard Zenodo metadata. Data referring to personal identifiable information will be restricted to internal use and not shared with third parties.

Metadata domain model used in Zenodo deposition will include:

Attribute	Description
<i>title</i> <i>string</i>	Title of deposition.
<i>Created</i> <i>timestamp</i>	Creation time of deposition (in ISO8601 format).
<i>Creators</i> <i>string</i>	Authors of the deposition.
<i>doi</i> <i>string</i>	Digital Object Identifier (DOI) assigned by the DOI registrant
<i>doi_url</i> <i>url</i>	Persistent link to your published deposition. Available for published depositions only.
<i>id</i> <i>integer</i>	Deposition identifier

Publication_date <i>timestamp</i>	Date of publication in ISO8601 format (YYYY-MM-DD).
modified <i>timestamp</i>	Last modification time of deposition (in ISO8601 format).
Keywords <i>string</i>	Free form keywords for the deposition

2.3 Increase data re-use

This section will be updated in subsequent versions of the DMP, while datasets will be outlined during the different phases of the project.

3. Allocation of resources

No costs are foreseen in making TRIP data FAIR-compliant, as Zenodo repository is funded by the EU. Also, DOI numbers will be assigned to TRIP datasets free of charge.

4. Ethics.

Ethics requirements linked to data management within the project will be covered in deliverables of work package WP. Further details will be reported in subsequent versions of the DMP.