PERsonalised Adaptive MEDICine

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Consortium members	**BULK & ATS & UEA & LBORO**
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Dissemination	**Confidential**

PERSONAL ADAPTIVE MEDICINE

Contents

Preamble to the Updated Version of the Data Management Plan

The initial Data Management Plan (DMP) was prepared and submitted as Deliverable at month 6 of the project. According to the work plan, an updated version is to be delivered at month 18.

Following a thorough review of the existing DMP by the consortium, it has been concluded that the procedures, policies, and responsibilities described in the original document remain fully valid. No changes have occurred with regard to the type of data collected and processed, nor with respect to legal, ethical, or organizational frameworks, that would necessitate an update of the plan.

The consortium has carefully assessed the DMP and confirms that it continues to meet the current requirements. Consequently, the deliverable is hereby submitted in the form of the original DMP, complemented by this preamble as justification.

1 Data Summary

Purpose of the Data Collection/Generation and its Relation to the Objectives of the Project

The goal of the project is to develop new methods for producing patient-specific capsules . To achieve this objective, numerous experimental series will be conducted. These experiments serve the following purposes:

Characterization of material behavior in the additive manufacturing process

Characterization of the release of active pharmaceutical ingredients (APIs)depending on environmental conditions, composition, and geometric shape of the capsule.

Types and Formats of Data Generated within the Project

The data generated will arise from the aforementioned experimental series focusing on the characterization of material behavior in the process and the characterization of drug release. These data will be collected in various formats suitable for subsequent analysis and evaluation.

Re-use and Origin of Existing Data

The project will utilize existing data on known pharmaceutical excipients and APIs. These are fundamental and will be used appropriately within the project. The origin of these data includes material data sheets from manufacturers and suppliers, as well as scientific publications.

Expected Size of the Data

It is anticipated that fewer than 100 experimental series will be conducted within the project, with each series comprising fewer than 1000 data points.

Data Utility

The data may be relevant for the development of new drug delivery forms as well as for the further development and utilization of the project results.

2 FAIR data

2.1 Making data findable, including provisions for metadata

The collected data originates from experimental series, which are detailed in scientific Open Access publications. The datasets will be referenced accordingly in these publications. The conventions used adhere to the general standards of pharmaceutical research, making them understandable to the relevant professional community without the need for extensive metadata collection. The context of the data is provided by the associated publications.

2.2 Making data openly accessible

Data that will be made openly accessible

All experimental series conducted for the characterization of material behavior and the pharmaceutical behavior of the manufactured dosage forms will be published, unless confidentiality agreements e.g. with external suppliers (especially material manufacturers) prevent it. If the geometric structure and material composition of the capsule are essential for interpreting the datasets, and publishing would not infringe IPR protection measures, these will be made available as CAD data. Standard data formats (e.g., 3mf, stl, stp) will be used, which can also be viewed with open-source software.

Use of Repositories

The generated data will be published via the B2Share platform provided by eudat.eu and linked with the corresponding publications through DOI references.

Methods and Software Tools to Access the Data

No special software tools are required to read the datasets, as they consist of simple diagrams characterizing material and release behavior. As mentioned above, the necessary CAD data will be provided in standard data formats that can be read with various freely available software. Since no separate software is needed to access the data, there are no plans to publish or document any software.

Decision Processes for Data Provision

Due to the small consortium, there will be no separate body for making decisions regarding data publication. Instead, these decisions will be made within the framework of the General Assembly.

2.3 Making data interoperable

As described above in section 2.2, the datasets are readable without special software, and the related CAD data necessary for interpreting the datasets will be provided in standard exchange formats (e.g., 3mf, stl, stp) that can be read with various freely available software. Special metadata are not necessary for the interpretation of the data and are therefore not planned. This approach ensures that the data is easily interoperable and accessible to the relevant professional community without the need for additional tools or metadata.

2.4 Increase data re-use (through clarifying licences)

Licensing of Data

All data will be published under the Creative Commons license type CC BY-NC (Attribution-NonCommercial).

Timeline to Make Data Available

The generated data will be released for publication only after a decision by the General Assembly. The General Assembly meets biannually, ensuring minimal delays in publication. Reasons for why data may not be published immediately or may be delayed include:

- The datasets reference information from third parties and are subject to existing confidentiality agreements.
- The consortium or parts thereof intend to file patents or implement other IPR protection measures as part of the project, and immediate publication of the data would be detrimental to this form of exploitation.

Since it is in the interest of the entire consortium to file patents and establish IPR positions as quickly as possible, any resulting delay in data publication will be kept to a minimum.

Re-Use of Data After End of the Project

The data will be available on the B2Share platform for at least five years after the project ends. The use of the data is governed by the Creative Commons license even beyond the end of the project.

Data Quality Assurance

The General Assembly will decide on the publication of the data and will also conduct a plausibility check of the datasets to be published. Additionally, the project's results are planned to be published in numerous peer-reviewed publications. Since these publications will be based on the released datasets, the peer-review process inherently provides quality assurance of the datasets by independent third parties.

3 Allocation of resources

Ensuring good scientific practice and thus guaranteeing a quality-assured data basis is the foundation of all research activities within the project.

Additionally, the budget for the work package "Dissemination & Exploitation" has been calculated with the consideration that it includes the workload for the quality assurance of the published data.

By using the B2Share platform, it can be assumed that there will be no additional costs for sustainably ensuring the accessibility of the generated research data.

4 Data security

Internal Data Storage and Exchange

The consortium uses a SharePoint platform administered by the Fraunhofer Society for storing and exchanging data within the consortium.

Security Measures by Fraunhofer Society

The Fraunhofer Society implements extensive measures to ensure a high level of data security in the operation of the SharePoint platform. This includes tools for versioning and data recovery, ensuring that data integrity and availability are maintained at all times.

Public Data Publication

As described, the publication of data will be conducted via the B2Share platform. This platform adheres to the European Union regulations for the security and integrity of the data stored there, ensuring that the published data is protected and remains reliable.

5 Ethical aspects

There are no ethical aspects to consider for this project, as no patient-specific or personal data will be collected.