Plan Overview

A Data Management Plan created using DMPonline

Title: Epigenetics and conformation of nucleic acids used for gene therapy (EPINUK)

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Project abstract:

The aim of the project “Epigenetics and conformation of nucleic acids used for gene therapy” is to implement research plans concerning the study of epigenetics and conformation of nucleic acids (hereinafter referred to as NA) and their regulatory proteins. The project will examine if modified RNA recognizes damaged DNA or if, instead, RNA modifications are a direct indicator of damage. This application will develop cooperation between a preclinical workplace, the clinical application sphere, and an excellent research team of experts in experimental and applied disciplines. Methodologies of mRNA modification will be optimized, which could be used in the future for the clinical preparation of mRNA vaccines. These could be a promising tool and not only limited to the treatment of tumors and other serious diseases. Through the specific key activity, the research group will further solidify its position as a top international hub for excellent research and create one of the world's finest research facilities dedicated to NA studies, which will be comparable with international standards. With a focus on support for internationalization and mobility, new internationally-recognized teams will be created to conduct nucleic acids research. International cooperation and mobility will be implemented in collaboration with prestigious European laboratories, and internationalization will be guaranteed by a scientific manager. The scientific work of the teams will be published in prestigious journals. An additional goal will be to build the highest quality mass spectrometry laboratory in the Czech Republic, which will expand the possibilities of analysis of nucleic acid modifications. In this respect, the infrastructure of the institutions involved will be extensively improved and modernized. Unique mRNA sequence modification methodologies that will target serious diseases will be optimized. The proposed mRNA sequences and their modifications will be tested in preclinical laboratories verifying the biological effects of mRNA vaccines on experimental models of cancer cells or ulcerative colitis.

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Copyright information:

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Data Collection

What data will you be collecting ?

Optimal data administration, data collection, and registration will be set up when the project is funded. Specific principles for data retention will be set, including archiving documentation for the obtained data, and ethical aspects of data storage, backup, and sharing will be ensured. In the proposed project, the position of data management expert, the data steward, will be established. The data steward will ensure the exchange of data and metadata between computer systems so that this exchange takes place accurately and predictably.

Proposed implementation steps will be established:

- Central database / Central data repository for storing generated experimental data.
- Transaction part / Data pumps to ensure automatic collection and validation of data from end measuring devices (microscopes, spectrometers, etc.)
- Web-based Data Management portal and user interface (UI) for user access to and management of research data. In addition, an environment for data sharing will be created.

Central database: We assume the creation of a central database/central data repository for storage and managing data obtained from research activities. The exact form and parameters of the solution will be based on the accumulated requirements of stakeholders (users and other stakeholders) from the 1st phase of the project - Analysis.

Data inputs: We expect to create a series of data pumps. This tool will extract and automatically upload data from all data sources.

We expect the creation of so-called universal connectors, which can be parametrically set in the future for other new sources of a similar format. Universal data connector is currently expected in the form: Input for measuring instruments that allow direct communication with the DB server and input for data in Excel format.

Prepare the data model: The data model serves as a map to show the links and relationships between each stored data. When designing the data model, we take into account all input data sources, security requirements, search requirements, and data access. We will create a data model in the form of a database diagram that will describe all tables and their links to each other.

Search, data acquisition, and data outputs: We will search for data through forms in the web environment. After opening the environment, you will be able to select from preset views of the data and filter their content according to the criteria you set. After searching for the required data range, you will be able to save the data in CSV to the local disk of the computer, which can then be used in other software and applications for further processing as statistical evaluation or visualization. From this place, users, in cooperation with the data manager, will be able to draw updated and validated data for further processing easily.

Data access security and GDPR: The central database will also ensure data security from the GDPR perspective. Users, in cooperation with data managers, have the option to time the data (exact date in the future) when sensitive data will be automatically anonymized or deleted in a controlled manner.

User roles: To ensure controlled and controlled access to data according to clearly specified rules, we will create a series of database access user role levels that will meet clear transparency and the ability to identify a person accurately. The exact specifications and role levels will be specified in the System Design and Implementation phase based on the findings from the Analysis phase.

Phases of the project

Phase 1 – Analysis:

We will define the scope and objectives of the project: We will clearly define the purpose and objectives of the project as well as its possible limitations. This will help us manage the development process and ensure that the resulting system meets user needs and key requirements.

Collect requirements: We collect and document functional and non-functional software requirements and jointly prioritize them based on their value to users and stakeholders. At this stage, we will work closely with all stakeholders to understand your needs and preferences, as well as explore industry standards or best practices that will be useful for implementation. System design and implementation:

We design the system: We develop a basic software design, including the overall architecture, user interface, and data model. This phase will involve creating models or prototypes to visualize the final system and ensure that it meets the requirements.

Phase 2 – Implementation:

We will implement the system: A specific code platform will be created with the required functionalities.

We will test the system: We will thoroughly test the software to make sure it meets the requirements and is free of errors. It will mainly be about creating test cases, carrying out tests, and correcting the identified deficiencies.

We deploy the system: We install the software in a production environment and ensure that it is properly configured and optimized for performance. We also train users in the use of the software and create configuration and user documentation.

Phase 3 - System Maintenance:

We will maintain the system: We will regularly monitor the performance and usage of the software. We also collect feedback from users to identify any issues or areas for improvement. We will use the information obtained to update and improve the software as needed continuously.

Mandatory procedures fulfilling the principles of open science will be as follows:

1. a) Three legible electronic copies of the final reviewed or published version of any manuscript accepted for publication shall be deposited in the repository system for scientific publications on the day of publication. Articles will be published as Open Access, including sources of primary data, stored in the data repository of the Institute of Biophysics of the Czech Acad. Sci.
2. b) Monographs and other long text formats shall be made available under the terms of a public license, excluding modification of the publication or its commercial use.
3. c) Information shall be provided (through the data steward managing the repository) on any other research output or any other tools needed to verify the conclusions of the scientific publication.
4. d) Raw data will be open and managed by the data steward.

Who will be involved in your data collection ?

Open access in science promotes cooperation between scientists and scientific institutions by facilitating access to scientific texts and data. Therefore, one of the important goals of the Institute of Biophysics of the Cezch Acad. Sci. is the implementation of a specialized Data Management system according to the FAIR Data Principles, which will provide a modern system infrastructure for the management, storage, and publication of data that will be acquired during research. The role of the data steward, and project manager, will be established when the project is funded. IT infrastructure of the Institute will be modernized to fulfill all conditions of FAIR principles:
Findable: Research data will be easily traceable through standard metadata and cataloging tags. **Accessible:** Research data will be accessible through open licenses or under specified conditions. Interoperable: The research data will be machine-readable and compatible with other systems. **Reusable:** Research data will be reproducible and can be used for further research or applications.

Ethics

Give a description of your Ethics

The Ethical Code of the Institute of Biophysics of the Czech Acad. Sci. (hereinafter referred to simply as “the IBP” or “the Institute”) represents a summary of moral requirements, rules, and principles determining the methods and procedures all employees follow when performing their work activities within the IBP. These requirements, rules, and principles are, above all, fundamental principles of human morality and require not to tolerate any discrimination or unequal treatment due to nationality, citizenship, race, gender, sexual orientation, religion, or a lack thereof, world view, or social status; furthermore, they require not to tolerate any corruption or other forms of dishonest conduct in any shape or form. IBP employees are aware that education, research, and innovation are the fundamental pillars of the development of today’s society. Trust in science is based on trust in the honesty of researchers as well as non-researchers when striving for new findings and results. The findings and results and their interpretation may be verified by the broader scientific community, whose members are the main addressees of these new findings and results. For science to remain trustworthy, it is essential for all IBP employees to be guided by the basic principles of morality, particularly honesty, and righteousness. IBP employees assume moral responsibility for all their work activities and the impact they have on society and the environment, which can be influenced by their actions and behavior. The Ethical Code is based on, among others, the principles of the currently valid Ethical Code for Researchers of the Czech Academy of Sciences. Furthermore, the Ethical Code is based on the principles of the Ethical Framework of Research, i.e., Czech Republic Government Resolution from 17 August 2005 No. 1005; the European Charter for Researchers, 2005/251/ES, Official Journal of the European Union of 22 March 2005; Rules of Good Scientific Practice, adopted by the Senate of the Max Planck Society on 24 November 2000; The European Code of Conduct for Research Integrity, 2011. As an internal rule, the Ethical Code is, together with the generally binding legislation, particularly labor law legislation and other internal rules, among the rules which are of utmost importance and represent a basic specification of the ethical norms applicable to every IBP employee, the IBP requires respect and compliance with these norms. Therefore, each IBP employee shall be aware that respect and observance of the ethical dimension of work and a good reputation are extremely important for the institution to be perceived in a good light. The Ethical Code emphasizes that ethical awareness is an essential part of the professional education and practice of all employees, and the ability to comply with the ethical norms and commitment thereto is an elementary aspect of the quality and high standard of research activities of the IBP.
Principles of publishing of findings and research results
A researcher:
a) may be cited as author or co-author of a text or publication if they creatively contribute to the creation thereof, e.g., the study designs and experiments and their implementation, to analysis, interpretation, theoretical processing, or data modeling, or to the creation of the publication, and if they agree to the co-authorship,
b) recognizes, in the text or publication, the scientific contribution of their predecessors and colleagues, which the researcher builds upon and provides a clear reference to the relevant source(s) when quoting the findings of other authors,
c) cites significant works which are not in agreement with their own results,
d) in case they find a significant error in their own published data, the researcher takes appropriate steps and adequate measures to remedy the situation, e.g., prints errata or other corrections,
e) does not unnecessarily divide the results and findings into several texts and publications to artificially increase the number of published works,
f) does not publish in an ethically questionable manner and does not use ethically

questionable publishing platforms.
Scientists of the Institute of Biophysics, Czech Academy of Sciences published their results with the aim of transmitting such results and findings to the scientific community, not just for the purpose of reporting works as published scientific outputs.