



PROJECT DELIVERABLE REPORT

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* Security: PU – Public; PP – Restricted to other programme participants (including JPI Services);
RE – Restricted to a group specified by the consortium (including JPI Services);
CO – Confidential, only for members of the consortium (including JPI Services)

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1- INTRODUCTION

Currently most datasets available within the ENPADASI partners were retrieved in project/consortia that lacked a paragraph stating the data sharing regulations and the intellectual properties rights (IPR) are therefore undefined. This lack of establishment of those rules makes data sharing after the finalization of a project problematic. Generally data sharing can be separated in metadata sharing and raw/individual data sharing. Therefore those types of sharing are described independently. In this deliverable we describe the issues and have some recommendations for the future.

2- LEGAL ISSUES RAISED BY THE DATA SHARING

2.1 METADATA SHARING AND LEGAL POINT OF VIEW

Metadata are data describing the outline and variables of a study along with quality assurance parameters integrated into the study design. Metadata are generally open for sharing, for instance the public registration or ethical approval of a study would require metadata to be public before the study may be started (e.g. www.clinicaltrials.gov). Generally these are also no IPR connected to this type of data and therefore hardly any or no agreements are necessary. In rare cases there are studies where metadata are kept secret due to IPR interests (e.g. treatments with specific compounds), however such studies cannot be published later in most peer-reviewed scientific journals and such studies are therefore not a main focus for ENPADASI. For this reason those studies are not covered by this deliverable.

2.2 DATA SHARING AND LEGAL POINT OF VIEW

- In order to share other data than metadata (i.e. detailed results and outcomes) between ENPADASI partners the legal arrangements in the consortium agreements should be checked and agreed by the consortium/program producing the data.

- Legal requirements according to data safety rules and ethical agreements related to your data should also be checked (see for this point also the other deliverables of WP5); fully anonymised data (i.e. data are fully anonymised when nobody (including the researcher) can identify the subject by the data set. Meaning that the ID-log and any other documents containing information that can be used to connect data with the subject has been destroyed) may be shared for any purpose in most countries (be aware of possible country specific rules in your country). Pseudonymised data may be shared only for purposes that are pre-defined in the ethical protocol and only pending on a data-transfer agreement between the data controller and the data processor. By new legislation the privacy of the subjects within the study should be secured as much as possible. This means that all available ICT solutions should be incorporated in data systems that contain non-anonymous or pseudonymized data, see also D5.1 and D5.2.



- If data is shared openly with everybody, there will be no IPR to the potential inventions resulting from use of the data by anybody. This is analogous to publishing data in a journal.
- if data transfer is planned between the data owner/consortium and new collaborators the data transfer agreement should be signed and should include a section on IPR.

3- APPROPRIATED EMBARGO PERIOD

As stated many consortium agreements currently lack a solid description on data sharing. This is remarkable as most data are indirectly published in journals that often require data sharing upon publication. Moreover, this also means that data are not used to their full potential. Important in such a consortium agreement is to include an embargo period, meaning the deadline after which data will be publicly shared. Currently the embargo period is already under discussion between funders and researchers. To our opinion an embargo period of maximally 3 years after finalization of a complex study is realistic. Generally the study is conducted during the period of the project/program and most simple analysis are done in that period as well. However, very often the more complex analysis by the consortium partners is only done in the years after the end of the project. Then writing an article on the outcomes often also takes a year, especially with the many co-authors in for instance EU projects. Then preparing the data and submitting the article takes another year. So in practice several years pass before the data could be made public in order to protect the publication rights and IPR of the consortium.

4- IPR ON THE DISCOVERY MADE ON COMBINED DATA: LICENCE

After sharing data people outside the original project or consortium may generate IPR on the data. The data transfer agreement may include specific details if only shared between specific persons or groups. The ownership may be either shared or owned by the inventors. If data are publicly shared it will be very hard to specify the owners of the invention, if not just owned by the people performing the analysis. This is, 1) because multiple datasets can be used for the analysis revealing the new information and potential for an invention, and 2) because it is hard to make arrangements for this. Therefore, we would recommend publishing data under the creative commons license. However, this will not always be possible or agreed upon. The FAIR data principles (used within ENPADASI) include solutions to include data on the IPR, which makes this information machine readable and thereby some of the above issues will be overcome.

ANNEX: TOOLS AND PRACTICAL INFORMATION FOR THE FUTURE DATA PROVIDER & USER

ANNEX 1: GENERIC PARAGRAPH FOR CONSORTIUM AGREEMENT



JOINT PROGRAMMING INITIATIVE – A HEALTHY DIET FOR A HEALTHY LIFE EUROPEAN NUTRITION PHENOTYPE ASSESSMENT AND DATA SHARING INITIATIVE

“The right of ownership to joint new foreground knowledge (*..state any limitations..*) shall belong to both Parties in proportion to the employees’ individual intellectual contributions. Any disposal of the Joint New Knowledge, including patenting, publication, or transfer of one Party’s rights shall require agreement between the Parties.”

In order to settle disagreements it is recommended that a paragraph is added to handle such issues:

“This agreement shall be construed and interpreted pursuant to the laws of [state the *Country*]. Venue for any litigation concerning this agreement shall be the [*state the name and location of the court*]. [*State any additional agreements on arbitration*]”