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Re-use of Research Data

Access to research data in the European Union is granted upon decisions made by entities that finance and conduct research. This matter has been changed by the Directive (EU) 2019/1024 of the European Parliament and of the Council of 20 June 2019 on open data and the re-use of public sector information. After implementation of the Directive, opening of research data will become a legal obligation and everyone everywhere will be able to use them. However, the Directive gives member states significant freedom. Considering the above, academic communities should become partners in the dialogue with political decision-makers. The paper describes the provisions of the Directive and the seven recommendations regarding national regulations related to re-use of research data, with particular consideration of their use in medicine.

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Keywords:
re-use of research data, re-use of public sector information, research data, open access, research data in medicine, health and medicine

https://doi.org/10.36128/priw.vi36.292

1. Introduction

Open science in essence refers to the transformation that science is undergoing due to globalization and ICT—just like any other sector in society—and it is therefore very likely that in the long term the adjective „open" should not be necessary as science will be open by default[1]. This can happen in Europe as a result of implementation of the directive on open data and the re-use of public sector information[2]. Thanks

1 Jean-Claude Burgelman, Corina Pascu, Katarzyna Szkuta, et.al. „Open Science, Open Data, and Open Scholarship: European Policies to Make Science Fit for the Twenty-First Century" *Frontiers in Big Data*, 2 (2019): 2019.00043. doi.org/10.3389/fdata.2019.00043.

2 Directive (2019): Directive (EU) 2019/1024 of the European

to the Directive 2003/98/EC specifying the rules of re-use of public sector information (PSI) every person, from all over the world, is able to make use of valuable data (Directive 2003)[3]. The entities from EU member states, indicated in the Directive, are basically obligated to grant free access to these data. As a result of the review of the Directive 2003, the scope of these data has been significantly increased by the aforesaid Directive 2019/1024, in particular by research data scientific knowledge is based on. The adopted rules regarding granting open access to research data are worth analyzing in order to assure their best possible application. The Directive 2019/1024 has to be implemented in EU member states until July 17, 2021. Currently, granting access to research data is made upon decisions of financing and research conducting entities. Over the years, integrity of research in the field of health and medicine and related reporting activities have been improved thanks to requirements on observing reporting guidelines, such as CONSORT or certain campaigns, for example The Lancet REWARD[4]. Demands to institutionalize actions regarding research data and imitative research based on such data have been raised by the open science movement in relation to all fields.

In case of directives we deal with the two-staged regulation. They point out a result to be achieved, while particular methods to make it happen are to be decided by member states during implementation and they generally have a free hand in this matter. The EU encouraged member states to implement changes, obligating them to grant open access to research data, however their scope and character depend on national legislation. It is a great opportunity for academic communities from various fields of science, that should participate in the dialogue with political decision-makers as partners. It is a unique possibility to open science in a real way, while simultaneously respecting constraints resulting from intellectual property rights and autonomy

Parliament and of the Council of 20 June 2019 on open data and the re-use of public sector information (recast) (Official Journal L 175.56). https://eurlex.europa.eu/legalcontent/EN/TXT/HTML/?uri=CELEX:32019L1024&from=EN. [accessed:24.08. 2020].

3 Directive (2003): Directive 2003/98/EC of the European Parliament and of the Council of 17 November 2003 on the re-use of public sector information (Official Journal L 345, 31/12/2003). https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32003L0098&from=en. [accessed: 24.08.2020].

4 The Lancet REWARD (REduce research Waste And Reward Diligence). https://www.thelancet.com/campaigns/efficiency. [accessed: 24.08.2020]; Research data. https://www.elsevier.com/about/policies/research-data. [accessed July 28.07.2020]; Benkler Y. The Wealth of Networks: How Social Production Transforms Markets and Freedom. New Haven and London: Yale University Press; 2006.

of entities conducting and financing scientific research. The said directive and the adopted national solutions in member states are also important for scientists from outside the EU. They will be able to make use of the said opening process. Thus, it should be thoroughly assessed how granting open access to research data should be performed in order to assure actual and practical impact on conducting of research, while treating the changes in the directive as an important breakthrough in terms of assuring openness within science. This paper is going to present the stipulations of the directive and to enunciate the possible recommendations regarding national regulations on re-use of research data. The text will refer to research data with particular attention paid to their use in medicine, due to the time of the pandemic, which particularly highlighted research data needs in this area.

Re-use of PSI, including research data, is related to the changes that occurred in the early 21st century, known as the Internet Revolution[5]. It was characterized by increasing importance of new technologies and development of the Internet and it was the time of development of first innovative network websites based on Web 2.0[6]. The characteristic feature of Web 2.0 websites is interaction and cooperation among users within a virtual community. This enabled a change in social behavior by allowing people to share not only their emotions and facts on their daily lives, but also effects of their work. There were also demands regarding openness of content, including sharing articles and other pieces of work. Thanks to technology it was possible to cooperate and share information and data. Sharing effects of one's work with any interested person is called social production of symbolic goods, that is presented as opposition against the information industrial economy[7]. Its model example is Wikipedia and in source literature it is the end of mass communication, in compliance with its definition valid in the 20th century, replaced by mass self-communication. Thanks to digital technologies it can be reached by the global audience and is used to post individual opinions being independent acts of independent persons[8]. The technological changes being described

5 Tim O'Reilly, *What is Web 2.0.* (Sebastopol: O'Reilly Media Incorporated: 2007), 92-99.

6 John Musser, Tim O'Reilly, *Web 2.0 Report: Principles and Best Practices* (Sebastopol: O'Reilly Media Incorporated: 2007); Manuel Castells, *Communication Power* (Oxford: Oxford University Press: 2009).

7 Yochai Benkler, *The Wealth of Networks: How Social Production Transforms Markets and Freedom* (New Haven and London: Yale University Press; 2006).

8 Douglas Rushkoff, *Open Source Democracy: How Online Communication is Changing Offline Politics* (London: Demos; 2003), 70-71. https://www.immagic.com/eLibrary/ARCHIVES/GENERAL/DEMOS_UK/D030000R.pdf [accessed: 24.08 2020].

had impact on people's attitude and were also treated as an element of social changes which purpose was to improve performance of functions of state[9]. It was proposed to make use of „collective intelligence of citizens" and to open the decision-making process, similarly to social production. As a neutral platform, the Internet encourages users to be active and it can be seen as a metaphor of awakening of public will to become involved in public matters[10].

In this context various concepts of opening and participation are created, with use of different terminology, ideological constructs or, finally, real actions. We are inside the currently evolving process of data opening being possible thanks to the Internet, but the origins of this process should be traced back several decades ago and found in the idea of free software (Free Software Foundation)[11]. The Open Access Movement started in the 1990s. The definition background of open access can be found in the following three documents: the Budapest Open Access Initiative, the Bethesda Statement and the Berlin Declaration[12]. The Budapest Open Access Initiative is treated as a gold standard for the rest of the aforesaid documents, as it underlines the

9 Miriam Lips, „*E-Government is dead: Long live Public Administration 2.0",* [in:] *ITC, Public Administration and Democracy in the Coming Decade*, ed. Albert Meijer, Frank Bannister, Marcel Thaens (Amsterdam-Berlin-Tokyo-Washington, DC: IOS Press, 2012), 30-41; Richard M. Stallman, *Free Software Free Society: selected essays of Richard M. Stallman* (Boston, MA, GNU Press, 2002). https://www.gnu.org/philosophy/fsfs/rms-essays.pdf.

10 Beth S. Noveck, *Wiki Government: How Technology Can Make Government Better, Democracy Stronger, and Citizens More Powerful* (Washington, DC: Brookings Institution Press, 2009).

11 Peter Wayner, *Free for All. How Linux and the Free Software Movement Undrcut the Hihg-TechTitans.* http://www.sisudoc.org/samples_by_language/en/pdf/free_for_all.peter_wayner.landscape.a4.pdf. [accessed: 28.07.2020]; Budapest Open Access Initiative. https://www.budapestopenaccessinitiative.org/. [accessed: 10.07. 2020; 28.07.2020].

12 Bethesda Statement on Open Access Publishing. http://legacy.earlham.edu/~peters/fos/bethesda.htm. [accessed: 24.08.2020]; Berlin Declaration on Open Access to Knowledge in the Sciences and Humanities. http://oa.mpg.de/lang/en-uk/berlin-prozess/berliner-erklarung. [accessed: 28.07.2020]; Budapest Open Access Initiative. https://www.budapestopenaccessinitiative.org/. [accessed: 10.07.2020; 28.07.2020]; Bogdan Fischer, „Autorskoprawne konteksty ponownego wykorzystywania danych badawczych", [in:] *Sto lat polskiego prawa handlowego. Księga jubileuszowa dedykowana Profesorowi Andrzejowi Kidybie*, t. II, ed. Małgorzata Dumkiewicz, Katarzyna Kopaczyńska-Pieczniak, Jerzy Szczotka (Warsaw: Wolters Kluwer; 2020), 553-576.

right to get acquainted, use, copy, distribute, publically share and disseminate derivative works, index, transfer as input data for computer software or any other fair use of material, without financial, legal or technical constraints. Thus, it covers not only data accessibility, but also their derivative use understood as the ability to make copies and to disseminate them. Such defined opening is conditioned by respecting moral rights by recognizing of authorship, controlling of integrity of works and assuring correct citation[13]. The assumptions for public data opening reach beyond strict referencing to data and are related to other theoretical paradigms base on the thematic „opening", such as open educational resources, open science or open government. The latter term, though used extensively, is not understood uniformly[14]. It is defined as use of technology, especially the technology of cooperation in the Web 2.0 core, in order to solve common problems at the local, national and international levels in a better way[15]. Other authors introduce different definitions of this term. They also use different terms, such as „Wiki Government" or „Public Administration 2.0"[16]. Within the perspective adopted in this analysis it is important that one of the postulates of the aforesaid movements was to grant open access to data financed from public funds. It was not only the matter of assuring the right to access to public information, but also of opening state information resources. Supporters of this movement treated public data as a significant good being a driving force of the information revolution and importance of access to these data was compared to importance of access to means of production for the industrial revolution. Here the postulates of open government and open science met, however it did take some time. Initially, members of the movement called for re-use of data created by public authorities and this matter was referred to in this way in the Directive 2003. It was only the amended version of this directive that finally sanctioned

13 Amanda Clarke, Mary Francoli, „What's in a name? A comparison of »open government« definitions across seven Open Government Partnership members" *JeDem*, No. 6 (2014): v6i3.227. doi: 10.29379/jedem.v6i3.227.

14 Tim O'Reilly, „Government as o platform", [in:] *Open Government: Collaboration, Transparency, and Participation in Practice*, ed. Daniel Lathrop, Laurel Ruma (Sebastopol: O'Reilly Media Incorporated, 2010), 11-42.

15 Benedikt Fecher, Sascha Friesike, „*Open Science: One Term, Five Schools of Thought",* [in:] *Opening Science*, ed. Sönke Bartling, Sascha Friesike (Cham, Heidelberg, New York, Dordrecht, London: Springer Open, 2014), 17-48. https://link.springer.com/content/pdf/bfm%3A978-3-319-00026-8%2F1.pdf. [accessed:_24.08.2020].

16 Lips*, E-Government is dead: Long live Public Administration 2.0,* 30-41; Stallman, *Free Software Free Society*.

the merger of the aforesaid attitudes. The debate on opening of science was going into a complete different direction and was closer to discussions about open access. It assumed granting open access to research data not by a decision made by public authorities, but by the interested parties.

The term of open science is ambiguous[17]. In terms of this paper the most important are opinions of followers of the democratic school, as they are converging with the directive goals specified in the recital no. 27. According to them, open access policy's purpose is to provide scientists and the general public with access to research data at the earliest possible stage of the dissemination process and to facilitate their use and re-use. Open access helps to improve quality, limits research duplication, brings forward scientific progress, counteracts frauds and can be also profitable for economic growth and innovativeness. The similar demands can be found in the source literature.

2. Importance of the directive for granting open access to research data

On the basis of the art. 10 sect. of the Directive 2019 the EU member states are obligated to conduct the „open access policy" regarding research data financed from public funds, in compliance with the rule of „openness by default" and the FAIR rules. Within this policy they should support availability of research data by means of adoption of a national policy and undertaking appropriate actions with purpose to assure such data are publicly available. Entities obligated to its execution are organizations conducting and financing scientific research. In the directive the EU legislator defines the guidelines for the activities performed in member states in this matter. Firstly, these activities should refer to research data within the scope they were created as a part of research financed from public funds. As a result, the term of „research data" should be discussed. On the basis of the directive documents are subject to re-use and it defines a document as "any content whatever its medium (paper or electronic form or as a sound, visual or audiovisual recording); or any part of such content" (art. 2 sect. 6). Apart from the definition of „documents", the directive establishes the specific category of documents, namely research data. According to the Directives, the term of „research data"' means documents in a digital form, other than scientific publications, which are collected or produced in the course of scientific research activities and are used as evidence in the research process, or are commonly accepted in the research community as necessary to validate research findings and results (art. 2 sect. 9). Research data are documents that meet these both conditions concurrently and are only in the digital form. These can be text

17 Jenn Riley, *Understanding metadata what is metadata, and what is it for?* (Baltimore, MD: National Information Standards Organization (NISO).__https://groups.niso.org/apps/group_public/download.php/17446/Understanding%20Metadata.pdf.

data expressed as words or digits, in the graphical (photos, drawings, charts, maps), audio or mixed forms, or the audiovisual form saved as digits. According to the recital 27 of the Directive 2019, research data include statistics, results of experiments, measurements, observations resulting from fieldwork, survey results, interview recordings and images. They also include metadata, specifications and other digital objects. Metadata are structurized information describing, explaining, localizing and facilitating in any other way the process of finding, use or management of information assets. Metadata are often called „data about data" or „information about information"[18]. Metadata can be various described research data. They allow for machines to recognize, read and connect them. Currently, it is the very important issue because of the large amount of research data. They enable searching for information or other objects saved in the digital form, as well as their control, understanding and long-term storage and management. The second condition that must be met by research data refers to a method of their collection. Research data are collected or produced within the research and scientific activities and used as evidence during the research process or must be generally accepted in the scientific community as necessary to verify correctness of findings and research results. Scientific papers are not research data as the latter differ from scientific articles relating to and commenting on findings resulting from scientific research being their source (the recital no. 27 of the Directive 2019).

Also, the Directive does not specify what it means that research is financed from public funds. It should be specified by national legislators by analyzing a research financing method in a given country and by determining to what extent co-financing of research excludes the obligation to make data available to be reused. For example, medical research may be co-financed by private funds, including by large pharmaceutical companies. It should also be underlined that national access policies should be arranged in an attractive way, enabling it to be adopted also by entities not obligated to do so.

Secondly, the activities being performed should be compliant with the „open by default" and FAIR rules. „Open by default" is one of the rules specified in the International Open Data Charter[24] constituting the set of rules and good practices regarding granting open access to public data. By „open by default" one should understand actions performed by public authorities towards citizens and other entities, presuming availability of data. However, according to these rule, not all data are available. Public authorities can limit data availability because of justified reasons. The „open by default" rule also includes creating the culture of openness not only by means of political decisions and legal solutions, but also via training and awareness-raising

18 International Open Data Charter, September 2015. https://opendatacharter.net/wp-content/uploads/2015/10/opendatacharter-charter_F.pdf.

programs, tools, guidelines and communication strategies (Principle 1, sect. 13-17)[19]. As there are no other references to the "open by default" rule in EU documents, it should be concluded that, regarding the Directive, the rule should be understood as specified in the Charter. It means that national policies should be based on presumed availability of research data financed from public funds, with the exceptions specified in the art. 10 sect. 1 sentence 2 of the Directive 2019. The FAIR rules are related to data openness, however to a limited extent, as not all open data need to be compliant with the FAIR rules. They have been developed with participation of academic communities, business sector, research financing agencies and scientific publishing houses as guidelines with purpose to improve the infrastructure supporting re-use of scientific data[20]. To have these rules be popularized more efficiently, their name includes the acronym derived from the words „**f**indable", „**a**ccessible", „**i**nteroperable" and „**r**eusable". The adjective „FAIR" itself brings a positive message, as it means „fair", „just", but also „equal" and „indiscriminating"[21]. According to the FAIR rules, all research objects should be findable, accessible, interoperable and reusable (FAIR) by both machines and humans. The said rules have been recognized and accepted by the EU[22]. They were also adopted as a part of the Horizont 2020 program[23]. The EU estimates the costs

19 Mark D. Wilkinson, et al., The FAIR Guiding Principles for scientific data management and stewardship. *Sci. Data* 3:160018 doi: 10.1038/sdata.2016.18.

20 Barend Mons, Cameron Neylon, Jan Veltrop, et. al. *Cloudy, increasingly FAIR; revisiting the FAIR Data guiding principlesfor the European Open Science Cloud. Information Services & Use.* (37): ISU-170824. doi: 10.3233/ISU-170824.

21 European Commission. Final Report and Action Plan from the European Commission Expert Group on FAIR Data European Commission Expert Group on FAIR Data. doi: 10.2777/15242018. Published November 2018. Accessed August 24, 2020.

22 Executive Board of the European Open Science Cloud (EOSC) – Strategic Implementation Plan, 2019. Brussels: Directorate General Research of Inovation European Commission. Julu 2019. doi: 10.2777/202370. [accessed: 24.08.2020; Directorate General Research of Inovation European Commission. Guidelines on Data Management in Horizon 2020. Juli 2016. http://ec.europa.eu/research/participants/data/ref/h2020/grants_manual/ hi/oa_pilot/h2020-hi-oa-data-mgt_en.pdf. [accessed: 24.08.2020].

23 European Commission. Cost-Benefit analysis for FAIR research data – Cost of not having FAIR research data, Published March 2018. March 2018. doi: 10.2777/02999. [accessed: 24.08.2020].

of failure to implement these rules in scientific research to be 10.2 bln EUR annually[24]. The rules themselves are not going to be described here and will be considered in the description of the recommendations for the national legislator in the next subsection of the article. Thirdly, the process of granting open access to data should consider the re-use limits related to intellectual property rights, personal data protection and confidentiality, security and legitimate commercial interests, in compliance with the following rule: „open as much as possible, closed only if necessary".

In the art. 10 sect. 2 of the Directive the legislator specifies the minimum scope of research data re-use that may have both the commercial and non-commercial purpose. This provision assumes that research data are made accessible for re-use after the two conditions are jointly met. These data are financed from public funds and have to be made available to the public by scientists, organizations conducting scientific research or organizations financing scientific research, via the institutional or thematic repository. In this context legitimate commercial interests, activities related to knowledge transfer and already existing intellectual property rights are considered. Such a solution seems to explain the assumptions of the recital 28 of the Directive 2019, in which it is underlined that, in order to avoid administrative workload, the obligations resulting from this directive should be applied only to these research data that have already been made accessible to the public by scientists, organizations conducting scientific research or organizations financing scientific research, via the institutional or thematic repository, and should result in neither additional costs related to downloading of data sets, nor a requirement of additional data maintenance. Member states can extend application of this directive to research data made available to the public via other data infrastructures than repositories, by publishing via open access, in the form of a file enclosed to a paper, an article within which non-processed data are made available (data paper) or a paper in a scientific journal in which high quality data sets are made available (data journal). Documents other than research data should still be excluded from the scope of this directive.

3. Recommendations for the national legislator

Considering the postulates of open data and experience related to providing access to information on public authority activities, eight recommendations can be expressed for the national legislator with purpose to have

24 Gaetano R. Lotrechiano, „Defining Collaboration Science in an Age of Translational Medicine" *Journal of Translational Medicine*, No. 2 (2014): 2-8. https://www.jscimedcentral.com/TranslationalMedicine/translationalmedicine-spid-collaboration-science-translational-medicine-1023.pdf.

the directive transposed. The final content of statutory solutions will have influence on development of factual scientific knowledge, including in the field of medicine, the ability to refer not only to knowledge created by other researchers, but also to verify the grounds of this creation, as well as multiple and versatile use of baseline data, including raw data.

Recommendation no. 1: implementation of open access to research data in public involvement. The directive specifies the minimum scope of obligations of member states, obligating them to conduct the appropriate policy, however, decisions of national authorities often and unfortunately result in implementation of only the minimum requirements specified in the directive. This was the case with transposition of the Directive 2003/98/EC. No consideration was made regarding the effect to be achieved as a result of implementation and for what purpose the directive was passed. The key point for implementation of the Directive 2019 in terms of research data is to determine the goal of transposition and it should be preceded by the intense dialogue between the academic community and the general public in order to increase trust to scientific research and results made available. The dialogue should not be limited to mechanical and thoughtless transposition of the directive provisions to the national legislation and "pretending" that the open access policy is indeed being implemented. This is why the actions to be performed by member states should be preceded by public consultations with representative members of academic communities of various fields and disciplines, not only the ones being potentially important for the economy, as the purpose of granting open access to science is not sole economic growth, but also development of science, without duplication of scientific research, that will allow for better spending of public assets for these pieces of research. Considering the above, the dialogue should be conducted with participation of representatives from various fields of science, in order to assure preparation of a solution acceptable by academic communities. They should know for what purpose science needs to be opened and what profits this brings and should not find the implemented regulations as additional bureaucratic workload and feel forced to disclose effects of their work for free. This recommendation is connected with the next one.

Recommendation no. 2: building the construct of re-use of research data on the culture of openness. Within the performed activities the member states should make efforts in order to build the culture of openness and to encourage to apply pro-active solutions related to a method of planning and conducting scientific research. In case of re-use it is as important as regarding access to public information. Cooperation between entities conducting and financing research and scientists themselves is necessary for re-use of research data. Let us pay attention to the fact that within the appropriate pro-active openness policy protection of both personal data and intellectual property rights will not be a limitation. Considering

the above, it was proposed to appoint the plenipotentiary for research data, as mentioned in the recommendation no. 7, being the leader in the area of the open approach to research data.

Recommendation no. 3: making efforts in order to assure translation via implementation of communication protocols and adopting systemic solutions ensuring the ability to use research within various fields and disciplines. This is going to be a method of implementing the postulate of „collaboration science" by means of interdisciplinary and transdisciplinary activities[25]. Transparency of research data communication and existence of translational and adaptation mechanisms will enable their opening for use not only in the multidisciplinary context, but also, as specified above, in terms of inter- and transdisciplinarity. Authorization to prepare grounds of translational procedures will assure transfer of information to repeated and final recipients and, finally, transfer of the said procedures to the general public. In medicine there are solutions that can be an example of good directional approach. This is translational medicine[26]. Its purpose is to translate achievements of basic science into everyday clinical practice), thus filling in the gap between basic and clinical research)[27]. Completely different disciplines are based on this type of experience, for example the building industry where the necessity of data transfer between science and practice is underlined[28]. So, on the one hand, it should be recommended to implement in national legislation

25 Julie T. Klein, „Interdisciplinarity and Transdisciplinarity: Keyword Meanings for Collaboration Science and Translational Medicine" *Journal of Translational Medicine Epidemiology*, No. 2 (2014): 2-7. https://www.jscimedcentral.com/TranslationalMedicine/translationalmedicine-spid-collaboration-science-translational-medicine-1024.pdf; Nikolaos C. Keramaris, Nikolaos Kanakaris, Chris Tzioupis, et.al. *Translational research: from benchside to bedside*, Injury, No. 6 (2008): 643-650. doi: 10.1016/j.injury.2008.01.051; Ioan Fazey, Lukas Bunse, Joshua Msika, Maria Pinke et al. „Evaluating knowledge exchange in interdisciplinary and multidisciplinary stakeholder research" *Global Environmental Change*, Vol. 25 (2014): 204-220.

26 Fazey, Bunse, Msika, Pinke, et al., „Evaluating knowledge exchange in interdisciplinary and multidisciplinary stakeholder research", 204-220; Brian C. Drolet , Nancy M. Lorenzi, „Translational research: understanding the continuum from bench to bedside" *Translational Research*, 157 (2011):1-5. doi: 10.1016/j.trsl.2010.10.002.

27 Fazey, Bunse, Msika, Pinke, et al. „Evaluating knowledge exchange in interdisciplinary and multidisciplinary stakeholder research", 204-220.

28 Marianne J. D'Onofrio, „A framework for a trans-disciplinary, translational research group for building innovation" *Procedia Engineering*, 118 (2015): 1274-1281.

the grounds for establishment of teams that would be designated to create the interdisciplinary and transdisciplianry translation model and data adaptation. Solutions in this matter can be introduced into legal regulations, but also within soft law, for example in good practice codes or data management strategies. It is also possible to consider implementation in large research projects of an obligatory element, namely development of translation and adaptation protocols, in order to ensure that the research data created within this process could be used in other fields of science. This recommendation is related to the recommendation no. 5 in terms of making data findable. On the one hand, creating of unique identifiers, yet to be discussed, will allow to avoid duplication of terminology for the same objects in different pieces of research and repositories, while on the other hand it will facilitate the process of development of communication, translation and adaptation protocols.

Recommendation no. 4: assuming presumed openness of research data financed from public funds. Financing of research data from public funds should mean these are open data. Member states can make exceptions from this rule, as permitted in the directive. Each closing of research data should be given clear factual and legal justification. Member states can also specify, when co-financing of research from non-public funds has impact on lack of application of the solutions being adopted.

Recommendation no. 5: **research data financed from public funds should be FAIR.** Law regulations should standardize a product made accessible for re-use. It should be recommended to make financing of research dependent on the obligation to apply the FAIR rules. In this context the law should impose the obligation to apply these rules for research financed from public funds. An assessment of compliance with these rules should be an obligatory element of project evaluation and subsequent audit during the project and after audit is completed. However, the general character of these rules should be remembered. Considering the above, their inclusion into valid law should be preceded with the debate about these rules and their assessment by representatives of various fields of science. The FAIR rules are a kind of an extralegal standard and, as a result of its informal character, these rules must become subject to juridization, with the reservation that it will be allowable to make them more detailed within general guidelines for specific fields of science and disciplines, while considering multidisciplinary, transdisciplinary and interdisciplinary projects. It will be also possible to supplement them at the stage of specific contests.

The following suggestions can be defined within the recommendation no. 5. Firstly, both research data and metadata used to describe them should be **findable by both machines and humans**. In order to be findable (meta)data must have a globally assigned unique and permanent identifier and be described by means of expanded metadata. They must also include an identifier of the data they describe. Meta(data) must be also registered or

indexed in searchable assets. Secondly, **data should be accessible** and it should be understood that, after finding data, a user must know how they can be granted access to them and, if necessary, authentication and authorization. In order to meet the aforesaid rule meta(data) must be acquired by means of an identifier with use of a standard communication protocol. It must be open, free of charge and universally executable. It must also allow to perform the authentication and authorization procedure, if necessary. On the other hand, metadata must be accessible, even when the data they describe cannot be acquired anymore. Thirdly, **research data should be interoperable** and it should be understood that data should be usually integrated with other data. They must be compatible with teamwork applications or software used to analyze, store and process data. (Meta)data should 1) use formal, accessible, shared and broadly applied language for knowledge presentation; 2) use glossaries compliant with the FAIR rules; 3) include qualified references to other (meta)data. Data exchange interoperability among various open data systems should be provided, both in the context of localization (local, national, EU-related) and fields of science.

Fourthly, **data must be reusable.** In order to achieve this metadata and data should be properly described by means of a multitude of accurate and crucial attributes in order to enable replication and/or merger in various configurations. This rule focuses on user's (human or machine) ability to decide about usefulness of data for specific purposes. As a result, a data issuer should provide not only metadata allowing to detect data, but also metadata describing the context they were generated for. This can include experimental protocols, manufacturer and brand of machine or sensor that created data, etc. Considering the above, meta(data) should be made accessible with a clear and available license for data use and their origins should be documented. Other persons using data should know where they come from, who should be cited and/or how an author wishes to be recognized. Thus, the description of workflow resulting in data creation should be enclosed in order to know who generated or collected them, but also how they were processed and whether they have been published before. Do they contain data from someone else, that could have been transformed or supplemented? It would be perfect, if this workflow was described in a machine-readable format. Additionally, (meta)data meet common standards regarding a given field of science. It is easier to re-use data, if they are structurized in a standardized way.

Recommendation no. 6: legislation supported by standardization. It should be suggested to harmonize this area by means of EU and international EN/IEC/ISO standards**.** Lets us mention the example of other approaches, like when specifying medical treatment methods or undertaking gradual activities with purpose to reduce the role of national specifications, social security institutions and medical associations, resulting in the

increasing role of the standardized EU healthcare system facilitating its use at the transnational level.

Recommendation no 7: **Appointment of the plenipotentiary for research data,** assisting entities obligated to execute statutory assumptions in connections with the transposed EU law, soft law or good practices. Their tasks should include, *inter alia*, preparing opinions and assistance in development of the data management strategy and the templates of data management plans. Their competences within the public administration structure depends on a member country. It can be an independent institution or be incorporated within the administration structure of the ministry competent in the area of science or the Chancellery of the Prime Minister. It can also be established as a collegial body. In case of establishment of a monocratic institution its operation can be assisted by the advisory commissions.

Recommendation no. 8: use of research data as grounds for development of evidence-based public policies. Consideration of the fact that research data constitute an important element of rationalized and systemic state and society activities related to public problems (development of public policies) during the lawmaking process. Research data are widely available within planning and preparation of a public policy and its subsequent verification. As a result, it is suggested to use research data in order to create evidence public policies are going to be based on. This applies for the most specified sectional policies, the sectoral policies (for example, in the area of medicine) and the holistic policies. Activities undertaken within public policies will not be random anymore and become planned and reactive.

Global importance of institutionalization and structurization of the approach to research data openness cannot be overstated. Increasing of their amount must be related to quality improvement, including understandability and, as a result, usefulness and effectiveness of innovative use. Despite addressing guidelines for the national legislator, the real effect of synergy and universality can be achieved through similar understanding and consideration of the aforesaid (or similar) solutions in as many countries all over the world as possible. Granting open access to research data is an international issue and the good example may be the necessity to provide accessibility of such data in relation with research on the SARS-CoV-2 coronavirus and the COVID-19 disease.

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