Automated Decision-Making Systems in Precision Medicine – The Right to Good Administration at Risk

Sarah de Heer(✉)

Department of Law, Lilla Gråbrödersgatan 4, 222 22 Lund, Sweden
sarah.de_heer@jur.lu.se

Abstract. Automated decision-making (**ADM**) systems – whose algorithms are based on Artificial Intelligence and more specifically on machine learning and deep learning – predict the likelihood of an outcome based on profiling the input data. ADM systems, which are predominantly developed by the private sector, are a promising device for the field of precision medicine, where medical intervention is based on the patient's unique profile that consists of their genomic data, medical records data, environmental data, and lifestyle data. Such ADM systems are used when diagnosing or creating a treatment plan for patients. As these ADM systems take a bodily sample, for example from blood or human tissue, to predict which diagnosis or drug regime is most suitable, they are governed by the *In Vitro* Diagnostic Medical Devices Regulation in the European Union. However, the general features inherent to coding algorithms based on machine learning and deep learning – amongst others i) the self-learning ability, ii) the lack of a causal link, and iii) the use of intellectual property rights –, may form perils to the right to good administration that prescribes the legal norms of administrative conduct, including towards individuals. Particularly, the right to be heard, the right to access one's file, and the duty to state reasons may face considerable hurdles. Thus, this contribution aims to scrutinise these risks to the right to good administration and proposes a research agenda to overcome them.

Keywords: Automated Decision-Making System · Precision Medicine · Right to Good Administration

1 Introduction

Automated decision-making (**ADM**) systems are tools based on Artificial Intelligence (**AI**) that predict the likelihood of an outcome by means of profiling. Their developers particularly rely on machine learning and deep learning – two subsets of the more general AI. The use of ADM systems is especially alluring in precision medicine, which is a subfield of medicine that adapts medical interventions to the patient's profile. In this context, the algorithm underlying the ADM system considers, amongst others, genomic data, medical records data, environmental data and/or lifestyle data [1]. In the European

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Union (**EU**), these ADM systems are governed by Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on *in vitro* diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU [2] (***In Vitro* Diagnostic Medical Devices Regulation**), as a bodily sample – for instance samples from blood or human tissue – serves as input data.[1] Concisely, as mentioned in its Article 1(1), the *In Vitro* Diagnostic Medical Devices Regulation governs the procedure of the ADM system from the moment they are placed on the market of the EU [2]. More concretely, as the development of these ADM systems requires expertise and ample of resources – as demonstrated by the use of machine learning and deep learning techniques –, the private sector predominantly creates them [3] and are thus to comply with the legal obligations stemming from the *In Vitro Diagnostic* Medical Devices Regulation. When interacting with the private sector, the public administration is to comply with the right to good administration, as embedded in Article 41 of the Charter of Fundamental Rights of the European Union [4] (**EU Charter**). This right to good administration includes a diverse subset of rights and principles, which all aim to safeguard the individual's right to defence during administrative proceedings [5]. However, this umbrella right to good administration may be at risk due to the generic features of the algorithm underlying ADM systems, which includes i) the self-learning ability, ii) the evidence of correlation – as opposed to causation –, and iii) the allocation of intellectual property rights.

The aim of this paper is to explore how these three general aspects of the algorithm underlying the ADM systems used in precision medicine affect the right to good administration. To this end, this contribution paints the background, which comprises the context in which these ADM systems are used (Sect. 2.1) and the legal framework that consists of the *In Vitro Diagnostic* Medical Devices Regulation with a specific focus on the principle of transparency it pursues and its transparency obligations (Sect. 2.2). After, this piece scrutinises the legal framework that comprises the right to good administration, which simultaneously consists of the legal benchmark against which the effects of the three general features of ADM systems in precision medicine are evaluated. After introducing the right to good administration (Sect. 3.1), this paper focusses on Article 41 EU Charter in which the right to good administration is embedded. In particular, this contribution dissects the three subrights that are expressly mentioned in Article 41(2) EU Charter (Sect. 3.2). Subsequently, this piece specifies the obstacles posed, caused by the characteristics of ADM systems to the right to good administration as outlined in Article 41(2) EU Charter (Sect. 4). Lastly, this paper concludes and proposes a research agenda in which the author suggests research recommendations to overcome the hurdles to the right to good administration (Sect. 5).

[1] The author points out that ADM systems that base their prediction on other data than those retrieved from human blood or tissue – for instance medical records or medical imagery – are not considered by the *In Vitro Diagnostic* Medical Devices Regulation but rather fall within the scope of the more generic Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC. For more information, see Sect. 2.2.

2 Setting the Scene

2.1 The Factual Context - Automated Decision-Making Systems in Precision Medicine

ADM systems in precision medicine use data retrieved from samples stemming from, for instance, the patient's blood or tissue to predict the likelihood that the diagnosis or the treatment plan fits the patient's unique profile [6]. As a result, ADM systems may be a useful tool for physicians in diagnosing their patients or determining a suitable treatment plan for their patients.

An example of an ADM system for the purpose of medical diagnoses in the field of precision medicine is 'CUP-AI-Dx', which identifies – by using RNA – the location of the primary cancer of patients diagnosed with the rare disease 'carcinoma of unknown primary' [7]. This type of cancer is difficult to treat since the primary cancer is unknown. As such, the ADM system may facilitate physicians to diagnose their patients by localising the primary cancer, and thereby help them to treat their patients. Another example in the field of precision medicine but focussing on treatment plans entails the identification of a suitable drug treatment for colorectal cancer by the ADM system 'IndiTreat'. This test helps decide which medicinal product is likely the most suitable for patients suffering from colorectal cancer by examining the patient's profile against a particular set of pharmaceutical products. Thus, this ADM system may help physicians to set up an effective treatment plan [8].

These ADM systems in precision medicine are characterised by three generic features, namely i) the self-learning ability, ii) the lack of a causal link, and iii) the allocation of intellectual property rights. First, *the self-learning ability* is rooted in the use of machine learning and deep learning techniques, which provides ADM systems with the ability to independently learn from its environment. Put differently, the algorithm underlying the ADM system has acquired the ability to self-evolve – that is to say without human intervention. As a result, grasping how the ADM systems reach its outcome based on the input data may be a cumbersome – if not an impossible – task. Second, these ADM systems may *lack a causal link*, since they may establish correlation between the input data and the acquired outcome. Thus, any alleged link between the input and the output may be solely a coincidence or caused by noise [9]. Third, these ADM systems largely enjoy protection rooted in *intellectual property rights*. Seeing the involvement of machine learning and deep learning techniques in the creation of these ADM systems – which requires specialised skills and competences and substantial resources –, ADM systems are mainly developed by the private sector [3]. Since the algorithm resulting from machine learning and deep learning may be the enterprise's competitive advantage, companies may opt to protect this advantage by using intellectual property rights, and more specifically the legislative framework governing trade secrets. Consequently, the protection mechanism provided by intellectual property rights may constitute an additional hurdle – and thus exacerbate – unravelling how the ADM system works.

2.2 The Legal Context - *In Vitro* Diagnostic Medical Device Regulation

General. ADM systems used to diagnose disease or to set up medical regimes are governed by Regulation (EU) of the European Parliament and of the Council of 5 April 2017

on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC [10] (**Medical Devices Regulation**) or by the *In Vitro* Diagnostic Medical Devices Regulation. The Medical Devices Regulation governs medical devices in the broad sense – the main restricting factors consisting of their use having a medical purpose and the manufacturer's intended purpose, as mentioned in Article 2(1) [10]. The *In Vitro* Diagnostic Medical Devices Regulation does not merely require this medical purpose and the manufacturer's intended purpose but also – in accordance with Articles 2(1) and (2) – demands that these medical devices provide specific information in the medical context acquired by the examination of samples of the human body – which includes those originating from blood or human tissue – in a controlled environment, such as a test tube or petri dish [2]. As ADM systems in precision medicine mostly base a suggested diagnosis or a medical treatment plan on genomic data that is derived from bodily samples – be it from blood or from human tissue – and is examined in a controlled environment, these ADM systems are governed by the *In Vitro* Diagnostic Medical Devices Regulation – which will thus be the focus of this contribution. To this end, the author notes that ADM systems may solely be regulated by the Medical Devices Regulation provided they only use samples that do not come from the human body but rather from, for instance, medical imaging or data given by the patient.

Zooming in on the legal context, a distinction is warranted as regards the assessment of an ADM system in precision medicine that – on the one hand – suggests a diagnosis and – on the other hand – suggests a pharmaceutical regimen. While both these ADM systems are '*in vitro* diagnostic medical devices' under Article 2(1) [2], ADM systems that propose a diagnosis fall under Article 2(2)(a), and those that determine drug sensitivity are a specific *'in vitro* diagnostic medical device' under Article 2(2)(e), namely a 'companion diagnostic', as they i) identify which patients are likely to respond to a treatment plan, and ii) identify which patients are anticipated to suffer serious negative side-effects due to the regimen (see Article 2(7)(a) and (b)) [2].

However, to determine the applicable regime in the *In Vitro* Diagnostic Medical Devices Regulation, it does not suffice to define the ADM systems in precision medicine in these relatively general terms, they also need to be further classified in accordance with the classification rules (Article 47(1) and Annex VIII). [2] *In vitro* diagnostic medical devices are grouped in Class A to Class D, which is determined by the risks posed to the individual and to public health in general [11]. Table 1 illustrates these risks posed by *in vitro* diagnostic medical devices in order to be categorised as 'Class A', 'Class B', 'Class C' or 'Class D'.

In sum, the *In Vitro* Diagnostic Medical Devices Regulation imposes the least stringent obligations upon 'Class A' *in vitro* diagnostic medical devices, and establishes the most demanding requirements on those grouped in 'Class D'. Both ADM systems recommending a diagnosis and ADM systems proposing a treatment plan involving medicinal products are placed in Class 'C', see Rule 3(f) Annex VIII and Rule 3(h) Annex VIII, respectively [2].

The Principle of Transparency. In accordance with Recital 1, the principal purpose of the *In Vitro* Diagnostic Medical Devices Regulation is to ensure transparency, which was amongst the main aims behind the revision of the preceding legislative act [12]

Table 1. Risks of the different classes of *in vitro* diagnostic medical devices

	Risk To Individual	**Risk To Public Health**
Class A	Low	Low
Class B	Moderate	Low
Class C	High	Moderate
Class D	High	High

in 2017. [2] Against this backdrop, it is, thus, no surprise that the *In Vitro* Diagnostic Medical Devices Regulation places the principle of transparency in the limelight. This principle is further echoed throughout the Recitals. To this end, the European legislator acknowledges in Recital 4 that transparency was not a concern in the previous legislative act, which resulted in the introduction of this type of obligations in the current *In Vitro* Diagnostic Medical Devices Regulation [2]. Unfortunately, determining the content of the principle of transparency is no clear-cut task, as it is a multifaceted concept, whose meaning is dependent on the context in which it is used. The question then arises what entails this principle of transparency in the *In Vitro* Diagnostic Medical Devices Regulation. In this legislative act, transparency is – simultaneously with adequate access to information – crucial for, amongst others, sound regulatory decision-making procedures, as mentioned in Recital 40 [2]. Consequently, this aim is set in the transparency obligations that are permeated in the main body of the *In Vitro* Diagnostic Medical Devices Regulation. However, these transparency obligations imposed on *in vitro* diagnostic medical devices vary and are determined by their classification, and thus by the risks posed to the individual using the *in vitro* diagnostic medical device and to the general public health. Depending on its classification, which in the case of ADM systems in precision medicine for the purpose of diagnosing patients and proposing a treatment plan including pharmaceuticals is 'Class C', additional requirements are applicable to safeguard transparency.

Transparency Obligations. Focussing on the requirements to place a 'Class C' *in vitro* diagnostic medical device on the market of the EU, Article 17 stands out seeing its all-encompassing scope, as it demands to draw up the EU Declaration of Conformity that certifies that all requirements of the *In Vitro* Diagnostic Medical Devices Regulation are observed [2]. As stipulated in Articles 10(5) and 15(3)(b), this comprehensive obligation is imposed on the manufacturers of all *in vitro* diagnostic medical devices [2]. Further, by signing the EU Declaration of Conformity, the manufacturer takes full responsibility that the ADM system in precision medicine complies with the *In Vitro* Diagnostic Medical Devices Regulation (Article 17(3)) [2]. As stated in Article 48, one of the obligations to obtain an EU Declaration of Conformity is to perform a conformity assessment, [2] which – quite literally – is an assessment to affirm that the requirements of the *In Vitro* Diagnostic Medical Devices Regulation have been fulfilled (Article 2(32) [2]. This evaluation can be done with or without the involvement of a third party, the Notified Body, which is designated by the Member State to perform the conformity assessment (Article 2(33) and (34)) [2]. Specifically in the case of a 'Class C' *in vitro* diagnostic

medical device, the Notified Body is to review the clinical evidence on its accuracy and verify the conclusions drawn by the manufacturer.[2]

Aiming our attention at the clinical evidence that is to be submitted by the manufacturer to the Notified Body, the clinical evidence aims to ensure that the *in vitro* diagnostic medical device is safe and produces the expected clinical benefits. Article 2(36) states that clinical evidence consists of [2].

- clinical data, and;
- results of the performance evaluation

Looking further into the results of the performance evaluation, the manufacturer is required – under Article 56(3) – to demonstrate: [2].

- scientific validity (Article 2(38)): this requires the *in vitro* diagnostic medical device to illustrate an association between the analyte and a clinical condition or physiological state [2]. Specifically in the context of an ADM system in precision medicine, this entails that the outcome produced by the underlying algorithm must indicate a link with a clinical condition or a physiological state [13];
- analytical performance (Article 2(40)): the *in vitro* diagnostic medical device is to show that the device can accurately discover and measure an analyte [2]. Looking at ADM systems in precision medicine, the output data should be accurate – as opposed to the detection and measurement of an analyte being accurate [13].
- clinical performance (Article 2(41)): here the *in vitro* diagnostic medical device must demonstrate a (medical) correlation between the results and the clinical condition or the physiological state [2]. Against the background of ADM systems in precision medicine, the output of the underlying algorithm ought to have a (medical) correlation with the clinical condition or the physiological state [13].

The above requirements linked to the EU Declaration of Conformity show that the principle of transparency, which aims to facilitate sound regulatory decision-making, is well-embedded in the *In Vitro* Diagnostic Medical Devices Regulation. During the conformity assessment procedure, the manufacturer is to submit a bulk of evidence demonstrating that the *in vitro* diagnostic medical device is safe to use and produce the anticipated clinical benefits, which requires the manufacturer to be transparent about how their *in vitro* diagnostic medical device works and their effects.

[2] For the review of clinical evidence during the conformity assessment of Class C *in vitro* diagnostic medical devices, which includes ADM systems in precision medicine that predict the likelihood the diagnosis fits the patient's profile, see Article 48(7), para. 1 and Annex IX, Sect. 4.4 *In Vitro* Diagnostic Medical Devices Regulation or Article 48(8), para.1 and Annex X, Sect. 3(c) *In Vitro* Diagnostic Medical Devices Regulation. For the review of clinical evidence during the conformity assessment of companion diagnostics, which encompasses ADM systems in precision medicine that predict the suitability of pharmaceuticals based on the patient's profile, see Article 48(7), para. 3 and Annex IX, Sect. 4.4 *In Vitro* Diagnostic Medical Devices Regulation or Article 48(8), para. 1 and Annex X, Sect. 3(c) *In Vitro* Diagnostic Medical Devices Regulation.

3 The Right to Good Administration

3.1 General Remarks

Before becoming a fully fledged human right within the context of the EU,[3] various elements of the – contemporary – right to good administration was already recognised by the Court of Justice of the European Union (**CJEU**) in its case law [5]. The right to good administration – in whatever form – is a pivotal human right that can hardly be overestimated. First, the right to good administration is an enabling right that facilitates individuals to effectively enjoy their fundamental rights, such as the right to an effective remedy. More concretely, the individual cannot be expected to enjoy their right to an effective remedy in case the administrative authority does not provide the underlying reasons for its decision in a clear and an intelligible manner. Put differently, the right to good administration is a vital precondition to exercise other fundamental rights [14]. Second, the right to good administration prescribes that the behaviour of public administration should be in accordance with written and unwritten law, which also includes their conduct towards individuals. Consequently, this right provides individuals with enforceable rights when interacting with public administration [14]. This demonstrates that the right to good administration is not merely a right that facilitates other human rights, but also – and perhaps more importantly – a 'stand-alone' human right [14].

3.2 EU Charter

Even though the EU Charter devotes an article to the right to good administration, much ink has been spilled about its precise status and scope. Based on its phrasing, only the Institutions, Bodies, Offices, and Agencies of the EU fall within the remit of the Charter right to good administration [15]. This reading has also been confirmed by the CJEU [16]. However, the CJEU has refined this black and white approach, and holds that general principles underlying the right to good administration are applicable to Member States when implementing EU law.

The right to good administration, as embedded in Article 41 EU Charter, is a procedural fundamental right [17] and plays a crucial role in procedures before administrative

[3] In some legal orders, good administration is still regarded a principle.

authorities.[4] Article 41 EU Charter is an umbrella concept[5] that contains a diverse set of rights and principles aimed at protecting the individual against the arbitrary use of power by administrative authorities. To this end, this myriad of rights and principles dictates how public administration ought to behave, especially in relation to individuals. Concentrating on Article 41's wording, the first paragraph encompasses an overall provision that entitles the individual '*[…] to have their affairs handled impartially, fairly and within a reasonable time […]*' [16]. This general right is further clarified in the second paragraph, which provides a non-exhaustive list of subrights. In particular, Article 41(2) EU Charter lists three rights that – undoubtedly – fall within the ambit of the right to good administration, namely i) the right to be heard, ii) the right to access one's file, and iii) the duty to state reasons. However, apart from these three rights that are explicitly mentioned, the umbrella right to good administration may encompass other rights and principles [15].

Before delving into the three procedural subrights under Article 41(2) EU Charter, the author holds that these three subrights are vital to the contextual principle of transparency in the light of the *In Vitro* Diagnostic Medical Devices Regulation, as both pursue sound regulatory decision-making procedures. Article 41(2) EU Charter mentions the following three subrights of the right to good administration, namely:

1. the right to be heard (subparagraph a)[6] is a context-specific right, which means that its content hinges on the circumstance under which it is invoked [15]. However, in general this right requires public administration to provide the individual an opportunity to make their stance effectively known before the adoption of the administrative decision that may adversely affect the individual concerned [18, 19]. This means that

[4] The author is aware that Notified Bodies are not necessarily part of public administration, which means that Article 41 EU Charter is not applicable. Nevertheless, the author argues that Notified Bodies may be regarded to fall under public administration based on a case handed down by the European Court of Justice, namely *A. Foster, G.A.H.M. Fulford-Brown, J. Morgan, M. Roby, E.M. Salloway and P. Sullivan and British Gas plc*, App no C-188/89. In this case, the European Court of Justice held that any body – irrespective of its legal form – may be on an equal footing with public administration, if that body is responsible for providing a public service under the control of the State per a measure adopted by the State. The author maintains that the same holds true as regards Notified Bodies. First, Notified Bodies are responsible for providing a public service, namely they are responsible for the conformity assessment, which is a prerequisite for the placement on the market of an ADM system in precision medicine. Second, Notified Bodies are both placed under the supervision of the State (see Articles 39 and 41 *In Vitro* Diagnostic Medical Devices Regulation) and appointed by the State (see Articles 35, 36, 38 *In Vitro* Diagnostic Medical Devices Regulation). Consequently, Notified Bodies are to comply with Article 41 EU Charter.

[5] The author is aware of the debate as regards the precise content of the right to good administration, as penned in Article 41 EU Charter. However, it is not this paper's aim to exhaustively discuss its elements. For an analysis of the content of the right to good administration, see for example Kanska, K.: Towards Administrative Human Rights in the EU. Impact of the Charter of Fundamental Rights. European Law Journal 10(3), 296–326 (2004).

[6] The right to be heard is also encapsulated in the case law of the European Court of Justice, see for example European Court of Justice.: *Transocean Marine Paint Association v Commission of the European Communities* App no 17/74, [15] (1974).

this right only materialises if the foreseen administrative decision may have adverse consequences for the individual. The right to be heard, thus, enables the administrative authority to consider the individual's point of view during the decision-making process. [17] This right consists of two components: first, public administration is obliged to notify the individual about the existence of the pending administrative decision, and second administrative authorities are to ensure that the individual is given the opportunity to effectively make their point of view known before adopting the administrative decision [20]. The above is also applicable to any other individual – not being the addressee of the administrative decision –, who is adversely affected by the adoption of the decision [6].

2. the right to access one's files (subparagraph b) [21] should be given to the individual both before and after the administrative authority adopts its decision. When providing access to their file before deciding on a case, the individual can give full effect to their right to be heard, as the individual can acquaint themselves with the information related to them held by public administration. Put differently, the right to access one's file is a vital precondition to effectively enjoy the right to be heard [22]. Given the status of the right to access one's file as an essential prerequisite of the right to be heard upon which individuals can rely who are negatively affected by the administrative decision – but are not the addressee –, the right to access one's file is, thus, also applicable to such individuals. When given access after the adoption of the administrative decision, the individual has the opportunity to understand the reasoning underlying the administrative decision and can thereby decide to seek – and if needed prepare for – judicial review [15]. Public administration are to provide the individual relying on their right to access their file all relevant information in their possession, except information covered by professional secrecy or business secrets [23, 24]
3. the duty to state reasons (subparagraph c)[7] requires public administration to state the reasons for their decision in a sufficiently precise manner that would allow the individual to understand the underlying reasons of the administrative decision. This would enable the individual to decide whether to appeal the decision in front of the court, which then can adjudicate based on the stated reasons [25]. The duty to state reasons serves a threefold purpose. First, the administrative decision-making procedure becomes more transparent, as it allows the individual to comprehend why the decision is taken and to decide whether to seek judicial redress (*individual perspective*). Second, administrative authorities are now to ponder upon which reasoning their decision is based, which counters arbitrary decision-making (*public administration perspective*). Third, the duty to state reasons is a prerequisite to perform effective judicial review (*judiciary perspective*) [15].

[7] The duty to state reasons is not based on general principles of EU law, but rather on existing Treaty provisions, which is elaborated in the case law of the Court of Justice of the European Union. See Craig, P.: Article 41. In Peers, S., Hervey, T., Kenner, J., Ward, A. (eds), vol. 1, pp. 1125–1152. Hart Publishing, Oxford (2021).

4 Obstacles to the Right to Good Administration

The three general features of ADM systems in precision medicine – namely i) the self-learning ability, ii) the proof of correlation instead of causation, and iii) the use of intellectual property rights – is a breeding ground for perils to the subrights of the right to good administration under Article 41(2) EU Charter, namely i) the right to be heard, ii) the right to access one's file, and iii) the duty to state reasons.

While grasping how the algorithm works may already be cumbersome – since this exercise may require expert knowledge and skills – *the self-learning ability* only further hinders deciphering how the algorithm reached its outcome – or even creates an inconceivable activity. This burden to the comprehension of how the algorithm works is created due to the algorithm's ability to evolve independently based on the input of its environment. Concretely, this means that the outcomes of 'CUP-AI-Dx' predicting the location of the primary cancer and of 'IndiTreat' forecasting the suitability of medicinal products for colorectal cancer may be based on different rules than those initially programmed. Consequently, the competitors and the Notified Body may not be able to decipher how the algorithm reached its prediction. Since the competitors of the company drawing up the EU Declaration of Conformity – and thus submitting the clinical evidence for review by the Notified Body – may rely on the right to be heard, it is questionable to which extent the competitors can effectively make their points of view known before the adoption of the administrative decision due to this self-learning ability. Thus, this means that the right to be heard may be at risk. The same holds true as regards the right to access one's file. The Notified Body may provide unrestricted access to the clinical evidence to the competitors, but they will most likely not grasp what the information entails and its significance, which renders the right to access one's file meaningless. The self-learning ability also jeopardises the duty to state reasons, as the Notified Body – even though provided with the clinical evidence – may not fully understand how the ADM system has reached its outcome. Particularly, the question arises whether the Notified Body can adequately review the accuracy of the clinical evidence and verify the conclusions drawn by the manufacturer. Thus, the Notified Body may not be able to substantiate their decision as regards the review of the clinical evidence in a clear and an intelligible manner, which leaves the sound regulatory decision-making process at risk. Furthermore, the Notified Body responsible for the conformity assessment may face difficulties to pinpoint how the algorithm may evolve in the future and how this may affect the clinical evidence. In short, a sound regulatory decision-making procedure may be at risk.

The same holds true as regards the *lack of a causal link* between the input data, which consists of the patient's blood or tissue sample, and the output data, which forms the likelihood of a diagnosis or of the suitability of a pharmaceutical product. Zooming in on the ADM systems 'CUP-AI-Dx' and 'IndiTreat', this means that their outcomes may be based on correlation – as opposed to causation. As a result, the competitors and the Notified Body may not gather the right picture as to how the algorithm underlying 'CUP-AI-Dx' and 'IndiTreat' work, and whether the algorithm functions accurately. Thus, the *lack of causation* may hinder the right to be heard of the competitors. Since any alleged link may – in fact – evidence correlation, the question arises whether competitors can effectively make use of their right to be heard as they may not be able to get to the heart of the matter. This also remains true as regards the right to access one's file. The data

the competitor is seeking may – in fact – not be included in the clinical evidence, as the algorithm does not demonstrate a causal link. Moreover, the duty to state reasons imposed on the Notified Body may become cumbersome. The Notified Body may be confronted with the potentially impossible exercise of verifying the clinical evidence, which may result in the Notified Body making their decision on incorrect information. Thus, this may adversely affect a sound regulatory decision-making procedure.

The use of *intellectual property rights* may worsen the hurdles posed to both the right to be heard and the right to access one's file, upon which the competitors may rely, since they may form an additional obstacle to comprehend how the algorithm underlying the ADM system in precision medicine works. Since the algorithm comprises the company's competitive advantage over their competitors, the algorithm underling 'CUP-AI-Dx' and 'IndiTreat' may be protected by the regime of intellectual property rights – most likely the regulatory framework of trade secrets. While these trade secrets are submitted to the Notified Body – which will thus not negatively impact the duty to state reasons –, they are not shared with the general public – which includes the competitors – under the right to access one's file. As a result, the competitors may also face difficulties effectively exercising their right to be heard. Therefore, a sound regulatory decision-making process may be hampered.

5 Conclusion – A Research Agenda

This contribution has demonstrated that the general characteristics of ADM systems in precision medicine – i) the self-learning ability, and ii) the lack of a causal link, and iii) the use of intellectual property rights – may very well imperil the right to good administration. In particular, this piece has illustrated the dangers to the three subrights expressly mentioned in Article 41(2) EU Charter, namely i) the right to be heard, ii) the right to access one's file, and iii) the duty to state reasons – and thereby to sound regulatory decision-making procedures.

This piece does not provide solutions to overcome the three established hurdles, rather it suggests three research lines to diminish these perils. The *first* line of recommendation is conducting more research aimed at achieving explainable AI. Specifically local explainability appears a promising field for ADM systems in precision medicine, since this field studies how AI may explain how it has reached the specific outcome based on the input data. In the meantime, however, this paper suggests focusing on creating more accurate and fairer algorithms, which is the *second* line of suggested research. Such algorithms may be achieved by ensuring that complete, representative, and accurate data are inserted both during the creation of the ADM system in precision medicine and during the input phase when the ADM system is in operation. The *third* proposal is an approach as opposed to a line of research, as this contribution calls for conducting interdisciplinary research. Consequently, not only researchers in the field of data science should explore how to overcome the established challenges to the right to good administration, but also experts in the field of law and healthcare professionals should be involved due to the interdisciplinary nature of the topic at hand, which covers all these fields of study. More importantly, these three specialisations should collaborate to achieve explainable ADM systems in precision medicine that conform to the right to good administration.

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