

PUBLIC SELECTION FOR ONE FIXED-TERM TENURE TRACK RESEARCHER (RICERCATORE A TEMPO DETERMINATO) WITH FULL TIME TEMPORARY CONTRACT PURSUANT TO ITALIAN LAW NO. 240/2010, ART. 24 AS UPDATED BY ARTICLE 14 OF DECREE LAW NO. 36, 30 APRIL 2022, CONVERTED WITH AMENDMENTS BY LAW NO. 79, 29 JUNE 2022, AT THE ACADEMIC FACULTY OF SOCIAL SCIENCES AND THE DIRPOLIS INSTITUTE IN THE ACADEMIC RECRUITMENT FIELD “COMPARATIVE LAW” (SC 12/E2) – ACADEMIC DISCIPLINE “COMPARATIVE PRIVATE LAW” (SSD IUS/02), ISSUED BY RECTOR’S DECREE 773 OF NOVEMBER 6, 2023

MINUTE OF THE THIRD MEETING

The Evaluation Committee for the selection of one fixed-term tenure track researcher (ricercatore a tempo determinato) for the Academic Recruitment Field “Comparative Law” (SC 12/E2) – Academic Discipline “Comparative Private Law” (SSD IUS/02) at the Academic Faculty of Social Sciences – the Dirpolis Institute of the Sant’Anna School of Advanced Studies - Pisa pursuant to Italian Law No. 240/2010, Art. 24 as updated by article 14 of Decree Law No. 36, 30 April 2022, converted with amendments by Law No. 79, 29 June 2022, appointed by Rector’s decree No. 115 of February 28, 2024, consists of:

- Prof. Ermanno Calzolaio, Full Professor of the Academic Recruitment Field “Comparative Law” (SC 12/E2) – Academic Discipline “Comparative Private Law” (SSD IUS/02) at the University of Macerata;
- Prof. Eugenia Dacornia, Professor at the National and Kapodistrian University of Athens;
- Prof. Caterina Sganga, Associate Professor of the Academic Recruitment Field “Comparative Law” (SC 12/E2) – Academic Discipline “Comparative Private Law” (SSD IUS/02) at the School, designated member by the Dirpolis Institute.

The Committee convened for the third time, via teleconference, on May, 2, 2024, at 9:30 am from the following locations:

Prof. Calzolaio located in Macerata, connected via Teams.

Prof. Dacornia located in Athens, connected via Teams.

Prof. Sganga located in Pisa, connected via Teams.

The draft of the following minute was agreed on and approved by the members of the Committee.

The President ascertained that all the members of the Committee were present and he declared the session open.

Each member of the Committee declared to have accessed online and examined the documents submitted by the candidates.

The Commission then carried out a collegial examination of the documentation and drew up a brief summary of the qualifications, curriculum and scientific production of candidates. The named assessments are annexed to and form an integral part of the present minute (Annex No. 1).

The Committee decided to reconvene on June 20, 2024 from 2.00 p.m in the Building in Via Santa Cecilia, 3, Pisa in the meeting Room at the second floor for the public interviews with the candidates.

At the end of the meeting, the Committee decided that the Chairperson/the Secretary will send a signed copy of these agreed minutes to Staff Office, together with the declarations of approval by the other members of the Committee. These declarations form an integral part of these agreed minutes.

The meeting was adjourned at 11.30 am.

THE COMMITTEE

The Secretary

ANNEX 1

PUBLIC SELECTION FOR ONE FIXED-TERM TENURE TRACK RESEARCHER (RICERCATORE A TEMPO DETERMINATO) WITH FULL TIME TEMPORARY CONTRACT PURSUANT TO ITALIAN LAW NO. 240/2010, ART. 24 AS UPDATED BY ARTICLE 14 OF DECREE LAW NO. 36, 30 APRIL 2022, CONVERTED WITH AMENDMENTS BY LAW NO. 79, 29 JUNE 2022, AT THE ACADEMIC FACULTY OF SOCIAL SCIENCES AND THE DIRPOLIS INSTITUTE IN THE ACADEMIC RECRUITMENT FIELD “COMPARATIVE LAW” (SC 12/E2) – ACADEMIC DISCIPLINE “COMPARATIVE PRIVATE LAW” (SSD IUS/02), ISSUED BY RECTOR’S DECREE 773 OF NOVEMBER 6, 2023

CANDIDATE: GALLESE Chiara

CURRICULUM

Chiara Gallese is a Marie Curie Fellow at the University of Turin, Department of Law (July 2023-June 2025) and a Fellow at the Information Society Law Center at the University of Milan (October 2023-October 2025). In the past she was post-doctoral research fellow at the University of Trieste, Department of Mathematics (July 2022-June 2023), Research Fellow and Subject expert at the LIUC (February 2022-June 2023), member of the Interdepartmental Laboratory “Bicocca Security Lab” at the Milano-Bicocca University (2017-2018), Visiting PhD candidate at the University of Tokyo (April-May 2017), the Max Planck Institute of Hamburg (March-June 2016) and Keio University (March-August 2015), and Research Intern at the Vanderbilt University (July-August 2016). She holds a Bachelor’s degree and a Master’s degree in Languages, law and economics of East Asia from the Ca’ Foscari University of Venice (2001-2004 and 2004-2006); a Juris Doctor degree (5 years) from the University of Padua (2007-2012), and a PhD in Private International Law and Asian Studies from the Ca’ Foscari University of Venice (2013-2017), for which she was awarded the Bonacossa National Prize for the Best PhD dissertation from the University of Pavia (2017).

Aside from her academic activities, she was also Senior Privacy consultant and Attorney at the PLS Legal law firm (2018-2019), and practiced as an attorney in other two law firms from 2015 to 2019.

She authored 16 publications from 2016 to 2023. 3 publications are in press and forthcoming in 2024. She also declared to have submitted 2 contributions and to have 3 manuscripts in preparation.

She self-certified two periods of maternity leave, from 9 February to 9 June 2003 and from 14 May 2019 to 31 January 2021.

QUALIFICATIONS

- A) Chiara Gallese was awarded her **PhD** in Private International Law and Asian Studies at the Ca’ Foscari University of Venice in 2017 with a thesis on “The reform of private international law in Japan”.
- B) From 2014 to date, she carried out a wide range of **teaching activities** as a tutor/lecturer (Ca’ Foscari University, 2014-15), teaching assistant (Waseda University, May 2017), Lecturer on different subjects (Eindhoven, 2020-2022), and invited lecturer in Jaipur, Ca’ Foscari, Padua and Trieste from 2022 to 2023.
- C) She carried out **documented research activities in qualified institutes in Italy and abroad**. She is currently a Marie Curie Fellow at the University of Turin, Department of Law (July 2023-June 2025), a Fellow at the Information Society Law Center at the University of Milan (October 2023-October 2025) and a Guest Researcher at the Eindhoven University of Technology (February 2022-today). In the past she was post-doctoral research fellow at the University of Trieste, Department of Mathematics (July 2022-June 2023), Research Fellow and Subject Expert at the LIUC (February 2022-June 2023, and a.y. 2020/21), Member of the Interdepartmental Laboratory “Bicocca Security Lab” at the Milano-

Bicocca University (2017-2018), Visiting PhD candidate at the University of Tokyo (April-May 2017), the Max Planck Institute of Hamburg (March-June 2016) and Keio University (March-August 2015), and Research Intern and the Vanderbilt University (July-August 2016).

- D) Chiara Gallese was involved in several **research project activities**. Those most related to the academic recruitment field 12/E2 are the Horizon 2020 projects at the Eindhoven University of Technology where she acted as a “Scientific Information Specialist”, carrying out privacy and ethical compliance tasks (February 2021 – January 2022). She was a postdoctoral research fellow at the University of Trieste in the context of the UNI4Justice project (2022-2023) and a research fellow at the LIUC University in the context of the REMIDE project (2021-2022). Currently and from 2022, she is a guest researcher at the Eindhoven University of Technology, working as an Ethics and Privacy Consultant in the context of Horizon Europe AIRISE project (2023-today). From 2023, she is also Multistakeholder Board member as Independent Advisor on Ethical and Legal issue in the Horizon Europe REALM project (2023-today). In 2020-2021, she participated at the EU COST-action “DigForAsp”. She also reports minor participations in other local university projects and in the drafting of EU projects.
- E) **organization, management and coordination – or participation – in national and international research groups**. Chiara Gallese is an editorial board member of Genius, an ANVUR A-Ranked journal from 2023. She is a fellow at the Information Society Law Center at the University of Milan (2023-2025), and was a member of the interdepartmental laboratory “Bicocca Security Lab” at the Milano-Bicocca University (2017-2018).
- F) She participated as a speaker at several **national and international conferences**. From 2015 to 2024, she self-certifies the participation at 40 event in Italy, Japan, UK, the Netherlands, Sweden, Belgium, the US, Russia, Spain.
- G) As to **national and international awards for research activities**, Chiara Gallese has been awarded a MSCA European postdoctoral fellowship (2023), a Law Excellence Early Scholar scholarship from the University of Turin (2022), a best paper award at the 19th IEEE International Conference on Computational Intelligence in Bioinformatics and Computational Biology in Ottawa (2022), the Bonacossa National Prize for the Best PhD Dissertation from Pavia University (2017), the “Best research work” award from Ca’ Foscari University (2014), together with a PhD scholarship (2013-2017).
- H) The candidate does not hold any other **European doctoral degree** recognised by international Boards as regards the academic recruitment fields where applicable.

PUBLICATIONS

The candidate submitted for evaluation the following twelve publications.

- 1) **(conference proceedings) Gallese, C.; Scantamburlo, T; Manzoni, L.; Nobile, M.S. (2023). Investigating Semi-Automatic Assessment of Data Sets Fairness by Means of Fuzzy Logic, in 2023 IEEE Conference on Computational Intelligence in Bioinformatics and Computational Biology (CIBCB), pp.1-10. Piscataway: IEEE, ISBN: 979-8-3503-1017-7, Eindhoven, 29/08/2023 - 31/08/2023, doi: 10.1109/CIBCB56990.2023.10264913**

The paper focuses on the challenges raised by the social bias conveyed by data sets into AI systems based on machine learning, and by the consequences they trigger in terms of perpetuation of such biases within the model. It offers a preliminary framework for the semi-automated evaluation of fairness in data sets, by combining statistical information about data with qualitative consideration. To this end, the paper addresses the issue of how much fairness can be included in a data set used for machine learning research, focusing on classification issues. To offer guidance for the use of data sets in critical decision-making processes, such as health decisions, it identifies six fundamental features (balance, numerosity, unevenness, compliance, quality, incompleteness) that could affect model fairness, and it develops a rule-based approach based on fuzzy logics

that combines these characteristics into a single score and enables a semi-automatic evaluation of a data set in algorithmic fairness research.

The candidate declares that her contribution to the joint work included the original conception of the piece, the construction of the theoretical legal model and the selection of the calculation technique and the software features. More specifically, she declared to have written three-quarter of the Introduction, half of the Conclusions and the entire description of the features of the datasets under Section III.

The paper is published online as an IEEE conference paper, which has a limited scientific relevance in the legal field compared to other scientific realms.

- 2) **(conference proceedings) Gallese C., Fuchs C., Riva S. G., Foglia E., Schettini F., Ferrario L., Falletti E., Nobile M. S. (2022), Predicting and Characterizing Legal Claims of Hospitals with Computational Intelligence: the Legal and Ethical Implications.** In: 2022 IEEE Conference on Computational Intelligence in Bioinformatics and Computational Biology (CIBCB). p. 1-9, IEEE, ISBN: 978-1-6654-8462-6, Ottawa, ON, Canada, doi: 10.1109/CIBCB55180.2022.9863033.

The paper proposes a fuzzy logic-based approach to analyze UK National Health Service public administrative data related to pre-and post-pandemic claims filed by patients, analyzing the legal and ethical issues connected to the use of Artificial Intelligence systems to take critical decisions having a significant impact on patients, including the management choices related to Intensive Care Unit bed allocations. It advances the state of the art by following an unsupervised approach and performing an analysis of UK hospitals by means of a computational intelligence algorithm integrating Fuzzy C- Mans and swarm intelligence. The paper concludes that computational intelligence should not be employed to take critical decisions that cause harm to data subjects, at least not without having fully informed them of the consequences of the processing, and without the intervention of a human in the decision-making process.

The candidate declares that her contribution to the joint work included the original conception of the piece, the construction of the theoretical legal model, the selection of the dataset. More specifically, she declared to have written the entire article, with the exclusion of the computational Sections (II-III).

This is an IEEE conference paper, which has a limited scientific relevance in the legal field compared to other scientific realms.

- 3) **(journal article) Chiara Gallese, A first comment to the proposal for a new Regulation on fair access and use of data (Data Act),** in Media Laws, n.3/2022

The article examines the proposal for an EU Data Act, which had been published shortly before the paper submission, assessing the new legal framework in light of the European digital strategy and the Strategy for Data and describing how the proposal was conceived. It explores the new Data Act definitions, scope, subject matters and most important innovative provisions and their impact on different stakeholders. The paper concludes with an analysis of gaps and limitations, and related suggestions on how to tackle them.

The article is single-authored and published on a review that is indexed as “A-ranked” (Fascia A) by ANVUR for Area 12 (Law).

- 4) **(journal article) Chiara Gallese, Legal aspects of the use of Artificial Intelligence in Telemedicine, Special Issue on Law and Ethics of Artificial Intelligence,** Journal of Digital Technologies and Law, ISSN Electronic: 2949-2483, n.2/2023

The paper analyses the legal implications of the use of AI in telemedicine, especially when continuous learning and automated decision-making systems are involved. It does it by exploring the legal framework regarding telemedicine and AI in Europe, with particular regard to sources such as the GDPR and the AI Act proposal, and by providing a thorough overview of the most relevant scholarly contributions in the field. On this basis,

it highlights outstanding issues that are not fully addressed by the current legislation, and proposes a range of legislative and non-legislative measures to fill in such gaps.

The paper is single authored and it is published on the Journal of Digital Technologies and Law, an open access peer-reviewed journal based in Russia but having an international board of editors (featuring also the candidate). It is not indexed on Scopus or SJR and is not present in the list of Scientific Journals and Reviews for Area 12 (Law) listed by ANVUR.

5) **(conference proceedings) Chiara Gallese, Suggestions for a Revision of the European Smart Robot Liability Regime, Proceedings of CIAIR 2022, Oxford, 2022**

The article explores liability issues pertaining AI and robots with regards to users, producers and programmers, with particular regards to cases when the use of machine learning techniques is involved. It assesses them against the current legislative framework, the policy actions and preparatory work undertaken so far and the proposal for an AI Act and Cyber-Resilience Act, and concludes with suggestions on new regulatory solutions for European lawmakers.

The article is single-authored and published online in the proceedings of the CIAIR 2022 Conference in Oxford.

6) **(journal article) Chiara Gallese, Regulating Smart Robots and Artificial Intelligence in the European Union, Journal of Digital Technologies and Law, n.1/2023, ISSN Electronic 2949-2483**

The paper, which in the version submitted to evaluation is entitled “Regulating smart robot and AI: some suggestions for a review of the AI Act proposal”, offers a thorough overview of the definitions offered of AI and robots by the literature, by a number of studies and preparatory works issued by EU institutions and by the proposal of AI Act, emphasizing the impossibility to reach common and overarching definitions in light of the highly heterogeneous actors at stake. Then, it moves to the analysis of the classification of risk categories proposed by the AI Act, explores regulatory solutions to prevent cyberattacks against old and obsolete software, machine learning models and black-boxes, and comments on security rules and standards for producers, programmers and users. It concludes by proposing a balanced system of security and standards, with related policy recommendations for the EU legislator to fill in the gaps left by the AI and Cyber-resilience Acts proposals.

The paper is single authored and it is published on the Journal of Digital Technologies and Law, an open access peer-reviewed journal based in Russia but having an international board of editors (featuring also the candidate). It is not indexed on Scopus or SJR and is not present in the list of Scientific Journals and Reviews for Area 12 (Law) listed by ANVUR.

7) **(book chapter) Chiara Gallese, Prospettive di riforma del diritto internazionale privato giapponese (Prospects for a reform of Japanese private international law) in M. Cestari, G. Coci, D. Moro, A. Specchio, Orizzonti giapponesi: ricerche, idee, prospettive, Aracne Editrice, Roma 2018, pp. 678 (ISBN: 978-88-255-2118-4)**

The paper offers a comprehensive overview of the main features of the reforms that have changed the international private law regulation in Japan from 1989 to 2006. It examines the reasons underlying the reform and assesses the persisting problematic features of the system, focusing on specific matters such as, inter alia, the definition of public order and of some mandatory provisions, the uncertain notion of residence, the lack of regulation of contractual choice of law/jurisdiction, the uneven regulation of the notion of point of attachment and its consequences, and a number of provisions on substantial subjects.

The chapter is single-authored and published by an Italian publishers.

- 8) **(conference proceedings) Gallese, C., Falletti E., Nobile, M.S., Ferrario, L., Schettini, F., Foglia, E., Preventing litigation with a predictive model of COVID-19 ICUs occupancy, 2020 IEEE International Conference on Big Data, 2111, Atlanta, GA, USA**

The paper builds on the observation that the COVID-19 pandemic has generated an overall slowdown in hospital activities that may cause delays in healthcare interventions, and the scarcity of resources can raise concerns over allocation criteria. These circumstances could lead to lawsuits against hospital and healthcare professionals. In this context, predicting the litigation rate could be useful to assess the economic impact of a dispute at a local and national level, allowing hospital managements and public institutions to perform a cost/benefit analysis to decide whether to invest resources to increase critical care surge capacity. To this end, the paper present CLIP (COVID-19 Litigation Prediction), a modeling approach supported by swarm intelligence designed to estimate the future number of patients, and then exploits a probabilistic model to predict the number of occupied intensive care beds, whose parameters are calibrated by means of Fuzzy Self-Tuning Particle Swarm Optimization. The contribution argues that the development and availability of such a predictive model could be further used with other clinical conditions and important diseases, thus helping policy-makers in taking decisions under uncertain variables.

The candidate declares that her contribution to the joint work included the original conception of the piece, the construction of the theoretical legal model, the selection of the data sets and the model to be used, and the assistance to computer scientists in developing the model itself. More specifically, she declared to have written paragraphs 1 and 2. The paper is published online as an IEEE conference paper, which has a limited scientific relevance in the legal field compared to other scientific realms.

- 9) **(conference proceedings) Chiara Gallese, Legal aspects of the use of chatbot apps for mental health support, in: Highlights in Practical Applications of Agents, Multi-Agent Systems, and Complex Systems Simulation – The PAAMS Collection, Communication in Computer and Information Science, Springer, 2022, L’Aquila, Italy**

The paper explores the implications of using conversational agents such as chatbot apps to provide psychological supports to patients. It starts with an introduction on the role that chatbots have increasingly acquired in the mental health care context in recent years. Then, it offers an overview of the data protection principles governing the use of chatbots, looking at the types of data processed, at the security measures that need to be implemented and the informed consent that needs to be collected, and at the obligations descending from the fact that such apps operate profiling and, albeit not often, automated decision making. The paper moves to the Medical Device Regulation (MDR) to understand whether and to which extent its definition of medical devices may be applied to chatbots and thus subject them to its rules. Then, it makes very brief references to the AI Act Proposal and the Data Act proposal, with similarly brief reference to the legal issues arising from the fact that the chatbot patients may be qualified as vulnerable users.

The paper is single-authored and is part of a conference proceedings collection.

- 10) **(journal article) Chiara Gallese, L’Orientalisme juridique et le droit japonais, Zeitschrift für Japanische recht, issue 21 n. 42, DJJV, Max-Planck-Institut für ausländisches und internationales Privatrecht (MPI), Hamburg, 2016**

The article, written in French, offers an interesting and thorough reconstruction of the notion of Orientalism in law, from the first essay on the topic authored by Said in 1979 to its elaboration in subsequent comparative law contributions in the following three decades. The candidate opts for the use of the plural term “orientalismes”, arguing that the phenomenon and the cultures it looks at should be observed from different angles and perspectives. It builds on the theories of Ruskola, which argues that the adoption of a functional approach in comparative law and the application of similar legal categories to all legal systems penalizes national traditions that do not fall within the civil vs common law dichotomy, to analyze the prejudices and criticisms that have historically afflicted the analysis of Japanese law. In this context, it comments on scholars belonging to different jurisdictions, with a particular focus on Italian authors, shedding light on the reasons behind the marginal role that the study of Japanese law has always played. The chapter concludes by arguing

that cultural aspects influence all legal systems and do not play a dominant role in the Japanese context as Occidental commentators may believe, and it proposes interesting solutions to overcome the limits the orientalist approach show and the consequences it caused in comparative legal studies.

The chapter is single-authored and published by a known international publisher.

- 11) **(book chapter) Chiara Gallese, Legal aspects of AI models in medicine. The role of interpretability, in: Big Data Analysis and Artificial Intelligence for Medical Science (B.Carpentieri, P.Lecce eds), Wiley, 2024, forthcoming**

The actual title of the chapter, as it results in the submitted draft, is “Legal Aspects of AI in the biomedical field. The role of interpretable models”. The chapter analyses the legal framework applicable of the development and the use of AI systems in the medical field. It focuses on fundamental principles of the GDPR and the AI Act proposals, with particular regard to transparency, legal basis of data processing, right of explanation, accountability, fairness and human oversight over high-risk AI systems. In this context, it explains the role that heterogeneous systems, where interpretable models work together with black boxes, may play to tackle the challenge of preserving accuracy while maintaining transparency in the use of AI models in medicine.

The chapter is single-authored and published by a known international publisher.

- 12) **(book chapter) Chiara Gallese, Daniela Besozzi, Le sentenze antiscientifiche: un mito creato dai media (Judgments against science: a myth created by the media) in Ius dicere in a globalized world. A comparative overview, RomaTre Press, 2018 (ISBN: 978-88-94885-96-5)**

The book chapter, co-authored with Daniela Besozzi, focuses on the apparent tensions between the administration of justice – *id est* the work of judges and attorneys – and the scientific community. It offers numerous examples of judicial decisions and the criticisms raised by journalists, who argued that attorneys and courts willfully disregard the scientific literature and drew conclusions that propose their own, unfounded vision of science. To confute this reading, the authors look into the specificities of each case and the role played by prosecutors and judges in each example, illustrating the real foundations of each decision. They conclude by arguing that this misinformation is based on the lack of public awareness of the features of our judicial system, and advocate for the adoption of specific countermeasures to prevent the media “slander” against the legal professions.

The contribution is part of a collection published on RomaTre Press, an institutional academic publisher. The candidate declares that her contribution to the joint work included the original conception of the piece and that she drafted the entire piece, while her co-author offered suggestions on the scientific (*sic*) part and corrected the proofs.

OVERALL CONSISTENCY OF THE SCIENTIFIC PRODUCTION

The scientific production of Chiara Gallese appears to be articulated along three research lines, which could be mostly identified in AI law, health law, privacy and data law, with isolated publications on Japanese law. In this respect, the outputs submitted to evaluation show an overall consistency and span across a variety of subjects, making use of interdisciplinary research approaches and, less often and less consistently, of comparative law methodology.

As to the intensity and temporal continuity of her scientific production, great part of her contributions are in the timeframe 2022-2024 (19 declared, out of which 2 submitted, 3 forthcoming and 3 still in preparation), followed by 1 publication in 2016, 2 in 2018, 1 in 2020 and 1 in 2021. Compared to her academic seniority which, according to the principle of normalisation adopted in the evaluation criteria approved by this Committee during its first meeting, equals to 2024-2013 (starting year of the PhD) + 1 = 12 years, and considering the 2 years of self-certified maternity leave (divided in two periods of 4 months and 1 year and 8

months respectively), her academic productivity has not been particularly intense nor continuous in time, and seems to have spiked only recently.

RESEARCH PROJECT

Chiara Gallese presented a research project on “EUDATA – A new EU comparative perspective for ethical assessment of Medical Data sets for AI training”.

EUDATA aims at pioneering the development of an innovative EU framework to ensure the fair creation of AI datasets in healthcare. It builds on the assumption that the policymaking process is not keeping up with technological advancements, for the current EU and national legal frameworks are fragmented and do not comprehensively address the multifaceted issues of clinical AI, from errors to unevenness in data and missing information in clinical data sets. EUDATA plans to employ evidence-based anticipatory regulation to identify, build and test solutions to these issues, investigating the biases during the creation of datasets for AI model training, involving all relevant stakeholders and employing novel approaches, such as post-colonialist and feminist theories, in 6 countries (Italy, Poland, Romania, Bulgaria, Hungary and Slovenia). The aim is to uncover the types of biases occurring in clinical data creation, offering a legal definition, the reasons why they occur, what is needed to create fairer AI clinical datasets, and how such fairness should be regulated and interpreted in light of the EU Digital Strategy.

CANDIDATE: MARTANI Andrea

CURRICULUM

Andrea Martani is currently a Post-doctoral researcher at the Institute for Biomedical Ethics (IBMB) of the University of Basel, and a Research Associate at the Faculty of Law of the Vrije Universiteit Amsterdam. He is elected member of the Expert Group for Open Research Data of the Swiss Academy for Arts and Sciences and Member of the Research Committee of the University of Basel. In the past he was Research and teaching assistant at the Institute for Biomedical Ethics of the University of Basel (2018-2021), Research Associate in the “Progetto BioDiritto” at Faculty of Law of the University of Trento (February 2017 – November 2017).

He was awarded his PhD (Dr.sc.med.) in Biomedical ethics from the Faculty of Medicine of the University of Basel in October 2021, for which he was awarded a prize by the Medical Faculty. He holds a J.D. (Laurea magistrale in Giurisprudenza) in European and Transnational Law from the University of Trento (2012-2028), during which he was a Visiting Student at the School of Law of the University of Reading (2014-2015) and at the Interfaculty Centre for Biomedical Ethics and Law of KU Leuven (February-July 2017).

He is the author of 29 publications (journal articles and book chapters, mostly co-authored), with almost 300 citations and an H-index of 7, 1 contribution in press and 3 contributions submitted and/or in peer review. In Basel, he delivers several courses at the undergraduate, Master’s and PhD level, for which was nominated for the “Future Talents” category of the Teaching Excellence Awards 2023.

QUALIFICATIONS

- A) Andrea Martani was awarded his **PhD** in Biomedical Ethics from the Faculty of Medicine of the University of Basel in October 2021 *summa cum laude*, with a thesis on “The datafication of Swiss healthcare and biomedical research: ethical and legal issues and the way forward for health data governance”.
- B) From 2018 to date, he developed and offered a wide range of **courses and seminars** at the University of Basel, Institute of Biomedical Ethics, Faculty of Medicine and Department of pharmaceutical sciences.
- C) He carried out **documented research activities in qualified institutes in Italy and abroad**. He is currently a Postdoctoral researcher at the Institute of Biomedical Ethics of the University of Basel (October 2021-today) and a Research Associate at the Faculty of Law of the Vrije Universiteit Amsterdam (January 2023-today). Before that, he was Research and Teaching Assistant at the Institute of Biomedical Ethics of the University of Basel (May 2018-October 2021) and Research Associate at the Faculty of Law of the University of Trento (February 2017-November 2017).
- D) As to **research projects**, Andrea Martani currently co-manages the ethical-legal work-package of a Dutch national project on how to improve the societal debate around gene-editing technologies. No further details are provided as to the project itself and its duration. He obtained funding from the Swiss Federal Office of Public Health for more than 40.000 CHF, although he does not specify the research project underlying the fund. He participated at the drafting and preparation of an ERC Advanced Grant – PI Professor Klaus Hoeyer, University of Copenhagen – awarded 2.5M euros.
- E) **organization, management and coordination – or participation – in national and international research groups**. Andrea Martani is elected member of the Expert Group for Open Research Data of the Swiss Academy of Arts and Science. He is an active member of the Institute of Biomedical Ethics at the University of Basel, participates as a Research Associate to a national research group at the Vrije Universiteit Amsterdam, and was also a Research Associate in the “Progetto BioDiritto” at the University of Trento (February 2017-November 2017).

- F) He participated as a speaker at several **national and international conferences**. From 2018 to 2024, he self-certifies the participation at 14 event in Italy, UK, Norway, Switzerland, India, Portugal, Germany, Belgium, and France. He also contributed to the organization of 4 conferences.
- G) As to **national and international awards for research activities**, Andrea Martani has been the recipient of an award of the Faculty of Medicine of the University of Basel for the PhD Dissertation. He obtained a funding from the Swiss Federal Office of Public Health, three scholarships from the University of Basel to attend and present international conferences for young promising scientists in 2018, 2019 and 2022.
- H) The candidate does not hold any other **European doctoral degree** recognised by international Boards as regards the academic recruitment fields where applicable.

PUBLICATIONS

The candidate submitted for evaluation the following twelve publications.

- 1) **(journal article) Martani A., Erard F., Casonato C., Elger B.S., The devil is in the details. An analysis of patient rights in Swiss cancer registries, in Journal of Medical Ethics, published online first 5 October 2021, doi: 10.1146/medethics-2021-107564**

The paper focuses on the recent reform of the Swiss cancer registration legislation, which implement rules about the recording of data in cancer registries that would allegedly go beyond a consent-based model, in order to balance accurate registration with the respect of patient rights. It analyses the operational norms of the new legislation and compares them with those of other systems, and it concludes that the Swiss rules closely resemble a system of registration based on informed consent, in partial contradiction with the objective pursued by the law makers. The article demonstrates how details of a single policy action are crucial to determine its true nature, and highlights some critical elements, from an ethical standpoint, of the recent Swiss reform.

The article does not specify what the individual contribution of each author was, but the candidate appears as the first and corresponding author. The paper is published on the Journal of Medical Ethics, which is an SJR Q1 journal for Health, Issues, Ethics and Legal Aspects of Health and Health Policies.

- 2) **(journal article) Martani A, Genevieve LD, Pauli-Magnus C, McLennan S, Elger BS, Regulating the secondary use of data for research: arguments against genetic exceptionalism, in Frontiers in Genetics, 2019, 10:1254**

The article uses Swiss law as a case study to argue that genetic exceptionalism in secondary use regulation is not justified for three reasons. First, although genetic data have particular features, also other non-genetic data can be extremely sensitive. Second, having different regulatory requirements that depend on the nature of the data hinders the creation of comprehensible consent form. Third, empirical evidence about public preferences concerning data reuse suggests that exceptional protection for genetic data alone is not justified. Against this background, the article claims that the regulation concerning data reuse should treat genetic data as important, but not exceptional.

The article does not specify what the individual contribution of each author was, but the candidate appears as the first and corresponding author. It is published on an SJR Q2 journal for Genetics and Molecular Medicine.

- 3) **(journal article) Martani A, Egli P, Widmer M, Elger BS, Data protection and biomedical research in Switzerland: setting the record straight, Swiss Medical Weekly, 2020 (150)w:20322**

The article aims at reviewing the interaction of data protection law and biomedical research with a focus on the Swiss context. It discusses three crucial nodes that shape the interplay of law and data processing in research. First, it examines the meaning of personal data, the requirements to classify data as personal, non personal, pseudonymized or anonymized and the implications of such classifications from a legal perspective.

Then, it considers the relationship between sector-specific data processing regulations for research and other laws on data protection. Last, it analyses the role of consent for data processing in research and its significance from a data protection perspective. The article concludes by underlining the importance of fostering reciprocal collaboration of data protection experts and biomedical researchers to facilitate the development of new projects.

The article does not specify what the individual contribution of each author was, but the candidate appears as the first and corresponding author. It is published on an SJR Q3 journal in Medicine (miscellaneous).

- 4) **(journal article) Martani A, De Clercq E, de Geyster C, Pennings G, Wangmo T, Elger BS, Deconstructing age(s): an analysis of the different conceptions of age as a legal criterion for access to assisted reproductive technologies, Journal of Law and the Bioscience, vol. 9, issue 2, July-December 2022, Isac036**

The article builds on gerontological, medical and sociological literature on the concepts of “age” and “aging” to distinguish three conceptions of age that are relevant for assisted reproductive technologies (ART) regulation: the chronological, the biological and the social-cultural one. It describes how the three concepts relate to ART and reproduction, and illustrates advantages and disadvantages of relying on each of them as a basis for limiting ART access. Last, it proposes a template for defining legal age limits for ART access in the law, based on the refined understanding of the different conceptions of age that it outlines, and discusses two potential objections to the proposal.

The article does not specify what the individual contribution of each author was, but the candidate appears as the first and corresponding author. It is published on an SJR Q1 journal for Law, but it does not feature in the ANVUR list of scientific reviews for Area 12 (Law).

- 5) **(book chapter) Martani A, Le incertezze del diritto nel contesto della sanità moderna: sfide presenti e future, in C Piciocchi, M Fasan, CM Reale (eds), Le (in)certezze del diritto: atti delle giornate di studio 17-18 gennaio 2019, Napoli, Editoriale Scientifica, pp.197-218**

The chapter attempts to offer an overview of a selected array of issues in medicine and healthcare that are afflicted by legal uncertainty, with the goal of offering a systematization of each matter and to propose an analytical approach that could start tackling such uncertainties. First, it summarizes the evolutionary paths of modern medicine and health care. Then, it identifies three paradigmatic areas featuring legal uncertainties, for different reasons and in different manners, on the basis of the results of a project aimed at developing solutions to overcome the difficulty in harmonizing health data collection in Switzerland without violating patients’ rights. Last, it concludes by highlighting the issues that require more elaboration in order to tackle the problem.

The article is single-authored and published in a collection by a renowned Italian publisher.

- 6) **(journal article) Martani A, Shaw D, Elger BS, Stay fit or get bit – Ethical issues in sharing health data with insurers’ apps, Swiss Medical Weekly, 2019 Jun 30, 149;149:w20089**

The article investigates the phenomenon of insurers’ apps permitting customers to share their data in exchange for monetary rewards currently available in Switzerland. It first describes the features and functioning of the app, then it presents some ethical aspects related to their use, with particular regard of transparency of data-sharing purposes, the potential discrimination among insured people, the “quantification” of users and the potential tension generated between solidarity and responsibility. The article concludes by emphasizing that insurers’ app are becoming a new paradigm for insurers in many countries, thus a thorough ethical assessment of their implications is required.

The article does not specify what the individual contribution of each author was, but the candidate appears as the first and corresponding author. It is published on an SJR Q3 journal in Medicine (miscellaneous).

- 7) **(journal article) Martani A, Genevieve LD, Elger BS, Wangmo T, 'It's not something you can take in your hands'. Swiss experts' perspectives on health data ownership: an interview-based study, BMJ Open 2021; 11(4): e045717**

The paper aims at analysing the perspective of Swiss experts on the topic of health data ownership and control. It reports on a qualitative studies where authors selected participants through purposive and snowball sampling and 48 experts. They identified different themes on which to test the beliefs of those interviewed, from the understanding on who should be identified as data owner to the justifications underlying the attribution of ownership and the market value for data. The results suggested that experts are still divided about who should be the data owner and also about what ownership would exactly mean, and show an ambivalence between the willingness to acknowledge patients as data owners and the fact that the efforts put by researchers to collect and manage data entitle them to assert ownership claim. Also a tendency to speak about data in market terms emerged.

The article does not specify what the individual contribution of each author was, but the candidate appears as the first and corresponding author. It is published on an SJR Q1 journal for Medicine (miscellaneous).

- 8) **(journal article) Martani A, Egli SM, Genevieve LD, Elger BS, Wangmo T, A role-model for data policies? Qualitative study on the governance of health data in Denmark, Health Policy and Technology, 2022, 100683**

The article explores to which extent it is true that Denmark has invested a lot in the branding of its health data landscape as a role model, with a focus on data access for secondary uses and research, to also see what other countries can learn from the Danish experience. It builds on semi-structured interviews conducted with 15 Danish stakeholders working as policymakers, researchers or public administrators in health. The article concludes that the Danish model also relies on a balance between extensive data usage and persisting limitations. In this sense, it should not be considered a dream system to blindly emulate, but a valuable example of how such balance can be found, without forgetting that the latter requires continuous adaptation. Since the willingness of a population to approve data usage may change for privacy concerns, regular policy renegotiations of the ethical underpinning of any health data landscape are crucial for their sustainability.

The article does not specify what the individual contribution of each author was, but the candidate appears as the first and corresponding author. It is published on an SJR Q1 journal for Biomedical Engineering and Health Policy.

- 9) **(Journal article) Martani A, Starke G, Personal responsibility for health: the impact of digitalization, Journal of Medical Law and Ethics, 2019; 7(3):241-258**

The article looks at the role that personal responsibility of patients may have as a potential remedy for the problem of resource allocation in health care systems. Systems of rewards and punishment based on it have proved very divisive, and in any case the implementation of personal responsibility in concrete policies has always encountered the problem of practical enforceability. The article shows how this hurdle can be overcome with the advent of digitalization in health, and discusses how by datafying health and making patients transparent may close the loophole of practical enforceability by allowing to trace health-related lifestyle choices of individuals as well as their exposure to avoidable risk factors. It concludes by addressing the limitations of this approach, and suggests that there are other ways in which the potential of digitalization can help with the allocation of resources in health care.

The article does not specify what the individual contribution of each author was, but the candidate appears as the first and corresponding author. It is published on a journal that is not indexed on SCOPUS, Scimago and ANVUR reviews.

- 10) **(journal article) Martani A, Genevieve LD, Poppe C, Casonato C, Wangmo T, Digital pills: a scoping review of the empirical literature and analysis of the ethical aspects, BMC Medical Ethics, 2020; 21(1):3**

The article maps studies where digital pills – an innovative drug-device technology that permits to combine traditional medications with a monitoring system that automatically records data about medication adherence as well as patients’ physiological data – have been tested on patients, and discuss the ethically relevant issues evident therein. It also performs a scoping review of the empirical literature on the matter. It concludes that evidence concerning DP is not robust and more research should be performed and study results made available to evaluate this digital medicine. The analysis of the ethically relevant aspects within empirical literature also underscored that there are concrete and specific open questions that should be tackled in the ethical discussion about this new technological solution.

The article does not specify what the individual contribution of each author was, but the candidate appears as the first and corresponding author. It is published on an SJR Q1 journal for Health Policy, Health and Issues, Ethics and Legal Aspects.

- 11) **(book chapter) Martani A, Hummel P, Eine neue Generation des Datenschutzes? Gegenwärtige Unvollständigkeit, mögliche Lösungswege und nächste Schritte, in G Richter, W Loh, A Buyx, S Graf von Kielmansegg (eds), Datenreiche Medizin und das Problem der Einwilligung, 2002, Springer, Berlin-Heidelberg**

The chapter focuses on whether there is a new Generation of Data Protection, the present incompleteness, the possible solutions and the next paths to be taken. It is first described therein the position that changing realities of data processing require new generations of data protection law. The focus is on understanding what characterizes such a generation and the reasons why a new generation might be required. In doing so, it is argued that data protection law is currently confronted with a number of open questions of principle that both point the way towards a next generation, but also suggest that there is a need to reform the *status quo*. These fundamental questions are developed in the article along three conceptual nodes: The subject matter (3.1), the object of protection (3.2) and the paradigm (3.3) of data protection law. Then biomedical research is used as a context in which further sector-specific questions arise in the further development of data protection (4). Finally, based on this discussion, hypotheses are formulated as to how the transition to a new generation could be realized.

The article does not specify what the individual contribution of each author was, but the candidate appears as the first and corresponding author. It is published by a known international publisher.

- 12) **(review in a journal) Martani A, Tomasi M, Casonato C, “I Think It’s Been Met with a Shrug”: Oncologists’ Views toward and Experiences with Right-to-Try, Journal of the National Cancer Institute, 2020 djaa 101**

The contribution is a very short review of a study published by Smit et al and having the same title. It is a 1-page long descriptive piece. In this sense, it cannot be understood as an innovative and original contribution to the state of the art, nor its methodological rigor may be properly assessed. Its relevance is limited to that of a study review.

The article does not specify what the individual contribution of each author was, but the candidate appears as the first and corresponding author. The review is published on an SJR Q1 journal for Cancer Research and Oncology.

OVERALL CONSISTENCY OF THE SCIENTIFIC PRODUCTION

The scientific production of Andrea Martani appears to be articulated along three research lines, which could be mostly identified in policy analysis in health law, empirical bioethics, and ethical-legal implications of new

health technologies and health care access. In this respect, the outputs submitted to evaluation show an overall consistency and span across a variety of subjects, making use of interdisciplinary research approaches. However, his contributions make use of legal research and analysis only as an ancillary tool to other aims and subject-matter assessments, with very limited use of comparative law methodologies.

As to the intensity and temporal continuity of his scientific production, he lists 29 publications (journal articles and book chapters, mostly co-authored), 1 contribution in press and 3 contributions submitted and/or in peer review, out of which 20 as first/corresponding author. The contributions span along the timeframe 2019-2024. Compared to his academic seniority which, according to the principle of normalisation adopted in the evaluation criteria approved by this Committee during its first meeting, equals to 2024-2018 (starting year of the PhD) + 1 = 7 years, his academic productivity in his field of research may be characterized as remarkably intense, consistent and continuous, without any interruption.

RESEARCH PROJECT

Andrea Martani presents a research project focused on understanding how regulation of innovative healthcare solutions evolve, adopting an ethical-legal approach. He aims at continuing the practice of his research skills at the crossroad of bioethics and healthcare, comparative legal analysis and empirical research. In the long term, he plans to develop a set of methodological tools to understand the complex mechanism how health regulation evolves, exploring three lines: (a) understanding the evolution of data protection law in the biomedical sector, with a focus on the causes underlying the fragmentation of practices, interpretation and implementation of open clauses featuring EU law by Member States. The candidate plans to use both comparative law theories and empirical analysis (interviews and other qualitative methods of data collection) to examine the impact that the implementation of data protection law by non-lawyers has in biomedical research; (b) understanding the regulation of new technological solutions that touch on modally-loaded bioethical issues, by investigating the divergences among Member States' approaches and the meta-legal factors underlying them.

CANDIDATE : PARZIALE Andrea

CURRICULUM

Andrea Parziale is currently Assistant Professor of Health law at the Department of Health, Ethics and Society of the Faculty of Health, Medicine and Life Science of Maastricht University (October 2023-today). From April 2022 to September 2023 he was Marie Sklodowska-Curie Fellow at the Institute for Transnational Legal Research of the Faculty of Law of Maastricht University with a project on “FullCompensation – Rationalising Full Compensation for Non-Pecuniary Damages to Reconcile Equal Treatment and Personalisation”. Before that, he was a post-doctoral researcher at the Institute for Biomedicine of EURAC Research in Bolzano (January 2021-March 2022) and at the LIDER-Lab of Scuola Superiore Sant’Anna (September 2020-December 2020). He was also *cultore della materia* (teaching assistant) in Private Law at the University of Pisa (2016-2019) and in Markets, regulation and law at LUISS University (2018) and research assistant at the LIDER-Lab of Scuola Superiore Sant’Anna (2015-2019). Along these commitments, he is also Adjunct Professor at the Department of Business and Management of LUISS Guido Carli University (September 2020-today), Scientific collaborator at the LIDER-Lab of Scuola Superiore Sant’Anna (March 2019-today), and reviewer-associated staff for the journal *Opinio Juris in Comparatione* (March 2014-today).

Aside from his academic activities, Andrea Parziale practiced in EU Antitrust Law at De Matteis Law firm in Rome (May 2019-May 2020) and in a variety of matters at Willkie Farr and Gallagher (Milan, October 2018-April 2019). He also interned at the EU Office for Investment for Health and Development of the WHO (November 2017-April 2018).

Andrea Parziale earned his PhD in Law at Scuola Superiore Sant’Anna (2015-2019), where he was also awarded a Honour Degree in Legal Sciences (2010-2016), in parallel with a Law Degree at the University of Pisa (J.D, 2010-2015).

He authored or co-authored 1 monograph in English, 39 journal articles, and 4 book chapters.

QUALIFICATIONS

- A) Andrea Parziale was awarded his **PhD** in Law from Scuola Superiore Sant’Anna in March 2019 with a thesis on “Civil Liability and Regulation in off label uses of medicines in the EU, France, Italy in March 2019.
- B) From 2018 to date, he developed and offered several **courses and seminars** at the University of Maastricht, LUISS University and University of Pisa.
- C) He carried out **documented research activities in qualified institutes in Italy and abroad**. He is currently Assistant Professor at the Department of Health, Ethics and Society, Faculty of Health Medicine and Life Science of Maastricht University (October 2023-today); Maria Sklodowska-Curie Fellow at the Institute for Transitional Legal Research of the Faculty of Law of the University of Maastricht (April 2022-September 2023), Scientific collaborator at the LIDER-Lab of Scuola Superiore Sant’Anna (March 2019-today); post-doc researcher at the Institute for Biomedicine of EURAC Research, Bolzano (January 2021-March 2022) and at the Scuola Superiore Sant’Anna (September 2020-December 2020).
- D) As to **research projects**, Andrea Parziale was PI in the Marie Curie Individual Fellowship project FullCompensation (2022-2023). He took part at the projects “CG – Research towards improving the governance of health data in cyberspace (Nordforsk fund, 2021-2022); the H2020 “ENLIGHTENme” (2021-2022); the EFRE 2020 “CHRIS-2D” (2021-2022); the Regione Toscana Bando Salute project “OPT-HepaC” (2020).
- E) **organization, management and coordination – or participation – in national and international research groups**. He is Scientific collaborator at the LIDER-Lab of Scuola Superiore Sant’Anna (March 2019-today), and reviewer-associated staff for the journal *Opinio Juris in Comparatione*

(March 2014-today). In the past, he was post-doc researcher at the Institute for Biomedicine at EURAC Research in Bolzano (2021-2022) and at the Lider-Lab of Scuola Superiore Sant'Anna (2020), and Intern at the European Office for Investment for Health and Development of the WHO.

- F) He participated as a speaker at several **national and international conferences**. From 2018 to 2024, he self-certifies the participation at 29 events in Italy, US, Austria, Belgium, Greece, Ireland, the Netherlands, Poland. He also contributed to the organization of 7 conferences.
- G) As to **national and international awards for research activities**, Andrea Parziale was awarded the Marie Curie Individual Fellowship project "FullCompensation" (2022-2023). He obtained funding for the 2021-2022 Nordforsk fund CG project.
- H) The candidate does not hold any other **European doctoral degree** recognised by international Boards as regards the academic recruitment fields where applicable.

PUBLICATIONS

The candidate submitted for evaluation the following twelve publications.

- 1) **(monograph) Parziale A, The Law of Off-label Uses of Medicines: Regulation and Litigation in the EU, UK and USA, Routledge, London-New York, 2022**

The book examines the regulatory framework for untested and unapproved (off-label) uses of medicines in the EU, UK and USA. It clarifies the regulatory mechanisms and litigation trends concerning off-licence prescriptions, and assesses how traditional, prevention-driven regulatory and civil liability rules are being adapted to tackle potential risks and scientific uncertainty. In this sense, it focuses on court cases on medical liability, product liability and state liability for each of the jurisdictions analysed, drawing meaningful conclusions. Specific attention is paid to the influence of the precautionary principle and its impact on the interpretation of civil liability rules, and comments on the impact of a precautionary-driven civil liability system on risk regulation. The book concludes by offering a final comparative assessment of the regulatory and civil/tort liability framework for off-label uses of medicines, sketching gaps and proposing alternative institutional mechanisms to tackle unknown risks.

The monograph is single-authored and it is published by a renowned international publisher.

- 2) **(journal article) Parziale A, La riforma italiana dei comitati etici nel contesto europeo: sfide, opportunità e spunti comparatistici, Rivista italiana di medicina legale e del diritto in campo sanitario, 2023, pp.103-121**

The article describes the main changes introduced by the Decree of the Ministry of Health of 26 January 2023 against the backdrop of the Italian "long reform" of ethics committees. It also discusses, with some comparative references, the potential and limits of the Decree in relation to the challenges posed both by the new authorization procedure for clinical trials under Regulation (EU) 536/2014 and by the most innovative forms of biomedical research. The article concludes with a number of possible measures regarding the composition and functioning of ethics committees, which could better enable them to deal with an increasingly challenging regulatory and research environment, also in light of a comparative analysis of several EU Member States.

The article is single-authored and it is published on an ANVUR A-ranked and SCOPUS indexed journal that is a leading Italian publication outlet for health law topics.

- 3) **(journal article) Parziale A, COVID-19 off-label uses of medicines: the role of civil liability and regulation, Geneva Papers on Risk and Insurance – Issues and Practice, 2023, pp.669-686**

The article maintains that civil liability may incentivize health actors to follow and react to the development of the evidence basis for off-label uses, but it is ultimately unable to incentivize additional research on the

matter. In light of the key role of off-label research to protect patients and the fact that it is also recommended by international medical ethics, the contribution proposes incentive mechanisms to tackle the problem. It argues that extending civil liability for unknown risks may have undesired effects on insurability and innovation, and criticizes current regulatory proposals for their ineffectiveness. The article then builds on the 2014 Italian reform of off-label uses to advocate for the establishment of a public fund financed by mandatory contributions from the industry, to be used by regulators in order to promote off-label research and develop guidelines for prescribers.

The article is single-authored and published on a SCOPUS-indexed journal (SJR Q2 for accounting, business-management, economics-econometrics and finance) that is also listed as Scientific Review by ANVUR for Area 12 (Law).

4) **(case note) Parziale A, “La bellezza è negli occhi di chi guarda”: la Corte di giustizia alla prova dell’intersezione tra farmaco e cosmetico, Il Foro Italiano, 2023, pp.39-47**

The case note comments on the CJEU’s decision in *C-616/20 M2Beauté Cosmetic GmbH v Bundesrepublik Deutschland*. After a thorough reconstruction of the national judicial path that led to the referral and a summary of the key points of the AG Opinion and the decision, the contribution focuses on its impact on the issue of borderline products and their scientific, economic and legal relevance, praising the guidelines it gives to national authorities to correctly classify them on the basis of their actual use, and its opening to the use of data coming from products having similar chemical compositions in order to qualify it (or not) as a medical product for therapeutical use. At the same time, the case note criticizes the conceptual conflict between this decision and the CJEU’s case law on the criteria to distinguish between a pharmaceutical and a food product, highlighting the risk of confusion and conflicting future decisions.

The case note is single-authored and published on an ANVUR A-ranked journal.

5) **(journal article) Parziale A, Rischio clinico e responsabilità civile del personale sanitario e della struttura per difetto di organizzazione, Rivista italiana di medicina legale e del diritto in campo sanitario, 2020, pp.2011-2026**

The article provides a brief review of the evolution of clinical risk management. On this basis, it describes the relevant principles established by the Italian Law no.24/2017, assessing them against dominant case-law trends on the civil liability of healthcare professionals and organizations for defective management. The paper tests the suitability of such a regulatory and judicial framework against the extraordinary pressure caused by the COVID-19 pandemic on public and private healthcare facilities in Italy, with particular regard to hospital-associated infections and delayed treatments of other facilities. It argues that while the current state of the art offers sufficient flexibility to consider the particularities of individual cases, it still fails to tackle the risk of a steadily increase of administrative costs related to litigation, which may lead to their unsustainability. Against the background of several scholarly suggestions in favor of the establishment of an indemnification fund for persons injured by COVID-19, the article maintains that such a fund should be entrusted with a right of recovery against healthcare organizations in the case of gross management defects, and urges further research on the risk of mass tort litigation against the Italian State and its Regions.

The article is single-authored and published on an ANVUR A-Ranked and SCOPUS-indexed journal.

6) **(journal article) Parziale A, Responsabilità civile da usi off-label di farmaci nell’UE: una prospettiva precauzionale, Opinio Juris in Comparatione, vol.I, 2020, pp.11-29**

The article investigates whether and to which extent civil liability and other institutional mechanisms may help clarifying the scientific uncertainties related to the off-label uses of drugs. To this end, it offers a comparative analysis of the regulatory framework and case law in the EU, Italy and France, which represent legal systems where off-label uses have triggered relevant legislative innovation. The assessment shows the presence of evolutionary paths, such as the judicial reinterpretation of civil liability rules through the lens of the

precautionary principle and the legislative provision of no-fault compensation systems and ADR mechanism, which may have a potential positive impact in the field of off-label uses, by clarifying the obligations of doctors, producers and regulators and facilitating damage compensation.

The paper is single authored and it is published on an ANVUR A-Ranked Italian journal.

- 7) **(case note) Parziale A, Competition law implications of off-label uses of medicines: F.Hoffmann-La Roche Ltd and others v Autorità Garante della Concorrenza e del Mercato (AGCM), European Competition Law Review, n.5, 2018, 232-237**

The case note comments on the CJEU's decision in case C-179/16 F.Hoffmann-La Roche Ltd and others v Autorità Garante della Concorrenza e del Mercato (AGCM). It offers a thorough analysis of the national judicial path that led to the referral to the Court, of the AG Opinion and of the final decision, offering interesting comments on the impact of this precedents on the definition of relevant market, the exemption of anti-competitive arrangements ancillary to a licensing agreement from the prohibition under Article 101(1) TFEU, the notion of restriction of competition by object, and the interpretation of the exemption under Article 101(3) TFEU and Article 2 of Regulation 772/2004 in the context of off-label uses of medicines. The contribution emphasizes the merit of the judgment in contributing to the definition of the boundaries between legitimate and illegitimate behaviors in the field, and providing flexible criteria for competition authorities to address the legal and scientific uncertainty that concern off-label uses of medicines. It also highlights potential paths for future decisions in the field, with regard to the possibility for competition law enforcement to tackle risk perception manipulations under scientific uncertainty.

The paper is single-authored and published in an ANVUR A-ranked international journal.

- 8) **(journal article) Parziale A, Orphan Drugs under EU competition law: the price is not right, Opinio Juris in Comparatione, vol.1, 2017, pp.97-121**

The article claims that the prohibition of abuse of dominant position could play a role in reducing orphan drugs' prices. First, it shows that market exclusivity provides orphan drugs manufacturers with a dominant position in their reference markets. Then, it applies and adapts the excessive price test developed by the CJEU to orphan drugs, arguing that civil liability could also play a role, by compensating the damages suffered by national health care systems. IT concludes by noting that recent enforcement developments in the EU concerning excessive prices of medicines confirm the potential role of competition law in curbing orphan drug prices.

The paper is single-authored and published on an ANVUR A-Ranked journal.

- 9) **(journal article) Parziale A, Il futuro dei farmaci orfani tra promozione della ricerca per la cura di malattie rare e i rischi di prezzi eccessivi: il ruolo del diritto della concorrenza, Contratto e impresa, n.4-5, 2016, 1245-1277.**

The article focuses on the challenges raised by orphan drugs for the health care systems and the protection of the right to health, due to the lack of incentives to innovate in the sector for private actors. Empirical evidence suggest that, due to the fragmented regimes of price fixation and reimbursements in the EU Member States, pharmaceutical companies are able to set up prices for orphan drugs that are much higher than those offered for common drugs. The article builds on the intuition, already advanced by some scholars, that this practice may entail a case of abuse of dominant position under Article 102(a) TFEU, and investigates whether and to which extent EU antitrust law may contribute to lower the level of orphan drugs prices, in an attempt to balance the need to incentivize private actors with the need to preserve public health and drug accessibility.

The paper is single-authored and published on a ANVUR A-ranked Italian journal.

- 10) **(book chapter) Parziale A, Staunton C, Research biobanks and external researchers under the European Data Protection regulation: between controller-processor relationship and joint controllership**, in J Faintuch, S Faintuch (eds), *Integrity of Scientific Research Fraud, Misconduct and Fake News in the Academic, Medical and Social Environment*, Springer, 2022, pp.93-100

The chapter maps the issues related to the GDPR qualifications of biobanks and external researchers. It outlines whether and under what conditions biobanks and external researchers are in a controller-processor relationship or joint controllers and the respective operational implications for biobanks. It then concludes with some general practical advice to research biobanks.

The article is published on a prestigious international publisher. It does not specify what the individual contribution of each author was, but the candidate appears as the first and corresponding author.

- 11) **(case note) Parziale A, L'uso off-label di Avastin (di nuovo) alla prova della Corte di giustizia: il delicato rapporto tra giudicato nazionale e rispetto del diritto dell'UE**, *Il Foro Italiano*, vol.IV, 2022, pp.474-481

The contribution is a case note commenting on the CJUE decision in C-261/21 *Hoffmann-La Roche Ltd et al v Autorità garante della concorrenza e del mercato*. After a thorough reconstruction of the national judicial path that led to the referral and a summary of the key points of the decision, the case note draws conclusions on its limiting impact on the previous CJEU's case law regarding the possibility to reopen final national judgments on the basis of the principle of effectiveness of EU law. Then, it elaborates on the effects that the remission to national courts the task to define the notion of relevant market, and the deceptive nature of the information shared by pharmaceutical companies on the risks connected to the off-label use of specific drugs will have on EU antitrust law in the pharmaceutical sector.

The case note is single-authored and published on an ANVUR A-ranked journal.

- 12) **(journal article) Parziale A, Mascalzoni D, Digital Biomarkers in Psychiatry Research: Data Protection qualifications in Complex Ecosystem**, in *Frontiers of Psychiatry*, vol.13, June 2022, Article 873392, 1-10.

The article discusses the GDPR legal qualifications of controller, processor and joint controllers in the complex ecosystem unfolded by the integration of digital biomarkers in psychiatric research, considering their implications and proposing some general practical recommendations. It aims at filling in the gaps in the literature with regards to the missing analysis of the implications of data protection law on the widespread use of digital devices, such as smartphones and wearables, to collect and use data related to mental health to conduct psychiatric research.

The article does not specify what the individual contribution of each author was, but the candidate appears as the first and corresponding author. The contribution appeared in *Frontiers of Psychiatry*, which is an SJR Q1 journal for Psychiatry and Mental Health, but does not appear in rankings or lists related to the Legal field.

OVERALL CONSISTENCY OF THE SCIENTIFIC PRODUCTION

The scientific production of Andrea Parziale appears to be articulated along four research lines, which could be mostly identified in medical liability, biomedical research law (cross-sectoral), the integration of biomedical innovation into healthcare settings, and the allocation of/access to research results, with isolated publications in the field of regulation of AI and algorithms, 3D printing and competition law in the pharmaceutical market. In this respect, the outputs submitted to evaluation show an overall consistency and span across a variety of subjects, making use of interdisciplinary research approaches, with a coherent, consistent and rigorous use of comparative law methodologies in most of the contributions.

As to the intensity and temporal continuity of his scientific production, he lists 44 contributions (1 monograph, 4 book chapters and 39 journal articles/case notes), both in Italian and in English and published on a wide array

of national and international outlets, all well ranked. The production is consistent in time and without interruptions from 2013 to date. Compared to his academic seniority which, according to the principle of normalisation adopted in the evaluation criteria approved by this Committee during its first meeting, equals to 2024-2015 (starting year of the PhD) + 1 = 10 years, his academic productivity has been intense, continuous and very consistent over time, and marked by the recent publication of a monograph with a prestigious international publisher, which consolidates his position in the international academic milieu on his main research area.

RESEARCH PROJECT

Andrea Parziale presented a research project that aims at (i) identifying the grey areas in the multilevel framework for healthcare and biomedical research and (ii) proposing solutions to improve both legal clarity over the responsibilities of the actors involved and protection of individuals' fundamental rights and trust.

The project builds on the candidate's past and ongoing research in health law across the main phases of the life cycle of biomedical innovation, leveraging on the comparative insights derived thereof. More specifically, he plans to focus on three research lines, and namely (1) bioethical and data protection implications of medical research, with particular regard to the use of health-related data for research; (2) evolving liability implications for medicines and medical devices, with a specific focus on the liability of healthcare actors for the use of innovative and personalized technologies; and (3) right to access to healthcare, considering the role of public-private collaborations and their impact on the organization of healthcare systems, and on the actual definition of the levels of assistance in the context of universal healthcare coverage, with a special attention devoted to global health and competition law.

PUBLIC SELECTION FOR ONE FIXED-TERM TENURE TRACK RESEARCHER (RICERCATORE A TEMPO DETERMINATO) WITH FULL TIME TEMPORARY CONTRACT PURSUANT TO ITALIAN LAW NO. 240/2010, ART. 24 AS UPDATED BY ARTICLE 14 OF DECREE LAW NO. 36, 30 APRIL 2022, CONVERTED WITH AMENDMENTS BY LAW NO. 79, 29 JUNE 2022, AT THE ACADEMIC FACULTY OF SOCIAL SCIENCES AND THE DIRPOLIS INSTITUTE IN THE ACADEMIC RECRUITMENT FIELD “COMPARATIVE LAW” (SC 12/E2) – ACADEMIC DISCIPLINE “COMPARATIVE PRIVATE LAW” (SSD IUS/02), ISSUED BY RECTOR’S DECREE 773 OF NOVEMBER 6, 2023

MINUTE OF THE LAST MEETING

The Evaluation Committee for the selection of one fixed-term tenure track researcher (ricercatore a tempo determinato) for the Academic Recruitment Field “Comparative Law” (SC 12/E2) – Academic Discipline “Comparative Private Law” (SSD IUS/02) at the Academic Faculty of Social Sciences – the Dirpolis Institute of the Sant’Anna School of Advanced Studies - Pisa pursuant to Italian Law No. 240/2010, Art. 24 as updated by article 14 of Decree Law No. 36, 30 April 2022, converted with amendments by Law No. 79, 29 June 2022, appointed by Rector’s decree No. 115 of February 28, 2024, consists of:

- Prof. Ermanno Calzolaio, Full Professor of the Academic Recruitment Field “Comparative Law” (SC 12/E2) – Academic Discipline “Comparative Private Law” (SSD IUS/02) at the University of Macerata;
- Prof. Eugenia Dacornia, Professor at the National and Kapodistrian University of Athens;
- Prof. Caterina Sganga, Associate Professor of the Academic Recruitment Field “Comparative Law” (SC 12/E2) – Academic Discipline “Comparative Private Law” (SSD IUS/02) at the School, designated member by the Dirpolis Institute.

The Committee convened for the fourth time, on June 20, 2024 at 2.00 p.m. in the meeting Room at the second floor in the Building of the School in Via Santa Cecilia, 3, Pisa.

The President ascertained that all the members of the Committee were present and he declared the session open.

The Committee ascertained that n.3 candidates are present.

The President informs the candidates that the interview will be held on alphabetic order and identify the candidates (identification form is Annex 1 to these minutes).

The Committee notes that in addition to the candidates, other interested parties are not present.

The President invites candidate Dr. Chiara GALLESE to hold her seminar to ascertain the knowledge of English language and then starts the interview about his qualifications, publications and research experience.

The President invites candidate Dr. Andrea MARTANI to hold his seminar to ascertain the knowledge of English language and then starts the interview about his qualifications, publications and research experience.

The President invites candidate Dr. Andrea PARZIALE to hold his seminar to ascertain the knowledge of English language and then starts the interview about his qualifications, publications and research experience.

At the end of the interviews, the Committee invited the candidates to leave the meeting room and continue the meeting.

Then, after a thorough debate, the Committee assigned the scores to the qualifications, to each publication submitted by the candidate and to the overall consistency of the scientific production, on the basis of the criteria defined in the preliminary meeting. The scores assigned are listed in Annex No. 2.

Thereafter the Committee summarised the scores assigned to the candidates.

Name and surname	Application number	Qualifications	Publications	Overall consistency of the scientific production	Final score
GALLESE Chiara	1487518	19.5	23.5	25	68
MARTANI Andrea	1492351	15.5	17.6	32	65.1
PARZIALE Andrea	1494661	20	32	38	90

On the basis of the scores obtained, the Committee declared Dr. Andrea PARZIALE winner of the selection.

Therefore, the Committee declared the work finished and decided that the Secretary will send a signed copy of this minutes to the Staff Office.

The meeting was adjourned at 18.00.

THE COMMITTEE

Prof. Ermanno Calzolaio (President)

Prof. Caterina Sganga (Secretary)

Prof. Eugenia Dacronia (Member)

ANNEX 2

Detailed scores

CANDIDATE: GALLESE Chiara

CURRICULUM

Chiara Gallese is a Marie Curie Fellow at the University of Turin, Department of Law (July 2023-June 2025) and a Fellow at the Information Society Law Center at the University of Milan (October 2023-October 2025). In the past she was post-doctoral research fellow at the University of Trieste, Department of Mathematics (July 2022-June 2023), Research Fellow and Subject expert at the LIUC (February 2022-June 2023), member of the Interdepartmental Laboratory “Bicocca Security Lab” at the Milano-Bicocca University (2017-2018), Visiting PhD candidate at the University of Tokyo (April-May 2017), the Max Planck Institute of Hamburg (March-June 2016) and Keio University (March-August 2015), and Research Intern at the Vanderbilt University (July-August 2016). She holds a Bachelor’s degree and a Master’s degree in Languages, law and economics of East Asia from the Ca’ Foscari University of Venice (2001-2004 and 2004-2006); a Juris Doctor degree (5 years) from the University of Padua (2007-2012), and a PhD in Private International Law and Asian Studies from the Ca’ Foscari University of Venice (2013-2017), for which she was awarded the Bonacossa National Prize for the Best PhD dissertation from the University of Pavia (2017).

Aside from her academic activities, she was also Senior Privacy consultant and Attorney at the PLS Legal law firm (2018-2019), and practiced as an attorney in other two law firms from 2015 to 2019.

She authored 16 publications from 2016 to 2023. 3 publications are in press and forthcoming in 2024. She also declared to have submitted 2 contributions and to have 3 manuscripts in preparation.

She self-certified two periods of maternity leave, from 9 February to 9 June 2003 and from 14 May 2019 to 31 January 2021.

QUALIFICATIONS

- I) Chiara Gallese was awarded her **PhD** in Private International Law and Asian Studies at the Ca’ Foscari University of Venice in 2017 with a thesis on “The reform of private international law in Japan” **(6/6 points)**.
- J) From 2014 to date, she carried out a wide range of **teaching activities** as a tutor/lecturer (Ca’ Foscari University, 2014-15), teaching assistant (Waseda University, May 2017), Lecturer on different subjects (Eindhoven, 2020-2022), and invited lecturer in Jaipur, Ca’ Foscari, Padua and Trieste from 2022 to 2023 **(3/3 points)**.
- K) She carried out **documented research activities in qualified institutes in Italy and abroad**. She is currently a Marie Curie Fellow at the University of Turin, Department of Law (July 2023-June 2025), a Fellow at the Information Society Law Center at the University of Milan (October 2023-October 2025) and a Guest Researcher at the Eindhoven University of Technology (February 2022-today). In the past she was post-doctoral research fellow at the University of Trieste, Department of Mathematics (July 2022-June 2023), Research Fellow and Subject Expert at the LIUC (February 2022-June 2023, and a.y. 2020/21), Member of the Interdepartmental Laboratory “Bicocca Security Lab” at the Milano-Bicocca University (2017-2018), Visiting PhD candidate at the University of Tokyo (April-May 2017), the Max Planck Institute of Hamburg (March-June 2016) and Keio University (March-August 2015), and Research Intern at the Vanderbilt University (July-August 2016) **(2/2 points)**.
- L) Chiara Gallese was involved in several **research project activities**. Those most related to the academic recruitment field 12/E2 are the Horizon 2020 projects at the Eindhoven University of Technology where she acted as a “Scientific Information Specialist”, carrying out privacy and ethical compliance tasks (February 2021 – January 2022). She was a postdoctoral research fellow at the University of Trieste in the context of the UNI4Justice project (2022-2023) and a research fellow at the LIUC University in the context of the REMIDE project (2021-2022). Currently and from 2022, she is a guest

researcher at the Eindhoven University of Technology, working as an Ethics and Privacy Consultant in the context of Horizon Europe AIRISE project (2023-today). From 2023, she is also Multistakeholder Board member as Independent Advisor on Ethical and Legal issue in the Horizon Europe REALM project (2023-today). In 2020-2021, she participated at the EU COST-action “DigForAsp”. She also reports minor participations in other local university projects and in the drafting of EU projects (2/2 points).

- M) **organization, management and coordination – or participation – in national and international research groups.** Chiara Gallese is an editorial board member of Genius, an ANVUR A-Ranked journal from 2023. She is a fellow at the Information Society Law Center at the University of Milan (2023-2025), and was a member of the interdepartmental laboratory “Bicocca Security Lab” at the Milano-Bicocca University (2017-2018) (1.5/4 points).
- N) She participated as a speaker at several **national and international conferences.** From 2015 to 2024, she self-certifies the participation at 40 event in Italy, Japan, UK, the Netherlands, Sweden, Belgium, the US, Russia, Spain (3/3 points).
- O) As to **national and international awards for research activities,** Chiara Gallese has been awarded a MSCA European postdoctoral fellowship (2023), a Law Excellence Early Scholar scholarship from the University of Turin (2022), a best paper award at the 19th IEEE International Conference on Computational Intelligence in Bioinformatics and Computational Biology in Ottawa (2022), the Bonacossa National Prize for the Best PhD Dissertation from Pavia University (2017), the “Best research work” award from Ca’ Foscari University (2014), together with a PhD scholarship (2013-2017) (2/2 points).
- P) **European degree** recognised by international Boards as regards the academic recruitment fields where applicable (0/2 points).

TOTAL POINTS FOR QUALIFICATIONS: 19.5/24.

PUBLICATIONS

The candidate submitted for evaluation the following twelve publications.

- 13) **(conference proceedings) Gallese, C.; Scantamburlo, T; Manzoni, L.; Nobile, M.S. (2023). Investigating Semi-Automatic Assessment of Data Sets Fairness by Means of Fuzzy Logic, in 2023 IEEE Conference on Computational Intelligence in Bioinformatics and Computational Biology (CIBCB), pp.1-10. Piscataway: IEEE, ISBN: 979-8-3503-1017-7, Eindhoven, 29/08/2023 - 31/08/2023, doi: 10.1109/CIBCB56990.2023.10264913**

The paper focuses on the challenges raised by the social bias conveyed by data sets into AI systems based on machine learning, and by the consequences they trigger in terms of perpetuation of such biases within the model. It offers a preliminary framework for the semi-automated evaluation of fairness in data sets, by combining statistical information about data with qualitative consideration. To this end, the paper addresses the issue of how much fairness can be included in a data set used for machine learning research, focusing on classification issues. To offer guidance for the use of data sets in critical decision-making processes, such as health decisions, it identifies six fundamental features (balance, numerosity, unevenness, compliance, quality, incompleteness) that could affect model fairness, and it develops a rule-based approach based on fuzzy logics that combines these characteristics into a single score and enables a semi-automatic evaluation of a data set in algorithmic fairness research.

The candidate declares that her contribution to the joint work included the original conception of the piece, the construction of the theoretical legal model and the selection of the calculation technique and the software features. More specifically, she declared to have written three-quarter of the Introduction, half of the Conclusions and the entire description of the features of the datasets under Section III.

The paper is published online as an IEEE conference paper, which has a limited scientific relevance in the legal field compared to other scientific realms. It adopts an original and innovative approach to the definition of fairness in data sets, using as a benchmark predominantly the EU legal system, with limited comparative references. The contribution is coherent with the specific profile of the call but has less relevance, from a methodological and conceptual standpoint, for the academic recruitment field (12/E2 – Comparative Law), as it shows a limited mastery in the comparative methodology.

- a) Originality, innovation, methodological rigor and relevance: **0.5 points;**
- b) coherence of the publication with the academic recruitment field and with the specific profile of the call, or with closely related interdisciplinary subjects: **0.2 point;**
- c) scientific relevance of the journal / publisher and its impact factor within the scientific community: **0.2 points;**
- d) analytical determination, on the basis of guidelines recognized by the relevant international scientific community of the individual contribution of the researcher in the case of works carried out in partnership: **0.5 points.**

Total: 1.4/3 points.

- 14) (conference proceedings) Gallese C., Fuchs C., Riva S. G., Foglia E., Schettini F., Ferrario L., Falletti E., Nobile M. S. (2022), Predicting and Characterizing Legal Claims of Hospitals with Computational Intelligence: the Legal and Ethical Implications. In: 2022 IEEE Conference on Computational Intelligence in Bioinformatics and Computational Biology (CIBCB). p. 1-9, IEEE, ISBN: 978-1-6654-8462-6, Ottawa, ON, Canada, doi: 10.1109/CIBCB55180.2022.9863033.

The paper proposes a fuzzy logic-based approach to analyze UK National Health Service public administrative data related to pre-and post-pandemic claims filed by patients, analyzing the legal and ethical issues connected to the use of Artificial Intelligence systems to take critical decisions having a significant impact on patients, including the management choices related to Intensive Care Unit bed allocations. It advances the state of the art by following an unsupervised approach and performing an analysis of UK hospitals by means of a computational intelligence algorithm integrating Fuzzy C-Mans and swarm intelligence. The paper concludes that computational intelligence should not be employed to take critical decisions that cause harm to data subjects, at least not without having fully informed them of the consequences of the processing, and without the intervention of a human in the decision-making process.

The candidate declares that her contribution to the joint work included the original conception of the piece, the construction of the theoretical legal model, the selection of the dataset. More specifically, she declared to have written the entire article, with the exclusion of the computational Sections (II-III).

The paper is original in its approach and offers an innovative take on the analysis of relevant datasets and on the application of AI methods to assess the efficiency of medical decisions. It also applies with methodological rigor the relevant legal framework to the matter, although in this respect the innovative nature of the article is limited to the very subject matter at stake (NHS data and hospitals) and does not relate to the general topic, which has been already investigated by a number of scholars from different disciplines. The contribution is undoubtedly coherent with the specific profile of the call, although it does not engage into a comparative analysis of the problem. This is an IEEE conference paper, which has a limited scientific relevance in the legal field compared to other scientific realms.

- a) Originality, innovation, methodological rigor and relevance of the publication: **0.5 point;**
- b) coherence of the publication with the academic recruitment field and with the specific profile of the call, or with closely related interdisciplinary subjects: **0.2 point;**
- c) scientific relevance of the journal / publisher and its impact factor within the scientific community: **0.2 point;**

- d) analytical determination, on the basis of guidelines recognized by the relevant international scientific community of the individual contribution of the researcher in the case of works carried out in partnership: **0.5 point**.

Total: 1.4/3 points.

15) **(journal article) Chiara Gallese, A first comment to the proposal for a new Regulation on fair access and use of data (Data Act), in Media Laws, n.3/2022**

The article examines the proposal for an EU Data Act, which had been published shortly before the paper submission, assessing the new legal framework in light of the European digital strategy and the Strategy for Data and describing how the proposal was conceived. It explores the new Data Act definitions, scope, subject matters and most important innovative provisions and their impact on different stakeholders. The paper concludes with an analysis of gaps and limitations, and related suggestions on how to tackle them.

The article, single-authored and published on a review that is indexed as “A-ranked” (Fascia A) by ANVUR for Area 12 (Law), offers a thorough analysis of the background of the Data Act and of its main provisions, and assesses its shortcomings with original conclusions and a methodologically sound approach, with a timely and relevant intervention in a debate that was unfolding at the time of publication of the contribution. The contribution is coherent with the specific profile of the call, but it only partially makes use of comparative law methodology since its focus is predominantly EU law.

- a) Originality, innovation, methodological rigor and relevance: **0.9 point**;
- b) coherence of the publication with the academic recruitment field and with the specific profile of the call, or with closely related interdisciplinary subjects: **0.3 point**;
- c) scientific relevance of the journal / publisher and its impact factor within the scientific community: **0.5 point**;
- d) analytical determination, on the basis of guidelines recognized by the relevant international scientific community of the individual contribution of the researcher in the case of works carried out in partnership: **1 point**.

Total: 2.7/3 points.

16) **(journal article) Chiara Gallese, Legal aspects of the use of Artificial Intelligence in Telemedicine, Special Issue on Law and Ethics of Artificial Intelligence, Journal of Digital Technologies and Law, ISSN Electronic: 2949-2483, n.2/2023**

The paper analyses the legal implications of the use of AI in telemedicine, especially when continuous learning and automated decision-making systems are involved. It does it by exploring the legal framework regarding telemedicine and AI in Europe, with particular regard to sources such as the GDPR and the AI Act proposal, and by providing a thorough overview of the most relevant scholarly contributions in the field. On this basis, it highlights outstanding issues that are not fully addressed by the current legislation, and proposes a range of legislative and non-legislative measures to fill in such gaps.

The paper is single authored and it is published on the Journal of Digital Technologies and Law, an open access peer-reviewed journal based in Russia but having an international board of editors (featuring also the candidate). It is not indexed on Scopus or SJR and is not present in the list of Scientific Journals and Reviews for Area 12 (Law) listed by ANVUR.

The article is coherent with the specific profile of the call, but makes a limited use of comparative law methodology as it focuses mostly on EU law, with limited references to national legal systems. It offers a comprehensive overview of the most relevant issues discussed by policymakers and the legal scholarship, with original and innovative takes on the matter mostly thanks to an interdisciplinary approach to single issues raised by telemedicine and their interrelations with the current legislative framework.

- a) Originality, innovation, methodological rigor and relevance: **0.8 point**;
- b) coherence of the publication with the academic recruitment field and with the specific profile of the call, or with closely related interdisciplinary subjects: **0.3 point**;
- c) scientific relevance of the journal / publisher and its impact factor within the scientific community: **0.1 point**;
- d) analytical determination, on the basis of guidelines recognized by the relevant international scientific community of the individual contribution of the researcher in the case of works carried out in partnership: **1 point**.

Total: 2.2/3 points.

17) **(conference proceedings) Chiara Gallese, Suggestions for a Revision of the European Smart Robot Liability Regime, Proceedings of CIAIR 2022, Oxford, 2022**

The article explores liability issues pertaining AI and robots with regards to users, producers and programmers, with particular regards to cases when the use of machine learning techniques is involved. It assesses them against the current legislative framework, the policy actions and preparatory work undertaken so far and the proposal for an AI Act and Cyber-Resilience Act, and concludes with suggestions on new regulatory solutions for European lawmakers.

The article, single-authored and published online in the proceedings of the CIAIR 2022 Conference in Oxford, is coherent with the specific profile of the call, but makes a limited use of comparative law methodology as it focuses mostly on EU law, with limited references to national legal systems. It offers a comprehensive overview of the most relevant issues discussed by policymakers and the legal scholarship with regard to civil liability and compensation of damages arising from the use of AI and robots. While being rigorous in the descriptive analysis, the arguments and conclusions advanced have been already addressed by the literature in the past, making the contribution only partially original and innovative.

- a) Originality, innovation, methodological rigor and relevance: **0.5 point**;
- b) coherence of the publication with the academic recruitment field and with the specific profile of the call, or with closely related interdisciplinary subjects: **0.3 point**;
- c) scientific relevance of the journal / publisher and its impact factor within the scientific community: **0.1 point**;
- d) analytical determination, on the basis of guidelines recognized by the relevant international scientific community of the individual contribution of the researcher in the case of works carried out in partnership: **1 point**.

Total: 1.9/3 points.

18) **(journal article) Chiara Gallese, Regulating Smart Robots and Artificial Intelligence in the European Union, Journal of Digital Technologies and Law, n.1/2023, ISSN Electronic 2949-2483**

The paper, which in the version submitted to evaluation is entitled “Regulating smart robot and AI: some suggestions for a review of the AI Act proposal”, offers a thorough overview of the definitions offered of AI and robots by the literature, by a number of studies and preparatory works issued by EU institutions and by the proposal of AI Act, emphasizing the impossibility to reach common and overarching definitions in light of the highly heterogeneous actors at stake. Then, it moves to the analysis of the classification of risk categories proposed by the AI Act, explores regulatory solutions to prevent cyberattacks against old and obsolete software, machine learning models and black-boxes, and comments on security rules and standards for producers, programmers and users. It concludes by proposing a balanced system of security and standards, with related policy recommendations for the EU legislator to fill in the gaps left by the AI and Cyber-resilience Acts proposals.

The paper is single authored and it is published on the Journal of Digital Technologies and Law, an open access peer-reviewed journal based in Russia but having an international board of editors (featuring also the candidate). It is not indexed on Scopus or SJR and is not present in the list of Scientific Journals and Reviews for Area 12 (Law) listed by ANVUR.

The article is coherent with the specific profile of the call, but makes a limited use of comparative law methodology as it focuses mostly on EU law, with limited references to national legal systems. It offers a comprehensive overview of the most relevant issues discussed by policymakers and the legal scholarship with regard to security and safety of AI agents and robots in Europe. It offers a very rigorous descriptive analysis, complemented by an assessment of the various opinions and proposals advanced by scholars and EU institutions, and it draws interesting arguments and conclusions which are to a certain extent original in their take, with a substantial contribution to the debate.

- a) Originality, innovation, methodological rigor and relevance: **0.8 point**;
- b) coherence of the publication with the academic recruitment field and with the specific profile of the call, or with closely related interdisciplinary subjects: **0.3 point**;
- c) scientific relevance of the journal / publisher and its impact factor within the scientific community: **0.1 point**;
- d) analytical determination, on the basis of guidelines recognized by the relevant international scientific community of the individual contribution of the researcher in the case of works carried out in partnership: **1 point**.

Total: 2.2/3 points.

- 19) **(book chapter) Chiara Gallese, Prospettive di riforma del diritto internazionale privato giapponese (Prospects for a reform of Japanese private international law) in M. Cestari, G. Coci, D. Moro, A. Specchio, Orizzonti giapponesi: ricerche, idee, prospettive, Aracne Editrice, Roma 2018, pp. 678 (ISBN: 978-88-255-2118-4)**

The paper offers a comprehensive overview of the main features of the reforms that have changed the international private law regulation in Japan from 1989 to 2006. It examines the reasons underlying the reform and assesses the persisting problematic features of the system, focusing on specific matters such as, inter alia, the definition of public order and of some mandatory provisions, the uncertain notion of residence, the lack of regulation of contractual choice of law/jurisdiction, the uneven regulation of the notion of point of attachment and its consequences, and a number of provisions on substantial subjects.

The chapter, single-authored and published by an Italian publishers, represents one of the very few contributions in Italian on Japanese law, and particularly on Japanese private international law. It offers a very thorough and methodologically sound analysis of the topic. The contribution is partially coherent with the academic recruitment field (12/E2 – Comparative Law), for it covers a foreign legal system but without offering real comparative insights. In addition, it does not relate to the specific profile of the call.

- a) Originality, innovation, methodological rigor and relevance: **0.8 point**;
- b) coherence of the publication with the academic recruitment field and with the specific profile of the call, or with closely related interdisciplinary subjects: **0.2 point**;
- c) scientific relevance of the journal / publisher and its impact factor within the scientific community: **0.2 point**;
- d) analytical determination, on the basis of guidelines recognized by the relevant international scientific community of the individual contribution of the researcher in the case of works carried out in partnership: **1 point**.

Total: 2.2/3 points.

- 20) **(conference proceedings) Gallese, C., Falletti E., Nobile, M.S., Ferrario, L., Schettini, E., Foglia, E., Preventing litigation with a predictive model of COVID-19 ICUs occupancy, 2020 IEEE International Conference on Big Data, 2111, Atlanta, GA, USA**

The paper builds on the observation that the COVID-19 pandemic has generated an overall slowdown in hospital activities that may cause delays in healthcare interventions, and the scarcity of resources can raise concerns over allocation criteria. These circumstances could lead to lawsuits against hospital and healthcare professionals. In this context, predicting the litigation rate could be useful to assess the economic impact of a dispute at a local and national level, allowing hospital managements and public institutions to perform a cost/benefit analysis to decide whether to invest resources to increase critical care surge capacity. To this end, the paper present CLIP (COVID-19 Litigation Prediction), a modeling approach supported by swarm intelligence designed to estimate the future number of patients, and then exploits a probabilistic model to predict the number of occupied intensive care beds, whose parameters are calibrated by means of Fuzzy Self-Tuning Particle Swarm Optimization. The contribution argues that the development and availability of such a predictive model could be further used with other clinical conditions and important diseases, thus helping policy-makers in taking decisions under uncertain variables.

The candidate declares that her contribution to the joint work included the original conception of the piece, the construction of the theoretical legal model, the selection of the data sets and the model to be used, and the assistance to computer scientists in developing the model itself. More specifically, she declared to have written paragraphs 1 and 2. The paper is published online as an IEEE conference paper, which has a limited scientific relevance in the legal field compared to other scientific realms. It adopts an original and innovative approach to the problem of predicting litigation rates in healthcare issues, using as a benchmark predominantly the EU legal system, with limited comparative references. The contribution is coherent with the specific profile of the call but has less relevance, from a methodological and conceptual standpoint, for the academic recruitment field (12/E2 – Comparative Law).

- a) Originality, innovation, methodological rigor and relevance: **0.5 point;**
- b) coherence of the publication with the academic recruitment field and with the specific profile of the call, or with closely related interdisciplinary subjects: **0.2 point;**
- c) scientific relevance of the journal / publisher and its impact factor within the scientific community: **0.2 point;**
- d) analytical determination, on the basis of guidelines recognized by the relevant international scientific community of the individual contribution of the researcher in the case of works carried out in partnership: **0.5 point.**

Total: 1.4/3 points.

- 21) **(conference proceedings) Chiara Gallese, Legal aspects of the use of chatbot apps for mental health support, in: Highlights in Practical Applications of Agents, Multi-Agent Systems, and Complex Systems Simulation – The PAAMS Collection, Communication in Computer and Information Science, Springer, 2022, L’Aquila, Italy**

The paper explores the implications of using conversational agents such as chatbot apps to provide psychological supports to patients. It starts with an introduction on the role that chatbots have increasingly acquired in the mental health care context in recent years. Then, it offers an overview of the data protection principles governing the use of chatbots, looking at the types of data processed, at the security measures that need to be implemented and the informed consent that needs to be collected, and at the obligations descending from the fact that such apps operate profiling and, albeit not often, automated decision making. The paper moves to the Medical Device Regulation (MDR) to understand whether and to which extent its definition of medical devices may be applied to chatbots and thus subject them to its rules. Then, it makes very brief references to the AI Act Proposal and the Data Act proposal, with similarly brief reference to the legal issues arising from the fact that the chatbot patients may be qualified as vulnerable users.

The paper is single-authored. While it is undoubtedly coherent with the academic recruitment field and the specific profile of the call, the contribution offers only a very general, concise introduction and overview of the problem, without entering into relevant details that would go beyond the state of the art, but rather suggesting that more research is needed to explore such issues. In this sense, its originality is very limited, as well as its innovation potential and overall relevance vis-à-vis the state of the art, while the methodological rigor cannot be appreciated in light of the extreme conciseness of the piece.

- a) Originality, innovation, methodological rigor and relevance: **0.1 point**;
- b) coherence of the publication with the academic recruitment field and with the specific profile of the call, or with closely related interdisciplinary subjects: **0.5 point**;
- c) scientific relevance of the journal / publisher and its impact factor within the scientific community: **0.1 point**;
- d) analytical determination, on the basis of guidelines recognized by the relevant international scientific community of the individual contribution of the researcher in the case of works carried out in partnership: **1 point**.

Total: 1.7/3 points.

22) (journal article) Chiara Gallese, L'Orientalisme juridique et le droit japonais, Zeitschrift für Japanische recht, issue 21 n. 42, DJJV, Max-Planck-Institut für ausländisches und internationales Privatrecht (MPI), Hamburg, 2016

The article, written in French, offers an interesting and thorough reconstruction of the notion of Orientalism in law, from the first essay on the topic authored by Said in 1979 to its elaboration in subsequent comparative law contributions in the following three decades. The candidate opts for the use of the plural term “orientalismes”, arguing that the phenomenon and the cultures it looks at should be observed from different angles and perspectives. It builds on the theories of Ruskola, which argues that the adoption of a functional approach in comparative law and the application of similar legal categories to all legal systems penalizes national traditions that do not fall within the civil vs common law dichotomy, to analyze the prejudices and criticisms that have historically afflicted the analysis of Japanese law. In this context, it comments on scholars belonging to different jurisdictions, with a particular focus on Italian authors, shedding light on the reasons behind the marginal role that the study of Japanese law has always played. The chapter concludes by arguing that cultural aspects influence all legal systems and do not play a dominant role in the Japanese context as Occidental commentators may believe, and it proposes interesting solutions to overcome the limits the orientalist approach show and the consequences it caused in comparative legal studies.

The chapter, which is single-authored, is consistent and coherent with the academic recruitment field 12/E2 Comparative Law. It applies well comparative law methodologies to analyze a topic that is often neglected, although not completely new, and it does it with a relatively original take and with a publisher of high scientific relevance.

- a) Originality, innovation, methodological rigor and relevance: **0.5 point**;
- b) coherence of the publication with the academic recruitment field and with the specific profile of the call, or with closely related interdisciplinary subjects: **0.5 point**;
- c) scientific relevance of the journal / publisher and its impact factor within the scientific community: **0.5 point**;
- d) analytical determination, on the basis of guidelines recognized by the relevant international scientific community of the individual contribution of the researcher in the case of works carried out in partnership: **1 point**.

Total: 2.5/3 points.

- 23) **(book chapter) Chiara Gallese, Legal aspects of AI models in medicine. The role of interpretability**, in: Big Data Analysis and Artificial Intelligence for Medical Science (B.Carpentieri, P.Lecce eds), Wiley, 2024, forthcoming

The actual title of the chapter, as it results in the submitted draft, is “Legal Aspects of AI in the biomedical field. The role of interpretable models”. The chapter analyses the legal framework applicable of the development and the use of AI systems in the medical field. It focuses on fundamental principles of the GDPR and the AI Act proposals, with particular regard to transparency, legal basis of data processing, right of explanation, accountability, fairness and human oversight over high-risk AI systems. In this context, it explains the role that heterogeneous systems, where interpretable models work together with black boxes, may play to tackle the challenge of preserving accuracy while maintaining transparency in the use of AI models in medicine.

The chapter, which is single-authored, offers a complete but concise overview of the main principles and rules applicable to AI models used in medicine at the EU level, showing full awareness of the current academic and policy debate. It does it with methodological rigor, although the approach and focus adopted do not present remarkable originality and innovative takes, apart from the conclusions related to interpretable models and the role they may play in the future. The contribution is coherent with the academic recruitment field and the specific profile of the call, and it is forthcoming in a collection published by an internationally renowned publisher.

- a) Originality, innovation, methodological rigor and relevance: **0.4 point;**
- b) coherence of the publication with the academic recruitment field and with the specific profile of the call, or with closely related interdisciplinary subjects: **0.5 point;**
- c) scientific relevance of the journal / publisher and its impact factor within the scientific community: **0.4 point;**
- d) analytical determination, on the basis of guidelines recognized by the relevant international scientific community of the individual contribution of the researcher in the case of works carried out in partnership: **1 point.**

Total: 2.3/3 points.

- 24) **(book chapter) Chiara Gallese, Daniela Besozzi, Le sentenze antiscientifiche: un mito creato dai media (Judgments against science: a myth created by the media)** in Ius dicere in a globalized world. A comparative overview, RomaTre Press, 2018 (ISBN: 978-88-94885-96-5)

The book chapter, co-authored with Daniela Besozzi, focuses on the apparent tensions between the administration of justice – *id est* the work of judges and attorneys – and the scientific community. It offers numerous examples of judicial decisions and the criticisms raised by journalists, who argued that attorneys and courts willfully disregard the scientific literature and drew conclusions that propose their own, unfounded vision of science. To confute this reading, the authors look into the specificities of each case and the role played by prosecutors and judges in each example, illustrating the real foundations of each decision. They conclude by arguing that this misinformation is based on the lack of public awareness of the features of our judicial system, and advocate for the adoption of specific countermeasures to prevent the media “slander” against the legal professions.

The contribution is part of a collection published on RomaTre Press and has mostly a national (Italian) focus, with very limited or no comparative references, and on topics that are only indirectly in line with the specific profile of this call. The chapter focuses on an original topic but it is rather descriptive in the analysis of the reasons that justify the adoption of each decision. The approach is justified by the aim of confuting the validity of the claims made by media on the lack of scientific soundness of the judicial analysis, which gives to the chapter a disseminative rather than scientifically rigorous and innovative touch.

The candidate declares that her contribution to the joint work included the original conception of the piece and that she drafted the entire piece, while her co-author offered suggestions on the scientific (*sic*) part and corrected the proofs.

- a) Originality, innovation, methodological rigor and relevance: **0.3 point**;
- b) coherence of the publication with the academic recruitment field and with the specific profile of the call, or with closely related interdisciplinary subjects: **0.2 point**;
- c) scientific relevance of the journal / publisher and its impact factor within the scientific community: **0.2 point**;
- d) analytical determination, on the basis of guidelines recognized by the relevant international scientific community of the individual contribution of the researcher in the case of works: **0.9 point**.

Total: 1.6/3 points.

TOTAL POINTS FOR PUBLICATIONS: 23.5/36

OVERALL CONSISTENCY OF THE SCIENTIFIC PRODUCTION

The scientific production of Chiara Gallese appears to be articulated along three research lines, which could be mostly identified in AI law, health law, privacy and data law, with isolated publications on Japanese law. In this respect, the outputs submitted to evaluation show an overall consistency and span across a variety of subjects, making use of interdisciplinary research approaches and, less often and less consistently, of comparative law methodology.

As to the intensity and temporal continuity of her scientific production, great part of her contributions are in the timeframe 2022-2024 (19 declared, out of which 2 submitted, 3 forthcoming and 3 still in preparation), followed by 1 publication in 2016, 2 in 2018, 1 in 2020 and 1 in 2021. Compared to her academic seniority which, according to the principle of normalisation adopted in the evaluation criteria approved by this Committee during its first meeting, equals to 2024-2013 (starting year of the PhD) + 1 = 12 years, and considering the 2 years of self-certified maternity leave (divided in two periods of 4 months and 1 year and 8 months respectively), her academic productivity has not been particularly intense nor continuous in time, and seems to have spiked only recently.

Points: 11/20

RESEARCH PROJECT

Chiara Gallese presented a research project on “EUDATA – A new EU comparative perspective for ethical assessment of Medical Data sets for AI training”.

EUDATA aims at pioneering the development of an innovative EU framework to ensure the fair creation of AI datasets in healthcare. It builds on the assumption that the policymaking process is not keeping up with technological advancements, for the current EU and national legal frameworks are fragmented and do not comprehensively address the multifaceted issues of clinical AI, from errors to unevenness in data and missing information in clinical data sets. EUDATA plans to employ evidence-based anticipatory regulation to identify, build and test solutions to these issues, investigating the biases during the creation of datasets for AI model training, involving all relevant stakeholders and employing novel approaches, such as post-colonialist and feminist theories, in 6 countries (Italy, Poland, Romania, Bulgaria, Hungary and Slovenia). The aim is to uncover the types of biases occurring in clinical data creation, offering a legal definition, the reasons why they occur, what is needed to create fairer AI clinical datasets, and how such fairness should be regulated and interpreted in light of the EU Digital Strategy.

The project is fully coherent with the academic recruitment field, for it addresses very relevant, topical and timely challenges for the advancement of health law and the regulation of healthcare systems.

The project shows some innovation potential compared to the state of the art, where a definition of the term “fairness” remains vague and controversial, and theories that classify and define biases in AI datasets are similarly heterogeneous and not adequately backed by definitions that are at the same time technologically and normatively sound. Some degree of originality can also be found in the objective to address in a holistic manner issues such as AI data management, fairness in clinical datasets and inclusion of patients’ views in AI creation, adopting a data-centered approach and including in participatory regulation strategies in health law considerations coming specifically postcolonial and feminist ethnography. Some aspects of the project remain vague, even after the discussion during the interview.

Points: 14/20

Total points: 25/40

Summary

Qualifications: 19.5/24

Publications: 23.5/36

Overall consistency of scientific production + research product: 25/40

Total for applicant: 68/100

CANDIDATE: MARTANI Andrea

CURRICULUM

Andrea Martani is currently a Post-doctoral researcher at the Institute for Biomedical Ethics (IBMB) of the University of Basel, and a Research Associate at the Faculty of Law of the Vrije Universiteit Amsterdam. He is elected member of the Expert Group for Open Research Data of the Swiss Academy for Arts and Sciences and Member of the Research Committee of the University of Basel. In the past he was Research and teaching assistant at the Institute for Biomedical Ethics of the University of Basel (2018-2021), Research Associate in the “Progetto BioDiritto” at Faculty of Law of the University of Trento (February 2017 – November 2017).

He was awarded his PhD (Dr.sc.med.) in Biomedical ethics from the Faculty of Medicine of the University of Basel in October 2021, for which he was awarded a prize by the Medical Faculty. He holds a J.D. (Laurea magistrale in Giurisprudenza) in European and Transnational Law from the University of Trento (2012-2028), during which he was a Visiting Student at the School of Law of the University of Reading (2014-2015) and at the Interfaculty Centre for Biomedical Ethics and Law of KU Leuven (February-July 2017).

He is the author of 29 publications (journal articles and book chapters, mostly co-authored), with almost 300 citations and an H-index of 7, 1 contribution in press and 3 contributions submitted and/or in peer review. In Basel, he delivers several courses at the undergraduate, Master’s and PhD level, for which was nominated for the “Future Talents” category of the Teaching Excellence Awards 2023.

QUALIFICATIONS

- I) Andrea Martani was awarded his **PhD** in Biomedical Ethics from the Faculty of Medicine of the University of Basel in October 2021 *summa cum laude*, with a thesis on “The datafication of Swiss healthcare and biomedical research: ethical and legal issues and the way forward for health data governance” **(5/6 points)**.
- J) From 2018 to date, he developed and offered a wide range of **courses and seminars** at the University of Basel, Institute of Biomedical Ethics, Faculty of Medicine and Department of pharmaceutical sciences **(3/3 points)**.
- K) He carried our **documented research activities in qualified institutes in Italy and abroad**. He is currently a Postdoctoral researcher at the Institute of Biomedical Ethics of the University of Basel (October 2021-today) and a Research Associate at the Faculty of Law of the Vrije Universiteit Amsterdam (January 2023-today). Before that, he was Research and Teaching Assistant at the Institute of Biomedical Ethics of the University of Basel (May 2018-October 2021) and Research Associate at the Faculty of Law of the University of Trento (February 2017-November 2017) **(2/2 points)**.
- L) As to **research projects**, Andrea Martani currently co-manages the ethical-legal work-package of a Dutch national project on how to improve the societal debate around gene-editing technologies. No further details are provided as to the project itself and its duration. He obtained funding from the Swiss Federal Office of Public Health for more than 40.000 CHF, although he did not specify the research project underlying the fund in the documentation attached to the application. He participated at the drafting and preparation of an ERC Advanced Grant – PI Professor Klaus Hoeyer, University of Copenhagen – awarded 2.5M euros. During the interview, he illustrated other research projects was/is still involved in. **(0.5/2 points)**
- M) **organization, management and coordination – or participation – in national and international research groups**. Andrea Martani is elected member of the Expert Group for Open Research Data of the Swiss Academy of Arts and Science. He is an active member of the Institute of Biomedical Ethics at the University of Basel, participates as a Research Associate to a national research group at the Vrije Universiteit Amsterdam, and was also a Research Associate in the “Progetto BioDiritto” at the University of Trento (February 2017-November 2017) **(2/4 points)**.

- N) He participated as a speaker at several **national and international conferences**. From 2018 to 2024, he self-certifies the participation at 14 event in Italy, UK, Norway, Switzerland, India, Portugal, Germany, Belgium, and France. He also contributed to the organization of 4 conferences (**2/3 points**).
- O) As to **national and international awards for research activities**, Andrea Martani has been the recipient of an award of the Faculty of Medicine of the University of Basel for the PhD Dissertation. He obtained a funding from the Swiss Federal Office of Public Health, three scholarships from the University of Basel to attend and present international conferences for young promising scientists in 2018, 2019 and 2022 (**1/2 points**).
- P) **European degree** recognised by international Boards as regards the academic recruitment fields where applicable (**0/2 points**).

TOTAL POINTS FOR QUALIFICATIONS: 15.5/24

PUBLICATIONS

The candidate submitted for evaluation the following twelve publications.

- 13) **(journal article) Martani A., Erard F., Casonato C., Elger B.S., The devil is in the details. An analysis of patient rights in Swiss cancer registries, in Journal of Medical Ethics, published online first 5 October 2021, doi: 10.1146/medethics-2021-107564**

The paper focuses on the recent reform of the Swiss cancer registration legislation, which implement rules about the recording of data in cancer registries that would allegedly go beyond a consent-based model, in order to balance accurate registration with the respect of patient rights. It analyses the operational norms of the new legislation and compares them with those of other systems, and it concludes that the Swiss rules closely resemble a system of registration based on informed consent, in partial contradiction with the objective pursued by the law makers. The article demonstrates how details of a single policy action are crucial to determine its true nature, and highlights some critical elements, from an ethical standpoint, of the recent Swiss reform.

The article does not specify what the individual contribution of each author was, but the candidate appears as the first and corresponding author.

The paper is published on the Journal of Medical Ethics, which is an SJR Q1 journal for Health, Issues, Ethics and Legal Aspects of Health and Health Policies. It adopts an original approach to the analysis of Swiss policy actions, combining different methodologies, but the purely legal part of the analysis is relatively limited. The contribution is coherent with the topic of the call, but makes very limited and cursory comparative reference and does not apply at any stage comparative law methodology.

- a) Originality, innovation, methodological rigor and relevance: **0.7 point;**
- b) coherence of the publication with the academic recruitment field and with the specific profile of the call, or with closely related interdisciplinary subjects: **0.2 point;**
- c) scientific relevance of the journal / publisher and its impact factor within the scientific community: **0.5 point;**
- d) analytical determination, on the basis of guidelines recognized by the relevant international scientific community of the individual contribution of the researcher in the case of works carried out in partnership: **0.5 point;**

Total: 1.9/3 points.

14) **(journal article) Martani A, Genevieve LD, Pauli-Magnus C, McLennan S, Elger BS, Regulating the secondary use of data for research: arguments against genetic exceptionalism, in Frontiers in Genetics, 2019, 10:1254**

The article uses Swiss law as a case study to argue that genetic exceptionalism in secondary use regulation is not justified for three reasons. First, although genetic data have particular features, also other non-genetic data can be extremely sensitive. Second, having different regulatory requirements that depend on the nature of the data hinders the creation of comprehensible consent form. Third, empirical evidence about public preferences concerning data reuse suggests that exceptional protection for genetic data alone is not justified. Against this background, the article claims that the regulation concerning data reuse should treat genetic data as important, but not exceptional.

The article does not specify what the individual contribution of each author was, but the candidate appears as the first and corresponding author. It is published on an SJR Q2 journal for Genetics and Molecular Medicine. The paper is original in its approach and offers an innovative take on the assessment of genetic exceptionalism in the regulation of secondary use of data for research. It provides a number of comparative hints to other legal systems, and adopts an interdisciplinary and policy analysis methodology to assess the Swiss legal system. The application of comparative law and pure legal methodology, however, is missing. In this sense, the contribution is undoubtedly coherent with the specific profile of the call, but is not consistent with the academic recruitment field.

- a) Originality, innovation, methodological rigor and relevance of the publication: **0.7 point;**
- b) coherence of the publication with the academic recruitment field and with the specific profile of the call, or with closely related interdisciplinary subjects: **0.2 point;**
- c) scientific relevance of the journal / publisher and its impact factor within the scientific community: **0.5 point;**
- d) analytical determination, on the basis of guidelines recognized by the relevant international scientific community of the individual contribution of the researcher in the case of works carried out in partnership: **0.5 point.**

Total: 1.9/3 points.

15) **(journal article) Martani A, Egli P, Widmer M, Elger BS, Data protection and biomedical research in Switzerland: setting the record straight, Swiss Medical Weekly, 2020 (150)w:20322**

The article aims at reviewing the interaction of data protection law and biomedical research with a focus on the Swiss context. It discusses three crucial nodes that shape the interplay of law and data processing in research. First, it examines the meaning of personal data, the requirements to classify data as personal, non personal, pseudonymized or anonymized and the implications of such classifications from a legal perspective. Then, it considers the relationship between sector-specific data processing regulations for research and other laws on data protection. Last, it analyses the role of consent for data processing in research and its significance from a data protection perspective. The article concludes by underlining the importance of fostering reciprocal collaboration of data protection experts and biomedical researchers to facilitate the development of new projects.

The article does not specify what the individual contribution of each author was, but the candidate appears as the first and corresponding author. It is published on an SJR Q3 journal in Medicine (miscellaneous). The originality of the contribution is limited to the study of the intersection of data protection law in three specific instances of biomedical research, with a focus on the Swiss environment. The analysis of the regulatory framework, on the contrary, is detailed but relatively descriptive. The contribution is coherent with the specific profile of the call, but it does not make use of comparative law methodology.

- a) Originality, innovation, methodological rigor and relevance: **0.5 point;**

- b) coherence of the publication with the academic recruitment field and with the specific profile of the call, or with closely related interdisciplinary subjects: **0.2 point**;
- c) scientific relevance of the journal / publisher and its impact factor within the scientific community: **0.1 point**;
- d) analytical determination, on the basis of guidelines recognized by the relevant international scientific community of the individual contribution of the researcher in the case of works carried out in partnership: **0.5 point**.

Total: 1.3/3 points.

- 16) (journal article) Martani A, De Clercq E, de Geyter C, Pennings G, Wangmo T, Elger BS, Deconstructing age(s): an analysis of the different conceptions of age as a legal criterion for access to assisted reproductive technologies, Journal of Law and the Bioscience, vol. 9, issue 2, July-December 2022, Isac036

The article builds on gerontological, medical and sociological literature on the concepts of “age” and “aging” to distinguish three conceptions of age that are relevant for assisted reproductive technologies (ART) regulation: the chronological, the biological and the social-cultural one. It describes how the three concepts relate to ART and reproduction, and illustrates advantages and disadvantages of relying on each of them as a basis for limiting ART access. Last, it proposes a template for defining legal age limits for ART access in the law, based on the refined understanding of the different conceptions of age that it outlines, and discusses two potential objections to the proposal.

The article does not specify what the individual contribution of each author was, but the candidate appears as the first and corresponding author. It is published on an SJR Q1 journal for Law, but it does not feature in the ANVUR list of scientific reviews for Area 12 (Law). The contribution is very innovative and original in its proposal to offer a multidisciplinary approach, with methodological rigor, to the definition of reproductive age to assess the legal eligibility to ART, advancing the state of the art in the field and proposing original solutions. The legal part of the analysis, however, is limited. The article is coherent with the topic of the call.

- a) Originality, innovation, methodological rigor and relevance: **0.6 point**;
- b) coherence of the publication with the academic recruitment field and with the specific profile of the call, or with closely related interdisciplinary subjects: **0.1 point**;
- c) scientific relevance of the journal / publisher and its impact factor within the scientific community: **0.5 point**;
- d) analytical determination, on the basis of guidelines recognized by the relevant international scientific community of the individual contribution of the researcher in the case of works carried out in partnership: **0.5 point**.

Total: 1.7/3 points.

- 17) (book chapter) Martani A, Le incertezze del diritto nel contesto della sanità moderna: sfide presenti e future, in C Piciocchi, M Fasan, CM Reale (eds), Le (in)certezze del diritto: atti delle giornate di studio 17-18 gennaio 2019, Napoli, Editoriale Scientifica, pp.197-218

The chapter attempts to offer an overview of a selected array of issues in medicine and healthcare that are afflicted by legal uncertainty, with the goal of offering a systematization of each matter and to propose an analytical approach that could start tackling such uncertainties. First, it summarizes the evolutionary paths of modern medicine and health care. Then, it identifies three paradigmatic areas featuring legal uncertainties, for different reasons and in different manners, on the basis of the results of a project aimed at developing solutions to overcome the difficulty in harmonizing health data collection in Switzerland without violating patients' rights. Last, it concludes by highlighting the issues that require more elaboration in order to tackle the problem.

The article, single-authored and published in a collection by a renowned Italian publisher, offers interesting considerations on matters that have been long discussed in the academic literature. Its limited innovative contribution comes from the use of suggestions coming from the result of a Swiss project, which brings interesting hints. Beyond this, and while being rigorous in the descriptive analysis and showing a remarkable awareness of the current debate, the arguments and conclusions advanced are not characterized by extreme originality. The contribution is consistent with the topic of the call and presents limited comparative hints.

- a) Originality, innovation, methodological rigor and relevance: **0.2 point**;
- b) coherence of the publication with the academic recruitment field and with the specific profile of the call, or with closely related interdisciplinary subjects: **0.3 point**;
- c) scientific relevance of the journal / publisher and its impact factor within the scientific community: **0.2 point**;
- d) analytical determination, on the basis of guidelines recognized by the relevant international scientific community of the individual contribution of the researcher in the case of works carried out in partnership: **1 point**.

Total: 1.7/3 points.

18) (journal article) Martani A, Shaw D, Elger BS, Stay fit or get bit – Ethical issues in sharing health data with insurers’ apps, Swiss Medical Weekly, 2019 Jun 30, 149;149:w20089

The article investigates the phenomenon of insurers’ apps permitting customers to share their data in exchange for monetary rewards currently available in Switzerland. It first describes the features and functioning of the app, then it presents some ethical aspects related to their use, with particular regard of transparency of data-sharing purposes, the potential discrimination among insured people, the “quantification” of users and the potential tension generated between solidarity and responsibility. The article concludes by emphasizing that insurers’ app are becoming a new paradigm for insurers in many countries, thus a thorough ethical assessment of their implications is required.

The article does not specify what the individual contribution of each author was, but the candidate appears as the first and corresponding author. It is published on an SJR Q3 journal in Medicine (miscellaneous). The article conducts an empirical analysis of data sharing and business practices on insurers’ apps and highlights, in a concise manner, a number of ethical issues arising from it. The innovative and original part of the contribution is limited to the practical application of arguments and theories that are already consolidated in the state of the art to this specific settings, via empirical analysis. The article is coherent with the topic of the call, but less close to the academic recruitment field.

- a) Originality, innovation, methodological rigor and relevance: **0.5 point**;
- b) coherence of the publication with the academic recruitment field and with the specific profile of the call, or with closely related interdisciplinary subjects: **0.3 point**;
- c) scientific relevance of the journal / publisher and its impact factor within the scientific community: **0.1 point**;
- d) analytical determination, on the basis of guidelines recognized by the relevant international scientific community of the individual contribution of the researcher in the case of works carried out in partnership: **0.5 point**.

Total: 1.4/3 points.

19) **(journal article) Martani A, Genevieve LD, Elger BS, Wangmo T, 'It's not something you can take in your hands'. Swiss experts' perspectives on health data ownership: an interview-based study, BMJ Open 2021; 11(4): e045717**

The paper aims at analysing the perspective of Swiss experts on the topic of health data ownership and control. It reports on a qualitative studies where authors selected participants through purposive and snowball sampling and 48 experts. They identified different themes on which to test the beliefs of those interviewed, from the understanding on who should be identified as data owner to the justifications underlying the attribution of ownership and the market value for data. The results suggested that experts are still divided about who should be the data owner and also about what ownership would exactly mean, and show an ambivalence between the willingness to acknowledge patients as data owners and the fact that the efforts put by researchers to collect and manage data entitle them to assert ownership claim. Also a tendency to speak about data in market terms emerged.

The article does not specify what the individual contribution of each author was, but the candidate appears as the first and corresponding author. It is published on an SJR Q1 journal for Medicine (miscellaneous). Although the paper offers an interesting empirical take on the perception of health professionals on matters that are heavily debated in legal scholarship and in policy studies, and established methodologies for qualitative research are well used, the contribution to the scholarly debate and state of the art is relatively limited. In addition, the article makes relatively limited link between the results of the interviews and the Swiss legal framework, nor does it draw relevant conclusions as to the consequences that such results should have in terms of potential policy recommendations. In this sense, the contribution is only limitedly coherent with the topic of the call and with the academic recruitment field.

- a) Originality, innovation, methodological rigor and relevance of the publication: **0.4 point;**
- b) coherence of the publication with the academic recruitment field and with the specific profile of the call, or with closely related interdisciplinary subjects: **0.1 point;**
- c) scientific relevance of the journal / publisher and its impact factor within the scientific community: **0.3 point;**
- d) analytical determination, on the basis of guidelines recognized by the relevant international scientific community of the individual contribution of the researcher in the case of works carried out in partnership: **0.5 point.**

Total: 1.3/3 points.

20) **(journal article) Martani A, Egli SM, Genevieve LD, Elger BS, Wangmo T, A role-model for data policies? Qualitative study on the governance of health data in Denmark, Health Policy and Technology, 2022, 100683**

The article explores to which extent it is true that Denmark has invested a lot in the branding of its health data landscape as a role model, with a focus on data access for secondary uses and research, to also see what other countries can learn from the Danish experience. It builds on semi-structured interviews conducted with 15 Danish stakeholders working as policymakers, researchers or public administrators in health. The article concludes that the Danish model also relies on a balance between extensive data usage and persisting limitations. In this sense, it should not be considered a dream system to blindly emulate, but a valuable example of how such balance can be found, without forgetting that the latter requires continuous adaptation. Since the willingness of a population to approve data usage may change for privacy concerns, regular policy renegotiations of the ethical underpinning of any health data landscape are crucial for their sustainability.

The article does not specify what the individual contribution of each author was, but the candidate appears as the first and corresponding author. It is published on an SJR Q1 journal for Biomedical Engineering and Health Policy. It effectively applies qualitative methodology to conduct interviews with Danish stakeholders and test their satisfaction with the Danish approach to health data policies. Through their feedback, the authors provide an original assessment of the Danish model, highlighting both strengths and pitfalls to better substantiate the common view of its system as a paradigm of successful regulatory solution, and use it as an example to

sustainable health data landscape to be replicated. The contribution is original in terms of focus, methodology and conclusions for the field of health policies, but has a very limited relevance for the legal debate. In this sense, it is only relatively coherent with the specific profile of the call.

- a) Originality, innovation, methodological rigor and relevance: **0.7 point**;
- b) coherence of the publication with the academic recruitment field and with the specific profile of the call, or with closely related interdisciplinary subjects: **0.1 point**;
- c) scientific relevance of the journal / publisher and its impact factor within the scientific community: **0.3 point**;
- d) analytical determination, on the basis of guidelines recognized by the relevant international scientific community of the individual contribution of the researcher in the case of works carried out in partnership: **0.5 point**.

Total: 1.6/3 points.

21) **(Journal article) Martani A, Starke G, Personal responsibility for health: the impact of digitalization, Journal of Medical Law and Ethics, 2019; 7(3):241-258**

The article looks at the role that personal responsibility of patients may have as a potential remedy for the problem of resource allocation in health care systems. Systems of rewards and punishment based on it have proved very divisive, and in any case the implementation of personal responsibility in concrete policies has always encountered the problem of practical enforceability. The article shows how this hurdle can be overcome with the advent of digitalization in health, and discusses how by datafying health and making patients transparent may close the loophole of practical enforceability by allowing to trace health-related lifestyle choices of individuals as well as their exposure to avoidable risk factors. It concludes by addressing the limitations of this approach, and suggests that there are other ways in which the potential of digitalization can help with the allocation of resources in health care.

The article does not specify what the individual contribution of each author was, but the candidate appears as the first and corresponding author. It is published on a journal that is not indexed on SCOPUS, Scimago and ANVUR reviews. It proposes an interesting mix of methodologies and approach to advance its arguments, and solidly rely on a remarkably detailed review of existing literature and theories. Its originality stands in the unconventional use of different disciplines to delve into the matter of patients' personal responsibility and to justify the use of the latter as a driver for the allocation of healthcare resources, without refraining from highlighting the inner limits and drawbacks of such a policy option. However, the article does not draw additional conclusions in terms of concrete legal arguments and related policy recommendations. In this sense, it is only partially coherent with the topic of the call and with the academic recruitment field.

- a) Originality, innovation, methodological rigor and relevance: **0.5 point**;
- b) coherence of the publication with the academic recruitment field and with the specific profile of the call, or with closely related interdisciplinary subjects: **0.1 point**;
- c) scientific relevance of the journal / publisher and its impact factor within the scientific community: **0.1 point**;
- d) analytical determination, on the basis of guidelines recognized by the relevant international scientific community of the individual contribution of the researcher in the case of works carried out in partnership: **0.5 point**.

Total: 1.2/3 points.

22) **(journal article) Martani A, Genevieve LD, Poppe C, Casonato C, Wangmo T, Digital pills: a scoping review of the empirical literature and analysis of the ethical aspects, BMC Medical Ethics, 2020; 21(1):3**

The article maps studies where digital pills – an innovative drug-device technology that permits to combine traditional medications with a monitoring system that automatically records data about medication adherence as well as patients' physiological data – have been tested on patients, and discuss the ethically relevant issues evident therein. It also performs a scoping review of the empirical literature on the matter. It concludes that evidence concerning DP is not robust and more research should be performed and study results made available to evaluate this digital medicine. The analysis of the ethically relevant aspects within empirical literature also underscored that there are concrete and specific open questions that should be tackled in the ethical discussion about this new technological solution.

The article does not specify what the individual contribution of each author was, but the candidate appears as the first and corresponding author. It is published on an SJR Q1 journal for Health Policy, Health and Issues, Ethics and Legal Aspects. The contribution offers an interesting empirical contribution to the state of the art in the field of digital pills and their testing, investigating often neglected ethical aspects emerging in studies thereof. It appears to apply rigorously qualitative methodology used in research for data charting and reporting of scoping reviews. It is partially consistent with the topic of the call and does not present elements of legal analysis.

- a) Originality, innovation, methodological rigor and relevance: **0.5 point;**
- b) coherence of the publication with the academic recruitment field and with the specific profile of the call, or with closely related interdisciplinary subjects: **0.2 point;**
- c) scientific relevance of the journal / publisher and its impact factor within the scientific community: **0.3 point;**
- d) analytical determination, on the basis of guidelines recognized by the relevant international scientific community of the individual contribution of the researcher in the case of works carried out in partnership: **0.5 point.**

Total: 1.5/3 points.

- 23) **(book chapter) Martani A, Hummel P, Eine neue Generation des Datenschutzes? Gegenwärtige Unvollständigkeit, mögliche Lösungswege und nächste Schritte, in G Richter, W Loh, A Buyx, S Graf von Kielmansegg (eds), Datenreiche Medizin und das Problem der Einwilligung, 2002, Springer, Berlin-Heidelberg**

The article focuses on whether there is a new Generation of Data Protection, the present incompleteness, the possible solutions and the next paths to be taken. It is first described therein the position that changing realities of data processing require new generations of data protection law. The focus is on understanding what characterizes such a generation and the reasons why a new generation might be required. In doing so, it is argued that data protection law is currently confronted with a number of open questions of principle that both point the way towards a next generation, but also suggest that there is a need to reform the *status quo*. These fundamental questions are developed in the article along three conceptual nodes: The subject matter (3.1), the object of protection (3.2) and the paradigm (3.3) of data protection law. Then biomedical research is used as a context in which further sector-specific questions arise in the further development of data protection (4). Finally, based on this discussion, hypotheses are formulated as to how the transition to a new generation could be realized.

It proposes an interesting mix of methodologies and approach to advance its arguments, and solidly rely on a review of existing literature. Its originality stands in dealing with the new Generation of Data Protection and presenting the biomedical research as a context in which further sector-specific questions arise in the further development of data protection. However, the article does not draw additional conclusions in terms of concrete legal arguments. In this sense, it is only partially coherent with the topic of the call and with the academic recruitment field. We have identified the fundamental questions necessary for the reorganisation, our aim was not to clarify them.

The article does not specify what the individual contribution of each author was, but the candidate appears as the first and corresponding author.

- a) Originality, innovation, methodological rigor and relevance: **0.5 point**;
- b) coherence of the publication with the academic recruitment field and with the specific profile of the call, or with closely related interdisciplinary subjects: **0.2 point**;
- c) scientific relevance of the journal / publisher and its impact factor within the scientific community: **0.3 point**;
- d) analytical determination, on the basis of guidelines recognized by the relevant international scientific community of the individual contribution of the researcher in the case of works carried out in partnership: **0.5 point**.

Total: 1.5/3 points.

- 24) (review in a journal) Martani A, Tomasi M, Casonato C, “I Think It’s Been Met with a Shrug”: Oncologists’ Views toward and Experiences with Right-to-Try, Journal of the National Cancer Institute, 2020 djaa 101

The contribution is a very short review of a study published by Smit et al and having the same title. It is a 1-page long descriptive piece. In this sense, it cannot be understood as an innovative and original contribution to the state of the art, nor its methodological rigor may be properly assessed. Its relevance is limited to that of a study review.

The article does not specify what the individual contribution of each author was, but the candidate appears as the first and corresponding author. The review is published on an SJR Q1 journal for Cancer Research and Oncology.

- a) Originality, innovation, methodological rigor and relevance: **0 point**;
- b) coherence of the publication with the academic recruitment field and with the specific profile of the call, or with closely related interdisciplinary subjects: **0 point**;
- c) scientific relevance of the journal / publisher and its impact factor within the scientific community: **0.3 point**;
- d) analytical determination, on the basis of guidelines recognized by the relevant international scientific community of the individual contribution of the researcher in the case of works carried out in partnership: **0.3 point**.

Total: 0.6/3 points.

TOTAL POINTS FOR PUBLICATIONS: 17.6/36

OVERALL CONSISTENCY OF THE SCIENTIFIC PRODUCTION

The scientific production of Andrea Martani appears to be articulated along three research lines, which could be mostly identified in policy analysis in health law, empirical bioethics, and ethical-legal implications of new health technologies and health care access. In this respect, the outputs submitted to evaluation show an overall consistency and span across a variety of subjects, making use of interdisciplinary research approaches. However, his contributions make use of legal research and analysis only as an ancillary tool to other aims and subject-matter assessments, with very limited use of comparative law methodologies.

As to the intensity and temporal continuity of his scientific production, he lists 29 publications (journal articles and book chapters, mostly co-authored), 1 contribution in press and 3 contributions submitted and/or in peer review, out of which 20 as first/corresponding author. The contributions span along the timeframe 2019-2024. Compared to his academic seniority which, according to the principle of normalisation adopted in the evaluation criteria approved by this Committee during its first meeting, equals to 2024-2018 (starting year of the PhD) + 1 = 7 years, his academic productivity in his field of research may be characterized as remarkably intense, consistent and continuous, without any interruption.

Points: 17/20

RESEARCH PROJECT

Andrea Martani presents a research project focused on understanding how regulation of innovative healthcare solutions evolve, adopting an ethical-legal approach. He aims at continuing the practice of his research skills at the crossroad of bioethics and healthcare, comparative legal analysis and empirical research. In the long term, he plans to develop a set of methodological tools to understand the complex mechanism how health regulation evolves, exploring three lines: (a) understanding the evolution of data protection law in the biomedical sector, with a focus on the causes underlying the fragmentation of practices, interpretation and implementation of open clauses featuring EU law by Member States. The candidate plans to use both comparative law theories and empirical analysis (interviews and other qualitative methods of data collection) to examine the impact that the implementation of data protection law by non-lawyers has in biomedical research; (b) understanding the regulation of new technological solutions that touch on modally-loaded bioethical issues, by investigating the divergences among Member States' approaches and the meta-legal factors underlying them.

The research project is presented against the background of the research trajectories followed by the candidate across the years. Its content is coherent with the academic recruitment field and the topic of the call. It has remarkable innovative potential compared to the state of the art, for it aims at investigating in an interdisciplinary fashion the drivers that lead to specific outputs in the law in action. During the interview, the candidate clarified very well the focus area of his future research agenda, offering sufficient ground to accurately establish the potential in advancing the knowledge in the field. However, the role played by comparative law methodology remained underexplored.

Points: 15/20

Total points: 32/40

Summary

Qualifications: 15.5/24

Publications: 17.6/36

Overall consistency of scientific production + research product: 32/40

Total for applicant: 65.1/100

CANDIDATE : PARZIALE Andrea

CURRICULUM

Andrea Parziale is currently Assistant Professor of Health law at the Department of Health, Ethics and Society of the Faculty of Health, Medicine and Life Science of Maastricht University (October 2023-today). From April 2022 to September 2023 he was Marie Sklodowska-Curie Fellow at the Institute for Transnational Legal Research of the Faculty of Law of Maastricht University with a project on “FullCompensation – Rationalising Full Compensation for Non-Pecuniary Damages to Reconcile Equal Treatment and Personalisation”. Before that, he was a post-doctoral researcher at the Institute for Biomedicine of EURAC Research in Bolzano (January 2021-March 2022) and at the LIDER-Lab of Scuola Superiore Sant’Anna (September 2020-December 2020). He was also *cultore della materia* (teaching assistant) in Private Law at the University of Pisa (2016-2019) and in Markets, regulation and law at LUISS University (2018) and research assistant at the LIDER-Lab of Scuola Superiore Sant’Anna (2015-2019). Along these commitments, he is also Adjunct Professor at the Department of Business and Management of LUISS Guido Carli University (September 2020-today), Scientific collaborator at the LIDER-Lab of Scuola Superiore Sant’Anna (March 2019-today), and reviewer-associated staff for the journal *Opinio Juris in Comparatione* (March 2014-today).

Aside from his academic activities, Andrea Parziale practiced in EU Antitrust Law at De Matteis Law firm in Rome (May 2019-May 2020) and in a variety of matters at Willkie Farr and Gallagher (Milan, October 2018-April 2019). He also interned at the EU Office for Investment for Health and Development of the WHO (November 2017-April 2018).

Andrea Parziale earned his PhD in Law at Scuola Superiore Sant’Anna (2015-2019), where he was also awarded a Honour Degree in Legal Sciences (2010-2016), in parallel with a Law Degree at the University of Pisa (J.D, 2010-2015).

He authored or co-authored 1 monograph in English, 39 journal articles, and 4 book chapters.

QUALIFICATIONS

- I) Andrea Parziale was awarded his **PhD** in Law from Scuola Superiore Sant’Anna in March 2019 with a thesis on “Civil Liability and Regulation in off label uses of medicines in the EU, France, Italy in March 2019 **(6/6 points)**).
- J) From 2018 to date, he developed and offered several **courses and seminars** at the University of Maastricht, LUISS University and University of Pisa **(3/3 points)**.
- K) He carried our **documented research activities in qualified institutes in Italy and abroad**. He is currently Assistant Professor at the Department of Health, Ethics and Society, Faculty of Health Medicine and Life Science of Maastricht University (October 2023-today); Maria Sklodowska-Curie Fellow at the Institute for Transitional Leal Research of the Faculty of Law of the University of Maastricht (April 2022-September 2023), Scientific collaborator at the LIDER-Lab of Scuola Superiore Sant’Anna (March 2019-today); post-doc researcher at the Institute for Biomedicine of EURAC Research, Bolzano (January 2021-March 2022) and at the Scuola Superiore Sant’Anna (September 2020-December 2020) **(2/2 points)**.
- L) As to **research projects**, Andrea Parziale was PI in the Marie Curie Individual Fellowship project FullCompensation (2022-2023). He took part at the projects “CG – Research towards improving the governance of health data in cyberspace (Nordforsk fund, 2021-2022); the H2020 “ENLIGHTENme” (2021-2022); the EFRE 2020 “CHRIS-2D” (2021-2022); the Regione Toscana Bando Salute project “OPT-HepaC” (2020) **(2/2 points)**.
- M) **organization, management and coordination – or participation – in national and international research groups**. He is Scientific collaborator at the LIDER-Lab of Scuola Superiore Sant’Anna (March 2019-today), and reviewer-associated staff for the journal *Opinio Juris in Comparatione*

(March 2014-today). In the past, he was post-doc researcher at the Institute for Biomedicine at EURAC Research in Bolzano (2021-2022) and at the Lider-Lab of Scuola Superiore Sant'Anna (2020), and Intern at the European Office for Investment for Health and Development of the WHO (**3/4 points**).

- N) He participated as a speaker at several **national and international conferences**. From 2018 to 2024, he self-certifies the participation at 29 events in Italy, US, Austria, Belgium, Greece, Ireland, the Netherlands, Poland. He also contributed to the organization of 7 conferences (**2.5/3 points**).
- O) As to **national and international awards for research activities**, Andrea Parziale was awarded the Marie Curie Individual Fellowship project "FullCompensation" (2022-2023). He obtained funding for the 2021-2022 Nordforsk fund CG project (**1.5/2 points**).
- P) **European degree** recognised by international Boards as regards the academic recruitment fields where applicable (**0/2 points**).

TOTAL POINTS FOR QUALIFICATIONS: 20/24.

PUBLICATIONS

The candidate submitted for evaluation the following twelve publications.

- 13) **(monograph) Parziale A, The Law of Off-label Uses of Medicines: Regulation and Litigation in the EU, UK and USA, Routledge, London-New York, 2022**

The book examines the regulatory framework for untested and unapproved (off-label) uses of medicines in the EU, UK and USA. It clarifies the regulatory mechanisms and litigation trends concerning off-licence prescriptions, and assesses how traditional, prevention-driven regulatory and civil liability rules are being adapted to tackle potential risks and scientific uncertainty. In this sense, it focuses on court cases on medical liability, product liability and state liability for each of the jurisdictions analysed, drawing meaningful conclusions. Specific attention is paid to the influence of the precautionary principle and its impact on the interpretation of civil liability rules, and comments on the impact of a precautionary-driven civil liability system on risk regulation. The book concludes by offering a final comparative assessment of the regulatory and civil/tort liability framework for off-label uses of medicines, sketching gaps and proposing alternative institutional mechanisms to tackle unknown risks.

The monograph is single-authored and it is published by a renowned international publisher. It covers a topic that is often neglected by academic scholarship, and it does it with a holistic approach that assesses how civil liability - as an alternative institutional mechanism - has complemented the regulatory measures already put in place by legal systems to address the matter. The author demonstrates an excellent command of comparative law methodology and draw meaningful conclusions to advance the state of the art. The contribution is undoubtedly coherent with the specific profile of the call, and in line with the academic recruitment field.

- a) Originality, innovation, methodological rigor and relevance: **1 point**;
- b) coherence of the publication with the academic recruitment field and with the specific profile of the call, or with closely related interdisciplinary subjects: **0.5 point**;
- c) scientific relevance of the journal / publisher and its impact factor within the scientific community: **0.5 point**;
- d) analytical determination, on the basis of guidelines recognized by the relevant international scientific community of the individual contribution of the researcher in the case of works carried out in partnership: **1 point**.

Total: 3/3 points.

14) **(journal article) Parziale A, La riforma italiana dei comitati etici nel contesto europeo: sfide, opportunità e spunti comparatistici, Rivista italiana di medicina legale e del diritto in campo sanitario, 2023, pp.103-121**

The article describes the main changes introduced by the Decree of the Ministry of Health of 26 January 2023 against the backdrop of the Italian “long reform” of ethics committees. It also discusses, with some comparative references, the potential and limits of the Decree in relation to the challenges posed both by the new authorization procedure for clinical trials under Regulation (EU) 536/2014 and by the most innovative forms of biomedical research. The article concludes with a number of possible measures regarding the composition and functioning of ethics committees, which could better enable them to deal with an increasingly challenging regulatory and research environment, also in light of a comparative analysis of several EU Member States.

The article is single-authored and it is published on an ANVUR A-ranked and SCOPUS indexed journal that is a leading Italian publication outlet for health law topics. The paper is original in its approach and offers an innovative take on the analysis of the recent reforms of ethical committees, offering interesting comparative references with insights on Austria, Belgium, France, Germany, the Netherlands and Spain. IT concludes with original proposals of reforms to introduce a new model of ethical committees, in order to accomplish the efficiency goals underlying Regulation (EU) 536/2014. The contribution is undoubtedly coherent with the specific profile of the call, and engages with a comparative analysis of the problem, in line with the academic recruitment field.

- a) Originality, innovation, methodological rigor and relevance: **0.9 point;**
- b) coherence of the publication with the academic recruitment field and with the specific profile of the call, or with closely related interdisciplinary subjects: **0.5 point;**
- c) scientific relevance of the journal / publisher and its impact factor within the scientific community: **0.5 point;**
- d) analytical determination, on the basis of guidelines recognized by the relevant international scientific community of the individual contribution of the researcher in the case of works carried out in partnership: **1 point.**

Total: 2.9/3 points.

15) **(journal article) Parziale A, COVID-19 off-label uses of medicines: the role of civil liability and regulation, Geneva Papers on Risk and Insurance – Issues and Practice, 2023, pp.669-686**

The article maintains that civil liability may incentivize health actors to follow and react to the development of the evidence basis for off-label uses, but it is ultimately unable to incentivize additional research on the matter. In light of the key role of off-label research to protect patients and the fact that it is also recommended by international medical ethics, the contribution proposes incentive mechanisms to tackle the problem. It argues that extending civil liability for unknown risks may have undesired effects on insurability and innovation, and criticizes current regulatory proposals for their ineffectiveness. The article then builds on the 2014 Italian reform of off-label uses to advocate for the establishment of a public fund financed by mandatory contributions from the industry, to be used by regulators in order to promote off-label research and develop guidelines for prescribers.

The article, single-authored and published on a SCOPUS-indexed journal (SJR Q2 for accounting, business-management, economics-econometrics and finance) that is also listed as Scientific Review by ANVUR for Area 12 (Law), offers a thorough comparative analysis of the ethics and regulation of off-label prescribing, covering also other institutional mechanisms such as civil (medical and product) liability and its role and limitations. It proposes an original critical discussions of current scholarly and policy proposals, advancing innovative suggestions for the way forward. The contribution is coherent with the specific profile of the call, and it demonstrates a very good command of comparative law methodology, which is at the core of the academic recruitment field of the call.

- a) Originality, innovation, methodological rigor and relevance: **0.9 point**;
- b) coherence of the publication with the academic recruitment field and with the specific profile of the call, or with closely related interdisciplinary subjects: **0.5 point**;
- c) scientific relevance of the journal / publisher and its impact factor within the scientific community: **0.4 point**;
- d) analytical determination, on the basis of guidelines recognized by the relevant international scientific community of the individual contribution of the researcher in the case of works carried out in partnership: **1 point**.

Total: 2.8/3 points.

16) **(case note) Parziale A, “La bellezza è negli occhi di chi guarda”: la Corte di giustizia alla prova dell’intersezione tra farmaco e cosmetico, Il Foro Italiano, 2023, pp.39-47**

The case note comments on the CJEU’s decision in C-616/20 *M2Beauté Cosmetic GmbH v Bundesrepublik Deutschland*. After a thorough reconstruction of the national judicial path that led to the referral and a summary of the key points of the AG Opinion and the decision, the contribution focuses on its impact on the issue of borderline products and their scientific, economic and legal relevance, praising the guidelines it gives to national authorities to correctly classify them on the basis of their actual use, and its opening to the use of data coming from products having similar chemical compositions in order to qualify it (or not) as a medical product for therapeutic use. At the same time, the case note criticizes the conceptual conflict between this decision and the CJEU’s case law on the criteria to distinguish between a pharmaceutical and a food product, highlighting the risk of confusion and conflicting future decisions.

The case note, which is single-authored and published on an ANVUR A-ranked journal, presents methodological rigor and shows a deep critical understanding of the problems at stake and the systemic impact of the CJEU decision. Due to the nature of the contribution, its innovative and original aspects pertain only to the short conclusions drawn by the candidate. The contribution is coherent with the academic recruitment field and the specific profile of the call.

- a) Originality, innovation, methodological rigor and relevance: **0.5 point**;
- b) coherence of the publication with the academic recruitment field and with the specific profile of the call, or with closely related interdisciplinary subjects: **0.5 point**;
- c) scientific relevance of the journal / publisher and its impact factor within the scientific community: **0.5 point**;
- d) analytical determination, on the basis of guidelines recognized by the relevant international scientific community of the individual contribution of the researcher in the case of works carried out in partnership: **1 point**.

Total: 2.5/3 points.

17) **(journal article) Parziale A, Rischio clinico e responsabilità civile del personale sanitario e della struttura per difetto di organizzazione, Rivista italiana di medicina legale e del diritto in campo sanitario, 2020, pp.2011-2026**

The article provides a brief review of the evolution of clinical risk management. On this basis, it describes the relevant principles established by the Italian Law no.24/2017, assessing them against dominant case-law trends on the civil liability of healthcare professionals and organizations for defective management. The paper tests the suitability of such a regulatory and judicial framework against the extraordinary pressure caused by the COVID-19 pandemic on public and private healthcare facilities in Italy, with particular regard to hospital-associated infections and delayed treatments of other facilities. It argues that while the current state of the art offers sufficient flexibility to consider the particularities of individual cases, it still fails to tackle the risk of a

steadily increase of administrative costs related to litigation, which may lead to their unsustainability. Against the background of several scholarly suggestions in favor of the establishment of an indemnification fund for persons injured by COVID-19, the article maintains that such a fund should be entrusted with a right of recovery against healthcare organizations in the case of gross management defects, and urges further research on the risk of mass tort litigation against the Italian State and its Regions.

The article, single-authored and published on an ANVUR A-Ranked and SCOPUS-indexed journal, offers an original contribution on the national debate on the application of the new Italian medical liability regulation vis-à-vis the damages caused by healthcare professional and organizations during the COVID-19 pandemic, with an innovative reading of clinical risk management that takes into account also the role of public decisionmakers (State and Regions), the risk of massive litigation this may entail and the preventive measures that should be deployed accordingly. The article is coherent with the topic of the call, although it does not present relevant comparative references and the related application of comparative law methodology.

- a) Originality, innovation, methodological rigor and relevance: **1 point**;
- b) coherence of the publication with the academic recruitment field and with the specific profile of the call, or with closely related interdisciplinary subjects: **0.3 point**;
- c) scientific relevance of the journal / publisher and its impact factor within the scientific community: **0.5 point**;
- d) analytical determination, on the basis of guidelines recognized by the relevant international scientific community of the individual contribution of the researcher in the case of works carried out in partnership: **1 point**.

Total: 2.8/3 points.

18) **(journal article) Parziale A, Responsabilità civile da usi off-label di farmaci nell'UE: una prospettiva precauzionale, Opinio Juris in Comparatione, vol.I, 2020, pp.11-29**

The article investigates whether and to which extent civil liability and other institutional mechanisms may help clarifying the scientific uncertainties related to the off-label uses of drugs. To this end, it offers a comparative analysis of the regulatory framework and case law in the EU, Italy and France, which represent legal systems where off-label uses have triggered relevant legislative innovation. The assessment shows the presence of evolutionary paths, such as the judicial reinterpretation of civil liability rules through the lens of the precautionary principle and the legislative provision of no-fault compensation systems and ADR mechanism, which may have a potential positive impact in the field of off-label uses, by clarifying the obligations of doctors, producers and regulators and facilitating damage compensation.

The paper is single authored and it is published on an ANVUR A-Ranked Italian journal. It offers a comprehensive overview of the current state of the art, with a rigorous application of comparative law methodologies, and offers an original reading of the interplay between different institutional solutions to tackle the most controversial challenges affecting a field that has been long neglected by legislators. The contribution is coherent with the topic of the call and perfectly in line with the academic recruitment field.

- a) Originality, innovation, methodological rigor and relevance: **1 point**;
- b) coherence of the publication with the academic recruitment field and with the specific profile of the call, or with closely related interdisciplinary subjects: **0.5 point**;
- c) scientific relevance of the journal / publisher and its impact factor within the scientific community: **0.5 point**;
- d) analytical determination, on the basis of guidelines recognized by the relevant international scientific community of the individual contribution of the researcher in the case of works carried out in partnership: **1 point**.

Total: 3/3 points.

19) **(case note) Parziale A, Competition law implications of off-label uses of medicines: F.Hoffmann-La Roche Ltd and others v Autorità Garante della Concorrenza e del Mercato (AGCM), European Competition Law Review, n.5, 2018, 232-237**

The case note comments on the CJEU's decision in case C-179/16 F.Hoffmann-La Roche Ltd and others v Autorità Garante della Concorrenza e del Mercato (AGCM). It offers a thorough analysis of the national judicial path that led to the referral to the Court, of the AG Opinion and of the final decision, offering interesting comments on the impact of this precedents on the definition of relevant market, the exemption of anti-competitive arrangements ancillary to a licensing agreement from the prohibition under Article 101(1) TFEU, the notion of restriction of competition by object, and the interpretation of the exemption under Article 101(3) TFEU and Article 2 of Regulation 772/2004 in the context of off-label uses of medicines. The contribution emphasizes the merit of the judgment in contributing to the definition of the boundaries between legitimate and illegitimate behaviors in the field, and providing flexible criteria for competition authorities to address the legal and scientific uncertainty that concern off-label uses of medicines. It also highlights potential paths for future decisions in the field, with regard to the possibility for competition law enforcement to tackle risk perception manipulations under scientific uncertainty.

The paper, single-authored and published in an ANVUR A-ranked international journal. Despite the nature of the contribution, which is concise and case-specific as typical for a case note, the candidate manages to introduce original considerations for the academic debate. The contribution is coherent with the topic of the call, although it makes limited use of comparative law references and methodologies.

- a) Originality, innovation, methodological rigor and relevance: **0.7 point;**
- b) coherence of the publication with the academic recruitment field and with the specific profile of the call, or with closely related interdisciplinary subjects: **0.3 point;**
- c) scientific relevance of the journal / publisher and its impact factor within the scientific community: **0.5 point;**
- d) analytical determination, on the basis of guidelines recognized by the relevant international scientific community of the individual contribution of the researcher in the case of works carried out in partnership: **1 point.**

Total: 2.5/3 points.

20) **(journal article) Parziale A, Orphan Drugs under EU competition law: the price is not right, Opinio Juris in Comparatione, vol.1, 2017, pp.97-121**

The article claims that the prohibition of abuse of dominant position could play a role in reducing orphan drugs' prices. First, it shows that market exclusivity provides orphan drugs manufacturers with a dominant position in their reference markets. Then, it applies and adapts the excessive price test developed by the CJEU to orphan drugs, arguing that civil liability could also play a role, by compensating the damages suffered by national health care systems. IT concludes by noting that recent enforcement developments in the EU concerning excessive prices of medicines confirm the potential role of competition law in curbing orphan drug prices.

The paper is single-authored and published on an ANVUR A-Ranked journal. It proposes a very innovative and original reading of the current CJEU case law in the field of antitrust law, linking it to the EU and US regulatory framework on orphan drugs and incentive regulation to demonstrate showing how leveraging on antitrust provisions could help tackling the challenge of excessing prices in the sector, while bringing in civil liability as an alternative institutional tool could help compensating the loss suffered by NHSs as a consequence of such practices. The contribution is consistent with the topic of the call and offers several comparative references, with a correct application of comparative law methodology, in line with the academic recruitment field.

- a) Originality, innovation, methodological rigor and relevance: **1 point;**

- b) coherence of the publication with the academic recruitment field and with the specific profile of the call, or with closely related interdisciplinary subjects: **0.5 point**;
- c) scientific relevance of the journal / publisher and its impact factor within the scientific community: **0.5 point**;
- d) analytical determination, on the basis of guidelines recognized by the relevant international scientific community of the individual contribution of the researcher in the case of works carried out in partnership: **1 point**.

Total: 3/3 points.

- 21) **(journal article) Parziale A, Il futuro dei farmaci orfani tra promozione della ricerca per la cura di malattie rare e i rischi di prezzi eccessivi: il ruolo del diritto della concorrenza, Contratto e impresa, n.4-5, 2016, 1245-1277.**

The article focuses on the challenges raised by orphan drugs for the health care systems and the protection of the right to health, due to the lack of incentives to innovate in the sector for private actors. Empirical evidence suggest that, due to the fragmented regimes of price fixation and reimbursements in the EU Member States, pharmaceutical companies are able to set up prices for orphan drugs that are much higher than those offered for common drugs. The article builds on the intuition, already advanced by some scholars, that this practice may entail a case of abuse of dominant position under Article 102(a) TFEU, and investigates whether and to which extent EU antitrust law may contribute to lower the level of orphan drugs prices, in an attempt to balance the need to incentivize private actors with the need to preserve public health and drug accessibility.

The paper is single-authored and published on a ANVUR A-ranked Italian journal. It proposes a very innovative and original reading of the current CJEU case law in the field of antitrust law, showing how a holistic approach to the orphan drugs regulation and its interaction with the general legislative framework on pharmaceutical products could assist in better specifying the abusiveness test under Article 120(a) TFEU when applied to price fixation in this sector. The contribution is consistent with the topic of the call and offers several comparative references, with a correct application of comparative law methodology, in line with the academic recruitment field.

- a) Originality, innovation, methodological rigor and relevance: **1 point**;
- b) coherence of the publication with the academic recruitment field and with the specific profile of the call, or with closely related interdisciplinary subjects: **0.5 point**;
- c) scientific relevance of the journal / publisher and its impact factor within the scientific community: **0.5 point**;
- d) analytical determination, on the basis of guidelines recognized by the relevant international scientific community of the individual contribution of the researcher in the case of works carried out in partnership: **1 point**.

Total: 3/3 points.

- 22) **(book chapter) Parziale A, Staunton C, Research biobanks and external researchers under the European Data Protection regulation: between controller-processor relationship and joint controllership, in J Faintuch, S Faintuch (eds), Integrity of Scientific Research Fraud, Misconduct and Fake News in the Academic, Medical and Social Environment, Springer, 2022, pp.93-100**

The chapter maps the issues related to the GDPR qualifications of biobanks and external researchers. It outlines whether and under what conditions biobanks and external researchers are in a controller-processor relationship or joint controllers and the respective operational implications for biobanks. It then concludes with some general practical advice to research biobanks.

The article, published on a prestigious international publisher, does not specify what the individual contribution of each author was, but the candidate appears as the first and corresponding author. The contribution is innovative and original in its conclusions, and it is consistent with the topic of the call, although it does not present comparative takes, for it focuses only on EU law.

- a) Originality, innovation, methodological rigor and relevance: **0.9 point**;
- b) coherence of the publication with the academic recruitment field and with the specific profile of the call, or with closely related interdisciplinary subjects: **0.3 point**;
- c) scientific relevance of the journal / publisher and its impact factor within the scientific community: **0.5 point**;
- d) analytical determination, on the basis of guidelines recognized by the relevant international scientific community of the individual contribution of the researcher in the case of works carried out in partnership: **0.5 point**.

Total: 2.2/3 points.

- 23) **(case note) Parziale A, L'uso off-label di Avastin (di nuovo) alla prova della Corte di giustizia: il delicato rapporto tra giudicato nazionale e rispetto del diritto dell'UE, Il Foro Italiano, vol.IV, 2022, pp.474-481**

The contribution is a case note commenting on the CJUE decision in C-261/21 *Hoffmann-La Roche Ltd et al v Autorità garante della concorrenza e del mercato*. After a thorough reconstruction of the national judicial path that led to the referral and a summary of the key points of the decision, the case note draws conclusions on its limiting impact on the previous CJEU's case law regarding the possibility to reopen final national judgments on the basis of the principle of effectiveness of EU law. Then, it elaborates on the effects that the remission to national courts the task to define the notion of relevant market, and the deceptive nature of the information shared by pharmaceutical companies on the risks connected to the off-label use of specific drugs will have on EU antitrust law in the pharmaceutical sector.

The case note, which is single-authored and published on an ANVUR A-ranked journal, presents methodological rigor and shows a deep critical understanding of the problems at stake and the systemic impact of the CJEU decision. Due to the nature of the contribution, its innovative and original aspects pertain only to the short conclusions drawn by the candidate. The contribution is coherent with the academic recruitment field and the specific profile of the call.

- a) Originality, innovation, methodological rigor and relevance: **0.5 point**;
- b) coherence of the publication with the academic recruitment field and with the specific profile of the call, or with closely related interdisciplinary subjects: **0.5 point**;
- c) scientific relevance of the journal / publisher and its impact factor within the scientific community: **0.5 point**;
- d) analytical determination, on the basis of guidelines recognized by the relevant international scientific community of the individual contribution of the researcher in the case of works carried out in partnership: **1 point**.

Total: 2.5/3 points.

- 24) **(journal article) Parziale A, Mascalzoni D, Digital Biomarkers in Psychiatry Research: Data Protection qualifications in Complex Ecosystem, in Frontiers of Psychiatry, vol.13, June 2022, Article 873392, 1-10.**

The article discusses the GDPR legal qualifications of controller, processor and joint controllers in the complex ecosystem unfolded by the integration of digital biomarkers in psychiatric research, considering their

implications and proposing some general practical recommendations. It aims at filling in the gaps in the literature with regards to the missing analysis of the implications of data protection law on the widespread use of digital devices, such as smartphones and wearables, to collect and use data related to mental health to conduct psychiatric research.

The article does not specify what the individual contribution of each author was, but the candidate appears as the first and corresponding author. The contribution appeared in *Frontiers of Psychiatry*, which is an SJR Q1 journal for Psychiatry and Mental Health, but does not appear in rankings or lists related to the Legal field. The contribution is innovative and original in its conclusions, and it is consistent with the topic of the call, although it does not present comparative takes, for it focuses only on EU law.

- a) Originality, innovation, methodological rigor and relevance: **0.9 point;**
- b) coherence of the publication with the academic recruitment field and with the specific profile of the call, or with closely related interdisciplinary subjects: **0.3 point;**
- c) scientific relevance of the journal / publisher and its impact factor within the scientific community: **0.1 point;**
- d) analytical determination, on the basis of guidelines recognized by the relevant international scientific community of the individual contribution of the researcher in the case of works: **0.5 point.**

Total: 1.8/3 points.

TOTAL POINTS FOR PUBLICATIONS: 32/36.

OVERALL CONSISTENCY OF THE SCIENTIFIC PRODUCTION

The scientific production of Andrea Parziale appears to be articulated along four research lines, which could be mostly identified in medical liability, biomedical research law (cross-sectoral), the integration of biomedical innovation into healthcare settings, and the allocation of/access to research results, with isolated publications in the field of regulation of AI and algorithms, 3D printing and competition law in the pharmaceutical market. In this respect, the outputs submitted to evaluation show an overall consistency and span across a variety of subjects, making use of interdisciplinary research approaches, with a coherent, consistent and rigorous use of comparative law methodologies in most of the contributions.

As to the intensity and temporal continuity of his scientific production, he lists 44 contributions (1 monograph, 4 book chapters and 39 journal articles/case notes), both in Italian and in English and published on a wide array of national and international outlets, all well ranked. The production is consistent in time and without interruptions from 2013 to date. Compared to his academic seniority which, according to the principle of normalisation adopted in the evaluation criteria approved by this Committee during its first meeting, equals to 2024-2015 (starting year of the PhD) + 1 = 10 years, his academic productivity has been intense, continuous and very consistent over time, and marked by the recent publication of a monograph with a prestigious international publisher, which consolidates his position in the international academic milieu on his main research area.

Points: 18/20.

RESEARCH PROJECT

Andrea Parziale presented a research project that aims at (i) identifying the grey areas in the multilevel framework for healthcare and biomedical research and (ii) proposing solutions to improve both legal clarity over the responsibilities of the actors involved and protection of individuals' fundamental rights and trust.

The project builds on the candidate's past and ongoing research in health law across the main phases of the life cycle of biomedical innovation, leveraging on the comparative insights derived thereof. More specifically, he plans to focus on three research lines, and namely (1) bioethical and data protection implications of medical research, with particular regard to the use of health-related data for research; (2) evolving liability implications

for medicines and medical devices, with a specific focus on the liability of healthcare actors for the use of innovative and personalized technologies; and (3) right to access to healthcare, considering the role of public-private collaborations and their impact on the organization of healthcare systems, and on the actual definition of the levels of assistance in the context of universal healthcare coverage, with a special attention devoted to global health and competition law.

The project is fully coherent with the academic recruitment field, for it addresses very relevant, topical and timely challenges for the advancement of health law and the regulation of healthcare systems. Its innovative potential is quite evident if compared to the state of the art, for it promises to identify and clarify a number of grey areas, provide critical analysis on how the law and regulations work in practice in the sectors covered, provide original and new interpretations of existing rules to tackle a number of pressing challenges, and leverage on the opportunities offered by innovative health practices and technologies. Further evidence of originality can also be found in the interdisciplinary approach the research project aims at implementing, bringing together bioethics, public health and socio-economic insights. These elements, as confirmed during the interview, offer potential for the candidate's research project to impact on parts of the gaps present in the state of the art, thus contributing to the advancement of knowledge in the field.

Points: 20/20.

Total points: 38/40.

Summary

Qualifications: 20/24

Publications: 32/36

Overall consistency of scientific production + research product: 38/40

Total for applicant: 90/100