

BRIEF
BIOROBOTICS
RESEARCH AND
INNOVATION
ENGINEERING FACILITIES

D.7.7 REPORT ON RESEARCH DISSEMINATION AND AWARENESS







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DISCLAIMER

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1. INTRODUCTION

This report illustrates the activities of dissemination that have been carried out within the WP7 from the start of the project in October 2022 until mid-December 2023 and plans out the activities that will be organized until the end of the project in March 2025. Emphasis is given to the activities planned for the achievement of the KPIs in terms of publications. As described in the grant agreement, the outputs of WP7 in terms of newly generated knowledge on the relevant legal framework (objective 7.3) encompass 3 journal articles, 6 book chapters and 9 articles in conference proceedings, as reported in Figure 1. Moreover, it was anticipated to disseminate the results through three awareness panels, two workshops and 24 policy briefs.

45 Objective, quantitative, and measurable indicators relevant to the monitoring and ex-post assessment of the expected results:

Title	Bimester	Objective, quantitative, and measurable indicators
Objective 7.1: Setup of the Law and Policy Hub and Stakeholders engagement	3	Successful submission of D7.1 and D7.2
Objective 7.2: Cross-field Regulatory Analysis	10	Successful submission of D7.3 and D7.4
Objective 7.3: development of new knowledge on the relevant legal framework	15	Successful submission and update of all WP7 deliverables. Targeted KPIs on a 3 years timeframe are: •JPUB_TOT: 3 •CPUB_TOT: 9 (with approximately equal distribution among CPUB_INT/NAT/SOU) •BPUB_CHA: 6 •PBRI_PUB: 24

Figure 1. Indicators of achievement of the WP7 results extracted from the grant agreement. For the purpose of this report, we focus on the last row reporting the number of expected publications

KPI	Description	Measurement units	Timing of update
PERS_TRAIN	Status of training of WP7 personnel with respect to the plan	%	Each 2
	(training courses are organized in WP1)		months
JPUB_TOT	Scientific publications in international journals enabled by BRIEF WP7	Number	Each year
CPUB_TOT	Number of scientific publications enabled by BRIEF WP7	Number	Each 6
CPUB_INT	presented at conferences and events, and breakdown (total,		months
CPUB_NAT	international, national, conferences in the southern Italian		
CPUB_SOU	regions)		
BPUB_MON	Total number of book contributions enabled by BRIEF	Number	Each 6
BPUB_CHA	WP7, and breakdown (monographies, chapters)		months
PBRI_PUB	Total number of policy-brief published	Number	Each 3
			months

 $Figure\ 2.\ KPIs\ from\ the\ grant\ agreement\ that\ illustrate\ the\ meaning\ of\ the\ acronyms\ of\ the\ planned\ publications$

2. PUBLICATIONS

Thanks to the thorough analysis carried out during the first year of the BRIEF project that includes an initial mapping of relevant normative sources across various disciplinary fields (see "D7.3 Cross-field regulatory analysis") and the needs in terms of legal support of BRIEF's stakeholders explored through a survey (see D7.2), it was possible to identify areas of research

and practice that acquire particular importance for carrying out trustworthy-by-design research and innovation in the robotics and biorobotics fields. The members of the Law and Policy Hub (LaPoH), which was set up at the beginning of the project and was provided of an Advisory Board of experts in various disciplines (see D7.1), offer multifaceted and interdisciplinary expertise that generates knowledge on various topics where the law imposes constraints and provides enablers for bioengineering research and innovation, spanning across artificial intelligence and robotics, personal and non-personal data management, intellectual property, health law, liability and risk management, cybersecurity and research ethics. In order to meet the established goals, a publication strategy was devised by the two technologists hired on BRIEF that includes the contribution of scholars within and outside of the Law and Policy Hub as well as of members of other BRIEF's WPs for a truly interdisciplinary perspective.

2.1. Journal articles

Three out of the three planned journal articles have been published on Neurocomputing, Journal of European Consumer and Market Law (EuCML) and Opinio Juris in Comparatione (see Appendix I for details), while additional articles have been submitted to important international venues such as Computer Law and Security Review; European Journal of Risk Regulation; International Data Privacy Law; and JMIR (Journal of Medical Internet Research) Human Factors. The articles cover a broad range of topics, ranging from data sharing and the reuse of health data, product liability, to consent management and privacy interfaces.

2.2.Book chapters

At the moment of writing the deliverable, a book proposal on the topic of "Scoping challenges for smart medicine and smart devices in the data society" is going to be submitted in early 2025 to Springer's "Data science, machine intelligence and law", which is a new book series that investigates the legal and ethical dimensions of data science, AI and robotics. The book will include two types of contributions, namely at least 6 chapters addressing legal challenges (around 8000 words) and some other chapters addressing technical-operational challenges (around 5000 words). The contributions are distributed across topics such as AI, data management, medical IoT devices, intellectual property, cybersecurity and liability. The authors are members of the BRIEF's Law and Policy Hub, as well as of the Advisory Board of the LaPoH and technologists and researchers working in the biorobotics facilities that are part of BRIEF. Some other authors are renown experts in the field (often young scholars) that have agreed to provide their contribution. Some of the chapters develop and expand policy recommendations that have been proposed in D7.6. Some others seek to provide answers to the practical needs that stem from the research activities of BRIEF's engineers. Such a publication strategy strengthens the collaboration among the various researchers and practitioners that collaborate on topics of relevance for BRIEF and provides opportunities for scientific exchange across disciplinary boundaries.

The abstract reads as follows: "Personalized medicine is the next scientific and commercial frontier: by recognizing the specificity of each human body, biomedical and bioengineering scientists are increasingly researching and developing data-driven treatments as well as smart digital and robotic devices that enable patients and medical personnel to benefit from highly accurate personalized processes of diagnosis and therapy. Examples are many and varied: genebased diagnostics, exoskeletons for rehabilitations, artificial limbs or 3D printed organs. This broad cutting-edge area of research and practice is regulated by a complex interplay of norms concerning personal and non-personal data, AI governance, cybersecurity, health law,

intellectual property, liability regimes and research ethics. As an ever-evolving domain where some regulations still need to be defined, approved and implemented, many open questions call for clarification to avoid legal uncertainty and enable the safe-by-design development of technologies. Such an effort is not only relevant from the purely legal perspective, rather it becomes even more relevant whenever the rules have to be interpreted and applied to specific technological applications. The aim of this book is to provide a guide to the most pressing challenges of the various technologies that constitute the technological enablers of personalized medicine and their possible solutions. This book gathers both legal and techno-operational contributions that span across disciplinary boundaries."

The timeline for publication sets the deadline for receiving the first drafts in June 2024, that will be reviewed over the course of summer. After the summer of 2024, a (probably hybrid) awareness panel will be held, with the aim of gathering additional feedback on the chapters and disseminating the research results to a wider public. After that and the collection of the final versions of the chapters that will include the edits spanning from the reviews and the conference, the book will be sent to Springer and ideally published in the first half of 2025.

2.3. Articles in conference proceedings

Meeting the goal of publishing 9 articles in national and international conference proceedings is the most challenging one for two reasons: first, unlike engineering and computer science research articles, legal scholarly contributions are published in journals rather than being presented at conferences; second, due to the financial nature of the PNRR for developing infrastructures, no budget has been foreseen to cover for the trips that participating to such conferences entails. Nevertheless, the publication plan that has been devised involves various members of the Law and Policy Hub other than the technologists hired on the project, therefore it should be possible to meet the objectives.

2.4.Policy briefs

WP7 foresees the publication of 24 policy briefs that summarize key aspects on relevant national and international legislation (or legislative proposals) distributed across the three years of the project. The first 8 policy briefs have been written by members of the LaPoH and have been presented at the 2023's awareness panel (see below). They cover key aspects of the General Data Protection Regulation, the Medical Directive Regulation and the Italian decrees that implement it in Italy, the Clinical Trials Regulation, the principle of accountability, data portability and the secondary use of health data. They are also being disseminated via the website of the LIDER Lab¹ as blogposts and have been made available to the other members of BRIEF on the project's shared folder on Microsoft Teams.

Two additional batches of 8 policy briefs each will be drafted along the second and third year of the project, stemming from the regulatory novelties and the needs of the members of the consortium. They will be published on the website of the LIDER lab and disseminated to the other members of the consortium.

3. DISSEMINATION ACTIVITIES

The dissemination plan foresees a series of activities that have the goal of increasing the awareness and knowledge of the members of the BRIEF consortium on key regulatory aspects

¹ https://www.lider-lab.it/news/

analyzed in WP7, as well as the wider national and international research and innovation community that revolves around the research groups involved in the project.

3.1.Awareness panels

The plan sets out the organization of (at least) three awareness panels. The first awareness panel ("Tecnologie BioRobotiche e abilitanti: il quadro giuridico di riferimento. Scenari operativi") was organized on the 20th of July 2023 in hybrid form and focused on the dissemination of the results of the first iteration of the cross-field regulatory analysis that was included in "D7.3 Cross-field Regulatory Analysis", as well as on the presentation of the first batch of policy briefs to the members of the consortium as well as to the wider public. An online awareness panel on the topic of the reuse of data and data anonymization was organized on the 13th of November 2023 ("Legality attentive personal data secondary uses in the digital and post-quantum cryptography") jointly with the PQ-REACT² and LeADS research projects.³ The flyers of the events can be found in Appendix II.

The next awareness panel is scheduled for the 5th of March 2024 and will include presentations on key challenges of biorobotics research. The panel will present the policy recommendations and the best practices that are included in the first iteration of "D7.6 Report on Policy Design and Advice". Moreover, both the members of the other BRIEF's WPs and the members of the LaPoH's Advisory Board have been invited to present their research activities, the related challenges and their findings with the goal of engaging the legal and engineering communities in an interdisciplinary dialogue to address emerging research and innovation questions of BRIEF's research fields.

3.2. Workshops

The plan sets out the organization of two workshops. These will have a practical slant and will engage the technologists of all WPs, some members of the LaPoH (especially those with expertise in IP and data management) and some members of the bioengineering research groups. A first meeting was held on the 21st of November 2023 in Pontedera to start mapping the main needs in terms of legal-ethical support to the bioengineering research activities and complement the results obtained in the survey on the stakeholders' needs (see "D7.2: Engagement Strategy"). The workshops will include hands-on activities on a selected cohort of specific research studies carried out by the bioengineering laboratories and will focus on, at least over the course of 2024, personal and non-personal data management. The workshops will not only seek to provide practical guidance to the bioengineers, probably over a few iterations, but will also ensure a more concrete understanding of their practices that is essential for the members of the LaPoH to test and validate the knowledge generated in WP7.

3.3.Other activities

In addition to the planned activities and the given KPIs, the technologists working on WP7 as well as other members of the LaPoH have also engaged in a series of supplementary activities where greater visibility was provided to the research findings of the project through further

² "Post Quantum Cryptography Framework for Energy Aware Contexts" is a project funded by European Union's Horizon Europe research and innovation programme under grant agreement N° 101119547. Website: https://pqreact.eu/

³ "Legality Attentive Data Scientists" (LeADS) is a project funded by European Union's Horizon Europe research and innovation programme under grant agreement N° 956562. Website: https://www.legalityattentivedatascientists.eu/

dissemination. Such events include conferences, workshops and academic lectures where the research findings were presented or discussed. The list of such activities is available in Appendix and will be regularly updated. Such endeavours for the exploitation of results will likely continue during the second and third of the project.

APPENDIX I: JOURNAL ARTICLES

Published journal articles:

- 1. Tartaglione E and others, 'Disentangling Private Classes through Regularization' (2023) 554 Neurocomputing 126612
 - https://www.sciencedirect.com/science/article/pii/S092523122300735X> accessed 28 November 20239
- 2. Gennari F, 'A tale of two cities? Fennia v Philips and Article 7 of the Product Liability Directive Update. Journal of European Consumer and Market Law (in press)
- 3. 'Ethics Lost in Translation: Trustworthy AI from Governance to Regulation Opinio Juris in Comparatio' (2023) 4 Opinio Juris in Comparatione 1
 https://www.opiniojurisincomparatione.org/articles/pre-print-4/ accessed 22 December 2023

APPENDIX II: AWARENESS PANELS









CODICE PROGETTO

PNRR M4C2 BRIEF IR0000036 - CUP J13C22000400007

I BRIEF- Awareness Panel

Tecnologie BioRobotiche e abilitanti: il quadro giuridico di riferimento. Scenari operativi

Il seminario presenta i risultati preliminari relativi all'analisi giuridica condotta al fine di sviluppare buone prassi per raggiungere la conformità etico-giuridica in tutte le fasi di sviluppo di tecnologie BioRobotiche e abilitanti.

20 luglio ore 9.15, Aula 5 – Sede Centrale – Scuola Superiore Sant'Anna & Online

9.15 - 9.30 Saluti e introduzione

Prof.ssa Arianna Menciassi, Prorettrice Scuola Superiore Sant'Anna e coordinatrice del progetto BRIEF Dr.ssa Selene Tognarelli, Project Manager progetto BRIEF, Scuola Superiore Sant'Anna

9.30 - 10.15 Il quadro normativo e gli scenari operativi

Dr.ssa Francesca Gennari, Tecnologa Privacy progetto BRIEF, Scuola Superiore Sant'Anna

10.15 - 10.30 Policy Briefs

Stefano Tramacere, Chiara D'Elia, Scuola Superiore Sant'Anna

10.30 - 10.45 Q&A

Modera: Dr.ssa Denise Amram, Scuola Superiore Sant'Anna

BRIEF - Biorobotics Research and Innovation Engineering Facilities

Riferimenti Evento: segrliderlab@santannapisa.it

Richiesto accreditamento per n. 2 crediti formativi presso il Consiglio dell' Ordine degli avvocati di Pisa Nel caso di interesse, compilare per favore il form di iscrizione https://doc.org/doc.org/format/de/d/ship.org/

https://docs.google.com/forms/d/e/1FAlpQLSfQRr47ITu2HgbjJy WrTCeo3BJoW22ihslb5 NP7OS0FArDw/viewform?usp=sf link







Figure 3. First awareness panel held on 20th July 2023













Legality attentive personal data secondary uses in the digital and post-quantum cryptography

PQ-REACT, BRIEF and LeADS joint Webinar 13th of November 2023 Time 12.00 – 13.00 CEST

12.00 – 12.15 Basics of personal data protection, *Prof.Maria Gagliardi*, *Sant'Anna School of Advanced Studies of Pisa*

12.15 – 12.30 The decomplex notions of personal data and anonymity, *Prof. Gabriele Lenzini*, *University of Luxembourg*

12.30 – 12.45 Secondary uses conundrums, *Prof. Giovanni Comandé, Sant'Anna School of Advanced Studies of Pisa*

12.45 - 13.00 Q & A

Join us on Webex:

https://santannapisa.webex.com/santannapisaen/j.php?MTID=m11af0e22b44d16e07abea5577b017ce3

Password: EEqPQVWe332 (normally not requested)



Contacts:
Segreteria Lider Lab
segrliderlab@santannapisa.it
The webinar will be recorded







Figure 4. Second awareness panel held on 13th November 2023

APPENDIX III: DISSEMINATION ACTIVITIES

- 28 April 2023: F. Gennari "Standards and Liability: what about mixed functions IoT e-health devices?" presentation at "Colloquium on cybersecurity in the health sector. Emerging challenges and priorities surrounding the digital transformation of health and care" (EUI)
- 15 July 2023: F. Gennari "Internet of Things (IoT) Responsabilità tra Policy e Diritto", academic lecture at Master SSOMPL (University of Pisa)
- 18 September 2023: A. Rossi "Roundtable on Legal Design" at State of Privacy 2023 organized by Garante della Protezione dei Dati Personali in Rome
- 25 September 2023: A. Rossi "Dark pattern & privacy: dal design manipolatorio a un design rispettoso dei diritti", interview at Privacy Week 2023
- 12 October 2023: F. Gennari "Cyber-Securité et Protection des Données à caractère personnel cours de formation pour magistrats du Niger, Tchad, Cameroun, Mali », academic lecture for judges from Niger, Tchad, Camerun and Mali organized by Scuola Superiore Sant'Anna and Ministry of Foreign Affairs and International Cooperation
- 22 October 2023: F. Gennari "Mastering Legal and Ethical compliance for Biorobotic and allied technologies", presentation at I-Rim (Makers fair) in Rome
- 14 November 2023: A. Rossi "Getting out of the ethical-legal maze of data scraping: how might we ease researchers' compliance tasks?", presentation at workshop "techno-legal challenges of data scraping" (University of Turin)
- 17 November 2023: F. Gennari "IoT and liability", academic lecture at Master Cybersecurity (University of Pisa)
- 6 December 2023: A. Rossi "The role of legal design for a user-centered data experience", presentation at webinar "Raising Awareness on Data Altruism between Gaps and Enablers" (Sant'Anna School of Advanced Studies"

Slides, flyers and other materials related to these activities are available on demand.