

THE EAHL INTEREST GROUP ON SUPRANATIONAL BIOLAW

2023 NEWSLETTER



EUROPEAN ASSOCIATION of HEALTH LAW

FOREWORD



Dear colleagues,

As we reflect on this fruitful year, we are pleased to present our 2023 newsletter, capturing the diverse activities of our interest group. We held this year mixed meeting in Aix-en-Provence on March 23rd, 2023. We would like to express our gratitude to all members for their valuable contributions and to the EAHL board for their unwavering support.

As the year concludes, we extend warm season's greetings and best wishes for a joyful New Year to all our esteemed members. May the upcoming year be filled with continued collaborations and academic success.

Best regards,

Aurélie, Mark, Pin Lean, Eloïse & Adrien

JOINT PUBLICATIONS BASED ON IG COLLABORATIVE WORK



European Commission Joint Statement for the EU Health Policy Platform's 2022 Thematic Networks, coordinated/led by Pin Lean Lau on behalf of the Centre for AI: Social and Digital Innovations and members from the EAHL IG (Eloise Gennet, Joaquin Cayon De las Cuevas, Inesa Fausch, Santa Slokenberga, Orsolya Varga, Vera Lucia Raposo, Michal Kocsik, Sofia Palmieri, Karina Palkova), the Validity Foundation (formerly Mental Disability Advocacy Centre) and Health Action International, Navigating Health Inequalities in the EU with AI-Driven Technologies - Joint Statement published on the EU Health Policy Platform (2023) under the Stakeholders' Network of the same title

Pin Lean Lau "Addressing Cognitive Vulnerabilities Through Genome Editing: Techno-Legal Adaptations for Persons with Cognitive Disabilities." Chapter in an edited volume, Genome Editing, Health Innovations & Responsible Regulation. Eds: T. Minssen, A. Nordberg & S. Slokenberga. Brill | Nijhoff (2023) (Coordination of EAHL IG members, Santa Slokenberga and Ana Nordberg. Also had contributions from other EAHL IG members such as Judit Sandor, Vera Lucia Raposo, Merle Spander, Anastasiya Kileva, Michal Kocsik, etc).

Vera Lúcia Raposo and Sofia Palmeri, 'Femtech and the Law (or a Tale of how Eve Fights to Overturn Adam and Take Control over her Body)', *BioLaw Journal /Rivista de Biodiritto*, n. 1, Special Issue, 2023, pp. 361-373, <https://doi.org/10.15168/2284-4503-2575>

Pin Lean Lau "Data Misuse and Mission Creep: Patient Involvement & Data". Research Entry in the EuroGCT Project Tree Pathway, European Gene and Cell Therapy Project Consortium (2023) <https://www.eurogct.org/de/node/552> (Coordination of Aurelie Mahalatchimy, Luc-Sylvain Gilbert and Edouard Habib).

Gennet Éloïse, Mahalatchimy Aurélie, « La plateforme des politiques de santé de l'Union européenne : un outil de participation civile à la construction du droit », *Revue de l'Union européenne*, janvier 2023, n°634, pp. 52-58.

Gennet Éloïse, Mahalatchimy Aurélie, « Orphan medicines », in Gormley Laurence, Purnhagen Kai & Garben Sacha (dir.), *OUP Online Encyclopedia of EU Law*, Oxford University Press, janvier 2023.

M Dayan, M Fahy, M Flear, S Greer, T Hervey, H Jarman, M McCarey, E Vlachaki, 'Parallel, divergent or drifting? Regulating healthcare products in a post-Brexit UK' *Journal of European Public Policy* 2023 <https://doi.10.1080/13501763.2023.2213721>

V Delhomme and T Hervey, 'The European Union's response to the Covid-19 crisis and (the legitimacy of) the Union's legal order' *Yearbook of European Law* (2023) <https://doi.org/10.1093/yel/yeac011>

M Wood, I Antova, M Flear, T Hervey, 'What Do "Left Behind Communities" Want? A Qualitative Study in the United Kingdom using Photo Elicitation' *American Political Science Review* (2023) [doi:10.1017/S0003055422001186](https://doi.org/10.1017/S0003055422001186)

M Wood, I Antova, M Flear, T Hervey, 'In a post-Brexit world, we need health policy reform that respects the NHS' 19 July 2023 <https://speri-blog.sites.sheffield.ac.uk/blog/in-a-post-brexit-world-we-need-health-policy-reform-that-respects-the-nhs>

M Dayan, T Hervey, M Flear, 'Does the Windsor Framework help resolve challenges for health?' *BMJ* 2023;381:p825 <https://doi.org/10.1136/bmj.p825>

Mark Flear, *Not What The Bus Promised: Health Governance After Brexit* (Hart, 2023) (with TK Hervey, I Antova and M Wood).

Individual publications from our members

Niall Coghlan, 'If the EU Picks Baby Genes', Verfassungsblog, 26 April 2023 <https://verfassungsblog.de/if-the-eu-picks-baby-genes/>

Niall Coghlan, 'Bridge to Nowhere: The Right to Integrity and the Accuracy and Weight of the Charter Explanations' in Clifton, Rab and Scorey KC, 'Building Bridges in European and Human Rights Law: Essays in Honour and Memory of Paul Heim CMG' (Oxford, Hart 2024) (In Press).

Frischhut, M. (2023). Access to Healthcare of Migrant 'Third Country Nationals'. In S. Garben & L. Gormley (Eds.), Oxford Encyclopedia of EU Law. Oxford University Press. <https://opil.ouplaw.com/display/10.1093/law-oeel/law-oeel-e179>

Frischhut, M. (2023). Eine Europäische Gesundheitsunion: Historische Ideen, aktuelle Pläne und Werte für einen resilienten Wiederaufbau. Zeitschrift Für Öffentliches Recht (ZÖR), 78(2), 177–201. <https://doi.org/10.33196/zoer202302017701>

Frischhut, M. (2023). Mandatory vaccination: Pandemics and selected human rights issues from an EU perspective. In E. Symeonidou-Kastanidou, K. Kipouridou, M. Milapidou, & T. Trokanas (Eds.), COVID19-Pandemic: Medical, legal and ethical issues (pp. 17–42). Nomiki Vivliothiki.

Pin Lean Lau, 'Disrupting MMORPGs Gaming: Exploring and Renegotiating End User License Agreements in the Metaverse', Journal of Strategic Contracting & Negotiations (SAGE) (2023) (In Press)

Pin Lean Lau, 'AI Gender Biases in Women's Healthcare: Perspectives from the UK and the European Legal Space', Special Issue of the Yearbook of Socio-Economic Constitutions, Law and the Governance of Artificial Intelligence, Springer International (2023) (In Press)

Pin Lean Lau, 'The FemTech Jacquerie: Situating Efficient Stewardship in Women's Health vis-à-vis the EU Artificial Intelligence Act', Book Chapter in an edited volume, The Challenges of Artificial Intelligence for Law in Europe (eds. Varju, M. and Mezei, K). Springer International Publishing (2023) (In Press)

Pin Lean Lau, 'AI in Healthcare in the UK', World Association of Medical Law (WAML) Newsletter (Ed. Judit Sandor), March 2023.

Pin Lean Lau, 'Genetics: Analysis, Therapy and Technology – Genetic testing or screening at a pre-birth stage', Chapter in an edited volume, *The Rights of Children in Biology and Medicine*. Uppsala University, Sweden. (Coordination of EAHL IG member, Santa Slokenberga, with Jameson Garland) (2023/24) (In Press).

Pin Lean Lau, 'A Pandemic of Power Relations: Bio-Constitutional Implications of Commodification & Endemic Inequalities in a De-Globalising Malaysia', Chapter in an edited volume, *Malaysia in a De-Globalising World: Conflicts and Uncertainties in the Age of Pandemic*, Springer Nature Singapore (Jan 2024) (In Press)

Pin Lean Lau, "Evolved Eugenics and Reinforcement of "Othering": Renewed Ethico-Legal Perspectives of Genome Editing in Reproduction". *BioTech*. 2023; 12(3):51. <https://doi.org/10.3390/biotech12030051>

Pin Lean Lau, "Accelerating UN Sustainable Development Goals with AI-Driven Technologies: A Systematic Literature Review of Women's Healthcare". *Healthcare*, 2023; 11 (3). pp. 1 - 16. ISSN: 2227-9032

T Hervey, 'EU Health Law' in C Barnard and S Peers, eds, 4th ed, *EU Law* (Oxford: OUP, 2023) 662-691

L Berro Pizzarosa, T Hervey, A de Ruijter, 'Abortion law in Europe: the promise and pitfalls of human rights and transnational trade law in the face of criminalization with exceptions' in M Ziegler, ed, *Research Handbook on International Abortion Law* (Cheltenham: Edward Elgar, 2023) 374-393

T Hervey and M Dayan, 'The Retained EU Law Bill creates an uncertain future for health' *The Nuffield Trust* 14 April 2023 <https://www.nuffieldtrust.org.uk/news-item/the-retained-eu-law-bill-creates-an-uncertain-future-for-health>

T Hervey and T Banerjee, 'Abortion rights in EU law: recent developments' *Rivista di BioDiritto/BioLaw Journal* (2023) 15 331-41 <https://teseo.unitn.it/biolaw/article/view/2571>

Nathalie De Grove Valdeyron, *Les interférences entre la politique de santé et la politique du numérique* (avec M. Blanquet) in *La politique européenne du numérique*, dir. Brunessen Bertrand, Bruylant 2023.

Nathalie De Grove Valdeyron, *Les 20 ans du règlement sur la législation et la sécurité alimentaire dans l'Union européenne, Bilan et perspectives* (dir. avec Marine Friant-Perrot), éd. Bruylant, 2023.

Nathalie De Grove Valdeyron, La libre circulation de denrées sûres et saines, de la prescription générale au contrôle effectif, in Les vingt ans du règlement sur la législation et la sécurité alimentaire dans l'Union européenne, 2023 (précité).

Nathalie De Grove Valdeyron, La politique de santé publique, Annuaire de droit de l'Union européenne, dir. Cl. Blumann et F. Picod (ed. Panthéon Assas) à paraître, 2023.

L.-S. Gilbert and A. Mahalatchimy, Market Access for ATMPs- Expediting marketing authorisation pathways, January 2023, EuroGCT website: <https://www.eurogct.org/research-pathways/commercialisation/market-access-atmps/expediting-marketing-authorisation-pathways>

L.-S. Gilbert and A. Mahalatchimy, Market Access for ATMPs- Expediting marketing authorisation pathways/ Conditional Marketing Authorisation, January 2023, EuroGCT website: <https://www.eurogct.org/research-pathways/commercialisation/market-access-atmps/expediting-marketing-authorisation-0>

L.-S. Gilbert and A. Mahalatchimy, Market Access for ATMPs- Expediting marketing authorisation pathways/ Marketing Authorisation under exceptional circumstances, January 2023, EuroGCT website: <https://www.eurogct.org/research-pathways/commercialisation/market-access-atmps/expediting-marketing-authorisation-1>

L.-S. Gilbert and A. Mahalatchimy, Market Access for ATMPs- Expediting marketing authorisation pathways/ Accelerated Assessment, January 2023, EuroGCT website: <https://www.eurogct.org/research-pathways/commercialisation/market-access-atmps/expediting-marketing-authorisation-2>

L.-S. Gilbert and A. Mahalatchimy, Market Access for ATMPs- Specificities of the marketing authorisation dossier for biosimilars, February 2023: <https://www.eurogct.org/research-pathways/commercialisation/market-access-atmps/standard-marketing-authorisation-pathway-1>

A. Delage and A. Mahalatchimy, Early interactions with regulators, July 2023, EuroGCT website: <https://www.eurogct.org/research-pathways/research-and-innovation/early-interactions-regulators>

A. Delage and A. Mahalatchimy, Early interactions with regulators- Support for innovative medicines' development, July 2023, EuroGCT website: <https://www.eurogct.org/research-pathways/research-and-innovation/early-interactions-regulators/support-innovative>

- A. Delage and A. Mahalatchimy, Early interactions with regulators- Support for innovative medicines' development: Support for innovative medicines' development at the EMA level, July 2023, EuroGCT website: <https://www.eurogct.org/research-pathways/research-and-innovation/early-interactions-regulators/support-innovative-0>
- A. Delage and A. Mahalatchimy, Early interactions with regulators/ Support specific to ATMPs' development at EMA level, August 2023, EuroGCT website: <https://www.eurogct.org/research-pathways/research-and-innovation/early-interactions-regulators/support-specific-atmps>
- A. Mahalatchimy, Therapy classification: Human body elements for therapeutic applications, July 2023, EuroGCT website.
- A. Mahalatchimy, Commercialisation: Advertising of ATMPs, July 2023, EuroGCT website.
- A. Scheer, V. Roby, A. Mahalatchimy, on behalf of the I-BioLex research project, Réponse à la consultation publique de l'Agence Européenne des Médicaments sur "Reflection paper on establishing efficacy based on single-arm trials submitted as pivotal evidence in a marketing authorisation", 29 September 2023.
- Akyüz K., Goisauf M, Chassang G. et al. Post-identifiability in changing sociotechnological genomic data environments. *BioSocieties*. 2023. doi: <https://link.springer.com/article/10.1057/s41292-023-00299-7>
- Béranger J. Chassang G. Le Digital Ethics Officer, un nouveau statut pour garantir l'éthique du numérique au sein de l'entreprise. *ActuIA*, vol.10. Janvier-Mars 2023. <https://bit.ly/3J8H5QF>
- Vera Lúcia Raposo and Man Teng long, 'Advance Directives in Macao: Not Legally Recognised, but...'. In D. Cheung & M. Dunn (Eds.), *Advance Directives Across Asia: A Comparative Socio-legal Analysis* (pp. 262-275). Cambridge: Cambridge University Press, 2023. doi:10.1017/9781009152631.018
- Vera Lúcia Raposo, 'Homo Chimaera After Homo Sapiens?: The Legal Status of Human-Non-Human Chimaeras with Human Brain Cells', *BioSocieties* <https://doi.org/10.1057/s41292-023-00302-1>
- Vera Lúcia Raposo, 'A Room With a View (And With a Gene Therapy Drug): Gene Therapy Medicinal Products and Genetic Tourism in Europe', In Slokenberga, S., Minssen, T., & Nordberg, A. (Eds.). *Governing, Protecting, and Regulating the Future of Genome Editing*. Leiden, The Netherlands: Brill -Nijhoff, 2023. Doi: <https://doi.org/10.1163/9789004526136>

Vera Lúcia Raposo, 'Artificial Intelligence, Fundamental Rights and Technological Development: Is There a Crowd in a Regulation?', WAML Newsletter, June 2023,

https://wafml.wildapricot.org/resources/Documents/WAML_Newsletter_57_June_23.pdf

Todorovic J, Stamenkovic Z, Stevanovic A, Terzic N, Kissimova-Skarbek K, Tozija F, Mechili EA, Devleeschauwer B, Terzic-Supic Z, Vasic M, Bjegovic-Mikanovic V, Santric-Milicevic M; COST Action 18218 participants Burden of Disease Collaborator Network. The burden of breast, cervical, and colon and rectum cancer in the Balkan countries, 1990-2019 and forecast to 2030. *Arch Public Health*. 2023 Aug 24;81(1):156. doi: 10.1186/s13690-023-01137-9. PMID: 37620889; PMCID: PMC10464494.

Andrade CAS, Mahrouseh N, Gabrani J, Charalampous P, Cuschieri S, Grad DA, Unim B, Mechili EA, Chen-Xu J, Devleeschauwer B, Isola G, von der Lippe E, Baravelli CM, Fischer F, Weye N, Balaj M, Haneef R, Economou M, Haagsma JA, Varga O. Inequalities in the burden of non-communicable diseases across European countries: a systematic analysis of the Global Burden of Disease 2019 study. *Int J Equity Health*. 2023 Jul 28;22(1):140. doi: 10.1186/s12939-023-01958-8. PMID: 37507733; PMCID: PMC10375608.

Akinsolu FT, Abodunrin OR, Olagunju MT, Adewole IE, Rahman NO, Dabar AM, Njuguna DW, Soneye IY, Salako AO, Ezechi OC, Varga OE, Akinwale OP. Community perception of school-based mass drug administration program for soil-transmitted helminths and Schistosomiasis in Ogun State, Nigeria. *PLoS Negl Trop Dis*. 2023 Jul 17;17(7):e0011213. doi: 10.1371/journal.pntd.0011213. PMID: 37459322; PMCID: PMC10374069.

Soares Andrade CA, Shahin B, Dede O, Akpeji AO, Ajene CL, Albano Israel FE, Varga O. The burden of type 2 diabetes mellitus in states of the European Union and United Kingdom at the national and subnational levels: A systematic review. *Obes Rev*. 2023 Sep;24(9):e13593. doi: 10.1111/obr.13593. Epub 2023 Jul 4. PMID: 37401729.

Gorasso V, Morgado JN, Charalampous P, Pires SM, Haagsma JA, Santos JV, Idavain J, Ngwa CH, Noguer I, Padron-Monedero A, Sarmiento R, Pinheiro V, Von der Lippe E, Jakobsen LS, Devleeschauwer B, Plass D; COST Action CA18218 participants. Burden of disease attributable to risk factors in European countries: a scoping literature review. *Arch Public Health*. 2023 Jun 25;81(1):116. doi: 10.1186/s13690-023-01119-x. PMID: 37355706; PMCID: PMC10290804.

Kovács N, Liska O, Idara-Umoren EO, Mahrouseh N, Varga O. Trends in dental care utilisation among the elderly using longitudinal data from 14 European countries: A multilevel analysis. *PLoS One*. 2023 Jun 9;18(6):e0286192. doi: 10.1371/journal.pone.0286192. PMID: 37294829; PMCID: PMC10256212.

Goddiksen MP, Johansen MW, Armond AC, Clavien C, Hogan L, Kovács N, Merit MT, Olsson IAS, Quinn U, Santos JB, Santos R, Schöpfer C, Varga O, Wall PJ, Sandøe P, Lund TB. "The person in power told me to"-European PhD students' perspectives on guest authorship and good authorship practice. *PLoS One*. 2023 Jan 12;18(1):e0280018. doi: 10.1371/journal.pone.0280018. PMID: 36634045; PMCID: PMC9836317.

Charalampous P, Haagsma JA, Varga O, et al. Burden of infectious disease studies in Europe and the United Kingdom: a review of methodological design choices. *Epidemiol Infect*. 2023 Jan 9;151:e19. doi: 10.1017/S0950268823000031. PMID: 36621004; PMCID: PMC9990389.

Lovas S, Varga O, Loney T, Ádám B. Chemical pollutants in closed environments of transportation and storage of non-dangerous goods - Insufficient legislation, low awareness, and poor practice in Hungary. *Int J Environ Health Res*. 2023 May;33(5):473-490. doi: 10.1080/09603123.2022.2035325. Epub 2022 Feb 6. PMID: 35128979.

Mark Flear, 'Stakeholder Perspectives and Experiences of the Implementation of Remote Mental Health Consultations During the COVID-19 Pandemic: A Qualitative Study' (2023) 23 *BMC Health Services Research* 623 (with H Galvin, S Desselle and others)

Kapelańska-Pręgowska J., Pucelj M.: Freedom of expression and hate speech : human rights standards and their application in Poland and Slovenia, *Laws*, MDPI AG, vol. 12, nr 4, 2023, p. 1-23, DOI:10.3390/laws12040064, IF(1,2)

Bień-Kacała A., Kapelańska-Pręgowska J., Tarnowska A.: Rise and fall of gender equality in Poland, W: *The rights of women in comparative constitutional law / Spigno Irene, Scotti Valentina Rita, Lima Penalva da Silva Janaína (red.)*, 2023, Routledge, ISBN 978-1-032-39383-4, s. 85-101, DOI:10.4324/9781003349488-7

Gennet Éloïse, « Leave no one behind: how France palliates inequities of access to healthcare professionals », *E AHL Newsletter*, n°1, ISSN: 2708-2784, septembre 2023, pp. 11-12.

JOINT PARTICIPATION TO CONFERENCES & ACADEMIC EVENTS



25 January 2023 : Mahalatchimy Aurélie, Gennet Éloïse, Panel discussion on EU pharmaceutical activity: challenges arising from the pharmaceutical strategy and beyond, Série de séminaire du EU Health Governance Research Network seminar series, en ligne.

21-22 March 2023: Aurélie Mahalatchimy, Mark Flear, Emmanuelle Rial-Sebbag, Eloïse Gennet, I-Biolex project meeting, Aix-en-Provence.

23 March 2023: Meeting of the Interest Group on supranational biolaw, Aix-en-Provence and online.

22-23 June 2023: Workshop at Maynooth University (Ireland) in the context of the Oxford University Press Encyclopedia of EU Law (health section) organized by Tamara Hervey and Ollie Bartlett. Attending members: Tamara Hervey, Ollie Bartlett, Markus Frischhut, Aurélie Mahalatchimy, Eloïse Gennet, Mark Flear, Mary Guy, Mirko Dukovic, Inesa Fausch.

April 2023: European Commission Joint Statement for the EU Health Policy Platform's 2022 Thematic Networks, coordinated/led by Pin Lean Lau on behalf of the Centre for AI: Social and Digital Innovations and members from the EAHL IG (Eloise Gennet, Joaquin Cayon De las Cuevas, Inesa Fausch, Santa Slokenberga, Orsolya Varga, Vera Lucia Raposo, Michal Kocsik, Sofia Palmieri, Karina Palkova), the Validity Foundation (formerly Mental Disability Advocacy Centre) and Health Action International, Navigating Health Inequalities in the EU with AI-Driven Technologies - Presentation of Joint Statement at the European Commission in Luxembourg

June 2023: Pin Lean Lau, Keynote presentation (as invited by EAHL IG members Joaquin Cayon-De las Cuevas and Juan-Ignacio Ochagavías-Colás), in the XVI Inter-Autonomous Meeting on Protection of the Patient. Science and Data as Ingredients for the Transformation of Healthcare Organisations (XVI Encuentro Interautonómico sobre Protección Jurídica del Paciente. Ciencia y datos como ingredientes de la transformación de las organizaciones sanitarias) (June 2023, UIMP, Santander, Spain), with presentation titled "Hidden Figures: Algorithm Data Biases in Health/Medical AI-Driven Technologies: European Law Perspectives".

June 2023 : Adrien Bottacci et Aurélie Mahalatchimy, « Quel futur pour le cadre juridique des tissus et des organes destinés à la transplantation ? Le cas des organoïdes », Journée d'étude ITEGOREC : Transplantation, technologies d'organes et droit, Compiègne, France, 14 juin 2023 (invités).

Conferences and events attended or organised by our members

21 October 2023: Speech Markus Frischhut on "The EU 'patient mobility'-acquis in the light of the new concept of a 'European Health Union" at the International Conference "European Health Union: Perspectives and challenges", organised by the Aristotle University Thessaloniki (AuTH) Laboratory for the Study of Medical Law and Bioethics in cooperation with the National Commission for Bioethics and Technoethics, the Thessaloniki Bar Association and the Thessaloniki Medical Association

5 July 2023: Guest speech Markus Frischhut and workshop "Mandatory vaccination: navigation from 'social solidarity' (ECtHR case Vavříčka) to other values" at the "8th International Summer School: Medical Law and Bioethics: Minors' health: legal, medical and bioethical aspects", organized by the 'Laboratory for the research of medical law and bioethics' at the Aristotle University of Thessaloniki, School of Law, in collaboration with the 'National Commission for Bioethics & Technoethics'

15-16 June 2023: EUPHA (European Public Health Association) 'Law and Public Health'-Section Conference on Strategic Litigation and Public Health in Liverpool, UK; contribution Markus Frischhut on "'Strategic lawsuits against public participation (SLAPPs) from the perspective of EU law (& values)"

13 April 2023: Presentation Markus Frischhut on "Solidarity in health conceptualized through the normative lenses of EU law and ethics" at the "Conference on EU Health Governance: An Opportunity for Trust and Solidarity?", at the University of Amsterdam

2-3 February 2023: Markus Frischhut discussant at the workshop "EU Rule-Making in Crisis", University of Salzburg

Pin Lean Lau, Academic Co-Convenor in the WhatNext.Law Conference on Living in the Cities of the Future and the Metaverse (February 2023, Lisbon, NOVA School of Law), with presentation titled "Where's Your Soul? : Privacy Challenges and Trustworthiness of Soulbound Tokens in Web3.0 and the Metaverse". (This conference was also attended by EAHL IG members who presented their individual/joint papers: Vera Lucia Raposo, Mirko Dukovic, and Sofia Palmieri.)

Pin Lean Lau, Academic Co-Convenor and Organising Committee Lead in the Daughters of Themis: International Network for Women Business Scholars, 8th Annual Workshop on Intersectionality and Business: Challenges, Reflections, Approaches (May-June 2023, Kea, Greece), with presentation titled "Intersectionality and Selective Reproduction: European Legal Imaginaries of Power, Privilege and Bodily Autonomy in Reproductive Technologies; Legal Syncretism Reimagined for the Global South."

Pin Lean Lau, 'The European Union's response to COVID-19', for Nordic Biomedical Law Conference, Faculty of Law, University of Bergen, Norway, 31 August-1 September 2023 (invited).

Pin Lean Lau, 'Co-production of skills and values learning: what we've learned from each other and how you might learn from our mistakes' (with Daniel Barrow, Civil Service Fast Stream and former student intern) for Thirteenth Annual Learning at City Conference, City, University of London, 29-30 June 2023 (invited).

Pin Lean Lau, 'Trust / Solidarity in EU health law' for EU Health Governance: an opportunity for trust and solidarity? Amsterdam Law Centre for Health and Life, Amsterdam Centre for European Law and Governance, Amsterdam Centre for European Studies, University of Amsterdam, 13-14 April 2023 (invited).

Pin Lean Lau, 'Legal and Regulatory Aspects of Health/Medical AI: European Perspectives for Endocrinology', Keynote for European Society of Endocrinology and European Society of Pediatric Endocrinology, Brussels, Belgium, 21 November 2023

Pin Lean Lau, 'Decolonizing and Defragmenting Future Spaces: Rethinking Regulatory Trends and Frameworks', Keynote for Whatnext.Law Annual Conference on Spaces of the Future, Lisbon, Portugal, 6 December 2023.

Tamara Hervey, 'The European Union's response to COVID-19', for Nordic Biomedical Law Conference, Faculty of Law, University of Bergen, Norway, 31 August-1 September 2023

Tamara Hervey, 'Co-production of skills and values learning: what we've learned from each other and how you might learn from our mistakes' (with Daniel Barrow, Civil Service Fast Stream and former student intern) for Thirteenth Annual Learning at City Conference, City, University of London, 29-30 June 2023

Tamara Hervey, 'Trust / Solidarity in EU health law' for EU Health Governance: an opportunity for trust and solidarity? Amsterdam Law Centre for Health and Life, Amsterdam Centre for European Law and Governance, Amsterdam Centre for European Studies, University of Amsterdam, 13-14 April 2023

Tamara Hervey, Social rights under the Ireland/Northern Ireland Protocol' for Maynooth Centre for European Law, Inaugural Workshop, 22 June 2023 (invited).

Tamara Hervey, 'Enhancing equality and diversity in legal education: current issues and perspectives' for Taylor's Law School, Malaysia, Expert Speaker Series, online by Zoom, 24 May 2023 (invited).

Tamara Hervey, 'Sharing experience: organising a section authors' conference' for OUP Online Encyclopaedia of EU Law: State of Play, Bruges, 21 April 2023. (invited).

Tamara Hervey, Roundtable panellist on Pedagogy in EU health law and policy, for Maastricht at 30: Exploring past, present and future drivers of EU health integration, Brussels, 21 April 2023 (invited).

Données de santé et IA, Colloque Rennes, juin 2023 (dir. B Bertrand, C. Castets-Renard et N De Grove-Valdeyron)

A. Mahalatchimy, Les spécificités règlementaires des essais cliniques pour les médicaments innovants, GT3M- Séminaire « Essais cliniques »- 13 avril 2023- Marseille, France (Invitée).

A. Mahalatchimy, Challenges for the implementation of the current EU legal frameworks to organoids, TESaCo Colloquium on « Biotechnologies: towards collective wisdom », « New forms of life: how should organoids be regulated? », 22nd May 2023, online (Invitée).

A. Mahalatchimy, Roundtable on "Regulatory Revolution: Global Harmonization for Safe Personalized Medicines", International Society for Cell & Gene Therapy 2023 Paris Annual Meeting, Paris, France, 31 May- 3 June 3 2023 (Invitée).

A. Mahalatchimy, Roundtable on "COVID-19 Hangover: How do we Regain the Trust in Research?" International Society for Cell & Gene Therapy 2023 Paris Annual Meeting, Paris, France, 31 May- 3 June 3 2023 (Invitée).

A. Mahalatchimy, Update on contributions on EU law on medicines, EU Health Law Seminar “Evolving EU health law following the Covid-19 pandemic”, Maynooth, Ireland, 23 June 2023 (Invitée).

A. Mahalatchimy, L.-S. Gilbert, A. Delage, O. Negre, The Marketing Authorisation of Advanced Therapy Medicinal Products in the European Union, International Society for Cell & Gene Therapy 2023 Paris Annual Meeting, Paris, France, 31 May- 3 June 3 2023 (POSTER); Abstract published in Cytotherapy Volume 25, Issue 6, Supplement, May 2023, Pages S160–S161.

A. Mahalatchimy, J. Juët, B. Bartos, F. Taboulet, The European regulation on Health Technology Assessment: balancing European and national levels, International Society for Cell & Gene Therapy 2023 Paris Annual Meeting, Paris, France, 31 May- 3 June 3 2023 (POSTER).

A. Mahalatchimy, V. Brunel, Which actors to influence the adoption of EU guidelines for Advanced Therapy Medicinal Products? International Society for Cell & Gene Therapy 2023 Paris Annual Meeting, Paris, France, 31 May- 3 June 3 2023 (POSTER); Abstract published in Cytotherapy Volume 25, Issue 6, Supplement, May 2023, Page S161.

A. Scheer, V. Brunel, S. Guion, I. Chiv, M. Morell, M. Durand, O. Joanina, V. Andrieu, A. Mahalatchimy, An exploratory analysis on the involvement of European organisations in the field of biomedical innovation, European Society for Gene & Cell Therapy Congress 2023, Brussels, Belgium, 24-27 October 2023 (POSTER)

V. Roby, A. Scheer, J. Veran, F. Sabatier, A. Mahalatchimy, Mapping the ATMPs Guidance Landscape, European Society for Gene & Cell Therapy Congress 2023, Brussels, Belgium, 24-27 October 2023 (POSTER)

L.-S. Gilbert, A. Delage, H.-Y. Kuo, A. Couturier, A. Mahalatchimy, The challenges of Advanced Therapy Medicinal Products manufacturing in the European Union: Strengths and limits of current regulatory tools, European Society for Gene & Cell Therapy Congress 2023, Brussels, Belgium, 24-27 October 2023 (POSTER)

A. Delage, L.-S. Gilbert, A. Mahalatchimy, Mapping regulators’ early interactions procedures to support innovation, European Society for Gene & Cell Therapy Congress 2023, Brussels, Belgium, 24-27 October 2023 (POSTER)

V. Brunel, A. Mahalatchimy, Comparing actors participating in the adoption process of SoHo and ATMP regulations at the European level, European Society for Gene & Cell Therapy Congress 2023, Brussels, Belgium, 24-27 October 2023 (POSTER)

T. Allouche, V. Brunel, F. Bechet, A. Mahalatchimy, Innovative therapy in European Parliament's positions: a numerical science-based vocabulary analysis, European Society for Gene & Cell Therapy Congress 2023, Brussels, Belgium, 24-27 October 2023 (POSTER)

A. Mahalatchimy, Introduction to the lunchtime symposium on GMOs- based ATMPs: current regulatory challenges and perspectives roundtable, European Society for Gene & Cell Therapy Congress 2023, Brussels, Belgium, 25 October 2023.

A. Mahalatchimy, La loi française relative à la bioéthique : évolutions et démocratisation, Conférence de l'Université Pour Tous-Cahors, 16 Février 2023, (Invitée).

27 January 2023 – Vera Lúcia Raposo, Event 'Mind your own Data', at Institute of Biomedical Sciences Abel Salazar, Porto. Presentation: 'Depois do Dr. House... o Dr. Robot (breves notas sobre a introdução da IA na saúde)' / 'After Dr. House... Dr. Robot (short notes on the introduction of AI in healthcare)

24 March 2023 – Vera Lúcia Raposo, 'Personalised Drugs Can Lead You to a Personalised Death in the EU (And that's All Because of a Legal Loophole)', Precision Medicine Conference. Ethical and Legal Issues, Erasmus School of Health Policy and Management, Escola Nacional de Saúde Pública (National School of Public Health), NOVA University, Lisbon.

30 March – Vera Lúcia Raposo, training session organized by AIDA – Portugal on Insurance, smart contracts, blockchain and artificial intelligence. Presentation: The proposed regulation on artificial intelligence and insurance.

25 May 2023 – Vera Lúcia Raposo, AI in Healthcare, The Institute for Futures Studies, Stockholm. Presentation: 'Does the Future Belong to AI Doctors? – No, it Belongs to Human-AI Interaction'

10 June 2023 – Vera Lúcia Raposo, European Society of Human Genetics Conference (ESHG 2023), Glasgow. Presentation: 'Therapeutic Gene Editing in Europe: What will it take to make it happen?'

27 June 2023 – Vera Lúcia Raposo, Forum Jurídico de Lisboa, Faculdade of Law of Lisbon University. Presentation: 'A Proposta de Regulamento da EU sobre Inteligência Artificial' /The EU Proposal for a Regulation on Artificial Intelligence'.

27 June 2023 – Vera Lúcia Raposo, Participation in the round table on bias and AI, at the Forum Jurídico de Lisboa, Faculdade of Law of Lisbon University.

30 July to 4 August – Vera Lúcia Raposo, 27th World Congress for Medical Law Vilnius, Lithuania. Presentation: “Algorithm, What Should I Do?” – The Medical Standard of Care to Use AI in Healthcare Delivery’

14 September – Vera Lúcia Raposo, lecture on ‘Clinicians’ and Patients’ rights to innovate and to use and to diffuse innovations’, at the event From Ideas to Impact: How Clinicians and Patients are Driving Medical Advancements, NOVA Medical School, Lisbon.

22 September - Vera Lúcia Raposo, Participation in the VIROS Symposium ‘AI and Health Robotics’, as commentator of the talk ‘Medical AI and Patients’ Right to Information in Medical Decision Making’

25 September – Vera Lúcia Raposo, Talk “‘I, Robot (AI-based robots under the AIA)’”, at the Workshop Regulating AI: The Impact of the EU AI ACT on Robotics for Agile Production’, organised by the project Robotics4EU (via zoom)

10 October – Vera Lúcia Raposo, Talk: ‘Artificial Intelligence in Healthcare: Health Data and Personal Care Robots’, at the University of Bristol Law School

16 October – Vera Lúcia Raposo, Talk: ‘Medical Liability, Standards of Care and AI’, at the University of Bristol Law School.

17 October - Vera Lúcia Raposo, Talk: ‘Facial Recognition in Healthcare’, at the University of Bristol Law School

Gennet Éloïse, Nicolas Guylène, « Le cadre juridique des essais cliniques au prisme des vulnérabilités », Séminaire invité, Séminaire « Essais cliniques » du Groupe de Travail « 3M Maladies Rares, Mutation, Méditerranée », Institut Marseille Maladies Rares (MarMaRa) et Institut Sociétés en Mutation en Méditerranée (SoMuM), Aix-Marseille Université, 13 avril 2023.

Gennet Éloïse, Animation des retours d’expérience dans le domaine des innovations biomédicales, Académie d’été de droit international et d’éthique en sciences et technologies, organisée par le CERIC et le CDSA, Aix-Marseille Université, 28 juin – 1er juillet 2023.

Gennet Éloïse, « Emphasizing the role of the Council of Europe in fostering equitable pandemic response and prevention », Preconference Workshop of the ESIL Interest Group on International Health Law, ESIL Conference 2023, Is International Law Fair?, Aix-en-Provence, 30 août – 2 septembre 2023.

Orsolya Varga, World Congress on Public Health in May 2023

Mark Flear, 'Addressing Epistemic Injustice: Perspectives from Health Law and Bioethics', Symposium convened by ML Flear, City, University of London, 15 September 2023

Julia Kapelańska-Pręgowska, Conference on Global Crisis and Global Legal Ordering, Organizer: Waseda University, Tokyo, Japan, presentation title: United Nations as the promoter of peace, justice and human rights. Is UNSC still fit for the purpose? (co-authored and presented with T. Antsupova)

Julia Kapelańska-Pręgowska, VIII Kujawian-Pomeranian Forum of Psychiatric Community Care, Venue: Bydgoszcz, Poland; presentation title: Protection of mental health from the perspective of international law - selected aspects.

Julia Kapelańska-Pręgowska, II Polish-Japanese Scientific Seminar, organizer: Nicolaus Copernicus University in Torun, Poland; presentation title: Gender equality In Poland. Selected issues.

Fabien Milanovic, Baptiste Moutaud, Adrien Bottacci, « Les organoïdes en action. Recherche interdisciplinaire en sciences sociales (sociologie, anthropologie, droit) », Webinaire du GDR Organoïde (via zoom), 30 juin 2023

Adrien Bottacci, « Les organoïdes cérébraux, les embryoïdes et les chimères : vers un régime des entités vivantes ? », Ecole d'été 2023 de la Chaire UNESCO Ethique, Science et Société, « Approches éthiques et juridiques de la vérité en science », Université d'été de Toulouse, atelier des jeunes chercheurs, 6 et 7 juillet 2023.

COMMON PROJECTS & COOPERATION



The Oxford Encyclopedia of EU Law [OEEUL], in S. Garben, L. Gormley (general editors); T. K. Hervey (Editor for European Health Law), partners involved: Joaquin Cayon (Spain); Nathalie De Grove-Valdeyron (France); Mirko Dukovic (Hungary); Inesa Fausch (Switzerland); Mark Flear (United Kingdom); Markus Frischhut (Austria); Eloïse Gennet (France); Mary Guy (United Kingdom); Tamara Hervey (United Kingdom); Pin Lean Lau (United Kingdom); Aurélie Mahalatchimy (France); Vera Lucia Raposo (Portugal); Santa Slokenberga (Sweden); Anniek De Ruijter (Netherlands); Annette Schrauwen; Florence Taboulet (France); Blandine Julliard-Condât (France); Vincent Delhomme; Ollie Bartlett (Ireland); Andre Den Exter (Netherlands).

- Tamara Hervey, OUP Online Encyclopaedia of EU Law, EU Health Law project, 2019-ongoing. Conferences organised with Ollie Bartlett, Maynooth School of Law and Criminology, Ireland, June 2023. IG's members in attendance: Mirko Dukovic (Hungary); Inesa Fausch (Switzerland); Mark Flear (United Kingdom); Markus Frischhut (Austria); Eloïse Gennet (France); Mary Guy (United Kingdom); Tamara Hervey (United Kingdom); Aurélie Mahalatchimy (France).

- Pin Lean Lau “European Union health databases: Eudravigilance; Eudamed; Clinical Trials database; Eudra-GDP database”. Encyclopaedia entries for the Oxford Encyclopaedia on European Union Health Law (2023).
- Mark Flear, Encyclopaedia of EU Law, Health Entries, Maynooth, June 2023

European Commission Joint Statement for the EU Health Policy Platform’s 2022 Thematic Networks, coordinated/led by Pin Lean Lau on behalf of the Centre for AI: Social and Digital Innovations and members from the EAHL IG (Eloise Gennet, Joaquin Cayon De las Cuevas, Inesa Fausch, Santa Slokenberga, Orsolya Varga, Vera Lucia Raposo, Michal Kocsik, Sofia Palmieri, Karina Palkova), the Validity Foundation (formerly Mental Disability Advocacy Centre) and Health Action International, Navigating Health Inequalities in the EU with AI-Driven Technologies

Aurélie Mahalatchimy, Mark Flear, Eloïse Gennet, Emmanuelle Rial-Sebbag, Tamara Harvey, I-BioLex project: <https://elsibi.hypotheses.org/i-biolex>

Aurélie Mahalatchimy, Adrien Bottacci, Organact: <https://elsibi.hypotheses.org/organact-2022-2026>

Aurélie Mahalatchimy, EuroGCT project (European consortium for communicating gene- and cell-based therapy information). H2020 project, GA965241, 1st February 2021 - 31 January 2026: <https://elsibi.hypotheses.org/eurogct>

- Lisa Fériol and Gauthier Chassang co-authored the webpage "Data collection, processing, controlling" on key elements of legal and ethical frameworks to consider in genes and cells therapy research. <https://www.eurogct.org/research-pathways/public-involvement-and-data/data-collection-processing-controlling>
- Gauthier Chassang and Lisa Fériol co-authored the webpage "Data sharing / Open Data" presenting key elements of legal and ethical frameworks to consider in genes and cells-therapy research. <https://www.eurogct.org/research-pathways/public-involvement-and-data/data-sharing-open-data>
- Vera Lúcia Raposo and Tomás de Brito Paulo, 'Genetic Data – Main Principles', EuroGCT, March 2023, <https://www.eurogct.org/research-pathways/public-involvement-and-data/data-protection/main-principles>
- Vera Lúcia Raposo and Tomás de Brito Paulo, 'Genetic Data – Data Classification', EuroGCT, March 2023, <https://www.eurogct.org/research-pathways/public-involvement-and-data/data-protection/data-classification>
- Vera Lúcia Raposo and Tomás de Brito Paulo, 'Genetic Data – Data Protection Authorities', EuroGCT, March 2023, <https://www.eurogct.org/research-pathways/public-involvement-and-data/data-protection/data-protection-authorities>

Projects from individual members

Participation Markus Frischhut in the 'Horizon Europe'-funded research project "FLASH" (Flexible Approaches to Support Health through financing), <https://flash-project.com/>

Pin Lean Lau, (PI) Research Initiative and Enterprise Fund UK 2023/2024 for project titled The Legal Governance of a Health Metaverse: Health, Immersive Biomedical Technologies, and Human Rights (Lex-HMT) (August 2023 to July 2024)

Pin Lean Lau, (PI) ICS funding award for project titled The Benefits and Impact of AI-Driven Technologies in Maternal & Reproductive Health Sustainability: Towards an Accelerated Achievement of UN SDGs 3 & 5 in the UK and Europe (January to July 2023)

Pin Lean Lau, (CI) BRIL seed money award for project titled Building resilience for the future: digital inclusion in 'dead spaces' for Marginalised Communities (January to July 2023)

Tamara Hervey, Brexit/Trade, International Relations and Health Tracker 2020-2023, with the Nuffield Trust, funded by the Health Foundation. Policy advice and data collection and analysis on the health implications of the UK's international relations, especially with the EU.

Tamara Hervey, Independent Commission on UK-EU Relations, invited to give evidence on health and social care, 1 June 2023

Tamara Hervey, UK Trade and Business Commission, invited to give evidence on the UK's healthcare and pharmaceutical sectors: requirements for a future trade deal, 23 April 2023

Tamara Hervey, Women on Web, Spain advice on litigation

Nathalie De Grove Valdeyron, Attribution d'une Chaire Jean Monnet en droit européen du numérique en santé (2023-2026)

Aurélié Mahalatchimy, Law, Public Policy and Social License for Next-Generation Regenerative Medicine:
<https://elsibi.hypotheses.org/regen-med-2022-2025>

Vera Lúcia Raposo, Invited as member of the External Ethical Advisory Board for the EU Horizon Project on AI and Medicine (EU Horizon project, AICE, on AI picture analysis of medical images taken by camera pills for cancer screening coordinated by Region Syddanmark and comprising 12 partners in the EU, Norway and the UK. <https://cai-x.com/aice/>)

Orsolya Varga, <https://www.burden-eu.net/>

Orsolya Varga, national project FI17198

Julia Kapelańska-Pręgowska, A co-investigator in a research grant funded by Nicolaus Copernicus University in Toruń, Poland, in the scheme of "Excellence Initiative - Research University" program called "Inter disciplinas excellentia". It entails collaboration with several researchers from a number of Polish and foreign universities over a monograph "Artificial Intelligence and International Human Rights Law: Developing Standards for a Changing World".