HALL – EKFZ Summer School 2025

Dresden, June 2 – 6, 2025

Femtech Meets Law

Advancing Women's Health Across All Ages Through Technology, Regulation, and Ethics

Program

TECHNISCHE UNIVERSITÄT DRESDEN

EKFZ Digital Health

VUB HALL HEALTH & AGEING LAW LAB

eUTOPIA Alliance of 10 European Universities

Themes

The program consists of themes exploring the intersection of health, law, and technology in the femtech space and will be covered through a combination of presentation-based sessions, interactive discussions, and mentoring opportunities.

- Regulation, Innovation, and Data Governance in Femtech
- Regulatory Ethics and Societal Responsibility: Menopause as a Case Study
- AI, Design Thinking, and Regulatory Oversight in Women's Health
- Data Gaps, Data Governance and Health Equity in Women's Health
- Law, Diversity, and Inclusion in Digital Health
- Legal and Regulatory Pathways in Femtech Product Development

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Program

Monday 2nd June, 2025

Time	Session	Speaker
8:30 – 9:00 AM	Welcome Coffee	
9:00 - 9:30 AM	Welcome Speech	Organisers of the Summer School
9:30 - 9:45 AM	Introduction	Rebecca Mathias — PhD candidate, EKFZ, TU Dresden
9:45 – 10:45 AM	Regulatory and Strategic Perspectives on Innovation Gaps	Dr. Andrea Biasiucci — CEO, confinis
10:45 – 11:05 AM	Break	
11:05 – 12:35 PM	AI-Driven Optimization of Infrastructure Placement and Cyber Security Architecture	Dr. Liqaa Nawaf — Senior lecturer and research leader in cybersecurity, Cardiff Metropolitan University
12:35 – 1:30 PM	Lunch Break	
1:30 – 2:30 PM	Menopause - a Missed Opportunity: Regulatory and Strategic Perspectives on Innovation Gaps	Dr. Andrea Biasiucci — CEO, confinis
2:30 - 2:45 PM	Break	
2:45 – 3:45 PM	Panel Discussion: The Pathologization of Aging	Dr. Andrea Biasiucci — CEO, confinis Celia Brightwell — PhD candidate/ Research associate, Chair of Digital Cultures, TU Dresden Dr. Christiane Hagel — President, Oxford FemTech Society ; Co-Founder FemTech Germany
3:45 - 4:15	Formation of presentation groups	
4:15 - 4:30 PM	Break	
4:30 - 5:00 PM	Optional : Travel to Dresden City Center (Own Expense)	Pre-registration required
5:00 - 6:15 PM	Optional: Dresden City Tour (Own Expense)	Pre-registration required
6:15- 8:00 PM	Optional: Dinner (Own Expense)	Pre-registration required

Program

Tuesday 3rd June, 2025

Time	Session	Speaker
8:30 – 9:00 AM	Welcome Coffee	
9:00 - 10:30 AM	Moving the needle on AI for impact in sexual and reproductive health and rights (Session online)	Tigest Tamrat — World Health Organisation Shada Al Salamah — World Health Organisation
10:30 – 10:50 AM	Break	
10:50 – 12:20 PM	When the Model Listens: Women, AI, and the Clinical Conversation	Shireen Saxena — VP External Affairs and Chief of Staff, Ada Health Prof Stephen Gilbert – Professor, EKFZ, TU Dresden
12:20 – 1:20 PM	Lunch Break	
1:30 – 3:00 PM	Challenges and Experiences in Building a Femtech Product	Dr. Tamara Radaković — Founder, Tamara Radaković Consulting
3:00 - 3:20 PM	Break	
3:20 – 5:00 PM	Interactive Session (Mentoring / Case Studies)	TBC
5:00 - 5:45 PM	Group preparation for assessment	

Wednesday 4th June, 2025

Time	Session	Speaker
8:30 – 9:00 AM	Welcome Coffee	
9:00 - 10:30 AM	The EHDS revolution and its effect on femtech	Cécile van der Heijden — Attorney-at law and Data Protection and Privacy Expert, Axon
10:30 – 10:50 AM	Break	
10:50 – 12:20 PM	Breaking New Ground: How Natural Cycles Pioneered FDA-Cleared Digital Contraception	Karolina Magnusson — Head of Regulatory and Compliance, Natural Cycles
12:20 – 1:20 PM	Lunch Break	
1:30 – 3:00 PM	Femtech Across Borders: Equity, Innovation, and Global Health Justice	Dr. Christiane Hagel — President, Oxford FemTech Society ; Co-Founder FemTech Germany
3:00 - 3:20 PM	Break	
3:20 – 5:00 PM	Life After Upload: policy implications from the life course of femtecth data (Session online)	Lauren Tonti — Law and Policy Lead at the Social Impact Lab, University of Missouri
5:00 - 5:45 PM	Group preparation for assessment	

Program

Thursday 5th June, 2025

	Session	
8:30 – 9:00 AM	Welcome Coffee	
9:00 - 10:30 AM	Interactive Session - Case study / Design thinking	
10:30 – 10:50 AM	Break	
10:50 – 12:20 PM	Perspectives on the EHDS Regulation with Reflections on FemTech	Paul Quinn — Law Professor, Vrije Universiteit Brussel
12:20 – 1:20 PM	Lunch Break	
1:30 – 3:00 PM	AI, Regulation & Entrepreneurship: Pioneering an LLM as a Medical Device	Dr. Vera Rödel — CEO and Co-Founder, Prof. Valmed® Co-Founder, transforming legal®
3:00 - 3:15 PM	Break	
3:15 – 4:45 PM	Group preparation for assessment	
4:45 - 7:00 PM	Optional hike to Lingerschloss (own expense)	Pre-registration required

Friday 6th June, 2025

Time	Session	Speaker
8:30 – 9:00 AM	Welcome Coffee	
9:00 - 10:30 AM	Presentations / Assessment	Participants
10:30 – 10:50 AM	Break	
10:50 – 12:20 PM	Presentations / Assessment	Participants
12:20 – 1:20 PM	Lunch Break	
1:30 – 3:00 PM	Presentations / Assessment/ Feedback	Participants
3:00 - 4:30 PM	Certificates and Farewell	

Session Details

Dr. Andrea Biasiucci

Dr. Andrea Biasiucci is a biomedical engineer and entrepreneur with a PhD in Brain-Machine Interfaces from EPFL. He is the CEO of confinis, a leading Swiss regulatory consulting firm specializing in medical devices, IVDs, and combination products. A business strategist with deep expertise in regulated software, AI, and MedTech, Dr. Biasiucci has a proven track record in agile transformation and organizational restructuring. He founded two neurotech startups—Intento (acquired by MindMaze) and braincredible (acquired by ANT Neuro)—pioneering innovations in AI and big data for healthcare. Previously, at Roche, he led global evidence operations, contributing to the integration of digital health solutions into regulated environments. Passionate about selfless leadership, he champions collaboration that empowers teams to drive innovation and operational excellence.

Menopause - a Missed Opportunity: Regulatory and Strategic Perspectives on Innovation Gaps

With over a billion women worldwide experiencing menopause, the lack of tailored solutions for managing symptoms represents a significant missed opportunity in both healthcare innovation and regulatory strategy. This session will explore how regulatory frameworks, societal discomfort, and the persistent underfunding of women's health contribute to an underserved market and unmet patient needs. While regulation is often blamed for stifling innovation, we will challenge that perception and demonstrate how strategic regulatory engagement can drive progress.

We'll discuss the current global landscape, identifying gaps in available products and solutions for menopausal women, and examine how embedding societal responsibility into regulatory strategies can foster innovation for underrepresented groups. Using menopause as a case study, we'll highlight successful combination products and digital health solutions, showing how regulation can be an enabler rather than a barrier. Finally, we'll address the stigma surrounding menopause and explore how shifting societal perceptions can unlock new opportunities for innovation and improved quality of life.

Session Details

Dr. Liqaa Nawaf

Dr. Liqaa Nawaf is a senior lecturer and research leader in cyber security at Cardiff Metropolitan University (CMU). She serves as Programme Director for the MSc Advanced Cyber Security and BSc Applied Cyber Security Apprenticeships within the School of Technologies and co-leads the Cybersecurity and Information Networks Centre (CINC).

With expertise in networks, artificial intelligence (AI), and cyber security, Dr. Nawaf focuses on integrating AI techniques into distributed systems and cyber security applications. She is a founding member of the Women in Cyber (WiCys) Society at CMU and an active participant in the Women in Cyber Wales Cluster.

Dr. Nawaf has secured multiple externally funded projects, including the Partnership for Education and Research (PER) Programme for Women in Cyber, funded by the British Council UK-Saudi Challenge Fund. She also supervises several PhD students specializing in AI, networks, and cyber security, contributing to advancements in the field.

AI-Driven Optimization of Infrastructure Placement and Cyber Security Architecture

In today's rapidly evolving digital landscape, identifying and mitigating cyber threats is crucial for developing robust security strategies. This talk explores key challenges in cyberspace, focusing on the increasing risks posed by cyber threats in the absence of proper legislation, ethical standards, and access control measures. Strengthening governance systems through clear security policies and enforcement is essential to reducing vulnerabilities.

The session will highlight the role of Artificial Intelligence (AI) and Metaheuristic Algorithms in cyber security. Inspired by human cognitive processes, AI-driven Neural Networks enhance threat detection and mitigation by predicting potential cyber risks. Additionally, the talk will examine how Machine Learning (ML) techniques can optimize cyber security frameworks.

A significant focus of this research is enhancing Wireless Mesh Network (WMN) security by optimizing infrastructure placement using AI. The discussion will demonstrate how AI-driven cyber security solutions can improve cyber resilience and adaptive security architectures.

Session Details

Celia Brightwell

Celia is a PhD candidate and research associate at the Chair of Digital Cultures. Her doctoral research project Cybercrones examines how age is produced culturally and technologically through a selection of paired science fiction texts and body technologies.

Panel Introduction : The Pathologization of Ageing

Emerging approaches to ageing are increasingly shaped by innovation at the intersection of health, wellness, and technology. From experimental communities and biohacking initiatives to new longevity-focused lifestyles and care models, these shifts raise important questions about how ageing is being framed, experienced, and governed. Celia's discussion explores how ideas of optimisation, intervention, and extended vitality are influencing perceptions of ageing and what these developments mean for individuals and society.

Panel Discussion

The panel will be an interactive discussion with Dr Andrea Biasiucci, Dr Christiane Hagel, and Celia Brightwell, who will reflect on the evolving intersections between ageing, health innovation, and societal norms. The conversation will also delve into the ethical, legal, and policy considerations that must guide interventions in this space while considering how to foster inclusive and equitable approaches to ageing in an increasingly technologized world.

Session Details

Tigest Tamrat

Tigest Tamrat is a Scientist in the Department of Sexual and Reproductive Health and Research at the World Health Organization based in Geneva, Switzerland. Her work focuses on the use of digital technologies, including artificial intelligence (AI), to advance sexual and reproductive health and rights (SRHR). Within this role, she leads multisite research on the design and impact of digital tools for strengthening delivery of sexual and reproductive health services, as well as the development of key WHO resources including the Classification of Digital Health Interventions, Guideline on Digital Interventions for Health System Strengthening, Digital Investment Implementation Guide, and more recently the Technical Brief on the role of AI in Sexual and Reproductive Health and Rights.

Shada Al Salamah

Shada Alsalamah is a contributor to the healthcare sector mode digital health transformation, and policymaking for better prevention, and treatment. Currently, Dr. Alsalamah is an Associat Digital Health, Information Systems Department, College of Compu Sciences, King Saud University, Riyadh, Saudi Arabia; a Technical Officer (Digital Health and AI), Strategy and Governance, Department of Digital Health and Innovation, World Health Organization, Geneva, Switzerland; and a Principle Investigator, Artificial Intelligence Center, Alfaisal University, Riyadh, Saudi Arabia. In addition, Dr. Alsalamah serves on a number of national and international boards and working groups including, but not limited to, The Organisation for Economic Co-operation and Development (OECD) Blockchain Expert Policy Advisory Board, Paris, France; The International Association for Trusted Blockchain Applications, Brussels, Belgium; ITU/WHO FG-Artificial Intelligence for Health (AI4H) Regulatory Considerations Working Group (WG-RC), Geneva, Switzerland; ITU/WHO FG-AI4H Dental Diagnostics and Digital Dentistry Topic Group (TG-Dental), Geneva, Switzerland; IEEE Computer Society Technical Committee on Security and Privacy; The Saudi Association for Information Security, Riyadh, Saudi Arabia; and The International Network for Forensic Odontology.

Moving the needle on AI for impact in sexual and reproductive health and rights

Moving the needle on AI for impact in sexual and reproductive health and rights

Artificial intelligence (AI) has emerged as a buzzword and is often referred to as a disruptive force for delivery and access to health information and services. Despite the growing interest in AI, the public health community is grappling with how to meaningfully harness the transformative potential of AI to improve health and wellbeing, while also minimizing the risks.

This session will include an overview of the role of AI in sexual and reproductive health and highlight the patterns and evidence of use in areas such as maternal health, sexually transmitted infections, and infertility. The presentation will also share nuanced risks and mitigation measures to promote the responsible use of AI in SRHR.

Dr Christiane Hagel

Dr Christiane HagelPresident of Oxford FemTech, Co-Founder of FemTech Germany, and a Postdoctoral Research Scientist at the University of Oxford. Her work focuses on health systems and policy research, with a particular interest in global health and digital health innovation. Through both academic and community-led initiatives, she champions inclusive approaches to women's health technology worldwide.

Femtech Across Borders: Equity, Innovation, and Global Health Justice

How do we ensure that digital health innovations—especially those branded as femtech—serve women equitably across diverse contexts? In this session, Christiane Hagel draws on her interdisciplinary research at the intersection of medicine quality, global health, and digital innovation to explore how femtech can both bridge and widen gaps in care. With a focus on low- and middle-income countries (LMICs), she will discuss tools related to neonatal care, dashboards, digital monitoring for substandard medicines, and frameworks for equitable tech deployment. The session will raise critical questions about who femtech is built for, whose needs it prioritizes, and how to build truly inclusive global health systems.

Session Details

Dr. Tamara Radaković

Tamara Radaković is a healthcare innovator, medical doctor, and strategic product leader passionate about building impactful solutions that empower individuals to take control of their health and wellbeing. As a Founder in Residence, she brings over seven years of experience in medical product development, with deep expertise in regulatory compliance (including MDR, security by design, and data privacy). Tamara has a proven track record of guiding product teams through complex go-to-market challenges in healthcare. Her consulting work spans the health and longevity space, offering tailored support in design thinking, product strategy, regulatory navigation, and market launch for medical and wellbeing technologies across Europe and the U.S.

Challenges and Experiences in Building a FemTech Product

This session will feature a candid discussion on the realities of building a FemTech product, from ideation to market. The speaker will introduce the product they are currently developing, outlining the motivation behind it and the specific unmet needs it seeks to address in the FemTech space. The conversation will explore the regulatory and legal hurdles encountered along the way and how these challenges have informed the product's strategy and design. Drawing on prior experience in health product development and collaboration with multidisciplinary teams—spanning quality, data, legal, regulatory, and compliance—the session will reflect on transferable lessons and unique hurdles specific to FemTech. It will also examine persistent barriers to market access, strategies to overcome them, and offer critical insights into the current landscape of FemTech products, including notable gaps and ethical concerns.

Session Details

Cécile van der Heijden

Cécile van der Heijden is an Amsterdam-based attorney-at law at Axon Advocaten. She specializes in data protection law and technological innovation in the Life Sciences sector. She advises her clients on various topics such as clinical research, data processing in relation to medical devices and market access for medical devices and medicines.

The EHDS revolution and its effect on femtech

The European Health Data Space Act (EHDS Act) will revolutionize the possibilities for research by creating new means of accessing existing health data. This can unlock new possibilities for women's health innovation. This session will explore the pivotal role of FemTech in advancing personalized care, reproductive health solutions, and gender-specific research. With the EHDS Act enabling secure cross-border data access, new opportunities arise for scientific discovery—but not without challenges. We'll delve into the ethical, legal, and privacy considerations, particularly under GDPR, as welll as place the EHDS Act in the context of research under the Medical Device Regulation (MDR). This interactive session will provide practical insights into leveraging the EHDS Act framework while fostering responsible innovation in FemTech.

Session Details

Karolina Magnusson

Karolina Magnusson is a medical device regulatory and compliance professional within the femtech and software space. She is currently the Head of Regulatory & Compliance at Natural Cycles where she has led major regulatory events such as the company's transition from MDD to MDR and the introduction of MDSAP certification as well as several 510ks with the US FDA based on the device's original deNovo clearance. Her speciality is software as a medical device (SaMD) compliance in small and medium sized companies. Karolina holds a MSc in Applied Physics and Electrical Engineering with a Biomedical Engineering profile from Linköping University. In addition to her professional endeavors, she is a vintage lover, a historical reenactor and an avid sewer of historical clothing.

Breaking New Ground: How Natural Cycles Pioneered FDA-Cleared Digital Contraception

Natural Cycles made history as the first FDA-cleared digital contraceptive, setting a precedent for their proprietary algorithm-driven birth control within regulatory frameworks. This session will explore the challenges and strategic decisions involved in securing approval through the de novo pathway, the complexities of proving efficacy compared to traditional contraceptive methods, and the regulatory variations across different markets, including the US and EU. It will also examine how the company balances clinical validation with user engagement, the role of strategic partnerships with other tech products in enhancing both functionality and compliance, and the broader implications of evolving regulations on femtech and digital reproductive health. As a category-defining company, Natural Cycles' experience offers valuable insights into the intersection of digital health, medical device regulation, and the future of femtech.

Session Details

Lauren Tonti

Lauren Tonti leads the Law and Policy Core at the University of Missouri's Social Impact Lab, where she explores the relationships between laws, policies, and health using legal epidemiology methods in order to better understand impacts on population health and well-being. Before earning her master's degree in public health from the Harvard T.H. Chan School of Public Health, Lauren received a Juris Doctor from Case Western Reserve School of Law. Lauren previously served as a contracted analyst within the Office of Public Health Law Services at the Centers for Disease Control & Prevention and scientific researcher at the Max Planck Institute for Social Law & Social Policy. Lauren is also a member of the New York State Bar.

Life After Upload: policy implications from the life course of femtech data

What happens to reproductive data after it's collected via femtech? This presentation explores the "lifecourse" of femtech data, analyzing how user agreements can shape its afterlife. Drawing on a systematic analysis of privacy agreements, we will examine current femtech practices to extrapolate lessons that inform a spectrum of policy options that support a person-focused femtech environment.

Session Details

Prof. Paul Quinn

Paul is active in pursuing a number of his research interests as a research professor at LSTS. This includes in areas such as data protection, privacy issues and problems related to stigmatization and discrimination. He is part of the Health and Aging Unit at LSTS where he co-ordinates research on such issues. Paul has developed considerable experience in privacy and data protection issues in the area of health care delivery and scientific research. He has been successful in securing participation for LSTS and the VUB in a large number of research projects as an expert on legal and ethical issues related to privacy and data protection issues. Paul is also a member of the University's Ethics Board for Research in the Social Sciences. Paul has also been active in research into issues associated with stigmatization and anti-discrimination approaches. He has been particularly active in developing a normative argument concerning the threats posed by stigmatizing expressions and language when used by the state. His PhD thesis was entitled "Stigmatizing State Expressions and the law". He has published a monograph on these issues with Routledge in 2015. Before joining the LSTS team Paul worked in the legal industry in the UK. He trained as a Barrister (Bar of England and Wales) and is a member of Greys Inn. He holds degrees in European and International Law (LLM, Institute of European Studies, Brussels), Law (MA, University Sheffield) and Biochemistry, (University of Sheffield).

Perspectives on the EHDS Regulation with Reflections on FemTech

This presentation will look at the main aspects of the European Health Data Space, the regulation came into force in March this year. It will look at the evolution of the proposal through to the final regulation, considering the many challenges and issues that remain. It will also consider some of these challenges through the lens of FemTech.

Session Details

Shireen Saxena

Shireen is a seasoned healthcare leader with 15 years of experience in care system redesign, Shireen is a seasoned healthcare leader with 15 years of experience in care system redesign, payment reform, health policy, and clinical AI/tech. She has worked with state and federal governments, providers, foundations, and life sciences companies across the US, Europe, Africa, and the Middle East and has considerable business development, strategy, and implementation expertise. She is currently the Vice President of External Affairs and Chief of Staff to the CEO at Ada Health, an AI-powered symptom assessment and care navigation platform certified as a Class IIa medical device in Europe.

Shireen is deeply passionate about increasing access and improving health outcomes for underserved and underrepresented populations, including shortening the path to diagnosis and treatment for women's health and mental health. She is a member of the Atlantik Brücke Young Leaders Program and the HAA's Women's Health At Work Advisory Board. Shireen holds a BA in psychology from Barnard College of Columbia University and MSc in international public health and gender studies from Charité-Universitätsmedizin Berlin.

When the Model Listens: Women, AI, and the Clinical Conversation

This 90-minute session explores the role of AI-driven diagnostics and wellness tools in transforming women's health. Through the lens of large language models (LLMs) and a specific case study on Ada Health, we'll examine their potential to enhance healthcare delivery, addressing pain points in women's health, as well as ethical, legal, and regulatory challenges.

Session Details

Prof. Stephen Gilbert

Professor of Medical Device Regulatory Science at TU Dresden's Else Kröner Fresenius Center for Digital Health, and News & Views Editor at Nature Digital Health, Stephen Gilbert brings over 15 years of experience at the intersection of clinical research, computational biology, and regulatory science. At TU Dresden, he leads a multidisciplinary research group focused on regulatory frameworks for medical devices and IVDs, with a strong emphasis on software and AI in healthcare. In addition to his academic work, he advises on high-level projects, including the European Commission's study on regulatory governance and innovation. His work consistently bridges scientific inquiry with policy advancement to support safe and effective digital health innovation.

Part 2: When the Model Listens: Women, AI, and the Clinical Conversation

This 90-minute session explores the role of AI-driven diagnostics and wellness tools in transforming women's health. Through the lens of large language models (LLMs) and a specific case study on Ada Health, we'll examine their potential to enhance healthcare delivery, addressing pain points in women's health, as well as ethical, legal, and regulatory challenges.

Session Details

Dr. Vera Rödel

Dr. Vera Rödel is a German lawyer with a Master's degree in Health and Medical Management. With over 12 years of experience in the pharmaceutical industry and the healthcare sector, she has led the Global Legal Neurology & Immunology and Cardio Metabolic & Endocrinology Team at Merck Legal Healthcare. Before joining Merck in 2014, Dr. Rödel worked at Boehringer Ingelheim and Linklaters LLP.

In Spring 2022, Dr. Rödel took on the role of Global Lead Antitrust at Merck, where she manages all antitrust matters on a global scale and leads the Global Antitrust Expert Group within Merck's Legal Department. In this capacity, she supports the Head of the Legal Department in reporting to the board and managing antitrust litigation and proceedings. Her responsibilities also include developing antitrust strategy, expanding the Global Antitrust Framework, and liaising with industry stakeholders, authorities, and legislators. Since 2023, Dr. Rödel has also been responsible for Risk Governance and Management.

In 2023, Dr. Rödel founded Prof. Valmed®, a pioneering platform for medical information retrieval, and assumed the role of CEO. Prof. Valmed® specializes in providing high-quality, validated medical information to physicians, scientists, and healthcare professionals. In addition, in 2024 Dr. Rödel founded transforming legal® a company bringing digital transformation and legal technology together while shaping the digital future of the legal profession.

AI, Regulation & Entrepreneurship: Pioneering an LLM as a Medical Device

Integrating AI in healthcare presents both opportunities and regulatory hurdles, and securing approval for an LLM as a medical device is a significant milestone. In this session, Vera will share her journey navigating regulatory complexities, the challenges of AI adoption in digital health, and how her legal expertise has shaped her approach. As a female founder in a rapidly evolving field, she will also discuss leveraging networks, overcoming investor challenges, and balancing the demands of entrepreneurship with personal life. This session will provide key insights for startups, innovators, and those shaping the future of AI-driven healthcare.