

Regulation & Innovation

- Teaching sessions: 9, 10, 11, 12 May 2023 (Online)
- Dragons Den session: 17 May 2023 (In person)

Teaching topics include:

- How regulatory processes work for medical devices
- Clinical regulatory landscape & adoption for AI
- How to build AI with highest levels of safety
- Overcoming obstacles innovators face
- Driving confidence in AI for health and care

With talks from Health Education England, Digital Health London, Newmarket Strategy, Lakera AI and more!

Organised by the [UKRI Centre for Doctoral Training in AI for Healthcare](#). To contact the organisers please email [Dr Ahmed Fetit <afetit@imperial.ac.uk>](mailto:afetit@imperial.ac.uk)

Learning outcomes

Upon completion of this programme, you will be expected to:

1. Demonstrate an understanding of how regulatory processes work for medical devices, including AI Software as a Medical Device (SaMD).
2. Develop an awareness of the clinical regulatory landscape in Britain and the EU, in the context of UKCA and CE marking.
3. Appreciate the importance of building AI with highest levels of safety, and demonstrate ways in which this can be achieved in healthcare.
4. Identify ways to pioneer in the health AI space and become aware of obstacles innovators face.
5. Present and defend a solid proposal to technology experts in the form of a product pitch.

Talks include

Dr Warren Macdonald

Introduction to medical device regulation

Working with AI and software raises questions about how it can be regulated and by whom, especially in the changing landscape in the UK medical world. But, in fact, the regulatory framework is fairly straightforward, and can be easily adapted into the development of software. In this session, we will consider why we need to be aware of this, and what things we need to look out for and apply.



Dr Warren Macdonald is an orthopaedic bioengineer with experience in clinical orthopaedics, research and industry; interested in implant and instrumentation design, fracture fixation devices and strategies and bone responses to system design and performance.

Having worked in three hospitals (over 8 years), three academic units (over 18 years), in the implant industry as a bioengineer (for 2 years), and having worked as a Consulting engineer in Orthopaedic Bioengineering for fifteen years, Warren has wide experience in academic practice, the clinical application of engineering and the commercial medical device area.

Talks include

Ele Harwich

The pathway to regulating AI technologies in healthcare

From idea generation to post-market surveillance, there are many regulatory requirements that apply to data-driven technologies like artificial intelligence. Building the knowledge of what to do and when to do it can be complex, however, in this session we will cover the various regulatory frameworks you need to consider from data protection to medical device regulation. We will also go over some tips and tricks to avoid any missteps along the way.

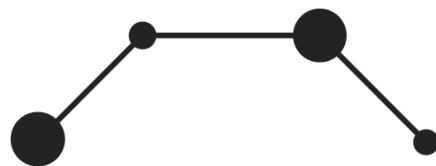


Ele's work focuses on helping clients within the digital health sector with their regulatory and go to market strategies. She has deep expertise in digital health with particular focus on cutting edge technologies, like artificial intelligence, and regulation.

She was previously Head of Collaborations at the NHS AI Lab and led on two key reports on the evaluation of AI-enabled medical devices, and ways to develop and deploy AI-enabled medical devices across jurisdictions.

She is a member of the British Standards Institution and is currently sitting on the "Validation framework for the use of AI within healthcare" committee (BS30440).

Meet the dragons



Kanwal Bhatia completed her PhD in Medical Image Computing at Imperial College London in 2007. She has since worked in academia, developing novel algorithmic techniques, as well as in industry and startups, translating those techniques to real-world practice. Based on these experiences, she founded Aival (Metalynx) in 2020, a startup aiming to accelerate adoption of AI by bridging the gap between vendors and healthcare providers. Aival provides software for the robust evaluation and monitoring of AI products at local clinical sites, building trust with clinical users before procurement and ensuring continued performance once in use.

Meet the dragons



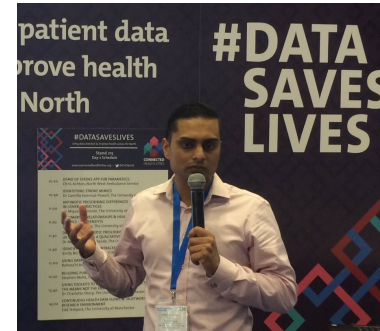
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Owen Johnson is a Senior Fellow working in Digital Health in the School of Computing at the University of Leeds. He is one of the Co-Directors of the UKRI Centre for Doctoral Training in AI for Medical Diagnosis and Care and is the Programme Leader for the MRes in Data Science and Analytics for Health. He has a commercial background in software development and IT leadership and teaches software engineering. He won the 2014 InnovateUK prize for his work developing ResearchOne, a data service providing an access route to 30 million primary care records. His research interests are in the application of process mining to care pathways and he helps lead PODS4H, the international community for Process Oriented Data Science for Healthcare.

Meet the dragons



**Health Research
Authority**



Zoher Kapacee has a background in life sciences and healthcare. He holds a BSc in Biochemistry and Biotechnology, a PhD in Regenerative Medicine from the University of Manchester, an MBA from the Alliance Manchester Business School, and a certification in AI for Business from the Insead Business School. Over the last seven years Zoher has worked on several data science projects and is currently Head of Data and AI at the Health Research Authority. On these projects he has worked with teams to apply statistical and ML methods to transform the way stroke is managed and to optimise antibiotic prescribing in UK secondary and primary care settings, respectively. More recently, Zoher worked on a H2020 project to help deliver personalised cardiac defibrillator therapy to those who needed it most. Zoher has also served as a mentor to several entrepreneurial ventures in the digital, technology and creative sectors.

Programme summary

ONLINE TALKS

Zoom link for all talks: <https://imperial-ac-uk.zoom.us/j/98607575982?pwd=YWtuSXk5UnVBQjllckhwai92RHB5QT09>

Tues 9 May

10:30-12:00 Warren Macdonald *Introduction to medical device regulation*

14:00-15:30 Ele Harwich *The pathway to regulating AI technologies in healthcare*

Wed 10 May

10:30-12:00 Mateo Rojas *How to build AI with highest levels of safety*

14:00-15:30 Kanwal Bhatia *My journey from academia to start-ups*

Thurs 11 May

10:30-12:00 Yasmin Stinchcombe *Digital health landscape in London*

12:15-13:45 Hatim Abdulhussein *How to drive confidence in AI for health and care*

Fri 12 May

10:30 - 11:00 Zoher Kapacee *Overview of the HRA and the regulatory pathway for AI interventions*

IN-PERSON EVENT

Wed 17 May

14:00-17:00 “Dragons Den” Challenge at Room 311 Huxley Building, South Kensington Campus.