

LET'S REGULATE AND INNOVATE!

Putting Laws into Action
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CHALLENGES FOR INNOVATION



Heavily regulated area



Improving health with technology is hard...



Consideration of people's wishes, professional practice and public benefit



Technology and law are both complex and not always understood by innovators and law makers / regulators

HOW DO WE ADDRESS THIS?

- Look at the tools regulation and wider standards give us
- Engineering approach to tooling development based on standards
- Standards for ongoing management
 - ISO 9001 and 27000 Series
- Laws – GDPR, provide Impact Assessment bases
- Communication – with developers, regulators and most importantly citizens



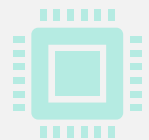


Oversight of competent authorities

For EHR systems
For AI Algorithms in use
GDPR compliance
Alignment with other Regulations



Be prepared to be audited



Learn a new language or find an interpreter

ICT and Innovation Sector with Regulators and Engineers
Two way Street

WHAT'S HERE AND WHAT'S AHEAD

KNOW THE FIELD!

- Learn about regulatory process and legal requirements
- Learn by doing
- Be clear on your focus
 - What is your tool doing
 - What data do you need?
 - How will it be handled?
 - A strong Data Protection Impact Assessment will help



THANK YOU!



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DISCUSSION