



Digital Health Uptake

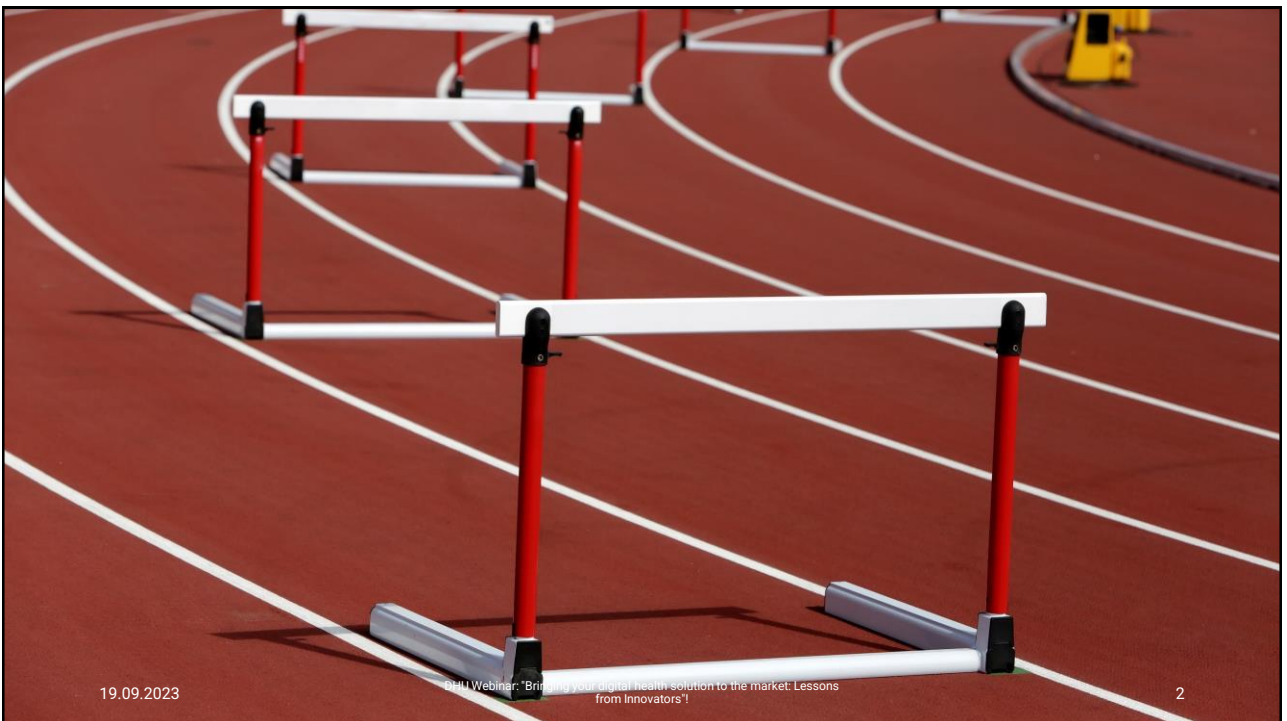
How start-ups face market access in Europe

Rita Campos, F6S



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Barriers

1. Validating solutions
2. Legislation & Regulation
3. Fragmented market

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Validating Solutions

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Digital Health Uptake 1. Validating solutions

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TESTING



PILOTING



CLINICAL STUDIES

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- ↪ Co-Design
 - Know your users (NOT customers) and involve them from the beginning
- ↪ Testing starts as an inside job
 - Robust functional and non-functional testing
- ↪ The first pilot -> Major milestone
 - Select stakeholders
 - Co-design the study
 - Ethics Committee Approval

What happens afterwards?

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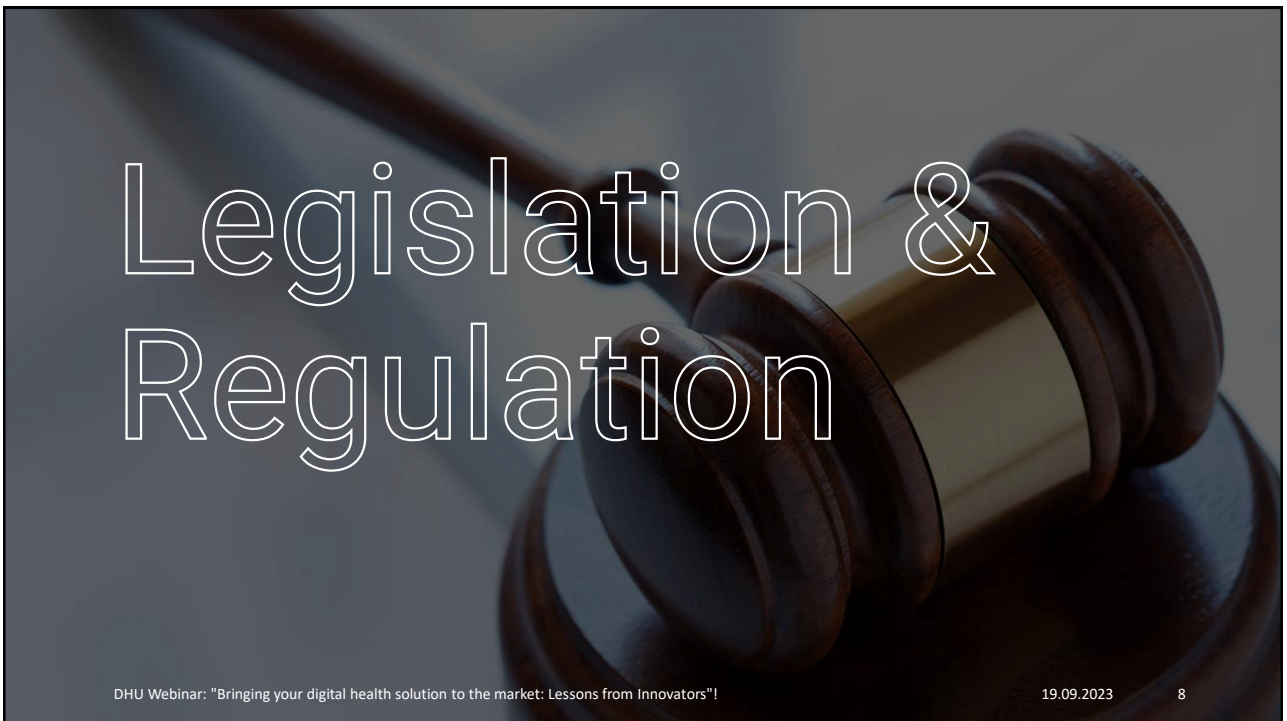
- Invest in professional communication
- Showcase your results
- Everyone likes success stories
- We relate to our peers

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Legislation & Regulation

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 **2. Legislation & Regulation** digitalhealthuptake.eu
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- Understand and interpret Medical Device Regulation
- Contact Notifying Bodies
- GDPR
- EU AI Act: first regulation on artificial intelligence
- Fragmented local regulations in terms of Health Technology Assessment
- Reimbursement paths

Anonymisation Guide
www.covid-x.eu

SEEK EXTERNAL SUPPORT

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Fragmented Market

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- ↪ Language
- ↪ Legislation & Regulation
- ↪ Culture & Context
- ↪ Interoperability

Standards & Data Models
Quality Seal **NETWORK!**

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Takeaways



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Major takeaways

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- Focus on what you do best!
- Demonstrate and showcase -> Communication
- Seek external support
- Collaboration vs Competition -> Network

Digital Innovation Hubs
european-digital-innovation-hubs.ec.europa.eu/edih-catalogue

One-stop shops supporting companies to become more competitive.

COVID^x
www.covid-x.eu

Material to support security & privacy, e.g. anonymisation guide.

LABEL² ENABLE 
label2enable.eu

Promoting a quality label for health apps!

Digital Health Uptake
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RADAR to discover and learn about digital health innovations in Europe.

F6S
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Services for startups and access to funding opportunities



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Rita Campos
Project Manager
rita@f6s.com





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