How start-ups face market access in Europe

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Barriers

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

Validating Solutions
1. Validating solutions

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

Legislation & Regulation
2. Legislation & Regulation

- 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

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Anonymisation Guide
www.covid-x.eu

SEEK EXTERNAL SUPPORT

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Fragmented Market
3. Fragmented market

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

Takeaways
Major takeaways

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

Digital Innovation Hubs

One-stop shops supporting companies to become more competitive.

COVIDX

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

LABEL2 ENABLE

Promoting a quality label for health apps!

Digital Health Uptake

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

f6s.com

Services for startups and access to funding opportunities

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Digital Health Uptake