

EDIH

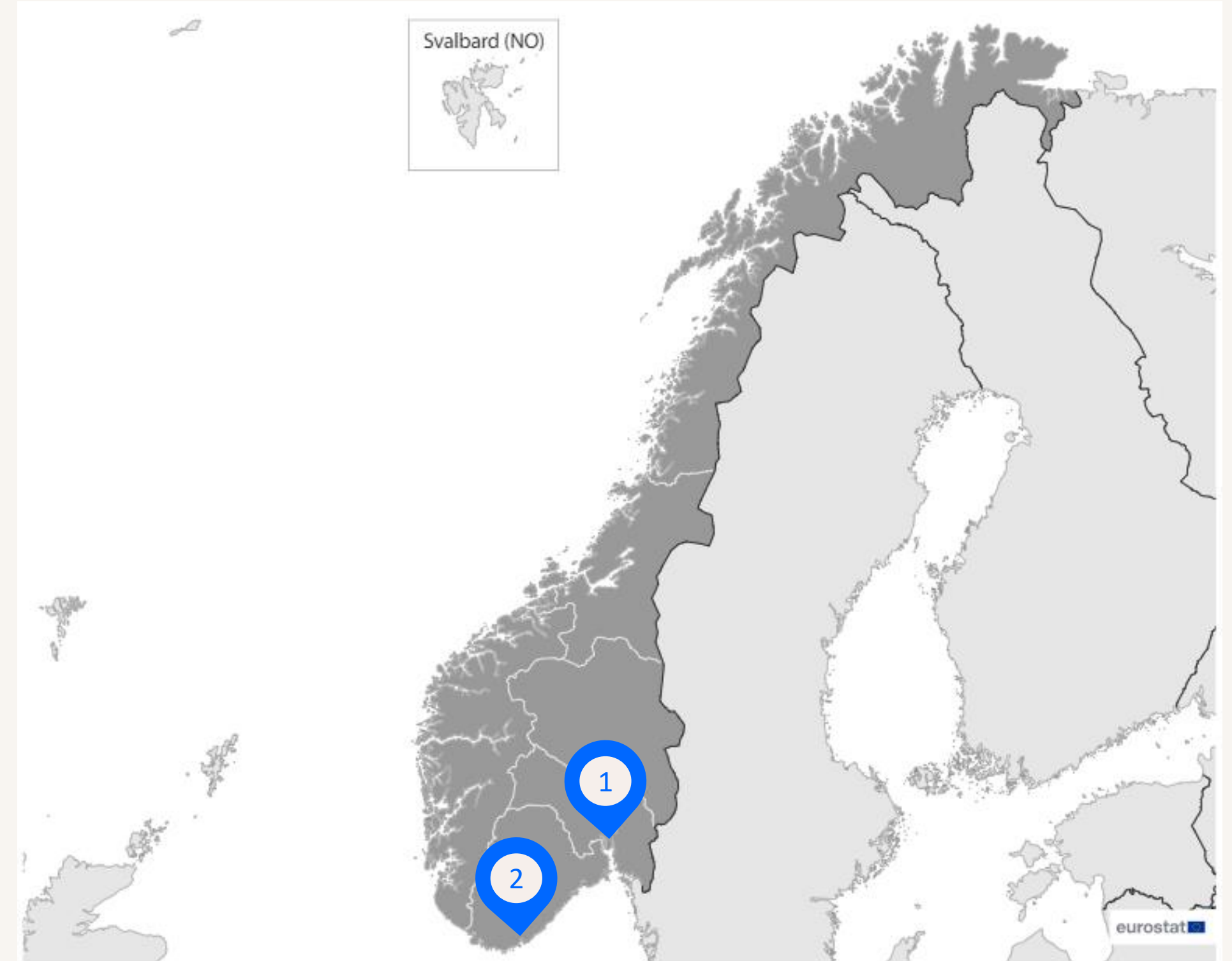
European Digital Innovation Hubs Network

Driving the EU's digital transformation



Norway

📍 EDIH



■ *European Digital Innovation Hubs

*Funded under Digital Europe Programme

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Members

2/2 *EDIHs



22

Sectors

EDIHs in Norway

Operate across diverse industries, from traditional sectors like energy, manufacturing, and healthcare to emerging fields like smart cities and life sciences.

Focus significantly on key areas such as maritime, petroleum engineering, and mining, reflecting Norway's industrial strengths and resource-based economy.

Emphasise sectors like education, community-led development and public administration, highlighting a commitment to societal growth and public sector innovation.

Network overview: 2 members – 2 EDIHs



Nemonoor



OCEANOPOLIS



15 Technologies

Norway's EDIHs prioritise innovation with technologies such as artificial intelligence, cybersecurity, digital twins, and internet of things, driving digital transformation and automation.

Focus on additive manufacturing, big data, and simulation engineering, reflecting a strong commitment to advanced manufacturing and data-driven decision-making.

Emphasis on a wide array of technologies, including robotics, virtual reality, photonics, and sensors, showcasing Norway's dedication to staying at the forefront of technological advancements.



Services

Norway's EDIHs offer extensive services in SME business development, finance, and innovation management, empowering businesses to thrive.

Dedicate resources to knowledge transfer, technology transfer, and technological innovation, ensuring the seamless adoption of cutting-edge technologies.

Emphasise ecosystem building and vocational training, fostering a strong innovation network and enhancing workforce skills.

Success stories

Building Competence in Regulatory Requirements for Global Market Entry of Medical Software

EDIH



Service type



Training and skills development

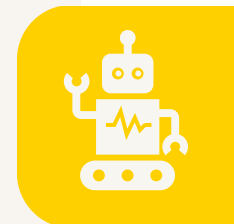


Challenges

Medicue needed to **develop in-house expertise in regulatory compliance**, particularly for FDA submissions in the US, to successfully bring its innovative medical software to global markets.

CUSTOMER

- Medicue AS
- [Website](#)
- Micro-sized enterprise with 1-9 employees.



Technologies

Cloud services



Solutions

Three-step training programme

- **Mapping:** identified the right submission pathways aligned with company goals;
- **Regulatory guidance:** developed a deep understanding of relevant requirements and documentation;
- **Submission management:** streamlined the process with a comprehensive checklist, ensuring efficiency and thoroughness.

Success stories

Building Competence in Regulatory Requirements for Global Market Entry of Medical Software



Thanks to EDIH Nemonoor the SME achieved:

- **regulatory expertise:**

the team gained in-depth knowledge of global market entry requirements, streamlining technical documentation and regulatory submissions;

- **faster market entry:**

improved documentation and understanding of submission pathways reduced costs and accelerated time to market;

- **proactive compliance:**

enhanced ability to anticipate and address regulatory challenges, ensuring product quality and compliance.



Results and benefits

- **Comprehensive knowledge**

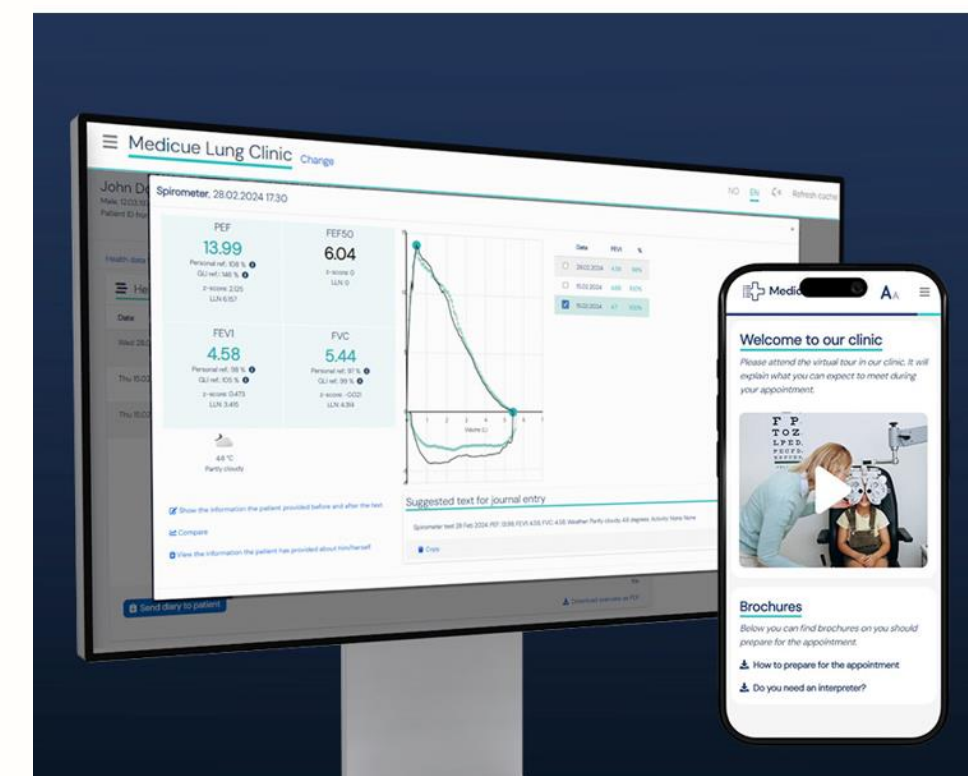
The team now possesses thorough knowledge of regulatory requirements, improving the quality of technical documentation.

- **Cost reduction**

Streamlined processes led to lower costs and faster product launches.

- **Enhanced communication**

Improved interaction with regulatory bodies, ensuring smoother approvals and market entries.



Medicue's innovative solutions enhance patient engagement and streamline regulatory compliance for global market entry.



Lessons learnt

- ✓ Success factors: structured services and clear communication were crucial in navigating complex regulatory landscapes.
- ✓ Continuous improvement: while there are no significant issues, potential exists to enhance training with interactive forums and practical-use cases.