1st Newsletter of the Joint Action

commented and approved by all partners

Planned release date 5 Sep 2024.

Suggested news channels for modification / approval by partners (please add a note if approved):

- Finnish Innovation Fund Sitra news (under Fair Data Economy?)
- HealthHub Finland EDIH and EDIH member(?) newsletters
- Finnish AI Region (FAIR) EDIH and EDIH member(?) newsletters
- Technology Industries of Finland (and AI Finland network) newsletter
- Healthtech Finland newsletter
- Finnish Startup Community blog (edited by FSC to suit their news/blog format)
- Danish Life Science Cluster newsletter
- Lean Entries blog (reference and text from the FSC news/blog)

Digital Tools to Explain the AI Act, Data Act and EHDS Regulation Released by a Finnish-Danish Joint Action by the End of 2024

Public and private parties in Finland and Denmark have come together in a joint action to produce a catalogue of e-tools to explain and educate the industry on the Artificial Intelligence (AI) Act, Data Act and the European Health Data Space (EHDS) regulation. The target of these parties, by the lead and funding of <u>The Finnish Innovation Fund Sitra</u>, is to enable informed decisions by the innovators and deployers of digital solutions regarding the new acts. This joint action also aims to collect evidence of the effect of these e-tools by surveys from the organizations involved. The e-tools are provided by <u>Lean Entries</u> through their regtech platform Entries, in English, and are scheduled for launch by the end of 2024. They are released for free use by all Finnish industrial sectors and the Danish health tech sector, from students and researchers to startups and corporations, throughout 2025.

In recent years, the EU has produced a compilation of new legislative acts to regulate digital products, the use of data and AI. Despite good intentions, this compilation resembles the multiverse of the Marvel Cinematic Universe (MCU): the cross-references require a true fan to follow and, even for them, the chance of misinterpretation remains substantial. This is at least until the European Commission and the EU Court of Justice produce a more detailed synopsis in the format of guidance, examples and preliminary rulings for the viewers across Europe and the world. While this takes several years, like it or not, the industry will need to respond to these regulations sooner, because the viability of today's digital innovations is eventually judged by these rules.

"We cannot waste time with compliance", says Ville Peltola, Head of Data and AI at <u>Technology</u> <u>Industries of Finland</u>. "In this joint action and the Entries regtech we see the opportunity to democratize regulations: Bring the capability of large corporations to the SMEs (small and medium size organizations). The market won't wait for everyone to learn the hard way." Youssef Zad, the Chief Economist of the <u>Finnish Startup Community</u>, underlines the regulatory burden on a national economy explaining that: "In surveys, regulatory compliance continuously pops up as one of the top challenges for startups. While the topic is not the most attractive, we should make sure the startups excel in the art and bind less of their time on regulations."

Sandra Liede, the Senior Legal Specialist of <u>Healthtech Finland</u> reminds of the current state of play in the medical device industry: "In this highly regulated sector innovators still struggle to comply with the newest EU medical device regulations, MDR and IVDR. The new legal acts only add to the complexity. We see great potential in Finnish digital and AI solutions for health care and want to make sure they spend the least time in reaching the international market. We need to focus on the grass roots level of innovation where tools like Entries lay down the reality in minutes at best."

"We've had tens of Danish health tech startups exploit the exixting tools", adds Signe Ulrik Holm, Project Manager from Research to Commercialization at <u>Danish Life Science Cluster</u>, and one of the originators to put this joint action into motion as a continuum to their previous Entries project. "The innovators say these tools support them in understanding the options for their regulatory journey and force them to have a critical view of their innovation from the regulatory perspective. We want to stay in the front line to help our innovators reach the market and are excited to join the action with the Finns."

Further partners for the action are the <u>Finnish Al Region (FAIR)</u> and <u>HealthHub Finland</u>, two European Digital Innovation Hubs (EDIHs), that together represent the majority of Finnish universities and cities and bring into play a host of expertise on research-to-business regarding digital products, Al and data. "The innovators and startups remain weary of the growing regulatory burden and the EDIHs seek the best practices to help them. We're happy to get them hands on with tools for the efficient knowledge transfer in such a crucial topic as regulatory compliance and spread the collected experience with the network of EDIHs.", agree Teemu Moilanen and Ilona Raitakari, management team members of their EDIHs.

"Regtech is a new field of software and infrastructure solutions that can power a regulated digital economy at scale. In the constantly evolving landscape of technology, it's crucial to support business by addressing the intersection of innovation, regulation and compliance. At Sitra, we collaborate with partners from different sectors to research, trial and implement bold new ideas that shape the future of the data economy.", concludes Laura Halenius, Senior Lead at Sitra and the chair of the joint action.

News on the launch of the Entries e-tools are released towards the end of 2024. For further information, please contact any of the steering committee member of the joint action:

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