

**Submission to the European AI IIA public consultation September 2020**

***Reinvent Europe as a startup continent***

We also see great value in finding the right balance between ethical use of AI technology and the opportunities it provides for Europe. But most of all, we believe in Europe's startups and want to see them thrive, scale and help Europe recover post Covid-19.

Many people believe in EU regulations as the key to putting Europe and European values first. In this light, many new regulations were adopted over the years; rules on copyright, e-privacy, P2B, GDPR - just to name a few. Rules aimed at the biggest players, but which ultimately hurt the smallest, who don't have the capital and skills to administer new processes, approvals, registrations, and other - sometimes - burdensome bureaucracy.

Time to market is absolutely crucial for a startup. If it takes too long to get your product, service or solution to market, there is a risk that your investors will no longer back you up or a competitor comes first. Entrepreneurship is not built to wait, while larger companies can more easily manage to wait half a year for an approval or process to be set up before launching.

Already, we have lost almost half of our unicorns to Brexit. In many ways, AI has the potential to reinvent Europe as a startup continent, and with AI solutions, we can actually solve some of our society's greatest challenges. Our member and Danish startup success, Corti, is a brilliant example of that; using AI technology to analyze millions of conversations with patients, identifying patterns and helping healthcare professionals to more efficiently predict and detect life-threatening situations. But in order for companies like Corti to thrive in Europe, we have to challenge the logic that more EU regulations will strengthen competition. At least we can see that previous regulations have made it harder and more difficult to scale as startups in Europe.

***Comments to the European Commission's proposed policy options***

**Policy option 0 (baseline).** We do believe there is merit in ensuring that the existing EU regulation is properly implemented with regards to AI before putting in place any new prescriptive AI-specific rules. Currently AI does not operate in a vacuum and is subject to a number of existing rules, including GDPR and medical devices regulation.

**Policy option 1 (industry-led intervention).** No matter what policy options are pursued, lending support to the industry in establishing and implementing norms of responsible practices and sharing best practices is worthwhile.

**Policy option 2 (legislation on voluntary labelling).** We are sceptical of the impact of a labelling scheme on the uptake of trustworthy AI in Europe. An administrative burden on startups and SMEs to comply with the onerous labelling obligations - if drafted on the basis of the EU High-Level Expert Group on AI - could significantly outweigh the benefits of such a scheme.

**Policy option 3 (legislation with mandatory requirements).** It's important to take a proportionate, risk-based approach balancing potential harms with the social/economic benefits. Any regulatory framework should be flexible to evolve with this dynamic technology and without unduly hindering AI-driven innovation.

- **We support a well-defined risk-based approach to the AI regulation** that takes into account both the severity and likelihood of harm. A sector and use base criteria at large seem to be a good starting point. Attempting to regulate things that may happen in the future holds back creativity. COVID-19 has shown it's vital to have fast and effective solutions. We must ensure that any future AI regulations don't compromise AI's ability to provide the right responses at the right time in such a crisis.
- **We strongly caution against an EU legislative act for all AI applications** that would make no distinction between the AI applications that can pose significant risk/harm and those with no or lower risk profile. Such a legislative instrument would be significantly unproportional to the challenges identified by the Commission, and create significant barriers for AI adoption, additional costs, delay and administrative burdens.

**We support the proposed ex-post enforcement model for when problems arise.**

Regulation should look at causes, effects and intended use. *Ex-ante* conformity assessments result in longer time-to-market, which hamper startups' potential success and result in higher costs. Instead of nourishing innovation, an ex ante model will effectively end up ring fencing established players. And leading AI-startups will need to relocate to the US or UK if they cannot focus money and resources on experimenting and developing their technologies.

If the Commission insists on an ex-ante enforcement model, we strongly caution against third party ex-ante assessments and recommend instead self-assessment procedures based on clear due diligence guidance. A practical approach would be for regulators to provide detailed templates and guidance on how to carry out and document the risk assessment, but delegate responsibility to those using and most familiar with the AI system.

**Avoid legal uncertainty - apply clear definitions for AI regulation.** We caution the European Commission to significantly expand the scope of future AI regulation to "*automated decision making*". Such a broad scope would create unproportional, unjustified regulatory obligations and likely lead to over-regulation by including all automated systems, even those that do not even pose any risk nor harms. It would also go against the initial direction to focus on a risk-based, double-criterion model for sectorial and use-based AI technologies. Further, we are concerned with introducing an open-ended concept of "*immaterial harm*". We propose as an alternative to refer to "*significantly restricting the exercise of fundamental rights*" which would also align with existing legislative frameworks.