ADIGITAL CONTRIBUTION

European Commission Public Consultation on

Artificial intelligence- ethical and legal requirements

1. **Scope**

Adigital welcomes the opportunity to respond to the Commission's Inception Impact Assessment on the proposed legislative initiative on AI. We welcome the policy Objective and Aims of the initiative, in particular the intent to ensure coherence and complementarity with other possible initiatives, e.g. affecting the Machinery Directive, the General Product Safety Directive or the product liability regime.

We support targeted policies that address companies' accountability for developing and operating trustworthy AI. Below are our comments on the legislative options outlined

In general, Adigital **cautions the Commission on considering to significantly expand the scope of the future AI regulation to the open ended category of "automated decision making."** This would go against the initial, thoughtful direction proposed in the AI whitepaper that proposes to focus on the risk-based, double-criterion for sectorial and application/use-based AI technologies. If AI were defined as "automated decision making" for the purpose of the future AI regulation, it would create unproportional, unjustified regulatory obligations that would not only deter development and deployment of AI-based applications in Europe, but also automated systems that do not pose any risk nor harms.

On a more specific note, Adigital reiterates the **concerns around introducing the open-ended concept of "immaterial harm" into the future AI legislation.** We propose as an alternative to refer to "significantly restricting the exercise of fundamental rights," which would closer align with the existing legislative framework.

2. **Comments on the policy options proposed**

   ➔ **Option 0 (baseline)**

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, medical devices regulation, and fundamental rights aquis. Therefore, before embarking on a new legislative instrument, a thorough

gap analysis should be performed. Most of the current legislative gaps to achieve trustworthy AI can be achieved by updating and amending current legislation, while also reviewing and empowering enforcement mechanisms and oversight bodies. Only the gaps that cannot be filled by the former require new regulation.

➔ **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. We support this Option for low-risk AI applications.

➔ **Option 2 (legislation on voluntary labelling)**

Voluntary labelling schemes can be helpful to consumers or end-users in some markets but we do not believe a single, one-size-fits-all labelling scheme would be effective across such a broad field as AI, given the hugely diverse range of products and services that will be deployed across all sectors.

Therefore, we remain skeptical on the impact of a labelling scheme on the uptake of trustworthy AI in Europe. An administrative burden on SMEs to comply with the onerous labelling obligations -- if drafted on the basis of the update Assessment List for Trustworthy AI from the EU High-Level Expert Group on AI -- could significantly outweigh the benefits of such a scheme.

➔ **Option 3 (legislation with mandatory requirements)**

Overall, the opportunity cost of not using AI should be part of the assessment when considering any future legislation aiming to reduce risk and harms from the use of AI applications. Legislation should ensure legal certainty, be proportionate and increase trust in AI without unduly hindering AI-driven innovation.

- **Option 3a**: We support the need for a public dialogue on the use of facial recognition technologies, which could lead to targeted legislation. Remote biometric identification systems may be a good example of an application to which mandatory requirements could be applied in a risk-based framework.

- **Option 3b:** Legislation should focus on high-risk applications, particularly applications where human autonomy or judgment are substantially ceded to an AI system. There should be a single risk assessment framework to identify high-risk AI, regardless of sector and without lists of exceptions.

  Any mandatory requirements for high-risk AI systems should be addressed to the actors best placed to address the risks. Similarly, liability is best allocated to the actor closest to the risk,

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2

as liability is highly context-specific. In a B2B context, contractual liability works well and should be maintained, allowing parties to negotiate an efficient allocation of risk that takes account of the specific use case. 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/application base criteria -- as proposed by the EC's whitepaper -- at large seem to be a good starting point.

- **Option 3c**: We do not support this option as it would significantly hamper the uptake and development of AI in the EU, against the stated Objective and Aims of the initiative. Therefore,**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 problems so far identified by the European Commission, create significant barriers for AI adoption (additional costs, delay, administrative burden) in Europe, result in opportunity costs in some applications due to lack of AI implementation, and risk lowering the bar for those AI applications that are very likely to raise significant risks.

- **Option 4: A combination of the options above taking into account the different levels of risk that could be generated by a particular AI application.**

We believe the Objective and Aims can best be met with a combination of Options 1, 3a and 3b, implemented through a co-regulatory approach and supported by globally recognized standards and industry-led codes of conduct.

In relation to a European governance structure on AI, we believe that in sectors where established structures already exist (medical devices, aviation etc.) these existing bodies are best placed to cover high-risk AI in their sectors, having the necessary sectoral expertise, operational relationships and track-record with relevant stakeholders. There may be value in a new European mechanism that provides best practice sharing and guidance across sectors, but its scope must be limited and its relationship to existing regulatory bodies clearly defined, so as to avoid fragmentation, inconsistency and the risk of stifling innovation.

In summary, we agree with the need for a consistent EU-wide regulatory framework for trustworthy AI. This will be essential to give stakeholders the confidence to develop and adopt AI-based solutions and realize the enormous benefits they offer. Building trust requires acknowledging valid concerns that exist regarding accountability, transparency, fairness, privacy and security, and putting in place appropriate regulatory mechanisms to manage those risks, while continuing to promote ongoing innovation and experimentation – getting that balance right requires a precision regulation approach that is clear and targeted.

An adequate scenario would include a combination of options 1, 2 (with the specificities above mentioned), 3a and 3b, providing EU citizens with a graded level of assurance / control / oversight of compliance with EU ethical guidelines, values and legal requirements aligned with the risk posed by AI uses and businesses . Companies or industries should be able to define their own guidelines, codes of conduct and best practices (Option 1); additionally, those aiming for higher trust on complying with EU ethical guidelines and values could voluntarily adhere to a voluntary labelling scheme (option 2) for already identified applications of AI posing a relevant risk to human rights, as could be the case of remote public biometric identification, should be subject to a set of mandatory targeted requirements (option 3b); finally, based on a risk approach using an identification criteria based on sector and use/application as proposed in the EC's White Paper, for the existing gaps in current legislation that cannot be covered by an update or amendment of such legislation, new ex-ante obligations should be defined and adopted.

3. **Enforcement**

Adigital **supports the ex post enforcement** for when problems arise as the most appropriate and proportionate mechanism, except in fields where ex-ante assessments are already established practice. In those situations, we recommend **aligning any ex-ante assessment with existing procedures.**

If the Commission insists on the ex-ante enforcement, **we strongly caution against a third party ex-ante assessment and recommend instead self-assessment procedures based on clear "due diligence" guidance from the regulators.** 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 to conduct an accurate assessment.

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4