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The Regulatory Landscape of AI

The Current State and Future Trends

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WELCOME AND HOUSEKEEPING



The Regulatory Landscape of AI

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Nikodem Latocha

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As the AI technologies proliferate, the Regulators are in the race to achieve the best balance between innovation and oversight.

The artificial intelligence (AI) technologies advance and proliferate globally, regulatory bodies are proactively implementing governance reforms. The regulatory landscape for AI is evolving rapidly, with various jurisdictions adopting diverse approaches to enforcement and oversight.



Fostering Innovation

Regulators aim to create an environment that encourages technological advancements and breakthroughs in AI.



Ensuring Proper Oversight

Simultaneously, they must implement safeguards to protect individuals and society from potential risks associated with AI technologies.



Protecting Public Interest

Oversight helps ensure that AI technologies align with societal values and do not infringe upon individual rights or public safety.



Promoting Ethical Development






By striking this balance, authorities hope to guide the AI industry towards responsible and ethical practices.






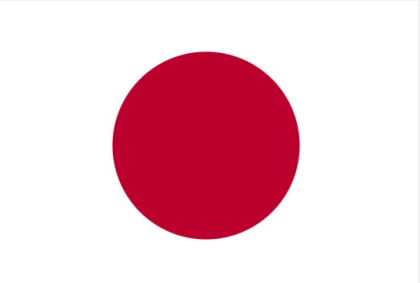

Adapting to Rapid Changes

The fast-paced nature of AI development requires regulators to be agile and responsive in their approach.

AI Regulations Implementation Strategies – Holistic approach to AI

 <p>European Union</p>	<p>The European Union has made significant progress in AI regulation with the European Parliament's approval of the comprehensive AI Act on March 13, 2024. This legislation is anticipated to be enacted in the near future, with full implementation expected around June 2026 following a two-year transition period.</p> <p>Complementing the AI Act, the EU is developing additional regulatory frameworks to address various aspects of AI governance. Of particular note is the proposed AI Liability Directive, which aims to establish clear guidelines for civil liability in cases where AI systems cause harm or damage.</p>
 <p>China</p>	<p>China stands at the forefront of jurisdictions who are actively introducing AI regulations. As they work on drafting a holistic AI framework, several specific AI applications are already governed by existing rules. These encompass:</p> <ul style="list-style-type: none"> • <u>Algorithmic Recommendations Management Provisions</u> • <u>Ethical Norms for New Generation AI</u> • <u>Opinions on Strengthening the Ethical Governance of Science and Technology</u>
 <p>Canada</p>	<p>Canada is advancing the AI and Data Act (AIDA) to safeguard Canadians from high-risk AI and promote responsible AI practices in line with global norms. AIDA emphasizes safety, human rights, and curbs reckless AI applications.</p> <p>In addition to AIDA, Canada has rolled out a Directive on Automated Decision-Making which lays down specific standards that the federal government must adhere to when utilizing automated decision-making systems.</p>
 <p>Brazil</p>	<p>Brazil is actively developing a comprehensive AI Bill, which seeks to prohibit specific high-risk AI systems, sets up a dedicated regulatory body, and imposes civil liability on AI developers and deployers.</p> <p>Additionally, it would require prompt reporting of significant security breaches and guarantee individuals the right to understand AI-driven decisions and correct biases.</p>
 <p>India</p>	<p>While India currently does not have specific AI governance legislation, the country is taking proactive steps to address this emerging field. The forthcoming Digital India Act is anticipated to incorporate provisions for regulating high-risk AI applications, demonstrating India's commitment to responsible AI development.</p> <p>Furthermore, recognizing the multifaceted challenges presented by AI, the Indian government has established a dedicated task force. This group of experts is tasked with examining the ethical, legal, and societal implications of AI. Their work is expected to lay the groundwork for a potential AI regulatory body and contribute to the enhancement of India's AI governance framework.</p>

AI Regulations Implementation Strategies – Case-by-case Strategy

 <p>United Kingdom</p>	<p>The United Kingdom has not implemented comprehensive AI regulation and does not intend to do so in the near future. Instead, the UK government has adopted a nuanced, sector-specific approach to AI governance. This strategy, outlined in the August 2023 Policy Paper titled "A pro-innovation approach to AI regulation" aims to leverage existing legal frameworks to provide guidance on AI implementation across various industries.</p> <p>In February 2024 the Office for Artificial Intelligence was integrated with the Department for Science, Innovation and Technology. This restructuring underscores the UK's dedication to aligning AI governance with wider technological and scientific endeavors.</p>
 <p>United States of America</p>	<p>While the U.S. lacks a unified AI regulation, it has established numerous guidelines and frameworks to govern the AI sector on a federal level.</p> <p>The US is adopting a case-by-case strategy to AI governance enforcement, avoiding an overly precautionary approach.</p> <p>Important documents:</p> <ul style="list-style-type: none"> • AI Training Act • FDA - Artificial Intelligence and Machine Learning in Software as a Medical Device • FDA - Using Artificial Intelligence & Machine Learning in the Development of Drug & Biological Products - Discussion Paper
 <p>Switzerland</p>	<p>Switzerland has also opted against introducing a standalone AI regulation, taking a path similar to the UK. It focuses on selectively amending existing laws to accommodate AI. This approach includes:</p> <ul style="list-style-type: none"> • integrating AI transparency rules into existing data protection laws; and • modifying the local competition laws, product liability laws, and general civil laws to address AI system needs. <p>A more substantial vision of the Swiss envisioned framework for AI regulation was clarified by the Position Paper from 2021 by the Swiss Digital Society Initiative in collaboration with the University of Zurich.</p>
 <p>Japan</p>	<p>Japan has adopted a flexible approach to AI regulation, favoring guidelines over strict laws. The government encourages industry self-regulation while providing key frameworks for responsible AI development and implementation. Notable guidelines include:</p> <ul style="list-style-type: none"> • Guidelines for Implementing AI Principles • AI Governance in Japan Ver. 1.1 <p>While Japan's existing sector-specific legislation, such as data protection, antimonopoly, and copyright laws, were not specifically designed for AI, they remain applicable and relevant in the context of AI technologies and applications.</p>
 <p>Australia</p>	<p>Australia has not yet enacted specific AI governance legislation or policies. Instead, the government is leveraging existing regulatory frameworks to oversee AI developments.</p> <p>For a comprehensive overview of Australia's AI governance landscape, refer to "The State of AI Governance in Australia," a report published in May 2023 by the University of Technology Sydney. You can access the report here: The State of AI Governance in Australia.</p>

The bottom line of AI regulation



AI transparency



Data privacy and personal data
protection regulations

There is a natural trend toward convergence of those two sectors; however, this sometimes raises legislative cases that are currently unresolved.

When Data Privacy and AI Regulations collide

General Data Protection Regulation (GDPR)

This comprehensive framework establishes stringent requirements for data privacy and security. Given that AI models extensively utilize data for both training and operational purposes, the GDPR has significant implications for AI development and deployment.

One notable provision of the GDPR is the "right to be forgotten", which empowers individuals to request the deletion of their personal data.

Consequently, organizations leveraging customer data for AI model training must implement robust mechanisms to ensure the capability to remove specific customer data upon request in compliance with this regulation.

General Data Protection Regulation (GDPR) + Rare Diseases

There are many challenges in the pharmacoepidemiology of orphan drugs. One of them is a lack of large volumes of data that are essential for building high-quality AI models. A different challenge arises from the data protection perspective.

Many rare diseases have a genetic origin. The use of AI in the context of genome sequencing raises significant privacy risks not only for patients but also for their families.

California Privacy Rights Act (CPRA)

This act incorporates provisions mandating certain businesses to disclose their use of algorithmic decision-making processes that impact individuals.

CPRA regulators are currently discussing the interpretation and enforcement of this rule, particularly in relation to AI and machine learning applications.

At the very least, it is anticipated that businesses falling under CPRA jurisdiction will be required to provide notification when employing AI for decision-making processes that affect individuals.

AI Ethics Officer as a new role governing the use of data?

Basic tasks concerning the AI systems	Data Protection Officer	AI Ethics Officer
Data Oversight	Ensures that personal data is processed in compliance with privacy laws	Evaluates how AI systems process and handle data, ensuring ethical use.
Regular Reviews	Conducts Data Protection Impact Assessments (DPIAs) to identify and minimize data protection risks.	Performs ethical reviews of AI projects to ensure alignment with ethical standards.
Guideline Development	Develops and updates data protection policies and guidelines.	Creates ethical guidelines for AI development and deployment.
Training	Educate teams on data protection regulations and best practices.	Provides training on ethical considerations in AI.

DPO vs. AI Ethics Officer: Who Do You Need to Stay AI-Compliant?, by Kostiantyn Ponomarov, Legal Nodes, <https://legalnodes.com/article/ai-ethics-officer-or-dpo>

AI Ethics Officer as a new role governing the use of data?

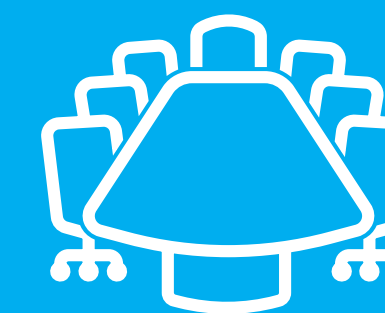
Technical knowledge

Since technology is the foundation of AI, the AI ethics champion and team must have a robust working knowledge of AI technologies. They can't credibly advise on AI ethics issues if they don't fully understand the capabilities and limitations of the technology. Although they won't be doing the actual coding of AI systems, they need a deep understanding of technical concepts such as the difference between supervised and unsupervised learning, how user consent is obtained, and whether the machine learning model being used supports transparency—all the small but important details that affect how an AI system is designed, developed, and deployed.



Business savvy and industry knowledge

AI ethics in a business context can't just be a philosophical exercise. Policies, frameworks, and other guidance related to AI ethics need to be usable in the real world. This requires practical business knowledge and experience. Without a clear understanding of the industry and business—and how AI ethics might affect various processes, systems, and stakeholder groups—AI ethics requirements can easily become so burdensome that they are simply ignored. An awareness of how the industry is addressing AI ethics is also crucial.



Regulatory knowledge

AI ethics involves much more than regulatory compliance. In fact, the pace of AI innovation is so rapid that related laws and regulations are almost always lagging behind what technology can do (and how social norms and public perceptions are shifting). However, regulatory knowledge is still essential. This includes not just knowledge of current regulations related to AI, such as data privacy laws, but also a forward-looking strategic perspective on what might arise in the future based on existing regulations and what ethics-related challenges are currently top of mind for lawmakers and regulators.



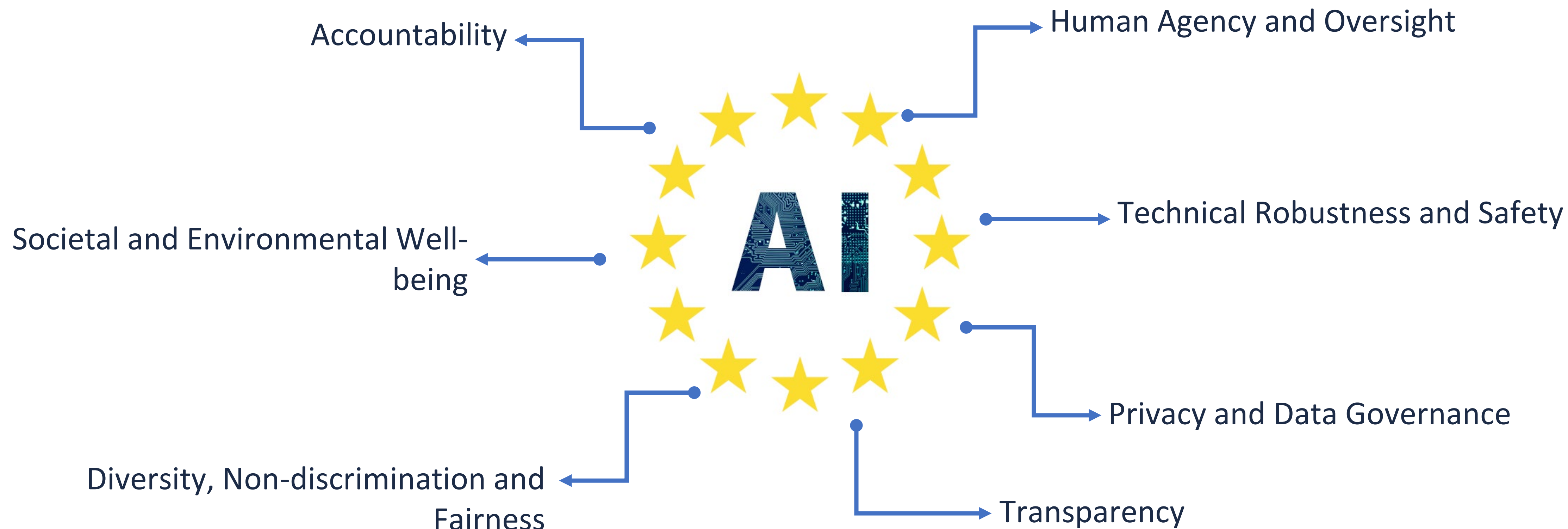
Communication skills and the ability to work across organizational boundaries

AI ethics issues are by their very nature complex and hard to understand. Also, they often require people to do things that are unintuitive or potentially burdensome. Helping people understand the issues and persuading them to change requires strong communication skills. This includes active listening, personal empathy, and the ability to clearly articulate what needs to be done—and why. It also requires the ability to operate effectively across organizational boundaries, up and down the corporate hierarchy, as well as across functions and business units—often without direct authority over the people involved.

Does your company need a Chief AI Ethics Officer, an AI Ethicist, AI Ethics Council, or all three? Positioning your organization for success on AI Ethics, by Beena Ammanath, Executive Director, Deloitte AI Institute

Assessment List for Trustworthy AI (ALTAI)

The **Assessment List for Trustworthy AI (ALTAI)** is an industry agnostic self-assessment tool developed by the High-Level Expert Group on AI (AI HLEG) and established by the European Commission.



Assessment List for Trustworthy AI (ALTAI)

Each section (named “Requirement”) includes a number of self-assessment questions grouped into subsections:

Human Agency and Oversight Human Agency and Autonomy Human Oversight	Transparency Traceability Explainability Communication
Technical Robustness and Safety Resilience to Attack and Security General Safety Accuracy Reliability, Fall-back Plans and Reproducibility	Diversity, Non-discrimination and Fairness Avoidance of Unfair Bias Accessibility and Universal Design Stakeholder Participation
Privacy and Data Governance Privacy Data Governance	Societal and Environmental Well-being Environmental Well-being Impact on Work and Skills Impact on Society at large or Democracy
Accountability Auditability Risk Management	

Emerging themes in AI regulation

Because few AI regulations are currently in effect, and most remain subject to interpretation, it is too early to say exactly how AI compliance will affect businesses at a large scale. However, existing rules and draft legislation suggest that a few key themes will dominate.



Transparency is Paramount

Regardless of the specific AI implementation, disclosure of AI technology usage is a crucial component of AI regulation.

While regulations such as the GDPR and CPRA do not prescribe specific methodologies for AI utilization, they do mandate that companies disclose their use of AI, particularly when it impacts individuals.



Regulatory Approach Based on AI Risk Assessment

Certain AI regulatory adopt a risk-based regulatory approach. AI applications deemed high-risk are subject to more stringent regulations compared to lower-risk AI deployments.

Consequently, regulators may impose varying protective measures for different AI systems depending on the intended use.



Absence of Technical Specificity in AI Legislation

To date, no major AI regulatory framework or draft legislation has attempted to specify technical parameters for AI system design, including acceptable AI model types or frameworks to follow.

It appears likely that future regulations will permit any technical approach that adheres to overarching privacy and security mandates.



Uniform Regulations Across AI Types

With few exceptions, such as China's mandates on generative AI, existing laws do not differentiate between various types of AI, including generative AI and predictive AI.

Instead, most regulations aim to apply consistent rules across all AI types.



Ambiguity in Enforcement Mechanisms

While many AI regulations stipulate maximum penalties - for instance, potential fines of up to 35 million euros for EU AI Act violations - the crucial phrase "up to" introduces uncertainty regarding the intensity of regulatory enforcement.

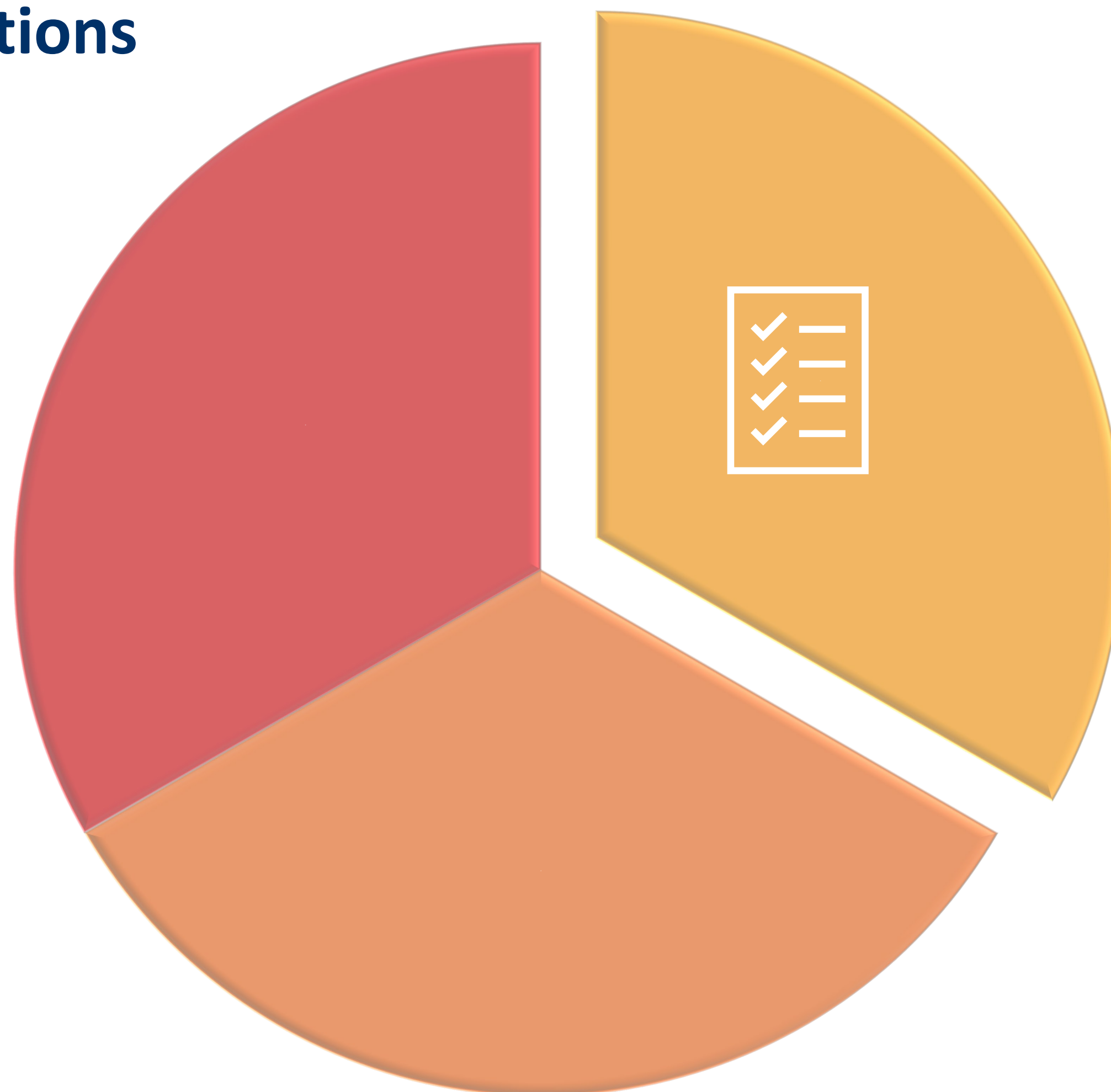
Similarities with the GDPR raise the possibility that a similar approach may be taken in the EU.

GDPR Fines in H2 2018: 9
(total 400.000 E)

GDPR Fines in May 2024: 30
(total >32 mil E)

Reflection paper on the use of Artificial Intelligence in the medicinal product lifecycle

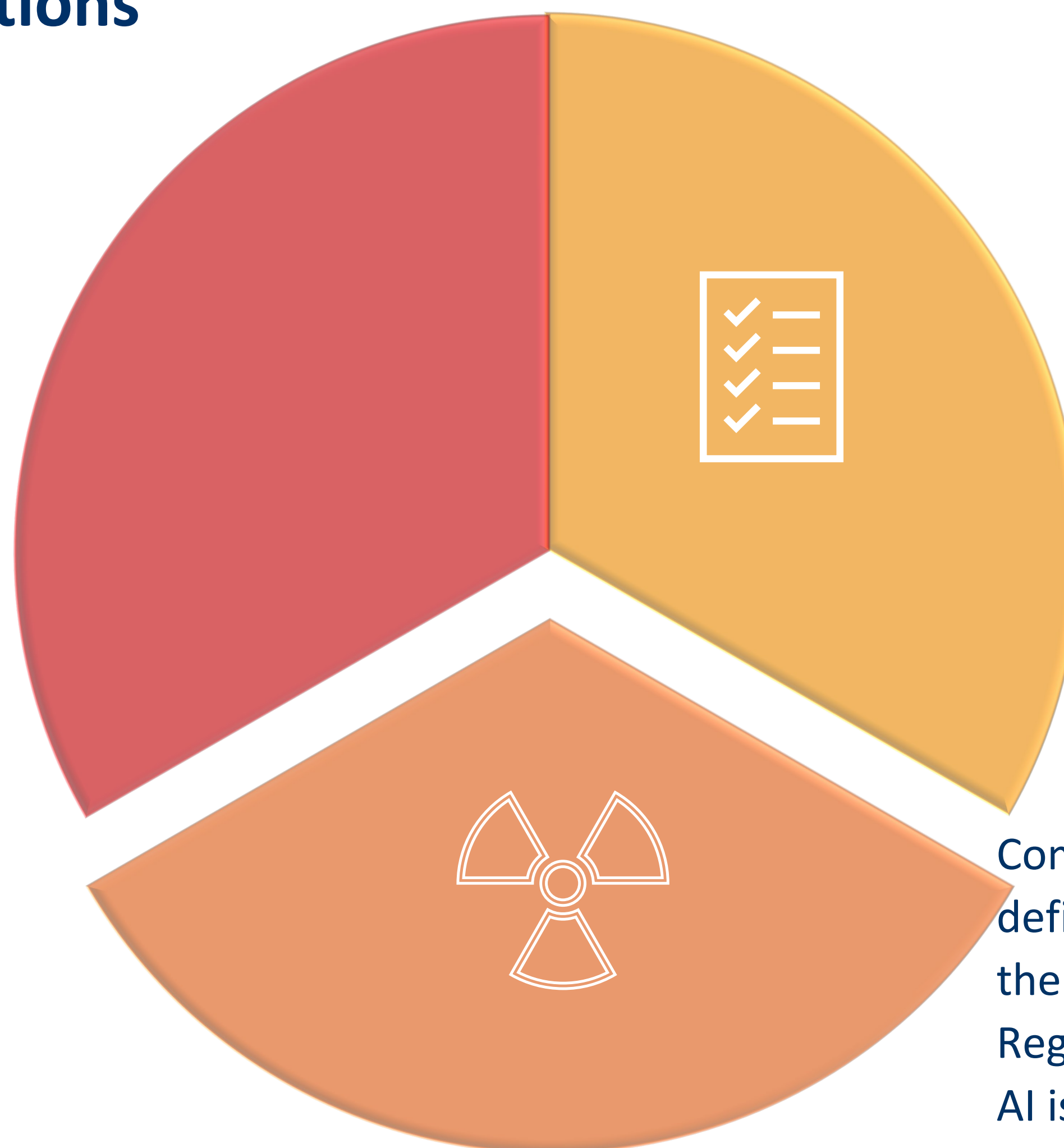
General considerations



EMA confirms that AI guidance documents should be read in conjunction with AI Act, AI Liability Directive, data protection (including GDPR), Cybersecurity Act, and specific medicines regulations.

Reflection paper on the use of Artificial Intelligence in the medicinal product lifecycle

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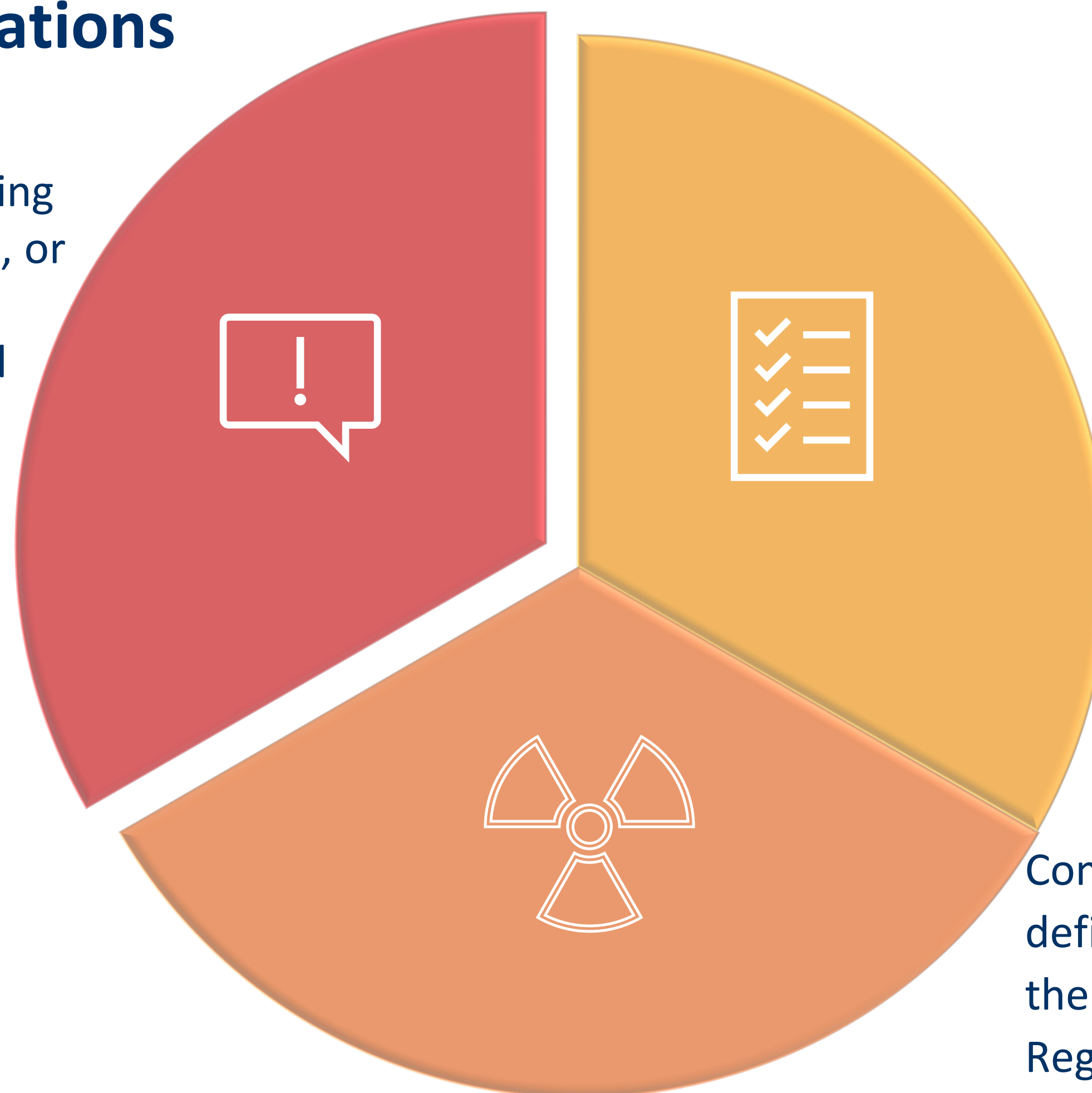
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Companies are encouraged to “proactively define the risk to be managed throughout the entire system lifecycle”.
Regulatory guidance on risk management in AI is planned.

Reflection paper on the use of Artificial Intelligence in the medicinal product lifecycle

General considerations

A Clinical Trial Sponsor, Marketing Authorisation Applicant/Holder, or Manufacturer is ultimately responsible for ensuring that all algorithms, models, datasets, and data processing pipelines comply with EU legislation.



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Clinical Trials



The full model architecture, logs from model development, validation and testing, training data, and description of the data processing pipeline “would likely be considered” parts of the clinical trial data or trial protocol dossier and thus may be requested at the time of market authorization, clinical trial application, or GCP inspection.

AI/ML models used for transformation, analysis, or interpretation of data within clinical trials are considered part of the statistical analysis and should follow applicable regulations in this area.

Reflection paper on the use of Artificial Intelligence in the medicinal product lifecycle

Clinical Trials - Transparency



“It is encouraged that models are published in an openly accessible repository prior to their deployment in a pivotal clinical trial, to allow third-party review and promote standardization.”

Reflection paper on the use of Artificial Intelligence in the medicinal product lifecycle



Clinical Trials

Incremental learning is **not** accepted.

Any modification of the model during the clinical trial requires a regulatory interaction to amend the statistical analysis plan.

Pharmacovigilance

Incremental learning is accepted in the post-authorization phase.

The Marketing Authorization Holder's responsibility is to validate, monitor, and document model performance to mitigate risks.

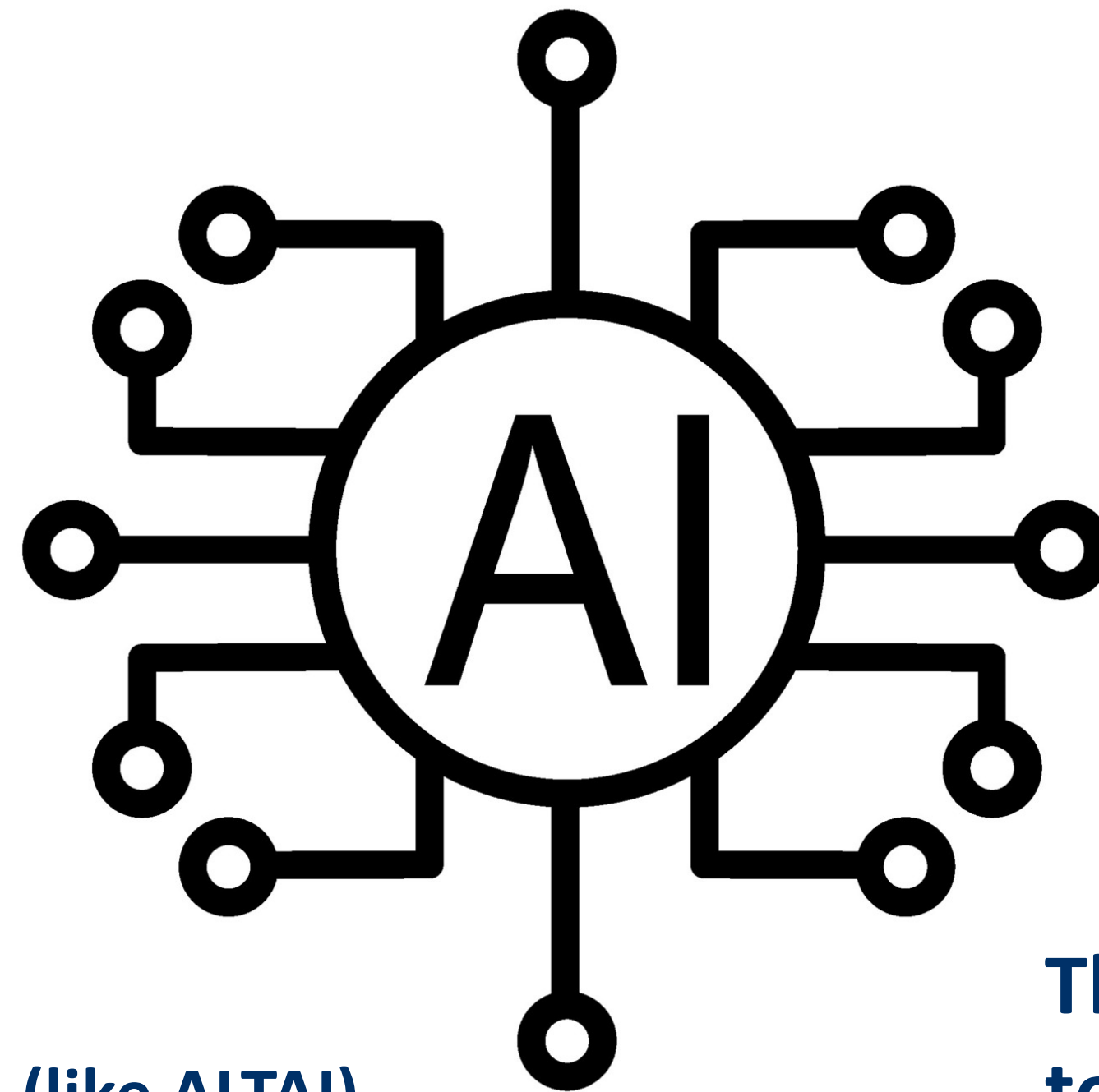
AI Regulations - Takeaways

Businesses must prioritize data privacy and transparency as cornerstones of their AI strategies. This is especially critical when leveraging personal data for AI model training or automated decision-making processes.

Especially in highly regulated environments, companies operating in these sectors must proactively prepare for stringent oversight and usage of the regulatory frameworks.

The existing assessments (like ALTAI) support the companies in proactive risk mitigation in multiple areas.

The AI regulatory landscape is rapidly evolving.



The problem is to balance innovation with oversight. There is no easy answer to this. Some issues are solved globally, and some are solved on a case-by-case basis.

There is a strong and emerging need to create oversight over AI at the company level, similar to the Data Protection Officers.

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Thank You



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