

Position Paper

Background

The European Commission has published their proposal for a regulation that covers many aspects of AI (Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL LAYING DOWN HARMONISED RULES ON ARTIFICIAL INTELLIGENCE (ARTIFICIAL INTELLIGENCE ACT) AND AMENDING CERTAIN UNION LEGISLATIVE ACTS COM/2021/206 final) in April 2021. The draft Artificial Intelligence Act (AIA) is a horizontal regulation implementing a risk-based approach to identify the level of control on AI Systems being placed on the European market. The members of the Team NB, the EU association for Notified Bodies for medical devices and IVDs publish this position-paper with the intention to express their opinion and concerns regarding the upcoming regulations, with a focus on the interface and overlap between the upcoming regulations and the Medical Device Regulation (MDR) and IVD Regulation (IVDR).

Definitions

Article 3(1): ‘artificial intelligence system’ (AI system) means software that is developed with one or more of the techniques and approaches listed in Annex I and can, for a given set of human-defined objectives, generate outputs such as content, predictions, recommendations, or decisions influencing the environments they interact with

Annex I:

- (a) Machine learning approaches, including supervised, unsupervised and reinforcement learning, using a wide variety of methods including deep learning;
- (b) Logic- and knowledge-based approaches, including knowledge representation, inductive (logic) programming, knowledge bases, inference and deductive engines, (symbolic) reasoning and expert systems;
- (c) Statistical approaches, Bayesian estimation, search and optimization methods.

Team NB Opinion:

The definition used includes terms related to logic and knowledge-based systems. This is an overly broad definition such that it could potentially include non-AI systems leading to confusion for the regulators, manufacturers and notified bodies. Since the goal of standardization is to provide harmonized definitions of technologies for the purpose of exchanges between relevant stakeholders, we recommend to use the definition found in the international standard “ISO/IEC 2382:2015, Information technology – Vocabulary”.

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Michael Rajnik



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Table of Contents Position Paper Sample Format

1. Understanding the eBook Position Paper Sample Format
 - The Rise of Digital Reading Position Paper Sample Format
 - Advantages of eBooks Over Traditional Books
2. Identifying Position Paper Sample Format
 - Exploring Different Genres
 - Considering Fiction vs. Non-Fiction
 - Determining Your Reading Goals
3. Choosing the Right eBook Platform
 - Popular eBook Platforms
 - Features to Look for in an Position Paper Sample Format
 - User-Friendly Interface
4. Exploring eBook Recommendations from Position Paper Sample Format
 - Personalized Recommendations
 - Position Paper Sample Format User Reviews and Ratings
 - Position Paper Sample Format and Bestseller Lists
5. Accessing Position Paper Sample Format Free and Paid eBooks

- Position Paper Sample Format Public Domain eBooks
- Position Paper Sample Format eBook Subscription Services
- Position Paper Sample Format Budget-Friendly Options
- 6. Navigating Position Paper Sample Format eBook Formats
 - ePub, PDF, MOBI, and More
 - Position Paper Sample Format Compatibility with Devices
 - Position Paper Sample Format Enhanced eBook Features
- 7. Enhancing Your Reading Experience
 - Adjustable Fonts and Text Sizes of Position Paper Sample Format
 - Highlighting and Note-Taking Position Paper Sample Format
 - Interactive Elements Position Paper Sample Format
- 8. Staying Engaged with Position Paper Sample Format
 - Joining Online Reading Communities
 - Participating in Virtual Book Clubs
 - Following Authors and Publishers Position Paper Sample Format
- 9. Balancing eBooks and Physical Books Position Paper Sample Format
 - Benefits of a Digital Library
 - Creating a Diverse Reading Collection Position Paper Sample Format
- 10. Overcoming Reading Challenges
 - Dealing with Digital Eye Strain
 - Minimizing Distractions
 - Managing Screen Time
- 11. Cultivating a Reading Routine Position Paper Sample Format
 - Setting Reading Goals Position Paper Sample Format
 - Carving Out Dedicated Reading Time
- 12. Sourcing Reliable Information of Position Paper Sample Format
 - Fact-Checking eBook Content of Position Paper Sample Format
 - Distinguishing Credible Sources
- 13. Promoting Lifelong Learning
 - Utilizing eBooks for Skill Development

- Exploring Educational eBooks

14. Embracing eBook Trends

- Integration of Multimedia Elements
- Interactive and Gamified eBooks

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web prophase prometaphase the cell prepares for mitosis at this stage the chromosomes are not clearly visible the chromosomes pairs of sister chromatids condense and become visible meanwhile the nucleolus and nuclear envelope disappear the centrioles begin moving to opposite ends of the cell and start forming the mitotic spindle metaphase

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