

# 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”.

# Position Paper Sample Format

**Gregory M. Scott, Stephen M. Garrison**

## **Position Paper Sample Format:**

**Command and Staff Action** United States. Marine Corps,1979      **FMFM.** United States. Marine Corps,

**Diplomacy and Negotiation for Humanitarian NGOs** Larry Winter Roeder, Jr.,Albert Simard,2013-05-25 Diplomacy and Funding for Humanitarian Non Profits is a practical guide to best practices in diplomacy and negotiation for non profits NGOs who work to convince governments and international institutions to effectively protect humans through disaster assistance sustainable development and the protection of cultures The volume proposes a holistic approach to humanitarian assistance by integrating non traditional and traditional humanitarian partners Users of the book will be prepared to speak to diplomats and government officials in any setting including war zones The book mainly focuses on approaching local and national governments the United Nations system the international Red Cross movement and other international organizations The reader will learn the rules of diplomatic protocol and much about the rules and procedures of major international bodies as well as how to leverage media and knowledge management for planning establishing and managing a humanitarian initiative To provide balance and real world relevance the guide draws on a compilation of the extensive activities of both authors across a range of development emergency management knowledge management and climate issues in government and in the NGO world as well as interviews with a broad range of scholars and officials from NGOs diplomatic missions the media the United Nations the Red Cross governments and corporations      *Public Relations Writing* Valerie

Fields,2024-08-22 Public Relations Writing Essential Skills for Effective Storytelling is a step by step how to guide that helps students develop and hone the skills they need to become strong writers and versatile storytellers within the Public Relations field Author Valerie Fields uses a practical approach providing students with tips and checklists for producing high quality content Sample templates writing exercises and case studies in each chapter give students the opportunity to analyze and craft strategic messages for specific audiences With a focus on storytelling social media and socially conscious content this text helps students understand the power of words within the larger context of our ever changing media landscape      **An**

**Insider's Guide to the UN** Linda M. Fasulo,2009-01-01 This guidebook illustrates the UN system while covering issues as diverse as terrorism peacekeeping human rights climate change and UN reform      **HQMC Supplement to the**

**Department of the Navy (DON) Correspondence Manual** United States. Marine Corps,1992      **Pfenninger and**

**Fowler's Procedures for Primary Care E-Book** John L. Pfenninger,Grant C. Fowler,2010-09-23 Pfenninger and Fowler s Procedures for Primary Care 3rd Edition is a comprehensive how to resource offering step by step strategies for nearly every medical procedure that can be performed in an office hospital or emergency care facility by primary care clinicians Designed for everyday practice the outline format allows speedy reference while the detailed text and clear illustrations guide you through each procedure The new edition of this best selling book features full color illustrations and easy access to the complete contents and illustrations patient forms and more online at [www.expertconsult.com](http://www.expertconsult.com) Understand how to proceed

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 scalpel vasectomy procedures to treat acute headaches and more Don't worry All the more basic office procedures are still  
 included with improved and updated discussions Pfenninger and Fowler provide the latest and most comprehensive  
 information on medical procedures that allow primary care physicians to more effectively treat their patients *Million  
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 Times Mirror Group He is the author of 12 books including *Getting Started in Consulting* 0 471 47969 1 and *Organizational  
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 Gregory M. Scott, Stephen M. Garrison, 2000 This comprehensive practical writer's manual created specifically for political  
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 political science at the same time **Research Involving Human Biological Materials: Commissioned papers** United  
 States. National Bioethics Advisory Commission, 1999 **The Political Science Student Writer's Manual and Reader's  
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*Family Therapy Review* Robert H. Coombs, 2004-09-22 This book offers a clear readable overview of all the knowledge and skills those training as marriage and family therapists and counselors need to pass final degree program certification or licensing examinations It is organized into three sections Basic Clinical Knowledge and Skills Common Client Problems and Career Issues Each chapter includes challenging study questions that enable readers to assess their own level of understanding 15 true false questions at the outset checking on baseline knowledge 30 multiple choice questions interspersed through the text underlining crucial points and 10 provocative discussion questions at the end facilitating synthesis Each chapter also provides a glossary of key terms and in addition to references annotated suggestions for further reading and Web site exploration Students and trainees will find Family Therapy Review Preparing for Comprehensive and Licensing Examinations a resource to which they will go on referring long after it has helped them through their examinations faculty and established professionals will find it a useful one stop summary of current thinking about best practice

**Joint Officer Handbook (JOH) Staffing and Action Guide** United States. Joint Chiefs of Staff. Joint Staff. J-7, 2010 This is a practical and easily accessible guide for those new to the joint environment and staff assignments With input from serving action officers and senior leaders here are the competencies and behaviors of highly effective and successful joint staff officers which provide a roadmap for career self development This is the most current joint information available for managing staff activities

Position Papers and Major Related Data for the Governor's Conference  
Commemorating the 100th Anniversary of the New York State Board of Social Welfare, 1967

**Research Involving Human Biological Materials: Commissioned papers. Privacy and the analysis of stored tissues**, 1999 **Handbook on Teaching Social Issues** Ronald W. Evans, David W. Saxe, 2007-10-01 There s no book like this one for educators interested in issues centered teaching More than 40 experts have contributed articles offering comprehensive coverage of the field of social issues education In addition to a full examination of objectives and methods contributors show how social issues can be taught as part of history geography the social sciences and global and environmental studies The challenges of

assessment curriculum and effective teacher education are fully explored With its teaching ideas and useful resource section this book is an indispensable addition to your library Contributors include Shirley Engle Anna Ochoa Becker Jack Nelson Carole Hahn Byron Massialas Jeff Passe Jesus Garcia Gloria Ladson Billings Merry Merryfield Patricia Avery Sam Totten Bill Wraga Walter Parker and James Shaver      *Global Clinical Trials Playbook* Menghis Bairu, Richard Chin, 2012-06-12

Pharmaceuticals companies biotech companies and CROs regardless of size all face the same challenge of managing costs and operational execution associated with bringing a valuable drugs and devices to market Because of timeline pressures and cost as well as the growing interest in neglected diseases and diseases affecting the emerging nations clinical trials are increasingly conducted in emerging markets and developing countries where infrastructure leadership skilled personnel and a governance are at a premium Working with academics regulatory professionals safety officers experts from the pharma industry and CROs the editors have put together this up to date step by step guide book to building and enhancing global clinical trial capacity in emerging markets and developing countries This book covers the design conduct and tools to build and or enhance human capacity to execute such trials appealing to individuals in health ministries pharmaceutical companies world health organizations academia industry and non governmental organizations NGOs who are managing global clinical trials Gives medical professionals the business tools needed to effectively execute clinical trials throughout the world Provides real world international examples which illustrate the practical translation of principles Includes forms templates and additional references for standardization in a number of global scenarios      **The Affective and Cognitive Domains** Barbara L. Martin, Leslie J. Briggs, 1986      **Academic Writing** Mary Kay Mulvaney, David A. Jolliffe, 2005 This unique interdisciplinary text and reader introduces students to the multiple genres of academic writing across the curriculum Academic Writing is the first text to offer a discussion of academic genres and writing to learn and learning to write in college an explanation of genre practices and conventions across the disciplines annotated examples of student papers across the disciplines written in response to actual college assignments instruction in research writing from sources and documentation and thematic clusters of professional readings as engaging examples of published academic writing Academic Writing will prepare students in all academic disciplines to succeed in today s challenging world of writing both in the classroom and in the workplace beyond

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