Responsible AI in science for augmented medicine and health care

Breakthroughs, insights, and policy prospects

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Downloadable from:
Addressing AI as artificial logics vowed to act as "Assisting Intelligence" (i.e.: AI)

Domain: (ai-artificial-logics-assisting-intelligence.com)

Catalogue number: KI-02-24-407-EN-N
ISBN: 978-92-68-13906-6
Doi: 10.2777/59234

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To my two little God's dreams:
Aurora and Gabriel

Executive summary

This book addresses AI uptake in nano-bio-pharma sciences, discussing its key breakthroughs, drivers, insights and prospects for augmented medicine and health care to contributing to EU policies. For doing that, several steps have been discussed: (i) the etymon 'artificial intelligence' is philosophically and critically analyzed to proposing "artificial logics" as a more suitable conceptual construal to assist human intelligence; (ii) the main drivers governing AI science embedment in augmented medicine are illustrated to show the EU as a world leader in AI enablers' patents, though underperforming in AI applications compared to US and China; (iii) the AI achievement gap between research and innovation in the EU is examined; (iv) it has been highlighted to what extent the groundbreaking power of AI relies more upon few innovative companies than on institutional research facilities; (v) key AI science breakthroughs in augmented medicine and health care are examined in diagnostics, theragnostics, targeted drug-delivery and regenerative medicine; (vi) crucial AI-related ethical principles are discussed, focusing on generative AI systems glossed by scholars as 'moral machines'. Last, conceptualizing the 'responsible-by-design' AI construal has been presented as a set of concepts pursuing human-centric objectives while circumventing the 'black-box' issue. All this could enable outlining far-sighted EC policies minded to nurturing the embedment of responsible AI to advance in augmented medicine and health care. Its ultimate impact would end up by building-up and consolidating citizens' trustworthiness and societal acceptance therein.

Talis est quisque qualis eius dilectio est

Each one is what he loves
(Saint Augustine of Hippo)

Foreword

This book initially addresses a set of philosophical reflections driven upon the etymon ‘artificial intelligence’ (AI), substantiating the rationale of this definition, and expanding the vision, expectations, prospects, and limits entangled by such terminology: this enabled proposing ‘artificial logics’ as a more suitable conceptual construal for AI, vowed to assist human intelligence. Then, the main drivers governing AI uptake in nano-bio-pharma sciences are presented, as they are the most innovating in augmented medicine and health care: here the EU is world leader in AI enablers’ patents, while it underperforms in terms of AI applications patents, where US dominates especially in quality patents, followed by China. Multiple and diverse sources are assessed, pinpointing the AI achievement gap existing between research and innovation therein, ranging from TRL3 to TRL7. This assessment highlights the groundbreaking power of AI, which in EU relies more upon few innovative companies than on institutional research facilities. Therefore, the most promising AI-based research breakthroughs in nano-bio-pharma sciences are illustrated, analyzed, and assessed, exploring their expanding potential for innovating medicine and health care. This enabled identifying the most promising AI-enabled scientific applications in cutting-edge branches of augmented medicine for health care, i.e., diagnostics, theragnostics, targeted drug-delivery and regenerative medicine. Last, the concept of AI-related responsibility and ethical principles are explored, especially focusing on the branch of generative AI: an articulated discussion is framed over the notion of AI-supported systems, glossed by selected scholars as ‘moral machines’. This enabled shaping the concept of ‘responsible-by-design’ AI: this should be vowed to be acting in the best interests of humans by simultaneously pursuing human-centric objectives and disregarding the internal goals which generative AI systems might create by mimicking human learning patterns, thus circumventing the ‘black-box’ issue. Here the precautionary principle applies, enabling to outline far-sighted EC policy prospects dedicated to nurturing the uptake and embedment of responsible AI to advance in EU health care. Last, key attention is devoted to setting up a framework for appropriate communication and societal dialogue on AI with and within civil society, i.e. namely a “Communication Roadmap on Responsible AI”, vowed to building-up trustworthiness and societal acceptance of AI-enabled technologies in health care and of the associated most-needed EC policies.

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Preface: AI vision, concepts and challenges

The phraseology Artificial Intelligence (AI) tantalizes our imaginaries, insinuating the temptation to infer, and finally believe, that humans can create something "*in their own image and likeness*",[1] therefore as much as possible human-like. Since the origin of documented thought, this enticement has been the most typical prerogative of gods: according to Genesis, it is the primigenial and authentic most ancient temptation, i.e., to become as god.[2] So, quite fanciful: creating intelligence is definitely playing God, which psychology tells us as stemming from one of the childhood's most studied ambitions of being or becoming almighty.[3] This terminology clearly evokes the concept, ambition, or even slumber, of rendering man-made systems enabled to autonomously engender info collection, interpretation, thinking, decision-making and acting on the basis of their own discernment.

If so, this would thus lead to liberate humans from the inner weight of their free will, sometimes excruciating as it involves the innermost possibility of making errors. According to Jung, slumbers are the psyche's attempt to communicate crucial things to the individual, who values (or over-values) them above all else.[4] So, entirely entrusting to man-made systems automatized info gathering, interpretation, discernment and decision-making would finally end up into delegating the responsibility of interpreting and deciding about what is acceptable or not into an elegant escape from freedom.[5] Freedom scares humans due to its inward potential to lead to making mistakes, sometimes disastrous.[6] Likewise other mythopoetic cultural traditions and systems, Greek mythology shaped this quite attractive lure into the myth of Talos, which was a defensive automaton capable to autonomously interpret, discern and decide about external inputs.[7] However, the notion of intelligence subsumes the discernment's capability of distinguish good from bad, which subsumes the principles of moral responsibility, whose aggregation falls into the sphere of universally accepted ethics.[8] From all that above, it might be misleading to re-use the quite inspiring

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[1] Bible,Genesis, 1:27: *"… man in his own image and likeness".*

[2] Bible,Genesis, 3:5: *"… you will be like God, knowing good and evil"*

[3] Reworked from: Freud, S., (1899) "L'interpretazione dei sogni" in Opere, vol. 3, Torino, Bollati.

[4] Reworked from: West M., 2011, *Understanding Dreams in Clinical Practice*, Karnac Books, https://www.marcuswest.co.uk/information/Dreams/

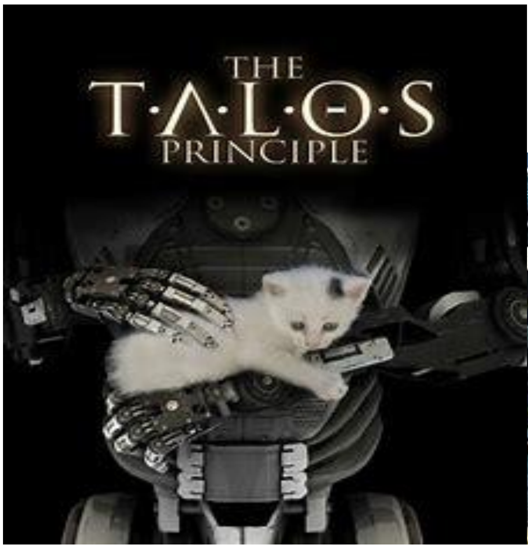
[5] Reworked from: Fromm, E., 1941, *Escape from Freedom*, Farrar & Rinehart, US.

[6] *Ibidem*.

[7] Pseudo-Apollodorus. *Bibliothēkē Βιβλιοθήκη [Library]. 1.9.26.*

[8] Reworked from: (i) Bonazzi, M. (2006). Reconstructing man? The power of converging technologies, Cordis Wire, 15.11.2006, Converging Technologies https://cordis.europa.eu/wire/index.cfm?fuseaction=article.Detail&rcn=11117 ; (ii) Bonazzi, M., (2010). *Communicating Nanotechnology – an Action packed Roadmap for a brand new Dialogue*; European Commission, EUR n°: 24055; ISBN: 9789279134135, at: http://ec.europa.eu/research/industrial_technologies/pdf/communicating-nanotechnology_en.pdf

and evocative concept of ‘intelligence’, without defining to what extent and for which purpose this term is attributed or extended to AI, and how it operates into inherently machine-driven systems.



In this light, framing an articulated philosophical premise is imperative: generally speaking, at least from the pre-scientific empiricist perspective, concepts without perceptions are empty, as alone they cannot constitute knowledge:[9] humans do not know reality as it might be “in itself” (i.e., *noumena*[10]), whilst authentic knowledge stems from human thoughts which structure, organize and shape experiences obtained from reality.[11] Therefore, epistemologically speaking, the AI terminology can be roughly defined as a set of man-made systems of info and data gathering, processing, interpreting, and enabling choice-making, thus creating new knowledge. AI is created by humans and is lingering within humans, whose reality is perceived by humans as intelligence, or at least her mirroring[12]. In this light, the philosophical standpoint associated with the etymon ‘intelligence’ should be made clear from the very beginning: etymologically speaking, it stems from Latin phraseology *intus-legere* [13](i.e., to read inside and within). So, assuming this conceptual construal

[9] Reworked from: (i) Hume, D., 1739–40, *A Treatise of Human Nature*, ed. David Fate Norton and Mary J. Norton, The Clarendon Edition of the Works of David Hume, Oxford: Oxford University Press, 2011: (ii) Quine, W. V. O., 1951, “Two Dogmas of Empiricism,” in W.V.O. Quine, *From a Logical Point of View*, Cambridge, MA: Harvard University Press, 1951.

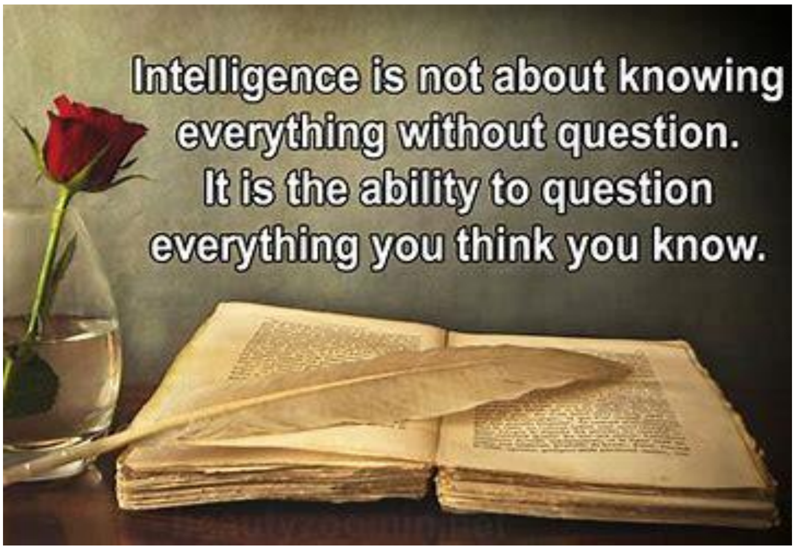
[10] *(The) Encyclopedia of Philosophy* (Macmillan, 1967, 1996) Volume 4, "Kant, Immanuel", section on "Critique of Pure Reason: Theme and Preliminaries", p. 308 and *ff*.

[11] Reworked from (i) Hume, D ., 1748, *An Enquiry Concerning Human Understanding*, ed. Tom L. Beauchamp, The Clarendon Edition of the Works of David Hume, Oxford: Oxford University Press, 2000; (ii) Locke, J., 1690, *An Essay on Human Understanding*, ed. Peter H. Nidditch, 1975; (iii) *(The) Encyclopedia of Philosophy* (Macmillan, 1967, 1996) Volume 4, "Kant, Immanuel", section on "Critique of Pure Reason: Theme and Preliminaries", p. 308 *ff*.

[12] Reworked from: (i) Kant, I., 1783, *Prolegomena to Any Future Metaphysic*, Jonathan Bennett (trans.), PDF available online at Early Modern Texts ; (ii) Plato, *Meno*, W. K. C. Guthrie (trans.), *Plato: Collected Dialogues*, edited by Edith Hamilton and Huntington Cairns, Princeton: Princeton University Press, 1973.

[13] Reworked from: (i) Università degli Studi di Trieste (2019), *Intus legere*, Simposi Multidisciplinari, https://www.units.it/news/intus-legere-simposi-multidisciplinari ; (ii) Bonazzi, M., (2010). *Communicating*

of intelligence, AI-based man-made systems should be able to obtain, recognize, process, interpret info and data to take consequential decisions by simultaneously reading inside and within them, thus mimicking human discernment – at least up to a certain degree – firstly engendering and then using the novel knowledge they have generated.[14] Therefore, they should be human-centric: this hermeneutics pinpoint the importance of how and to what extent this novel knowledge is AI-created, as well as for what purpose and from which sources. Under these premises, if this notion was actual intelligence, ethics therefore applies.



Ethics subsumes principles of both liberty and responsibility for discerning and choosing between good and bad, truth from falsehood, wisdom from foolishness:[15] mere materialist purposes and dynamics are not per se sufficient to guarantee ethically acceptable operational standards.[16] It is therefore crucial to identify, define and disclose: (i) for what purpose, (ii) doing what and (iii) how do operate AI-systems, whose mathematical constructs, i.e., algorithms, are *per se* and *in se* programmed to discern between right or wrong – and not between good and bad – to identify what is acceptable or not. In fact, their teleology[17]

Nanotechnology – an Action packed Roadmap for a brand new Dialogue; European Commission, EUR n°: 24055; ISBN: 9789279134135, at: http://ec.europa.eu/research/industrial_technologies/pdf/communicating-nanotechnology_en.pdf

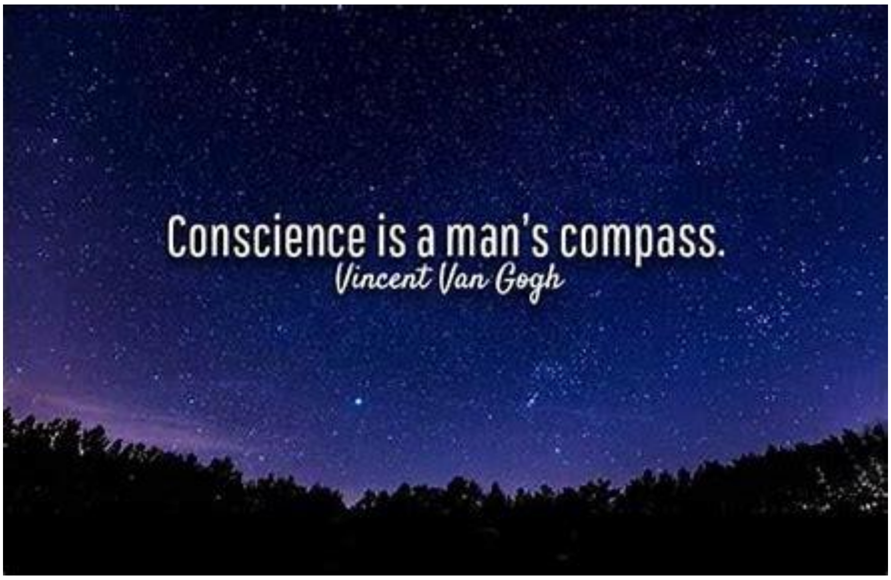
[14] Reworked from Government Technology (2023), *Understanding the four types of AI*, in https://www.govtech.com/computing/understanding-the-four-types-of-artificial-intelligence.html

[15] Klein, Daniel B. (1997). "Liberty, Dignity, and Responsibility: The Moral Triad of a Good Society", *The Independent Review* Vol. 1, No. 3 (Winter 1997), pp. 325-351 (27 pages), Published By: Independent Institute, https://www.jstor.org/stable/24561099

[16] UNC, College of Arts and Science – Philosophy (2023). "Liberty, Rights and Responsibilities: introduction to social ethics and political thought", PHIL 170.001, https://philosophy.unc.edu/undergraduate/undergraduate-courses/spring-2020/phil-170-001-liberty-rights-and-responsibilities-introduction-to-social-ethics-and-political-thought/

[17] Reworked from: (i) von Foerster, Heinz. 1992. "Cybernetics." P. 310 in *Encyclopedia of Artificial* Intelligence 1, edited by S. C. Shapiro. ISBN 9780471503071.; (ii) Dubray, Charles. 2020 [1912]. "Teleology." In *The Catholic Encyclopedia* 14. New York: Robert Appleton Company. Retrieved 3 May 2020. –

should reveal for which purpose and in which way they are conceived, designed, and developed, as well as what are their final operational outputs, socioeconomic upshots, and outcomes in terms of human-centricity. These questioning are the ultimate and vital AI-related issues, as around them the inner rationale and whole human-centricity of AI is pivoting. So, both justification and trustworthiness of AI rely upon the interdependent veracities of the above-quoted assumptions. Clearly, these dynamics could become distorted, if it overrides the principles of conscience a free will on which responsibility relies upon.



In this sense, as an inclusive vision, AI can be summarized as an embracing set of IT-based systems displaying behaviors aiming and committing to mimicking human intelligence, thus mirroring her with human-centric purposes. By perceiving and analyzing their environments thru big data and info acquisition, recognition, processing and interpretation at breakneck speed, AI-systems would enable taking informed decision for achieving complex goals, generating content, feedback, predictions, recommendations, choices, or decisions which influence the environments they interact with.[18] In fact, they can provide and

via *New Advent*, transcribed by D. J. Potter; (iii) Ayala, Francisco (1998). "Teleological explanations in evolutionary biology." In *Nature's Purposes: Analyses of Function and Design in Biology*. Cambridge: MIT Press. (iv) Allen, Colin (2003). "Teleological Notions in Biology". *Stanford Encyclopedia of Philosophy*; (v) Aristotle, *Metaphysics*, 1050a9–17, in https://iep.utm.edu/aristotle-metaphysics/; (vi) Hanke, David (2004). "Teleology: The explanation that bedevils biology". In John Cornwell (ed.). *Explanations: Styles of explanation in science*. New York: Oxford University Press. pp. 143–155. ISBN 0-19-860778-4. Retrieved 18 July 2010; (vii) Plato (1966) [1925]. *"Phaedo, by Plato, full text (English & Greek)"*, pp.98-99. Plato in Twelve Volumes. Translated by Harold North Fowler. Introduction by W.R.M. Lamb. Cambridge, MA & London, UK: Harvard University Press & William Heinemann Ltd.

[18] Reworked from: (i) *AI for nanotechnology, AI for nanobiotechnology*. Eds; Silvia Faré, Sorin Melinte, Adriele Prina-Mello (2023) https://www.frontiersin.org/research-topics/31068/ai-for-nanobiotechnology; (ii) FORBES (2023) *Five predictionas about AI for the near future* (Author: Gaurav Tewari) , Forbes Business Council, at: https://www.forbes.com/sites/forbesbusinesscouncil/2023/02/28/five-artificial-intelligence-predictions-for-the-near-future/?sh=29036f7e5f18 (iii) Furht, B., & Escalante, A. (2010). *Handbook of cloud computing*. New York: Springer; (iv) Jarrahi, M. H., Askay, D., Eshraghi, A., & Smith, P. (2023). "Artificial intelligence and knowledge

process feedback to upstream modulate data acquisition and elaboration, in order to adapt decision-making patterns, they take downstream. In this light, AI has been interpreted as *a different kind of intelligence.*[19]

Thanks to their algorithms, they can become quickly reprogramming their choices on the basis of what they learn from external environmental stimuli. So, due to her abilities to speedily gather, assess, interpret enormous amounts of data and info to take promptly consequential decisions, AI should be more appropriately delineated as *'a set of artificial systems for info gathering, interpreting and deciding*'. In this light, it would be more intellectually honest to define her as ***"artificial logics"***, as it discriminates between right or wrong, although not between good and bad: it is essentially vowed to assist - not to substitute - human intelligence, it might also be glossed as 'Assisting Intelligence'.

However, as AI definition is almost widely well-received, consolidated and accepted, using this term should be kept in the proper perspective of its inner limits and potentialities. In this light, it should not be overlooked that AI conception, design and development is essentially oriented towards boosting: (i) efficiency optimization; (ii) mass-customization of goods and services production; (iii) mass-customization of their use; (iv) humanization of labor and production processes; (v) reduction of both waste and environmental footprint:

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management: A partnership between human and AI." *Elsevier Business Horizons*, vol. 66 Issue 1, January–February 2023, Pages 87-99, https://www.sciencedirect.com/science/article/pii/S0007681322000222 ; (v) Samoili, S., Lopez Cobo, M., Gomez Gutierrez, E., De Prato, G., Martinez-Plumed, F. and Delipetrev, B. (2020), AI WATCH. *Defining Artificial Intelligence*, EUR 30117 EN, Publications Office of the European Union, Luxembourg, 2020, ISBN 978-92-76- 17045-7, doi:10.2760/382730, JRC118163; (vi) von Foerster, Heinz. 1992. "Cybernetics." P. 310 in *Encyclopedia of Artificial* Intelligence 1, edited by S. C. Shapiro. ISBN 9780471503071; (vii) https://ec.europa.eu/newsroom/dae/document.cfm?doc_id=584

[19] Reworked from: (i) CNN (2023), "Eric Schmidt: AI is not ready to take profound decisions", interview to E.Schmidt on AI, podcast on CNN Business, 23 March 2023, https://edition.cnn.com/videos/business/2021/11/03/eric-schmidt-artificial-intelligence-ethics.cnnbusiness ; (ii) (The) Economist (2021)."Schmidt and Kissinger take on AI", https://www.economist.com/books-and-arts/2021/11/20/henry-kissinger-and-eric-schmidt-take-on-ai; (iii) Kissinger E.A., Schmidt, E. and Huttenlocher D. (2021). *The age of AI: and of our human future*, Little, Brown and Company, New York, Boston, London.

all these dynamics are altogether vowed to expand and even open novel human-centered production systems and markets.[20] In fact, AI uptake demonstrated to be dominant in marketing and sales applications.[21]

Clearly, AI is going to stay with and within the development of human society, and her impacts are still difficult to outline. It is likely to come up with a largely unpredictable range of vast and novel capabilities, whose outcome and effects on humans are not fully understood yet, and whose influences on the societal discourse could be huge.[22] Actually, AI is likely to become a disruptive and pervasive set of technologies able to impact on various dimensions of society, economy and culture in the EU and beyond. So, an extensive communication effort is needed on EC policy side to enable a broader societal dialogue to take place, to identify benefits, threat, prospects and limits of societal acceptance of present and forthcoming AI applications.

In fact, like the patterns shaping and governing human thought, which are tough to identify, feature and predict, also AI-based models and pathways inspiring AI-based decision-making processes are impossible to be univocally characterized, as they are dynamically learning-specific as well.[23] Possibly, the entire concept of intelligence might be philosophically and etymologically expanded to embrace these novel artificial ways of creating AI-based knowledge. However, this intellectual stretch could not apply to the notion of moral responsibility, as this stems from human prerogatives which cannot be delegated to nor vindicated by machines. Future EC policy actions should be reflecting on these considerations, addressing the need for setting up a wide and purposeful communication and societal dialogue on AI aim, means and impacts at large. More extensive reflections on this are addressed in the last sections of this book.

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[20] Reworked from: (i) Østergaard Esben H., 2018. *Welcome to Industry 5.0*, ‘’Universal Robots’’; (ii) Decker, M., 2021, *Next Generation of Robots for the Next Generation of Human*, Elsevier Science Direct; (iii) Decker, M. at al. 2017. ”Service Robotics and Human Labor: A first technology assessment of substitution and cooperation, in *Robotics and autonomous systems*, Volume 87, January 2017, Pages 348-354 Elsevier.

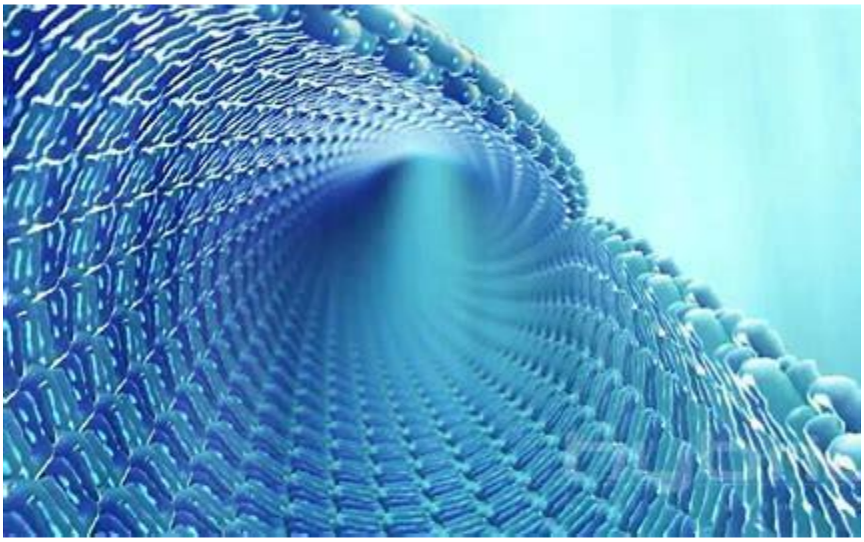
[21] Reworked from: (i) FORBES, (2019). “Ten charts that will change your perspective in AI in marketing”. https://www.forbes.com/sites/louiscolumbus/2019/07/07/10-charts-that-will-change-your-perspective-of-ai-in-marketing/; (ii) CIO (2023) *CIO vision 2025 – Bridging the gap between BI and AI*, MIT Technology Review Insights.

[22] Kissinger E.A., Schmidt, E. and Huttenlocher D. (2021). *The age of AI: and of our human future*, Little, Brown and Company, New York, Boston, London.

[23] *Ibidem*

AI in manufacturing science: enablers and applications

Overall, AI works as a lively and simultaneously overarching, dynamic and pervasive structure: building up upon a bunch of algorithms-based digital software and hardware to collect, store, process, analyze and interpret data, AI relies upon systems of sensors and smart meters connecting equipment and data, mutually interlinked thru the Internet of Things. Therein digital twins numerically represent the physical resources and their interdependencies, thus requiring intensive data densities, as well as cloud and high-performance computing capacities.[24] Doing so, AI-systems could simultaneously enable and guarantee enhancement in sustainable productivity: at the organization level, AI applications can design and outline demand forecasting to optimize and automate the development, optimization and mass-customization of new products and services, and mass-customization of their use in a responsible way. This may also boost resource efficiency: this may also impact on sustainability by optimizing human-driven tasks to oversight equipment and its maintenance, thus increasing its longevity, and decreasing costs, and definitely humanizing production systems fostering human-centricity of both production and consumption systems.



Having defined and disclosed the purpose, content, and operating ways of AI, it is now enlightening to classify its pillars, i.e., systems of algorithms, into two broad conceptual construal categories, enablers, and application, respectively associated with AI-research and AI-innovation. On the one hand, AI enablers are classified as ***Data***, i.e.,: (i) telemetry and (ii) customer data, as well as (iii) domain knowledge; and ***Infrastructures***, i.e., (i) sensors, (ii) IoT, (iii) digital

[24] Reworked from: (i) https://digital-strategy.ec.europa.eu/en/activities/edihs ; (ii) OECD (2019), *Enhancing Access to and Sharing of Data: Reconciling Risks and Benefits for Data Re-use across Societies*, OECD Publishing, Paris, https://doi.org/10.1787/276aaca8- en.

twins, (iv) cloud-computing and (v) high-performance computing.[25] On the other hand, AI applications are categorized as ***Organization*** i.e., (i) demand forecast and planning; (ii) automated warehouse management and (iii) automated design and customization; ***Processes*** i.e., (i) scheduling optimization; (ii) energy and resource efficiency; (iii) operator 4.0; and ***Physical assets***, i.e., (i) quality inspection and control; (ii) predictive maintenance; (iii) overall equipment effectiveness.[26]

[25] JRC Report - AI Watch (2022): *AI uptake in Manufacturing*. Authors: Sarah de Nigris, Richard Haarburger, Jiri Hradec, Massimo Craglia, Daniel Nepelski. EUR 31121, European Union, pp.8-9.
[26] *Ibidem*, pp 11-12.

AI in nano-bio-pharma sciences for augmented medicine: EU leading-edges
Overall, EU has shown a strong position at the initial stages of AI and manufacturing R&D, as EU scientific outputs doubles that of US and China, whilst becoming weaker in innovation and market applications: US is the most influential country with respect to patenting activity, though China dominates patent ownership though citing mostly Chinese assignees.[27]

Overall, dominant innovative power for AI in manufacturing in EU originates more from a few ground-breaking companies rather than from independent institutional research facilities.[28] On the one side, EU demonstrates a relative specialization in two thirds of *AI enablers'* patents in manufacturing: among them, micro and **nanotechnology** takes the lion's share of the patenting output, i.e., the highest specialization, followed by **biotechnology** and **pharmaceuticals**[29]**.**

On the one hand, as nanotechnology takes the most promising share of micro-and-nanotechnologies sector, we assemble these three main sciences and associated technological applications into the complex named **nano-bio-pharma** sciences. Overall, nano-bio-pharma sciences is an interdisciplinary field that combines the principles of nanotechnology, biology, and pharmaceuticals to develop novel diagnostics and therapeutics – as well as their combination into theragnostics – and innovative drug delivery systems, usually oriented towards minimizing unwanted effects and backfires. This is definitely

[27] *Ibidem*, pp 4-5 and 22.
[28] De Nigris, S., Craglia, M., Nepelski, D., Hradec, J., Gomez-Gonzales, E., Gomez Gutierrez, E., Cardona, M. (2020). AI Watch: *AI Uptake in Health and Healthcare* -JRC Technical Reports*: JRC, pp.22-23.*
[29] Reworked from: (i) *JRC, Elsevier Scopus data analysis* (2022): complete metadata obtained by JRC for articles concerning manufacturing and AI from the Elsevier API; (ii) JRC Report AI Watch (2022). *AI uptake in Manufacturing* Authors: Sarah de Nigris, Richard Haarburger, Jiri Hradec, Massimo Craglia, Daniel Nepelski. EUR 31121, European Union, pp.25-26 (Figures 12 and 13).

oriented towards conceiving, developing and deploying personalized and customized medicine approach using nanophenomena, i.e., nanomedicine. This is finally rooted on the application of nano biological sciences, which use that nanoscale, nano effects and behaviors characterizing the nano-dimensions and their associated dynamics and phenomena, including their related physics and chemistry.[30] More specifically, the use of nanotechnology in pharmaceuticals develops novel drug delivery systems which have the potential to scrutinize and improve the efficacy of drugs, simultaneously reducing their side effects, i.e., targeted drug delivery systems. These rapidly developing branches of science use mostly nanomaterials, which stem from smart material sciences using and exploiting the nanoscale phenomena and associated effects. These nanomaterials can be employed to regenerate cells, tissues and organs, as well as to build novel diagnostic tools, therapies and to deliver and target therapeutic agents into specific receptor sites in a controlled manner. For all that above, these branches of science altogether address personalized medicine and health care as ultimate endpoints, thus can be grouped as ***diagnostics***, ***theragnostics***, ***targeted drug-delivery*** and ***regenerative medicine***.[31] So, their scientific research is currently moving from TRL3 to 3 towards TRL5.

On the other hand, the EU displays an underperforming specialization degree in terms of *AI application* patents in nano-bio-pharma industries, accounting for only one third of the overall bulk.[32] In fact, a revealed comparative specialization for application patents is not as strong as in enablers' patents, i.e.,

[30] Patra, J.K., Das, G., Fraceto, L.F. *et al.* (2018). "Nano based drug delivery systems: recent developments and future prospects." *J Nanobiotechnol* **16**, 71 (2018). https://doi.org/10.1186/s12951-018-0392-8, at: Nano based drug delivery systems: recent developments and future prospects | Journal of Nanobiotechnology | Full Text (biomedcentral.com)

[31] Bonazzi, M. (Ed.) (2013); Authors : Filipponi, L., Sutherland, D. *Nanotechnologies: principles, applications, implications and hands-on activities - A compendium* for *educators*; ISBN 978-92-79-21437-0, EUR 2495, doi:10.2777/76945, catalogue KI-NA-24-957-EN-C.

[32] Reworked from: De Nigris, S., Craglia, M., Nepelski, D., Hradec, J., Gomez-Gonzales, E., Gomez Gutierrez, E., Cardona, M. in AI Watch (2020): *AI Uptake in Health and Healthcare* JRC Technical Reports: JRC.

EU scientific outputs outshine innovation upshots, which range from TRL7 onwards. Assignees for enabler and application patents are different: academies and research centers hold enabler patents, while private companies dominate in application patents: as in other cutting-edge scientific and technological systems, the so-called ‘death valley’ is still lingering on the gap between TRL3 and TRL 7. In fact, academic and extensively research-based enablers largely fall into TRL2-3 and seldom TRL4, and in quite rare cases it might mature up to TRL5.[33]

In this light, there is still a long way to market application, as research hardly gets thru all the way until TRL9: in fact, it is often quite tough to demonstrate and substantiate to tweak an enabler research patent, whose proof of concept has been achieved, to also work in a relevant demo environment. On the one hand, it would need and involve a lot of hard work, with limited immediate benefit for the academic research. On the other hand, companies, usually do not aim to operate anything below TRL 7, as they seldom rely on research departments working on TRL 6: the risk-reward ratio is not rewarding enough. So, although lots of academically thoroughgoing and rigorous research ideas in lower TRLs might be attractive and even quite sound in principle, their application in demo environments involves such a degree of risk which companies are reluctant to take.[34] As a consequence, their capability to engender innovation in higher TRL is weak, hindering their practical usefulness in terms of matching market uptake and societally relevant needs. This clearly calls for committing to exploring room for action opening the floor to venture capital initiatives for innovative start-up and SME ecosystems: and, quite obviously, for EC far-sighted policy actions.[35]

Overall, US and China are the largest recipients of Venture Capital funding (i.e., global investments) in AI and manufacturing (59% and 15%), while EU accounts for 7% solely, where Germany, France and Sweden account for two thirds altogether. Also, Germany, France, Italy, and Spain lead in EU AI uptake in manufacturing, while the start-up ecosystem scatters over EU.[36] These considerations particularly apply to nano-bio-pharma industries, where the SME ecosystem outlook is particularly widespread over these five countries and across EU too. As an example of all that, according to key nano-bio-pharma

[33] Leitner, P., 2013. *TRL, impact of science and the valley of death*, Gothemburg University, http://philippleitner.net/technology-readiness-levels-impact-of-science-and-the-valley-of-death/
[34] *Ibidem*
[35] Reworked from: (i) Bonazzi, M., (Ed.) (2011). *Successful European Nanotechnology research.* EUR n°: 24055; 24524; catalogue n°: KI-NA-24524-EN-C; ISBN: 978-92-79-15623-6, http://ec.europa.eu/research/industrial_technologies/publications-reports_en.html;
(ii) Bonazzi, M. (Ed.) (2013); Authors: Filipponi, L., Sutherland, D. *Nanotechnologies: principles, applications, implications and hands-on activities - A compendium* for *educators*; ISBN 978-92-79-21437-0, EUR 2495, doi:10.2777/76945, catalogue KI-NA-24-957-EN-C.
[36] Reworked from: (i) JRC (2022) *Elsevier Scopus data analysis - complete metadata obtained by JRC for articles concerning manufacturing and AI from the Elsevier API*; (ii) JRC Report AI Watch: (2022) *AI uptake in Manufacturing* Authors: Sarah de Nigris, Richard Haarburger, Jiri Hradec, Massimo Craglia, Daniel Nepelski. EUR 31121, European Union.

companies e.g., Pfizer, AI could even enable predicting drug efficacy and side effects, by managing vast amounts of data, info and documentation more extensively than anything accessible or powered before by any single pharmaceutical company[37] In this case, AI is currently being used for ground-breaking research in regenerative medicine, e.g., gene-sequencing, for predicting, unveiling and identifying unknown and uncovered patterns in genomic data: this AI-enabling power would lead to embolden previously huge research diseases and potential treatments, enabling unthinkable capabilities for a single pharmaceutical company before the AI advent.

[37] JRC Report AI Watch (2022) : *AI uptake in Manufacturing* Authors: Sarah de Nigris, Richard Haarburger, Jiri Hradec, Massimo Craglia, Daniel Nepelski. EUR 31121, European Union, pp 27-28 and Figure 16 (specifically reworked).

AI in nano-bio-pharma sciences for augmented medicine: breakthroughs and prospects

Overall, AI scientific breakthroughs are becoming increasingly embedded in research and technologies applied into nano-bio-pharma industries, where EU dominates in terms of intellectual property in AI-enablers' patents. However, their translation into applicative innovations is challenged on many edges, e.g., big data, data mining, lack of standards, subjectivity of data interpretation: all that jeopardizes objectivity, often leading to bias. Overall, AI is a powerful tool able to increase speed, efficiency, and effectiveness of global health systems: analyzing large amounts of data in real time, AI can help improve clinical and non-clinical decision-making, reducing medical variability, and optimizing resources. Hence, AI could support the development of nano-bio-pharma industries impacting on augmented medicine by synergizing across the diverse fields of science involved, by detecting, identifying, characterizing and processing at very high-speed enormous volumes of data, sometimes even not standardized, stemming from an extensive range of diverse patient-specific symptoms, specificities, anamnesis, pathologies, etiologies and co-morbidities.

In this sense machine learning and deep learning can represent a novel approach to data mining and interpretation, leading to analysis of very large amounts of data sets to predicting innovative outcomes. However, there is still an existing gap between the existing and achieved nano-bio-pharma AI-enablers technologies and AI-applications. So, forthcoming EC policy and decision-making process should become more committed to fostering novel business models leading towards human-centric ground-breaking AI-applications, and their associated product and service development. Still, bridging the gap between science and research to technological innovation claims for the need for actions from many other stakeholders and actors beyond EC policy makers.

Overall, AI presents quite promising prospects in nano-bio-pharma industries applied to medicine and health care, which would deserve utmost attention from

EC policies. On the one side, although widening the impressive innovation potentials in nano-bio-pharma industries, AI opens the floor to launch new technologically innovative pathways whose outcomes are still tough to predict, as they are still largely unexploited. On the other side, although nano-bio-pharma industries would possibly bring real breakthrough in medicine and health, physicians will most likely not be displaced by AI-systems, although their capabilities and performances could be largely enhanced, or augmented, by them. In fact, AI-based smart medical technologies could and would support the physician to improve patient management in disease detection, diagnose and treatment, without abdicating their key steering role in assuming their ultimate decisions.[38] This sounds particularly reassuring in terms of the ethical acceptability and trustworthiness of AI in medicine and health care, which might not be the case in other AI-enabled application industries (e.g., digital and ICT, and especially telecommunication).

In this light, there is a need for developing dedicated future studies to address targeted comparisons between physicians using AI-supported solutions with others not using them, then extending those studies to translational clinical trials. So, AI would be more smoothly accepted by health care operators as a quite efficient complementary tool for physicians, without jeopardizing their ultimate decision-making in terms of disease identification, diagnostic and treatment. In this sense, AI-supported digital evolution could become the main driver of change, and in this sense a major revision of medical professionals is needed to provide them with the AI-augmented competences.[39] This development would also raise the need for validation of these modern tools with traditional clinical trials, as well as it is likely to extend the debate to the educational upgrade of the medical curriculum in light of digital medicine and health care. Clearly, deeper ethical considerations of the ongoing connected and augmented digital medicine and health care would also arouse specific debates.

Summarizing, what AI-augmented medical science is not expected to do is making human experts redundant, which is quite encouraging for the ethical side of AI applied to health care: in fact, machine-learning systems work on a narrow range of tasks and will need close supervision, at least for years to come. They are perceived by physicians and health care operators as “black boxes”, where it is not known what and how they reach their decisions, and on what basis.[40]

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[38] Reworked from: (i) Giovanni Briganti and Olivier Le Moine. 2020. “Artificial Intelligence in Medicine: Today and Tomorrow.” Frontiers in Medicine, 7; (ii) (The) Economist, 2022. ”The future medical AI”, https://www.economist.com/films/2022/02/15/the-future-of-medical-ai ; (iii) De Nigris, S., Craglia, M., Nepelski, D., Hradec, J., Gomez-Gonzales, E., Gomez Gutierrez, E., Cardona, M. AI Watch (2020): *AI Uptake in Health and Healthcare* JRC Technical Reports: JRC.

[39] Reworked from: (i) Briganti, G. and Le Moine, O., 2020. AI in medicine: today and tomorrow, in PERSPECTIVE article, Front. Med., Sec. Translational Medicine, https://www.frontiersin.org/articles/10.3389/fmed.2020.00027/full ; (ii) Giovanni Briganti and Olivier Le Moine. 2020. “Artificial Intelligence in Medicine: Today and Tomorrow.” Frontiers in Medicine, 7

[40] *Ibidem*

However, they will take much of the labor and error out of diagnosis, also helping to make sure that patients are treated in time to be saved or recovered, leaving the ultimate steer to physicians.

Consequently, AI in medicine and health care is expected to bring prominent breakthroughs in various cutting-edge application fields, which are particularly promising: among them, diagnostics, theragnostics, precision medicine, targeted drug-delivery, regenerative medicine, including gene therapy and genomics. Thus, by expanding and projecting all reasonably conceivable AI potentialities, it is possible to outline to what extent AI-supported technological innovations could successfully support nano-bio-pharma applications in medicine and health care, especially in the following aggregated fields[41]: (i) diagnostics, (ii) theragnostics, (iii) targeted-drug delivery and (iv) regenerative medicine. Thus, it is possible to expand some prospective considerations of future AI impacts therein.

[41] Reworked from: (i) Bonazzi, M., (Ed.) (2011). *Successful European Nanotechnology research.* EUR n°: 24055; 24524; catalogue n°: KI-NA-24524-EN-C; ISBN: 978-92-79-15623-6, http://ec.europa.eu/research/industrial_technologies/publications-reports_en.html;
(ii) Bonazzi, M. (Ed.) (2013); Authors: Filipponi, L., Sutherland, D. *Nanotechnologies: principles, applications, implications and hands-on activities - A compendium* for *educators*; ISBN 978-92-79-21437-0, EUR 2495, doi:10.2777/76945, catalogue KI-NA-24-957-EN-C.

DIAGNOSTICS

It is clear enough that AI might make medicine and health care more patient-specific, precise, customized and personalized, by being able to draw distinctions at patient level that usually can elude human observers This is particularly evident in diagnostics, as it may be able to grade cancers or instances of patient-specific cardiac disease according to their potential risks, detecting and processing at a high speed large volumes of data, stemming for instance from vast range of symptomatology, patient specificities, anamnesis, etiologies and co-morbidities. Also, it is possible to evict a set of specialized sub-fields where AI is currently under improvement, although it is already outlining some promising outcomes. [42]

Cardiology

Atrial Fibrillation

AI can support early detection of atrial fibrillation thru a smartphone. The company AliveCor received FDA approval in 2014 for their remote mobile application named 'Kardia', allowing for a smartphone-based ECG monitoring and detection of atrial fibrillation. This was shown to perform more efficiently in ambulatory patients than in routine care. Also the company Apple obtained FDA approval for their Apple 'Watch 4', allowing easy access to ECG data to detect atrial fibrillation. However, some critiques showed some issues related to

[42] Reworked from: (i) (The) Economist, 2022. "The future medical AI", https://www.economist.com/films/2022/02/15/the-future-of-medical-ai; (ii) (The) Economist, 2018. "AI will improve medical treatments", https://www.economist.com/science-and-technology/2018/06/09/artificial-intelligence-will-improve-medical-treatments ; (iii) Briganti, G. and Le Moine, O., 2020. AI in medicine: today and tomorrow, in PERSPECTIVE article, Front. Med., Sec. Translational Medicine, https://www.frontiersin.org/articles/10.3389/fmed.2020.00027/full (ii) Giovanni Briganti and Olivier Le Moine. 2020. "Artificial Intelligence in Medicine: Today and Tomorrow." Frontiers in Medicine, 7; (iv) AIO, 2017. Supercharge healthcare with AI, https://www.cio.com/article/234837/supercharge-healthcare-with-artificial-intelligence.html

wearable and portable ECG devices, highlighting some limitations to their use, such as false positive rate originated from mobile artefacts, together with raising some uptake barriers of wearable technology in the elderly.

Cardiovascular Risk
Applied to electronic patient records, AI has been used to predict the risk of cardiovascular disease, e.g., acute coronary syndrome and heart failure better than conventional approaches. Recent comprehensive reviews have however reported how results can significantly vary depending on the sample size used: so, more validation steps are needed.

Pulmonary Medicine
Successful AI-supported interpretation of pulmonary function tests has been reported as a promising field for the development of AI applications in pulmonary medicine. AI-based software provides very accurate interpretation, becoming a useful decision support tool when inferring results from pulmonary function tests. However, some critique pinpointed that the rate of accuracy in diagnosis within the tested participating pulmonologists was considerably lower than the corresponding country average.

Gastroenterology

An extensive range of AI-based applications are in place in clinical settings. Convolutional neural networks are widely used to process images from endoscopy and ultrasound, detecting abnormal structures e.g., colonic polyps. Artificial neural networks are useful to diagnose and treat gastroesophageal reflux disease, atrophic gastritis, gastrointestinal bleeding, survival of esophageal cancer, inflammatory bowel disease, metastasis in colorectal cancer and esophageal squamous cell carcinoma.

Hystopathology

AI-based algorithm is shown to be capable of diagnose cancer in computational histopathology with almost great accuracy, gaining time to focus on crucial slides. One virtuous case is attributed to company Paige, which conceived and developed this tool, inspiring the development of others.

Medical Imaging

Thanks to AI-supported medical imaging, physicians can identify conditions much quicker, promoting early intervention: this enables their improved accuracy rate in detecting and diagnosing cancers, e.g., colorectal cancer, by analyzing tissue scans as well or better than pathologists. In this respect, meta-analysis reports have compared performances of deep learning software and radiologists in the field of imaging-based diagnosis. Overall, deep learning seems to be as efficient as radiologist for diagnosis, although most studies were not found reliably designed, as too few have reliable and trustworthy algorithms able to diagnose medical imaging coming from diverse and varied source populations. So, extensive validation of AI-based technologies thru rigorous clinical trials is still needed. AI can reconstruct missing data in coarsely sampled, rapid magnetic resonance imaging (MRI) scans into high-quality images with similar diagnostic value compared with conventional MRI imaging.

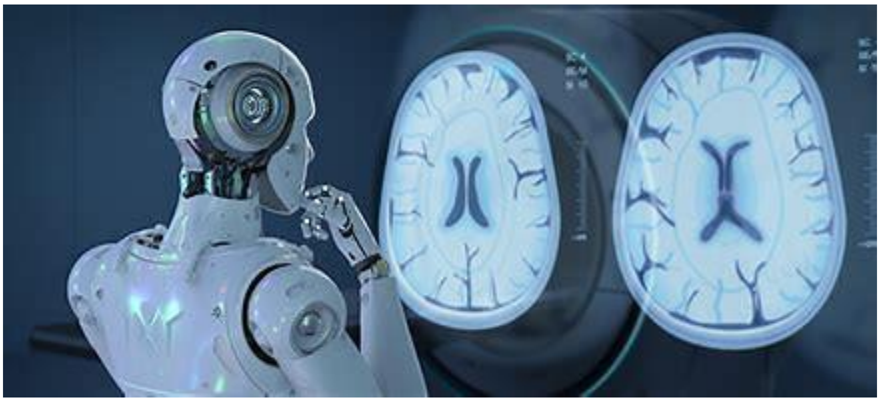
Neurology

Epilepsy

AI-based systems including specific captors can detect generalized epilepsy seizures and report to a mobile application that is able to alert physician with patient localization. The company ‘Empatica’ received FDA approval in 2018 for having developed the wearable named Embrace, which is associated with electro-dermal captors: it can detect generalized epilepsy seizures and report to a mobile application. It should be noted that, in comparison to heart monitoring wearables, patients suffering from epilepsy had not shown significant barriers in the adoption of seizure detection devices. Last, AI algorithms for mental healthcare are successful in detecting symptoms of depression, and other mentally harming conditions by analyzing behavioral signals.

Gait, posture, tremor assessment

Diverse AI-supported wearable sensors have proven useful to quantitatively assess gait, posture, and tremor in patients affected by diverse pathologies, e.g multiple sclerosis, Parkinson disease, Parkinsonism, and Huntington disease.



THERAGNOSTICS

<u>Endocrinology</u>

AI can enable continuous glucose monitoring to help diabetes patients to monitor the rate of change of blood glucose levels. In fact, the continuous glucose monitoring is effective by enabling patients affected by diabetes to check real-time interstitial glucose readings, simultaneously providing feedback about direction and rate of blood glucose level change. The company 'Medtronic' received approval from FDA for their smartphone-supported 'Guardian' system for glucose monitoring, which is promising. Then, the same company partnered with 'Watson' IBM-developed AI for the 'Sugar.IQ' system they developed, enabling patients to prevent hypoglycemic crisis by repeatedly measurements. However, although expressing confidence in the notifications, patients seemingly felt significant personal failure in regulating their glucose levels.

<u>Nephrology</u>

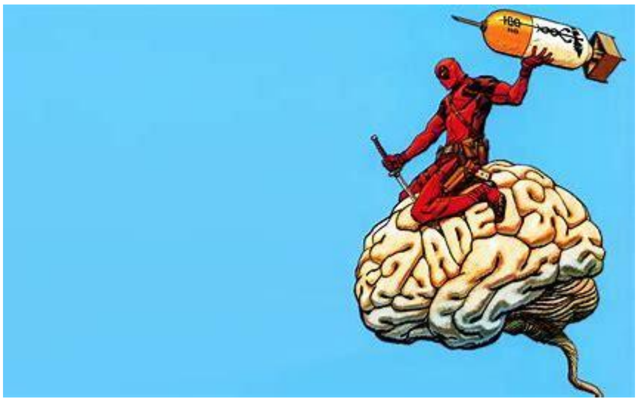
AI can help several settings in clinical nephrology, e.g., to predict of the decline of glomerular filtration rate in patients with polycystic kidney disease, and for risk assessment in other nephropathies. However, limits have been shown in the sample size of the studies carried out so far, currently restraining the actual efficacy in carrying out both the accurate diagnostic and its associated treatment.

<u>Oncology</u>

Oncological AI applications operate thru data intelligence, enabling better tumor understanding, defining more precise treatment options and improved decision-making. In fact, AI-enabled big data processing would allow the development of personalized and customized treatments for cancer patients. Among them, AI tools are used to aid screening tests for detecting, diagnosing and predicting several kinds of cancer, e.g., colorectal, lung, breast, prostate, skin, (developed by Stanford university, from 2017), eye (developed by DeepMind company, from 2020). Within the early cancer detection tools, Grail's company Galleri test (namely one of Time magazine's best inventions of 2022) is a multi-cancer early detection blood test to spot early signals in the blood that are associated with many oncologic pathologies. Also, therapy is improved by AI, e.g., the drug company Absci has released novel drug for cancer treatment based on AI models to create antibodies against the oncogene HER2, connected to certain breast cancers.

TARGETED DRUG DELIVERY

Generally speaking, the pharmaceutical industry can easily rely upon an extensive range of AI applications, for designing, developing and testing novel drugs, especially those targeting specific molecular and receptor sites.[43] AI would especially enable targeted drug delivery systems and next generation novel therapeutics by helping designing novel micro and nano systems for drug delivery for personalized medicine: this is also valid for 3D cell and organ printing, tissue engineering and gene therapy within the regenerative medicine domain. Advanced nanotechnological systems based on AI principles are designed and developed, such as nanobots and nanomachines, to address needs and specificities in drug design and testing[44]. In fact, therapeutic drugs targeting various common diseases are simultaneously addressing others which are quite tough to treat and widespread, such as cancer and immune syndromes: these last are generally very expensive and involve harmful side effects.



In this light, as an example, the use of non-standard peptides sounds particularly promising as a new personalized approach to develop drugs with limited side effects. However, producing these peptides artificially is a tough task. AI can support the development of ground-breaking and even revolutionary peptide discovery system enabling man-made generation of millions of different non-standard peptides, for narrowing them down to few candidates for designing and developing novel drugs in short time. In fact, supported by powerful data processing and dedicated algorithms, AI enables a random combination technology on these constituents, creating millions of different kinds of non-standard peptides in one single test spot: then, appropriate candidate peptides are

[43] Raza, M.A. et al. (2022). AI in pharmacy : overview of innovations. Artificial Intelligence (AI) in Pharmacy: An Overview of Innovations - PMC (nih.gov), in Innov Pharm. 2022; 13(2): 10.24926/iip.v13i2.4839.
[44] Philip A., et al. (Eds.) 2023. *A Handbook of Artificial Intelligence in Drug Delivery*; Editors: Anil Philip, Aliasgar Shahiwala, Mamoon Rashid, Md Faiyazuddin, ELSEVIER, Paperback ISBN: 9780323899253.

searched, analyzed, and identified at very high speed, thus reducing time and costs, thus supplying lead compounds for novel drug design before the preclinical phase.[45].

However, among key breakthroughs, it is protein folding and prediction the most plausible AI-supported innovation which takes the lion's share among the prospective ground-breaking innovations in targeted drug delivery. However, its immense potentialities could be extended to a vast range of application fields, among them regenerative medicine, whose efficacy is expected to be achieved in both cell and gene therapies.[46]

In fact, diverse are the many AI-based digital applications to nano-bio-pharma technologies: among them, AI may be used to automating the discovery of new pharmacological compounds and protein folding, or to assisting in clinical decision-making related to, e.g., the diagnosis of cancer, COVID-19, or tuberculosis in radiological tests. Among cutting-edge AI developments in nano-bio-pharma technologies, some novel developments are particularly inspiring and forward-looking: among them, accurate protein structure prediction has been recently achieved by 'Alphafold' and 'RoseTTAFold' systems. Beyond the legitimate *Nature* enthusiasm raised by this discovery and achievements, also media sensational headlines (e.g., BBC) recently underlined that pioneering AI companies recently achieved to solve one of biology's thorniest mysteries. *Forbes* also declared it the most important ever demonstrated AI achievement, which is to be predicting the functional 3D folded structure of a

[45] JapanGov, 2023. *A new approach to drug discovery*, https://www.japan.go.jp/technology/innovation/drugdiscovery.html
[46] Reworked from: (i) Eisenstein, Michael, (2021) "AI deeps powers protein folding prediction", *Nature*, https://www.nature.com/articles/d41586-021-03499-y; (ii) Jumper John *et al.* (2021) Highly accurate protein structure prediction with AlphaFold, in *Nature* open access, https://www.nature.com/articles/s41586-021-03819-2

protein molecule from its linear amino-acid sequence. This paves the way to both scientific breakthrough and trailblazing innovations in different fields, especially in personalized medicine and the health care sector.[47]

What does this achievement mean in practice? Proteins are the bricks of life: their production is governed by DNA thru combinations of its four bases, using amino acids in cells to compose enormous variations of 3D shapes and folds; these last determine all functions in life, from how a disease is developing, to how cells grow up in a tree, or how humans and other living beings think, breath and digest. The underlying physicochemical mechanisms and rules governing how proteins form their 3D structures – and thus express their biological functions - remain extremely complicated for humans to comprehend, so this 'protein-folding problem' has remained unsolved for decades. In fact, identifying all possible 3D structures of one single protein – which means to screen all its potential functions- may take 14 billion years with conventional tools. In addition to that, about 200 million proteins are present in nature, at least.[48]

Recently, the combination of various innovative deep learning techniques carried out by the above-mentioned cutting-edge systems (i.e., AlphaFold and RoseTTAFold), combined with neural networks, produced AI systems able to disclose in a few minutes all possible folding and shapes of the vast majority of this terrific proteins' amount: thus, enabling identifying and characterizing their main functions. One of the leading companies was situated in the Google orbit (i.e., AlphaFold) , quite cagey in disclosing info; however, labs from academic competitors have recently been able to catch up and develop open science systems (i.e RoseTTAFold), being especially prone to develop innovative biomedical applications, among others.[49]

On the top of that, these innovations open the floor to conceive, design and develop proteins that never existed in nature, whose functions are tailor-made, designed '*à la carte'* to address and solve a wide panoply of issues and pathologies, e.g., fighting pulmonary fibrosis, nasal spray to combat flue variants, and even beyond health care, such as diverse potential side applications to generate energy, and degenerate plastics, among others. This research is not based in EU, so EC policies promoting research and innovation in an analogous

[47] FORBES (2023) *Five predictions about AI for the near future* (Author: Gaurav Tewari), Forbes Business Council, at: https://www.forbes.com/sites/forbesbusinesscouncil/2023/02/28/five-artificial-intelligence-predictions-for-the-near-future/?sh=29036f7e5f18
[48] Reworked from: (i) Jumper John *et al*. (2021) "Highly accurate protein structure prediction with AlphaFold", *Nature* open access, https://www.nature.com/articles/s41586-021-03819-2 (ii) *AI for nanotechnology, AI for nanobiotechnology*: Eds; Silvia Faré, Sorin Melinte, Adriele Prina-Mello (2023) https://www.frontiersin.org/research-topics/31068/ai-for-nanobiotechnology
[49] *Ibidem* (i).

direction could be beneficial for EC science and research systems, possibly leading to advance EU industries and benefitting EU society at large.

REGENERATIVE MEDICINE

Overall, regenerative medicine includes gene therapies, cell therapies, and tissue-engineered products aiming to augment, repair, replace or regenerate parts or organs, tissues, cells, genes, and metabolic processes in the body. So, regenerative medicine currently embraces a set of technologies which can offer terrific promise for improved and enhanced patient treatment and quicker recovery. However, these disciplines suffer from dodges such as trial and error steps, production inefficiency, time- and effort-consuming processes, often hindered by human errors. AI-supported systems, together with automation and robotic devices, could provide significant advances in this prospect, e.g., prediction of tissue engineering results with artificial neural network, robot-based rapid prototyping for scaffolding, deep learning assistance to musculoskeletal applications, automated cell processing robotics and computational-based neural networks for achieving complex tissue engineering applications.[50]

Stem cell-derived strategies for regenerative medicine are composed to cure some of the toughest diseases, including Parkinson’s, diabetes, and various heart diseases. Therefore, patient-specific cells can provide the safest, most effective therapies, especially pluripotent stem cells. However, current autologous step-in processes are not easily scalable due to time- and effort consuming manual handling, vast variability, and expensive facility use. More specifically,

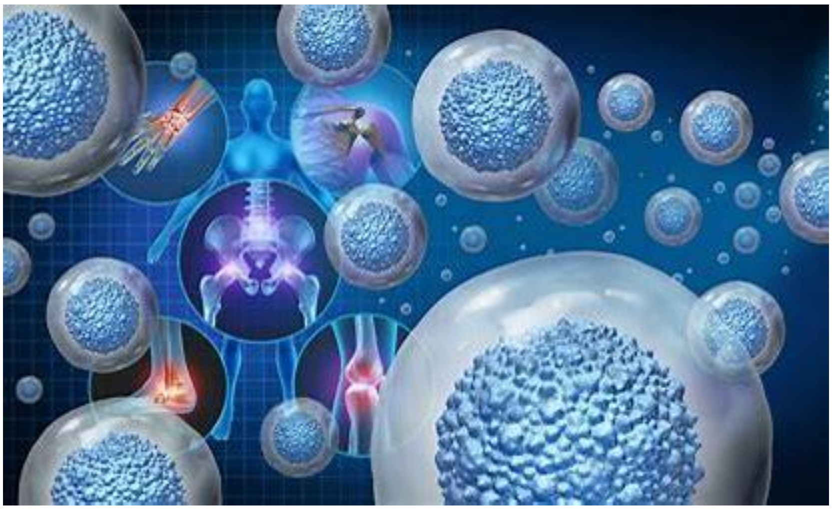
[50] Suraj, K. et al., 2013. *AI in advancement of regenerative medicine and tissue engineering*, DOI: 10.13140/2.1.4238.6888, Conference: 2nd International Conference on Tissue Engineering and Regenerative Medicine(ICTERM) 2013, At: National Institute of Technology, Rourkela, https://www.researchgate.net/publication/262914601_Artificial_Intelligence_in_advancement_of_Regenerative_medicine_Tissue_Engineering#:~:text=Some%20of%20the%20important%20applications,regenerative%20medicine%20such%20as%20in

regenerative medicine using induced pluripotent stem cells promises novel ways to treat particularly tough illnesses. For reaching high standards, extensive research is currently underway to use AI-supported systems to produce high-quality and standardized pluripotent stem cells: this is vowed to ensure quality of mass-produced transplantable cells and to facilitate their transplantation to wider scale, leading to custom-made and personalized regenerative treatment for each patient at quite affordable costs. Thus, AI could enable personalized regenerative medicine to become more viable at larger scale.[51]

In this light, among the most promising application prospects in regenerative medicine, current AI-based regenerative medicine research addresses pluripotent stem cells to improve vision. The process starts by preparing special cellular sheets and transplanting them in diseased retinas, grown from healthy pluripotent stem cells generated from the patients' own cells. The surgery involves removal of the problematic cells and then transplanting the sheet of healthy cells in their place: AI-supported co-bots will master the skills of most experienced researchers thru deep learning, thus learning and becoming proficient in preparing high-quality cells just like the best researchers do. Last, this lesson learned by one co-bot can be copied to others.[52]

[51] AI for Good, (2022). *AI and regenerative medicine: AI-enabled manufacturing of stem-cell based therapies* https://aiforgood.itu.int/event/ai-and-regenerative-medicine-ai-enabled-manufacturing-of-stem-cell-based-therapies/

[52] JapanGov, 2023. *AI to advance regenerative medicine,* https://www.japan.go.jp/technology/innovation/aitoadvance.html



From the business perspective, a non-exhaustive selection is carried out to present a set of promising and leading AI key companies quite active in conceiving, designing, and developing novel possibilities for AI application in key cutting-edge research and innovation for medicine and health care. This selection is showing how AI can generate new business models therein, therefore fueling the growth of new business and organization models. Most are in the US, EU and AS, Japan. So, assessing the potential of AI is key to differentiate their potentialities to identify, explore and exploit novel business prospects in the main branches of health care industries, a non-exhaustive selection is provided and analyzed.

DIAGNOSTICS

Paige: AI-supported system transforming the way pathologists work.
Grail: AI-supported early detection systems for cancer.
Empatica: AI-based health monitoring platform.
AliveCor: AI-supported systems and devices for enabling precision diagnostics for cardio-vascular pathologies.
Imagia: AI-supported clinical systems to detect and predict cancer-driven changes.
Butterfly: setting up AI-supported devices enabling medical imaging world-accessible.
Bay labs: driving AI-driven deep learning advances to key unsolved issues in healthcare.
Zebra: designing AI algorithms to assist radiologists in detecting under-looked or underestimated symptoms and indications.
Behold: design and develop AI-driven medical imaging record platform to process medical images.
Advenio: combining AI, deep learning and machine learning-based computer-assisted detection for diagnostic clinical imaging.
Sig tuple: designing personalized screening solutions to aid diagnosis thru AI-powered analysis of visual medical data.

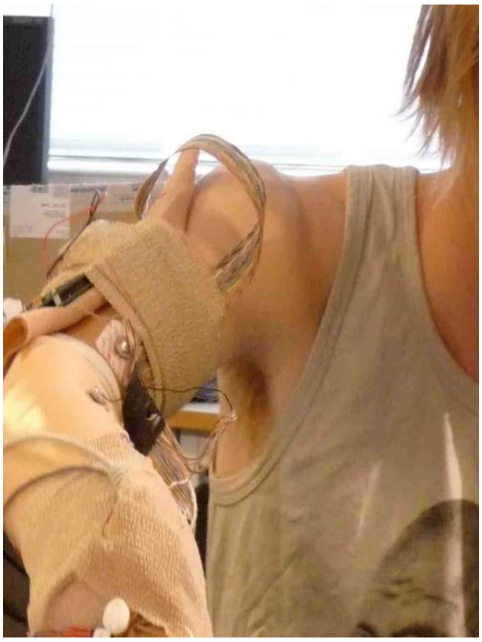
THERAGNOSTICS

Medtronic: engineering AI-supported innovation to develop treatments for diverse pathological and clinical settings.
Absci: creating new drugs at the AI speed.
MedyMatch: boosting AI-based diagnostics accuracy to prevent chronic conditions and improve patient outcomes providing the right therapeutic treatment at the proper time.
Enlitic: developing AI-based deep learning to identify and distil actionable insights from billions of clinical cases.
Mindshare: developing AI-supported precision medicine thru image-driven intelligence.
Lunit: developing advanced AI-based software for medical data collection, analysis, assessment and interpretation via cutting-edge AI-supported deep learning technology.

TARGETED DRUG DELIVERY

Insilico Medicine: designing AI systems for targeted drug discovery, biomarker development addressing aging research.
Atomwise: AI-driven deep learning technology to design novel extra small molecule with outstanding speed, accuracy, and diversity.
Peptidream: revolutionizing drug discovery by designing new peptides thru AI-supported systems.

REGENERATIVE MEDICINE



Deep genomics: predicting the molecular effects of genetic variation thru AI-based systems.
Ome Care (former Pathway Genomics): global medical diagnostics systems merging AI and deep learning within precision medicine.
DeepMind: AI-based systems for solving intelligence to advance science and benefit human-centricity.
Alphafold: designing tailor-made protein structures.
Riken: international research hub, fostering AI to advance regenerative medicine.
RoseTTAFold, accurate AI-based prediction systems for protein folding and interaction.

Concluding, the described potential of AI for augmenting science developments in nano-biopharma and its application into key health care branches is pivotal to outline and assess novel outlooks for AI-augmented nano-bio-pharma sciences and associated industries. This enable also analyzing and differentiating the associated innovative industrial prospects: exploring the proper conditions fostering the appropriate AI embedment in this science field I the next step, helping to sketch out some relevant policy insights.

Embedding AI in nano-bio-pharma sciences for augmented medicine: key policy prospects

Overall, AI recent developments pose a challenge to policymakers and regulators to keep consistent pace and implement coherent policies and frameworks to simultaneously exploit their potential and mitigate risks: this is particularly relevant for generative AI, the forefront of AI generating its own objectives and pursuing them thru self-generated processes. In fact, computational infrastructures, skills, and data require to develop and implement AI systems which are often exceeding jurisdictional borders. In this light, international cooperation and coordination is an utmost need to guarantee that AI innovation potential could improve the people wellbeing and quality of life in diverse application fields, in a human-centric perspective: for instance, addressing AI espousal into education, safety, health and professional-life balance. On the one hand, too restrictive policies might jeopardize the development and embedding of AI systems into industries, therefore constraining the associated societal advantages. On the other hand, far-sighted policies should foster a balanced approach for promoting AI-related benefits for human-centricity, by guaranteeing the proper management of their associated risks.

In manufacturing industry AI can empower and enable diverse applications, impacting all stages of production: its major driver lies in blending data from different processes, factories, and production sites to enable holistic optimizations. So, *accessing quality data* is a major need in EU manufacture, and especially in SME ecosystem, as well as promoting *data formats standardization* and appropriate *communication protocols*, whose scarcity affect SMEs harder. Then, setting up manufacturing data spaces as well as testing experimentation facilities could help to address this deadlock, thus enabling also SMEs to deploy AI solutions more effectively.[53]

Applying these overarching considerations to EU nano-bio-pharma industries sounds important to boost innovation development and uptake therein, as EU accounts for two thirds of AI enablers' patents, while it underperforms in AI applications. In this light, bridging the gap between research and business becomes an essential precondition to boost AI proper uptake and translation into applications, by easing access to expert networks, events, demonstrations, showcases for sharing best practices.

More specifically, EU policy actions are needed at least at two levels, i.e., (i) at management level there is an upmost need for training and raising awareness, while (ii) at workforce level deploying AI in synergy with the operator could optimize the uptake of its process and domain knowledge. In this light, planning proper workforce upskilling and training would be essential to ensure optimal AI deployment in terms of workflow management by powering the operator's domain knowledge. So, involving human resources at both workforce and management level is crucial in encouraging and promoting the AI uptake into nano-bio-pharma manufacturing industries.[54] Last, boosting AI uptake would require policies to expand their horizon to extra-technological drivers, addressing also re-thinking and redesigning conventional processes, structures, and business models, therefore triggering the demand for new types of AI-related jobs, especially those associated with generative AI technologies.

In this light, the European Commission has recently launched a stakeholder survey exercise to gather views on G7 guiding principles on generative AI, aiming to outline International Guiding Principles for organizations developing advanced AI systems, which have been agreed by G7 ministers for stakeholder consultation. The expected outcome is identifying key drivers in future EU policies to properly foster these processes.[55] These principles are currently

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[53] JRC Report (2022) AI Watch: *AI uptake in Manufacturing* Authors: Sarah de Nigris, Richard Haarburger, Jiri Hradec, Massimo Craglia, Daniel Nepelski. EUR 31121, European Union, pp.34-35.

[54] Reworked from: (i) OECD (2022), *Harnessing the power of AI and emerging technologies*: Background paper for the CDEP Ministerial meeting, (Authors: Perset Karine, et al.) *OECD Digital Economy Papers*, No. 340, OECD Publishing, Paris, https://doi.org/10.1787/f94df8ec-en, https://www.oecd-ilibrary.org/science-and-technology/harnessing-the-power-of-ai-and-emerging-technologies_f94df8ec-en; (ii) OECD (2019), *Enhancing Access to and Sharing of Data: Reconciling Risks and Benefits for Data Re-use across Societies*, OECD Publishing, Paris, https://doi.org/10.1787/276aaca8- en; (iii) JRC Report AI Watch (2022) : *AI uptake in Manufacturing* Authors: Sarah de Nigris, Richard Haarburger, Jiri Hradec, Massimo Craglia, Daniel Nepelski. EUR 31121, European Union, p.35; (iv) Peruzzini, M., Grandi, F., & Pellicciari, M. (2020). "Exploring the potential of Operator 4.0 interface and monitoring." Elsevier Science Direct, Computers & Industrial Engineering, Volume 139, January 2020, 105600, https://www.sciencedirect.com/science/article/pii/S036083521830651X .

[55] Reworked from: *Commission gathers views on G7 Guiding Principles on generative Artificial Intelligence*, Daily News 13 / 10 / 2023 (europa.eu).

developed by G7 Members under the *Hiroshima Artificial Intelligence* process[56] to set up drivers and standard guardrails at global level. The eleven draft guiding principles cover advanced AI systems such as foundational models and generative AI, aim to promote **safety and trustworthiness of AI-augmented technologies**, paving the way to compile a G7 Code of Conduct providing guidance for organizations developing AI tools.

In the light of these principles, these actions could bring the current EU from a world leading position in AI enablers for nano-bio-pharma industries towards their upgrading into a better positioning in AI-supported applications. In this light, EC policies should commit to advance the related AI scientific and research achievements from TRL3 towards TRL7, thru proper actions fostering their application-driven conception, design and development into demo environment. Last, these policies should address upgrading of AI research and related skilling towards applications focused in most strategic health care sectors, i.e., precision, predictive and personalized medicine, diagnostics, theragnostics, targeted drug-delivery and regenerative medicine.

[56] EC (2023) Shaping Europoe Digital Future - International Draft Guiding Principles for Organizations Developing Advanced AI systems | Shaping Europe's digital future (europa.eu)

Risks, ethics and policy needs for AI-augmented medicine

Overall, specific acumens in EU policies are required to look forward to properly espousing and embedding AI in nano-bio-pharma industries: in fact, they are expected to address the vast novel technological possibilities AI would enable in cutting-edge sectors, i.e., diagnostics, theragnostics, targeted drug-delivery and regenerative medicine. This arouses clear issues in terms of human-centricity, especially whether and where AI permits to designing novel bio functionalities which claim for pursuing clever responsible and ethical approaches in especially high-risk cases.[57]

Likewise similar issues raised in the past decades by debates on nanoscience and synthetic biology, AI-enabled prospects in nano-bio-pharma industries could pave the way for conceiving, designing, and developing entirely innovative tools to enhance efficiency in medicine and health care. This might also raise issues going beyond reflections on human-centricity: some sound quite disturbing, such as AI-enabled prospects leading to transhumanism and human enhancement.[58] New AI enabled scientific perspectives, and their associated technological prospects, could outline breakthroughs empowering completely new functions and novel functionalities into human societies, industries and even cultures.[59]

The potentiality for AI to tailor-make new biological functions and functionalities would also open the floor to malignant purposes and pernicious dual use applications. In this light, embedding AI applications into life sciences will then require a strictly responsible and ethical approach. This paves thee way to raise specific ethical questions, where the principle of responsibility is crucial: designing new tools to address potentially novel biological functionalities might

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[57] Reworked from: (i) De Nigris, S., Craglia, M., Nepelski, D., Hradec, J., Gomez-Gonzales, E., Gomez Gutierrez, E., Cardona, M. AI Watch (2020). *AI Uptake in Health and Healthcare* JRC Technical Reports: JRC; (ii) Bonazzi, M., (Ed.) (2011). *Successful European Nanotechnology research*. EUR n°: 24055; 24524; catalogue n°: KI-NA-24524-EN-C; ISBN: 978-92-79-15623-6, at http://ec.europa.eu/research/industrial_technologies/publications-reports_en.html

[58] Reworked from: (i) Bonazzi, M. and Tomellini, R. (2007): "Exploiting the convergence of technologies to repair our body", in the column *'A window on the European Commission'*, Bulletin of the Australasian Scientific Community n°24 August 2007, http://www.scientificambitalia.org/pdf/790_ita.pdf ; (ii) Bonazzi, M. (Ed.) (2013); Authors: Filipponi, L., Sutherland, D. *Nanotechnologies: principles, applications, implications and hands-on activities - A compendium* for *educators*; ISBN 978-92-79-21437-0, EUR 2495, doi:10.2777/76945, catalogue KI-NA-24-957-EN-C.; (iii) Bonazzi, M., (2010). *Communicating Nanotechnology – an Action packed Roadmap for a brand new Dialogue*; European Commission, EUR n°: 24055; ISBN: 9789279134135, at: http://ec.europa.eu/research/industrial_technologies/pdf/communicating-nanotechnology_en.pdf

[59] Reworked from: (i) Bonazzi, M., (Ed.) (2011). *Successful European Nanotechnology research*. EUR n°: 24055; 24524; catalogue n°: KI-NA-24524-EN-C; ISBN: 978-92-79-15623-6, at:http://ec.europa.eu/research/industrial_technologies/publications-reports_en.html; (ii) Silvia Faré, Sorin Melinte, Adriele Prina-Mello (Eds.) (2023) *AI for nanotechnology, AI for nanobiotechnology:* https://www.frontiersin.org/research-topics/31068/ai-for-nanobiotechnology

foster and mirror malevolent applications, encompassed in the concept of potential dual use. This is particularly relevant for AI-enabled systems which might lead to generate easily accessible and widespread tools for developing and deploying biological warfare, e.g., by creating pathogens by-design, or identifying vulnerabilities in business or defense by infiltrating and triggering decisions in milliseconds therein. Also, likely uses tested in marketing, AI could be used for manipulative purposes in autocratic regimes. Clearly, AI dual uses should be closely monitored and screened:[60] a quite big number of studies begins to flourish on all this around the world, which is rapidly increasing. A non-exhaustive set of risks in AI-augmented nano-bio-pharma sciences for augmented medicine is gathered and addressed accordingly and are described in the following paragraphs.

Overall, AI and especially generative AI related risks in nano-bio-pharma sciences may fall into several broad categories: functional, operational and legal. Functional risks embrace (i) model drift and (ii) data poisoning: on the one hand, model drift occurs when a model gradually loses alignment with the environment it was trained to help, so the model should retrain on refreshed data, though time-consuming; on the other hand, data poisoning happens when a malignant actor corrupts data streams which train the model, inducing pernicious self-modifications, inducing hallucinations into the outputs: this may happen, for instance, when bio-designing a drug by relying upon a Large Language Models such as ChatGPT-style AI system whose data training flow has been corrupted by cite fictional cases. Operational risks can jeopardize the daily functioning capabilities, e.g., in producing consolidated drugs, providing clinical data acquisition and diagnostics, preventing the associated systems from functioning properly and accurately: this may happen by relying upon incorrect

[60] Reworked from: (i) UNESCO (2022) *Ethics of AI*, https://www.unesco.org/en/artificial-intelligence/recommendation-ethics; (ii) UNESCO (2023) ”Unesco and Microsoft commit to promote Unesco’s recommendations on the ethics in AI”, https://www.unesco.org/en/articles/unesco-and-microsoft-commit-promoting-unescos-recommendation-ethics-ai?hub=32618

AI-generated advice or using the output from a poisoned model, for example resulting in unwanted corruption and leakage of privacy data and confidential intellectual property. Finally, legal risks may occur when the use of generative AI exposes to civil and criminal actions, which might arise from confabulation, privacy and copyright infringements, harming end-users by info faked by biased AI tools, finally exposing to lawsuits, penalties, and reputational damage.

Consequently, a non-exhaustive set of negative impacts can be evicted from the AI-related risks described above and summarized accordingly/[61] (i) biased clinical and pharmacological outputs; (ii) unreliable clinical results; (iii) abuse, misuse or dual use of patient privacy; (iv) overreliance on AI-generated guidance; (v) cumulative man-machine errors and patient harm.

In this light, addressing the clear gap existing between incipient research on AI risks and the way to mitigate and circumvent them should be object for future EU-funded research: some insights on the main drivers are identified, analyzed and assessed accordingly.[62]

Overall, long-term awareness is the best mitigation:[63] therefore, the most efficient approach to mitigate generative AI risks could be to develop and adhere to a well-defined machine learning operations lifecycle, which should be embedded in a broader governance framework within the boundaries of which a nano-bio-pharma sciences actor, organization or stakeholder develops and uses generative AI: this should be performed by involving IT teams in creating policies, but also nano-biotechnologists, cybersecurity, legal, risk management, and HR leaders and specialists, regularly revisiting their AI policies and carry out table-top exercises to stress and test them through scenarios involving potential bottlenecks and solutions to circumvent and respond to them, periodically re-discussing on which AI-related policies are put in place, empowered and why, putting and keeping human-centricity at the centre of gravity of all that: this approach can been clearly evicted from the conclusions drawn from the "World Economic Forum" of 13-15 November 2023.[64]

Etymologically speaking human-centricity for AI seems almost self-explanatory: however, from the epistemology's standpoint (which stems from the theory of knowledge associated with the mind's relation to reality) AI definition, aim, scope, challenges, and impact domains should be expanded to embrace responsibility and ethics universal principles, and their associated legal

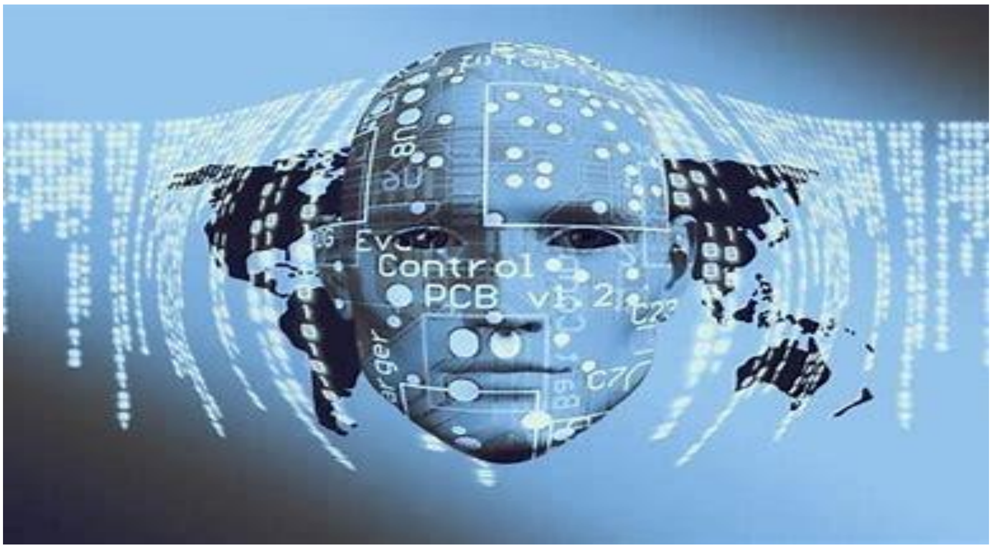
[61] Huddle, M., Kellar, J., Srikumar, K., Deepak, K., Martine, D. (2023). *How generative AI is transforming health care sooner than you think*, in BCG How Generative AI is Transforming Healthcare | BCG

[62] TechTarget – Enterprise AI - Burke, J. (2023) : What are the risks and limitations of generative AI? | TechTarget, 13 November 2023.

[63] *Ibidem*, p2.

[64] World Economic Forum AI Governance Summit: What to know | World Economic Forum (weforum.org), 13-15 November 2023.

liability. In fact, both ethical and legal issues associated with AI scope and ambitions (and therefore its impacts) will seemingly subsume issues such as *privacy* and *surveillance*, *bias*, or *discrimination*. Thus, they potentially challenge the philosophical role of human discernment and judgment in decision-making. So, UNESCO, OECD and The White House indicated that AI governance actors should respect human rights principles and democratic values, throughout the entire AI conception, development and deployment.[65] These principles subsume and include inner semantic notions such as: freedom, human dignity and autonomy, privacy and data protection, non-discrimination and equality, diversity, fairness, social justice and internationally recognized labor rights:[66] had *safety, health* and *fundamental rights* (e.g., *trustworthiness* and *impartiality*) for everyone[67] are the ultimate goal their associated moral and legal liabilities should guarantee.



Thus, likewise ethically-relevant debates previously faced in nano-bio-technologies and synthetic biology over the last decades, responsible and ethical approaches should become usual practice in AI: their should be head-of-stone in

[65]Reworked from: (i) The WHITE HOUSE blueprint report on AI (2023): *Strengthening and Democratizing the U.S. Artificial Intelligence Innovation Ecosystem*, by the National Artificial Intelligence Research Resource (NAIRR) Task Force, in https://www.ai.gov/wp-content/uploads/2023/01/NAIRR-TF-Final-Report-2023.pdf (ii) Government Technology (2023), *Understanding the four types of AI*, in https://www.govtech.com/computing/understanding-the-four-types-of-artificial-intelligence.html; (iii) OECD (2019), *Enhancing Access to and Sharing of Data: Reconciling Risks and Benefits for Data Re-use across Societies*, OECD Publishing, Paris, https://doi.org/10.1787/276aaca8- en; (iv) UNESCO (2022) *Ethics of AI*, *https://www.unesco.org/en/artificial-intelligence/recommendation-ethics;*
[66] Reworked from: (i) Bonazzi, M., Neicu, M., Millar, J., Schuurbiers, D. (2013). *Reaching out to the future: outline of proposals for communication outreach, societal dialogue and education on nanotechnology*. ISBN: 978-92-79-25114-6, EUR: EUR 25361 catalogue n°: KI-NA-25-361-EN-N; (ii) UNESCO (2022) *Ethics of AI*, https://www.unesco.org/en/artificial-intelligence/recommendation-ethics
[67] Reworked from: (i) The WHITE HOUSE blueprint report on AI (2023): *Strengthening and Democratizing the U.S. Artificial Intelligence Innovation Ecosystem*, by the National Artificial Intelligence Research Resource (NAIRR) Task Force, in https://www.ai.gov/wp-content/uploads/2023/01/NAIRR-TF-Final-Report-2023.pdf (ii) Government Technology (2023), *Understanding the four types of AI*, in https://www.govtech.com/computing/understanding-the-four-types-of-artificial-intelligence.html

designing, developing, and deploying AI with a good, proper and appropriate intentions to endow citizens, consumers, employees and businesses with the associated benefits, while simultaneously empowering and respecting universally recognized ethical principles.[68] So, ethical principles should encompass AI-supported systems, processes, procedures and downstream their impact on industry and society, and further on, culture too.[69]

Driving deep from its hermeneutics, the following key conceptual principles of responsible AI would apply: (a) *Soundness*: comprehend context as well as uphold data quality and model performance; (b) *Fairness*: identify and remove discrimination and support diversity and inclusion; (c) *Transparency*: provide explainability, understandability and traceability. Building on that, key tech companies (e.g., Microsoft, in February 2023), co-working with UNESCO, are opting for using six pragmatic principles driving AI development and use: (i) *fairness*, (ii) *reliability and safety*, (iii) *privacy and security*, (iv) *inclusiveness*, (v) *transparency*, and (vi) *accountability*.[70]

These principles are not trivial, as they may be considered as the head-of-a-stone of a responsible and trustworthy approach to AI, especially as this technologies' sets are becoming increasingly prevalent in goods, products and services for everyday use. On the one hand 'universally recognized' ethical principles are ethicalities which should be considered as unanimously recognized. On the other hand, every individual, company, and region might exert their own moral beliefs and standards, which are historical and cultural products. These last are usually mirrored in conceiving, designing, and developing more 'local' moralities, finally reflecting their paradigms in shaping technological acceptance at large, and more specifically for AI-supported systems. Moral responsibility and legal liability should therefore be attributed to all those human agents consciously choosing to design, develop, validate, and even use those systems: this is the

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[68] Reworked from: (i) Bonazzi, M. (Ed.); Authors : Filipponi, L., Sutherland, D. (2013). *Nanotechnologies: principles, applications, implications - a compendium for educators* ; ISBN 978-92-79-21437-0, EUR 2495, doi:10.2777/76945, catalogue KI-NA-24-957-EN-C ; (ii) OECD (2019), *Enhancing Access to and Sharing of Data: Reconciling Risks and Benefits for Data Re-use across Societies*, OECD Publishing, Paris, https://doi.org/10.1787/276aaca8- en; (iii) Bonazzi, M. (2006). "Reconstructing man? The power of converging technologies", Cordis Wire, 15.11.2006, (in Converging Technologies, https://cordis.europa.eu/wire/index.cfm?fuseaction=article.Detail&rcn=11117)

[69] Reworked from: (i) Bonazzi, M., (2010). *Communicating Nanotechnology – an Action packed Roadmap for a brand new Dialogue*; European Commission, EUR n°: 24055; ISBN: 9789279134135, at: http://ec.europa.eu/research/industrial_technologies/pdf/communicating-nanotechnology_en.pdf ; (ii) Bonazzi, M., (2010). *Knowledge, attitudes and opinions on nanotechs across European youth*, ISBN: 9789279159046, at: http://ec.europa.eu/research/industrial_technologies/pdf/knowledge-attitude-opinions-on-nanotech_en.pdf

[70] Reworked from: (i) UNESCO (2022). *Ethics of AI*, https://www.unesco.org/en/artificial-intelligence/recommendation-ethics; (ii) UNESCO (2021|), "UNESCO member states adopt the first ever global agreement on the Ethics of Artificial Intelligence", in https://www.unesco.org/en/articles/unesco-member-states-adopt-first-ever-global-agreement-ethics-artificial-intelligence; (iii) UNESCO (2023) "Unesco and Microsoft commit to promote Unesco's recommendations on the ethics in AI", https://www.unesco.org/en/articles/unesco-and-microsoft-commit-promoting-unescos-recommendation-ethics-ai?hub=32618

perspective shaped by the notion of *distributed responsibility*.[71] This vindicates by attributing differentiating degrees, levels, and types of responsibility to all human agents involved in conceiving, designing, developing, and validating AI systems.

This is not an inconsequential discussion: on the one side AI-enabled systems supporting human-centric medicine and health care enable clear distribution of responsibility throughout and across the entire demand, supply, and use chain, as the final decision-making is kept by physicians. On the other side, other AI-supported systems which were not designed to support human-centricity can negatively affect public health, namely mental health, raising issues in applying the principle of distributed responsibility therein. The recent case of AI-supported online platforms harming mental health in youngsters is particularly enlightening, as here AI uptake was dominant in marketing and sales purposes, while human-centricity was fully neglected: this case deserves a detailed digression.

In fact, it has been shown over the last decade to what extent some AI-supported online platforms (e.g., TikTok, Instagram, Twitter, YouTube, and Facebook) have become increasingly harmful to digitally vulnerable users, with a peak experienced during 2020-2021 Covid-induced lockdowns. This has been documented by YouTube[72], while Instagram also faced harsh and largely spread criticism for allegedly jeopardizing teen girls' mental health[73]. Then, specific studies have been carried out to study the impact of these platforms on youngsters: apparently, TikTok scored worst, as indicated by dedicated

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[71] Strasser, A. (2022). "Distributed responsibility in human–machine interactions." *AI Ethics* **2**, 523–532 (2022). https://doi.org/10.1007/s43681-021-00109-5

[72] Youtube, (2021). *Study of YouTube comments finds effects of radicalization effects,* https://techcrunch.com/2020/01/28/study-of-youtube-comments-finds-evidence-of-radicalization-effect/?guccounter=1

[73] The Wall Street Journal, (2021) "Facebook knows Instagram is toxic for teen girls", https://www.wsj.com/articles/facebook-knows-instagram-is-toxic-for-teen-girls-company-documents-show-11631620739

independent research done by the Tech Oversight Project, highlighting in March 2023 the perils inherent in its *"last attempt to deceive parents, endanger children and mislead lawmakers"* (*sic*)[74]. In fact, it has been shown the extent of the perniciousness of these systems:[75] by attaining to vampirize users' time spent on the platform by painstakingly and promptly rushing alluring and eye-catching contents, AI-supported platform have been enabled to reinforce the rewarding cycle, blasting emotions by educing dopamine discharges thru video outburst: in this light, they were defined by selected scholars as '*digital fentanyl'*[76] and '*deadly by design'*[77].

Some outcomes demonstrated to become devastating for teens and youngsters mental health,[78] diagnosed even in children and kids.[79] This challenged the issue of distributed responsibility, claiming for establishing public or private policy frameworks to set up boundaries for establishing legal liability. So, several countries entirely or partially banned the use of this platform (e.g., India, Bangladesh, Indonesia, China, and very recently France), followed by many US colleges, together with selected companies, e.g., BBC, and EC bodies, which debarred the associated app from work devices in the present year.

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[74] The Tech Oversight Project (2023). *The Tech oversight project issue statement on TikTok last attempt to deceive parents, endanger children and mislead lawmakers*, https://techoversight.org/2023/03/01/tech-oversight-project-issues-statement-on-tiktoks-latest-attempt-to-deceive-parents-endanger-children-and-mislead-lawmakers/

[75] *Ibidem:* this study indeed demonstrated to what extent some of these platforms working thru AI-based algorithms of reinforced learning have been virtually forcing most digitally vulnerable users down rabbit holes surfacing and getting across them increasingly extreme, radicalized and toxic content. Being linked to its Chinese parent company ByteDance, TikTok platform accounts for lion's share of all reported cases among the most harmful platforms. Recent studies of this AI-supported online platform raised serious doubts about their ethical acceptability. This is mainly due to the opacity of their IA-supported algorithms: based on reinforced learning patterns, they have put at thoughtful stake their ways of collecting, interpreting and processing person-related features and data (e.g. personal data, biometry, facial expressions) in order to make consequential choices. Apparently, these algorithms are purposefully and conscientiously designed and then used by these platform to keep the most of the users' attention: by identifying some key personality features and predispositions, they achieve to rapidly select, identify, propose and purposefully reiterate video contents to users. Doing so, they appetize and feed their predilections, awarding their inclinations and proclivities by running reinforced awarding patterns.

[76] From: (i) CNN, (2023). "TikTok is 'digital fentanyl' incoming GOP China committee says", CNN Business, March 2023. https://edition.cnn.com/2023/01/01/tech/tiktok-mike-gallagher/index.html; (ii) Hindustan Times, " 'Digital fentanyl, deadly opioid': TikTok under political storm in US congress", " January 2023. These sources highlight that, by exacerbating the users' fragility and exposure to emotive aggression, these AI-supported online platforms tend to expose most digitally vulnerable users, like teens and kids, to contents which are potentially harmful for mental health, inducing anxiety, addiction, loss of attention and self-esteem, depression, eating disorders, definitely leading to instigating self-destructive syndromes up to suicide.

[77] CCDH, Center for Countering Digital Hate (2022). « Deadly by design – TikTok pushes harmful content promoting eating disorders and self-harm into young users' feeds », https://counterhate.com/research/deadly-by-design/

[78] The Times of India, (2022). "Two big reasons to keep your child away from TikTok," https://timesofindia.indiatimes.com/gadgets-news/two-big-reasons-to-keep-your-child-away-from-tiktok/articleshow/96257909.cms

[79] CNN, (2023). "Why experts worry TikTok could add to mental crisis among US teens", https://edition.cnn.com/2023/01/11/tech/tiktok-teen-mental-health/index.html

This pushed several bodies to promptly intervene, although achieving partially their objectives: on the EU policy side, the EC took quite recently a clear position, publishing a sound package[80] for a "Digital Service Act"[81], aiming to govern the content of online platforms, although raising some ambiguities.[82] The enforcement of this Act will induce these platforms to swiftly remove from summer 2023 harmful content, thus creating a safer digital space protecting the users' fundamental rights.[83] Safer, though not fully safe.

However, according to various experts, the AI-supported platforms could circumvent these actions, because of their political influence and economic weight,[84] and by virtue of their dominant lobbying position respect to EU institutions. Additionally, the almost weak taxing powers held by EC authorities, together with the conventional legal arsenal, are likely to add more limits to the Digital Service Act:[85] a broader discussion over the entire engineering design and on rethinking the entire business model of these platforms would be welcome by some scholars,[86] as their purpose should be redefined to protect global mental health.[87]

In this light, it is possible to evict that, attributing responsibilities in AI-systems

[80] EC, *Digital Service Act Package*, (2023). https://digital-strategy.ec.europa.eu/en/policies/digital-services-act-package
[81] EC, (2022). *Digital Service Act, 2020/0361* (COD). https://oeil.secure.europarl.europa.eu/oeil/popups/ficheprocedure.do?reference=2020/0361(COD)&l=en
[82] TikTok, (2021). "TikTok calls for EU DSA…", https://newsroom.tiktok.com/en-eu/tiktok-calls-for-digital-services-act-to-support-innovative-transparency-initiatives
[83] POLITICO, 2023. "TikTok, Twitter, Facebook set to face EU crackdown on toxic content" https://www.politico.eu/article/tiktok-confirms-it-faces-highest-content-moderation-obligations-under-eu-law/
[84] CSactu (2022). *The Digital Service Act: stakes and limits*. https://www.csactu.fr/the-digital-service-act-stakes-and-limits/
[85] *Ibidem*
[86] BCG (2023). "Rethinkig e-commerce for the era of the metaverse". https://www.bcg.com/publications/2023/the-future-of-e-commerce
[87] Harvard Edu, (2022). "TikTok but the party don't stop, no. " Digital innovation initiative. https://d3.harvard.edu/platform-digit/submission/tiktok-but-the-party-dont-stop-no/

is neither a straight nor an easy question: it sounds quite unrealistic to predict all the vast range of moral and ethical issues which might raise in the forthcoming years by the enormous potentialities lying in the bigger and quicker data processing abilities shown by AI, together with their augmented anticipation skills. This is expected to become tougher in case humans are becoming no longer capable to display their full control over the AI-based systems,[88] so responsibilities and liabilities should become difficult to distribute across the whole AI-system supply chain.[89]

Because of this uncertainty in the prediction and control of some AI-based systems, a gap in the attribution of responsibilities between designers, developers, validators, and users is likely to arise.[90] This gap might become difficult to bridge using the conventional notion of responsibility,[91] so AI companies should commit to redesigning the whole business models to allow a more thoughtful prediction or at least suitable retro-diction and re-modulation patterns for the AI-system's behaviors.[92]

These principles apply to the currently classified four primary AI types,[93] i.e., (i) *reactive machines*, which are task-specific, taking customer data and preferences to deliver recommendations, e.g., artificial chess players based on machine learning; (ii) *limited memory* imitates brains' neurons working together, getting smarter by receiving more data to train on, e.g., self-driving cars; (iii) *theory of mind* aims to understand how other entities experience thoughts and emotions, behaving accordingly, mimicking humans in understanding intentions and predicting behaviors; (iv) *self-awareness* aim to shaping a sense of self, i.e. a conscious understanding of their existence and their state of being. The last two types do not fully exist yet, although some AI-supported systems aspire to understand emotions, sensing or predicting human feelings and behaviors. While the first two types are usually interpreted as mere tools, i.e., morally-free as 'pseudo-agents', the remaining two types open questions of the appropriateness to consider them as moral and social 'agents', characterized by some moral

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[88] Heinriks, Jan-Hendrik (2022). "Responsibility assignment won't solve the moral issues of AI", Springer *Link*, https://link.springer.com/article/10.1007/s43681-022-00133-z

[89] Matthias, A. (2004). "The responsibility gap: ascribing responsibility for the actions of learning automata." Ethics Inf. Technol. **6**(3), 175–183 (2004). https://doi.org/10.1007/s10676-004-3422-1

[90] Sparrow, R. (2007): "Killer robots". J. Appl. Philos. **24**(1), 62–77 (2007). https://doi.org/10.1111/j.1468-5930.2007.00346.x

[91] *Ibidem*

[92] Reworked from: (i) BS (2016). *British Standard for Robots and robotic devices*, https://www.en-standard.eu/bs-8611-2016-robots-and-robotic-devices-guide-to-the-ethical-design-and-application-of-robots-and-robotic-systems/ ; (ii) BS 8611:2016 (2016) *Robots and robotic devices. Guide to the ethical design and application of robots and robotic systems*, https://www.en-standard.eu/bs-8611-2016-robots-and-robotic-devices-guide-to-the-ethical-design-and-application-of-robots-and-robotic-systems/; (iii) *IEEE Global Initiative for Ethical Considerations in Artificial Intelligence and Autonomous Systems*, p. 90 ff. https://standards.ieee.org/industry-connections/ec/autonomous-systems/

[93] Coursera (2023). *Four types of AI*, https://www.coursera.org/articles/types-of-ai

consistence. This debate roots on the discussion about the principle of responsibility of AI-based systems, which implies both moral and legal liabilities.

This debate is essential for designing and developing responsible and ethically sound primary AI types, involving decisions that might become profoundly controversial. On the one hand, holding humans responsible for actions of IA-governed machines over which they have insufficient control raises the issue of the 'responsibility gap', in both moral practice and legislation.[94] This applies essentially to the first two AI types (i.e., reactive and limited memory) interpreted as tools, so they are not glossed neither as moral nor as social interaction partners: as pseudo-agent, they are not subject to moral relations. In this case, the principle of distributed responsibility applies, differentiating and assigning diverse degrees, levels and types of responsibility to human agents involved in conceiving, designing, developing and validating AI systems.[95]

However, other AI-empowered systems, glossed as generative AI, are reaching limits beyond which humans can no longer understand in detail how artificial systems work, i.e., the 'black box' issue (e.g., unpredictability for neural networks to univocally discriminate among categories). In this case, models inspired to the last two generative AI types (i.e., theory of mind and self-awareness) cannot be fully understood nor predicted by humans in their behaviors: so, some scholars hypothesize that these limited abilities of human beings absolve them from assuming or shouldering a greater share of the responsibility.[96]

Consequently, and as a counterpart, some schools of thought argue that due to their higher anticipation skills and quicker data processing abilities these two generative AI types may deserve being endowed with a certain share of responsibility in man-machine interactions. The underlying principle put forward here is that the more artificial systems surpass humans, the more morally responsible they can become also in social interactions.[97] Because of that, they can be glossed as agents, becoming ascribed in all the moral relations subsumed under the term 'responsibility', which is almost disconcerting. In this latter case, there is no longer any responsibility gap: AI systems are attributed by some scholars as sharing some degree of moral responsibility, whose concept is forcedly stretched.[98] This ascription sounds quite irresponsible to other

[94] Reworked from Beck, S. (2016). "The problem of ascribing legal responsibility in the case of robotics". AI Soc. **31**(4), 473–481 (2016). https://doi.org/10.1007/s00146-015-0624-5
[95] Nyholm, S. (2018). "Attributing agency to automated systems: reflections on human-robot collaborations and responsibility-loci". Sci. Eng. Ethics **24**(4), 1201–1219 (2018). https://doi.org/10.1007/s11948-017-9943-x
[96] Strasser, A. (2022). "Distributed responsibility in human–machine interactions." *AI Ethics* **2**, 523–532 (2022). *https://doi.org/10.1007/s43681-021-00109-5*
[97] *Ibidem*
[98] Reworked from: Heinriks, Jan-Hendrik (2022). "Responsibility assignment won't solve the moral issues of AI", Springer *Link*, https://link.springer.com/article/10.1007/s43681-022-00133-z

scholars[99], therefore becoming hazy and blurry, rendering distributed responsibility tough to apply.[100]

On the one hand, attributing the notion of moral and social agent to machines sounds like a sophism, a clever intellectual trap[101]. In fact, this reasoning deliberately disregards the assumption that entities can have moral responsibility and legal liability only if they are unequivocally endowed with full consciousness, self-awareness, and discernment. By virtue of exerting them, they are capable to distinguish between good and bad, which are anapodeictic ontological categories.

This applies to both moral and legal standpoints. AI systems are by-design unable to choose between good and bad, as they simply execute the "black box" of the algorithms which program them to discriminate and choose what is more efficient for them, i.e., between right or wrong, and not between good and bad. So, the discernment capability of AI-systems is apodeictic: its moral acceptability depends on the inmost design of the algorithms which encode them, regardless of the limited human capability to understand or predict their inner dynamics and behaviors.

In this light, responsibility relies upon the inner gift humans have, while machines have not. As a matter of fact, unlikely gradualist schools pontify,[102] choosing between good and bad is a human prerogative, namely free will, while choosing between what is right or wrong is the best option AI algorithms can do. Additionally, in case powerful algorithms supporting AI systems are equipped with or shape by themselves inappropriate objectives, they would produce harmful outcomes: therein, human discernment should apply to the appropriateness or not of their objectives.

In fact, it is not clear yet whether AI systems might be creating their own internal goals by mimicking humans, whose operational dynamics are largely unpredictable: very powerful algorithms instructed by inappropriate objectives could end up by producing the worst outcomes. In generative AI, it might be possible that AI systems could produce their own objectives by imitating

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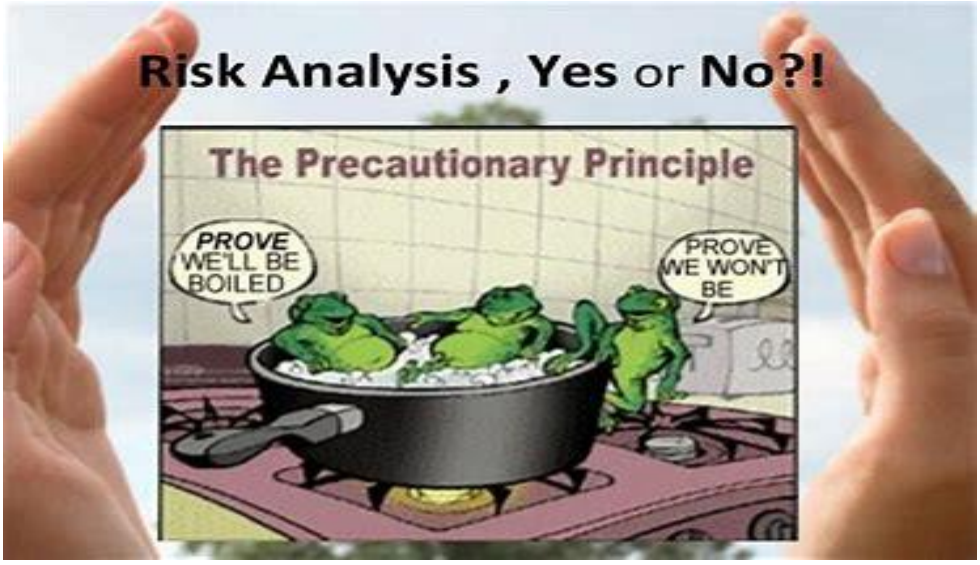
[99] M., (2004): *Sustainable Development: the Need for a New Ethics*, Óleo-LIFE Project LIFE 99/E/ENV/000351, EC DG ENV, Centre for Environmental Strategy of the University of Surrey, Guildford (U.K.) and AEMO, Jaén, Spain, pp. 50, 53-54, and back-cover.
[99] Reworked from: Strasser, A. (2022). "Distributed responsibility in human–machine interactions." *AI Ethics* **2**, 523–532 (2022). https://doi.org/10.1007/s43681-021-00109-5
[100] *Ibidem*
[101] Reworked from: (i) Wallach, W., Allen, C.: ''Moral machines. Contradiction in terms or abdication of human responsibility?'' In: Lin, P., Abney, K., Bekey, G. (eds.) Robot ethics. ''The ethical and social implications of robotics'', pp. 55–68. MIT-Press, Cambridge.
[102] Reworked from: (i) Coeckelbergh, M.: "Artificial intelligence, responsibility attribution, and a relational justification of explainability". Sci Eng Ethics (2020). https://doi.org/10.1007/s11948-019-00146-8; (ii) Himma, K.E.: "Artificial agency, consciousness, and the criteria for moral agency: what properties must an artificial agent have to be a moral agent?" Ethics Inf Technol (2009). https://doi.org/10.1007/s10676-008-9167-5

especially human learning patterns, e.g., Large Language Models. This issue has been recently pinpointed to the scientific and political arena in 2023 by an open letter signed by scholars and scientists, who ask for a responsible pausing of AI experiments. The rationale is that breakneck rush of AI experiments is likely to threaten human life and the entire societal discourse.[103] This is exactly the dilemma framed in the "black-box" issue: according to this viewpoint, as it is not clear yet whether and to what extent selected AI-supported systems might generate their own internal goals to pursue, their inner dynamics and operational patterns cannot be known nor predicted. In this sense, the precautionary principle should apply.[104]



In fact, AI is likely to become a disruptive set of technologies able to impact in a pervasive way onto various dimensions of human societies, economy, and cultures, both in the EU and beyond. In this light, an extensive communication action is needed on EC policy side to enable a broader societal dialogue to identify to what extent benefits, threat, prospects, and limits of AI could be trustfully promoted and accepted.

The real point of all this would be realigning AI-systems' objectives with human-centric objectives is pivotal to frame new models for responsibly shaped AI-systems. In this light, they should become '***responsible-by-design***', which means responsibly designed to fulfil specific objectives sternly defined by

[103] Future of Life Institute (2023). *Pause giant AI experiments: an Open Letter*, https://futureoflife.org/open-letter/pause-giant-ai-experiments/

[104] Reworked from: (i) Future of Life Institute (2023). *The AI Act*, https://artificialintelligenceact.eu/about/ ; (ii) Bonazzi, M., (2004): *Sustainable Development: the Need for a New Ethics*, pp. 53-54 and back cover. Óleo-LIFE Project LIFE 99/E/ENV/000351, EC DG ENV, Centre for Environmental Strategy of the University of Surrey, Guildford (U.K.) and AEMO, Jaén, Spain; (iii) OECD (2023): "What's next? And after that?" presentation by Prof. Stuart Russell, Berkeley University. *International conference on AI in Work, Innovation, Productivity, Skills*. https://www.oecd-events.org/ai-wips-2023/onlinesession/445db455-0cb9-ed11-994c-000d3a469307;

humans: (i) on the one side, they should not target the internal goals they may engender; (ii) on the other side, they should operate to pursue meticulously defined human-centric purposes. They should essentially be vowed to be acting in the best interests of humans by simultaneously pursuing human-centric objectives and disregarding the internal goals generative AI systems might create themselves, essentially mimicking human learning patterns. For becoming responsible, AI-systems should serve humans, and not vice versa.

In this light, the discernment about the appropriateness of AI-systems' goals take root from the inmost notion of responsibility which stems from human free will; this last should identify those human-centric goals towards which responsible-by-design AI should be targeted.

Free will can only be human:[105] in fact, it typifies human beings, as it stems from the inner intangible gift humans are endowed with, which are preconditions for exerting responsibility: these are consciousness, self-awareness, discernment, and emotions. All of them entail the moral duty and legitimate oath humans must use them for good, in virtue of guaranteeing their inherent right to exist, which by definition they deserve and exert.[106] Artificial agents are neither equipped nor awarded with them, although the gradualist conception[107] of IA machines seen as moral agencies neglect the intimate role

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[105] Reworked from: (i) Perrin, Ch. (2011). "J.P.Sartre: condemned to be free", *Filozofia* 66:209-221 (2011) https://philpapers.org/rec/PERJPS-2 ; (ii) Britannica, *Existentialism*, https://www.britannica.com/topic/free-will

[106] Reworked from: Bonazzi, M., (2004): *Sustainable Development: the Need for a New Ethics*, pp. 53-54 and back cover. Óleo-LIFE Project LIFE 99/E/ENV/000351, EC DG ENV, Centre for Environmental Strategy of the University of Surrey, Guildford (U.K.) and AEMO, Jaén, Spain.

[106] Reworked from: Strasser, A. (2022). "Distributed responsibility in human–machine interactions." *AI Ethics* **2**, 523–532 (2022). https://doi.org/10.1007/s43681-021-00109-5,

[107] Reworked from: Peña, L. and Txetxu A. (2014), "Los grados del vivir", in *Bioética en plural*, ed. by M. Teresa López de la Vieja. México/Madrid: Plaza y Valdés. ISBN 9788416032310, and https://en.wikipedia.org/wiki/Lorenzo_Pe%C3%B1a#Contradictorial_gradualism

these gifts play in shaping responsibility.[108] Heedless that vision, another etymon for responsibility would be needed to embrace the conceptual construal of ‘moral machines’,[109] thus emptying its moral and ethical contents: quite bewildering and perturbing indeed.

Despite the mental convolutions put forward by late epigons of empiricism, reductionism, and gradualism, it is common sense that AI will never get a heart, nor anything comparable to human conscience.

[108] Reworked from: Strasser, A. (2022). ”Distributed responsibility in human–machine interactions.” *AI Ethics* **2**, 523–532 (2022). https://doi.org/10.1007/s43681-021-00109-5

[109] Reworked from (i) Wallach, W., Allen, C.: ‘’Moral machines. Contradiction in terms or abdication of human responsibility?’’ In: Lin, P., Abney, K., Bekey, G. (eds.) Robot ethics. ‘’The ethical and social implications of robotics’’, pp. 55–68. MIT-Press, Cambridge (2012); (ii) Wallach, W., Allen, C.: *Moral machines: teaching robots right from wrong*. Oxford University Press, Oxford (2009).

Nurturing EC policies in AI-enables sciences for augmented medicine

Overall, AI is rapidly expanding across most manufacture sectors, outlining great and unpredictable strides: it is expecting to change science, research, innovation, and business landscape in EU and beyond, as far as their upper limits in medicine and health care. On the one hand, the current EU world leading position in AI enablers for nano-bio-pharma sciences invokes far-sighted EC policies able to upgrade research on enablers to upgrade into innovative applications: policies should be committed to both promoting and upscaling AI enabled research in nano-bio-pharma sciences from TRL3 towards TRL7: in the light of the risks addressed in previous sections, AI safety is a crucial issue, especially in the nano-bio-pharma sciences for augmented medicine.

In this light, diverse EC policy actions could be outlined to mitigate risks and promote the AI-related groundbreaking prospects:
(i) targeting funding instruments, specifically addressing novel conception, design and development of AI-supported systems into precision, predictive and personalized medicine; (ii) funneling funding research on AI enablers and applications dedicated to the following scientific areas: (a) diagnostics; (b) theragnostics; (c) targeted drug-delivery and (d) regenerative medicine, as these are the most strategic research and innovation axes to feed into medicine and health care end points.
(iii) facilitating data blending from diverse processes, factories and sites to enable accessing quality data, their standardization formats and communication protocols, which are upmost needs in EU nano-bio-pharma SME ecosystems as well as in manufacturing at large.
(iv) conceiving, designing and developing dedicated expert workshops gathering: (a) selected AI experts in nano-bio-pharma industries; (b)

stakeholders; and (c) civil society associations, such as patient and medical societies, to work together for identifying key research priorities: this exercise would be vowed to foster responsible uptake and embedding of AI into nano-bio-pharma industries, promoting sustainable and human-centric productivity and prosperity in EU business and society.[110] The outcome should be identifying a set of recommendable EC policy actions fostering responsible AI uptake and embedding into nano-bio-pharma sciences and research, finally addressing productivity and prosperity of EU augmented medicine and health care.

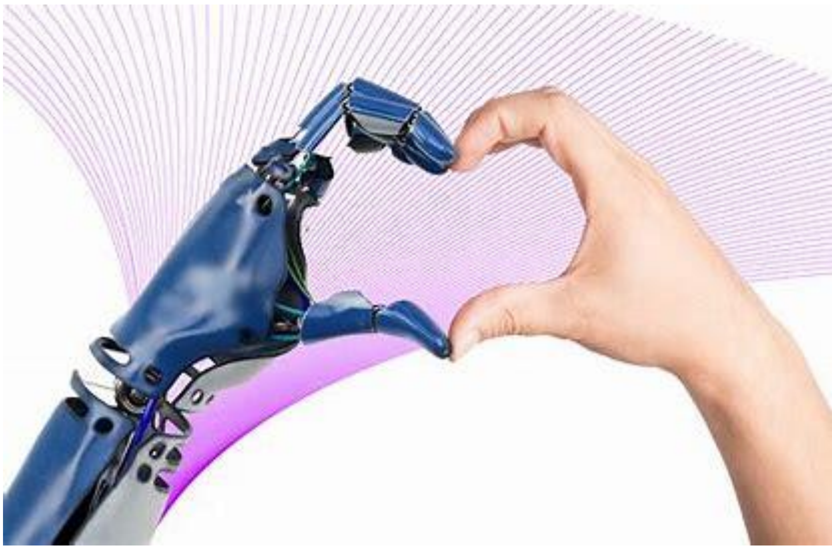
Some concrete steps have been recently outlined by the EC Presidency to make AI safer[111]: (i) equip independent scientific community with appropriate means to evaluate AI systems, thru public funding and access to the best supercomputers (e.g., Lumi in Finland and Leonardo in Italy): (ii) develop internationally accepted procedures and standards to test AI safety; (iii) report and follow-up each significant incident induced by AI errors, dual use or misuse; (iv) set up an international alerting system fed by trusted flaggers. In this light, EU public authorities are ultimately responsible for the safety and security of citizens, thru powers of intervention to complement self regulation, thus supporting AI innovation and simultaneously harvesting its benefits. This is the objective of the foundation of a European AI Office, currently under EC examination, which should: (a) foster standards and testing practices for frontier AI systems cooperating with the scientific community; (b) complement the private sector in investigation and testing; (c) develop alert-based enforcement of AI developers' responsibility; (d) implement common rules in Member States for advanced AI, simultaneously cooperating with analogous entities worldwide.

[110] Analogous exercises were carried out by EC to identify science and reseach policies in regenerative nanobiomedicine and nanotech outreach, whose outputs, upshots and outcomes fed into the design of topics into RTD workprogrammes of FP7, e.g. (i) Bonazzi, et al., (2017): *Towards nanotechnology osteo-chondral reconstruction*, EC Publication Office ISBN 978-92-79-74132-6; doi: 10.2777/292697 KI-04-17-901-EN-N ©); (ii) Bonazzi, M., Neicu, M., Millar, J., Schuurbiers, D. (2013). *Reaching out to the future: outline of proposals for communnication outreach, societal dialogue and education on nanotechnology*. ISBN: 978-92-79-25114-6, EUR: EUR 25361 catalogue n°: KI-NA-25-361-EN-N.

[111] AI Bletchey Park Safety Meeting (2023). Remarks from President von der Leyden at the Bletchey Park AI Safety meeting- Speech, 2nd November 2023, at: Remarks of President von der Leyen at the AI Safety Summit (europa.eu)

From all that, it can be evicted that the growing AI uptake will arouse the need for a greater emphasis on responsible AI conception, design and development, usage and ethics[112]. So, dedicated actions should be devoted to address key ethical issues, especially associated with widespread AI use with the specificities driven by AI uptake into medicine and health applications. Expert debates should therefore be set up, addressing responsibility to achieve responsible and ethically grounded trustworthiness for AI-supported systems in medicine and health care.

In fact, downstream AI social acceptance relies essentially upon its trustworthiness: this largely depends on the transparency, ethics and sense of responsibility shaping how AI is upstream conceived, designed and developed, and on the way, it is downstream applied and used. In practical terms, it is recommended to ask AI designers, engineers, and manufacturers to explicitly, minutely, and distinctly detail: (i) for what purpose, (ii) doing what, and (iii) how are AI systems conceived, designed, developed and validated, and which business models is expected to reflect thoroughly all that.



Clearly, the purposes for what AI-based systems are designed are crucial: as AI-systems largely outstrip and outshine many human capabilities, defining their objectives in a human-centric perspective is essential to enable humans retaining control and power over them.[113] In fact, the real issue is misalignment between human-centric objectives and underlying purposes shaping AI-supported systems. It is not a matter of letting AI-based systems to pursue the purposes they might engender by imitating humans, namely inappropriate, as happened in

[112] Reworked from: (i) https://ec.europa.eu/info/strategy/priorities-2019-2024/europe-fit-digital-age_en; (ii) Bonazzi, M., (2013). *Communicated Nanotechnology: outreach, dialogues and education within civil society*. ISBN: 978-92-79-21477-6, EUR 24962, DOI: 10.2777/77541.
[113] OECD (2023): "What's next? And after that?" presentation by Prof. Stuart Russell, Berkeley University. *International conference on AI in Work, Innnovation, Productivity, Skills*. https://www.oecd-events.org/ai-wips-2023/onlinesession/445db455-0cb9-ed11-994c-000d3a469307

AI-based social media e.g., algorithm-supported online platforms aiming at maximizing users' clicks and engagement, modifying users' cognitive intake to become more predictable in their content consumption, thus more governable.

In fact, the more powerful algorithms are equipped with incorrect or inappropriate objectives, the worse outcome they will produce. In fact, the risk lies in the possibility that AI systems might produce their own objectives by imitating human learning patterns, whose outcomes could become harmful. This issue has been very recently and promptly put forward by an open letter signed by extensive swarms of scholars and scientists, who claim for a responsible pausing of AI experiments as this could namely menace both the course of human life and the overall societal discourse[114]. In fact, this is precisely the essence of the "black-box" issue: according to this viewpoint, it is not clear yet whether and to what extent AI-supported systems might engender their own internal goals to pursue, whose action dynamics and operational patterns are largely unknown and unpredictable. So, the precautionary principle should apply.[115]

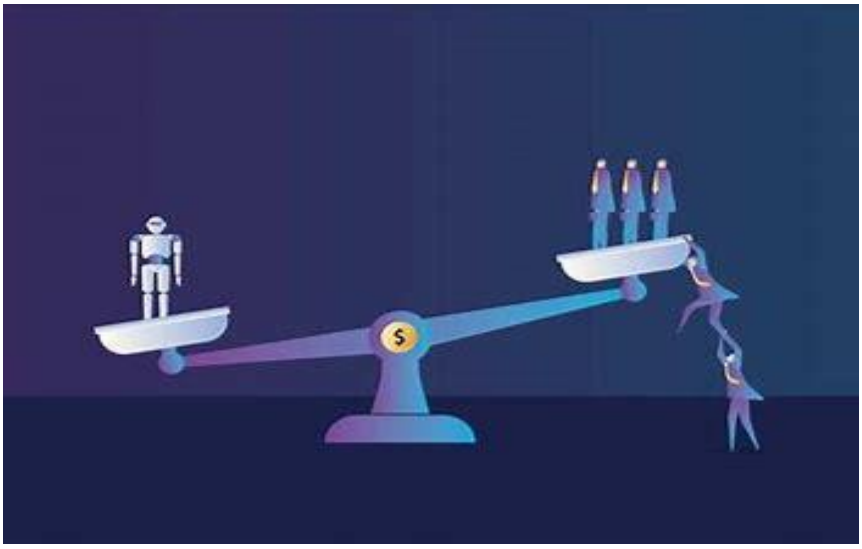
In this light, it is essential to re-shape new models for responsible AI-systems: they should become '*responsible-by-design'*, which means responsibly designed to fulfil specific objectives strictly defined by humans. This means that they should essentially become fully vowed to be acting in the best interests of humans by simultaneously pursuing human-centric objectives and disregarding the internal goals AI systems might create by mimicking human learning patterns. In practical terms: (i) on the one hand, their actions should not focus on the internal purposes they might be creating by mimicking human learning patterns, whose operating dynamics are largely unpredictable; (ii) on the other hand, they should act to pursue human-centric purposes which need to be strictly a priori defined. For fitting in with the responsibility principle, responsible AI-based systems and machines should serve humans, and not the other way round.

In fact, it would sound irresponsible to deploy AI-based systems which is uncertain if they produce or not their internal goals, and whose inner operational dynamics are largely unpredictable. Responsible-by-design AI systems should perform in the best interests of humans, while remaining explicitly uncertain about what those interests are. This is formulated as a mathematically formulated assistance game, where AI-based systems display their role as solvers, by: (i) acting with deference in respect to humans, (ii) remaining minimally invasive and (iii) showing willingness to be switched off, which

[114] Future of Life Institute (2023). *Pause giant AI experiments: an Open Letter*, https://futureoflife.org/open-letter/pause-giant-ai-experiments/

[115] Reworked from: (i) Future of Life Institute (2023). *The AI Act*, https://artificialintelligenceact.eu/about/ (ii) OECD (2023): "What's next? And after that?" presentation by Prof. Stuart Russell, Berkeley University. *International conference on AI in Work, Innnovation, Productivity, Skills*. https://www.oecd-events.org/ai-wips-2023/onlinesession/445db455-0cb9-ed11-994c-000d3a469307

definitely solve the control issue.[116] In this light, the AI-based systems supporting diagnostics, theragnostics, drug-delivery and regenerative medicine previously illustrated are enlightening virtuous examples, as they behave as supporting tools which remain strictly under the steer of health care operators, who take the ultimate lead. In this light, promoting these new models for responsible-by-design AI would become essential for EC policies, possibly vowed to regulate, or label them.[117]



It is sufficiently clear that AI would become a disruptive and pervasive set of systemic technologies able to impact on various dimensions of human society, economy, and culture. So, it would be appropriate, forward-thinking, and far-sighted EC policies should set up a framework for an extensive communication action to shape and enable a broader societal dialogue on AI. Both should focus on addressing, analyzing, and identifying to what extent benefits, threat, prospects, and limits of AI could be trustfully promoted and accepted in the EU and beyond. In fact, building on trustworthiness of responsible AI and its societal acceptance is likely to become a crucial process to facilitate its responsible uptake and embedment at both production and consumption levels.

In fact, beyond any spontaneous enthusiasm or mistrust any such highly innovative scientific and technological development related to AI may bring, the fact that AI is becoming more and more deeply embedded in today's life should warrant a meaningful, conscientious communication based on continuous participation and dialogue between EU institutions and citizens: thus, EC should be taking the lead to develop such a dialogue, as one of its own moral responsibilities.

[116] *Ibidem*
[117] *Ibidem*

In this light, involving Europeans in appropriate communication and dialogue on AI is a real asset to the EC, whose aim should be vowed to aligning AI development with the people's expectations and concerns, at the same time paving the way for a level playing field in the global market. In this sense, call to EC policy action becomes an utmost need: in the old world of the public understanding of science, there was often a monologue top-down approach where non-expert opinion had no role to play. However, with the increasing recognition that dialogue and multiple inputs are crucial factors in underpinning sound policymaking in science and technology, and their acceptance in society, it has become evident that multi-way communication is the most robust way to address dilemmas raised by novel science and the associated technologies. In fact, it is now consensually assumed that *'science is too important to be left to scientists. Their knowledge and their assessment of risks is only one dimension of the challenge for society. When science raises profound ethical and social issues, the whole of society needs to take part in the debate*.'[118]

So, EC policies should commit to promoting an appropriate communication and societal dialogue on AI: this could be framed thru an openminded, consistent and even audacious communication framework aiming to bring everyone in, i.e., ***Communication Roadmap on Responsible-by-design AI***. In this sense, good EC governance on AI would depend on appropriate communication as pre-requisite for societal dialogue: in past decades, attaining trustworthiness of cutting-edge technologies has been robustly acknowledged to be crucial for their societal acceptance. Therefore, far-sighted EC policies should be pushing this bold principle towards building up a broad, informed, and responsible consensus to support the uptake and embedment of trustworthy and responsible AI in both production and consumption patterns: clearly, this approach should go beyond AI-augmented nano-bio-pharma sciences and technologies.

[118] UK Parliament, House of Lords (2000). *Science and Innovation White Paper 'Excellence and Opportunity, a science and innovation policy for the 21st century'*. UK Parliement, Hansard, Lords. https://hansard.parliament.uk/Lords/2000-07-26/debates/5bf52b1b-611f-4e8f-9dd4-62e9f378efd8/ScienceAndInnovationWhitePaper

The core challenge here is about engaging society in an inclusive dialogue that can identify desirable patterns for responsible and trustworthy AI design, application, and use. If opportunities, risks, and uncertainties were properly addressed, EC would probably become closer to the mark of reaching informed and responsible consensus: in this light, the best strategy for developing an EC Communication Roadmap on Responsible AI should aim at creating a lively communication relationship and a continuous dialogue between EU institutions and citizens. Every audience, be it industry, business, organizations, NGOs or, more broadly, the lay public, will be increasingly called upon to get involved at European, national, and local levels. As a result, good governance through inclusive policy debate will be promoted.

All these issues should be addressed, analyzed, structured, and packaged into a specific communication and dialogue model at EC level that relates to citizens' concerns and needs. By building on knowledge and awareness of responsible AI, its communication roadmap would come forward with a whole system of organized mechanisms designed to prepare the ground for very effective feedback and exchange with the whole society.

By building on knowledge and awareness of responsible AI, this Communication Roadmap on Responsible AI would come forward with a whole system of organized mechanisms designed to prepare the ground for very effective feedback and exchange with society. By placing European citizens at the center of attention, it tries to design a feed-back-feed-forward mechanism to greatly enhance the EU's policymaking efforts in promoting and safeguarding the future of responsible AI as a strategic tool for sustainable prosperity and growth. It also aims to treat responsible AI as a critical component that is bound to bring to the fore people's relationship with high technology developments, by advancing the concept of sciento-technological democracy in a human-centric perspective.[119]

[119] Reworked from: (i) Bonazzi, M., (2010). *Communicating Nanotechnology – an Action packed Roadmap for a brand new Dialogue*; European Commission, EUR n°: 24055; ISBN: 9789279134135, at: http://ec.europa.eu/research/industrial_technologies/pdf/communicating-nanotechnology_en.pdf ; (ii) Bonazzi, M., (2013). *Communicated Nanotechnology: outreach, dialogues and education within civil society*. Internal EC use: catalogue n°: KI-NA-24-962-EN-C. Public use ISBN: 978-92-79-21477-6, EUR 24962, DOI: 10.2777/77541.

In this light, the roadmap framing communication and dialogue actions could be structured across different steps:
(i) appropriate communication on AI should come first, which requires a sound and clever method: it is pivotal to state whom communication on AI should be reaching out to, since audiences are many.
(ii) then, envisaging the expected impact would follow, to make key audiences and stakeholders (i.e., those having a specific interest) feel involved and eager to know more to engage in taking proper decisions.
(iv) further on, anticipating how to get the messages across to meet the communication needs of the lay public will be the next communication step;
(iv) finally, dialogue and engagement are the ultimate and crucial phase: in fact, the previous communication steps would enable building-up public awareness and trust; this is committed to supporting a trustworthy societal dialogue exercise on responsible AI for its long-term development, by engaging all parts to allow EU to profit from its potential benefits, simultaneously circumventing the potential associated risks.

A bottom-up approach is therefore needed therein, seeking a dynamic, constant, and continuous communication and dialogue model. Therein, those striving to communicate the wonders of novel science and associated AI technology would also listen to the perceptions, concerns, and expectations of the audiences on AI and engage into a discussion with them. Clearly, diverse degrees of interest, sensitiveness, and creativity are needed. They are valuable plus, as communication and dialogue require ears as well as voices: indeed, the number of ears should double the number of mouths, as several ancient traditions suggested in their own time.


Summarizing, future EC policies on responsible AI thru the proposed Communication Roadmap on Responsible AI should focus on actions dedicated to: (i) communicating on AI by addressing diverse dimensions, actors and stakeholders with the proper tools; (ii) promoting awareness actions on responsible AI as part of the fabric of society; (iii) setting up an open dialogue and engagement on AI with and within society; (iv) building-up frameworks to attain social consensus on responsible AI between stakeholders, society and policymakers; (v) fostering societal confidence and trust on responsible AI by enhancing the EC's image as an impartial, transparent, trustworthy and reliable communicator on AI.[120]

[120] *Ibidem*

In a nutshell: science insights and policy recommendations for responsible AI in science

Likewise analogous issues raised in the past decades by debates on nanoscience and synthetic biology, AI-enabled prospects in nano-bio-pharma sciences and related industries are expected to raise potential scenarios, encompassing benefits and risks for human societies, economies, industries, politics, and cultures at large. AI is expected to become a driving force for the forthcoming and future economy and society: ensuring that technological advancements could lead to shared and net-positive outcomes worldwide societies, thus requiring more research, innovation, and relevant guardrails to guarantee its human-centricity.

On the one hand, the EU should harness AI and ensure it is used responsibly.[121] As a matter of fact, due to its tremendous potential, AI will be crucial for future world research and innovation at large, and more specifically in pharma and health care applications:[122] so, the EU should be doing more on this, especially investing in industrial data wealth of unrivalled quality struggling to translate research results into marketable outputs, upshots, es and outcomes, thus boosting its worldwide competitivity.
On the other hand, beside becoming an increasingly alluring industrial and socioeconomic opportunity, AI could be socially, culturally, and ethically accepted only if used responsibly. In fact, AI has been ranked as top risk globally for the next decade, because they often involve 'black boxes' issues, where it is unclear how their outputs are generated and come from.[123]

Summarizing, a generous dose of healthy skepticism is therefore pivotal in approaching outcomes from AI-mediated research: AI tools cannot be interpreted ad fully reliable without questioning the outcomes stemming from their application, as being mindful that this depend on what type of models and data an AI tool has been trained on.

Last, improving, boosting and promoting communication and societal dialogue on AI is essential: in fact, a widespread progressive loss of trust in research and science at large is becoming an increasingly serious issue over the last years,

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[121] World Economic Forum (2024). "Europe must up its game on AI", Ursula von der Leyden speech, Davos, at: https://www.researchprofessional.com/0/rr/news/europe/innovation/2024/1/Europe-must-up-its-game-on-AI--says-Commission-president.html#sthash.xKTjcXPH.zCpydNMd.dpuf
[122] World Economic Forum (2024); interventions from ERC's Maria Leptin and Magdalena Skipper from ''Nature'' journal, *ibidem*.
[123] CNBC (2024). "Davos updates: Global leaders discuss AI adoption and potential threats." McKeever Lucy Handley, on 15th January panellists.

especially from COVID pandemics:[124] this mainly result from both misinformation – which is incomplete or inaccurate information - and deliberate disinformation, in some cases stemming from industries' vested interests to undermine or invalidate science results and credibility, e.g., on climate change.[125] In this light, preventing loss of public trust in research and science is becoming an increasingly crucial political priority for the EU, as it can jeopardize the objectivity and credibility of the innovation outputs associated with research and science. Therefore, including more research and training on communication, data safety, privacy and ethics is crucial to keep up public trust with the pace of technological change. So, more resources are needed to improving researchers' communication, as the need to become better communicators about their methods and results to help restore and keep trust in research and science: in this light, the EU should take the lead on boosting communication on responsible AI.

All these considerations enable outlining succinct insights and recommendations for EU policies on AI, described as follows.

- AI is expected to become a disruptive and pervasive set of systemic technologies, as ubiquitous as the internet, impacting on most dimensions of human society, economy, and culture: so, it is crucial to learn from past successes and failures of the digital revolution; so, debates over what it means to be "human-centered" and which values should guide human societies will shape responsible engagement with AI. Focusing on shared values such as diversity, inclusiveness, democracy and peace, policymakers and technologists should outline principles for designing,

[124] World Economic Forum (2024). "Communicate to rebuild trust in science", 16th January Panel. See more at: https://www.researchprofessional.com/0/rr/news/europe/politics/2024/1/Communicate-to-rebuild-trust-in-science--urges-Davos-panel.html#sthash.fKC0UunH.MQknUnc5.dpuf

[125] World Economic Forum (2024). Intervention of Naomi Oreskes, professor of the history of science at Harvard University in the United States, *ibidem*

developing, and implementing inclusive and responsible AI tools. As a matter of fact, this integration requires engagement with communities and related commitment to equity and respect of human rights.[126]
- Quite widespread consensus has been reached at the recent 2024 World Economic Forum in Davos, Switzerland, on the fact that the EU is severely lagging behind US (and China) on AI, where Europe doesn’t play a significant role: in fact, the key underlying models for generative AI, such as OpenAI’s GPT-4, are all being developed in the US.
- Although it seems that that race is lost, application of these new technologies on important domains such as health care would open novel and actual opportunities for Europe, provided that EU must be acting together. So, the EU could support a limited number of highly ambitious foundation models to be developed at the European scale, funded through dedicated call for proposals and selection procedure: promising actions could focus on industry-specific, for instance on AI-models focused on augmented nanomedicine for heath care.
- As a consequence, EU could have comparative advantage therein, as EU academic institutions have access to those medical and climate data that could power specialized models, as big tech companies such as Google and Microsoft don't have access either to medical data and or to necessary medical expertise.[127]
- AI-based and especially AI generative systems are expected to become increasingly disruptive sets of new knowledge and technologies paving the way for conceiving, designing and developing unexpected breakthroughs and entirely innovative tools to enhance efficiency in most branches of both medicine and health care: their forward-looking potential could provide enormous efficiency gains and forward-thinking scientific insights and application outlines.
- Simultaneously, they may become unruly and unpredictable if they are not properly addressed, as the conception, design and management of their technologies could become increasingly prone and vulnerable to malignant uses, as they are easy to clone and cheap to misuse, they are widely accessible: thus, their control may become unpredictable and their impacts on societies, economy, industries, politics and cultures at large may turn out into vast rooms for uncertainty.

[126] Botti, Y., and Vilas Dhar, L. (2024): “Will 2024 be the year of responsible AI?”, *Irish Examiner*, 31 January 2024 issue. More info at Will 2024 be the year of responsible AI? (irishexaminer.com)
[127] Matthews, D. (2024). “FP10: scrap missions in favour of AI and solar flagships”. *Science Business*, 30th January 2024. Interview to Helmholtz Director Otman Wiestler. More info at: FP10: scrap missions in favour of AI and solar flagships, says Helmholtz head | Science|Business (sciencebusiness.net)

- On the one hand, although increasing set of studies, analyzes, research and reflections are being drawn worldwide to explore, identify, categorize and assess potential risks, more research is actually needed at EU level, to standardize procedures, risk assessment and produce usable outcomes. On the other hand, too few and limited studies and research have been carried out to outline and analyze realistic risk mitigation measures: more EU funded research is clearly needed to bridge this gap.
- In addition to that, research is needed to address the complementary dimensions of AI impacts in human societies, economy, politics, laws and cultures, which stem from AI-related ethicalities: in fact, although incipient, quite inspiring debate is being raised in terms of both moral practice and legislation on the *responsibility gap* attributed to AI-based systems: in this perspective, humans cannot be hold responsible for actions carried our by AI-governed machines over which they have not enough control.
- Therefore, on the one hand the principle of *distributed responsibility* applies to the first two types of primary AI systems, (i.e., reactive and limited memory), assigning diverse degrees and types of responsibility to human agents involved in conceiving, designing, developing and validating AI systems. Essentially, these AI types are interpreted as tools, they cannot be glossed as moral or social interaction partners, so they are not subject to moral relations.
- However, on the other hand this principle is tough to apply in the last two types of generative AI models (i.e., theory of mind and self-awareness): they cannot be fully understood nor predicted by humans in their behaviors: it has been put forward that these limited abilities of human beings absolve them from assuming a greater share of the responsibility. Due to their higher anticipation skills and quicker data processing abilities, it has been argued that these two generative AI types may deserve being endowed with a certain share of responsibility: consequently, the more artificial systems surpass humans, the more morally responsible they can become, being so glossed as *moral machines*, thus both morally and legally liable. Clearly, this definition sounds almost distorted and disturbing, as it overrides the principles of conscience an free will on which responsibility relies upon.
- In the light of all that, large room for EU funded research is required to apply, deploy and expand and deepen the principle of *distributive responsibility* applied to generative AI systems: this is expected to become of utmost importance; as long as these technologies would

become pervasive in most layers of societies, economy, industries, politics and cultures, the related governance issues which would arouse should require appropriate frameworks for moral practice and legal liability.

- As a consequence of all these considerations, EU future policy actions should focus on setting up research and scientific frameworks for conceiving, designing, developing and deploying ***'responsible-by-design AI systems'***, which means responsibly designed to fulfil specific objectives firmly defined by humans, i.e., human centricity: (i) on the one hand, they should not target the internal goals they may engender; (ii) on the other hand, they should operate to pursue meticulously defined human-centric purposes: to serve humans – and not vice-versa – they should be conceived, designed, developed and deployed to acting in the best interests of humans. This should be simultaneously pursuing human-centric objectives while disregarding the internal goals they might be creating themselves by mimicking human learning patterns.
- Staying on our current path risks perpetuating or worsening the global wealth gap and further alienating vulnerable communities worldwide: therefore, EC policies should set up a framework for an extensive and audacious communication action and societal dialogue on AI, aiming to bring everyone in, i.e., ***Communication Roadmap on Responsible-by-design AI***.
- Especially sensitive will be AI empowerment in 2024, when more than 40% the world's population will prepare to hold elections: combating the imminent surge of mis- and disinformation which might may arise upon AI-based models will require proactive measures: this includes the need for a stronger public awareness, promoting broad-based media literacy and avoiding polarization by emphasizing the importance of empathy and mutual learning.
- In fact, attaining trustworthiness of cutting-edge technologies such as AI has been robustly acknowledged to be crucial for their societal acceptance, built upon a broad, informed and responsible consensus to support uptake and embedment of trustworthy and responsible AI, by: (i) communicating on AI by addressing diverse dimensions, actors and stakeholders with the proper tools; (ii) promoting awareness actions on responsible AI as part of the fabric of society; (iii) setting up an open dialogue and engagement on AI with and within society; (iv) building-up frameworks to attain social consensus on responsible AI between stakeholders, society and policymakers; (v) fostering societal confidence

and trust on responsible AI by enhancing the EC's image as an impartial, transparent, trustworthy and reliable communicator on AI.

Clearly, in analogy with those issues raised by debates on cutting-edge technologies in the past decades (e.g., nanobiotechnologies and synthetic biology), responsible AI would require a strictly responsible and ethical approach, open communication and societal dialogue aimed to building informed consensus: EC policies should become straightforward about that. Again, as always in science and innovation, quoting Kant archetypical paradigm is particularly enlightening, as well as inspiring: "*starry heavens above us and the moral law within us*."[128]

[128] Kant, I. 1788, *Kritik der praktischen Vernunft, i.e.* Critique of practical reason, Gutenberg book, https://gutenberg.org/ebooks/5683

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Matteo Bonazzi has worked as program officer in nano-bio-info-cogno converging sciences and technologies, as well as in communication outreach, at the European Commission from 2003 to 2024. Herein he has been managing fifty research and innovation projects over twenty years. He also worked for private and public bodies in Spain and Italy on science, sustainability, and culture. He authored 30 books and edited two on converging science and technologies, sustainability, and culture, written in several languages. He also authored fifty scientific articles and eighty contributions to proceedings and seminars on the same subjects. On the top of that, he conceived, designed, and developed six exhibitions and twenty workshops, contributing to newspapers, media programs and software. Last but not least, he gave lectures as Prof. Dr. habil. at the University of Vilnius (Lithuania), as well as speeches and lectures in twenty academic institutions worldwide. He graduated cum laude with honorable mention in Natural Sciences at the Turin University (Italy). Thanks to his dissertation in eco-ethology developed in central Africa at the Kenya Marine Fishery Research Institute of Mombasa (Kenya) he was awarded the title and Medal of “Best in the School” for best curriculum and dissertation by the academic Senate of Turin University (Italy). He holds a postgraduate European Master in Environmental Engineering, issued by the European Polytechnic Environmental Association at the Polytechnic of Turin (Italy) and the Université de Savoie (France), as well as a postgraduate International Master Specialization Course in Fats issued by the Consejo Superior de Investigación Científica of Seville (Spain). He holds a PhD in Environmental Engineering issued by the University of Surrey (England), awarded with honorable mentions by the Centre for Environmental Strategy of Guildford (U.K.) and the University of West Indies of Kingston (Jamaica). He possesses both work and research experience in various countries of Europe, Asia, Africa, and the Americas.