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*Public Procurement of AI for the EU Healthcare Systems. First Insights from the Spanish Experience**

María Estrella Gutiérrez David
(Associate Professor of Constitutional Law at Universidad Complutense de Madrid)

José Luis Quintana Cortés
(Lawyer. Partner of Rodríguez Castaño Abogados)

ABSTRACT Based on a sample of 20 selected tenders, this paper analyses the public procurement of AI solutions for healthcare systems, providing insights into the why (public need), the what (domain of application of AI) and the how (innovation strategies, procurement procedures, safeguards in tender specifications to ensure trustworthy AI).

1. *Introduction*

Healthcare services constitute one of the most important economic sectors in Europe, accounting for almost 10% of GDP, and 15% of government expenditure. A large number of investments are focused on the digital transition in healthcare (e-Health), including telemedicine, amounting approximately to EUR 12 billion.[1]

Looking ahead, the adoption of a regulatory proposal to create the European Health Data Space ("EHDS Proposal")[2] is expected as one the key priorities of the European Commission in the area of health. The purpose of the EHDS is to promote health-data exchange, support digital-health services and research on new preventive strategies, diagnosis and treatments of diseases, medicines, medical devices and health outcomes. Not by chance, along with its primary use, the EHDS Proposal also envisages the processing of electronic health data for secondary purposes, *inter alia*, "training, testing and evaluating of algorithms, including in medical devices, AI systems and digital health applications, contributing to the public health or social security, or ensuring high levels of quality and safety of health care, of medicinal products or of medical devices".[3]

In recent years, contracting authorities of the EU National Healthcare System (NHCS) have been engaged in the purchase of Artificial Intelligence (AI) solutions to tackle the challenges of the 21st century healthcare.

Procurement notices published by EU contracting authorities on digital platforms or buyers' profile show that this trend will continue and increase in the future. The extent to which this is the case remains opaque,[4] as there is no clear map of public purchases of AI solutions.

To address this challenge, this paper seeks to draw a first systematic picture of the current state of public procurement of AI solutions for

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[1] European Commission, *Recovery and resilience scoreboard. Thematic analysis Healthcare*, December 2021, 3-4, https://ec.europa.eu.

[2] See Proposal for a Regulation of the European Parliament and of the Council on the European Health Data Space (COM/2022/197 final). Article 1(1) of the Proposal defines the EHDS as a data space "providing for rules, common standards and practices, infrastructures and a governance framework for the primary and secondary use of electronic health data". In general, "Data Spaces" are common and interoperable infrastructures that bring together (i) the deployment of data sharing tools and services for pooling, processing and sharing of data by an open number of organisations, as well as the federation of energy-efficient and trustworthy cloud capacities and related services; (ii) data governance structures which determine, in a transparent and fair way, the rights of access to and processing of the data; (iii) improving the availability, quality and interoperability of data – both in domain specific settings and across sectors. See also European Commission, *Common European Data Spaces*, SWD(2022) 45 final, Brussels, 23 February 2022.

[3] Article 34.1(g) of the EHDS Proposal.

[4] M. Hickok, *Public procurement of artificial intelligence systems: new risks and future proofing* in *AI & SOCIETY*, 2022, 1, 7. https://doi.org/10.1007/s00146-022-01572-2.

the NHCS in Europe with a special focus on Spain. In the context of the Spanish research project PID2021-128621NB-100, funded by the Ministry of Science and Innovation of Spain and FEDER funds, this contribution will try to provide some valuable insights into:
1) the *why*: the public needs to be met and challenges to be solved;
2) the *what*: the applications of AI and use cases, and;
3) the *how*: the procurement procedures implemented and, if any, the specific tender requirements to ensure appropriate safeguards to address the inherent risks of the use of AI in the NHCS.

2. *The context*

Particularly after the COVID-19 pandemic, public-healthcare systems have come under the spotlight due to the digital transformation. E-Health applications, including AI-based solutions, are starting to facilitate a holistic approach to health.

AI techniques, such as Machine Learning, Deep Learning or Natural Language Processing ("ML", "DL" and "NLP", respectively) have a very wide field of application. They can be used to improve the quality, efficiency and equity of national-healthcare systems ("NHCS").[5]

As a data-driven technology, AI has many potential applications to reduce uncertainty in medicine, and more specifically, in classifying patients' conditions (diagnostic uncertainty), in explaining why and how patients develop specific diseases (pathophysiological uncertainty), in determining the most appropriate treatments for them (therapeutic uncertainty) or in assessing the results of a specific treatment (prognostic uncertainty).[6]

In particular, AI can be used in public-health systems to discover new drugs, interpret X-ray images, or understand the progression of a disease and perform early diagnosis.[7] For example, during the COVID-19 outbreak, ML models were proposed to improve systems for triaging patients to the most appropriate services –for example, Intensive Care Units "ICU"– based on severity predictions.[8]

AI can also play an essential role in analysing and processing health data through the implementation of Electronic Health Records ("EHR")[9] or wearable devices and sensors via the Internet of Things ("IoT").[10]

Furthermore, AI models are being used to predict costs by private insurers, non-profit hospitals or governmental agencies,[11] and to optimise available healthcare resources by encouraging the automation of repetitive tasks.[12]

The pandemic has been nothing more than a catalyst for the design, deployment and acquisition of AI solutions by national-health systems.[13]

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[5] E. Harwich and K. Laycock, *Thinking on its own: AI in the NHS*, Reform, 2018, 1, 17-22, https://allcatsrgrey.org.uk.

[6] F. Cabitza, D. Ciucci and R. Rasoini, *A Giant with Feet of Clay: On the Validity of the Data that Feed Machine Learning*, in *Medicine*, in F. Cabitza, C. Batini and M. Magni (eds.), *Organizing for the Digital World. Lecture Notes in Information Systems and Organisation*, Cham, Springer International Publishing, 2019, 122.

[7] Department of Health and Social Care, *The future of healthcare: our vision for digital, data and technology in health and care*, 2018, https://www.gov.uk/. This policy paper contains a range of use cases related to the applications of AI in the UK National Healthcare System.

[8] V.V. Khanna, K. Chadaga, N. Sampathila, S. Prabhu and R. Chadaga, *A machine learning and explainable artificial intelligence triage-prediction system for COVID-19*, in *Decision Analytics Journal*, vol. 7 (100246), 2023, 1, 2, https://doi.org/10.1016/j.dajour.2023.1002.46; M.A. Deif, A.A.A. Solyman, M.-H. Alsharif and P. Uthansakul, *Automated Triage System for Intensive Care Admissions during the COVID-19 Pandemic Using Hybrid XGBoost-AHP Approach*, in *Sensors (Basel)*, vol. 21, no. 19, 2021, 6379, 1-17, Doi: 10.3390/s21196379.

[9] See S. Locke, A. Bashall, S. Al-Adely, J. Moore, A. Wilson and G.B. Kitchen, *Natural language processing in medicine: A review*, in *Trends in Anaesthesia and Critical Care*, vol. 38, 2021, 4-5.

[10] H. Ronte, K. Taylor and J. Haughey, *Medtech and the Internet of Medical Things How connected medical devices are transforming health care*, Deloitte Centre for Health Solutions, 2018, 1, 2, 10, www2.deloitte.com.

[11] C.W.L. Ho, J. Ali and K. Caals, *Ensuring trustworthy use of artificial intelligence and big data analytics in health insurance*, in *Bulletin of the World Health Organisation*, vol. 98, no.4, April 2020, 264.

[12] T. Qian Sun and R. Medaglia, *Mapping the challenges of Artificial Intelligence in the public sector: Evidence from public healthcare* in *Government Information Quarterly*, vol. 36, no. 2, 2019, 368.

[13] For example, an EU-funded project, "Symptoma", developed an AI-based health chatbot that, after considering the information entered by a user, asked specific follow-up questions to identify the most likely symptoms that are strong indicators of certain diseases, assessed them, and returned a list of potential medical causes sorted by their probability. And, like many other countries, the UK developed algorithms to identify patients using datasets collected from hospital admissions, primary care EHRs and prescription records and to draw up high-risk patient lists to recommend them complete shielding. See European Commission, *Symptoma, Better Diagnosis for Patients with Rare and Complex Diseases*. CORDIS. EU results, https://cordis.europa.eu; A. Sheikh, M. Anderson, S. Albala *et al*., *Health infor-*

Not only are the NHCS engaged in the development of in-house AI applications, but also in the purchasing commercial-off-the-shelf (COTS) or bespoke software based on AI. In fact, tender notices published by contracting authorities show that European NHCS have long been procuring AI solutions for many implementations in the area of healthcare.

When considering public purchases, it is important to bear in mind that the procurement of works, services and supplies by European contracting authorities, including public entities pertaining to NHCS, is governed by Directive 2014/24/EU of the European Parliament and of the Council of 26 February 2014 on public procurement and repealing Directive 2004/18/EC (hereinafter, "Directive 2014/24/EU"), provided that the economic thresholds set out in Article 4 of the Directive are exceeded. In those cases, contracting authorities must procure these works, services and supplies in accordance to the procedures set forth in the Directive, and its well-established principles of freedom of access to tenders, equal treatment and non-discrimination of economic operators, transparency and proportionality of the procedures.[14]

Therefore, public procurement procedures will be the main instrument for the acquisition of AI solutions by public-health systems, being Directive 2014/24/EU a negative boundary.

3. *Are NHCS committed to procuring trustworthy AI-driven solutions?*

While the deployment and use of AI systems in the European public sector continues to escalate, there are growing concerns that specific human rights, including social rights and access to public services, are being adversely impacted by algorithmic systems.[15]

For example, discrimination-related pitfalls of AI (measurement errors, selection bias, algorithmic uncertainty, inequitable deployment or racially-tailored medicine) are common claims against the use of AI in healthcare environments.[16]

Another critical aspect is the trade-off between performance and interpretability of AI-models. Complex models may provide greater predictive capacity but less interpretable results. In this respect, the use of "black box" models in the clinical workflow would also raise concerns about the model transparency and the interpretability of the results in relation to the different stakeholders.[17]

The big question then is whether or not public procurement is keeping AI-driven solutions for the NHCS free from these adverse (individual or societal) impacts. In other words, are the NHCS buying trustworthy AI solutions? Are these solutions somehow aligned with the future European Regulation on AI?

To properly answer these questions, it is first necessary to draw a reliable map of the state of public procurement. This will enable us to analyse the extent to which tender specifications have put in place appropriate safeguards to ensure that planned purchases mitigate the inherent risks of AI.

3.1. *Constraints to a reliable mapping of AI procurement for the NHCS*

There is no clear map of AI procurement in the public sector. This opaqueness is due to several reasons.

Firstly, the instruments to ensure the publicity of tenders (aggregated tender platforms or buyers' profiles) are not designed for general transparency and public-information purposes but to provide bidders access to tenders with a view to increase equal treatment for all interested parties, efficiency and transparency of the procurement

mation technology and digital innovation for national learning health and care systems in *Health Policy*, vol. 3, July 2021, 383-396, 394-395. www.thelancet.com.

[14] See Recitals (1), (90) and Article 18(1) of the Directive 2014/24/EU.

[15] Council of Europe, *Algorithms and human rights: study on the human rights dimensions of automated data processing techniques and possible regulatory implications*, 2018, 30, https://rm.coe.int/algorithms-and-human-rights-en-rev/16807956b5. In particular, the Council has identified a major risk of "social sorting in medical data as algorithms can sort out specific citizen groups or human profiles, thereby possibly preventing their access to social services".

[16] S. Hoffman and A. Podgurski, *Artificial Intelligence and Discrimination in Health Care* in *Yale Journal of Health Policy, Law, and Ethics*, vol. 19 (3), 2020, 1-49, http://hdl.handle.net/20.500.13051/5964.

[17] J. Gerlings, M. Søndergaard Jensen, and A. Shollo, E*xplainable Al, But Explainable to Whom? An Exploratory Case Study of xAI* in C.P. Lim, A. Vaidya *et al*. (eds.), *Healthcare in Handbook of Artificial Intelligence in Healthcare. Vol. 2: Practicalities and Prospects*, Cham, Springer, 2022, 169, 172-174.

procedures.[18]

Secondly, the decentralisation of the instruments to ensure the publication of tender's notices and the different scope of the obligations to publish pertinent information on tenders[19] may lead not only to different levels of transparency depending on the public sector (national, regional or local), but also to a real fragmentation of the public-procurement information.[20]

Thirdly, the design of user interfaces on procurement platforms and the usability standards applied to tender portals or buyer profiles also vary among European countries and contracting authorities. This variation leads to technical gaps that impede a genuine identification of tenders of interest and access to relevant tender information. For example, the predefined search criteria of the Spanish tender platform, PLACE,[21] result in technical constraints that make it very complex to produce a complete, systematic and reliable map of public purchases of AI-enabled solutions across the NHCS.[22]

Even if the tendering platforms allow a free-text option as a search criterium, this feature does not ensure a comprehensive identification of the tenders of interest when the keywords used in the query are not present in the contract title. Turning to the French contracting system, the keyword "intelligence artificielle" (or related terms such as "machine learning", "deep learning", or similar) did not return any tenders of interest on the platform, "Plataforme des Achats de l'État",[23] although there is evidence that NHCS contracting authorities have launched calls for tenders of AI solutions.[24]

In the UK, "Find a Tender" is a service for searching and tendering for high-value contracts (over £138,760 including VAT). Unlike other European tendering platforms, Find a Tender's search tool is not restricted by the fact that the keywords used must appear in the title of the contract. For example, if one enters "artificial intelligence" + "NHS" as search criteria, the platform returns 39 notices.[25] In turn, the UK platform only provides a summary description of the specifications, whereas others in the EU usually publish all relevant documents associated with the tenders and, most interestingly, also the technical and administrative specifications.[26]

3.2. *Discussion and goals*

The future EU Regulation on AI ("AIA")[27]

[18] See Recital (52) of the Directive 2014/24/EU.

[19] See, *inter alia*, Articles 48 (prior information notices), 49 (contract notices), 50 (contract award notices), 51 (form and manner of publication of notices) or 53 (electronic availability of procurement documents) of the Directive 2014/24/EU.

[20] Cfr. J.M. Gimeno Feliú, *La reforma comunitaria en materia de contratos públicos y su incidencia en la legislación española. Una visión desde la perspectiva de la integridad*, in J.M. Gimeno Feliú, I. Gallego Córcoles, F. Fernández González and J.A. Moreno Molina (eds.), *Las Nuevas Directivas de Contratación Pública*, X Congreso de la Asociación Española de Profesores de Derecho Administrativo, Pamplona, Thomson-Reuters Aranzadi, 2015, 37-105, 50.

[21] The Spanish Public Sector Procurement Platform ("Plataforma de Contratos del Sector Público") is the online platform that enables the open consultation of tenders published in the Buyer's Profiles of the State, regional, and local contracting authorities hosted on the platform, as well as those of other public bodies utilizing different procurement platforms but publishing their calls for tender and results through aggregation mechanisms in PLACE. See Ministry of Finance and Civil Service, *Plataforma de Contratación del Sector Público*, available at https://contrataciondelestado.es.

[22] The predefined search criteria include the tender reference docket (if known), identification of the contracting authority, choice of contract type, Common Procurement Vocabulary (CPV) code, or date range. By using the pre-defined search criteria, the tool often returns a lengthy list of contracts. This poses a practical challenge in discriminating those tenders of interest for the purposes of the research. Conversely, free text cannot be used as a search criterion.

[23] See the French Platform, also called "PLACE", available at https://www.marches-publics.gouv.fr/ (last access on 28 January 2024).

[24] Assistance Publique-Hôpitaux de Paris, *L'AP-HP s'engage dans un partenariat d'innovation et va utiliser l'intelligence artificielle pour le codage des diagnostics des séjours courts*, 12 September 2019, https://www.aphp.fr/.

[25] GOV.UK, *Find a tender*, https://www.find-tender.service.gov.uk/ (last access on 28 January 2024).

[26] In the context of public purchases of AI solutions, access to tender documents is essential for a reliable mapping of AI-driven purchases in the public sector. The analysis of those documents provides very useful insights into the state-of-the-art of the solutions, thereby allowing the traceability of the specific (technical or legal) requirements in order to assess whether or not public purchases have an appropriate risk approach in relation to the intended purpose of the AI systems implemented in the NHCS.

[27] European Commission, Proposal for a Regulation of the European Parliament and of the Council laying down harmonised rules on artificial intelligence (Artificial Intelligence Act) and amending certain union legislative acts, Brussels, 21 of April 2021 (COM/2021/206 final). Although at the time of writing, EU co-legislators are still engaged in trilogue negotiations to agree on the final text after the amendments proposed by the Council and the Parliament, for the purposes of this paper, references to the AIA will be done in relation to the proposal of the European Commission, including appropriate ref-

is intended to set out horizontal obligations for high-risks AI systems, including those having adverse impacts on health, security and fundamental rights. At the same time, a growing body of soft law is emerging at the international and European level to provide standards for the implementation and development of trustworthy AI.

However, when planning the acquisition of AI-enabled solutions for the NHCS, the lack of a regulatory framework should not prevent contracting authorities from putting in place specific measures to adequately address inherent risks of AI acquisitions.

It is, therefore, necessary to assess the extent to which current public-procurement rules, procedures, and specifications ensure the implementation of trustworthy AI, aligned with the future AIA in the public sector at large, and especially within the public-healthcare systems.

Considering the above scenario, this paper seeks to:

1. Provide a general mapping of public procurement of AI solutions in the EU NHCS (identification of the procurement of innovation strategies rolled out, taxonomies of procurement procedures used, and characterisation of the AI solutions tendered);
2. Identify potential interdependencies between the risks inherent in AI and those associated with the procurement process;
3. Examine whether the tender specifications ensure that the AI solutions purchased –whether COTS or custom software– provide sufficient guarantees for reliable AI in accordance with the future AIA and emerging standards.

3.3. *Methodological approach*

To achieve the foregoing goals, multidisciplinary resources have been consulted, including but not limited to various tendering portals (eTendering, Italy, Spain), sectoral legislation applicable to public procurement and AI, soft law, guidelines for AI procurement from international organisations or European public purchasers, or works from the fields of computer sciences, biomedical research and ethics.

The scope of our review has comprised general databases (Scopus, Web of Science, ProQuest, or Dialnet); and databases specialised in health (Science Direct, Pubmed or medRxiv).

The timeline has covered from 2015 to 2023, and the languages of research were English and Spanish. The search string to identify relevant literature has included the keywords 'Artificial Intelligence' AND 'Healthcare' AND 'Public procurement'.

The analysis of the documents retrieved reveals two major findings.[28]

On the one hand, the existing research on public procurement of AI focuses mainly on general topics such as:

1. The use of AI for the innovation of procurement procedures (e.g. automatic definition of product requirements, support in negotiation and supplier selection, prediction of bidder's offers, procure-to-pay compliance, anomaly detection);[29]
2. The general identification of the associated risks to public purchasing of AI (eg. transparency, robustness and societal/individual impacts, human oversight, AI impact assessments, audits, and legal control of AI for decision making);[30]

erences to the amendments introduced by the EU Parliament and Council when necessary. The trilogue meetings between the European Commission, Council and Parliament started last June and continued in July, September, October and December 2023. See European Parliament, *Legislative Train Schedule. Artificial intelligence act. In "A Europe Fit for the Digital Age"*, 20 October 2023, https://www.europarl.europa.eu. In the last phase of the trilogue meetings, a Draft Agreement version was released on 21 January 2024. The text is available at https://artificialintelligenceact.eu.

[28] It is important to note that the purpose of this literature review is not to carry out a bibliometric study, but to identify relevant publications on public procurement of AI within the public healthcare sector.

[29] M. Guida, F. Caniato, A. Moretto and S. Ronchi, *The role of artificial intelligence in the procurement process: State of the art and research agenda*, in *Journal of Purchasing and Supply Management*, vol. 29, no. 2, 2023 (100823), https://doi.org/10.1016/j.pursup.2023.100823; R. Nai, E. Sulis and R. Meo, *Public Procurement Fraud Detection and Artificial Intelligence Techniques: a Literature Review* in *EKAW'22: Companion Proceedings of the 23rd International Conference on Knowledge Engineering and Knowledge Management*, Bozen-Bolzano, September 26–29, 2022, https://ceur-ws.org; S. Jiménez, A. Ortiz and D. Alonso, *Predicción de ofertas para contratos públicos. Aplicación de la inteligencia artificial a los datos de contratación*, in J.M. Gimeno Feliú (dir.), *Observatorio de los Contratos Públicos 2021*, Pamplona, Aranzadi 2022, 491-505.

[30] World Economic Forum, *Unlocking Public Sector AI. AI Procurement in a Box: Workbook. Toolkit*, June 2020 ("WEF Guidelines"), https://www3.weforum.org; J. Miranzo Díaz, *Inteligencia artificial y contratación pública*, in I. Martín Delgado and J.A. Moreno Molina (dirs.), *Administración electrónica, transparencia y con-*

3. The key aspects in the design of the procurement procedures and relevant clauses in public contracts for AI solutions,[31] or the potential inconsistencies in the contract-classification system concerning the acquisitions of off-the-shelf/ bespoke software (supply or service contracts) and management of intellectual property rights.[32]

On the other hand, out of all the literature reviewed, only a few publications specifically discuss AI procurement in the healthcare sector.[33]

To draw a first picture of the AI procurement for healthcare, general guidance on innovation procurement –be it public procurement of innovative solutions ("PPI") or pre-commercial procurement ("PCP")– has been consulted. In addition, the production of international and European standards for trustworthy IA[34] and the ongoing discussion of the future AIA have resulted in the first specific guidelines for AI procurement (World Economic Forum,[35] European Commission,[36] UK Government,[37] City of Amsterdam,[38] City of Barcelona[39]), including AI procurement in healthcare sector (UK Government[40]). Consequently, to further enrich our analysis this emerging corpus of guidance has also been considered.

This theoretical background has been completed with the creation of a database with tenders of interest. The database is part of the research project PID2021-128621NB-100 referred to above. It covers the period dating from 2015 to the present and is updated from time to time. The consultation of PLACE, other platforms and buyer profiles has resulted in the identification of nearly 60 tenders.[41] From these listed tenders, a sample has been extracted and is now presented in Annex I (Refs. [1]-[5]) and Annex II below (Refs. [6]-[20]) for the purposes of our review. Each tender is identified in the Annexes by its docket reference, and numbered from [1] to [20].

While most of the tenders are focused on the Spanish NHCS (Annex II), some tenders launched by EU institutions and retrieved

tratación pública, Madrid, Iustel, 2020, 105-142; M. Hickok, *Public procurement of artificial intelligence systems: new risks and future proofing* in *AI & Society*, October 2022, https://doi.org/10.1007/s00146-022-01572-2; E. Gamero Casado, *Supervisión, auditoría y control jurídico en la contratación pública de soluciones de robotización e inteligencia artificial para soporte a la toma de decisiones* in *Observatorio de la Contratación Pública*, October-November 2022, www.obcp.es.

[31] I. Gallego Córcoles, *La contratación de soluciones de inteligencia artificial*, in E. Gamero Casado and F.L. Pérez (coords.), *Inteligencia artificial y sector público. Retos, límites y medios*, Valencia, Tirant lo Blanch, 2023, 504-564.

[32] J. Miranzo Díaz, *La contratación pública como elemento de control, garantía e impulso de la IA pública*, 2024, https://congresoaepdavigo2024.es.

[33] See A. García-Altés A, M. McKee, L. Siciliani *et al*., *Understanding public procurement within the health sector: a priority in a post-COVID-19 world*, in *Health Economics, Policy and Law*, vol. 18, no. 2, 2023, 172–185, Doi:10.1017/S1744133122000184; L. Silsand, G-H. Severinsen, L. Linstad and G. Ellingsen, *Procurement of artificial intelligence for radiology practice,* in *Procedia Computer Science*, vol. 219, 2023, 1388-1395; K. Selviaridis, A. Hughes and M. Spring, *Facilitating public procurement of innovation in the UK defence and health sectors: Innovation intermediaries as institutional entrepreneurs*, in *Research Policy*, vol. 52, no. 2, 2023, https://doi.org/10.1016/j.respol.2022.104673.

[34] OECD, *Recommendation of the Council on Artificial Intelligence* of 22 May 2019 ("OCED Recommendations"); High-Level Expert Group on Artificial Intelligence, *Ethics guidelines for trustworthy AI,* European Commission, 8 April 2019 ("HLEG Ethics Guidelines").

[35] WEF Guidelines, 1-17.

[36] European Commission, Proposal for standard contractual clauses for the procurement of Artificial Intelligence (AI) by public organisations. High-Risk version, September 2023 ("European Commission H-R Standard Clauses") https://public-buyerscommunity.ec.europa.eu. Although, for the purposes of this paper, the reference to the European Commission's standard clauses will, in most cases, be made to this high-risk version, there is also a non-high-risk version, applicable to other algorithmic systems that does not necessarily qualify as 'AI systems.' This latter version seeks to cover simpler software rule-based systems, given that their use in the public sector may also require increased accountability, control and transparency in certain cases.

[37] Office for Artificial Intelligence, *Guidelines for AI procurement. A summary of best practice addressing specific challenges of acquiring Artificial Intelligence technologies in government*, 8 June 2020 ("UK Guidelines"), https://www.gov.uk/.

[38] City of Amsterdam, *Standard Clauses for Procurement of Trustworthy Algorithmic Systems*, version 2.0, 17 June 2021, ("Amsterdam Standard Clauses"), https://www.amsterdam.nl.

[39] City of Barcelona, *Definition of work methodologies and protocols for implementing algorithmic systems*, 31 January 2023 ("Barcelona Methodologies"), https://ajuntament.barcelona.cat.

[40] J. Joshi and D. Cushnan, *A buyer's guide to AI in health and care. 10 questions for making well-informed procurement decisions about products that use AI*, NHS England Transformation Directorate, 2020 ("UK NHS Buyer's Guide"), https://transform.england.nhs.uk.

[41] Systematizing the selected tenders and analysing their respective tender documents, including preliminary market consultations, and memoranda justifying the public need addressed by the contract, have allowed the development of this database leading to the initial analysis of the state of public procurement for AI solutions within the NHCS.

from the eProcurement platform, "TED. eTendering", have been also considered (Refs. [1]-[3]).[42] To complete our sample, some tenders of the Italian Agenzia Nazionale per i Servizi Sanitari Regionali ("AGENAS")[43] have been listed as well.

Consultations through the national procurement platform in Spain, PLACE, have identified some contracts dating back to 2015 and 2016 (Ref. [6], [7] in Annex II).

To illustrate the current state of AI-solution procurement for the NHCS, constant references are made to the 20 tenders in the sample. Additionally, insights are extracted from tender specifications across 21 tables.

The analysis of tender specifications has been conducted based on two criteria: (i) identification and characterisation of the public-procurement procedures applied, and (ii) characterisation of AI-solutions in healthcare. The first criterion offers insights into the challenges associated with the procurement process, while the second one provides a view of what the NHCS is procuring and allows us to identify potential risks inherent in the disruptive nature of AI technology.

The application of the criteria above results in the identification of the following risks in the public procurement of AI solutions for the NHCS.

Risks inherent in procurement procedures	**Risks inherent in AI solutions**
- Potential inconsistencies arising from the interaction with harmonized legislation (eg. AIA or Medical Devices Regulations); - Lack of national or regional strategies for AI; - Lack of planification of AI purchases; - Complexity and length of the procedure; - Lack of multidisciplinary teams and skills; - Inadequate identification of public needs to be met; - Management of Intellectual Property rights and vendor lock-in effects	- Regulatory compliance of legacy AI systems; - Lack of prior AI impact assessment - Determining whether or not AI is the right solution; - Purchasing COTS software vs bespoke software; - 'Gold-plated' *versus* 'functional' specifications; - The intended purpose and the evolving nature of AI systems; - Lack of provisions in tender specifications ensuring trustworthy AI/future alignment with AIA (eg. data quality, transparency and explainability, performance and error metrics).

Table 1. Inherent risks in AI procurement

4. *What is being procured by the NHCS? The challenging interaction between the future AIA and MDR/IVRDR Regulations*

A thorough literature review shows that the transformative potential of AI for healthcare includes a bundle of applications in the following major areas:[44]

1. AI in clinical practice: clinical-decision support with alerts and reminders, prognosis and risk prediction, medical image interpretation (contouring, segmentation and pathology detection), emergency medicine, surgery, adaptative interventions, tools integrated with EHR;
2. AI solutions for patients and their families: personalised treatments, conversational agents, telemedicine and health monitoring, timely personalized intervention, assistance for individuals with disabilities;
3. AI in healthcare administration: patient-flow management, coding, scheduling, detection of fraudulent activity, healthcare audits;
4. AI in biomedical research: clinical research, drug discovery, clinical trials, mining EHR data and extraction of patterns, phenotyping, improved access to

[42] European Commission, *TED.eTendering* in *SIMAP. Information system for public procurement*, https://etendering.ted.europa.eu/. Notice that TED eTendering will be gradually discontinued and replaced by the Funding and Tenders (F&T) Portal.

[43] AGENAS, *Gare in corso*, www.agenas.gov.it/bandi-di-gara-e-contratti/avvisi-bandi-e-inviti/gare-in-corso.

[44] K. Lekadir, G. Quaglio, A. Tselioudis Garmendia and C. Gallin, *Artificial intelligence in healthcare. Applications, risks, and ethical and societal impacts,* European Parliamentary Research Service (EPRS), Panel for the Future of Science and Technology (STOA), 2022, 5-14, Doi:10.2861/568473; M. Matheny, S. Thadaney Israni, M. Ahmed and D. Whicher (Ed.) *Artificial Intelligence in Health Care. The hope, the Hype, the Promise, the Peril*, Washington DC., National Academy of Medicine, 2022, 65-86. See also, E. Harwich and K. Laycock, *Thinking on its own: AI in the NHS*, January 2018, 17-22, https://allcatsrgrey.org.uk; G. Mahadevaiah, P. RV, I. Bermejo *et al.*, *Artificial intelligence-based clinical decision support in modern medical physics: Selection, acceptance, commissioning, and quality assurance* in *Medical Physics*, vol. 47, issue 5, 2020, e228-e235, e229, https://doi.org/10.1002/mp.13562.

biomedical literature;
5. AI for public health: health communication and AI-enabled health campaigns, chronic-disease management, disease surveillance, environmental and occupational health, prior authorisation in healthcare benefits and pharmacy.

Most of the AI solutions in the sample of Annex I and II can be included in one or more of the applications above.

Areas of application	Tenders of interest
Pathology detection, clinical decision support, personalised medicine.	[16][17] [18]
Delivery of remote-healthcare services (telemedicine, telerehabilitation, personal assistants, self-care).	[5] [10] [20]
Management and optimisation of available healthcare resources (patient triage, waiting lists, effectiveness of treatments).	[8] [13]
Secondary uses of health data (analysis of data for biomedical research).	[16] [17]
Research and development, consultancy services on AI applications in healthcare.	[1] [7]
Promotion and improvement of health services (e.g. sentiment analysis and assessment of health services by end-users, promotion of healthy lifestyles).	[4] [6] [18]
Epidemiological predictive analysis and early-warning of public-health threats.	[2] [3]
Fraud detection in social benefits.	[12]
Provision of data repositories (e.g. Health Data Lakes) and IT infrastructures supporting AI models based on cloud (PAAS, SAAS, IaC) or on premise.	[4] [5] [13] [14] [15] [16] [19] [20]

Table 2. Application of AI in the NHCS

4.1. *Purchasing AI-solutions for NHCS likely under the future AIA*

Following Article 3(1) of the AIA, an AI system is a "software that is developed with one or more of the techniques and approaches listed in Annex I and can, for a given set of human-defined objectives, generate outputs such as content, predictions, recommendations, or decisions influencing the environments they interact with". For example, many of the tenders in the sample include use cases aimed at developing AI models to make predictions or recommendations.

Output model	Description in tender specifications
Predictions	Predicting the number of emergency admissions in relation to airborne particle concentration [18]. Prediction of weaning failure and length of stay in ICU [19].
Recommendations	Recommendation engine that suggests which patients on the waiting list should be prioritised for surgery based on their personal, clinical, social and urgency characteristics to potentially reduce waiting times [13].

Table 3. Output models in tender specifications

Considering the definition of the "AI systems" proposed by the European Commission, many of the sampled contracts imply the development of one or more techniques and approaches listed in Annex I of the AIA, in particular, ML approaches (including supervised, unsupervised, reinforcement learning, DL); logic and knowledge-based approaches (including knowledge bases, inference and deductive engines or expert systems) or statistical approaches, Bayesian estimation or search and optimisation methods.[45]

[45] However, the list of techniques proposed by the Commission has been discussed by the EU institutions. The Economic and Social Committee found no added value in Annex I and recommended removing it entirely from the AIA, as some of the techniques are not considered AI by AI scientists and a number of important AI techniques would be missing in the Commission's Proposal (see EESC 2021/02482, of 22 December of 2021, par. 3.2). According to the Parliament mandate, the definition of AI systems should be amended to align with the definition agreed by the Organisation for Economic Co-operation and Development (OECD) and suppress Annex I, while the Council narrowed down the definition to systems developed through ML approaches and logic- and knowledge-based approaches and supressed Annex I (see ST 15698 2022 INIT, 15698/22, of 6 December 2022). At the time of writing and at this point of the trilogue negotiations, it appears that the Commission, Parliament and Council have not reached an agreement on Annex I. However, the co-legislators have proposed a new definition of "AI systems" catching the adaptative nature (*continuous learning*) of AI systems (which is typical of many ML models). The common definition proposed reads as follows: "An AI system'

Looking at the tender specifications of the AI solutions in the sample, some of them describe the application of AI in a very broad way, without detailing or prescribing a concrete AI technique or approach (Refs. [1], [10], [11], [15]), whereas other tender documents indicate the specific learning approaches to be implemented, such as ML and DL (Refs. [2]-[5], [7], [9], [13], [14], [16], [18-20]), including expert systems (Refs. [7], [8]), or statistical learning (Ref. [16]). Some tender specifications define in a very detailed way the learning problem to be addressed by the contractor, e.g. regression, classification, clustering, anomaly detection, or structured prediction.[46]

Learning problem	Description in tender specifications
Regression	- Predicting the duration of sickness absence due to illness or accident [12]. - Prediction of unscheduled readmissions in the month following discharge [18].
Classification	- Selection of patients for active search in rare diseases [13]. - Comparison of the results of pharmacological treatments (success or failure cases), based on the different prescriptions made for pathologies of the same nature [13].
Clustering	- Group population to benefit from primary and secondary prevention [4]. - Grouping chronic patients based on similarities to personalise healthcare and optimise the use of resources based on the level of care prescribed by the healthcare professional [18].
Anomaly detection	- Monitoring Telemedicine platform with advanced analytics systems capable of detecting anomalous patterns that are not obvious or even new, using ML [4].
Dimensionality reduction	- Disease prevention and control and early warning of public-health threats using social media by applying unsupervised ML/DL models on dimensionality reduction for data compression [3].
Structured prediction	- Segmentation of mammography and pathological-anatomy imaging to predict the cancer-risk index in a marked area of the image, and to produce marks on the processed images to identify the detection made [11].

Table 4. Learning problem in tender specifications

4.2. *Qualification of an AI system as a Medical Device Software (MDSW)*

Most of the tenders of interest include the design, development and deployment of AI-driven software and applications with an intended medical purpose.

In principle, the fact of being AI-based software tools and, at the same time, software to be used for an intended medical purpose, either on its own right, or driving or influencing the use of a (hardware) medical device or *in vitro* diagnostic medical device, would trigger the application of the AIA and Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices ("MDR") or Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on *in vitro* diagnostic medical devices ("IVMDR")[47] (hereinafter jointly, "MD Regulations"). As explained below some of the AI solutions listed in Annexes I and II could qualify as MDSW under the MD Regulations.[48]

AI-driven software[49] to be used, alone or in

(AI system) is a machine-based system designed to operate with varying levels of autonomy and that *may exhibit adaptiveness after deployment* and that, for explicit or implicit objectives, infers, from the input it receives, how to generate outputs such as predictions, content, recommendations, or decisions that can influence physical or virtual environments" (see Draft Agreement of 21 January 2024).

[46] In relation to tasks and learning problems in ML, see ISO/IEC 23053:2022(en) Framework for Artificial Intelligence (AI) Systems Using Machine Learning (ML), at 5-7.

[47] Cfr. K. Lekadir *et al*., *Artificial intelligence in healthcare*, 31; F. Zanca, C. Brusasco, F. Pesapane *et al*., *Regulatory Aspects of the Use of Artificial Intelligence Medical Software*, in *Seminars in Radiation Oncology*, vol. 32, no. 4, 2022, 432-433, https://pubmed.ncbi.nlm.nih.gov.

[48] It should be noticed that MD Regulations entered into force on 16 March 2022, and many provisions were scheduled to take effect gradually.

[49] For the purposes of this paper, the term "software" is aligned with the definition given by Medical Device

combination, for one or more of the *specific medical purposes* laid down by the MDR[50] could qualify, in principle, as medical-device software (MDSW). This includes software modules (eg. module providing and expert-system assistance for medical-decision making) and applications (e.g. operating on a mobile phone, in the cloud or on other platforms) with a medical purpose.[51]

Typical examples of medical devices qualified as MDSW would be decision-support software which "combine general medical information databases and algorithms with patient-specific data" (e.g., Ref. [13]); telemedicine systems to "allow monitoring and/or delivery of healthcare to patients at locations remote from where the healthcare professional is located" (e.g., Ref. [5]); telesurgery "to conduct a surgical procedure from a remote location" (using, for instance, virtual reality); or web systems "for the monitoring of clinical data" which "interacts with a medical device (e.g. implanted devices or homecare devices), and uses a transmitter to send the information over the internet or a mobile network"[52] (e.g., Ref. [20]).

In particular, decision-support software would usually be considered a medical device when it applies automated reasoning, such as algorithms or more complex series of calculations, provided that: (i) it is linked to a specific medical device, or (ii) it is intended to influence the actual treatment (e.g., dose, time of treatment), or (iii) it results in a diagnosis or prognosis (e.g., providing future risk of disease).[53]

In the same vein, AI-driven software intended to be used, solely or principally, for the purpose of providing information on one or more of the functions listed under IVMDR could qualify as *in vitro* diagnostic medical device.[54] This would be the case of an AI tool that assists or replaces clinicians in the examination of prepared biopsy samples,[55] an Image Management System (IMS) which incorporates complex quantitative functions to support post-processing of images for diagnostics purposes[56] (e.g., Ref. [11], [13][57]),

Coordination Group ("MDCG") established by the Article 103 of the MDR. The MDCG defines "software" as "a set of instructions that processes input data and creates output data". In particular, AI-driven software computes input data (e.g. data given through speech recognition, formatted for medical purpose records such as DICOM file or ECG or EHR, data received from/transmitted by devices or unformatted clinical documents in paper) to produce output data (e.g. audio data, digital or printed documents, screen display data –including numbers, characters, picture, graphics) in the form of content, predictions, recommendations, or decisions. Cfr. MDCG, *Guidance on Qualification and Classification of Software in Regulation (EU) 2017/745 – MDR and Regulation (EU) 2017/746 – IVDR*, October 2019, 5, https://health.ec.europa.eu.

[50] Article 2(1) of the MDR define 'medical device' as "any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes:
- diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability,
- investigation, replacement or modification of the anatomy or of a physiological or pathological process or state,
- providing information by means of in vitro examination of specimens derived from the human body, including organ, blood and tissue donations,
- and which does not achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such mean".

[51] MDCG, *Guidance*, 3, 17-18.

[52] *Idem*, 18-23. By contrast, software intended for non-medical purposes, such as invoicing or staff planning or software for general purposes supporting communication systems to transfer electronic information (e.g., prescription, referrals, images, patient records), do not qualify as medical-device software.

[53] Cfr. Medicine & Healthcare Products Regulatory Agency (UK), *Guidance: Medical device stand-alone software including apps (including IVDMDs)*, 12, www.gov.uk/.

[54] MDSW fulfilling the definition of an *in vitro* diagnostic medical device falls under Article 2(2) of the IVMDR, provided that it is intended to be used "solely or principally for the purpose of providing information on one or more of the following: (a) concerning a physiological or pathological process or state; (b) concerning congenital physical or mental impairments; (c) concerning the predisposition to a medical condition or a disease; (d) to determine the safety and compatibility with potential recipients; (e) to predict treatment response or reactions; (f) to define or monitoring therapeutic measures."

[55] Cfr. Medicine & Healthcare Products Regulatory Agency, *Guidance: Medical device*, 13.

[56] MDCG, *Guidance*, 23.

[57] Pursuant to Article 48 of the IVMDR Devices in Classes B, C and D do require a conformity assessment by a notified body. In addition, Rule 3 stipulates that *in vitro* devices are classified as class C if they are intended, *inter alia*, to be used in screening, diagnosis, or staging of cancer. For example, among the use cases listed in the technical specifications related to the advanced analytics for the Public Health System of Andalusia launched Red.es (Ref. [13]), the 'radiological imaging analysis to support breast cancer screening' is aimed at generating a pre-diagnosis in mammography images for breast cancer screening. This imaging analysis using AI would help identify which images should be studied by radiodiagnostic specialists with the highest priority. According to the specifications, the scope of the case

or expert systems intended to provide information for predicting predisposition to any specific disease by capturing and analysing multiple results obtained for one patient by means of *in vitro* examination of body samples, possibly combined with information from medical and non-medical devices[58] (e.g., Ref. [17]).

Where the intended purpose of the MDSW output data falls under both the definitions set out in the MDR and IVDR, a weighting of the data sources based on how determinant the information is to fulfil the intended medical purpose should be conducted to determine which Regulation applies to the MDSW.[59]

It is clear, then, that MDR and IVMDR apply to medical devices and *in vitro* MDSW, including AI-driven software. The examination of the tenders in the sample shows that certain contracts are classified as supply of medical-software packages (Ref. [20]) or medical-software development services [Ref. [5], [17], [20]).

Qualifying an AI system as a medical device triggers the application of number of obligations provided by the MD Regulations,[60] among others, the third-party conformity assessment and the CE marking. Some of the tenders in the sample, including the development of medical software based on AI, require the provision of mandatory CE marking of conformity (Refs. [5], [13], [20]).[61]

However, despite the long list of quality and safety requirements, many aspects specific to AI that may adversely impact on health are not addressed by the MD Regulations (e.g., continuous learning of the AI models, identification of algorithmic biases, transparency and explainability of complex models, trade-offs between performance and accuracy).[62]

4.3. *To be or not be a 'high-risk system': constraints associated with the in-house exception*

According to the risk approach followed by the AIA (unacceptable risk, high risk, limited risk, and low or minimal risk), AI systems identified as 'high-risk' are identified with those having a "significant harmful impact on the *health*, safety and fundamental rights of persons in the Union [emphasis added]". In particular, "in the health sector where the stakes for life and health are particularly high, increasingly sophisticated diagnostics systems and systems supporting human decisions should be reliable and accurate". Consistently, those risks generated by AI systems should be "duly prevented and mitigated".[63]

Considering the wording of the AIA, it appears that the EU legislator implies that AI

would end in the satisfactory statistical validation, "excluding any *potential requirements for homologation and CE marking necessary* for the systematic use of the tool in the healthcare field [emphasis added]". See Red.es, *Pliego de Prescripciones Técnicas que regirán la realización del contrato de "servicio para la implantación de una solución corporativa de analítica avanzada, basada en tecnologías Big Data, para el sistema sanitario público de Andalucía"*, 18 January 2021, 89, https://contrataciondelestado.es/.

[58] MDCG, *Guidance*, 22.

[59] *Idem*, 10-11, 24. For example, a given MDSW is designed to reduce ICU transfers, readmissions, adverse events and length of stay by generating a risk score to trigger care processes. By default, the risk score includes respiratory rate, heart rate, blood pressure and peripheral oxygen saturation (SpO2). However, a user can configure it to include other parameters, including results from *in vitro* diagnostic medical devices. The intended purpose of the device includes "concerning a physiological or pathological process or state (by investigation of this process or state)" (Article 2(2)(a) of the IVMDR); "to define or monitoring therapeutic measures" (Article 2(2)(f) of the IVMDR); "diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability" (Article 2(2) (h) of the MDR). In principle, the information provided by the MDSW and the intended purpose of the software are within the scope of the in vitro diagnostic medical device definition. Yet, the significance of the information derived from the medical device drives the intended purpose. This is because the data received from the *in vitro* diagnostic medical device are not considered to be determinative for the overall calculation result (output) achieved by the MDSW, resulting in the qualification of the software as an MD MDSW subject to the MDR.

[60] Among others, a stricter pre-market control, increased clinical investigation requirements, third-party conformity assessment with a view to the placing on the market or putting into service, reinforced and continuous monitoring across the device's lifecycle, and improved transparency.

[61] For example, in the ROSIA project (Ref. [20]), it was expected that some of the proposed solutions would fall within the scope of the MDR. Therefore, bidders were requested to describe, in their technical proposals, whether any of the elements had already been approved for conformity declaration. If not, they were asked to specify the stage at which they were in the process of obtaining approval. See Instituto Aragonés de Ciencias de la Salud, *ROSIA. Tender Forms Call for Tender Phase 2. Technical Specifications,* Docket No. PHASE 2 ROSIA PCP 101017606, 1 February 2023, 13, https://contrataciondelestado.es/.

[62] Cfr. K. Lekadir *et al*., *Artificial intelligence in healthcare*, 30.

[63] Recitals (27) and (28) of the AIA. Both the Council and the Parliament's versions retain the same wording as the AIA on this point.

systems deployed and used in healthcare are likely to be qualified as inherently 'high-risk systems.' Simply put, many AI tools that qualify as MDSW under the MD Regulations would also be considered 'high-risk systems' pursuant to the AIA.[64] This interpretation is supported by some scholars.[65]

However, a careful examination of the interplay between the MD Regulations and the AIA shows that some MDSW, in principle qualified as medical devices or *in vitro* diagnostic medical devices, would fall out of the scope of Article 6 of the AIA.

While a case-by-case analysis would be necessary, pursuant to Article 6 of the AIA, high-risk systems would comprise:
(i) AI systems qualified as MDSW under the MD Regulations, provided that they are subject to a third-party *ex-ante* conformity assessment[66] –Article 6(1)(a) and (b);
(ii) Certain stand-alone AI systems listed in Annex III of the AIA, in particular, those AI systems which evaluate or condition access to and enjoyment of public services and benefits[67] – Article 6(2).

Both "high-risk" classification rules in Article 6 of the AIA call for further clarification to determine the applicability of the horizontal requirements (Articles 9-15) and obligations (Articles 16-29) laid down in the AIA.[68]

From a public-procurement perspective, the criterion of an *ex-ante* third-party conformity assessment under the MD Regulations would significantly reduce the number of AI-driven MDSW that would qualify as 'high-risk' systems, regardless of their adverse impact on health.

Essentially, by exempting MDSW from the *ex-ante* conformity-assessment obligation, the application of the 'in-house exemption' implies removing one of the *concurring conditions* laid down in Article 6(1)(b) of the AIA to qualify an AI system as 'high-risk'. Consequently, if one of the substantive conditions is not met, then the medical device would not qualify as a 'high-risk' system.

The in-house exemption applies to medical devices that are manufactured and used within the same EU health institution[69] on a non-industrial scale to address specific needs of target-patient groups which cannot be met at the appropriate level of performance by an equivalent CE-marked device available on the market.[70]

Except for the relevant general-safety and performance requirements specified in Annex I of the MDR and the IVDR, in-house medical devices are exempt from most provisions of the Regulations, including conformity-assessment procedures.[71] Article 5(5) of both

[64] Cfr. K. Lekadir *et al*., *Artificial intelligence in healthcare*, 31, finding that "[i]t appears that many medical AI tools, especially those that are autonomous, will be categorised as high-risk."

[65] See H. Van Kolfschooten, *EU regulation of artificial intelligence: challenges for patients' rights*, in *Common Mark. Law Rev*. 59(1), 81–112 (2022), http://dx.doi.org/10.2139/ssrn.3997366. The author found that "'[h]igh risk' includes AI-systems that are intended to be used in products regulated at the EU level as listed in Annex II, including the MDR. This means that all medical devices that fall under the MDR are classified as 'high risk' under the AIA."

[66] Recitals (30) and (31) of the AIA.

[67] See, in particular, Annex III (5) (a) and (c) of the AIA.

[68] On the one hand, Articles 9-15 of the AIA set forth a list of requirements in relation to quality of data sets used, technical documentation and record-keeping, transparency and the provision of information to users, human oversight, and robustness, accuracy and cybersecurity. On the other hand, Article 24 would apply to product manufacturers of medical devices imposing on them the obligations set out in Articles 16-23 (putting in place a quality management system; drawing-up the technical documentation; recording of automatically generated logs; undergoing the relevant conformity assessment procedure; taking corrective actions where necessary; registration of the high-risk AI system in the EU database; duty of information and cooperation with the national competent authority; affixing CE marking), while Article 29 lists the obligations applicable to users of high-risk AI systems (use of the AI system in accordance with the accompanying instructions of use, implementation of the human oversight measures indicated by the provider, ensuring the relevance of the input data in relation to the intended purpose, monitoring the operation of the system, keeping the logs automatically generated, use of the information resulting from the transparency obligation laid down in Article 13 to conduct data protection impact assessment under the GDPR or the Directive 680/2016).

[69] A "health institution" is an organisation the primary purpose of which is the care or treatment of patients or the promotion of public health. Health institutions include hospitals, as well as laboratories and public health institutes that support the health-care system and/or address patient needs, but which do not treat or care for patients directly. The concept does not cover establishments primarily claiming to pursue health interests or healthy lifestyles (gyms, spas, wellness and fitness centers). See Recitals (30) and (29), and Articles 2(36) and 2(29) and 36 of the MDR and IVMDR, respectively.

[70] Recitals (30) of the MDR and 29 of the IVMDR.

[71] Some of the mandatory requirements laid down by the MDR and IVMDR for placing on the market or putting into service MDSW qualified as medical device or *in vitro* diagnostic medical device comprise, transparency and traceability obligations, classification of devices, conformity assessment procedures and CE marking, clinical investigations and clinical evaluation, vigilance

MD Regulations establishes the conditions to which health institutions must adhere to in order to apply this exception.[72]

Outside the scope of Article 5.5 of the MD Regulations are medical-device applications that allow patients to use the application outside the health institution. For example, patients may enter or access medical data that are subsequently used by healthcare professionals.[73] This could be the case of applications used in telemedicine, telemonitoring or telerehabilitation of patients. In this respect, some telemedicine platforms (e.g., Refs. [5], [20]) require the CE marking of conformity.

However, it is unclear whether the concept of "in-house devices" refers only to medical devices manufactured by the health institution on its own right, or includes also medical devices whose manufacture has been outsourced to a supplier through public-procurement procedures.[74]

The procurement practices of the National Health Service (NHS) in the United Kingdom may provide some insight into this particular issue. According to the NHS Guidelines, when AI-driven MDSW to be procured by the NHS consists of a COTS solution, then it will meet the two conditions (component or system covered by relevant Union-harmonisation legislation and mandatory undergo of a third-party conformity assessment) to be qualified as a 'high-risk system.' In contrast, if the AI-driven MDSW is a bespoke solution, then it will apply the *in-house* exception and, no conformity assessment will be required.[75]

In addition, Article 5(5) of the MD Regulations allows Member States to restrict the manufacture and the use of any specific type of such devices, some national legislations have constrained the scope of the in-house exception. Accordingly, in Spain, Article 9 of the Royal Decree 192/2023, of 21 March, governing medical devices, establishes that manufacture of devices by healthcare institutions for the exclusive use of the institution itself may only be carried out by healthcare institutions legally qualified as hospitals. In addition to this exclusion of healthcare institutions other than hospitals, the Spanish regulation prohibits the "subcontracting" of any of the manufacturing activities of medical devices and excludes Class IIb, Class III and implantable devices from the scope of Article 5.5 of the MDR.

Together with AI medical software subject to the MD Regulations, the AI systems described in Annex III of the AIA are qualified as 'high risk' systems. These stand-alone systems may include specific applications in health, in particular, AI systems intended to be used by public authorities or on behalf of public authorities in the area of healthcare to evaluate the eligibility of natural persons for public-assistance benefits and services, as well as to grant, reduce, revoke, or reclaim such benefits and services, or to dispatch, or to prioritise the dispatching of emergency first-response services, including medical aid.[76] The

and market surveillance, continuous documentation and update of risk and quality management systems. Conformity assessment procedures are regulated in Articles 52-60 of the MDR and 48-55 of the IVMDR.

[72] The obligations under Article 5(5) of the MD Regulations include the prohibition to transfer the in-house medical device to another legal entity and industrial scale manufacturing, justification that the specific needs of a target patient group cannot be met (with the appropriate level of performance) by an equivalent device available on the market of CE-marked devices, appropriate documentation relating to the design and manufacture of the device at the disposal of a competent authority, public declaration that the applicable general safety and performance. requirements are met, implementation of an appropriate quality management system (QMS), and follow-up and reporting of incidents and corrective actions.

[73] MDCG, *Guidance*, 7.

[74] Idem, 5-6, define how the term 'manufactured' is to be understood, but does not clarify whether the manufacture must be carried out exclusively by the health institution with its own human and material resources, or whether the term 'manufactured' can also include a supplier on behalf of the health care institution using the legal instruments provided by national legislation (e.g. public procurement, administrative agreements, public-private partnerships).

[75] Cfr. NHS, *A buyer's guide*, 20, 24. The NHS guidance is aimed at the public procurement of 'off-the-shelf' AI applications, i.e. products packaged by suppliers as ready to use, which are required to meet CE marking requirements *ex ante*. The guidance clearly excludes bespoke projects, which may include *in-house* manufactured devices outside of the MD regulations.

[76] The amendment of the European Parliament to the provisions contained in Annex III (a) and (c) clarifies the scope of application to healthcare field. According to the Parliament, Annex III (a) of the AIA should read as follows: "(a) AI systems intended to be used by or on behalf of public authorities to evaluate the eligibility of natural persons for public assistance benefits and services, *including healthcare services* and essential services [emphasis added]. In addition, Annex III (c) should say: "(c) AI systems intended to evaluate and classify emergency calls by natural persons or to be used to dispatch, or to establish priority in, the dispatching of emergency first response services, including by police and law enforcement, firefighters and medical aid, as well as of *emergency healthcare patient triage systems* [emphasis added]."

amendments of the Parliament to these provisions explicitly include those AI-systems to evaluate the eligibility of natural persons for "healthcare services" and "emergency healthcare patient triage systems".

This would be the case of the expert system procured by the Regional Government of Valencia which classifies according to the risk severity of the incident the healthcare demand for emergencies, out-of-hospital emergencies and medical calls to emergency number 112 using ML/DL techniques (Ref. [8]), or the AI-based decision-support system acquired by EGARSAT, an auxiliary entity of the Social Security, for predicting the duration of sickness absence due to illness or accident which could affect social security benefits or even trigger administrative sanctions if fraudulent patterns are detected (Ref. [12]).

Even if AI systems acquired for the NHCS qualify as high-risk systems falling under the conditions of Article 6 (qualification as medical device subject to a third-party conformity assessment pursuant to the MD Regulations or stand-alone systems listed in Annex III), there would still be many other AI applications posing risks to life and health that could otherwise fall outside such a qualification. This classification means that AI-systems in healthcare that do not fall under Article 6 are formally considered to "pose 'limited risk' and therefore [are] minimally regulated under the AIA", although they may still have adverse effects on human health.[77]

This is exemplified by personal-assistant systems, like the advanced system called AVATAR procured by the Regional Health Service of Galizia (Ref. [10]),[78] which generates alerts for both patients and health professionals based on risk patterns identified by AI systems. False alerts or a lack of alert/response resulting from erroneous interpretation of risk patterns by the AI system could have adverse consequences for patients.

However, exemptions –as those illustrated above– from the stricter regime provided by the AIA for high-risk systems would clearly contradict the wording of Recital (28) of the Proposal.[79]

5. *AI solutions for NHCS in the context of innovation procurement*

While digitisation and digitalisation[80] are prerequisites for AI applications, this data-driven technology is a further step in digital transformation. AI is reshaping organisations and augmenting organizational innovation[81] through the introduction and implementation of new or significantly-improved goods, services, methods or organisational practices.

In particular, AI involves a "transformational potential" for healthcare services, by "supporting diagnostic decisions, predicting care needs, informing resource planning, and game-changing research".[82]

[77] See Van Kolfschooten, *supra* cited.

[78] According to the technical specifications, the advanced personal assistant includes:
User interfaces enabling patients to receive information adequately from health professionals and the health system.
A module that integrates automated devices for collecting events related to physiological parameters, movement, displacement, or behavior of patients within the autistic spectrum, those with visual or hearing difficulties, or neurodegenerative diseases. The most relevant variables identified for triggering immediate alerts and/or actions include heart rate, arrhythmias or cardiac arrest, sleep rhythm, loss of consciousness, convulsive crises, and time-distance control (geolocation of the patient and monitoring distance from specific points like home or residence).
Advanced functionalities utilizing AI techniques, along with facial, postural, and voice recognition systems for detecting physiological and/or behavioral patterns. These patterns can be correlated with event information and existing data in health center information systems, such as medical records.
A module capable of generating alerts and individualized warnings for patients, caregivers, and professionals based on identified patterns associated with high-risk situations.

[79] In relation to the classification of an AI system as high risk, Recital (28) of the AIA says: "AI systems could produce adverse outcomes to health and safety of persons, in particular when such systems operate as components of products […] Similarly, *in the health sector where the stakes for life and health are particularly high, increasingly sophisticated diagnostics systems and systems supporting human decisions should be reliable and accurate*. The extent of the adverse impact caused by the AI system on the fundamental rights protected by the Charter is of particular relevance when classifying an AI system as high-risk [emphasis added]."

[80] Digitization is the process of changing information from analogue to digital form, and digitalization is the processes which involves the application of digital technologies to a wide range of existing tasks and enable the performance of new tasks, and include both the innovation process itself and a key driver of innovation. Katuu, Shadrack, *Management of public sector records in the digital age*, 2022, 2, Doi:10.13140/RG.2.2.25539.48163; Oslo Manual, 38.

[81] N. Haefner, J. Wincent, V. Parida and O. Gassmann, *Artificial intelligence and innovation management: A review, framework, and research agenda*, in *Technological Forecasting and Social Change*, vol. 162, 2021, 3, https://doi.org/10.1016/j.techfore.2020.120392.

[82] NHS, *A buyer's guide*, 5.

Because of this transformative nature, the public procurement of AI-driven solutions can be easily placed in the context of *public procurement of innovation*.

On the one hand, *innovation* consists of "a new or improved product or process (or combination thereof) that differs significantly from the unit's previous products or processes and that has been made available to potential users (product) or brought into use by the unit (process)".[83] In a nutshell, an innovation is a new idea or invention that has been implemented and launched (or is in the process of being launched) on the market.[84]

On the other hand, the public procurement of innovation refers to any procurement that has one or both of the following aspects: (i) buying the process of innovation – research and development services – with (partial) outcomes; (ii) buying the outcomes of innovation. In this process, the public buyer first describes its needs, thereby stimulating suppliers to develop innovative products, services or processes not yet on the market. Then, the public buyer acts as an early adopter and acquires a product, service or process that is new to the market or has substantially new features. Finally, the innovation fostered by AI may disrupt the existing ecosystem "by creating different actors, flows and values (disruptive innovation)", or it may even require a deeper transformation "involving structural or organisational reforms (transformative innovation)" if unmet needs arise.[85]

There is no general definition of healthcare innovation that covers all the legal, operational and clinical aspects of assessing the innovative nature of a device or product. The most relevant notion to qualify a healthcare innovation would appear to be: "the satisfaction of an unmet medical need". In the R&D phase, a healthcare product (a medical software) or procedure is considered innovative when it presents a novelty other than a simple technical evolution in relation to the existing healthcare technologies, making it possible to satisfy an unmet medical need. In the commercialization phase, new or significantly improved supplies or services are considered innovative. In addition, innovation procurement could target services relating to organizational innovation in patient care, quality of life for carers and caregivers, and the environmental footprint of healthcare products.[86]

Procurement can be used strategically to support the adoption of AI across government and rip off the benefit from economies of scale in the deployment of AI technologies.[87]

Obwegeser and Müller have provided a three-tiered classification to capture the relationship between innovation and public procurement: (1) public procurement for innovation (PPfI); (2) public procurement of innovations (PPoI), and (3) innovative public procurement (IPP).[88]

[83] OECD and Eurostat, Oslo Manual 2018: Guidelines for Collecting, Reporting and Using Data on Innovation. The Measurement of Scientific, Technological and Innovation Activities, 4th Edition, OECD Publishing, Paris/Eurostat, Luxembourg, 2018, 20, https://doi.org/10.1787/9789264304604-en. The OECD definition contains two key aspects: the innovation can cover both an activity and the result of the activity; and, the term "unit" describes the agent responsible for the innovation. See also Article 2(22) of the Directive 2014/24/EU which defines "innovation" as "the implementation of a new or significantly improved product, service or process, including but not limited to production, building or construction processes, a new marketing method, or a new organisational method in business practices, workplace organisation or external relations inter alia with the purpose of helping to solve societal challenges or to support the Europe 2020 strategy for smart, sustainable and inclusive growth".

[84] Observatoire Économique de la Commande Publique, *Guide Pratique. Achat Publique de Innovant*, Miniestère de l'Économie et des Finances, 2020, https://www.economie.gouv.fr. Therefore, an innovation must be distinguished from an invention by its operational nature: the innovation is about to be or has just been commercialised. At the crossroads between inventions and commercialised products is the work of Research and Development (R&D), which corresponds to all activities relating to fundamental research, applied research and experimental development, including the creation of technological demonstrations, with the exception of the creation and qualification of preproduction prototypes, tooling and industrial engineering, industrial design and manufacturing.

[85] European Commission, *Guidance on Innovation Procurement* (C(2021) 4320 final), Brussels 18 June 2021, 5.

[86] Ministère de la Santé et de la Prévention, *Guide opérationnel de l'acheteur d'innovation en santé. Préparer, contractualiser, exécuter, reporter les achats d'innovation en santé*, version 0, January 2023, 7, https://sante.gouv.fr.

[87] UK Guidelines, 13.

[88] N. Obwegeser and S.D. Müller, *Innovation and public procurement: Terminology, concepts, and applications* in *Technovation*, vols. 74-75, 2018, 4-5, https://doi.org/10.1016/j.technovation.2018.02.015. As to the authors, PPfI includes the use of public procuring by contracting authorities as a demand-side tool to drive innovation, i.e. as a part of innovation public policies; PPoI refers to the use of public procurement to innovate public services; and IPP is identified with models of innovative and ICT-enabled public procurement. While the third approach emphasises the potential uses of AI

By extrapolating these taxonomies into our analysis, a distinction can be drawn between public procurement as a demand-side tool to drive innovation for healthcare systems through AI (PPfAI), and public procurement of AI-enabled solutions to innovate NHCS (PPoAI).

Innovation-procurement strategies, i.e. public procurement of innovative solutions (PPI) and pre-commercial public procurement (PCP), can be placed under the umbrella of PPfI (Refs. [7] [11], [16], [17], [18], [20]), whereas the procurement of AI to enhanced and improve public-health services relates to PPoAI (Refs. [4], [5], [6], [8]-[10], [12], [15], [19]).

5.1. *Open-market consultations*

Considering the evolving and ever-changing nature of the market, the innovative dimension of the procurement decision to acquire AI software or apps for the NHCS, whether classified as medical devices or not, may face constraints due to a potential lack of comprehensive knowledge regarding existing solutions that are suitable to meet public needs.

By collaborating closely with companies, contracting authorities can verify that their criteria for quality, cost, deadlines, environmental and social performance are in proportion to the capacities and constraints of the sector concerned, and mitigate the risk of mismatches between supply and demand, thus reducing the likelihood of excessive costs, poor quality, or unsuccessful bids. [89]

Open market consultations (OMC) can help the contracting authority to determine whether potential innovations may satisfy the public need to be met and to identify potential vendors within a certain sector of the market.

In this sense, Article 40 of Directive 2014/24/EU allows contracting authorities to seek advice from independent experts or market participants. However, this should be done in a manner that avoids distorting competition and ensures compliance with the principles of non-discrimination and transparency. Moreover, in OMC on innovative procurement, the guarantee of confidentiality constitutes an insurmountable barrier.[90]

Therefore, conducting OMC could be a crucial strategy in innovation procurement in general and in AI for the healthcare sector in particular. National health services, with the assistance of the discussed multidisciplinary teams, should advocate for the adoption of an AI solution only if it proves to be the most suitable option for their requirements and after thorough assessment of all associated implementation risks.

In essence, the primary objective of conducting an OMC is to assess the state of the art before starting a procurement procedure in order to gain a comprehensive understanding of the relevant market. Preliminary market consultation allows the public buyer to achieve several key objectives:[91]

- To uncover creative ideas from the market;
- To define the conditions for addressing the challenge at hand;
- To foster opportunities for collaboration among market entities and with public buyers;
- To assess the organization's readiness to address opportunities and risks associated with innovation;
- To define and refine the subject-matter of the contract, including the best terms and conditions governing it.

There is no one-size-fits-all method for conducting market consultations. In certain instances, public purchasers may possess sufficient knowledge and only require clarifications or updates, while in other scenarios, more extensive research or analysis may be necessary to determine the appropriate definition of the AI solution to be procured.

Considering the substantial technical expertise demanded by both AI and the healthcare sector, OMC plays a crucial role in helping public purchasers determine the suitability of an AI approach. This involves evaluating the accessibility of relevant and representative data or the need to establish appropriate governance mechanisms for data management and sharing. Additionally, OMC

to innovate the procurement process (which is beyond the scope of this paper), the first and the second ones are very useful taxonomies for analysing the current state of art of the public procurement of AI-enabled solutions in the NHCS.

[89] Observatoire Économique de la Commande Publique, *Guide Pratique*, 10.

[90] M. Mesa Vila, *Fases de las licitaciones de compra pública de tecnología innovadora*, in *La compra pública de innovación en la contratación del sector privado*, J.A. Carrillo Donaire (coord.), INAP, Madrid, 2019, 55-56.

[91] C(2021) 4320 final, 38.

may help to identify core aspects of the technical specifications, such as data-quality requirements, bias avoidance, expected accuracy and performance levels, appropriate metrics, determination of use cases, maintenance and update obligations, compliance with technical standards, measures to ensure an ethical approach, milestones and deliverables, profile and skills of the teams in charge of the performance of the contract, etc.

Some tenders in the sample illustrate how PPI and PCP tenders are usually preceded by OMC.

For example, in the context of the third call of the FID Health Program by the Ministry of Science and Innovation (2019), the Health Department of the Autonomous Community of Madrid presented three projects for Public Procurement of Innovation that were favourably selected in November 2019, and received a 50% grant from the Pluri-regional European Regional Development Funds (ERDF) from the Spanish Ministry of Science and Innovation. The three Projects covered:

- MEDIOGENOMICS: Platform and expert system built on a SaaS approach, allowing the generation of clinical reports from raw genomic data from healthy/sick individuals, continuously updated to the state of the art, through the integration of AI-based software, to improve the efficiency and effectiveness of diagnosis, reducing time and sample handling.
- INTEGRA-CAM: A platform that enables home monitoring and follow-up of the intrinsic capacity of elderly people for early detection of disability or dependency situations, integrating patients, caregivers and healthcare professionals (primary and specialised care).
- INFOBANCO: Regional data-network architecture (Data Lake) enabling the collaborative exploitation of health data (clinical, research, and administrative) from various sources (primary care, hospitals, emergencies, pharmacy) to improve healthcare and innovation, value-based healthcare (VBHC), biomedical research, and other secondary uses.

The tendering of contracts INFOBANCO (Ref. [16]) and MEDIOGENOMICS (Ref. [17]) through their respective PPI procurement calls was preceded by a market consultation.

Market consultations in INFOBANCO and MEDIOGENOMICS Projects

Objectives of the OMC

- Receive proposals and innovative solutions that identify, specify, and evaluate both market needs and capabilities to delve into detailed solutions and proposals, leading to innovative and sustainable developments to achieve the goals set in each of the projects.
- Acquire sufficient knowledge about market capabilities and functional specifications that involve innovation and are feasible to be achieved through a potential Public Procurement of Innovation.
- Inform economic operators about the plans of the Health Department and the requirements they will be demanded to participate in the processes.
- Define the technical and administrative specifications for future PPI tenders.

Method and procedure:

- Publication of the call on the website of Health Department.
- Workshops and seminars with interested participants (more than 200 attendees). Presentation of the projects and questions from the participants.
- Participants had to fulfill a questionnaire describing their proposals, their elements of innovation (new technologies and innovative solutions), R+D expected outcomes, Technology Readiness Level (TRL) of the proposed solutions, intellectual-property-rights (IPR) limitations.
- Reception of the proposals in the time limit stipulated in the call.
- Interviews with some proponents to obtain further clarifications of the proposal in accordance with two relevant criteria: the functional approach and degree of innovation of the proposals.
- Examination of the proposals by an expert panel.

Common conclusions to be considered when drafting tender specifications:

- There were various solutions based on existing technology, although they did not fully meet the needs outlined and required by the Health Department. Therefore, innovative development was required to address the specific challenges of the three projects.
- The innovation proposals presented had an initial development ranging between TRL 6 and TRL 7, making the most suitable option to initiate a Public Procurement of Innovative Technology for the projects.

- Governance and data security were crucial points in all the projects due to their private and clinically-sensitive nature. Therefore, future specifications should consider compliance with GDPR, consent management, traceability systems, access, and related policies. - In relation to IPR, it was found that the model best suited to the projects was for the entity to keep the exclusive rights over the pre-existing base products provided by the entities under the contract. However, the IPR for any additional developments within the framework of the contract would be exclusive to the Health Department or shared between the Health Department and the entity.

Table 5. Open market consultations in innovation procurement for healthcare

5.2. *PPI and PCP strategies*

Where research and development (R&D) services are to be procured with a view to developing an innovative custom solution, public-health services will be able to procure research and development.

In cases where the public buyer retains exclusive rights to the benefits arising from R&D, including intellectual and property rights (IPR), the procurement of research-and-development services would fall within the scope of the public-procurement Directives. In turn, when the public buyer does not reserve all the benefits of the research and development services, such acquisitions would be exempt from the public-procurement Directives.[92] The first approach is PPI and the second is PCP.

As innovation procurement constitutes an administrative action to enhance R&D+i, implementing innovation-procurement strategies that combine PCP and PPI in a complementary way, public purchasers can drive innovation from the demand side.[93]

On the one hand, exempt from the application of public-procurement rules, PCP is characterised by competitive development in phases, risk-benefit sharing under market conditions, and separation from the deployment of commercial volumes of end-products/services.[94] It follows from the characterisation of PCP that this approach is used in those areas where existing solutions on the market do not meet a public buyer's needs.[95]

On the other hand, the deployment of commercial volumes of newly developed products and services would fall under the scope of the PPI. Consequently, PCP and PPI are complementary approaches.

PPI involves acquiring innovative solutions that do not require further R&D but are not yet available on a large-scale commercial basis. Nevertheless, they can be developed within a reasonable period of time, allowing for public-health services to perform compliance testing. In PPI, public purchasers act as early adopters or first buyers of innovative commercial end-solutions newly arriving on the market. It is also the best way to drive innovation and efficiency in public services. Hence, PPI involves the purchase of prototypes or the first complete products or services developed after the R&D phase, their testing and evaluation in order to select the best option before the final full-scale

[92] C(2021) 4320 final, 55.

[93] J.A. Carrillo Donaire and J. Tarancón Babío, *Concepto, sentido, objetivos y perspectivas de la compra pública de innovación*, in *La compra pública*, 17-19.

[94] Commission of the European Communities, *Pre-commercial Procurement: Driving innovation to ensure sustainable high quality public services in Europe*, COM(2007) 799 final, Brussels 14 December 2007; Pre-Commercial Procurement, Digital Strategy, last update 7 June 2022. https://digital-strategy.ec.europa.eu/en/policies/pre-commercial-procurement. In the first place, in PCP contracting authorities acquire R&D services from multiple competing suppliers simultaneously. This allows the comparison of alternative solution approaches and the identification of the most cost-effective solutions available in the market to meet the public needs. The R&D process is divided into phases, including solution design, prototyping, original development, and validation/testing of a limited set of initial products. The number of competing R&D suppliers decreases after each phase. Engagement in the initial phases of the R&D process allows public purchasers to identify potential policy and regulatory issues at an earlier stage. In the second place, risk-benefit sharing under market conditions is a key aspect of PCP. The risks (costs) and benefits (results) of the contract, including Intellectual Property Rights (IPRs) are shared between the public purchaser and companies under market conditions. This risk-benefit sharing encourages both parties to pursue widespread commercialization, the uptake of new solutions, standardization, and the publication of R&D results, thereby reducing the fragmentation of public demand. Finally, PCP is limited to the development and purchase of a restricted volume of initial products or services. This limitation is imposed because, in a service contracts like PCP, the total value of acquired supplies must remain below 50% of the overall PCP contract value. As PCP focuses on research and development, it does not encompass large-scale production for commercial volumes of end-products.

[95] C(2021) 4320 final, 56.

purchase.[96]

Depending on the specifications inherent to each product or service, PPI can be organized through regular procedures (open or restricted) and special procedures (negotiated tender, competitive dialogue, and partnership for innovation).[97]

Tenders in the sample show that both approaches have been used in the procurement of AI solutions for the NHCS. While PPI procurements were conducted in relation to contracts, PCP [11], [16], [17] was the strategy followed in [7], [18] and [20].

In the ROSIA project (Remote Rehabilitation Service for Isolated Areas), three public purchasers from Spain, Portugal and Ireland jointly sought the development of a comprehensive rehabilitation service enabling service providers to provide telerehabilitation, and self-management of rehabilitation & self-care at home, with a focus on remote areas by engaging patients and caregivers. To achieve this goal, the procurement process was preceded by an OMC seeking to collect comprehensive and detailed information related to existing experience, knowledge, solutions, budgetary constraints, and to provide feedback on the future PCP scope and phases.[98]

The project was divided into phases, which were further delineated across three consecutive PCP calls. Reference **[20]** in Annex II corresponds to Phase 1 of the entire project. Tender specifications included AI approaches, virtual reality and IoMT.[99]

The three PCPs in the ROSIA Project

The context

Contracting authorities participating in ROSIA were in urgent need of reorganising their rehabilitation services. The are tools already available in market, such as AI, virtual reality, augmented reality, gamification, depth cameras, sensors and IoMT, which have proven clinically effective in supporting telerehabilitation.

The challenges

However, telerehabilitation is a complex process:

- For the healthcare system. On the one hand, it implies an internal process of transformation towards specifically-tailored integrated-care models. On the other hand, handling the transference of sensitive data and integrating a large and diverse set of digital therapeutics into their own ICT systems.
- For developers. They face fragmented-care models, lack of prescribed procedures, and the diversity of ICT health systems to integrate. The costs of development are prohibitive.
- For patients. While having a significant impact on patients' lives and on their medical conditions, rehabilitation processes may have negative side effects on patients' lives when patients are forced to travel long distances to specialist rehabilitation centers (as is the case of patients living in remote and depopulated areas).

The PCP: unlocking tele-rehabilitation market

In this stand-off, a PCP process, where public procurers work in direct collaboration with the research capacity of the market, is in a unique position to unlock the situation.

ROSIA PCP was seeking to unlock the telerehabilitation market by purchasing the

[96] *Idem*, 58.

[97] J.A. Carrillo Donaire *et al*., *Concepto, sentido, objetivos*, 35.

[98] See Instituto Aragonés de Ciencias de la Salud, *ROSIA OMC Report,* PLACE, 31 March 2022, 33-39, 113, 117, available at https://contrataciondelestado.es/. Among the value-added proposals presented, some participants showed expertise on the application of AI in health status to support remote assessment and monitoring of physical function, prediction of falls and frailty, including neurorehabilitation tools based on virtual reality with AI tested in real environment with real patients; the development of AI medical devices with CE marking, or accountable AI. The OMC final Report made some recommendations for the future PCP in relation to:
Technology Readiness Level (TRL): The project was expected to start with a TRL of 5-6 and end with a TRL of 8-9.
Technological elements: ROSIA would be an open platform with trusted layers where services could share data, analysis and targeted interventions. As integration with the public health IT systems of three different countries is complex, the tender specifications should include the development of a sandbox that would allow a minimum set of data from the health systems of the three purchasers to be made available during the project to implement integrated care models.
Certification pathway: The tender specifications would include the implementation of a certification process for applications and devices included in the ROSIA catalogue, in line with the MDR.
IPR: While companies that were more reluctant to grant purchasers a free user licence seemed to have a better understanding of the clinical reality behind the ROSIA challenge (42%), those that promoted more open approaches seemed to require more clinical knowledge (58%). It was therefore recommended that representatives of both approaches should compete in ROSIA PCPs to compare outcomes, timescales and budgets.

[99] Instituto Aragonés de Ciencias de la Salud, *TD1-Request for tender*, PLACE, 11 May 2022, 17-31, *TD2 - Challenge Brief*, PLACE, 11 May 2023, 31-54, both available at https://contrataciondelestado.es.

development of a technological innovation ecosystem, enabling service providers to provide telerehabilitation, and self-management of rehabilitation & selfcare at home, at scale.
The ecosystem's design would allow flexible implementation of a value-based and integrated-care model, data driven intervention and the integration of third-party solutions.
The PCP proposed that the ROSIA Innovation Ecosystem be composed of three core elements that the 3 public purchasers could share across region:
- **ROSIA Open Catalogue**: A menu of evidence-based safe certified ICT solutions and services to be prescribed by a care team. All these services will allow the seamless sharing of clinical data with patients' consent.
- **ROSIA Developer Layer**: The development of architecture and layer for developers with open API's & governance tools to facilitate apps and services that uniformly can plug into the diverse backends of the buyer's regional infrastructures. This layer was expected to allow developing solutions based on existing modules and will aid existing research projects in becoming market solutions.
- **ROSIA Open Platform**: An open cloud-native platform to host shared services, communication, and manage Integrated Clinical Care Pathway builders, ePROM/ePROM protocol editor, data sharing, analytics, consent, login, business logic and other core shared services. The cloud platform could be provided privately or publicly as long as it complies with the ROSIA governance defined in the technical specifications (best practices and standards, openness, handover & education for each region, maintenance and updating).

The ROSIAS's PCPs
The project was split into three phases corresponding to consecutive PCP calls.
- **Phase 1. The solution design (PCP's Docket No. ROSIA PCP 101017606).** The selected contractors were asked to provide a solution design (architecture and components), including the governance approach; to determine the approach to be taken to develop ROSIA solution and/ or services needed, and to demonstrate the technical, financial; and commercial feasibility of the proposed concepts and approach to meet the procurement needs.
- **Phase 2. Prototyping (PCP's Docket No. PHASE 2 ROSIA PCP 101017606)**: In a first stage, the development, demonstration and validation under laboratory conditions of non-or-partial prototypes of key system components should take place. In a second stage, the prototypes would be designed as functional prototypes and would be expected to demonstrate component behaviour and system-wide interaction.
- **Phase 3. Field-testing (PCP's Docket No. PHASE 3 ROSIA PCP 101017606)**: In this final Phase, the prototypes would be used in the provision of care remotely, the Open Platform would seamlessly communicate to all enrolled users and to report and manage care for test individuals and selected pathologies. The validation of the ecosystem readiness with healthcare professional and patient users would include the deployment of sandbox-testing tools matching procurers ICT systems setting.

Table 6. Pre-commercial Procurement of AI for healthcare

5.3. *Choosing the appropriate procurement procedure for innovation*

The European Commission Guidelines on innovation procurement recommend public purchasers to use procurement procedures that do not prescribe a specific solution, but rather describe problems and needs, leaving room for suppliers to propose alternatives.

Therefore, the procurement of AI-driven solutions for healthcare should not be straightforward. The objective is not simply to obtain standardized products that align with conventional-procurement procedures, such as the open procedure, or the selection of the most economically-advantageous offer solely based on the economic criterion of price.[100]

Instead, there is a need for the adoption of more innovative procedures where the purchased solution is not rigidly defined in the specifications. In such cases, criteria such as quality and, notably, the ethical considerations of AI implementation could carry significant weight in the selection process for determining the most economically-advantageous offer.[101]

In consequence, to secure AI systems aligned with the public needs of the NHCS, public-health systems should employ "innovation friendly procurement procedures" (competitive procedures with negotiation,

[100] C(2021) 4320 final, 25.
[101] *Idem*, 42-44.

competitive dialogue, innovation partnerships)[102] when, for example, the needs of the contracting authority cannot be met without adaptation of readily available solutions or they include design or innovative solutions.[103] These procedures can facilitate the integration of new technologies, incorporate provisions for testing and prototyping before final procurement commitments, and foster collaboration among various bidders or encourage market participation in the exploration of alternative solutions.

If procedures that enhance market engagement or allow for contact and collaboration between procurers and bidders are inherent to the procurement of innovation, then open and restricted procedures should be discarded when procuring AI-driven innovative solutions.

Upon reviewing the tenders in the sample, the open procedure[104] emerges as dominant, having been applied in all (Refs. [1]-[4], [6]-[8], [12]-[20]) but four instances (Refs. [5], [10]-[11]). Regardless of the innovative nature of the AI-driven solutions or the lack of readily-available solutions in the market to meet specific needs, it is clear that the open procedure is the option preferred by public purchasers.

While special procedures (procedures with negotiation, competitive dialogue, innovation partnerships) are better suited to innovation procurement, the clear preference of purchasers for the open procedure may be due to the greater legal certainty and control over deadlines and timing on the one hand, and the lower complexity, duration and fewer resources needed on the other.[105]

All specific procedures in the sampled tenders have been utilized, except for the innovation partnership.

Leaving aside the risks of vendor lock-in or the fact that the continuous learning of some AI models could change the intended purpose of the contract, open procedures may work better for standardised products available in the market. However, this will not be the case for many of the contracts in the sample, as the public needs to be met are associated with specific use cases for which the market has not yet provided COTS solutions. The call for tender launched by Red.es is an example of application of AI solutions to use cases pre-defined by the tender specifications (Ref. **[13]**).[106]

AI solutions for 15 use cases in the Healthcare System of Andalucia

The context

As part of the Primary Care Renewal Strategy, the Andalusian Health Service (SSPA) developed a Population Health Database with traditional analytical capabilities.

The challenge

The SSPA aimed to apply advanced analytics with AI, including ML and DL approaches, to enable massive-information exploitation from the Population Health Database and overcome the technological limitations of the traditional Business Intelligence environment.

The use cases described in the technical specifications

It was expected that the prospective contractor would provide an on-premise software and hardware platform with the capability to hybridize with the cloud. This platform is intended for the development and deployment of AI-driven solutions, to be applied in at least 13 use cases listed below:

1. Defining factors that influence morbidity and predicting associated future health risks.
2. Designing optimal pathways and personalisation in the provision of health services.
3. Optimising the distribution of quotas in primary care based on the frequency of visits, the time spent per visit, the complexity of visits and/or patients, the number of pathologies or chronicity.
4. Segmenting chronic patients, across a pre-defined population, based on the level of care required.
5. Comparing the results of pharmacological treatments in pathologies of the same type.
6. Using predictive models for the evolution of population groups in terms of health-resource consumption.
7. Recommending engine to optimise the surgery waiting list.
8. Identifying and preventing drug-drug interactions that may cause health risks in poly-medicated patients.
9. Identifying target patients for new pharmacological treatments.

[102] *Idem*, 52.
[103] Cfr. Article 26(4)(a) of the Directive 2014/24/EU; Article 31, paragraph 2.
[104] Article 27 of the Directive 2014/24/EU.
[105] M. Mesa Vila, *Fases de las licitaciones*, 60.
[106] See Red.es, *Pliego de Prescripciones Técnicas*, 4-5, 13, 84-93.

10. Using radiological image analysis to support breast cancer screening.
11. Processing clinical text using NLP technologies to develop a CIE10 and SNOMED codifier.
12. Detecting public-health alerts based on social-network analysis.
13. Optimising hospital contingency plans to reduce surgical waiting lists or waiting times for hospital specialists by predicting the availability of hospital beds and staff or the need for healthcare resources.
14. Predicting demand for services in private centres as part of a hospital agreement with the regional public health system.
15. Identifying factors that can predict sepsis in patients.

Table 7. AI COTS solutions aligned with pre-defined use cases in healthcare

In the same vein, the 'MedP Big Data' project, launched by the Regional Governments of Gran Canarias and Valencia, sought the design of AI algorithms, a patient-healthcare system interface, support tools for clinical decision-making, and a hybrid platform that operates both on the cloud and on-site upon request. The objective was to apply these solutions to a wide range of use cases (almost 20), with a special focus on chronic pathologies of oncological and cardiovascular nature, and optimising protocols in advanced cases, both for individual diagnosis and treatment and for population and research settings.[107]

A key factor influencing the decision between applying a procedure with negotiation or opting for competitive dialogue is the level of definition of the subject matter that the public purchaser intends to procure.[108] In the context of public procurement for AI solutions in healthcare, the former scenario involves a contracting authority with a precise understanding of the nature, elements, features, and functionalities of the solution. Conversely, in the latter case, the subject matter of the contract is less defined, and the contracting authority lacks sufficient knowledge about the optimal way to address the public need. Consequently, in such instances, the authority relies on the market to present available choices in advance.

Tender procedures with negotiation will offer public health-service authorities the possibility to award these contracts with greater flexibility, particularly in cases where off-the-shelf AI-solutions are unavailable in the market or where the negotiation process allows public buyers to negotiate adaptations of existing elements or conditions for the development of an innovative solution. In the procurement of the assistant system, AVATAR, the Regional Healthcare System of Galizia justified the application of the procedure with negotiation (Ref. **[9]**).[109]

AVATAR
The state of the art in the market There are already numerous technological solutions aimed at improving health available in the market for various pathologies, thanks to the development of mobile applications linked to sensors. **The challenge** One of the most significant needs in healthcare processes is to enhance and strengthen communication between healthcare professionals and patients, especially where a significant health problem or risk is detected, requiring prompt action. In such cases, the information to be communicated serves as a warning or alert. **The enhanced solution: justifying the**

[107] Gobierno de Canarias and Generalitat Valenciana, *Pliego de Prescripciones Técnicas para la Contratación de un Servicio de I+D del Proyecto "Medicina Personalizada Big Data", mediante Procedimiento Abierto de Adjudicación y Tramitación Ordinaria, Tipo Compra Pública Precomercial*, 28 December 2021, 5,6, 18-29. Use cases described in the tender specifications covered, inter alia: the application of NLP in the domain of clinical reports using semantic tagging SNOMED CT; description of lumbar pain pathophysiology through the application of predictive-analytics techniques based on medical imaging with magnetic resonance; home monitoring of chronic situations and hospital discharges, with reference to oncology patients undergoing treatment in day hospitals and home hospitalization, and application in other related cases (patients in the first month post-hospital discharge, in home palliative care; or patients with diabetes mellitus, psychopathologies, EPOC, chronic pain, among other pathologies); patient segmentation in the most relevant pathologies; measurement and prediction model of the efficiency of primary-care functional units; patient selection for clinical trials and for active search for rare diseases; prediction of unplanned readmissions in the month.

[108] M. Mesa Vila, *Fases de las licitaciones*, 61.

[109] SERGAS, *Informe del Servicio Promotor para la Contratación mediante la Modalidad de Compra Pública de Tecnología Innovadora por el Procedimiento de Licitación con Negociación, del Servicio de Desarrollo y Fase Demostración de un Sistema de Asistente Personal (AVATAR) y un Generador de Alertas Inteligentes que aumente la Autonomía del Paciente*, 6 September 2018, 7; and, *Pliego de Prescripciones Técnicas*, 31 August 2018, 9-10, https://www.contratosdegalicia.gal/.

procurement with negotiation
The project aimed to address these two components collectively: the improvement and optimization of bidirectional communication among patients, professionals, and caregivers, combined with the management of warnings and alerts generated in the monitoring process of patients' biological or behavioural parameters. The design of the solution should particularly consider the needs of individuals with communication difficulties (persons within the autism spectrum, with neurodegenerative diseases, with visual, auditory, mobility impairments). This enhancement of communication could be achieved through augmented reality, personalized avatars, text-to-voice systems, etc. The tender specifications, in particular, emphasized the use of avatars, as they enable the visualization of our health in the future or improve understanding of how to treat a disease through new treatments by simulating different alternatives.

Table 8. Procedure with negotiation for an AI solution

A specific derogation, contained in Article 32(3)(a) of Directive 2014/24/EU, allows the use of a negotiated procedure without prior publication for the procurement of research and development supplies. The products or services procured must be supplied exclusively for the purpose of research, experiment, study or development, and the contract shall not include series production aimed at establishing commercial viability or amortising research-and-development costs.

Under Article 32(3) (b) of the Directive, this procedure can also be applied where supplies or services can be supplied only by a particular economic operator for any of the reasons established by the Directive, *inter alia*, the lack of competition for technical reasons, or the protection of exclusive rights, including intellectual-property rights. In this sense, the apparent lack of competition in the application of differential privacy and NLP to the processing of health records and the protection of exclusive IPR of a legacy-proprietary software seems to be behind the application of the negotiated procedure without prior publication in the procurement of the advanced expert-healthcare AI-support system for the exploitation of the Hospital Infanta Leonor's electronic medical records (Ref [9]).[110]

Competitive dialogue is a procedure consisting of two rounds, whereby the contracting authority describes its needs in a descriptive document or a contract notice, establishes the minimum requirements for candidates and defines the criteria for awarding the contract on the basis of the Best Price Quality Ratio (BPQR).[111]

Upon confirming candidates' adherence to the selection criteria, the buyer commences a competitive dialogue with those meeting the minimum requirements in order to determine the feasibility and suitability of the solution. Individual negotiations are carried out with each candidate, prioritizing the confidentiality of their respective solutions. This demands a significant level of technical proficiency from the public purchaser's team and considerable time investment. Establishing milestones serves to evaluate negotiation progress and eventually streamline the candidate shortlisting process over time.[112]

Competitive dialogue provides an opportunity to discuss and define with the candidates the appropriate technical or financial solution, which the public authority is not in a position to define alone and in advance. This procedure facilitates an iterative co-building process with suppliers to develop a technical solution that best aligns with the requirements of the public purchaser. This approach goes beyond exclusive-price negotiations, providing an avenue to explore innovation possibilities collaboratively with suppliers.[113]

While the innovative character of the competitive dialogue may consist of technical, financial or administrative aspects, or a complete reorganisation of the public purchaser's operational process, the use of this procedure for the procurement of AI solutions usually relies on the technical aspects of the challenges.

[110] Hospital Universitario Infanta Leonor, I*nforme justificativo del procedimiento negociado sin publicidad en la adjudicación del contrato de servicios titulado: "Evolución, soporte y mantenimiento de un sistema experto avanzado de apoyo a la atención sanitaria, implementado con inteligencia artificial, para la explotación de la información (Big data) contenida en el conjunto de las historias clínicas electrónicas del Hospital Universitario Infanta Leonor*, 22 July 2019, 1-2, https://contratos-publicos.comunidad.madrid/.

[111] C(2021) 4320 final, 53.

[112] *Ibidem*.

[113] Ministère de la Santé et de la Prévention, *Guide opérationnel*, 28-29.

For example, one of the largest health trusts in Norway launched the AIRad project in early 2020 to procure and implement ready-to-use commercial AI solutions to optimise the screening of computer tomography, magnetic resonance and X-ray images, and match them with an algorithm-detected pathology for quicker follow-up. Due to the complexity of the tender, the contracting authority used a competitive-dialogue procedure to develop the specifications in collaboration with the vendors involved. The dialogue-based tendering process sought to (i) overcome the difficulties of relying on algorithms that had not been validated on data from the Health Trust's own patient population, (ii) compare the pros and cons of acquiring CE-marked single-algorithm vendors or platform solutions for testing, validating and tailoring AI models to specific use cases prior to implementation in clinical practice, and (iii) ensure appropriate integration with the Trust's existing infrastructure and organisational practices.[114]

Further examples of the competitive dialogue can be found in the tenders of Annexes I and II: the AI-driven platform for Primary Health Care (Ref [4])[115] launched by the AGENAS and the CADIA project for a support system for cancer detection based on imaging screening with AI techniques procured by the SERGAS (Ref. [11]).

Justification of the competitive dialogue in CADIA
- Addressing the needs identified by the contracting authority that cannot be fulfilled through existing solutions in the market. Then, it is deemed necessary for bidders to undertake prior design or adaptation work.
- The contract encompasses services that involve the integration of innovative solutions.
- The service requirements are rooted in emerging technologies, specifically AI techniques. The technical specifications cannot be precisely established by reference to a standard, European Technical Assessment, Common Technical Specification, or technical reference.

Table 9. Competitive dialogue for an AI solution

6. *Planning AI procurement for the NHCS: 'what to buy'*

AI public procurement is not exempt from challenges that affect the entire procurement process, from the preparation of the tender (preliminary engagement with the market if appropriate, identification of specific needs to be met with the contract, design of the specifications, and development of the procurement procedure) to the execution of the contract and the establishment of appropriate controls.

Due to the disruptive and evolving nature of AI and its potential impacts on healthcare, contracting authorities should consider some specific guidelines to guide their procurement procedures, not only from the perspective of the strategic use of public procurement as a tool for innovation in NHCS, but also as a tool to ensure the acquisition of trustworthy solutions.

6.1. *Alignment with national or regional strategies for AI adoption in NHS*

Contracting authorities should align their AI procurement with relevant national or regional AI-strategy initiatives and guidelines from agencies that inform government policies on new technologies. Before engaging in an AI deployment, contracting authorities should consider how their pursuit of an AI system aligns with their overall national or regional strategies. This allows contracting authorities to incorporate secondary policy objectives into their strategic procurement, potentially leveraging economies of scale by aggregating demand for AI systems.[116]

An additional benefit of aligning with a

[114] L. Silsand *et al.*, *Procurement of artificial intelligence for radiology*, 1388-1395.

[115] AGENAS, *Avviso di indizione di una procedura di dialogo competitivo per l'affidamento di un contratto avente ad oggetto la progettazione di dettaglio, la realizzazione, la messa in esercizio e la gestione di una piattaforma di Intelligenza Artificiale*, 21 October 2022, https://www.agenas.gov.it/. Pursuant to the Decision no. 5 of 9 January 2024, the AGENAS temporarily and precautionarily suspended the competitive dialogue procedure following a formal request for information by the Italian Data Protection Authority, Il Garante per la Protezione dei Dati Personali. The request of the Il Garante sought clarification on the legal basis of the processing, the technical and organizational measures to implement data protection by design and by default principles across the platform, and the methodology to implement the "Decalogo per la realizzazione di servizi sanitari nazionali attraverso sistemi di Intelligenza Artificiale" of September 2023 passed by Il Garante. Network Digital 360, *Piattaforma di intelligenza artificiale per l'assistenza sanitaria: al via la fase finale della procedura per la realizzazione. Aggiornamento: gara sospesa*, 22 January 2024, www.healthtech360.it.

[116] UK Guidelines, 13.

national or regional AI strategy is that there may be specific support for initiatives that align with the strategy, such as access to additional experts. To improve their practices, contracting authorities could actively seek collaboration across departments and disciplines. Contracting authorities could also share knowledge and feedback through expert communities, such as the digital purchasing community, professional networks or meet-ups. Within the department or unit responsible for procurement, it could be helpful to set up platforms and networks to share information, experiences and best practices on buying AI-enabled solutions.[117]

In the case of the tenders corresponding to Spain, with some exceptions, there is a general absence of specific national or regional AI strategies in the health sector.

In accordance with Decision SLT/954/2023 of 19 March, the Government of Catalonia has published the Programme for the Promotion and Development of Artificial Intelligence in Health ("Health/AI Programme"). The aim of the programme is to create an enabling environment for innovation in the Catalan health sector through the development and implementation of AI solutions to improve the health of citizens, using the knowledge generated by the Catalan Public Health System (SISCAT). In doing so, Health/AI Programme seeks to prioritise prevention and improve the quality of care and sustainability of the health system. The goals of the Programme do emphasise the importance of the transfer of knowledge, trustworthy and verified AI solutions, the strategic alignment with overall healthcare planning, public procurement for public value, and true engagement of relevant stakeholders. Accordingly, the Health/AI programme functions include:[118]

- Strengthening the health AI ecosystem by supporting research, development and innovation that facilitates knowledge transfer to SISCAT to increase its capacity to develop AI.
- Adopting innovation as a catalyst for the implementation of AI according to assessment methodologies at clinical, ethical, legal and technological levels before implementation in SISCAT and verification of the functioning and impact of the algorithms by experts in different fields of knowledge.
- Promoting the improvement of SISCAT efficiency by developing AI solutions on a systemic scale to optimise human welfare, provided that all evaluation criteria guaranteeing the reliability of the solutions are met.
- Facilitating the strategic alignment of all relevant stakeholders in response to the overall policies and priorities of SISCAT, as defined in the Catalan Health Plan.
- Ensuring that the processes of procurement and implementation of AI in the health sector progress and establish a broader vision of AI that enables innovation systems of public value.
- Encouraging the participation and involvement of the entire Catalan health system to ensure a significant improvement in the quality of information and the achievement of results with a greater impact on the whole system with the resources allocated.

The tender specifications of some of the annexed contracts are contextualised with European, national or regional strategies linked to specific components of National Recovery and Resilience Plans of the Next Generation Funds devoted to the eHealth and the use of AI for personalised medicine services (Refs. [4], [5], [15]).

In accordance to the corresponding specifications, the Telemedicine platform procured by the Italian Agency, AGENAS (Ref. [5]), was aligned with: (i) the Italian Recovery and Resilience Plan (Mission 6, Component 1, sub-investment 1.2.3 "Telemedicine"); (ii) the European Health Data Space, a key pillar of the strong European Health Union (European Commission's EU Global Health Strategy 2022) and it is the first common EU data space in a specific area to emerge from the European Strategy for Data 2020.

In the same vein, the Spanish Ministry of Health (Ref. [15]) sought to procure development applications for the digital transformation of the National Health System, including the implementation of AI and NLP-driven analytical tools, along with other data-driven technologies such as big data,

[117] WEF Guidelines, 10.

[118] Departament de Salut, *RESOLUCIÓ SLT/954/2023, de 19 de març, per la qual es crea el Programa per a la promoció i desenvolupament de la intelligència artificial al sistema de salut*, Official Gazette of the Generalitat de Catalunya, no. 8881, 23 March 2023, https://portaldogc.gencat.cat.

blockchain and robotics. The contract was framed within the Spanish Digital Health Strategy of the NHCS of 2021, which is linked to the National Plan for Recovery, Transformation and Resilience, and several Spanish digital strategies (Digital Spain 2025, Science, Technology and Innovation Strategy, Artificial Intelligence Strategy, Personalised Medicine Strategy).

It is important for contracting authorities to ensure that their technology and data strategies are updated to incorporate the use of AI technologies. Consideration should be given to aligning the work of contracting authorities with other teams in central or regional government departments and organisations that are leading relevant AI initiatives, and establishing networks to share insights and learn from best practice.[119] In this sense, Directive 2014/24/EU does not prevent the practices of joint procurement between contracting authorities.[120]

An example of joint procurement is the project ROSIA (Ref. [20]), where the lead procurer, the Institute of Health Science of Aragón (IACS) acted on behalf of the Buyers Group, which was composed by VALDE INNOVA (Spain), Instituto Pedro Nunes (Portugal), The International Foundation for Integrated Care (The Netherlands), The Decision Group (The Netherlands), Instituto para la Experiencia del Paciente (Spain), PPCN.xyz Aps (Denmark) and the Municipalities of Penela and Soure (Portugal). In the same line, the European Food Safety Authority (EFSA) and other EU bodies jointly sought assistance for statistical and epidemiological analyses using AI methodology (Ref. [2]), and the Governments of Gran Canaria and Valencia also launched a joint procurement (Ref. [18]).

6.2. *The expertise of the contracting authority: the need of multidisciplinary teams*

Many contracting authorities may be faced with a lack of skilled and multidisciplinary teams to conduct the appropriate analysis of whether or not an AI system is the optimal solution to meet a public need. There are inherent risks in this, insofar as the authority can be prone to rely on vendors or private consultants that could "shape the framing of the need, or even create the perception of a need in the first place, which then kicks off the procurement process".[121]

To avoid such risks, most international and national standards for AI procurement emphasise the need for multidisciplinary teams covering all areas of knowledge that may be affected by the implementation of AI solutions. That is, specialists in medical science, computer science, data engineering, the applicable legal regime or ethics. In addition, such teams should be encouraged to have expertise in the design, procurement, operation and control of AI systems.

Only in the absence of such experience or the appropriate profiles, external assistance may be contracted to fill the existing gaps. At this point, it is important to highlight the necessary presence of lawyers who must not only be the architects of the contracting procedure,[122] but must also play a fundamental role in ensuring that the solution to be implemented complies with all applicable regulations without infringing patients' rights. In this sense, lawyers will have to work together with other experts to enrich the process of integrating AI into national health systems.

The lack of technical expertise is of particular concern when contracting authorities choose to purchase third-party AI software and hardware, including off-the-shelf AI models, AI-as-a-Service (AIaaS), AI Platform-as-a-Service (AIPaaS). This option could lead to vendor lock-in effects and also increase associated risks if contracting authorities do not fully understand the model (or the data it uses), do not have sufficient control over risks (such as managing data bias, addressing model explicability, or optimising performance), or become overly reliant on AI or overly confident in the accuracy of AI.[123]

6.3. *Conducting prior AI impact assessment*

Conducting initial AI impact assessments in a systematic way at the beginning of the procurement process, and ensuring that their

[119] UK Guidelines, 13.
[120] Recital (71) of the Directive 2014/24/EU.
[121] M. Sloane *et al*., *AI and Procurement*, 10.
[122] I. Gallego Córcoles, *La contratación pública como impulsor y garante del uso de soluciones basadas en inteligencia artificial*, in E. Gamero Casado (dir.), *Inteligencia artificial y sector público. Retos, límites y medios*, Valencia, Tirant lo Blanch, 2023, 524.
[123] Cfr. Bank of England, *FS2/23 – Artificial Intelligence and Machine Learning. Feedback statement 2/23*, 26 October 2023, https://www.bankofengland.co.uk.

preliminary findings inform the procurement, will be critical prior to the acquisition of an AI system. Impact assessments provide a better understanding of the potential impact of using AI and the ways in which potential risks can be mitigated. A team with diverse skills should support the contracting authority in conducting impact assessments and ensuring that the use cases and procurement process reflect their key findings.[124]

According to the Office for Artificial Intelligence in the UK, an AI impact assessment should reflect:[125]

1. The needs of the contracting authority and the public benefit of the AI system.
2. Human and socio-economic impacts of the AI system.
3. (Unintended) consequences for the existing technical and procedural environment.
4. Data quality and any potential inaccuracy or bias.
5. Any potential unintended consequences.
6. Whole-of-life cost considerations, including ongoing support and maintenance requirements.
7. Associated risk and mitigation strategies, including key point of the 'go/no go' decision where applicable.

In its protocol for the implementation of algorithmic systems in municipal services, and applicable to public procurement, the City of Barcelona provides for a mandatory, but non-binding, impact assessment of algorithmic high-risk systems from the very moment the service is conceived. This assessment will be carried out by an Advisory Board on Artificial Intelligence, Ethics, and Digital Rights, and will include the following information related to the algorithmic system to be tendered: description, purpose, scope, policy, and timeline for use; description of the application context; necessity and proportionality of the system; identification of parties involved; ethical review, including values and conflicts (trade-offs); impact on fundamental rights of affected individuals and communities; human oversight; definition of potential risks, mitigation measures; and recommendations.[126]

Importantly, there are examples of risk-assessment methodologies for automated decision making, such as the Government of Canada's Directive on Automated Decision Making. The "Algorithmic Impact Assessment (AIA)" is a self-assessment tool that allows Canadian departments and agencies to better understand and manage the risks associated with the implementation of automated decision systems. The tool consists of 51 risk and 34 mitigation questions, and provides a raw impact score based on based on several factors (system's design, algorithm, decision type, impact and data) and a mitigation score based on organisational and technical measures (consultations with internal and external stakeholders and de-risking and mitigation measures related to data quality, procedural fairness, and privacy).[127] To further transparency and trustworthiness of implemented AI systems, the Open Government Portal makes it publicly available the completed AIAs of various public bodies. Accordingly, the Portal has published AIAs in the area of healthcare.[128]

For its part, the European Law Institute has produced a set of model rules with procedural and substantive provisions for conducting impact assessments of algorithmic decision-making systems, including an extended questionnaire for completing the Impact Assessment Report.[129] The model rules cover, *inter alia*, the conditions triggering the application of an impact assessment, coordination with other impact-assessment procedures, initial risk evaluation (screening procedure) for systems not subject to a mandatory impact assessment, the content of the impact-assessment report, specific provisions for high-risk systems, publication of the assessment and iterative review, and accountability mechanisms. The proposed content of the impact assessment shows a clear alignment with the EU HLEG Guidelines and the AIA. The content of the impact assessment and the extended questionnaire can be adapted for its implementation in the procurement process of AI solutions for the NCHS.

[124] UK Guidelines, 24; WEF Guidelines, 8-9.
[125] UK Guidelines, 26.
[126] Barcelona Methodologies, 14-15.
[127] Government of Canada, *Algorithmic Impact Assessment tool*, last update 25 April 2023, https://www.canada.ca.
[128] Veterans Affairs Canada, Algorithmic Impact Assessment Results - Mental Health Benefit, 9 December 2022; Public Health Agency of Canada, Algorithmic Impact Assessment - ArriveCAN Proof of Vaccination Recognition, 27 October 2021, https://open.canada.ca.
[129] European Law Institute, *Model Rules on Impact Assessment of Algorithmic Decision-Making Systems Used by Public Administration*, Vienna, 2022, 16-51.

Scope and content of the AI Impact Assessment	
Provisions (Article 6 of the Model Rules)	**AIA (Articles)**
Description of the purpose and operation of the system	
Development of the system, in particular its algorithms.	11 Annex IV
Nature and technical characteristics of the system.	
Selection of training, validation and testing data.	
Context in which the system is used, in particular the public needs to be meet.	
System's interrelation with other digital systems (internal or external).	
Assessment of the performance, effectiveness and efficiency of the system	
In particular, whether the performance of the system might be flawed by low-quality data during its use.	13(3)(b)(iv), (4)
Assessment of the specific and systemic impact of the system on…	
Fundamental or other individual rights/interests (esp. rights to privacy and data protection, non-discrimination).	13(3)(b)(iii)
Societal and environmental well-being.	
End-user contracting authority, acceptance of the system/decisions by the staff, risks of over/under-reliance on the system, level of digital literacy, and technical skills within the authority.	14(4)
Assessment of the measures taken to ensure	
Maximisation of benefits to be achieved by the system with regard to public needs.	
Minimisation of identified risks and mitigation of possible negative outcomes.	14(2)
Human agency, oversight and control of the system.	14(1)(3)
High-quality data.	10
Accuracy across groups, precision and sensitivity.	15(2)(3)
Technical robustness and safety; resilience to attacks; data security; fall-back plans; reliability; and replicability of decisions.	15(3)(4)
Transparency of the system and explainability of its decisions.	
Traceability to enable the monitoring of the system's operations.	12
Accountability, in particular oversight, auditability, clear allocation of responsibilities, self-monitoring, benchmarking, and possibility of redress for injury or harm caused by the system.	17
Final determination of the risk level, unless the system is listed as 'high risk'.	9
Overall assessment of necessity and proportionality of processing operations in relation to the purposes, (esp. trade-offs between different factors considered in the impact assessment and reasonable alternatives to the envisaged system).	Annex IV (2)(b)
Reasoned statement on the legality of the use of the system under the applicable law, esp. data-protection law, administrative law and sectoral legislation	
Any additional information	

Table 10. Methodology for an AI Impact Assessment

As the disproportionate individual and social impacts of AI systems become more apparent, there is also a pressing need to introduce in the procurement process iterative risk and impact assessments, which importantly should include not only an *ex-ante* evaluation before starting the tender, but also during the post-implementation maintenance.[130]

In this sense, as part of this iterative approach to risk throughout the lifecycle of the public contract, contracting authorities should regularly review the assessments and their key findings,[131] taking into account any 'substantial modifications' to the intended purpose of the contract that may occur.[132]

[130] Cfr. M. Sloane *et al.*, *AI and Procurement*, 22.
[131] UK Guidelines, 14.
[132] See European Commission's Standard Contractual Clauses, 3. The document defines a "substantial modification" as "a change to the AI System following the Delivery which affects the compliance of the AI System with the requirements set out in these Clauses or results in a modification to the Intended Purpose" (Article 1.1). According to the contractual clauses of the Commission, there are some specific obligations addressed to document substantial modifications that may happen during the life cycle of the contract. In particular, the contractor must update the technical documentation and the in-

A review of the tenders of interest found no evidence that any AI-impact assessment was conducted before the tender notice was submitted, or that it was required in tender specifications. Even though most of the tenders implied systematic processing of large amounts of health data with a new technology –such as AI– , just only a few of them required a DPIA among the contractual obligations of the supplier (Refs. [4], [5], [13], [16], [18], [20]). Furthermore, in certain cases, there is no requirement for the supplier to furnish a DPIA when the contract purpose is to enhance legacy systems with new AI modules that could affect data processing (Ref. [9]).

6.4. *Building a credible use case for health care: Is AI the right solution?*

Neither EU public procurement rules nor Member States' national laws say what a public body "has to buy". Specifically, Directive 2014/24/EU makes it clear that nothing therein "obliges Member States to contract out or externalise the provision of services that they wish to provide themselves or to organise by means other than public contracts".[133]

Then, one of the problematic challenges in NHCS is the difficulty for contracting authorities of NHCS "to understand the *need* that is intended to be addressed and what, among many possible trade-offs, is the best solution". The reasons for this are due to the uncertainty and urgency of medical practice, risks of over or under provision, specificity of goods or services being purchased, barriers to market entry for new products, lack of health workers with appropriate skills, and asymmetry of information in favour of providers to the detriment of purchasers.[134]

The purchasing decision starts with a clear identification by the contracting authority of the public need to be met. It is easy for public purchasers to "overlook this critical step" due to the novelty and lack of awareness of AI technologies.[135]

An unmet need may arise from: (i) a problem that negatively impacts the delivery of the public service; (ii) a need or desire of a public purchaser to improve the quality and/or efficiency of the public service or a new emerging operational requirement; (iii) policy objectives to address medium to long-term societal challenges; (iv) legislative/regulatory requirements to deliver higher quality/efficiency public services.[136] If the notion of "acquisition" is broadly understood in the sense of "obtaining the benefits of the works, supplies or services in question",[137] the public need to be met by the contract should reflect the benefits of the public contract for the public service to be delivered by the public entity responsible of the service. The public need shall be aligned with the goals of the sector recognised in public-health policies, and particularly, with the improvement in health (including equitable improvement) and responsiveness to the legitimate expectations of users and societies.[138]

Moving forward, once the public need and the problem/challenge have been identified, the contracting authority must articulate the rationale behind the decision of choosing AI. There is an essential premise that purchasers need to consider: AI is not a one-size-fits-all or general-purpose solution that can solve every single problem. This basically means that, for the time being, current applications of AI are focused on performing narrowly-defined tasks. Whilst AI can help public bodies meet public needs, other, simpler solutions may be more effective, less risky and less expensive.[139]

When assessing if AI could help to meet the public need, NCHS contracting authorities should consider whether: (i) the problem to solve is associated with a large quantity of data which an AI strategy could learn from; (ii) analysing data would be so large and repetitive that it would be difficult for humans

structions for use at least with every substantial modification during the term of the contract, and subsequently make them available to the contracting authority (Article 4.4). Additionally, the automatic recording of log events shall include the identification of situations that may lead to any substantial modification in order to ensure an appropriate level of traceability of the AI System's (Article 5.2.b).

[133] Recital (5) Recital (4) of the Directive 2014/24/EU.

[134] European Commission, Public procurement in healthcare systems, 12-14.

[135] UK NHS Buyer's guide, 20.

[136] Cfr. European Assistance for Innovation Procurement, *The EAFIP toolkit on innovation procurement. Module 2*, Version 2021-2, European Commission, 2021, 1, 8-21.

[137] Recital (4) of the Directive 2014/24/EU.

[138] European Commission, Public procurement in healthcare systems, 77.

[139] Office for Artificial Intelligence and Government Digital Service, *A guide to using artificial intelligence in the public sector*, 27 January 2020, 1, 10, https://www.gov.uk/.

to do it effectively and efficiently; (iii) the outputs can be tested against empirical evidence to ensure the accuracy of the model; (iv) model outputs would lead to problem-solving in the real world; the datasets in question are available –even if preprocessing is required– and can be used ethically and safely.[140]

The European Centre for Disease Prevention and Control (ECDC) is a public health agency of the European Union (EU) which assesses risks and provides appropriate guidance to help countries prevent and respond to outbreaks and public-health threats. Through its mandate, the ECDC collects, analyses, and disseminates data on over 50 infectious disease concerns (e.g., COVID-19, influenza, HIV/AIDS, hepatitis, measles, tuberculosis, antimicrobial resistance). The ECDC's legal framework and its Strategy 2021-2027 prioritize the early detection and response to public-health threats as its core activities. The Agency launched a call for tender to support ECDC's utilization of AI strategies, encompassing ML and DL, in its surveillance procedures and other essential public-health duties. Additionally, the aim of the tender was to enhance the early detection of public-health risks through social-media channels, related training of learning models required to properly handle and sustain these outputs.[141]

EUROPEAN CENTRE FOR DISEASE PREVENTION AND CONTROL (ECDC)
2. Technical specifications **2.1. General background** Article 14 of Regulation (EU) 2022/2371 on serious cross-border threats to health defines the need to ensure the "continued development of the digital platform for surveillance", including the application of "artificial intelligence for data validation, analysis and automated reporting, including statistical reporting". ECDC detects public-health threats though its Epidemic Intelligence (El) processes, which include monitoring on a routine basis some epidemiological indicators for specific diseases (COVID-19, dengue, cholera, measles) and social-media platforms as a source of early detection of public-health threats. This monitoring has different challenges, including increased number of sources, changes in the sources, large amount of data and formats for extracting the data (e.g., text, images or video). As of 2022, automatization of EI processes is mainly based on the use of R programming, with sporadic use of other technologies (Scala and Python), which has required increasing the capacity on this type of technology for its sustainable use and maintenance. ECDC aims to further improve the efficiency and timeliness of EI activities as well as activities in other areas of surveillance and other core public-health functions through the application of AI, including automatization of processes, ML and DL algorithms and NLP.

Table 11. Assessing the public need of AI solutions in public-health surveillance

7. *Key challenges in formulating AI tender specifications for the NHCS*

Drafting tender specifications could be challenging, as it is necessary to avoid potential tensions that may arise between the formal aspects (the procurement process) and the substantive aspects (including specific safeguards in the tender specifications to mitigate the specific risks of procuring an AI solution to meet a public need).

In between, an *ex-ante* AI-impact assessment will empower public purchasers of the NHCS to proactively identify potential risks, such as lack of relevant and representative data, bias, errors, adverse individual or societal impacts, overfitting or underfitting, non-replicable models, black boxes, or lack of transparency, interpretability, and explainability. This assessment will enable the design of appropriate technical and organizational safeguards to be implemented in tender specifications.

While the AIA is still under discussion at the time of writing, some tender specifications are beginning to consider the general alignment of bidders' proposals with the future AIA (Ref. [4], [16]).

Some of the challenges that public purchasers may face when drafting tender specifications can be identified by analysing and characterising the contracts in the sample.

[140] Central Digital and Data Office and Office for Artificial Intelligence (UK), *Assessing if artificial intelligence is the right solution*, 10 June 2019, https://www.gov.uk/.
[141] European Centre for Disease Prevention and Control, *About ECDC, 2024*, https://www.ecdc.europa.eu/; ECDC Public Health Functions Unit, *Call for Tenders OJ/2023/PHF/26497. Artificial intelligence for surveillance and other core public health functions. Framework service contract. Tender Specifications*, 2021/07, version 1.4., https://etendering.ted.europa.eu/.

7.1. *COTS vs bespoke software: tracing CPV Codes and avoiding vendor lock-in risks*

While international or national guidelines on AI procurement do not specify whether public purchases of AI systems should be classified as service or supply contracts,[142] the CPV codification assigned to the contracts in the sample indicates that the procurement of AI software or applications for the NHCS includes both COTS and bespoke solutions, with a clear predominance of the latter. This aligns with the high-demanding technological component of the challenges faced by the NHCS and the specificity of the use cases.

CPV Code	Contract
48460000: Analytical, scientific, mathematical or forecasting software package.	[13]
48180000: Medical software package.	[20]
72000000: IT services: consulting, software development, Internet and support.	[9] [10] [13] [16] [20]
72212180-4: Medical software development services.	[17] [20]
72230000-6: Custom software development service.	[4] [5]
72200000-7: Software programming and consultancy services.	[19]

Table 12. Tracing COTS and bespoke AI software through CPV Codes

However, the same contract may encompass different products and services resulting in a mixed contract. This occurs when an IA COTS solution is purchased, requiring some adaptations, such as incorporating new databases or maintaining and updating the solution. In such cases, the provisions of Article 3 of Directive 2014/24/EU should be considered, and their legal status determined based on the higher estimated value of the respective services or supplies. The practice of EU contracting authorities reveals that many contracts extend beyond the mere acquisition of a COTS or bespoke AI solution. They typically involve other complex ICT products and services[143] including the development of platforms where AI models undergo training, validation, and testing (Refs. [4], [5], [13], [16]-[20]).

The procurement of AI cannot be treated "with the same off-the-shelf purchasing philosophy as other IT systems". First, in the context of public procurement, it is well known that reliance on third-party technology can result in undesirable vendor lock-in effects,[144] especially, in cases of black-box models, reliance on third-party data, non-interoperable AI solutions, restrictive licensing of IPR, or lack of specific provisions in the contract to allow for maintenance of the AI solution independent of the vendors.[145]

Second, the design of public policies legally vested in the authority may be replaced by a "policy making by third party design". In this sense, the decision to optimize a given public task –let's say, clinical triage and validation of medical waiting lists– may involve assumptions about the *expected typical behaviour*, thereby reflecting policy decisions in a manner distinct from other public purchases.[146] Furthermore, as learning from data necessitates making assumptions, different AI models encoded in vendor-

[142] When a software package is procured 'off the shelf' (division 48), it is considered a supply and is governed by the procurement rules on supplies, whereas software programming or the procurement of 'custom software' (division 72) should be considered a service and is governed by the rules on services. See European Commission, *Public Procurement in the European Union. Guide to the Common Procurement Vocabulary (CPV)*, 2008, p. 7. In Spain, the Spanish Central Administrative Court for Contractual Appeals established the following criteria in the in Consultation 58/2018 in relation to the purchase of computer programs. A public contract will be classified as a supply contract when AI solutions already developed and placed on the market are purchased. On the other hand, the contract should be considered as a service contract when the AI solution is customised for the national health system.

[143] For example, in the case of the software and hardware platform to exploit the 'Population Health Database' of the Regional Public Health System of Andalusia (Ref. [13]), the technical specifications covered up to 15 use cases, and the CPV codes of the contract comprised both supplies and services: 72000000-IT Services: consulting, software development, Internet, and support, 32420000-Networking equipment., 48460000-Analytical, scientific, mathematical, or predictive software packages, 48610000-Database systems, 48800000-Information systems and servers, 72212460-Analytical, scientific, mathematical, or predictive software development services, 72312000-Data input services, 72316000-Data analysis services, 72317000-Data storage services, 72322000-Data management services. See Red.es, *Condiciones Específicas del Pliego de Cláusulas Administrativas Particulares que regirán la realización del Contrato de 'Servicio para la implantación de una solución corporativa de analítica avanzada, basada en tecnologías Big data, para el Sistema Sanitario Público de Andalucía'*, PLACE, 4, https://contratacion delestado.es/.

[144] M. Sloane *et al*., *AI and Procurement*, 17.

[145] WEF Guidelines, 26.

[146] *Idem*, 18.

packaged solutions will inevitably make different assumptions, rendering them good for certain tasks but not others.[147]

Third, the so-called "automation-induced complacency"[148] would lead public officials to blindly trust the infallibility of the supplier's AI solution, ultimately resulting in human users routinely relying on the output generated by the solution and not questioning whether it might be flawed (errors in medical software design), unfair (biased health data underrepresenting part of the patient population) or even harmful (false negatives in cancer detection or false positives determining the wrong allocation of public resources).

Finally, public purchasers may be able to buy AI technology as an off-the-shelf product if they are looking for common applications of AI, for example, optical-character recognition. However, buying COTS software may not always be suitable as the specifics of the public-body datasets, the public needs to meet and the problems to solve could mean the supplier would have to build from scratch or significantly customise an existing AI model. In addition, COTS solutions will still need to be integrated into an end-to-end service of the public body,[149] which may envisage satisfying specific and mandatory interoperability and security requirements according to sectoral legislation applicable in the public sector.

An example of vendor lock-in may be the service contract in Ref. [9] for the development, support and maintenance of an advanced expert-healthcare support system. The expert system consisted of a free-text interpretation engine (NLP based on AI), capable of exploiting the clinical information contained in the hospital' EHCR. Previously, in 2016, the hospital had already acquired certain licences for the use of a specific solution that allowed it to exploit the data contained in the medical records. In 2019, the same contractor was again selected through a negotiated procedure without publication for reasons of exclusivity, as the software developer was the only company able to market the platforms previously acquired. In particular, the expert system acquired by the hospital corresponded to the evolution of three modules integrated in of-the-self platforms and then merged into a single application, which was renamed with the registered trademark of the same supplier as in 2016 (Ref. [9]).

7.2. *Gold-plated v. functional specifications*

In general, public buyers can draft technical specifications descriptively (input specification) or functionally (output specification). Whereas a descriptive specification provides a clear framework within which the public purchaser can oversee the contractor's performance, the rigidity of the specifications may leave no room or incentive for innovation or improvement of the good or service. With descriptive specifications, the public buyer prescribes the detailed solution and takes full responsibility for its quality and performance levels. Over-specifying can inflate costs, prompting public buyers to ensure that the 'gold-plated' option aligns with their actual needs.[150]

In addition, there is a high risk of artificially narrowing down competition and favouring specific processes or applications, in breach of Article 42.4 of Directive 2014/24/EU.[151]

Where the purchaser has a good understanding of the market potential or the most suitable technology to meet the public needs, descriptive technical specifications are most useful. However, even in these situations, some flexibility in the performance parameters can facilitate innovation and ultimately contribute to the achievement of the desired outcome.[152]

Conversely, functional specifications establish minimum requirements concerning the methods for achieving a desired outcome and prevent excessively low-performing tenders. EU legislation on public procurement promotes functional and performance specifications, considering them suitable for

[147] Cfr. P. Domingos, *The Master Algorithm. How the Quest for the Ultimate Learning Machine will remake your World*, New York, Basic Books, 2018, 24.
[148] R. Binns and V. Gallo, *Automated Decision Making: the Role of Meaningful Human Reviews*, Information Commissioner's Office [UK], 12 April 2019, https://ico.org.uk.
[149] Office for Artificial Intelligence and Government for Digital Service, *A guide to using artificial intelligence in the public sector*, 27 January 2020, 16, https://www.gov.uk/.
[150] Crown Commercial Service, *How to write a specification –Procurement Essentials*, 16 November 2021, www.crowncommercial.gov.uk.
[151] Cfr. Recital (74) Directive 2014/24/EU.
[152] C(2021) 4320 final, 42-43.

fostering innovation.[153]

Most of the tender specifications in the sample do not prescribe a particular AI solution but rather make a general reference to AI strategies to achieve the desired outcomes (Ref. [4], [9], [10], [11], [13], [14], [15], [16], [17], [18], [19]) mostly enunciated as use cases. At times, AI may not be the sole approach, and the contract leaves room for other data-driven technologies, such as blockchain (Ref. [15]). In some cases, the specifications detail the AI strategy and the learning models to be developed by the contractor (Refs. [3], [5], [8], [12]).[154]

For example, the tender launched by the European Centre for Disease Prevention and Control sought the implementation of AI, including ML and DL, in the processes and tasks related to surveillance and other core public-health functions, as well as the related training required to properly handle and sustain these outputs (Ref. [3]). In this respect, the tender specifications described in a general way the strategies, the learning problem and the models to be implemented according to the instructions given in the corresponding deliverables (DLV).

Strategy, learning problem and models for disease prevention and control	
DLV 5	**ML model for regression or classification**
	The objective is to prepare a ML model to solve a regression problem using K nearest neighbours (K-NN), linear regression, linear support vector machine (SVM) or similar methods; or to solve a classification problem using k-NN, logistic regression, decision trees, random forest, linear or Radial basis function SVM, or similar methods.
DLV 6	**DL model for regression or classification problem**
	The objective is to prepare a DL model to solve a regression or classification problem using neural networks, convolutional neural networks or similar methods.
DLV 7	**Unsupervised model**
	The objective is to prepare a ML/DL unsupervised model on clustering for anomaly detection, data/image clustering, segmentation, among others; or on dimensionality reduction for data compression, noise reduction and data visualisation, among others.

Table 13. AI strategy, learning problems and models in tender specifications

Functional specifications are used to identify the essential properties of AI models to ensure their quality and trustworthiness (e.g., accuracy, performance, transparency, interpretability, or explainability). These properties can be described in tender specifications as general goals for the contractor to achieve, rather than imposing specific thresholds. This is evident in the technical specifications of the Population Health Database project (Ref. [13]).[155]

Safeguards to ensure trustworthiness of AI models
Analytical Modelling - Selection of the analytical-modelling approach: the most appropriate analytical-modelling technique(s) will be selected for each use case based on the problem to be solved. - Evaluation design: prior to constructing the analytical model, the evaluation method to be employed to determine the quality and validity of the analytical model (based on parameters such as its performance, reliability, robustness, or explainability, among others) will be defined and approved by Red.es. - Model construction and training: once the analytical-modelling technique(s) has(have) been selected, the model will be constructed and trained on the previously-prepared data. One or more analytical models may be generated in this phase. - Evaluation of the analytical model: the analytical models will be interpreted based on pre-existing knowledge and pre-established success criteria. In this evaluation phase, factors such as accuracy and generality of the model will be assessed.

Table 14. Example of functional specifications

In the same vein, tender specifications sometimes require the contractor to ensure the accuracy of the models by implementing various metrics, but without defining the specific metric or establishing concrete

[153] Recital (74) and 42(3) (a) of the Directive 2014/24/EU.

[154] In relation to ML strategies or paradigms, learning problems and frequent models, see European Union Agency for Cibersecurity (ENISA), *Securing Machine Learning Algorithms*, December 2021, 7-10, DOI: 10.2824/874249.

[155] See Red.es, *Pliego de Prescripciones Técnicas*, 50.

thresholds. For example, in relation to the expert system tendered by the Government of Valencia to assist 112 operators in classifying healthcare needs for hospital and out-of-hospital emergencies, the technical specifications require an evaluation of the system on the basis of "different metrics" from the point of view of its clinical, economic and social impact (Ref. [8]). Similarly, the two calls for tenders launched by the Galizia Health Service (SERGAS) for the development of a personal assistant system (AVATAR) to increase patient autonomy (Ref. [10]) and the support system for cancer detection based on image analysis using AI (Ref. [11]) included, as one of the award criteria, "the level of detail of the proposed indicators and *metrics* to be used to verify the achievement of the proposed functional objectives (emphasis added)".

7.3. *Appropriate definitions*

The standard clauses provided by the tender specifications should include a list of appropriate and specific definitions in relation to the subject-matter of the public contract and the context of development and implementation of the AI solution that will be procured.

Providing appropriate definitions in the tender specifications can be quite challenging as many AI-related concepts may have different meanings depending on the context and the relevant stakeholders involved. Therefore, the substantiation of the relevant concepts in the tender specifications could be necessary.

A typical example of this could be the term "(algorithmic) transparency". Depending on the relevant domain concerned, "transparency" may have different meanings, namely the technical domain (e.g., in the field of 'XAI'), the ethical domain (e.g., OECD Recommendations, EU HLEG Guidelines, Alan Turing FAST Truck Principles), the legal domain (Article 13 of the AIA) and the contractual domain (WEF Guidelines, EU Commission Standard Clauses, Amsterdam Standard Clauses, Barcelona Methodologies). In addition, the degree of algorithmic transparency required in a particular context may require timely and appropriate adaptation of the relevant information on the AI system in relation to the affected stakeholders. These stakeholders may include the public purchaser and public employees as end-users of the AI system, supervisory authorities, individuals and groups likely or intended to be affected by the AI system, or even citizens as legitimate holders of freedom of information rights.

Another polysemic term is "parameter". For example, in ML contexts a "parameter" is an internal variable of the model that affects how it computes its outputs. Parameters are tuned during the training of the model using some optimisation procedures.[156] Although the AIA refers to the term 'parameter' in this proper technical meaning,[157] it is important to note that the term is often used by the lawmaker as a blanket concept, the exact meaning of which remains undefined.[158]

A list of AI-related definitions is included in the standard clauses of both the EU Commission and the City of Amsterdam.

European Commission	City of Amsterdam
AI System	Algorithmic System
Intended Purpose	Intended Use
Public Organisations Datasets	Decisions
Supplier Data Sets	Procedural

[156] See, for instance, ISO/IEC 22989:2022(en). Information technology - Artificial intelligence - Artificial intelligence concepts and terminology, at 3.3.4 and 3.3.8. Examples of parameters are "coefficients" of linear and logistic regression models, "weights" and "biases" in a neural network. Unlike parameters, the "hyperparameters" are values which control the learning process and the model parameters resulting from it. Hyperparameters are selected prior to training and can be used in the processes to help estimate model parameters. Examples of hyperparameters include the number of network layers, learning rate for neural networks; the number of leaves or depth of a tree; K value for K-means clustering or the maximum number of iterations of the expectation maximization algorithm.

[157] See Article 3(29) in relation to the training model and Annex IV.2.b) in relation to the technical information of the AI system to be provided to end-user, inter alia, "the relevance of the different parameters" within the system.

[158] For example, Article R.311-3-1-2 of the French the Code of Relations between the Public and the Administration (CRPA) specifically stipulates that the individual administrative decisions shall contain a notice informing, among other aspects, about "the *processing parameters*, and, where appropriate, their weighting, applied to the individual situation of the interested party". The Spanish Law 12/2021, on 28 September has amended the Employees Statute of 2015 in order to recognise the right of the works council to be informed by the company of "the *parameters*, rules and instructions on which algorithms or artificial intelligence systems are based, that affect the decision-making having an impact on working conditions, access to and maintenance of employment, including profiling".

and Third-Party Data Sets	Transparency
Reasonably Foreseeable Misuse	Technical Transparency
Substantial Modification	Explainable/ Explainability

Table 15. Definitions in tender specifications

Unlike the European Commission Standard Clauses, the City of Amsterdam defines "Algorithmic System" instead of "AI System". The reason for this option is twofold. Firstly, it was opted to bring applications using data analysis and/or statistics and other elements of the definition within the scope of the Standard Clauses. This is because, in actual practice, certain software often employed lacks self-learning logic (or any other AI strategy), but its application can still have significant, and sometimes unforeseen or unintended, impacts on citizens. Secondly, the term "Algorithmic System" is more aligned with the principle of technological neutrality, as it ensures the applicability of the Standard Clauses "on the basis of the impact the algorithmic system has on CITIZENS rather than on the basis of the technology used",[159] whether or not it is AI-enabled technology.

This point is crucial because some algorithmic systems implemented by public administrations have been questioned by supervisory authorities or courts precisely due to their adverse impacts on the rights and interests of the governed.[160] Therefore, the algorithmic systems within the scope of the Amsterdam Standard Clauses make it possible that certain safeguards will be applicable to them, such as requirements to ensure statistical inaccuracy, fairness and explicability of outcomes. Also, it is noteworthy that the AIA also encompasses "statistical approaches" in the list of AI techniques and approaches. In this regard, the Canadian Directive on Automated Decision-Making of 2019 applies to automated decision systems that "draw from fields like statistics".

7.4. *The "intended purpose" of the AI system: describing the problem*

The "intended purpose" or "intended use" describes the specific problem or problems previously identified by the public purchaser and that the AI/algorithmic system is to solve. In this context, the term "problem" should be interpreted in a broad sense.[161]

Public purchasers should be clear about the "intended use" of the AI/algorithmic solution, specifying "what exactly it can be used for and the exact conditions under which it can be used". In addition, a clear determination of the "intended use" is also relevant to assess the solution's performance, especially in self-learning models.[162]

An example of a description of the "intended purpose" of an AI system is the AZUD project (Ref. [14]), led by the Health Service of the Autonomous Community of Murcia ("SMS"). This project sought to develop and implement a data-lake platform that would allow the storage of any type of useful information, supporting a big data approach oriented towards clinical practice with patients. An important part of the information systems of the SMS is devoted to the analysis of previously collected data in order to obtain relevant information for healthcare management and decision-making at different organisational levels. This healthcare and administrative information is stored in a data warehouse in a structured format. On the basis of this existing infrastructure, the SMS then considered the need to capture and process the large amount of patient-generated information which is available in the existing systems (internal and external). In the memorandum justifying the public need to be met by the performance of the contract, the SMS described the challenge and the problems to be solved by the contractor.[163]

[159] See Amsterdam Standard Clauses, 5-6.

[160] This is the case of some algorithmic systems applied in the education sector to assign vacant positions to teaching staff according to the interprovincial mobility call (such as the algorithm of the Ministero dell'Istruzione, dell'Università e della Ricerca in Italy), to automatically process the national pre-enrolment procedure in the first year of public university (like Parcoursoup in France), to predict the grade that students would have achieved if official exams had taken place (as implemented by Ofqual in the United Kingdom). See M.E. Gutiérrez David, *Government by Algorithms at the Light of Freedom of Information Regimes. A Case-by-Case Approach on Automated Decision-Making Systems within Public Education Sector* in *Indiana Journal of Global Legal Studies*, vol. 30, no. 2, 2023, 105-172.

[161] Amsterdam Standard Clauses, 7.

[162] UK NHS Buyer's Guide, 10, 25.

[163] Servicio Murciano de Salud, *Memoria de Necesidad e Informe de Propuesta. Data Lake Sanitario del Servicio Murciano de Salud Proyecto "AZUD"*, Subdirección General de Tecnologías de la Información, 28 May 2021, 3-4, https://contrataciondelestado.es/.

SMS' AZUD PROJECT
The large amount of clinical information and the variety of formats and sources of information (external and internal) useful for clinical practice represent a technological challenge that can only be met by employing new storage, processing and analysis mechanisms. In order to transform this amount of patient information into useful insights for clinical practice, it is necessary to: 1. Facilitate the integration of internal-information sources (first-party data), information sources from collaborating companies and organisations (second-party data), and third-party information sources (third-party data). 2. Industrialise the complex data processes through automatic orchestration. 3. Correlate these disparate sources for informed clinical decision-making that is not currently available. 4. Define and implement predictive models using machine learning to anticipate anomalous and risky situations and take the necessary action to eliminate or reduce the impact. 5. Industrialise the predictive models to ensure their correct operation over time. 6. Automate the actions triggered by the implemented predictive models.

Table 16. Defining the intended purpose of the AI solution for healthcare

7.5. *Data quality and data governance*

Data, whether personal or not, play a crucial role in the implementation of AI solutions. The importance of this is highlighted in the existing Guidelines for AI procurement, where it is emphasized that clarifying the technical and ethical limitations of data usage in tender specifications is essential. This clarification is necessary to mitigate risks such as bias, discrimination, fairness concerns, unintended individual and societal impacts, or deviation from the intended purpose of the AI system.

Risks in medicine and healthcare encompass various facets, including the potential for AI errors to put patients at risk, privacy and security concerns, and the use of AI in ways that could exacerbate social and health inequalities. This exacerbation can occur either through the incorporation of existing human biases and discriminatory patterns into automated algorithms, or through the use of AI in ways that accentuate disparities in access to healthcare services. Scholars have provided illustrative examples, such as the harm resulting from incomplete or biased data used in the development of an AI-powered pulse oximeter. Due to incomplete data representation, the device tended to overestimate blood oxygen levels in patients with darker skin, leading to undertreatment of their hypoxia.[164] In the same way, racial biases have been reported in algorithms of healthcare programmes for high-risk patients in COTS solutions procured by public-health systems.[165]

In particular, there is scientific evidence that race-adjusted algorithms are being employed in clinical practices, perpetuating health inequities. Scholars have compiled some of these algorithms that incorporate race correction. Adjustments in AI models are typically justified on the basis of the existing patterns extracted from historical data and concerning patient attributes, clinical outcomes, and certain assumptions about what is considered the *ground truth*.[166]

Relevant studies have indicated that many AI applications designed for diagnosing

[164] F. Federspiel, R. Mitchell, A. Asokan, C. Umana and D. McCoy, *Threats by artificial intelligence to human health and human existence*, in *BMJ Specialist Journals*, vol. 8, no. 5: e010435, 2023, DOI: 10.1136/bmjgh-2022-010435.

[165] Z. Obermeyer, B. Powers, C. Vogeli and S. Mullainathan, *Dissecting racial bias in an algorithm used to manage the health of populations* in *Science*, no. 366 (6464), 2019, 447-453, DOI: 10.1126/science.aax2342.

[166] D. A. Vyas, L. G. Eisenstein and D. S. Jones, *Hidden in Plain Sight - Reconsidering the Use of Race Correction in Clinical Algorithms*, in *The New England Journal of Medicine*, vol. 383, 2020, 874-882, https://www.nejm.org/doi/10.1056/NEJMms2004740. The authors have analysed the use of algorithmic models in several areas of clinical practice (e.g. cardiology, obstetrics, nephrology, and urology). The research illustrates some significant examples. Because of the difficulties in measuring kidney function directly, some algorithmic models have been developed to determine the estimated glomerular filtration rate (eGFR) from a measurable indicator such as the serum creatinine level. Higher eGFR values indicate better kidney function. The algorithmic models tend to report higher eGFR values for black people. This is based on the idea that black people release more creatinine into the blood, partly because they are supposed to be more muscular. Analyses have questioned this assumption, provided that "race is a social rather than a biological construct". In despite of this, the race-corrected eGFR still remains the standard. It is argued that discarding race adjustment of eGFR could lead to overdiagnosis or overtreatment of black individuals, even if such adjustment could delay referral of these patients for specialist care or transplantation.

COVID cases or predicting patient outcomes - some of which are commercialised and utilized in hospitals - were deemed unsuitable for clinical use due to serious errors in the data they relied upon, posing a high risk of bias.[167]

Taking into account the existing Guidelines for IA procurement, public purchasers of the NCHS should consider the following circumstances when drafting tender specifications:[168]

1. appropriate analysis (collection, when necessary), structuring and editing of data according to a motivated approach in relation to the specific domain of application or use cases;
2. whether all data to be included in the databases have the same level of protection;
3. whether the data meet the criteria of fairness and avoidance of bias;
4. the possible limitations (due to representativeness, provenance, clarity, completeness, accuracy, proxy predictors) of the data should be assessed in advance;
5. appropriate data-governance schemes and personal-data protection.

In the first place, large quantity of data is required to develop AI solutions, specially, in the context of personalised medicine and other potential high-risk applications of AI in the domain of healthcare. In this regard, public purchasers should assess whether their data are of high-enough quality for AI, considering the following elements: accuracy, completeness, uniqueness, timeliness, validity, sufficiency, relevancy, representativeness, and consistency.[169]

In the second place, considering that most of the tenders in the sample require the implementation of ML or DL approaches, the quality of data becomes of paramount importance due to the strong ties between quality and accuracy of AI models. In effect, when assessing the accuracy of learning methods using public-health datasets of an observational nature, or surveys with high non-response rates, it is crucial to consider the presence of bias within the dataset. Bias occurs when the dataset does not accurately represent the population of interest in significant aspects. This mismatch may result in accuracy estimates that cannot be reliably replicated when these methods are implemented in real-world scenarios. Another issue to bear in mind is the presence of confounders, i.e. variables that are correlated with both the outcome and the predictors. AI models may inadvertently learn to predict these confounding variables rather than the actual outcome of interest, leading to inflated accuracy within the dataset. Furthermore, when bias and confounding variables co-exist, the situation becomes even more problematic. In such cases, confounding variables may be correlated with the outcome within the dataset, but not within the broader population. This scenario may result in a learning model that appears to be highly accurate within the dataset, but is ultimately ineffective for practical purposes.[170]

In the third place, the data quality of training, validation and testing-data sets is a pivotal requirement of the AIA.[171]

[167] See The Alan Turing Institute, *Data science and AI in the age of COVID-19. Reflections on the response of the UK's data science and AI community to the COVID-19 pandemic*, 13-14, 2021, www.turing.ac.uk; L. Wynants, B. Van Calster, G. S Collins *et al*. *Prediction models for diagnosis and prognosis of covid-19: systematic review and critical appraisal* in *BMJ* (Clinical research ed.), vol. 369, m.1328, 7 April 2020, Doi: 10.1136/bmj.m1328; M. Roberts, D. Driggs *et al.*, *Common pitfalls and recommendations for using machine learning to detect and prognosticate for COVID-19 using chest radiographs and CT scans* in *Nature Machine Intelligence*, vol. 3, 2021, 199-217, https://doi.org/10.1038/s42256-021-00307-0; W.D. Heaven, *Hundreds of AI tools have been built to catch covid. None of them helped* in *MIT Technology Review*, 30 June 2021, www.technologyreview.com. Common errors detected encompassed the utilization of poor-quality data due to incorrect labelling, the inclusion of duplicate data, sourcing data from unknown origins, incorporating data that did not accurately represent the target population (such as paediatric patients), or the underrepresentation of vulnerable and underserved groups (such as ethnic minorities or low socio-economic status populations). Furthermore, inadequate or absent internal or external validation of models, along with overfitted models –trained on insufficient or small datasets, were also identified. Consequently, the predictive performance of some tools might have significantly diminished in real clinical settings when confronted with new input data.

[168] WEF Guidelines, 18-19; NHSX A Buyer's Guide, 14, 44, 51; Amsterdam Standard Clauses, 14; Barcelona Methodologies, 15-16, 18.

[169] WEF Guidelines, 7; Central Digital and Data Office and Office for Artificial Intelligence, *Guidance Assessing if artificial intelligence is the right solution*, 10 June 2019, https://www.gov.uk/.

[170] D. Pigoli, K. Baker, J. Budd *et al*., *Statistical Design and Analysis for Robust Machine Learning: A Case Study from COVID-19*, arXiv:2212.08571v2 [cs.SD], 27 February 2023, https://arxiv.org.

[171] See Recital (44) of the AIA: "High data quality is essential for the performance of many AI systems, especially when techniques involving the training of models

In this sense, Article 10 of the AIA subjects these data sets to appropriate data-governance and management practices. In line with such practices, tender specifications should consider: the relevant design choices; data collection (making a clear a clear distinction between healthcare data provided by public purchaser, the contractor or third-parties); relevant data preparation processing operations (e.g., annotation, labelling, cleaning, enrichment, aggregation); the formulation of relevant assumptions, notably with respect to the information that the data are supposed to measure and represent; a prior assessment of the availability, quantity and suitability of the data sets that are needed to design the AI solution for the intended purposes; examination in view of possible biases; the identification of any possible data gaps or shortcomings, and how those gaps and shortcomings can be addressed; trainings' relevant representativeness, completeness and freedom from errors , data sets' validation and testing, including adequate statistical properties as regards the persons or groups of persons (e.g., clinicians, patients, caregivers, targeted population) on which the AI system is intended to be used; the intended purpose of the AI system in relation to the features or elements that are peculiar to the specific geographical, behavioural or functional setting within which the AI system is intended to be used.[172]

The European Commission emphasizes that for non-high-risk AI, compliance with data quality and other requirements[173] is not mandatory under the AI Act. Nonetheless, the Commission suggests that contractual clauses for the procurement of AI by public purchasers enhance the reliability of AI applications acquired by public organizations. This can be achieved by incorporating specific contractual provisions tailored to non-high-risk AI systems.[174]

When looking at the tenders of interest, tender specifications do include specific provisions on data pre-processing (Ref. [3], [4], [19]), data governance ([2], [4], [18], [20]) or training, validation or testing of models and re-training with new data.

Typically, data-quality requirements are formulated in a very general and broad manner. Technical specifications provided by the Regional Health Service in Murcia have established a number of requirements in relation to data quality.[175]

Data quality requirements in the AZUD Project
Data quality: Tools are necessary to measure and display the quality of data stored in the Data Lake, with the following objectives: Providing contextual information about the datasets (metadata). Identifying distinct dimensions using a unique ID. Mapping and standardising information where feasible. Establishing key performance indicators (KPIs) to identify potentially erroneous data.

Table 17. Data quality requirements in tender specifications

Some tender specifications require appropriate safeguards to ensure the replicability of the AI models developed (Ref. **[2]**). The joint procurement launched by the European Food Safety Authority (EFSA) and other EU bodies defined the following data-management tasks.[176]

Data management tasks in epidemiological analyses
Data management tasks may include data analysis (including related data management when necessary), statistical or mathematical modelling, simulation modelling, design and analysis of the results of epidemiological

are used, with a view to ensure that the high-risk AI system performs as intended and safely and it does not become the source of discrimination prohibited by Union law. High quality training, validation and testing data sets require the implementation of appropriate data governance and management practices".

[172] See Article 10(2), (3), and (4) of the AIA; Article 3 of the European Commission Standard Clauses.

[173] The European Commission Standard Clauses encompass mandatory requirements under the AIA such as technical documentation, risk management system, automatic recording of events (logging capabilities), transparency, human oversight, accuracy, robustness, cybersecurity, quality management system, conformity assessment, corrective actions, post-market monitoring.

[174] European Commission, *Proposal for standard contractual clauses for the procurement of artificial intelligence by public organisations version*, 4 April 2023, https://public-buyers-community.ec.europa.eu/.

[175] Servicio Murciano de Salud, *Pliego de Prescripciones Técnicas. Data Lake sanitario del Servicio Murciano de Salud Proyecto "AZUD"*, Subdirección General de Tecnologías de la Información, 28 May 2021, 7, https://contrataciondelestado.es/.

[176] EFSA, *Updated Tender Specifications. Assistance for Statistical and Epidemiological Analyses and related data management, using conventional and Artificial Intelligence methodology, and for training and ad hoc consultation upon request*, 16 October 2020, 7, https://etendering.ted.europa.eu.

studies, computational support, and methodological consultations or training. This may require the processing and loading of data in various formats (e.g. structured text files, SAS datasets, Excel spreadsheets, XML, MS Access and Oracle Databases) and the use of specific software (e.g. R, STAN, SAS, Python etc.). Additionally, the contractor should be able to provide Artificial Intelligence (AI)/Machine Learning (ML) solutions in case they can be considered appropriate/relevant or an improved way of dealing with the problems at hand. Each task will require appropriate reporting and documentation to allow reproducibility of all results.

Table 18. Replicability of AI models

In the tender specifications corresponding to the call for tender launched by the Catalan Institute of Health, te team of Data Scientists from the successful bidder were tasked with developing and training predictive algorithms on the Cloudera Corporate Platform supporting clinical decision making in the integral care of critical patients. Specific tasks were needed to ensure data quality.[177]

Preparing data sets and AI models for Health Data Lakes infrastructures
- Processing, cleaning, normalizing, and harmonizing historical data from the Data Lake within the Cloudera Corporate Cloud Platform. - Implementing methods to correct missing or erroneous data wherever feasible. - Conducting exploratory data analysis in collaboration with clinical professionals to gain insights. - Recommending a set of the most suitable Machine Learning or Deep Learning algorithms and providing training. - Evaluating and validating the optimal model based on quality criteria defined by CatSalut. - Conducting on-demand re-training of the model using new data from patients who have completed their ICU stay.

Table 19. Pre-processing of health data, training, validating and testing AI models

[177] Institut Catàla de la Salut, *Plec de prescripcions tècniques per a la contractació de l'entorn d'intel·ligència artifical i uci estesa del projecte de millora i ajuda a la presa de decisions clíniques de l'atenció integral del pacient crític en l'Hospital Universitari de Bellvitge i el Consorci Corporació Sanitaria Parc Taulí*, 29 July 2022, 8, https://contractaciopublica.cat.

7.6. *Transparency and explainability of the AI system*

Requirements for "interpretability", "transparency", and "explainability" of AI systems are commonly found in the wording of soft law and sectoral legislation on AI. Often, these terms are used interchangeably. However, in the technical domain, these concepts have distinct meanings. Specifically, in the field of Explainable Artificial Intelligence (XAI), there is a distinction between them.[178]

[178] Firstly, the "interpretability" means how understandable or intelligible an AI model is to a human observer. The interpretability of a model is greater if it is easy for a person to reason and trace in a coherent way why the model arrived to a particular decision or outcome. See A. Barredo *et al.*, *Explainable Artificial Intelligence (XAI): Concepts, taxonomies, opportunities and challenges toward responsible* AI, in *Information Fusion*, vol. 58, 2020, 82, 84. https://doi.org/10.1016/j.inffus.2019.12.012; D. V. Carvalho, E. M. Pereira, J. S. Cardoso, *Machine Learning Interpretability: A Survey on Methods and Metrics*, in *Electronics*, vol. 8, no. 8, 832, 2019, https://doi.org/10.3390/electronics8080832.
Secondly, the "transparency" of an AI model is determined by the degree of intrinsic interpretability of a specific model. Therefore, transparency is an attribute of the model that defines the degree of comprehensibility that a model itself has for a human observer. Transparency can be assessed at three levels. Firstly, at the model level ("simulability"), it involves how replicable the model is by a human from its data and parameters in a reasonable time. Secondly, at the component level ("decomposability"), it involves the intuitive explanation of the model's components, including inputs, parameters. Thirdly, concerning the learning algorithm ("algorithmic transparency"), it refers to understanding the process that the model employs to generate a specific outcome from the data. See B. Mittelstadt, C. Russell and S. Wachter, *Explaining Explanations in AI*, in *Proceedings of the Conference on Fairness, Accountability, and Transparency*, FAT* '19, January 2019, 2. http://dx.doi.org/10.1145/3287560.3287574; B. Lepri, N. Oliver, E. Letouzé *et al*., *Fair, transparent and accountable algorithmic decision-making processes. The premise, the proposed solutions, and the open challenges* in *Philosophy & Technology*, vol. 31, 2018, 611, 619; ICO & Alan Turing Institute, *Explaining decisions made with AI*, last update 27 October 2022, 69, https://ico.org.uk/. Consequently, an AI model is considered transparent if it is interpretable by itself (i.e., if the overall performance of the model, its individual components, and its learning algorithm are intelligible or understandable to a human). See Barredo, *Explainable Artificial Intelligence*, 88–100.
Finally, the "explainability" is an active attribute of the model that refers to the ability to generate an explanation of the model's behaviour based on the data used, the results obtained, and the entire decision-making process according to the audience for which the explanation is intended (e.g., authorities, experts, third-party auditors, certification bodies, public at large, individuals affected by the model's decision). Explanations are instruments by which the decisions of an AI model can be

In relation to AI solutions for NHCS qualified as high-risk, the AIA would impose transparency obligations (Article 13): "High-risk AI systems shall be designed and developed in such a way to ensure that their operation is *sufficiently transparent* to enable users to interpret the system's output and use it appropriately. An *appropriate type and degree of transparency* shall be ensured, with a view to achieve compliance with the relevant obligations of the user and of the provider set out in Chapter 3 of this Title [emphasis added]".[179]

However, the approach taken by the AIA appears insufficient.[180]

Firstly, the European Commission's proposal lacks legal definitions for key terms such as "transparency", "sufficiently transparent", "to interpret" or "explainability". Consequently, the responsibility for making AI systems interpretable and explainable falls within the discretion of the AI system provider or developer.

Secondly, the appropriate form and level of transparency appear to be relative and merely instrumental with a view to achieve compliance with other requirements of the AIA, as emphasized in Recital 47, which calls for "a degree of transparency". The broad wording of the AIA could imply that a general form of transparency, provided through "relevant documentation" and "instructions", may satisfy this requirement by covering aspects like the intended purpose, accuracy, robustness, risks, performance metrics, input-data specifications, *inter alia*.

Thirdly, the AIA does not address the concept of "explainability", so it remains open to interpretation the question of whether Article 13 of the AIA requires the implementation of XAI techniques (e.g., subrogate models, LIME, SHAP, counterfactuals) and the choice of approach (e.g., post-hoc, local or global explanations) to ensure interpretable models.

Furthermore, the Commission's approach to explainability represents a significant departure from that proposed by the HLEG Ethics Guidelines. In the AIA, explainability remains completely blurred, with Recital (47) being the sole explicit reference to it within the entire Commission's proposal.[181] By contrast, explainability is a core element of ethical and trustworthy systems within the HLEG Guidelines, as it is addressed not only

explained in a more clear, understandable, transparent, and interpretable manner. Therefore, if interpretability is the ultimate goal, explanations are tools to achieve the interpretability of the model. Carvalho, *Machine Learning*, 15. In turn, a distinction must be made between models that are "interpretable by design" (i.e., "transparent models") and models that, not being interpretable *prima facie*, can nevertheless be explained by means of different techniques which extract relevant information from the model to generate explanations. Mittelstadt *et al.*, *Explaining Explanations*, 83.

[179] Pursuant to Articles 13(2) and (3), high-risk AI systems shall be accompanied by instructions for use that shall include concise, complete, correct, clear, relevant, accessible and comprehensible information to users. The information shall include: characteristics, capabilities and limitations of performance of the high-risk AI system (intended purpose, the level of accuracy, robustness and cybersecurity tested and validated, any known or foreseeable circumstance which may lead to risks to the health and safety or fundamental rights, its performance as regards the persons or groups of persons affected by the system, specifications for the input data, or any other relevant information on the training, validation and testing datasets used); the changes to the high-risk AI system and its performance pre-determined by the provider at the moment of the initial conformity assessment; the human oversight measures; the expected lifetime of the high-risk AI system and any necessary maintenance and care measures.

[180] See D. Schneeberger, R. Röttger, F. Cabitza *et al.*, *The Tower of Babel in Explainable Artificial Intelligence (XAI)*, in A. Holzinger, P. Kieseberg, F. Cabitza *et al.* (eds.), *Machine Learning and Knowledge Extraction. CD-MAKE 2023. Lecture Notes in Computer Science*, vol 14065, Cham, Springer, 2023, 65, 70. https://doi.org/10.1007/978-3-031-40837-3_5.

[181] Recital (47) of the AIA reads as follows: "Furthermore, the exercise of important procedural fundamental rights, such as the right to an effective remedy and to a fair trial as well as the right of defence and the presumption of innocence, could be hampered, in particular, where such AI systems are not sufficiently transparent, *explainable* and documented [emphasis added]." If, from a technical standpoint, explanations are tools to achieve the interpretability of non-transparent models, then it could be argued that XAI techniques to ensure explainability may be implied by Article 13(3)(d) of the AIA. This provision requires that instructions accompanying the high-risk system shall include "the human oversight measures referred to in Article 14, including the *technical measures put in place to facilitate the interpretation of the outputs of AI systems by the users* [emphasis added]. In particular, Article 14(4)(d) mandates that technical measures to ensure human oversight shall allow to "*correctly interpret* the high-risk AI system's output, taking into account in particular the characteristics of the system and the *interpretation tools and methods available*." Annex IV (d) reiterates the need to include this information in the technical documentation. Regardless of the intended meaning behind the aforementioned provisions, the fact is that the AIA presents two significant shortcomings: the absence of requirements regarding the model explainability and the apparent oblivion –deliberate or not– in relation to concrete guarantees of transparency and explainability for potential recipients of algorithmic systems, whether individuals, specific groups, or society at large.

to the user of the system, but also to the collectives and individuals affected by the decisions or outcomes of the system.[182]

The European Parliament introduced an amendment in Article 13(1) defining transparency.[183] Accordingly, the Parliament included a new Article 68(c), which recognised the right to an explanation of individual decision-making, clearly echoing Recital (71) of the GDPR. This right would be enforceable where a decision or output of high-risk systems produce legal effects, or similarly significantly affect a person in a way that he or she considers to adversely impair his or her health.[184] The Draft Agreement also recognises this right to an explanation, with some relevant changes to the Parliament's version.[185]

The constraints identified in the AIA could lead to a downgrading of the level of guarantees required in the public procurement of AI solutions in healthcare.

Against this background, the Amsterdam Standard Clauses differentiates between "Procedural Transparency",[186] "Technical Transparency"[187] and "Explainability",[188]

[182] The HLEG Ethics Guidelines, at 18, defines the explainability as "the ability to explain both the technical processes of an AI system and the related human decisions (e.g. application areas of a system)." The Guidelines make a difference between *ad-intra* explainability (technical explainability), and *ad-extra* explainability (collective or individuals concerned). "Technical explainability – explains the HLEG– requires that the decisions made by an AI system can be understood and traced by human beings. Moreover, trade-offs might have to be made between enhancing a system's explainability (which may reduce its accuracy) or increasing its accuracy (at the cost of explainability). Whenever an AI system has a significant impact on people's lives, it should be possible to *demand a suitable explanation of the AI system's decision-making process*. Such explanation should be timely and adapted to the expertise of the stakeholder concerned (e.g. *layperson*, regulator or researcher). In addition, explanations of the degree to which an AI system influences and shapes the organisational decision-making process, design choices of the system, and the rationale for deploying it, should be available".

[183] The new sub-paragraph in Article 13(1) reads: "Transparency shall thereby mean that, at the time the high-risk AI system is placed on the market, all technical means available in accordance with the generally acknowledged state of art are used to ensure that the AI system's output is interpretable by the provider and the user. The user shall be enabled to understand and use the AI system appropriately by generally knowing how the AI system works and what data it processes, *allowing the user to explain the decisions taken by the AI system to the affected person* pursuant to Article 68(c) [emphasis added]". This provision has been removed from the Draft Agreement reached by the co-legislators in January 2024, and has instead been included in Recital (14a).

[184] The provision introduced by the Parliament stipulated that: "1. *Any affected person* subject to a decision which is taken by the deployer on the basis of the output from a high-risk AI system which produces legal effects or similarly significantly affects him or her in a way that they consider to adversely impact their health, safety, fundamental rights, socio-economic well-being or any other of the rights deriving from the obligations laid down in this Regulation, shall have *the right to request from the deployer clear and meaningful explanation* pursuant to Article 13(1) on the role of the AI system in the decision-making procedure, the main parameters of the decision taken and the related input data. 2. Paragraph 1 shall not apply to the use of AI systems for which exceptions from, or restrictions to, the obligation under paragraph 1 follow from Union or national law are provided in so far as such exception or restrictions respect the essence of the fundamental rights and freedoms and is a necessary and proportionate measure in a democratic society. 3. This Article shall apply without prejudice to Articles 13, 14, 15, and 22 of the Regulation 2016/679 [emphasis added]."

[185] Compare the European Parliament's version of Article 68(c) with the version proposed in the Draft Agreement. Whereas the former recognised "the right to request from the provider a clear and meaningful explanation, in accordance with Article 13(1), of the role of the AI system in the decision-making process, the main parameters of the decision taken and the related input data"; the Draft Agreement eliminates the reference to Article 13(1) and opens the door for the user of the high-risk system to freely determine "the main elements of the decision taken". Furthermore, Article 68(c)(2) of the Draft Agreement has removed safeguards against any restriction or derogation to this right in the Union or Member State legislation by suppressing the requirement that the exceptions or limitations must "respect the essence of fundamental rights and freedoms and [be] a necessary and proportionate measure in a democratic society".

[186] See Amsterdam Standard Clauses, 8. "Procedural Transparency" is defined as "the provision of information on the purpose of the Algorithmic System and the process followed in the development and application of the Algorithmic System and the data used in that context, which should in any event be deemed to include the provision of an understanding of the choices and assumptions made, the categories of data used in the development of the Algorithmic System, the way in which human intervention is provided for in the Algorithmic System, the method used to identify risks, the risks identified, and the measures taken to mitigate the risks, as well as the parties that were involved in the development of the Algorithmic System and their roles."

[187] See Amsterdam Standard Clauses, 9 "Technical Transparency" is defined as "the provision of information enabling [the contracting authority] to understand the technical operation of the Algorithmic System, which may in any event be deemed to include the disclosure of the source code of the Algorithmic System, the technical specifications used in developing the Algorithmic System, the data used in developing the Algorithmic System, technical information on how the data used in developing the Algorithmic System were obtained and edited, information on the method of development used and the development process undertaken, substantiation of the choice for a particular model and

indicating a clear alignment with the HLEG Ethical Guidelines.

By ensuring Procedural Transparency, the contracting authority should seek to:[189]

- Gain an understanding of the process followed by the contractor in the development and application of the system and the choices made by the contractor during that process.
- Form an opinion on the quality of an algorithmic system without needing the information that is required if Technical Transparency is to be provided.
- Be able to provide general information to citizens or individuals affected on the use of the system and to explain the operation thereof, thus ensuring accountability.

By including Technical Transparency clauses, the contracting authority seeks to gain all the information that is necessary to assess the technical quality and the technical operation of the system, including the disclosure of the source code, the technical specifications used in developing the system, and appropriate information on the data used in developing the system (how the data were obtained, edited and used), the substantiation of the choice for a particular model and its learning parameters, and the performance of the system.[190]

The purpose of rendering the system explainable is different from technical transparency:[191]

- It enables the public purchaser to provide individuals or citizens with relevant information, on an individual level, to understand why the system reaches a specific decision or outcome (prediction, recommendation, ranking), allowing them to challenge such decision or outcome particularly in legal proceedings if necessary.
- It must be possible that public purchasers can explain individuals or citizens what changes must be made to the input to arrive to a different result.
- Unless the tender specifications expressly require otherwise, making the system explainable will in any event include a clear indication of the key factors that have led the system to a particular outcome and the changes that must be made in order to arrive at a different one.
- When preparing the specifications, the contracting authority may opt not to require the contractor to explain why the system arrives to a particular outcome, but the key factors that have led the system to such outcome. This provision is crucial because if the procured solution relies on black-box models, pinpointing the exact reasons for a specific outcome might be challenging. However, it remains feasible to identify the key factors that have contributed to the outcome.

Article 13(1) of the European Commission Standard Clauses also includes a specific provision imposing the obligation of the contractor to explain the functioning of the AI System on an individual level. This obligation encompasses the duty of the contractor, during the term of the Agreement to assist the public purchaser at its first request, to explain how the AI System arrived at a particular decision or outcome to the persons or group of persons on which the AI System is (intended to be) used. This assistance will include, at least, a clear indication of the key factors that led the AI System to arrive to a particular result and the changes to the input that must be made in order for it to arrive to a different outcome. As this specific obligation is complementary to the duty of transparency laid down in Article 6 of the Standard Clauses, it follows that the transparency requirement mandated by the AIA has not been conceived - at least in the Commission's approach - to ensure the explainability of high-risk AI systems.[192]

its parameters, and information on the performance of the Algorithmic System."

[188] See Amsterdam Standard Clauses, 9. "Explainable/Explainability" is defined as follows: "Being able to explain on an individual level why an Algorithmic System leads to a particular decision or outcome. […] this will in any event include a clear indication of the key factors that have led an Algorithmic System to a particular result and the changes to the input that must be made in order to arrive at a different result. Making an Algorithmic System Explainable includes the provision of all the technical and other information required in order to explain, in objection proceedings, appeal proceedings or other legal proceedings, how a Decision has come about and to offer the other party and any other interested parties the opportunity to assess the way in which a Decision has come about, so as to offer the other party realistic legal protection."

[189] See Article 5(1) of the Amsterdam Standard Clauses and the additional explanation to the provision.

[190] See Article 5(2) of the Amsterdam Standard Clauses and the additional explanation to the provision.

[191] See Article 5(4) of the Amsterdam Standard Clauses and the additional explanation to the provision.

[192] See European Commission Standard Clauses, 6, 9-10.

Given the flawed approach of the AIA to the requirements of transparency, interpretability and explainability of AI models, it is understandable that public procurement of AI solutions, in general, lacks the appropriate safeguards to adequately ensure that purchased COTS or bespoke solutions comply with these requirements. However, this could be highly problematic in the field of healthcare.

For example, the relevance the transparency requirement of the AI models has been highlighted by the AGENAS in relation to the provision of health services through telemedicine platforms and applications (Ref. [5]): "[…] it is crucial to adopt 'Transparent AI' systems and models, which allow physicians, healthcare managers and caregivers to have full visibility of the decision-making criteria adopted with the support of the system, while respecting the patient and the ethical complexity underlying clinical actions."[193] But the importance given to 'Transparent AI' seems insufficient. While the use of AI algorithms (such as machine learning and NLP for speech recognition) is expected to be implemented in this component to serve as decision-support tools for diagnosis and treatment of patients, the technical specifications do not include concrete provisions to ensure the transparency, interpretability and explainability of the predictive-modelling component of the platform.[194]

Only but a few tender specifications encompass requirements for contractors to ensure explainable AI.

For example, Lot 1 of the tender specifications published by the ECDC (ref. **[3]**) specifically required the contractor "to support ECDC with the implementation of artificial intelligence, including machine learning and deep learning, in the processes and tasks related to surveillance and other core public health functions, as well as the *related training required to properly handle and sustain these outputs* [emphasis added]." Notably, the deliverable DL9 was focused on "Explainable AI", the objective of which is to develop a R or Python code for explainable AI in order to improve the "interpretability of AI models". Additionally, Sub-deliverable 1 (DL9S1): "Development of R or Python code with local and/or global model-agnostic methods and specific methods for [Deep Learning] interpretation. Some examples of methods used can be found in: https://christophm.github.io/interpretable-ml-book".[195]

In the case of tenders in Annex II, none but three technical specifications include provisions addressed to ensure the explainability of the models.

Tender specifications	Requirements of explainability and interpretability
POPULATION HEALTH DATABASE (Ref. [13])	The platform must facilitate the interpretation and bias analysis of the artificial-intelligence models to be developed. The successful bidder must ensure explainability and bias reduction in all analytical models developed within the project to address the specified use cases.
INFOBANCO (Ref. [16])	The data-governance model (registration, access, and usage) will encompass "explainability and traceability requirements," aligning with

[193] AGENAS, *Proposta di partnership pubblico privato ai sensi degli artt. 180 e 183, c. 15, del Decreto legislativo 18 aprile 2016, no. 50 per l'AFFIDAMENTO DELLA CONCESSIONE per la progettazione, realizzazione e gestione dei Servizi Abilitanti della Piattaforma Nazionale di Telemedicina. PNRR - Missione 6 Componente 1 sub-investimento 1.2.3. "Telemedicina". Caratteristiche dei servizi e della gestione. Capitolato Gestionale*, 12 October 2022, 69, https://www.agenas.gov.it/.

[194] Idem, 70. In particular, the platform must incorporate a predictive modelling component (Sistema AI di Smart Suggestion) utilizing AI techniques such as NLP and Speech Recognition to serve as decision-support tools for diagnosis and treatment. Specifically, AI algorithms, leveraging patient-generated data including responses to questionnaires, chat messages, photos/videos of injuries/medications, and patient categorization, will generate active alerts correlated with information from stratified databases in regional and national health repositories. Recommendations from the AI models will guide healthcare personnel in specific actions for timely and appropriate support, whether health-related, psychological, or socio-sanitary, aimed at enhancing patient adherence to treatment pathways. The operational principle must be grounded in the systematic use of the Bayesian approach for calculating the ex-post probability of occurrence of the unknown event to be predicted ('likelihood' function), based on available evidence. This includes symptoms manifested by the patient during teleconsultation sessions (if present) or structured clinical observations recorded in the relevant Electronic Health Record (FSE 2.0), as well as experimental results from clinical efficacy trials for therapies targeting the patient's specific pathological conditions.

[195] ECDC, Tender Specifications, 11-12, 19.

	initiatives and future European regulations such as the Data Governance Act, European Health Data Space, Data Act, and AI Act.
PMED BIG DATA (Ref. [18])	The interpretability specified in the technical requirements pertains exclusively to the metrics of specificity (minimum false positives) and sensitivity (minimum false negatives). This requirement applies to use cases including home monitoring of chronic conditions and hospital discharges, therapeutic optimization, identification of opportunities for deprescription, and patient segmentation based on relevant pathologies.

Table 20. Explainability and interpretability in technical specifications

7.7. *Accuracy and performance metrics in tender specifications*

Trustworthiness of AI systems can be decomposed into several component properties, including accuracy, bias mitigation, transparency and explainability, privacy, resilience and security, reliability, robustness, and safety. There are different methods (metrics) to measure each property, its strengths and limitations or in what circumstances one metric would be preferable to another.[196]

As AI models provide a predictive output, accuracy is one of the paramount properties to be considered when such models are designed to be deployed in the healthcare context. The probability of a prediction can be interpreted as the "accuracy level" of the model. Put simply, if a given classifier (e.g. a convolutional neural network) predicts with 95% accuracy that a set of dots in a mammography image is a breast cancer, it could be said that the model has a "high accuracy classification". Otherwise, if the prediction is made with 55% accuracy, the algorithm could be said to have a "low accuracy classification".[197]

In this sense, accuracy is an AI system's property which refers to the system's ability to make correct judgements based on data or models. Accuracy of AI systems is an estimate of the closeness of a measured value to the exact value. High levels of accuracy are of paramount importance in situations where the AI system directly impacts human lives.[198]

The importance of this property is even stressed by some technical specifications in relation to AI-driven telemedicine solutions: "[…] the accuracy of the MD [Medical Device] is of great importance as it can seriously compromise the diagnostic process and endanger the patient's life" (Ref. [4]).

Accuracy then becomes critical to *correctly classify* mammography images for cancer detection (Ref. [11]), DAN variants for diagnosis of genetic diseases (Ref. [17]), healthcare demand for hospital and out-of hospital emergencies for patient triage (Ref. [8]); *make correct predictions* on morbidity in pandemic situation, epidemiological anticipation, forecasting, (Ref. [3]), weaning failure and length of stay in Intensive Unit Care (Ref. [19]); or *provide appropriate recommendations* for early warning of public-health threats (Ref. [3]) or to improve pharmacological treatment of complex chronic patients or surgery waiting lists (Ref. [13]).

In such cases, an evaluation process should be required to support, mitigate and correct unintended risks from inaccurate predictions, ensuring that error rates can be identified, measured and mitigated.[199] In this regard, performance metrics are used to measure the accuracy of the learning models by diagnosing their potential errors. Each metric has a specific technical interpretation, so it must always be linked to specific use cases.[200]

In this regard, when high-risk systems are engaged, the AIA stresses the importance of some of these components of trustworthy AI systems, including accuracy: "[…] if an AI

[196] AIME Planning Team, *Artificial Intelligence Measurement and Evaluation at the National Institute of Standards and Technology*, National Institute of Standards and Technology, June 2021, https://www.nist.gov. The OECD has published a catalogue of metrics to help AI stakeholders develop and deploy trustworthy AI systems. The list provides specific metrics to measure fairness, human well-being, privacy and data governance, robustness and digital security, safety, transparency and explainability. See OCDE, *Catalogue of Tools & Metrics for Trustworthy AI*, 2023, https://oecd.ai/. As of 11 November 2023, the OECD list covers 101 metrics.

[197] Cfr. ENISA, *Securing Machine Learning Algorithms*, 14 December 2021, 10, https://www.enisa.europa.eu.

[198] HLEG Ethical Guidelines, 17.

[199] *Ibidem*.

[200] S. Teki and A. Bajaj, *How to Improve ML Model Performance*, 29 September 2023, https://neptune.ai.

system is not trained with high quality data, does not meet adequate requirements in terms of its performance, its *accuracy* or robustness, or is not properly designed and tested before being put on the market or otherwise put into service, it may single out people in a discriminatory or otherwise incorrect or unjust manner (emphasis added)".[201]

In particular, it is critical to ensure that the performance of the models are consistent enough "throughout their lifecycle and meet an appropriate level of *accuracy*, robustness and cybersecurity in accordance with the generally acknowledged state of the art". For this reason, the AIA makes it mandatory to communicate the level of accuracy and accuracy metrics to the users or deployers of the AI system.[202]

In addition to robustness, cybersecurity, and consistent performance, accuracy (defined as "an appropriate level of accuracy") is one of the requirements for high-risk systems. Specifically, Article 15(2) of the AIA stipulates that "[t]he *levels of accuracy* and the *relevant accuracy metrics* of high-risk AI systems shall be declared in the accompanying instructions of use" (emphasis added). The original provisions of Article 13 of the AIA, which lists the relevant information to be included in the instructions of use, have been slightly modified in the Draft Agreement of the AIA. Accordingly, Article 13(b) requires that such instructions include, among other relevant information:[203]

- The level of accuracy, including its metrics.[204] robustness and cybersecurity against which the high-risk AI system has been tested and validated and which can be expected, and any known and foreseeable circumstances that may have an impact on that expected level of accuracy, robustness and cybersecurity;
- When appropriate, its performance regarding specific persons or groups of persons on which the system is intended to be used.

In the context of public procurement of AI systems for the NHCS, tender specifications should include specific requirements on accuracy thresholds. It is crucial to determine and verify the level of accuracy of AI models in relation to the task (classification or regression), its purpose, and the context of its use, bearing in mind that the expected performance of a model may vary. For example, in healthcare, classification models are often associated with diagnostics, being the class labels positive and negative. This would be the case of certain proteins associated with the risk of cancer. Then, when the classifier is run, it is possible to compare the list of true proteins (the ground truths) to the proteins recognized correctly or wrongly by the model (the predicted values). In this context, the trade-offs between "sensitivity" (also called "recall") and "specificity" metrics are critical. In particular, the ability to capture the true positive cases (sensitivity) may be particularly important if the AI solution is expected to be used in early breast-cancer screening tests. But at the same time, if sensitivity is overemphasised, the proportion of true negative cases correctly identified as such (specificity) would be unacceptably low. However, when reliable detection of positive cases is clearly important in a given context, the trade-off with sensitivity needs to be considered carefully.[205]

Moreover, trade-offs between precision and recall must be carefully addressed, as differences between them may affect the fairness of the model or may lead to adverse impacts.[206]

From the list of the tenders of interest, only some of them include specific provisions in the tender documents requiring the implementation of performance metrics. The joint procurement of Regional Governments of Valencia and Canarias, PMed Big Data (Ref. [18]), represents the best example of how performance metrics are required in relation to some use cases of Phase 1 of the

[201] Recital 38 of the AIA.
[202] Recital 49 of the AIA.
[203] In relation to the technical documentation required for high-risk AI systems, ANNEX IV of the AIA includes a detailed information about the metrics used to measure accuracy the monitoring (paragraph 2g); and the functioning and control of the AI system, "in particular with regard to its capabilities and limitations in performance, including the *degrees of accuracy for specific persons or groups of persons* on which the system is intended to be used and the *overall expected level of accuracy* in relation to its intended purpose; the foreseeable unintended outcomes and sources of risks to health and safety, fundamental rights and discrimination in view of the intended purpose of the AI system (emphasis added)."
[204] The reference to accuracy metrics was introduced in the AIA by an amendment of the Council mandate, and accepted in the Draft Agreement of January 2024.
[205] UK NHS Buyer's Guide, 34-36.
[206] Information Commissioner Office, *Guidance on AI and data protection*, version 2.0.17, 15 March 2023, 40, https://ico.org.uk.

project.[207]

USE CASE 7 (FHASE 1)- Description of the pathophysiology of low back pain using analytical prediction techniques from MR imaging
Minimum quality of model development in the first phase: the quality of the model will be determined on the basis of the following metrics: - Sensitivity: achieved 75%: 250 points. - Precision: achieved 75%: 250 points. - Accuracy: achieved 75%: 250 points. - F1 score: achieved 75%: 250 points. - The achievement of the milestone will be certified by the prediction of the delivered sample with an approximate accuracy of at least 75%. - Evaluation criteria for moving on to the second phase: the quality plus in terms of model development will be assessed using the following metrics: - Sensitivity: achieved 80%: 15 points; 85% achieved: 25 points. - Precision: achieved 80%: 15 points; 85% achieved: 25 points. - Accuracy: 80% achieved: 15 points; 85% achieved: 25 points. - F1 score: achieved 80%: 15 points; 85% achieved: 25 points.

Table 21. Accuracy thresholds in technical specifications

Completing this approach, for phase 2 of the project, technical specifications stipulated that, for each of the use cases, specificity (minimum false positives) and sensitivity (minimum false negatives) would be measured. By the end of June 10, 2023, the minimum values required by Spanish or European regulatory agencies for authorization as a diagnostic support device, were set at 95% and 90%, respectively. In at least half of the cases, it had to be reported that the prediction is of high probability and achieve 98.5% and 95% compared to human professionals.[208]

In the MEDIOGENOMICS project (Ref. [17]), tender specifications require that the automated retrieval and extraction of medical information must have a minimum quality of sensitivity and specificity, with errors in no more than 1% of text extractions and 2% of speech extractions.

In other tenders, technical specifications prescribe concrete metrics such as sensibility, specificity or the Area under the ROC Curve, but it does not stipulate any error thresholds (Refs. [8], [18]).

In many cases, users of AI systems emphasize model-error metrics while omitting the corresponding evaluation of the potential impacts of errors. For instance, a very low probability of error (e.g., 0.1% of false negatives), but with potential adverse impacts arising from this error (e.g., death of a patient), may not be assumable by the organization.[209]

8. *Concluding remarks: challenges for the NHCS in public procurement of AI solutions*

In general, procurement procedures must ensure the fulfilment of clinical and technical requirements, while also considering the pertinent regulatory and financial contexts.[210] In this respect, procurement procedures ought to serve as a mechanism to enhance efficiency, thereby fostering improved health outcomes. In addition, they should be used as a policy tool to achieve a range of objectives, including promoting innovation, supporting small and medium-sized enterprises, fostering sustainable growth and advancing social objectives such as building more inclusive public-health systems.[211]

A fresh and comprehensive approach on public procurement should be contemplated, shifting away from the rigid, bureaucratic administrative role - solely focused on obtaining work, supplies, or services - towards recognizing public procurement as a legal tool serving public purchasers to effectively fulfil the broader public interest and policies.[212]

More specifically, public procurement

[207] Gobierno de Canarias and Generalitat Valenciana, *Pliego de Prescripciones Técnicas*, 22.
[208] *Idem*, 25.

[209] A. Zlotnik, *Artificial Intelligence in Public Administrations: Definitions, Project Feasibility assessment and Application Areas* in *Boletic* (2019), no. 84, 2019, 27–28.
[210] S.C. Mathews, M.J. McShea, C.L. Hanley, A. Ravitz, A.B. Labrique and A.B. Cohen, *Digital health: a path to validation* in *NPJ Digital Medicine* vol. 2, no. 38, 2019, https://pubmed.ncbi.nlm.nih.gov/31304384.
[211] A. García-Altés *et al*., *Understanding public procurement within the health sector*, 172-185.
[212] European Commission, Europe 2020. A strategy for smart, sustainable and inclusive growth, Com(2010)2020, Brussels 3 March 2020; Council Conclusions. Public investment through public procurement: sustainable recovery and reviving a resilient EU economy, 2020/C 412I/01, Official Journal of the European Union, 30 November 2020.

should serve to design "a new architecture that allows the harmonious articulation of the so-called circles of excellence –service excellence (thinking first of people), process excellence (doing the right thing without undue bureaucracy) and technical excellence (having talent and knowledge)".[213]

Despite the beneficial outcomes, there are significant challenges that need to be addressed before any AI solution can be procured and deployed into public-health services.

The review of the sampled tenders reveals relevant challenges for NHCS in relation to the past, present, and future procurement of most AI solutions. These challenges can be classified on the basis of four criteria: the potential qualification of the procured solution as a high-risk AI system; the specific complexities of the procurement process in the healthcare sector; the legal and ethical risks due to the individual or societal impact of AI systems in healthcare; and the formal and substantive aspects of the procurement procedure and the design of tender specifications.

8.1. *The challenging interplay between the AIA and the MD Regulations and the problem of legacy systems*

At the macro level, there is no regulatory framework for AI with a sufficient level of development and maturity within the European Union, apart from fragmented national legislation.

The AIA is still under discussion. However, when planning the acquisition of AI-enabled solutions for the NHCS, the absence of a regulatory framework should not prevent contracting authorities from putting in place specific measures to adequately address inherent risks of AI acquisitions.

Moreover, once the AIA comes into force, it is likely to be quite challenging to bring legacy AI systems into full compliance with the EU Regulation's horizontal mandatory requirements for high-risk systems, irrespective of whether these systems are based on COTS or bespoke solutions.

For the time being, it remains unclear whether the AIA will be applicable or not to legacy AI systems already placed on the market or put into service before the effective date of application of the Regulation.[214]

However, if the Act is ultimately applicable to such legacy systems,[215] it is likely to be quite challenging to bring them into full compliance with the AIA, irrespective of whether those systems are based on COTS or bespoke solutions.

8.2. *Complexities of procurement process can be exacerbated by AI*

At the micro level, contracting authorities will face specific challenges.

In the first place, the role of public administrations as guarantors may determine the deployment of different AI applications in the NHCS than in the private sector.[216] In this sense, healthcare is a highly sensitive area, where AI-enabled solutions must be designed for public use in order to meet the needs of all citizens. Whereas such constraints are not necessarily present in the private sector, public-sector purchases should be in the public interest, which means higher standards of compliance.[217]

In the second place, the purchase of AI solutions by public-health services also poses a major challenge in terms of planning and design of these procurement procedures, as many highly complex transactions are involved. To a greater or lesser extent, the disruptive nature of AI is beginning to shape the existing procurement processes, given that "uncertainty" is a dominant feature of AI solutions in terms of functionality, behaviour and organizational consequences.[218]

At the same time, such uncertainty may

[213] J.M. Gimeno Feliú, *El necesario big bang en la contratación pública: hacia una visión disruptiva regulatoria y en la gestión pública y privada, que ponga el acento en la calidad*, in *Revista General de Derecho Administrativo*, no. 59, 2022.

[214] Cfr. Article 83 of the AIA. With the exception of the effective date of application of the AIA (12 or 36 months before its entry into force), the Council's version contains the same provisions as the Commission's with regard to AI systems already placed on the market or put into service.

[215] In line with the demands of the EU Parliament, European Economic and Social Committee, European Data Protection Supervisor or European Data Protection Board.

[216] I. Georgieva, T. Timan and M. Hoekstra, *Regulatory divergences in the draft AI Act. Differences in public and private sector obligations*, European Parliamentary Research Service, Brussels, May 2022; M. Manzoni, R. Medaglia, L. Tangi, C. Van Noordt, L. Vaccari and D. Gattwinkel, *AI Watch. Road to the Adoption of Artificial Intelligence by the Public Sector*, JRC-European Commission, Luxembourg, 2022.

[217] M. Sloane *et al*., AI and Procurement, 7-8.

[218] L. Silsand *et al*., *Procurement of artificial intelligence for radiology*, 1388, 1389.

trigger potential challenges during the procurement process of AI solutions for NHCS in relation to the selection of the adequate procurement procedure and/or the design of the tender specifications to put in place appropriate safeguards in order to ensure trustworthiness and iterative evaluation of the purchased AI solution.

In the third place, public-health purchasers often lack extensive knowledge of existing solutions on the market or may not be aware of the specific public needs to be addressed, or the optimal technological solution for the problem at hand. There may also be an imbalance between purchasers, public-health services, and suppliers, particularly due to existing barriers that hinder competition and limit the number of economic operators bidding for tenders. Similarly, difficulties may arise regarding the ownership of intellectual property resulting from AI products or the incorporation of interoperable solutions that prevent vendor lock-in.[219]

In the fourth place, the quality of the AI solutions purchased is highly dependent on technical requirements, such as having standardised and secure repositories of multidimensional data, ensuring the accuracy of the AI models over time, industrialising the deployment and control of the models, or ensuring the security and confidentiality of the data throughout the lifecycle of solutions.[220] Furthermore, to understand how the diagnosis, prognosis or treatment pathways are reached, thereby increasing the buy-in from medical staff, an adequate degree of transparency and interpretability is needed over the results produced by AI systems.[221]

Finally, contracting authorities should be provided with appropriate human and material resources "to build up literacies and capacities" around the collective and individual impacts of procuring AI solutions. This literacy and capacity building should include the exchange of expert knowledge across public buyers.[222]

8.3. *Legal and ethical risks of AI solutions*

At the macro-level, there are also many legal and ethical challenges associated with the use of AI in health sector.

Because of the sensitive nature of healthcare, it is not a coincidence that the future AIA will set forth specific rules for AI systems that can create a high risk to "health and safety or fundamental rights of natural persons", regardless that they operate as stand-alone systems or components of products (e.g. medical devices).[223]

*Prima faci*e, AI solutions are prone to collide with fundamental rights enshrined by the Charter of Fundamental Rights of the European Union (EU Charter) and the constitutional texts of the Member States. This could be the case of the right to privacy and personal-data protection,[224] insofar as these AI applications would process particularly sensitive data of citizens such as health data.[225] By the same token, the right to equality and non-discrimination[226] could be compromised, given the risk of classifying or stratifying patients into groups or subgroups according to the processing of data by AI solutions resulting in discriminatory or stigmatising decisions.

From an ethical perspective, the dilemma will always be "who" and "what" the AI is used for,[227] along with considerations of transparency, lack of bias, inclusiveness, etc.[228]

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[219] See European Commission, *Public procurement in healthcare system: Opinion of the Expert Panel on effective ways of investing in Health (EXPH)*, Luxemburg, Publications Office of the European Union, 2021, 1, 8, Doi:10.2875/832331; García-Altés *et al*., *Understanding public procurement within the health* sector, 172-185.

[220] J.C. Sanchez Rosado and M. Diez Parra, *Impacto de la inteligencia artificial en la transformación de la sanidad: beneficios y retos*, in *Economía industrial*, no. 423, 2022, 129-144.

[221] Harwich and Laycock, *Thinking on its own*, 24, 42-43.

[222] M. Sloane *et al.*, *AI and Procurement*, 28.

[223] See Recitals (27), (28), (43), and Article 6 in relation to Annex II. 8 and Annex III. 5 of the AIA.

[224] Respectively, Articles 7 and 8 of the EU Charter.

[225] L. Cristea Uivaru, *The protection of sensitive data: Digital Health Record and Big Data in Health*, Barcelona, J.B. Bosch Editor, 2018.

[226] Articles 20 *et seq*. of the EU Charter.

[227] A cancer-predictive model used by the public health system to make early diagnoses is not the same as an AI model used by an insurer to grant or deny a health insurance or, even to determine the health insurance premium. See S. Hoffman and A. Podgurski, *Artificial intelligence and discrimination in health care*, in *Yale Journal of Health Policy, Law and Ethics*, vol. 19, no. 3, 2020, 1, 31; C.W.L. Ho, J. Ali and K. Caals, *Ensuring trustworthy use of artificial intelligence,* in *Bulletin of the World Health Organisation*, vol. 98, no. 4, 2020, 263, 264.

[228] World Health Organization, *Ethics and governance of artificial intelligence in health: WHO guidance: summary*, 2021, https://apps.who.int/iris/handle/10665/350263.

8.4. *Addressing formal and substantive challenges of AI procurement for the NCHS*

Deciding whether or not to procure AI solutions for the NHCS and drafting tender specifications could be challenging, as it is necessary to avoid potential tensions that may arise between the formal aspects (the procurement process) and the substantive aspects (including specific safeguards in the tender specifications to mitigate the specific risks of procuring an AI solution to meet a public need). In between, an ex-ante AI impact assessment will help to identify the specific individuals, targeted patients or societal risks of the AI solution.

On the one hand, the formal aspects of the procurement process require the public purchaser to take strategic decisions on whether AI is the best solution to meet the public need identified by the public purchaser, the appropriateness and feasibility of implementing an innovation procurement approach (PPI or PCP), an adequate analysis of the state of the art, and market engagement to launch open-market consultations, the type of procedure to be used (open or specific innovation procedures), the expertise and multidisciplinarity of the public officials in charge of evaluating the bidders' offers, whether to acquire a COTS or a bespoke solution, the type of tender specifications (descriptive or functional), the appropriate management of intellectual-property rights.

On the other hand, tender specifications should consider specific safeguards to avoid the inherent risks of implementing AI in healthcare in relation to the identified use cases. An ex-ante AI impact assessment will enable public purchasers of the NHCS to proactively detect potential risks and design appropriate technical and organisational measures and safeguards to be implemented in tender specifications.

Irrespective of whether the AI system is classified as "high risk" or not, the public purchaser should ensure that the technical and administrative specifications include appropriate provisions, including safeguards in line with the future AIA, to ensure: the quality and validation of data sets for the intended purpose, the integration and interoperability of the AI solution with the existing infrastructure and organisational practices of the health service, technical and procedural transparency and explainability approach to ensure an adequate level of interpretability of the AI solution in relation to the end user of the system and the individuals or collectives concerned, human oversight, robustness and security, adequate metrics to minimise errors and optimise the performance of the procured solution, full compliance with the intended purpose throughout the life cycle of the AI system, a documented risk-management system in relation to the specific risks of the AI solution, and technical documentation of the procured solution to be provided by the contractor in a timely manner.[229]

[229] Final note from the authors: At the time of publication of this work, the European Parliament had adopted the final version of the AIA (See legislative resolution of 13 March 2024, P9_TA(2024)0138). Consequently, references in this work to the AIA in the Commission's proposed version (COM/2021/206 final) or the trilogue text (Draft Agreement of 21 January 2024) may have changed.

9. *Annexes: tenders of interest*

9.1. *Annex I: eTendering (EU) and Ministero della Salut (Italy)*

Contracting authority	Subject-matter	AI strategy	Procurement innovation strategy/ Procedure type	Awarded
Notice Reference: Ref. [1]. SMART 2019/0056				
European Commission DG CONNECT	Study aiming to analyse the progress on the adoption of AI technologies for the benefit of patients and EU healthcare sector, and to provide an overview of the current situation across EU Member States, with a view to support and inform EU policy initiatives to harness AI and Big Data for digital transformation and improvement of EU healthcare (Lot 2).	Review of relevant available data, surveys, methodologies, indicators and metrics in EU healthcare sector.	Open Procedure	23/09/2019 (Closed) No info on contractor in eTendering
Notice Reference: Ref. [2]. OC/EFSA/AMU/2020/02				
European Food Safety Authority (EFSA) and other EU bodies	Providing assistance to EFSA for statistical and epidemiological analyses, related data management and other relevant tasks using AI methodology, as well as for training and *ad hoc* consultation upon request.	AI and MLT models e.g. NLP, text classification, NER models etc.).	Open Procedure	25/11/2020 (Closed) No info on contractor in eTendering
Notice Reference: Ref. [3]. OJ/2023/PHF/26497				
European Centre for Disease Prevention and Control (ECDC)	Implementation of AI in the processes and tasks related to surveillance and other core public-health functions, with further improvement of early warning of public-health threats using social media, as well as the related training required to properly handle and sustain these outputs.	ML/DL model for regression or classification problem. Unsupervised models on clustering or dimensionality reduction. NLP models. AI interpretability methods.	Open Procedure Framework Agreement	01/09/2023 (closed) No info on contractor in eTendering
Notice Reference: Ref. [4]. CIG 94572555B6				
Italian National Agency for Regional Healthcare Service (AGENAS)	Design, implementation, deployment and management of an AI platform to support primary health care.	ML, DL, Federated learning.	Competitive dialogue Piano Nazionale di Ripresa i Resilienza	No info Deadline for tenders: 16/12/2022
Notice Reference: Ref. [5]. CIG: 9423681B90				
Italian National Agency for	Design, implementation and management of the enabling services of	ML (Bayesian approach), NLP, NPL-	Open Procedure Piano Nazionale	01/03/2023

Regional Healthcare Service (AGENAS)	the National Telemedicine Platform for fast data access to be processed and updated, both through traditional techniques and innovative approaches (AI di Smart Suggestion), which include a teleconsultation module integrating NLP, Augmented Reality and predictive modelling.	speech recognition (speech-to-text-to-analysis), Augmented Reality.	di Ripresa i Resilienza	

9.2. *Annex II: PLACE and buyer profiles (Spain)*

Contracting authority	Subject-matter	AI strategy	Procurement innovation strategy/ Procedure type	Awarded
Notice Reference: Ref [6]. 123/15-SV				
State public undertaking, Red.es	Information system under Big Data architecture for sentiment analysis of the Regional Health Service of Castilla-La Mancha (SESCAM).	Classification algorithms.	Open Procedure	22/09/2015
Notice Reference: Ref. [7]. 2016/051				
National Institute for Health Management (INGESA)	R&D to build a clinical information repository and 4 expert systems (hypercholesterolaemia, diabetes mellitus, emergency and telemonitoring of chronic patients) for predictive analysis and decision-support based on the repository.	No information available on PLACE (only prior contract notice).	PCP Open Procedure	No info available on PLACE.
Notice Reference: Ref. [8]. CNMY18/AVSRE/4				
Presidency of the Regional Govt' of Valencia	Expert system to assist 112 operators in the classification of healthcare demand for emergencies, out-of-hospital emergencies and medical calls to emergency number 112.	Naïve Bayes, FAN, TAN, neural networks and other algorithms with best performance.	Open procedure	12/06/2018
Notice Reference: Ref. [9]. 2023-PR-036 (2019-3-009)				
University Hospital Infanta Leonor	Development, support and maintenance of an advanced expert healthcare support system, implemented with AI, for the exploitation of the information (Big Data) contained in the hospital's electronic medical records.	NLP, ML, neural networks.	Negotiated procedure without publication	22/06/2019
Notice Reference: Ref. [10]. LN-SER1-18-041				
Galician Health Service (SERGAS)	Personal-assistant system (AVATAR) which generates intelligent alert generator to increase patient autonomy.	(Undetermined) AI techniques for pattern behaviour detection and advanced system for facial, body posture and voice recognition .	Negotiated procedure	24/06/2019
Notice Reference: Ref. [11]. DC-SER1-19-003				
Galician	Support system for cancer detection	(Undetermined)	PPI	27/09/2019

Health Service (SERGAS)	(CADIA) based on the analysis of mammography and pathological anatomy imaging with AI techniques.	Optimal statistical analysis method.	Competitive Dialogue	
Notice Reference: Ref. [12] 2020/LIC/0026				
EGARSAT, Auxiliary entity of the Social Security System	Design, development, implementation and maintenance of AI-based support-information decision systems for predicting the duration of sickness absence due to illness or accident; predicting the number and type of sickness absence 12 months ahead and segmenting it by diagnosis, cause and month; ongoing maintenance of predictive models for 3 to 4 years.	ML (Regression, Clustering, Classification, Recommendation), ANN, Random Forest, SVM.	Open Procedure	24/09/2020
Notice Reference: Ref. [13]. 067/20-SP				
State public undertaking, Red.es	Corporate solution (software and hardware platform) for advanced analytics based on Big Data, ML and DL technologies for the Public Health System of Andalusia (SAS), enabling massive exploitation of the 'Population Health Database'.	ML, DL.	Open Procedure	02/08/2021
Notice Reference: Ref. [14]. CSE/9900/1101001998/21/PA				
Health Service of Murcia (SMS)	Design, implementation, setup and development of a health-data lake platform in the Health Service of Murcia (AZUD Project).	ML.	Open Procedure	18/11/2021
Notice Reference: Ref. [15]. 202150PA0009				
Ministry of Health	Development of applications for digital transformation in the National Health System of the Ministry of Health.	Analytical tools, AI, NLP, other (Big Data, Blockchain, Robotics).	Open Procedure National Plan of Recovery, Transformation and Resilience	11/03/2022
Notice Reference: Ref. [16] 51/2021 (A/SER-032254/2021)				
Health Dpt.' of the Regional Govt.' of Madrid	Development and implementation of a three-layer Data Lake architecture (INFOBANCO) for health system learning, conceived as a standardised repository of health data generated by different sources (clinical, administrative and research systems), for care improvement and innovation, personalised medicine, biomedical research and other secondary uses.	Tools for building analytical and predictive models based on statistics (statistical learning) and computer science (machine learning, deep learning, AI), federated learning.	PPI Open Procedure	22/03/2022
Notice Reference: Ref. [17]. 52/2021 (A/SER-032253/2021)				
Health Dept.' of the Regional Govt.' of Madrid	Expert platform (MEDIOGENOMICS) that automatically combines the entire process of an individual's genomic study, clinical information obtained	Automatic retrieval and encoding of relevant clinical data from electronic/ paper reports and consulta-	PPI Accelerated open procedure	29/03/2022

	during consultation and massive sequencing of 380 genomes using NGS with continuous updating in real time and integration with EHR, aimed at optimising genetic diagnosis for the patient/citizen and improving diagnostic tools for genetic diseases.	tions (speech-to-text) using NLP and ML techniques. Analysis of genomic information contained in EHR with ML techniques.		
Notice Reference: Ref. [18] 18/CPP/1				
Health Depts.' of the Regional Govts.' of Gran Canarias and Valencia	Development of an interoperable solution, «MEDICINA PERSONALIZADA BIG DATA», («PMed Big Data») integrating (i) a patient-health system interface for data collection to register lifestyle and promotion of health, assisted by AI; (ii) predictive clinical tools for support decision; (iii) a platform that operationalises available data into useful functionalities for patient care. The interface and support-decision tools will respond to the listed use cases and meet specific objectives (personalized treatments and early diagnose, reduction of adverse effects, effectiveness of treatments for complex chronic patients, improvement of healthcare resources).	NLP, ML/DL.	PCP Open procedure	06/04/2022
Notice Reference: Ref. [19]. CSE/AH02/1101308996/23/PO				
Catalan Institute of Health (ICS)	Development of AI models on the Data Lake type historic repository available at the proprietary Cloudera Platform to improve and support clinical-decision making in the integral care of critical patients and their families (CRITIC-CONTAS) according to the expected use cases (prediction of weaning failure, length of stay in ICU) and optionally (prediction of shock, cardiorespiratory arrest, coma, respiratory failure, discharge from the ICU to the ward).	ML, DL.	Open Procedure	06/06/2023
Notice Reference: Ref. [20] ROSIA PCP 101017606				
Health Sciences Institute of Aragón and others	New solutions to be developed and tested to address and unlock the tele-rehabilitation market by purchasing the development of a technologically-innovative ecosystem, enabling service providers to provide telerehabilitation, and self-management of rehabilitation & self-care at home, at scale.	AI analytics/ML, Augmented Reality.	PCP Open procedure	29/09/2022