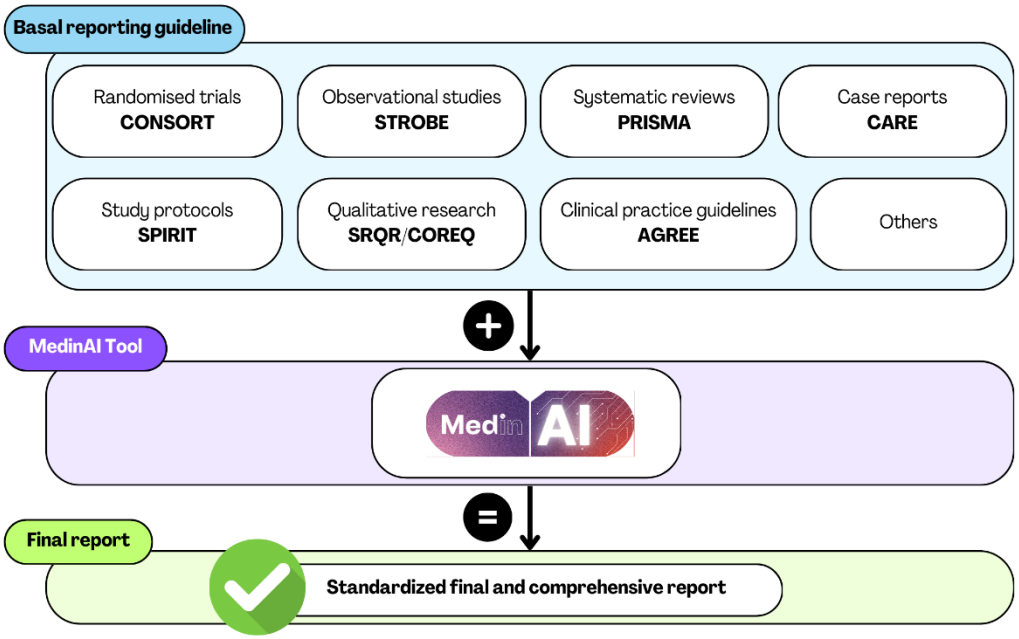
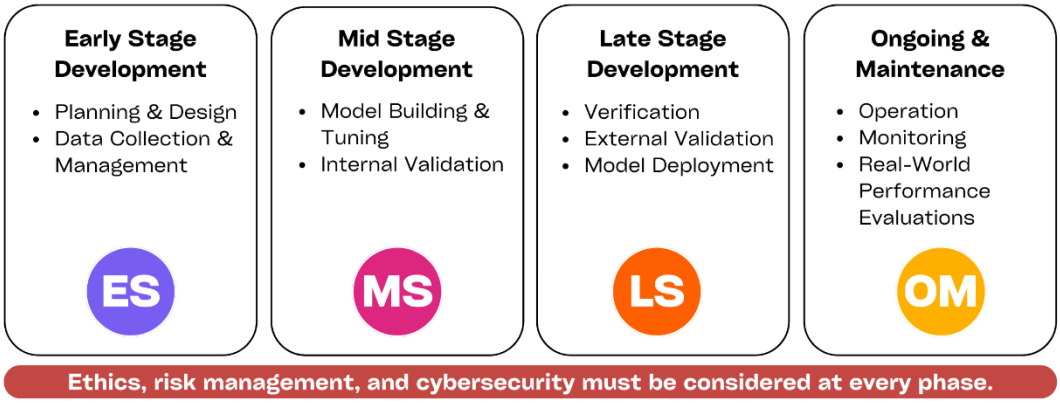
Guidelines for Reporting Artificial Intelligence Studies in Medicines, Pharmacotherapy, and Pharmaceutical Services

Step 1) MedinAI function in concert with other critical reporting tools to enhance the quality and transparency of research.



Step 2) Since the tool is highly multidisciplinary, it's important to review the **Explanation and Elaboration (E&E) document** to familiarize yourself with the relevant concepts and terms before finalizing the tool.

Step 3) Required items may vary depending on the phase of AI development. Authors should report as much information as possible, with phase-specific recommendations listed next to each item according to the legend below.



Research conducted at: UFPR Universidade Federal do Paraná · PPGASFAR Programa de Pós-Graduação em Assistência Farmacêutica

Ethics Committee approval number: CAAE 75582923.3.0000.0102

Guidelines for Reporting Artificial Intelligence Studies in Medicines, Pharmacotherapy, and Pharmaceutical Services (MedinAI)

CORE DOMAIN

1. Study		Page the item was reported on
ES MS LS OM	1.1. Study design	8 - 9
	1.2. Basal reporting guideline that was used	9
	1.3. Study location	6
	1.4. Study timeline	9
	1.5. Study setting	9

2. Core of the artificial intelligence (AI) model		Page the item was reported on
ES MS LS OM	2.1. Stage of the AI development/life cycle	6
	2.2. Collaborative development (multidisciplinary and interdisciplinary team)	6
	2.3. Classification of the type of high-level algorithm used Examples: machine learning, deep learning, evolutionary, ensemble, and/or rule-based algorithms etc.	6
	2.4. Specification of algorithm methodologies Examples: supervised, unsupervised, semi-supervised, reinforcement learning, convolutional neural networks, recurrent neural networks, generative adversarial networks, transformer models, random forests, boosting algorithms etc.	6
	2.5. Performance metrics Examples: accuracy, precision and recall, area under the ROC curve, fairness, and/or bias.	6, 13-14
	2.6. Predictive analysis capabilities and analysis	6
	2.7. Publication of source code and models to promote transparency and reproducibility	6
	2.8. Explainability	
	2.9. Domain generalization techniques applied to avoid domain shift	
	2.10. Operation in real-time or through batch processing	
LS OM	2.11. External validation	

3. Legal and regulatory bias		Page the item was reported on
ES MS LS OM	3.1. Legislative jurisdiction considered during development and year Example: Jurisdiction of the European Union (2024); Jurisdiction of the United States (2023).	

4. Core of the AI-based application		Page the item was reported on
ES MS LS OM	4.1. Interoperability and integration with healthcare systems	6
LS OM	4.2. Presence of a user-friendly interface (UI)	6
	4.3. User experience (UX) tests	6

5. Data		Page the item was reported on
ES MS LS OM	5.1. Introductory description of data	6
	5.2. Statement confirming the use of real-world or synthetic data	6
	5.3. Data acquisition	6
	5.4. Authorization for data use	6
	5.5. Data privacy and security	6
	5.6. Data anonymization	6
	5.7. Data governance practices	6
	5.8. Data cleaning and preparation	6
	5.9. Handling of missing data	6
	5.10. Data subsets	6
	5.11. Adequate population and/or data representativeness or disclaimer	6
	5.12. Detection of seasonal variations in data	
	5.13. Compliance with data protection regulations Examples: General Data Protection Regulation (GDPR), Health Insurance Portability and Accountability Act (HIPAA), Lei Geral de Proteção de Dados (LGPD), and others.	
	5.14. Data sharing to promote transparency and reproducibility	

6. Trustworthy use of AI by healthcare professionals		Page the item was reported on
ES MS LS OM	6.1. Responsibilities assigned to the AI and those assigned to the healthcare professionals	
	6.2. Professionals' responsibilities in verifying AI recommendations using other techniques	
	6.3. The extent to which professionals should trust AI at its current stage of development	
LS OM	6.4. Considerations on education and training of healthcare professionals in the use of the AI	

7. Model update, quality, and cost-effectiveness This section may not apply to all models or stages of development, but researchers must report them when appropriate.		Page the item was reported on
ES MS LS OM	7.1. Handling of model drift/degradation and adaptation to new scientific evidence	
	7.2. Specification of roles and accountability for model maintenance and quality across stakeholders	
	7.3. Channel for receiving user and/or patient feedback	
LS OM	7.4. Cost-effectiveness considerations considering economic, clinical, and humanistic outcomes	
OM	7.5. Continuous monitoring post-implementation	
OM	7.6. Post-marketing surveillance actions	6

DOMAIN: ETHICAL CONSIDERATIONS IN MEDICATION AND PHARMACOTHERAPY

8. Ethics		Page the item was reported on
ES MS LS OM	8.1. Ethics committee/institutional review board (IRB) approval or exemption	Not applicable
	8.2. Detailed informed consent process	Not applicable
	8.3. Procedure and methodology on promotion of respect for patient autonomy and patient privacy	Not applicable
	8.4. Procedure and methodology for data override or deletion upon patient/organization request	Not applicable
	8.5. Robust testing to prevent unfavorable outcomes influenced by socioeconomic factors, racial and ethnic identity, population groups, vulnerable groups, and genetic variability	Not applicable
	8.6. Procedure and methodology used to ensure that AI is accessible and beneficial to all groups of people, regardless of their background, to promote fairness and equity (justice allocation of AI utilization)	Not applicable
	8.7. Comprehensive disclose of funding sources, including contributions from industry, government grants, and institutional support	Not applicable

DOMAIN: MEDICINES AS PRODUCTS

This domain is required for product-oriented AI models and for service-oriented AI models with medicines information.

9. Medicines considerations		Page the item was reported on
ES MS LS OM	9.1. Description of medicines data profile	Not applicable
	9.2. Usage of data regarding non-approved medicines	Not applicable
	9.3. Usage of data with off-label indications, doses, and/or posology	Not applicable
	9.4. Outcome measures	Not applicable

10. Specific quality and safe usage precautions considered by the AI regarding medicines		Page the item was reported on
ES MS LS OM	10.1. Analysis of bias in medicine data	Not applicable
	10.2. Analysis of bias in outputs	Not applicable
	10.3. Bias mitigation	Not applicable
	10.4. Testing for intrinsic or incorporated conflicts of interest in data Example: Determining the prevalence of each specific medicine brands in the dataset	Not applicable
	10.5. Testing for bias in the primary dataset related to health conditions	Not applicable
	10.6. Testing for improper, unsafe, and/or incorrect medicine names, doses, posology, and indications	Not applicable

11. Legal and regulatory bias regarding medicines		Page the item was reported on
LS OM	11.1. Model outputs alerts for medications not allowed or approved in certain markets or regions	Not applicable

DOMAIN: SERVICES RELATED TO MEDICINES AND PHARMACOTERAPY

This domain is required for AI models involving services; otherwise, evaluate medicine as products domain only.

12. Service		Page the item was reported on
ES MS LS OM	12.1. Service description	Not applicable
	12.2. Professionals responsible for providing the service	Not applicable
	12.3. Detailed description of the target receivers/audience for the service	Not applicable
	12.4. Service primary goals	Not applicable
	12.5. Service settings	Not applicable
	12.6. When the service takes place or is triggered	Not applicable
	12.7. Actions needed to be performed by the professional	Not applicable
	12.8. Necessary input resources or information for the service to be performed	Not applicable
	12.9. Specified frequency for the service delivery	Not applicable
	12.10. Professional autonomy regarding the service	Not applicable
	12.11. Extent of service automation	Not applicable
	12.12. Outcome measures	Not applicable

13. Specific quality and safe usage precautions considered by the AI regarding services		Page the item was reported on
ES MS LS OM	13.1. Analysis of bias in outputs	Not applicable
	13.2. Bias mitigation	Not applicable
	13.3. Testing to avoid improper, unsafe, and/or incorrect actions performed by the user	Not applicable

14. Legal and regulatory bias regarding services		Page the item was reported on
LS OM	14.1. Model outputs alerts for services not allowed or approved in certain markets or regions	Not applicable

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