Plan Overview

A Data Management Plan created using DMPonline

Title: AI governance frameworks in healthcare: a transdisciplinary scoping review.

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Template: 2 - VU GDPR registration form for research 2021 v1.1

Project abstract:

This study combines a systematic scoping review of healthcare AI governance instruments with a transdisciplinary multi-stakeholder workshop. The scoping review maps and compares binding and non-binding governance frameworks relevant to artificial intelligence in healthcare across global, regional, and national jurisdictions (2015–present), following the PRISMA-ScR protocol. The workshop component uses a Nominal Group Technique-informed structured procedure to validate the scoping review findings, prioritise governance gaps, and co-produce implementable recommendations with participants drawn from five stakeholder categories: regulators, AI developers, health-system implementers, civil society representatives, and researchers.

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Copyright information:

AI governance frameworks in healthcare: a transdisciplinary scoping review.

0. General information

0.1 Document version & date

Version 1.0 — 30/04/2026

0.2 Project title

AI governance frameworks in healthcare: a transdisciplinary scoping review.

0.3 Project summary

This study maps and compares healthcare AI governance instruments across global, regional, and national jurisdictions using a two-part methodology: a systematic scoping review following the PRISMA-ScR protocol, and a transdisciplinary multi-stakeholder workshop. The scoping review identifies binding and non-binding legal instruments governing AI in health settings (2015–present) across six world regions. The workshop uses a Nominal Group Technique-informed procedure to validate the scoping review evidence map, prioritise governance gaps, and co-produce implementable recommendations with stakeholders from five categories: regulators, AI developers, health-system implementers, civil society representatives, and researchers. The study aims to contribute to safer, more equitable, and implementable governance of AI in health systems globally.

0.4 At which VU Faculty is this project situated?

- Faculty of Science (BETA)

0.5 Your contact details

Gloria Brambilla, MSc student, Faculty of Science, Vrije Universiteit Amsterdam.
Email: g.brambilla@student.vu.nl.

0.6 List other people involved, including those at partner organisations in the project (if applicable)

Daniella Brals, primary supervisor, Amsterdam Institute for Global Health and Development (AIGHD).
Email: d.brals@aighd.org.

Role: Academic supervision

0.7 Project code (if applicable)

Not applicable.

0.8 Funding organisation & grant number (if applicable)

Not applicable.

0.9 If there is another DMP connected to this form, please provide a link (when applicable)

Not applicable.

1. Data description

1.1 Will you use existing data? If yes, what is their source?

Yes. The scoping review component uses existing publicly available documents: binding and non-binding governance instruments (legislation, regulations, strategies, guidance documents, and standards) relevant to AI in healthcare, retrieved from academic databases (Scopus, Web of Science, HeinOnline), grey literature repositories (BASE, CORE, Policy Commons), legal portals (EUR-Lex, GovInfo, WorldLII, ECOLEX, WIPO Lex), and organisational repositories (OECD iLibrary, IMDRF, ISO, IEC, IEEE, HL7). These are publicly accessible documents and contain no personal data.

1.2 Will you collect or produce new data? If yes, please describe how.

Yes. New data will be collected through a multi-stakeholder workshop. Data collected includes: written informed consent forms and conflict of interest disclosure forms (containing participant names and signatures); structured facilitator notes taken during the session; anonymised digital board exports from the shared workspace (Miro); ranked outputs and voting results (anonymised); and optional audio recordings if all participants consent. A participant code system will be applied immediately upon consent, separating all identifiers from content data.

1.3 Describe the population/participants/subjects that will be studied

Adult professionals with expertise or experience in healthcare AI governance, recruited purposively from five stakeholder categories: (1) regulators and public authority staff, (2) AI developers and

industry representatives, (3) health-system implementers, (4) civil society and patient advocacy representatives, and (5) researchers. Participants are not vulnerable individuals. No minors are included. Participation is voluntary and unpaid.

1.4 Do you process any of the following (personal) data?

- Contact details
- Addresses
- Name

Yes. The following personal data are processed: names and email addresses (for consent and scheduling); handwritten or digital signatures (on consent forms); professional affiliations (on COI forms, aggregated and not attributed in reporting); and voice recordings (optional, only if all participants consent). No special category data as defined under GDPR Article 9 are collected, with the exception that COI disclosures may incidentally reference professional or financial interests.

1.5 Do you process the personal data based on informed consent?

- Yes, using digital consent
- Yes, with oral consent **

Yes. Written, opt-in informed consent is obtained from all participants prior to the workshop, using a consent form approved in coordination with the BETHCIE ethics self-check (completed 12/03/2026). Consent covers data use, confidentiality, the Chatham House Rule, and optional audio recording. Consent forms are stored separately from all content data files. If participants do not send the consent form before the workshop, it will be asked for at the beginning of the meeting.

1.6 On what legal ground will the data processing take place if it is not based on informed consent?

- Not applicable, I use informed consent

1.7 Does the data collection include any of the following types of personal data?

COI disclosure forms may contain information about professional financial interests (e.g., equity holdings, consulting fees, funding relationships). This information is collected in aggregate form only, is not attributed to individuals in any output, and is used solely for research governance purposes. No other special category data under GDPR Article 9 is collected.

1.8 If your research involves special categories of personal data (previous question) and you will not use explicit informed consent, what is the legal ground for the exemption?

Not applicable. Explicit informed consent is obtained for all data processing, including COI disclosures.

2. Storage and back-up during the research process

2.1 What measures will you take to secure and protect data during the research process? Please describe, for each separate data asset how you will ensure data security, where the data assets are stored & backed up, and who has authorization to access the asset.

Data assets are managed as follows:

— *Consent forms and COI disclosures* (high risk): stored as scanned PDFs in a restricted-access folder on SURFdrive, accessible only to the student researcher (Gloria Brambilla) and supervisor (Daniella Brals). Never merged with content data files.

— *Participant code key* (high risk): stored in a separate, password-protected file on SURFdrive, in a different folder from all data files. Accessible only to the student researcher.

— *Workshop notes and digital board exports* (medium risk): anonymised before filing. Exported immediately after the session. Participant names replaced with codes before any analysis or sharing.

— *Audio recordings* (high risk, if made): transferred to SURFdrive immediately after the session and deleted from the recording device. Deleted after transcription and anonymisation. Transcripts use participant codes only.

— *Scoping review data* (low risk): publicly available documents. Stored in Zotero (reference management) and a structured charting spreadsheet. Contains no personal data.

All digital files are stored on SURFdrive (VU-approved, GDPR-compliant institutional storage). No personal data is stored on personal devices, commercial cloud services, or unencrypted media.

2.2 Which tools are used in the collection, processing or storage of data during research?

- Atlas.Ti *
- SURFDrive
- Zoom

— Miro (online collaborative whiteboard): used during the workshop for annotation, voting, and co-production activities. Participants join via a shared link without creating an account. Miro is GDPR-compliant and offers a Data Processing Agreement (DPA). *(See 2.5 regarding EEA data transfer.)*

— SURFdrive: institutional cloud storage, used for all data storage and backup.

— Zoom or equivalent video conferencing platform (VU-approved): used for the online workshop session.

— Rayyan: used for screening of scoping review records. Contains only bibliographic data, no personal data.

— Zotero: used for reference management. Contains only bibliographic data, no personal data.

2.3 What other tools or software do you intend to use during your research?

Name:
Role:
Country:

2.4 Is it necessary to transfer the (physical or digital) data assets to other locations or research partners? If yes, please describe how you secure the file transfer.

- No

No transfer of personal data to external partners or other institutions is planned. The supervisor (Daniella Brals, AIGHD) may access anonymised outputs on SURFdrive for supervision purposes. The participant code key and consent forms are not shared with the supervisor.

2.5 Do you transfer personal data outside of the European Economic Area (EEA)? If Yes, please provide additional information

- No

3. Legal and ethical requirements, codes of conduct

3.1 Do you require approval of an ethical committee for this project? If yes, please indicate which ethical committee and whether you have obtained approval for this project.

- No

An ethics self-check was completed through the Research Ethics Review Committee of the Faculty of Science (BETHCIE), Vrije Universiteit Amsterdam, on 12/03/2026 (VUnet ID: okt040). The self-check confirmed that the study does not require further ethics review by the BETHCIE. No formal ethics approval letter was required or obtained. The self-check confirmation document is retained by the researcher.

4. Data archiving and publishing

4.1 Which data assets will be archived and which will be published?

— *Archived only (not published)*: anonymised workshop notes, digital board exports, ranked outputs, and transcripts (if made). These will be archived on SURFdrive for 12 months and then securely deleted.

— *Published*: research findings (evidence map, ranked governance gaps, co-produced recommendations) will be published as part of a master's thesis and potentially in an academic journal (*Lancet Global Health* is the target journal). No personal data will appear in any published output.

— *Deleted after use*: consent forms, COI disclosures, participant code key, and audio recordings (after

transcription) will not be archived beyond the 12-month retention period.

4.2 Where will you archive your data assets?

SURFdrive (VU institutional storage), in access-controlled folders. Research outputs (thesis, publications) will be archived in the VU institutional repository upon submission.

4.3 What other archive(s) do you intend to use to archive data assets?

Name:
Role:
Country:

Not applicable.

4.4 For how long will the data be available in the archive?

Personal data and identifiable records: 12 months after completion of the study (estimated end date: 30/06/2026), after which they will be securely deleted.
Anonymised research outputs (thesis, publications): archived in the VU institutional repository in accordance with VU's standard retention policy.

4.5 Where will you publish your data assets? (if applicable)

Research findings will be published in the master's thesis (VU repository) and potentially in an academic journal. No personal data will be published. The evidence map and anonymised outputs may be made available as supplementary materials upon publication, subject to supervisor approval.

5. Data management responsibilities and procedures

5.1 Who will be responsible for management of the data assets during the project? Please specify their name, position, role in the project, and faculty/ institution/ group.

Gloria Brambilla, MSc student, Faculty of Science / AIGHD, Vrije Universiteit Amsterdam. Email: g.brambilla@student.vu.nl.
Role: sole data collector, analyst, and data manager for this project.

5.2 Who will be responsible for management of the data assets after completion of the project (e.g. the project lead/ dedicated data manager/ department head)? Please specify

their name, position, role in the project, and faculty/ institution/ group.

Gloria Brambilla, in consultation with Daniella Brals (supervisor, AIGHD). After the 12-month retention period, Gloria Brambilla is responsible for secure deletion of all personal data assets. Anonymised research outputs remain archived in the VU institutional repository.

5.3 For data that are only available upon request, what methods will be used to handle requests for access and how will data be made available to those requesting access?

Personal data will be deleted 12 months after study completion and will not be available upon request thereafter. During the retention period, access to anonymised outputs may be granted by the researcher upon reasonable request, subject to confirmation that no individuals can be identified. Requests should be directed to g.brambilla@student.vu.nl.