EUROPEAN GYNAECOLOGY AI RESEARCH SOCIETY (EGAIRS) PROTOCOL

Multinational Collaborative Framework for Artificial Intelligence in Gynaecology

1. Definition

European Gynaecology AI Research Society (EGAIRS) is federated multinational collaborative platform for artificial intelligence research in gynaecology to enable precision medicine.

2. Executive Summary

The European Gynaecology AI Research Society (EGAIRS) is an international collaborative initiative designed to establish a large-scale, high-quality, multicentre data ecosystem to advance artificial intelligence (AI) research in gynaecology.

Through a federated, ethically governed, and academically driven infrastructure, EGAIRS enables the development, validation, and implementation of diagnostic, prognostic, and therapeutic AI models, supporting the transition toward precision medicine in women's health.

3. Background & Rationale

Despite rapid advances in AI, progress in gynaecology remains limited by:

- Fragmented datasets across institutions
- Small sample sizes insufficient for robust modelling
- Lack of external validation
- Underrepresentation of diverse populations

EGAIRS addresses these barriers by creating a **collaborative research ecosystem** that enables:

- Aggregation of large-scale datasets
- Standardisation of clinical data

- Cross-border validation
- High-impact translational research

4. Vision

To establish EGAIRS as the **leading European platform for AI-driven innovation in gynaecology**, delivering clinically meaningful, safe, and scalable solutions that improve patient outcomes.

5. Mission

- To enable **collaborative, high-quality AI research**
- To develop **clinically validated predictive models**
- To support **precision medicine and personalised care**
- To foster **academic excellence and leadership across Europe**

6. Strategic Objectives

Primary Objectives

- Build a **pan-European federated data network**
- Develop and externally validate **AI-based predictive models**
- Enable **individualised risk prediction and treatment strategies**

Secondary Objectives

- Promote standardisation in data collection
- Facilitate high-impact publications
- Support training and research capacity building
- Enable access to large datasets for investigator-led research

7. Study Design

- **Design:** Multicentre, multinational observational research platform
- **Structure:** Federated registry with project-based sub-studies
- **Scope:** All subspecialties within gynaecology

8. Data Architecture

Federated Model

EGAIRS adopts a **federated data architecture**, ensuring:

- Data remains within the originating institution
- Only de-identified or aggregated data is shared
- Optional federated learning without data transfer

Data Flow

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Local Hospital System → Secure Local Node → De-identified Dataset → EGAIRS Platform
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9. Data Collection Framework

Data Domains

- Demographics
- Clinical variables
- Imaging
- Laboratory data
- Surgical interventions
- Histopathology
- Outcomes

Key Principles

- Standardised data dictionary
- Structured data entry templates
- Prospective and retrospective inclusion
- Interoperability with existing hospital systems

10. Artificial Intelligence Methodology

- Machine learning and deep learning models
- Internal and external validation
- Calibration and clinical utility assessment
- Explainability frameworks (e.g., SHAP)
- Continuous model refinement

11.1 Steering Committee

The EGAIRS Steering Committee represents the **central governing body** of the society.

Composition

- One appointed representative from each contributing centre
- Core executive members (Chair, Scientific Lead, Data Lead)

Responsibilities

- Strategic direction and long-term vision
- Approval of research proposals
- Oversight of data access and usage
- Governance of authorship and publication policies
- Ensuring ethical compliance and transparency
- Development of future initiatives, partnerships, and funding strategies

Strategic Role

The Steering Committee is responsible for:

- Shaping the **scientific agenda of EGAIRS**
- Identifying priority research areas
- Expanding the network across Europe and internationally
- Facilitating grant applications and funding opportunities

12. Data Access & Research Use

EGAIRS is committed to enabling **equitable and transparent access to data for research purposes**, particularly for contributing centres.

Key Principles

- Data is a **shared academic resource**
- Access is governed, not restricted
- Priority is given to contributing institutions

12.1 Data Access Process

Investigators wishing to use EGAIRS data must:

1. Submit a **research proposal/protocol**, including:

    - Study objectives
    - Methodology
    - Variables required
    - Statistical plan

2. Proposal review by the **Steering Committee**
3. Approval based on:

    - Scientific merit
    - Feasibility
    - Ethical considerations
    - Avoidance of duplication

4. Data access granted in:

    - De-identified format
    - Controlled environment where required

12.2 Data Use Rights

- Contributing centres have **priority access**
- Multi-centre collaborative projects are encouraged
- External collaborations require Steering Committee approval

13. Authorship & Academic Recognition

EGAIRS adopts a **transparent, fair, and contribution-based authorship framework**, aligned with ICMJE recommendations.

13.1 Authorship Structure

Tiered Authorship Model

Tier 1 — Writing Committee

- Study conception
- Analysis
- Manuscript drafting

Tier 2 — Steering/National Leads

- Study design contribution
- Oversight and coordination

Tier 3 — Contributing Investigators

- Data contribution
- Local study implementation

Tier 4 — Collaborative Group

- Listed as “EGAIRS Collaborative Group”

13.2 Authorship Criteria

Authorship eligibility is based on:

- Volume of data contributed
- Data completeness and quality
- Participation in study design or analysis
- Active engagement in manuscript development

13.3 Academic Benefits

Participation in EGAIRS provides:

- Co-authorship in high-impact publications
- Opportunities for **lead and senior authorship roles**
- Access to large-scale datasets for independent research
- Increased academic visibility across Europe

14. Benefits of Participation

Academic Benefits

- Participation in **landmark multicentre studies**
- Access to **large, high-quality datasets**
- Opportunities for **PhD and fellowship research projects**

Institutional Benefits

- Benchmarking against European standards
- Recognition as part of a **leading research network**
- Enhanced competitiveness for grants and funding

Clinical Benefits

- Development of clinically validated AI tools
- Improved diagnostic and prognostic capabilities
- Contribution to evidence-based practice

Strategic Benefits

- Positioning as a **leader in AI-driven healthcare innovation**
- Access to future **industry collaborations and translational research**
- Participation in shaping the future of precision gynaecology

15. Ethics & Regulatory Compliance

- Full compliance with GDPR
- Local ethical approvals required
- Patient confidentiality strictly maintained

16. Data Ownership & Intellectual Property

- Data ownership remains with the originating institution
- EGAIRS acts as a coordinating and analytical body
- Joint ownership of collaborative outputs

17. Data Security

- Encrypted transfer protocols
- Secure servers and controlled access
- Regular audits

18. Quality Assurance

- Annual data audits
- Completeness and accuracy scoring
- Feedback to centres

19. Implementation Plan

Phase 1: Governance & Pilot

Phase 2: Platform Development

Phase 3: Pilot Research

Phase 4: Expansion & Scaling

20. Conclusion

EGAIRS provides a **robust, ethical, and scalable framework** for advancing AI research in gynaecology through multinational collaboration. By integrating data, expertise, and innovation, EGAIRS aims to redefine clinical research and enable the widespread adoption of precision medicine.