

## **GOVERNANCE & OVERSIGHT**

### **Governance Before Automation**

Buiten.ai operates as a European Clinical Governance Infrastructure. Its foundation is governance — not automation.

The infrastructure is designed for supervised accountability within high-sensitivity healthcare and insurance environments. It does not function autonomously and does not replace institutional decision-makers.

Cross-border healthcare requires structured trust.  
Structured trust requires explicit governance.

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#### **1. Human-in-the-Loop Architecture**

All analytical outputs generated within the infrastructure are supervised.

No reimbursement decision, institutional evaluation, or compliance signal is executed automatically without human oversight.

The system produces structured governance signals:

- Alignment indicators
- Variance notifications
- Contextualized complication signals

Final decisions remain within:

- Insurance institutions
- Clinical review boards
- Institutional governance bodies

AI supports review processes — it does not determine outcomes.

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#### **2. Oversight Structure**

The governance framework operates under multi-layered oversight:

##### **2.1 Academic Oversight**

The Indication Matrix and methodological framework are developed and recalibrated by an academic consortium.

Periodic review ensures:

- Clinical validity

- Evidence alignment
  - Threshold updates
  - Risk adjustment recalibration
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## **2.2 Technical Oversight**

The AI signal architecture includes:

- Version-controlled logic updates
- Model change documentation
- Structured release cycles
- Performance monitoring

Silent model changes are not permitted.

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## **2.3 Institutional Oversight**

Participating institutions retain:

- Review authority
- Appeal mechanisms
- Signal interpretation rights
- Documentation correction pathways

Governance is collaborative, not unilateral.

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## **3. Explainability & Transparency**

The infrastructure applies Explainable AI (XAI) principles.

Each signal includes:

- Trigger parameter
- Reference threshold
- Divergence metric
- Risk-adjustment modifier
- Mapping confidence level

No opaque probability scores are delivered without traceable reasoning.

Transparency is structural — not optional.

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## 4. Bias Monitoring & Fairness Controls

Healthcare governance systems risk penalizing high-complexity centers if contextual risk is ignored.

Buiten.ai integrates structured fairness safeguards:

- Age-weighted baseline modeling
- Comorbidity indexing
- Frailty adjustment
- Case-mix normalization

Complexity is contextualized — not penalized.

Bias monitoring mechanisms periodically evaluate:

- Signal distribution asymmetry
- Specialty-level variance
- Institutional clustering effects

Governance must protect complexity, not suppress it.

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## 5. Regulatory Alignment

The infrastructure is designed in accordance with:

- EU AI Act principles
- GDPR data minimization standards
- Purpose limitation requirements
- Role-based access control

The architecture follows the principle of:

Coordination without concentration.

Data remains purpose-bound and visibility is role-restricted.

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## 6. Data Governance & Access Separation

Operational components are separated by role:

- Clinical referral layer
- Institutional transparency layer
- Insurance review layer

Each layer operates with restricted data access privileges.

Identity data is never cross-border centralized.

Signal logic is auditable.

Cross-domain data aggregation is prevented by architectural design.

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## **7. Governance Philosophy**

Buiten.ai is not a regulatory authority.

It does not impose sanctions.

It does not publish rankings.

It does not override clinical autonomy.

It provides:

Structured comparability

Risk-adjusted contextualization

Transparent variance signaling

Governance enhances intelligibility.

It does not enforce uniformity.