AI Project Risk Assessment Summary Template

To be completed prior to project initiation in a European pharmaceutical company

# 1. Project Information

**Project Title:**

**Project Sponsor:**

**Project Manager:**

**Date of Assessment:**

**Departments Involved:**

**Assessment Prepared By:**

# 2. Executive Summary

Provide a concise overview of the project, its objectives, and the purpose of the risk assessment.

# 3. Risk Assessment Methodology

Briefly describe the risk assessment approach (qualitative, quantitative, mixed), frameworks, and tools applied.

# 4. Key Risk Areas Analyzed

* **Data Privacy & Protection** (compliance with GDPR and sector-specific regulations)
* **Data Integrity & Quality**
* **Model Transparency & Explainability**
* **Model Bias & Fairness**
* **Cybersecurity**
* **Regulatory Compliance**
* **Operational Impact**
* **Ethical Considerations**
* **Business Continuity & Resilience**
* Other (specify as needed)

# 5. Impact Assessment

Summarize the potential impacts identified for each risk area analyzed. Use a structured format (e.g., low/medium/high or numerical scoring) and provide a brief rationale.

# 6. Mitigation Measures Adopted

For each risk area, list the mitigation or control measures implemented or planned. Indicate responsible parties and timelines, where appropriate.

# 7. Residual Risk Profile

Provide a summary table or narrative of the residual risks after mitigation, highlighting any risks remaining above the company’s risk appetite and the rationale for their acceptance.

# 8. Roles and Contributions of Responsible Functions

* **Data Protection Officer (DPO):** Oversight of privacy and data protection compliance
* **IT Security Lead:** Technical safeguards and cybersecurity measures
* **Quality Assurance:** Validation of data integrity and model performance
* **Regulatory Affairs:** Ensuring alignment with pharmaceutical regulations
* **AI/Data Science Lead:** Model development, monitoring, and bias assessment
* **Ethics Committee:** Review of ethical implications
* Other function heads (specify as needed)

Describe the specific contributions and responsibilities of each function in both the risk assessment process and the implementation of mitigation actions.

# 9. Approval and Sign-off

Include signature fields and dates for all major responsible roles, confirming risk awareness and acceptance prior to project commencement.

# 10. Appendices

* Detailed Risk Register
* Additional Analyses and Supporting Documentation
* References