

From Promise to Practice: Translating Artificial Intelligence into Scalable Innovation Capability in Spanish Pharmaceutical R&D

1. Problem, Aims, and Research Questions

Artificial Intelligence (AI) is widely regarded as a transformative force in pharmaceutical research and development (R&D), with the potential to accelerate drug discovery, improve decision-making, and reduce attrition rates. Despite increasing investment and strategic prioritisation, many AI initiatives remain confined to pilot projects and fail to scale into sustained organisational capabilities.

This gap between the technical promise of AI and its realisation as scalable organisational capability is particularly salient in regulated environments such as pharmaceutical R&D, where adoption depends not only on technological feasibility but also on organisational structures, governance mechanisms, regulatory constraints, and trust, explainability, and decision-making governance. Within this context, Spain offers a relevant empirical setting due to its multinational pharmaceutical presence, evolving digital capabilities, and active policy environment.

This study examines how AI is translated from isolated initiatives into scalable innovation capability within the Spanish pharmaceutical R&D ecosystem. It conceptualises this challenge as a ‘translation problem’, where the value of AI depends not only on technical performance but on the organisational and governance conditions that enable its integration into decision-making and innovation processes. The study addresses three research questions: how AI initiatives are translated from pilot projects into scalable organisational capabilities; which organisational, governance, and regulatory factors enable or constrain this process; and what implications these dynamics have for innovation performance, organisational strategy, and national competitiveness.

2. Justification and Relevance

Pharmaceutical R&D continues to face structural productivity challenges, within a broader European context increasingly focused on competitiveness and technological transformation, including rising costs, long

development timelines, and high failure rates. While AI is positioned as a key lever to address these issues, empirical evidence of its sustained organisational impact remains limited. Existing literature has largely focused either on technical applications in drug discovery or on broad accounts of digital transformation, with less attention to the organisational and governance conditions required for scaling AI in practice.

This study shifts the focus from what AI can do to how it creates value within organisations. It is relevant to industry leaders seeking to move beyond pilot-driven experimentation, policymakers and regulators aiming to enable responsible innovation, and academic research addressing the intersection of AI, organisational transformation, and innovation systems. By focusing on Spain, the study examines a context where global pharmaceutical structures intersect with national regulatory frameworks, offering a lens to understand how institutional environments shape AI adoption and scaling.

3. Theoretical Basis

The study adopts a socio-technical systems perspective, conceptualising AI adoption as the result of interactions between technological capabilities, organisational structures, and institutional environments. This perspective is particularly appropriate in pharmaceutical R&D, where innovation processes are deeply embedded in regulatory frameworks and complex decision-making systems.

The analysis integrates insights from socio-technical systems theory, general-purpose technology literature, dynamic capabilities, and emerging frameworks on AI governance, explainability, ethical and trustworthy AI. Together, these perspectives allow AI to be understood not merely as a tool, but as an organisational capability whose value depends on alignment between technical, organisational, and institutional dimensions.

4. Research Design

The study follows a qualitative, exploratory–explanatory design. Data will be collected through semi-structured interviews with approximately 20–30 senior stakeholders across the Spanish pharmaceutical

ecosystem, including pharmaceutical companies, regulatory bodies, industry associations, and technology providers.

Data will be analysed using thematic analysis, following an iterative coding process to identify patterns related to AI adoption, scaling mechanisms, governance structures, and perceptions of trust and decision-making. A reflexive approach will be adopted to address potential researcher bias, acknowledging the researcher's professional position while ensuring analytical rigour through triangulation across stakeholder groups.

5. Data and Preliminary Insights

Preliminary observations suggest that AI adoption is widespread at the pilot level but uneven in terms of scaling. Key barriers include data fragmentation, organisational silos, regulatory uncertainty, and limited trust and explainability in AI-driven decisions. Conversely, successful scaling appears to depend on governance frameworks, integration into decision processes, and alignment between technical and business functions. These insights reinforce the focus on the translation from experimentation to organisational capability.

6. Expected Contributions

The study contributes by providing an empirically grounded analysis of AI adoption in pharmaceutical R&D and by explaining how organisational and governance conditions shape the translation of AI from pilot initiatives into scalable innovation capability in regulated environments. It extends socio-technical and innovation frameworks in a national innovation context.

7. Practical Relevance

The findings will inform pharmaceutical organisations in designing governance and organisational models that enable AI scaling, support regulators in shaping governance frameworks that balance innovation, accountability, and societal impact, and contribute to strengthening innovation capacity within the Spanish ecosystem. The study ultimately seeks to bridge the gap between AI as technological promise and AI as operational reality.

8. References

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