WHITEPAPER

DATA SOVEREIGNTY AS A STRATEGIC PILLAR IN PHARMA AND BIOTECH IN EUROPE

BASED ON EXPERT INSIGHTS FROM THE CIONET X LCL **ROUND TABLE ON AI IN PHARMA AND BIOTECH**, FEATURING KEYNOTE SPEAKER PROF. STEIN AERTS. (MAY, 2025)

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INTRODUCTION

From genome sequencing to clinical trials, secure access to high-quality data is critical for pharma and biotech. As artificial intelligence reshapes every stage of the life cycle, robust data governance has become indispensable. With Europe reinforcing its data and AI regulations, and global powers like the US, China and Russia asserting stronger digital influence, the concept of data sovereignty has come to the forefront. It raises fundamental questions: Who controls the data? Where is it stored, and under whose jurisdiction? And how do we balance scientific openness with privacy, ethics and compliance?

These themes were explored during a recent CIONET x LCL roundtable, where leaders from GSK, Johnson & Johnson and UCB joined the discussion. The session was led by Prof. Stein Aerts, Scientific Director at VIB.AI. His organisation pioneers a new generation of biological research through the integration of machine learning and computational biology.

This whitepaper distils the key insights from the roundtable. It makes the case for building an AI ecosystem in Europe and argues that data sovereignty is essential to ensure that breakthroughs in pharma and biotech reflect European values and remain under European jurisdiction.

> **“Data sovereignty is crucial for Europe’s competitiveness and digital independence.”**

Leaders from GSK, Johnson & Johnson, LCL and UCB in discussion

WHAT IS DATA SOVEREIGNTY?

Data sovereignty refers to the principle that data is governed by the laws of the country where it is collected and stored. The most well-known example of data sovereignty in practice is the General Data Protection Regulation (GDPR) of the European Union. It sets strict rules for how the personal data of EU citizens must be processed.

For research institutions and companies, the question of data sovereignty extends beyond compliance. It is about long-term autonomy. Relying on non-European platforms introduces legal uncertainties and strategic dependencies. In sectors like pharma and biotech, where sensitive health data is at stake, data sovereignty is more than a legal matter; it is fundamental to research integrity, patient privacy, and strategic independence.

AI AND DATA-DRIVEN SCIENTIFIC DISCOVERIES

Artificial intelligence is steadily finding its place in pharmaceutical and biotech companies. It's being used to streamline research, support clinical trials, and improve manufacturing through better monitoring. Pharma companies are building smart knowledge platforms that make internal expertise easier to access and interpret, a trend confirmed by multiple participants during the roundtable. By linking their databases to AI models, they can quickly spot differences between local and global procedures, for example, and retrieve how similar cases were handled in the past.

From an academic perspective, AI enables entirely new research paradigms. "We use machine learning to find the question, not just the answer," explained Prof. Stein Aerts. Rather than starting from a hypothesis, VIB.AI researchers start with the data and let meaningful patterns emerge. AI helps researchers connect data across molecular, cellular and population levels, revealing connections that were previously hidden or too complex to detect. "AI moves all the directions, not just one. It can do research where these crossroads come together," one researcher at the table noted. But the insights are only as strong as the people interpreting them. Algorithms can detect correlations, but it takes scientific expertise to know what to pursue, what to question, and how to validate.

FROM OPEN SOURCE TO SHARED RESPONSIBILITY

Many of the tools and models that power AI in life sciences originate in academic labs, often supported by public funding or competitive research grants. When released as open source, these tools are typically licensed for academic use only. This reflects a growing awareness that broader applications, including commercially successful drug development, should ideally be accompanied by some form of return. The question is not whether industry may benefit from these innovations, but how we can ensure that part of the value flows back to the research ecosystem that made them possible.

During the discussion, participants explored ways to encourage shared responsibility in the use of academic tools. One idea was to set up a voluntary fund, supported by industry, to help maintain research software that is widely adopted. Another suggestion was a light-touch licensing model, where tools remain open and free to use, but include a reminder to acknowledge and support the research behind them.

Although views on the topic are still maturing, one ambition was clearly shared by all participants. They all expressed a strong desire to create a healthier innovation cycle, where openness and sovereignty reinforce each other, and where the public value of data-driven science is actively reinvested in research ecosystems.

“We should make the software open to all, but also find a way to support the teams who build and maintain it.”

Prof. Stein Aerts, VIB.AI

COMPLIANCE AS A CATALYST

If data is the driver of scientific discovery, and open collaboration the ambition, then sovereignty must become an enabler. Everyone at the roundtable recognised the importance of strong regulation. Frameworks like GDPR and the upcoming AI Act have set essential standards for privacy, trust and ethical data use in Europe. Still, several participants pointed out that in practice, diverging interpretations of regulation can delay collaboration. Months may be spent aligning on compliance before any scientific work begins.

To turn regulation into a catalyst rather than a barrier, participants stressed the need for clarity, shared standards and practical frameworks. This applies not only to policy but also to infrastructure. As awareness of digital sovereignty grows, organisations are rethinking how and where they store sensitive data. One participant noted that “Belgian companies and institutions, especially in healthcare, increasingly choose to keep data within national borders.” Their motivation is strategic: protect confidentiality, maintain control and reduce dependency on foreign jurisdictions.

European regulation, in this light, is not a burden. It is a strategic counterweight to global digital powers like the US and China. Data sovereignty, when put into practice with clear and consistent frameworks, enables innovation that is secure, transparent, and grounded in European values.

Looking for reliable infrastructure
that guarantees data sovereignty in Europe?

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