



LEO Pharma Artificial Intelligence Ethical Principles

Preamble

Employing AI to support scientific advancement with respect to the highest ethical standards

Artificial Intelligence (AI) is set to transform pharma by accelerating improvements and efficiencies across the entire value chain. It has already shown its potential to accelerate drug development, further the understanding of complex dermatological diseases, optimize clinical trials, and automate tasks related to risk and pharmacovigilance. It is also an area which requires frameworks and principles to support AI adoption and innovation, while also guaranteeing the safety and fundamental rights of people and businesses.

This document reflects the guiding working principles for those involved in developing and implementing AI solutions in LEO Pharma, internal employees and external consultants and vendors, are expected to follow. This document aims to offer a concrete framework and a statement of duty that can guide decisions and make sure we highlight any possible blind spots in our everyday processes related to AI. These principles do not replace relevant legal and regulatory requirements and should be read as guiding principles only. As regulatory and legal frameworks are adopted and the body of good practice in AI advances, we intend to continuously evolve and formalise these guidelines.

Introduction

A practical definition to guide the development and implementation of AI

There are multiple definitions of AI used by scientific community, primarily because 'intelligence', especially when related to human intelligence, is difficult to define. Our definition of AI is a technical definition, and it reflects current practices and applications in the industry, focusing mainly on the techniques and approaches related to AI algorithms, systems and solutions. As such, 'AI' refers to software and algorithms developed using specific elements of AI like machine learning (ML) and Natural Language Processing (NLP) applications, which use algorithms and training datasets to achieve operational objectives. Outputs are often implemented as software solutions and programmes. This approach to AI is practical, with the objective to generate new insights, reduce workload, optimise processes and improve efficiency.

While AI tools promise a series of benefits to improve overall patient experience and business performance, they also raise some ethical questions that need to be carefully addressed.



Case Studies

AI projects implemented in LEO Pharma

LEO Pharma has already developed and implemented several AI projects across its value chain and in line with its corporate mission to help people achieve healthy skin. These are some examples:

Delphi

In January 2021 LEO Pharma launched Delphi, a new platform that focuses on using state-of-the-art machine learning to enhance and speed up drug discovery. Delphi builds on in-house expertise and ongoing initiatives, making the best use of our involvement with an academic/industry consortium to implement state-of-the-art AI for drug discovery. Version 1.0 of Delphi consists of a custom software application that allows the Drug Discovery team to train models to predict drug properties and features.

iSearch

iSearch is an intelligent platform supported by machine learning to help manage complex, text-heavy databases easier and faster. Launched in October 2011, iSearch was born out of the Q&A Database, a pilot built in 2020 to support the management of documents pertaining to marketing approvals. The platform can support a large number of databases simultaneously through a user-friendly, no-code interface for database administrators and users.

'Next Best Action' platform

Data and algorithms have the potential to improve the performance of CRM systems and to support the commercial teams with new insights. LEO Pharma is exploring how employing predictive analytics and machine learning could power a decision support system for field teams. 'Next Best Action' was launched in 2020 as a pilot to identify how specific commercial teams interact with data and CRM platforms, and build a decision support tool to improve their experience.



LEO Pharma AI Ethical Principles

Reflective of the LEO Pharma corporate values and Code of Conduct, our objective is to ultimately deliver responsible and accountable AI. The moral principles we uphold complement all the relevant internal procedures and regulations applicable in LEO Pharma in relation to the use of data and digital systems.

All the AI systems and solutions we develop, employ, or apply within LEO Pharma are governed by the following ethical principles: 1) **Human centrality**; 2) **Fairness**; 3) **Safety & Reliability** and 4) **Ownership & accountability**. Each of these ethical principles are detailed below.



1) Human centrality

- We strive to develop AI solutions that promote human well-being and respect the rights and dignity of all people (patients, vendors, employees of LEO Pharma, participants in clinical trials etc) and the public interest. People's right to privacy and access to information are examples of human rights that our systems will strive to uphold. We employ human-centric design across all phases of development.
- We make sure humans remain in control of the AI systems; we aim to aid and improve decision making, not to take it away from humans. We focus on building intelligible, transparent, and responsive systems where the outcomes of algorithms can be explained and traced all the way back to the data on which they are based. We



continuously monitor and assess the systems we implement to ensure they correspond adequately to expectations and requirements.

- We disclose to users when they interact with AI systems and explain the limitations of such interactions – e.g., when ‘talking’ to a chatbot. We also aim to offer alternative ways for humans to engage as is relevant for the specific system or process.
- While looking to address current needs with our AI solutions, our overall approach will be long-term: we aim to develop AI solutions that are sustainable, have a minimum impact on the environment and are energy efficient.

2) Fairness

- Quality of data is paramount to building AI solutions that are fair, efficient, and relevant. We take reasonable steps to employ robust and inclusive datasets in our data and AI systems and solutions. We continuously seek ways to improve the quality and the level of representativeness of the data we employ, aiming to employ datasets that are reflective of the populations the solutions are intended to serve.
- We strive to use training datasets that are representative, robust, and relevant. Where differences are identified, we aim to identify potential bias and, to the extent this is possible, take corrective actions to include data properties related to minorities, sub-groups, and vulnerable groups.
- We are transparent and disclose the limitations of applications that might be unfairly biased due to insufficient inclusion of population sub-groups or non-representative data. We continuously assess and look to re-train algorithms when more data becomes available to improve the output and performance of our AI systems.

3) Safety & Reliability

- All the data and AI systems are implemented following the Quality Assessments and Procedures as explained in the relevant Standard Operating Procedures and IT rules in LEO Pharma.
- We thoroughly test any system before implementation and continue to monitor that it functions as intended after its roll-out to a production environment accessible by users.
- We protect personal data in line with current legislation and Data Privacy procedures in LEO Pharma. Where possible, we work with anonymised data and protect individuals from re-identification. All data we collect follow the legal requirements for user consent.
- We diligently assess the risks associated with the proper functioning of our AI and data system and put in place mitigation plans to ensure continuity of service and reliability of outputs. We submit our software applications and algorithms for regular review.



4) Ownership & accountability

- We are accountable for the quality, safety, and security of our AI systems. We perform business and regulatory impact assessments before integration and deployment. We take accountability for our use of Data and AI Systems throughout their life cycle, so their use is appropriate and monitored over time.
- We continuously develop data and AI skills across LEO Pharma to enable the understanding of the AI principles and approaches, and to contribute to a data-driven culture and enable professional standards concerning data & AI systems.
- We take a proactive leadership position in data and AI systems, with a forward-looking process to identify opportunities and mitigate risks in the adoption of AI. We believe coordination and open dialogue with governments, regulatory, and industry bodies are crucial to developing safe and beneficial AI. We will actively participate in the relevant ethical forums around data and AI systems in pharma.

Last updated: 26/11/2021

Sources:

In the process of developing this document various publications, opinion pieces and industry best practices have been reviewed, including the following main sources:

- **Proposal for a Regulation of the European Parliament and of the Council, Laying Down Harmonised Rules on Artificial Intelligence (Artificial Intelligence Act) and Amending Certain Union Legislative Acts**, Brussels, 21.4.2021, COM(2021) 206 final, 2021/0106(COD) Available <https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1623335154975&uri=CELEX%3A52021PC0206>.

- Thomaz, Felipe and Efremova, Natalia and Mazzi, Francesca and Clark, Gregory and Macdonald, Ewan and Hadi, Rhonda and Bell, Joseph and Stephen, Andrew T., **Ethics for AI in Business** (June 22, 2021). Available at SSRN: <https://ssrn.com/abstract=3871867> or <http://dx.doi.org/10.2139/ssrn.3871867>

- **Ethics and governance of artificial intelligence for health: WHO guidance**. Geneva: World Health Organization; 2021. Licence: CC BY-NC-SA 3.0 IGO.