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Parexel principles for artificial intelligence

Building an AI roadmap with solutions that are conceived, developed, and deployed responsibly

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Artificial intelligence (AI) is transforming drug development by accelerating target discovery, optimizing molecules, and enabling better decision making through rapid interrogation of massive amounts of data. We have seen increasing uptake of, and investments in, AI across the life sciences sector. Recent technological advances, energized by the first foundation models including large language models (LLMs), have boosted interest and made AI application development and implementation even more accessible.

Parexel is committed to the development of innovative, high-value, high-quality use cases for AI. We believe AI provides tools to help manage the increasing complexity of clinical development, including opportunities to expedite development timelines for products to reach patients quicker.

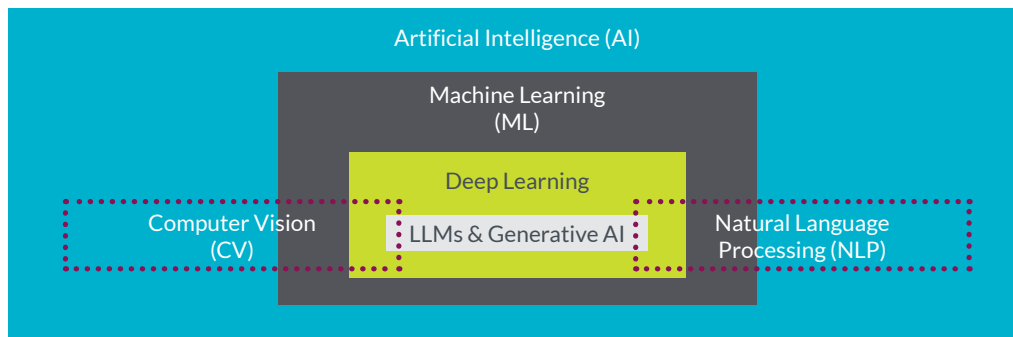Through well-designed AI, we see opportunities to:

> Enable rapid access to current, accurate, and complete context-specific information

> Automate manual processes, enabling our colleagues to focus on higher value work

> Expedite generation of original content and routinely required standard documents

At the same time, we are mindful of the potential for harm when AI applications are developed with insufficient attention to risks. This includes risks associated with the data used to train an AI algorithm, the regulatory acceptability of an AI application, and in-use monitoring.

›› AI defined

While there is no universally accepted definition of artificial intelligence, we believe it is helpful to share how we define AI at Parexel: *The use of a computer-based, pre-trained algorithm that offers intelligent outputs based on its interpretation of the inputs it receives.*

We believe it is also helpful to note the relationship between various types of AI, as illustrated here.

Through **machine learning**, computers learn from data and improve their performance as they identify patterns and make predictions. Traditional machine learning requires some human intervention to correct mistakes. **Deep learning**, a subset of machine learning, allows algorithms to improve their results with far less human intervention as the algorithms train themselves on massive amounts of data. **Computer vision**, which enhances a machine's ability to interpret and understand images or videos, can tap into machine learning or deep learning. The same is true for **natural language processing**, which allows computers to understand, interpret, and generate human language.

Large language models (LLMs) are establishing themselves as a preeminent technology for handling text-based problems. LLMs are based on neural networks that have been pre-trained on vast amounts of text-based information. For specialized tasks, users can further refine LLMs through additional training on smaller, more problem-specific datasets.

Six principles of an ethical approach

The six principles set out below describe how Parexel conceives, develops, deploys, and monitors AI applications intended for use in clinical development and throughout our business. By adhering to these tenets, we ensure that Parexel respects the rights of all relevant stakeholders, mitigates or eliminates known risks, and uses AI applications safely.

1. Thoughtful design and deployment

We are guided by the need for fairness and equity, bias minimization, transparency and a sound ethical approach. The AI solutions we design and deploy always respect these fundamental points, and we monitor them in use to ensure performance does not degrade over time. Our AI solutions align with our corporate mission to speed life changing medicines to market *With Heart*™, and empower patients with a better understanding of diseases and treatments. Through direct patient involvement, we enhance the efficiency and effectiveness of clinical studies.

2. Accountability and senior-level governance

Given the strategic significance of AI technologies for our business and stakeholders, Parexel has created a robust system of senior-level accountability for our pipeline of developing and deployed AI solutions. The AI steering committee includes representatives of our executive leadership team, including the chief quality, administration and information officers, and is chaired by our chief clinical data and digital officer. This group ensures that AI projects offer a clear value opportunity and are carefully considered from a risk and quality perspective. Quality risks, issues, and events associated with use of AI technologies are also regularly reported to and reviewed by our chief quality officer.

3. Human oversight and control

We understand the importance of skilled human oversight when using AI. AI is subject to certain types of errors, including LLM 'hallucinations' in which incorrect information is presented as fact. It is crucial, then, that application outputs are carefully reviewed, and corrected if needed, before they are accepted and used. AI users are trained to recognize the types of errors that could be expected based on what we observe during the development process. We encourage our users to adopt recognized best practices as such practices emerge. Our human-in-the-loop model is designed to ensure confidence in quality.

4. Transparent AI

When reviewing output generated by an AI application, users are made aware that the content comes from an AI system, ensuring they appreciate the need to confirm its accuracy, validity, and integrity. Similarly, and whenever relevant, users are notified of the risk of 'hallucination' and the need to confirm the factual correctness of generated content. Where we train or fine-tune an AI algorithm using curated data sources, we document those data sources and will disclose them to users where this is likely to be important for confidence in the model outputs. Where our AI solutions are not fully transparent (for example, because we leverage LLMs) we will also make this clear. Through this approach, we ensure users of our AI technologies are aware of its limitations, enabling them to be used appropriately.

5. Regulatory conformance and legal compliance

Clinical development is highly regulated, and regulatory agencies closely monitor the use of AI. While global health authorities have been receiving AI-aided submissions for years, this number has grown and will only accelerate further. Regulators are beginning to indicate their areas of AI focus and while it remains an evolving space, they are likely to take a risk-based approach in their assessment of AI solutions, addressing any potential for risk of harm to patients.

As regulatory guidance is developed, Parexel ensures that the way we develop and use AI conforms to applicable regulatory requirements. We continue to comply with applicable data protection legislation.

6. Security and privacy

Like all web-enabled technologies, AI applications create specific cyber and data-related risks. At Parexel, these risks are managed by our chief information and security officer as part of our overall cyber governance framework.

Certain AI applications may also give rise to new or increased risks associated with the integration and processing of disparate datasets, particularly when these include personal health data. Parexel fully complies with applicable legislation on handling such data and we ensure that our controls remain adequate in the context of our AI solutions.

We may update Parexel's AI principles from time-to-time to ensure they remain current in this rapidly evolving environment.

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As we continue to develop AI to meet the needs of our customers, patients, and colleagues, every solution we deliver is guided by our principles. We believe our commitment to ethical, transparent AI builds trust among all stakeholders and enables Parexel to deliver more innovative and effective services to meet the challenges of ever-increasing complexity in clinical development.

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With Heart™

>>> We're always available
for a conversation

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