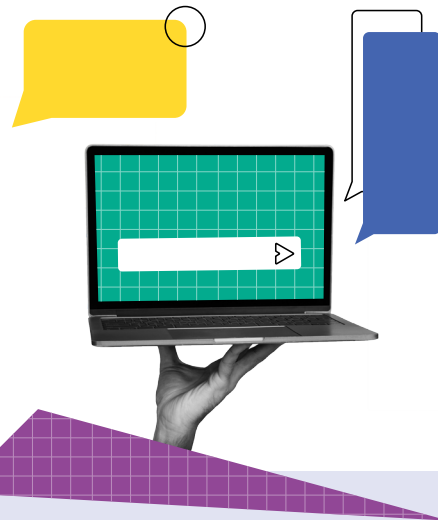Factsheet

4 principles for safe and responsible use of LLMs

Large language models (LLMs) are a category of generative artificial intelligence trained on large amounts of text. You can use LLMs to draft emails, create, proofread and rephrase text, search and summarise information, for learning, coding and more.

## Recommendations for medicines regulatory staff

Ensure safe input of data

- Learn about each LLM application you can use and adapt to the organisation's control level.

- Draft prompts carefully, ensuring they don't contain sensitive information like personal data, intellectual property, and passwords.

- Only copy-paste text from trusted sources.

Apply critical thinking and cross-check outputs

- Review LLMs outputs for trustworthiness, reliability, and fairness.

- Redraft the output to avoid the risk of copyright violations.

- If most of the final text comes from LLMs, be transparent and disclose it.

- Ask the LLM to validate its answer, cross-check it with other sources, and ask the LLM to only use the content provided. Consider additional quality control based on risks.

- If you use LLMs for coding, review and test the code.
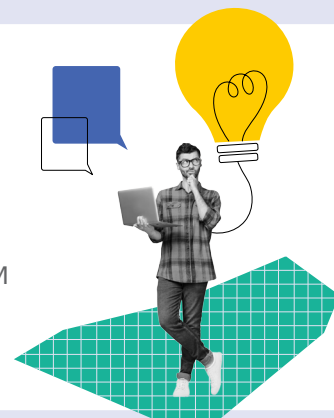
Keep up to date with how to make best use of LLMs

- Learn how to use LLMs for efficiency and environmental savings.

- Reach out to training networks and/or centres of expertise in the European medicines regulatory network for additional training.

Know who to consult and report issues to

- Report incidents or severely biased or erroneous outputs.

- Contact the information security team and/or Data Protection Officer if you have concerns.

Interested in learning more? Read the Guiding principles on the use of large language models in regulatory science and for medicines regulatory activities by EMA and the Heads of Medicines Agencies.