21 March 2024
EMA/126785/2024
European Medicines Agency

Scientific Explorer - Frequently Asked Questions (FAQs)

Table of contents

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

1.1. What is Scientific Explorer?

Scientific Explorer is a search engine to aid European Medicines Regulatory Network's (EMRN) scientific staff (who have access to IRIS) to find information effectively, and incorporates AI techniques. It brings efficiency by facilitating the searching of regulatory and scientific information for regulatory precedents. Scientific Explorer has been initially developed to search the large dataset of scientific advice letters. IRIS is an EMA system used to manage regulatory procedures including advice submissions.

1.2. Why has Scientific Explorer been developed?

Embedded in the HMA-EMA joint Big Data Steering Group workplan and Multi-annual AI workplan 2023-2028, the launch of Scientific Explorer marks an important milestone in harnessing the capabilities of AI to help extract information from the Network's knowledge sources. The multi-annual AI workplan 2023-2028 explicitly foresees a knowledge mining roadmap and Scientific Explorer can be viewed as the first in production deliverable on knowledge mining.

1.3. When was the solution launched?

The solution was launched on 4 March 2024.

1.4. Who can access and use Scientific Explorer?

Users of the tool are from EMA scientific committee members, EMA staff or staff from national competent authorities(NCAs) who are entitled to access the IRIS platform that handles scientific advice data. Scientific Explorer is for European Medicines Regulatory Network use only.

The Scientific Advice Working Party (SAWP) delegates and assessors, and EMA scientific advice officers are starting to use Scientific Explorer as an aid for information retrieval for regulatory precedents relevant to their procedures. Its use is also offered to EMA scientific committee members (CHMP, COMP, CAT, PDCO and PRAC) and their NCAs assessors who contribute to scientific advice procedures.

1.5. What are key features of Scientific Explorer?

Scientific Explorer enables searching in document text, in key targeted information harvested in a standardised and validated way from these documents using AI techniques, as well as in procedure-related information from IRIS. Users can easily work with the search results and visualise all source documents. Thus, Scientific Explorer helps existing European Medicines Regulatory Network users to search information they already have access to more effectively with the support of AI techniques. Importantly, AI is not being used to generate new information or text that will be considered in the procedure.

Regarding the use of AI in scientific explorer, a set of controlled, standardised and validated questions (also called "Prompts") are used to extract regulatory and scientific information from each advice letter. These categorised pieces of information are then made available to the search engine to reduce the time required by the EMRN staff to find the information they seek.

It is emphasised that this use of AI is an aid to information retrieval; users are provided with dedicated training before using Scientific Explorer, during which they are informed on how to use the solution as well as the validation approach followed. Users are strongly advised to visualise and verify the source documents. Once the source documents have been identified, the assessors will open these documents to access information directly. Currently source documents relate to scientific advice procedures on

medicinal products for human use: i.e. scientific advice letters, protocol assistance letters, qualification advice letters or opinions, and clarification letters.

1.6. How is Scientific Explorer used by EMRN staff?

It is emphasised that use of AI is an aid to information retrieval; users are provided with dedicated training before using Scientific Explorer, during which they are informed on how to use the solution as well as the validation approach followed. Users are strongly advised to visualise and verify the source documents. Once the source documents have been identified the assessors will open these documents to access information directly. As an example, previous procedures where discussions on statistical analysis or complex trials were documented can now be effectively retrieved by users.

1.7. What data has been used to develop Scientific Explorer?

In Scientific Explorer, the AI model operates as a static system for information extraction. The extractions are taken solely from the provided documents, in this case scientific advice letters. The AI model is not trained for this purpose. Scientific Explorer uses a large language model in EMA's secure cloud environment which ensures that all the data is processed in servers within the EU. No EMA data are used to train new models. The version of OpenAI used, is private to EMA's use.

1.8. How can the AI information retrieval be trusted?

To establish trust in the AI techniques used for information retrieval, EMA and NCA validated the AI-extracted information on a set of documents, by extracting the same information manually from the same documents. Each AI extraction was scored and two measures, precision and recall, were combined to a single metric, the F1 score, a standard approach in the evaluation of AI techniques.

Where necessary, the wording of the AI instruction (the prompt), has been adjusted to improve the F1 score. As a result, F1 scores for the AI extractions in Scientific Explorer ranged from 0.89 to 0.94 which indicate a high degree of precision and reliability. EMA gathered feedback during Scientific Explorer development and used it to validate and improve the AI extraction mechanism. All users of the system are strongly encouraged to provide feedback.

1.9. What are use cases for Scientific Explorer?

The first release of Scientific Explorer focuses on scientific advice letters relating to medicinal products for human use. Other potential use cases of Scientific Explorer for information retrieval will be explored in the future for other regulatory documents.

1.10. Where can I find additional information?

Please refer to the public Scientific Explorer demo given during the EMA Quarterly System Demo - Q4 on 19 December 2023.

For general queries on Scientific Explorer please contact the Agency via AskEMA: Send a question to the European Medicines Agency. For any Scientific Explorer technical questions please submit a ticket via ServiceNow.