# Quality Assurance in Regulatory Submissions

- **How much time does your team spend manually verifying data in regulatory submissions?**
- **Where are the biggest compliance and accuracy bottlenecks in your research workflows?**
- **Have regulatory delays ever occurred due to inconsistencies in submission documents?**
- **How confident are you that your submissions align with compliance and regulatory guidelines?**
- **What if AI could detect discrepancies, generate content, and speed up submission reviews?**

Years of discovery and development effort go into creating new interventions before trials and regulatory submissions get started. No matter your company size or phase of product development, regulatory submissions are challenging, requiring strict adherence to data accuracy and consistency. Failed applications are costly, slowing approvals as the process needs to start again with longer timelines and delays in drug development.
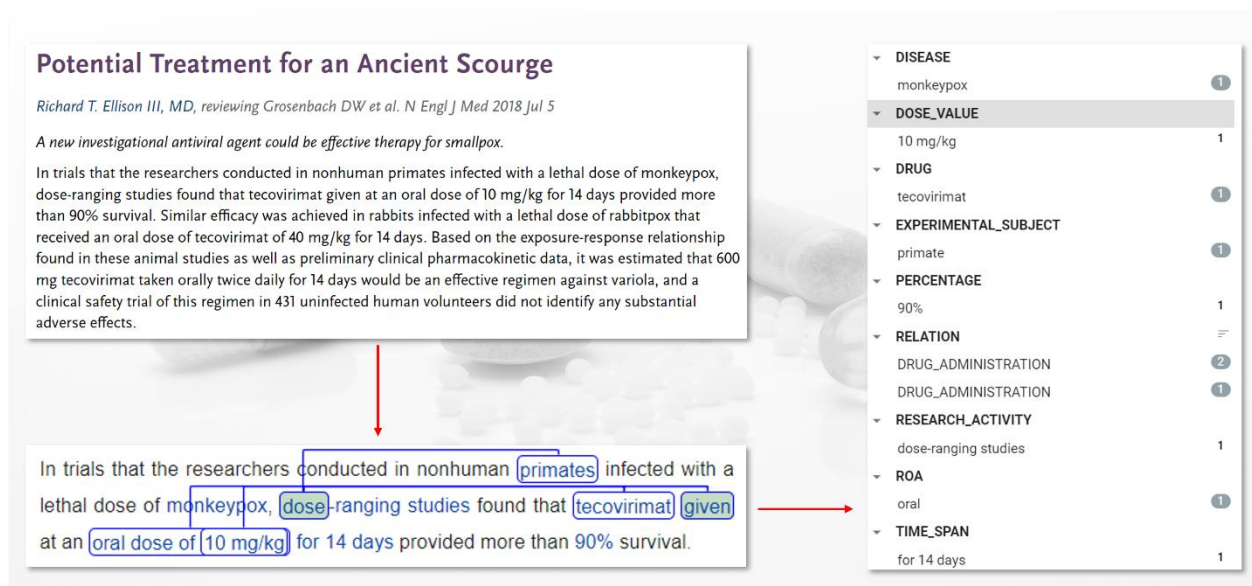
The process of writing submissions and quality audits involves numerous steps and requires close coordination by research, non-clinical, or clinical departments with regulatory, safety, quality, marketing, and other stakeholders. Companies can mitigate submission quality and data conformance issues in regulatory reports by automatically identifying discrepancies between information in the report and source materials. Expert.ai designed an AI-powered solution for quality control and content generation to build smarter, more efficient workflows that streamline study report creation, source data verification, quality review processes, and regulatory approvals.

Measured Outcomes

- **Mitigate the risk of regulatory delays** by catching errors early
- **Accelerate submission preparation** with AI-driven data validation
- **Enhance consistency** between reports, summaries, and source materials
- **Reduce overall quality control review time** for faster approvals
- **Support regulatory teams** with intelligent tools for seamless compliance

AI-Driven Quality Control & Content Generation Solution

Expert.ai's advanced AI solution automates document quality checks and content creation, ensuring submission accuracy while reducing manual effort. Designed for scientists, document managers, and regulatory affairs teams, our technology:

- **Performs AI-powered quality checks** to detect inconsistencies in toxicology, pharmacokinetics, and clinical data
- **Automates content generation**, helping researchers create reports and regulatory documents aligned with source data
- **Compares submission documents** to study reports to verify accuracy before regulatory submission

● **Ensures compliance** with internal policies and health authority guidelines by following structured document outlines
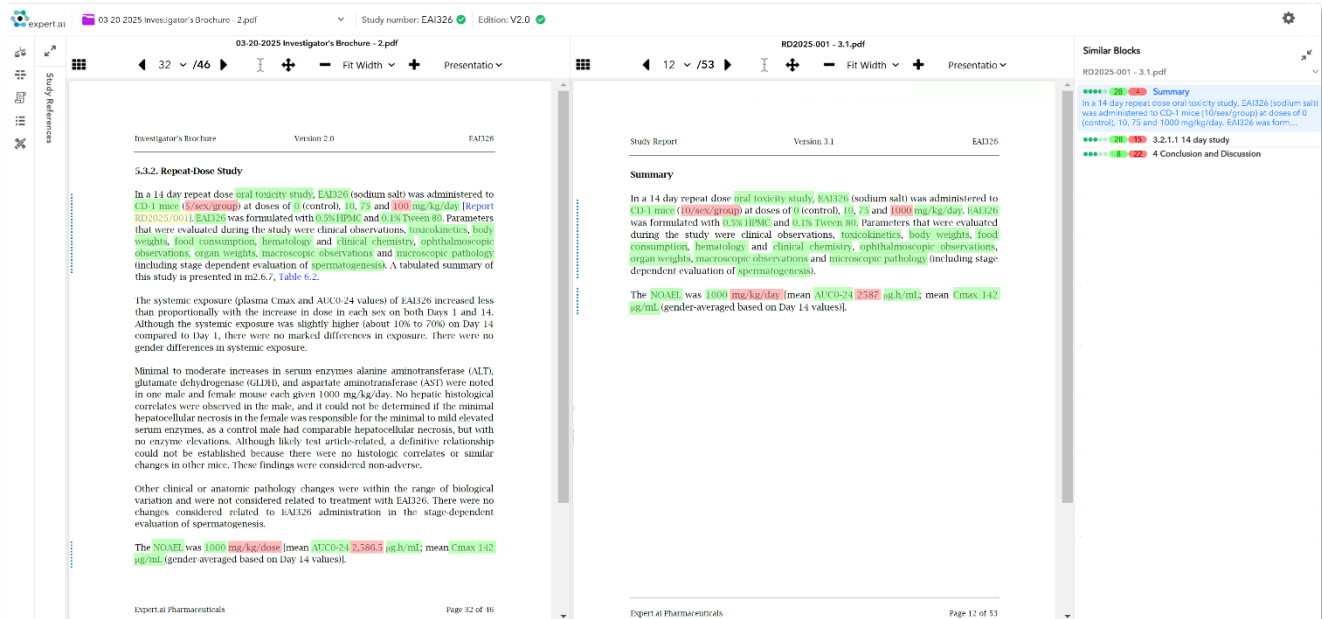
Core Functionalities

Expert.ai's solutions for Life Sciences and Healthcare provide medical, research, pre-clinical, clinical, regulatory and knowledge management teams with the highest quality, standards-based and most consistent Life Sciences knowledge models available. Teams can now accelerate quality assurance processes for regulatory reporting by using a hybrid AI approach combining neuro-symbolic, generative, and agentic artificial intelligence. Our solution for quality assurance in regulatory submission transforms the internal documentation workflow and regulatory submission process:

● **Text and Data Comparison**: Automatically detects discrepancies between summary reports and supporting studies.

● **Automated Report Generation**: Uses AI to generate structured content from reference materials.

● **Intelligent Review & Validation**: Identifies misalignments and ensures conformance with submission standards.