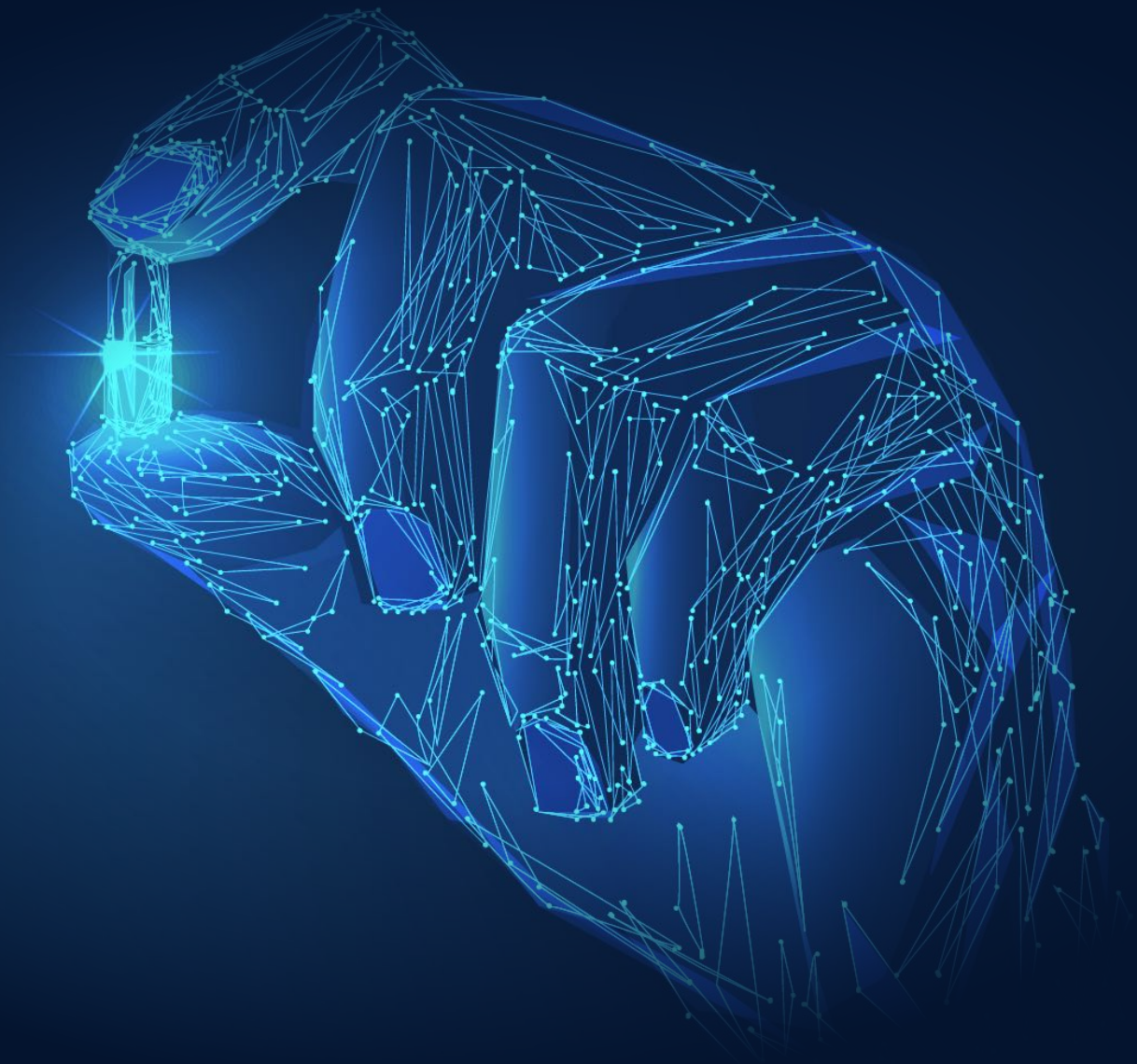
The Next Radical Change in Pharma

Bringing AI and NLG to Clinical Study Reports



Co-created by

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Introduction

Pharma walks a hard road getting life-saving drugs to market. That's why speed becomes so crucial in the New Drug Application approval process. In this process, pharma companies face many challenges such as the race to market, competition and maintaining compliance with stringent regulatory requirements—both internal and external.

Speeding the drug application process has always been crucial, but it gained even more importance during the COVID-19 pandemic as daily case counts and deaths surged worldwide. How does pharma respond to that challenge, effectively … and ethically?

"COVID changed a lot in this industry, but development cannot be rushed at any cost," says Emmanuel Walckenaer, CEO of Yseop. "Life sciences is a unique industry. It's highly regulated and safety is paramount. You cannot do just anything. There are no compromises. That's why I believe that AI is a great solution to speed the drug development process and do it safely."

Emmanuel Walckenaer
CEO of Yseop

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Even deep into the process, long after the drug or vaccine has been successfully tested, the road to regulatory approval must pass through the Clinical Study Report (CSR). Medical writers invest weeks—sometimes months—into writing CSRs that explain in detail the methods of clinical trials and their results. These long, complex scientific reports command a pivotal role in the decisions that regulators will make regarding whether a drug goes to market.

CSRs – Sanofi's Last Mile Before Approval and Launch

Challenge

Just a few years ago, automating the organization of clinical trial data into a solution that would draft vast parts of a CSR report was unthinkable. That's when Sanofi, a Paris-based multinational pharmaceutical company, approached Yseop about creating an Augmented Medical Writer. Together, Sanofi and Yseop explored AI options that could reduce the considerable amounts of time, effort and medical expertise invested into CSRs.

> *"In Sanofi's Last Mile, in their Phase III before a drug goes to market," says Walckenaer, "you have to analyze the impact of your drug on tens of thousands of patients. That generates massive amounts of clinical data. You have to analyze that data before it goes to the FDA in the CSR. It's a high-stakes document. Based on that CSR, they will say 'yes' or 'no.'"*

Emmanuel Walckenaer
CEO of Yseop

In the Last Mile of the CSR process, Sanofi spent thousands of hours writing multiple CSRs each year. This was in addition to testing and building a go-to-market strategy while meeting regulatory requirements. The costs to Sanofi's clinical and medical teams in terms of money, time and effort were enormous.

Actions Taken

The Yseop/Sanofi team looked at how AI, Machine Learning and Natural Language Generation (NLG) could help automate the structured data points of the CSR. The team researched how an Augmented Medical Writer could deliver the insights that Sanofi needed for its CSRs, effectively and efficiently.

The project team prioritized four main goals for the Augmented Medical Writer:

- → To automate 30% of the CSR in three Therapeutic Areas
- → To empower medical writers to generate accurate content quickly
- → To integrate best practices and company standards
- → To include an intuitive UX via Word integration

In creating the solution, the teams joined together cutting-edge AI technology with a hunger for speed, accuracy and an appetite for large data processing. Team members then fed Sanofi's enormous datasets to the model and benchmarked its performance daily, in order to build the solution rapidly.

Results

While NLG cannot grasp the nuances and complexities available to human intelligence, the Augmented Medical Writer solution delivers true value where humans cannot. The solution produces quality repeated text in a consistent style across documents that might have otherwise been split across multiple human writers with varying skills, expertise and approaches. Creating that consistent style and voice across a team of medical writers producing CSRs was a key objective for Sanofi and a bridge to the automated, streamlined workflow that they needed to convert data into useful commentary.

Conclusion

AI promises radical change to the pharmaceutical industry. AI-powered algorithms can now conduct tasks that once required human intelligence to complete. The coming of the pandemic has clarified AI's contribution to the future of pharma–driven by the race to find a vaccine to slow and stop the spread of the coronavirus.

Natural Language Generation brings automated intelligence to the CSR process. With the efficiencies offered by AI and NLG, pharmaceutical companies can get drugs to regulators, and the market, sooner. This helps both those who need the drugs and those who need the ROI to continue producing them.

AI, in its ideal state, blends pure Machine Learning and Natural Language Generation with the expertise of the people around it. Clearly, CSR content will never be fully generated from scratch, but now there's a structure and AI solution to make creating these labor-intensive reports much easier.

In that Last Mile before drug approval, Machine Learning gets the grunt work done. With the augmented report writer, the Yseop/Sanofi team noted:

- Saving immense amounts of time and money when analyzing thousands of datasets
- Providing quality natural language content in the voice of the medical writers
- Removing the risk of manual errors while ensuring high-quality, accurate and fully traceable content
- Streamlining processes and producing reports more quickly to accelerate regulatory submission

The augmented report writer saved precious time, allowing Sanofi to focus on its core mission: to protect and improve the health of people worldwide.

"Now, we're in discussions with eight of the top twenty pharma companies in the world," says Walckenaer. "We're clearly not at a POC stage anymore. This is going mainstream in eighteen months. Things are evolving quickly. I think technology and, more importantly, people are ready for that."

For a task like converting 30 tables into data for 20 pages of a CSR, Sanofi's medical writers once needed hours to review the data, process it and convert it to words on a page. By implementing the Augmented Medical Writer, the project team noted a 30% savings of time.

While AI cannot tell the medical writer what to write, it can help them dive into the data and get plain outcomes in plain English. The solution helps put research into words—analyzing the data first and then generating natural language to explain it.

The team concluded that the Augmented Medical Writer accomplished four main goals:

- Saving immense amounts of time and money when analyzing thousands of datasets
- Providing quality natural language content in the voice of the medical writers
- Removing the risk of manual errors while ensuring high-quality, accurate and fully traceable content
- Streamlining processes and producing reports more quickly to accelerate regulatory submission

> *"How can AI, Natural Language Processing and Machine Learning help automate the structured data points of the CSR and bring insights?" asks Walckenaer. "It works … and the efficiency gain is pretty substantial for the medical writer. It can save time by eliminating writing and rewriting."*

Emmanuel Walckenaer
CEO of Yseop

In that Last Mile, medical writers spend vast amounts of their time compiling standard commentary in the CSR for submission. Yseop and Sanofi chose to take a different path. Together, they developed a solution that harnesses intelligent automation and delivers a 30% savings of time.

"You have to make it easy. Make it cool. Sanofi, for example, named their solution. The key is to consider AI as a helping colleague, but don't underestimate the resistance of your human workers.

Focus

"Don't be obsessed with technology. This is for end-users. Whether it's powered by Machine Learning or Natural Language Generation or whatever, end-users do not care. That's the engine. Ensure that the end-users and the medical writer know that they are still the engine that gets the job done. They are just getting new high-tech tires to make the job much easier.

"Start small, with trials. Measure the efficiency. How many hours or minutes have you saved? You have to build confidence in the tool. Don't do it for technology's sake. Deploy and position it correctly. Take slow steps."

"You have to make it easy. Make it cool. Sanofi, for example, named their solution. The key is to consider AI as a helping colleague, but don't underestimate the resistance of your human workers.

How do you know your implementation has worked?

"The sign of a successful deployment," says Walckenaer, "is that the customer comes to you with five more reports to automate. This is a sign of success. You start with one. Get feedback and get it right. Then you move on to the others."

Emmanuel Walckenaer
CEO of Yseop

Encouraging Adoption

The Yseop/Sanofi team also considered how best to ensure adoption by medical writers, managers and stakeholders in the process. **“How can we position AI so people will love it?”** asks Walckenaer. **“We get rid of tedious tasks. We measure satisfaction. We survey customers. Now they have a top-notch solution. This is critical in getting people to adopt AI.”**

Creating AI solutions means servicing humans. Thinking about the interface where people encounter the tech often carries more weight than the tech itself. In creating the interface, industry experience becomes critical in enhancing the likelihood of adoption and top-down approaches often fail.

To succeed in fostering AI adoption, even among uneasy workers, it’s important to show them that they’re in control, in charge. Whether it’s a three-line summary or a 300-page analysis, workers need to see how it will be accomplished—and how they will manage the new process with increased ease and efficiency.

Equally important is mastering their style and integrating it into the NLG solution. Introducing a new AI solution empowers workers and augments their skills—messaging that becomes critical to deliver, clearly and effectively. The solution’s ease of use must also be conveyed—in taking their hard-won knowledge and transforming it into vehicles of communication, created with more confidence and in less time.

To Emmanuel Walckenaer, fostering AI adoption comes down to positioning and focus:

Positioning

“If a project manager or leader believes AI will replace FTEs, the solution becomes very difficult to employ. You have to get the right positioning, augment gaps and make their life easier. You can have a top-notch tool and the technology to do a stellar job, but it comes down to internal communication. You must show the users how this technology will make them and the business better, but only if the two work together.

About Yseop

The next industrial revolution is being led by artificial intelligence and the automation of repetitive tasks to enhance human capacity in the workplace. At Yseop, we are leading this workplace revolution. Our vision is to empower people to work smarter and faster, liberating them from tedious, repetitive tasks, by automating complex business processes.

We do this through advanced Natural Language Generation (NLG) technology and our suite of specialist tools that support report writing, sales management and other business processes. These leverage artificial intelligence to make sense of complex data sets, generating written narratives accurately, quickly and at scale.

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About Emerj Artificial Intelligence Research

Emerj Artificial Intelligence Research is a market research and advisory company focused exclusively on the business impact of AI.

Companies that thrive in AI disruption run on more than just ideas. They leverage data and research on the AI applications delivering return in their industry today and the AI capabilities that unlock true competitive advantage into the future - and that's the focus of Emerj's research services.

Leaders in finance, government, and global industries trust Emerj to cut through the artificial intelligence hype, leverage proven best-practices, and make data-backed decisions about mission-critical priorities.

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