Assessment of the efficiency of a Chat GPT-based tool, MyGenAssist, in an industry pharmacovigilance department for case documentation: a cross-over study

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Abstract

Background: At the end of 2023, Bayer AG® launched its own internal large language model (LLM), MyGenAssist®, based on Chat GPT® technology to overcome data privacy concerns. It may offer the possibility to decrease their harshness and save time in repetitive and recurrent tasks that then could be dedicated to activities with higher added value. Although there is a current worldwide reflection whether Artificial Intelligence should be integrated to Pharmacovigilance, medical literature doesn't provide enough data concerning LLMs and their daily applications in such a setting. Here, we studied how this tool could improve case documentation process, which is a duty for authorization holders as per European and French Good Vigilance Practices.

Objective: To test whether the use of a LLM could improve the Pharmacovigilance documentation process.

Methods: MyGenAssist® was trained to draft templates for case documentation letters meant to be sent to the reporters. Information provided within the template changes depending on the case: such data comes from a table sent to the LLM.
We then measured the time spent on each case for a period of four months (2 months before using the tool and 2 months after its implementation). A multiple linear regression model was created with the time spent on each case as the explained variable, and all parameters that could influence this time were included as explanatory variables (use of MyGenAssist®, type of recipient, number of questions, user). To test if the use of this tool impacts the process, we compared the recipients' response rate with and without the use of MyGenAssist®.

Results: An average 23.3% (CI95: 13.8%-32.8%) time saving was made thanks to MyGenAssist® (P<.001, adjusted R-square=0.286) on each case, which could represent an average 10.7 working days saved each year. The answers' rate wasn't modified by the use of MyGenAssist® (41.67% vs 36.49%, P=.57), whether the recipient was a physician or a patient. Any significant difference was found regarding the time spent by the recipient to answer (2.20 vs 2.65 days after the last attempt of contact, P=.64). The implementation of MyGenAssist® for this activity only required a two-hour training of the PV Team.

Conclusions: Our study is the first to show that a Chat GPT-based tool can improve the efficiency of a GxP activity without needing a long training of the workforce. These first encouraging results could be an incentive for the implementation of LLM in other processes.

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Keywords: MyGenAssist, large language model, artificial intelligence, Chat GPT, Pharmacovigilance, efficiency.

Introduction

Artificial intelligence (AI) is currently at the center of attention in a lot of disciplines. Health is no exception. For instance, AI could be useful for the analysis of pictures either for detecting local signs of catheter-associated infections[1], or for reducing both time and costs required for drug discovery[2]. It could also play a role in the education of future healthcare professionals[3].

The last years already provided evidences that the use of AI would benefit pharmaceutical companies[4] [5] [6]. However, in their majority, those studies used complex applications of AI to extract or synthesize data from documents like health records[7] [8] or contents from social medias[9] [10] [11].

While not yet reachable to a wide audience, large language models (LLM), offer possibilities to integrate AI in several domains without requiring a long training of the workforce, thanks to its accessibility and its ease to use. While everyone can use some LLMs which are in open access like Chat Generative Pre-trained Transformer (ChatGPT®) since November 2022[12], getting an adequate answer sometimes requires to gradually improve the prompts. Hence, the integration of LLMs in work environment can provide new soft skills at low cost and promote empowerment of workers. Several studies already showed that pharmacists and other healthcare professionals are willing to use LLMs as a help in their work[13] [14] [15].

However, the use of LLMs raises concerns about data privacy. Recent news showed that the information provided by some users in their prompts could be transferred by ChatGPT to others[16]. This threat can be answered to by companies with the opportunity to develop their own LLM for internal use.

Hence, Bayer AG® launched on September 21st, 2023 its own internal LLM called MyGenAssist®, based on ChatGPT® technology.

Bayer®, as a market authorization holder in Europe, has the duty to set a system to collect, register and analyse adverse events related to its products according to European[17] and French Good Vigilance Practices[18] (GVPs) and the European Directive 2001/83/CE[19]. Tasks related to this imperative follow internal procedures which make some of them repetitive and time consuming. A semi-automatization of these tasks thanks to a LLM could make them less arduous for workers and procure more time for other activities at higher added value.

In the Pharmacovigilance (PV) field, the Giens Workshop[20] in 2022 aimed to initiate a reflection about the integration of AI in this area and highlighted the actions implying the writing of a letter to contact a patient or a healthcare professional as a good opportunity for this. To the best of our knowledge, no study described LLMs' use cases in Pharmacovigilance from a daily and practical perspective.

In this study, we aim to determine whether the use of MyGenAssist® in PV case documentation process can provide improvement in efficiency, meaning save time without leading to a decrease in answers' rate.

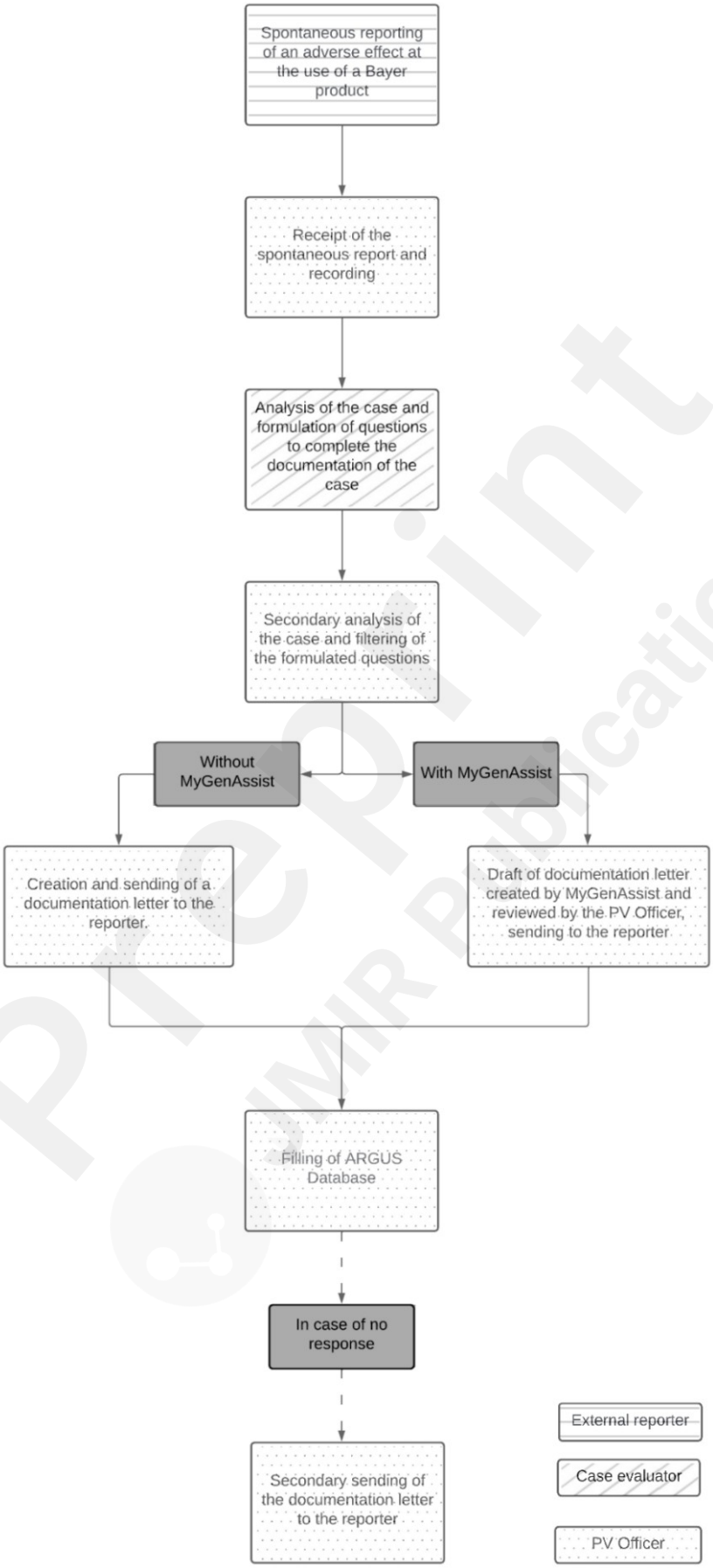
Methods

Description of the activity and materials used

Description of the case documentation process and potential contribution of MyGenAssist®

The current internal process for collecting, recording, and documenting spontaneous case reports of adverse drug events at Bayer France is described here (Figure 1): reporters can notify Bayer® about cases by phone, mail, or electronic means. The report will be compiled into a source document, which will then be added to an internal PV database by a local PV Officer. The source document will then be analysed by a case evaluator who is part of the company's global PV team. Based on the global analysis, the PV Officer will be in charge of defining the final list of relevant questions to complete the case. The Good PV Practices (GVPs), written by the French Agence Nationale de Sécurité du Médicament et des produits de santé (ANSM), add a duty to contact the reporter a second time if the first attempt of contact was unsuccessful[18].
MyGenAssist® will be added to this process at the stage of drafting documentation letters. This large language model (LLM) will be used to write a first draft of the letters, which will then be reviewed and modified if needed by the PV Officer.

Figure 1. Description of the process for documenting spontaneous notifications of adverse drug events.



Software and applications used

MyGenAssist® is a LLM internal to Bayer® based on the technology of ChatGPT4Turbo® (Open AI®, San Francisco, California, USA), a conversational agent based on generative AI[21]. All manipulations performed on this internal LLM can be reproduced on ChatGPT®, which is accessible to the public online.

PV cases reported to Bayer® are compiled on an internal PV database supported by the ARGUS® PV case management software developed by Oracle® (Austin, Texas, USA)[22]. This software assigns a specific reference to each case. It contains all documents related to the case, as well as information regarding the actions taken to analyse the case, such as attempts to contact the reporter.

The questions formulated by the case evaluators following their analysis of the case are listed on the FAST® application. The PV Officer can select the relevant questions and can add others if needed.

Use of MyGenAssist® for the activity

PV case documentation letters are written according to templates validated by an internal process. Two templates exist depending on the type of recipient (patients or healthcare professionals). The PV Officer can adapt the template in function of the PV case. To make the LLM pre-draft the PV case documentation letters, the two templates are used. The elements of the templates corresponding to information specific to each case are replaced by titles placed into brackets in the letter templates. These two letter templates are then provided via the following prompt as shown in *Supplementary data*.

Staff training

In order to train staff to use MyGenAssist® specifically for this activity, a training session was planned before initiating its use. The above-described operating mode was given to the PV Officers. A training phase was also planned to verify their good understanding of the use of the tool. The operating procedure was also formalized for the use of potential new arrivals. To allow PV Officers to report any difficulties or suggestions for improvement regarding the operating procedure, meetings were scheduled every other week until the termination of the study.

Data collection

The study was conducted between January 2nd and May 3rd, 2024. The time spent on each case was measured from the moment the PV case is acknowledged until the letter is sent and the Argus® database is filled out.

Over an initial period of 9 weeks, the time spent on drafting each documentation letter, without the use of MyGenAssist®, was measured. Over a second equivalent period, the time spent on the same task, but using the LLM as a drafting aid, was also measured. During the two periods, apart from the addition of MyGenAssist®, no significant changes in the management of the activity took place: the 3 same workers, two experimented on the task and a newcomer, were present throughout the four months of the study, and the process didn't undergo any notable modifications.

Statistical analysis

Calculation of time savings

To determine the average time saved for each case thanks to MyGenAssist®, a multiple linear regression is performed in which the explained variable is the time spent per case.

To highlight the impact of MyGenAssist®, all parameters that could potentially influence the

time spent per case are considered and included in the regression model as an explanatory variable (Figure 2):

$Y = a_1 X_1 + a_2 X_2 + a_3 X_3 + a_4 X_4 + a_5 X_5 + b$

_ X_1: Use of MyGenAssist®.

_ X_2: Type of recipient. The letter template differs significantly depending on this parameter. It may also be necessary to simplify the questions contained in the letter for patients, leading to more time spent on the task.

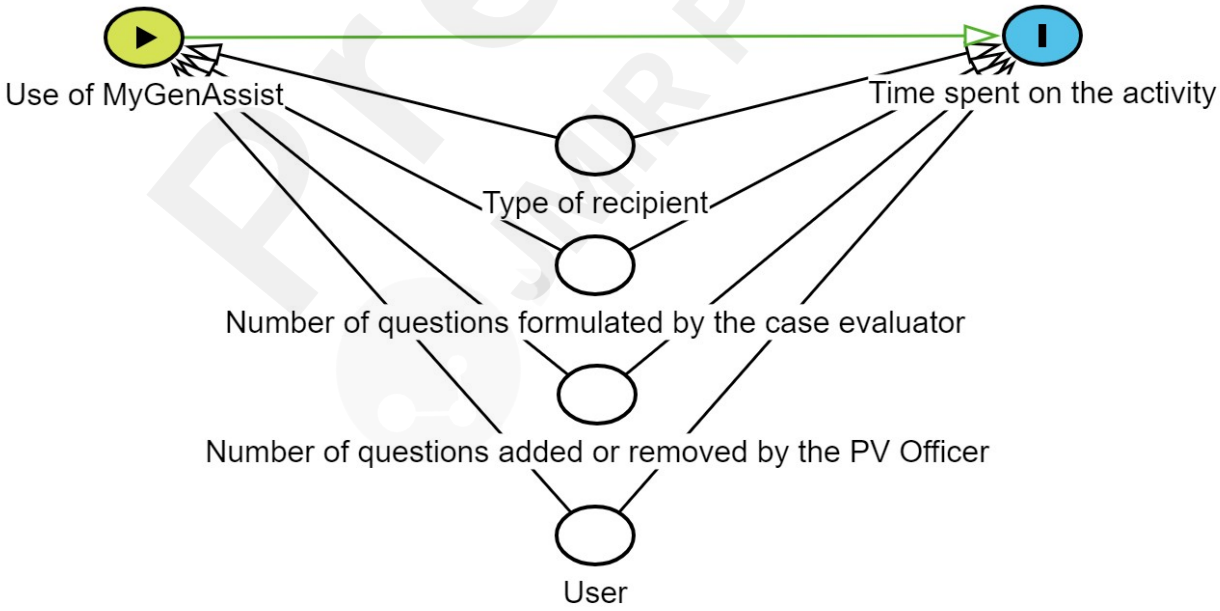
_ X_3: Number of questions formulated by the case evaluator. This parameter can also impact the time spent. Each question is asked in English. Without the use of MyGenAssist®, a French translation is automatically provided by the internal software FAST®, but the translations need to be reviewed and the questions sometimes need to be adapted according to the recipient. This adaptation is a step in the workflow whose duration could be correlated to the number of questions. When using MyGenAssist®, this latter also provides a translation of the questions, but some adaptation work is still necessary.

_ X_4: Number of questions added or removed by the PV Officer. The PV Officer has the option to remove questions prepared by the case evaluator considering them irrelevant in the context of the case. Conversely, this latter can also add questions to obtain information considered as necessary. Adding questions or considering the removal of questions from the case processor leads to additional reflection time that can impact the overall duration of the task.

_ X_5: User. The user is taken into account. The personal characteristics of the user, such as their experience in the activity, will influence the time spent on the task.

a_1, a_2, a_3, a_4, and a_5 are respectively the coefficients of the variables X_1, X_2, X_3, X_4, and X_5, and b is the intercept.

Figure 2. Causal diagram of factors potentially impacting the time spent on the activity.



The multiple linear regression is performed using the R® software with the 'lm' function.

Cases are randomly distributed among the PV Officers without considering the context of the case, the type of recipient, and the number of questions a priori. The number of questions formulated is not related to the type of recipient.

Measurement of effectiveness

The reliability of the LLM is not studied because the use of MyGenAssist® is intended only as an aid in drafting documentation letters. However, a measure of the effectiveness of the task with or without the tool is carried out. For this, a comparison of the proportion of cases for which a response from the recipient was obtained after the first and the second contact attempt is made, depending on whether MyGenAssist® was used or not. A subgroup analysis is also realized in function of the type of recipient (physician or patient). The comparison is made on R® thanks to the 'chisq.test' function.

Results

Statistical study

The study included 122 cases (48 without the use of MyGenAssist and 74 with its use). The average time spent on each case was 19.05 minutes (CI95: 17.97-20.12 minutes). The average time for cases handled without the use of MyGenAssist was 22.25 minutes (CI95:20.09-24.41 minutes) and 16.97 minutes (CI95: 16.17-17.77 minutes) when the LLM was used (Figure 3). When all factors which potentially impact the time spent on the activity are taken into account in a multiple linear regression model, an average 23.3% (CI95: 13.8-32.8%, P<.001) of time savings were realized for each case thanks to MyGenAssist (adjusted R-square: 0.286, df=115) (Table 1). All explanatory variables of the linear regression model got a p-value inferior to 0.05, apart from the number of questions added or removed by the PV Officer (P=.055).

Figure 3. Time spent on each case in function of the use of MyGenAssist.

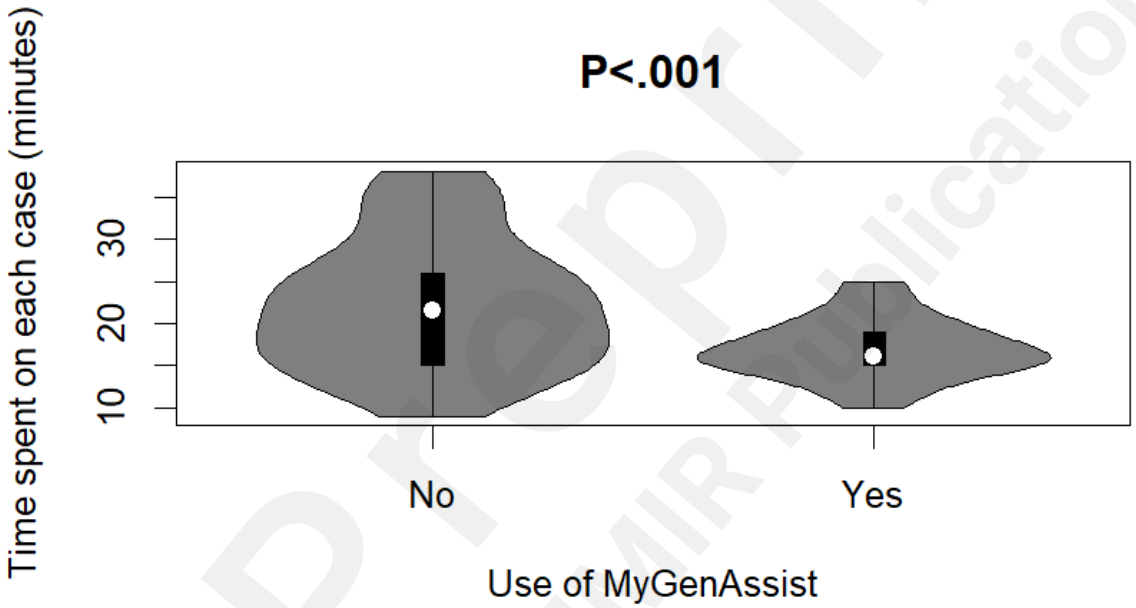


Table 1. Influence of explanatory variables on the time spent on a case.

	Coefficient (CI95)[a]	**p-value**
Use of MyGenAssist	-23.3% (-32.8% - -13.8%)	<.001
Letter sent to a healthcare physician	-10.5% (-19.8% - -1.2%)	.03
Each additional question formulated by the case evaluator	2.3% (0.7% - 4.0%)	.006
Each additional question added or removed by the case evaluator	2.2% (0.1% - 4.4%)	.055
Fastest vs slowest user	-18.7% (-32.7% - -4.8%)	.009

a A logarithmic transformation was performed to fulfil the conditions of the linear regression model (the actual model is: $\log T = a_1X_1 + a_2X_2 + a_3X_3 + a_4X_4 + a_5X_5$), hence the result obtained is a percentage of difference of time in function of each parameter.

According to the number of spontaneous PV reports for which a documentation request was necessary during the last three years, it can be estimated that the time saved on the activity with the use of the LLM could be between 66.20 and 108.70 hours per year, on the basis of an average 23.3% time saved on the average 22.25 minutes spent on a case without the use of MyGenAssist. Based on a working day of 8 hours, the use of MyGenAssist for this activity in the three previous years could have saved an average 10.7 days of work per year (Table 2).

Table 2. Potential time saved on the PV case documentation process each year with the use of MyGenAssist.

Year	**Number of PV cases requiring documentation request**	**Potential time saved (CI95) (h)**	**Potential time saved (CI 95) (working days)[b]**
2021	1258	108.70 (64.38 – 153.01)	13.6 (8.0 – 19.1)
2022	947	81.82 (48.46 – 115.19)	10.2 (6.1 – 14.4)
2023	767	66.27 (39.25 – 93.29)	8.3 (4.9 – 11.7)

b A working day is considered to last 8 hours.

No statistical difference has been found regarding the answers' rates after one attempt of contact, whether MyGenAssist® was used or not: 31.25% of letters produced without MyGenAssist® were provided with an answer and 24.32% when the generative AI was used for

the writing (P=.40, χ^2=0.71, df=1). The same situation occurred after two attempts: 41.67% without the tool vs 36.49% (P=.57, χ^2=0.33, df=1). In a subgroup analysis in function of the type of recipient, these results were consistent (Table 3).

Table 3. Answers' rates to letters sent for PV case documentation in function of the use of MyGenAssist® and the type of recipient.

	Without the use of MyGenAssist®	**With the use of MyGenAssist®**	**P**	**χ^2**	**df**
Total	20/48 (41.67%)	27/74 (36.49%)	.57	0.33	1
Physicians	14/29 (48.28%)	15/45 (33.33%)	.20	1.65	1
Patients	6/19 (31.58%)	12/29 (41.38%)	.49	0.47	1

In cases for which an answer is provided, the average time between the answer and the last attempt of contact does not differ significantly (Figure 4): 2.20 days (CI95: 1.27-3.13 days) when the letter was written without MyGenAssist® and 2.65 days (CI95: 1.90-3.41 days) with its use (P=.64, t=-0.46, df=44).

Figure 4. Comparison of the duration time between the answer and the last attempt of contact in function of the use of MyGenAssist.

Staff meetings

Before the study, a two-hour training was planned to present the use of MyGenAssist® in the PV case documentation process to the PV Officers. During the study, meetings were planned in the team on a two-week basis. No difficulties in the use of MyGenAssist® were identified and users only suggested slight improvements in the prompt used to consider specific cases for which additional elements are required in the letter. An operating mode, detailing all the steps required to use MyGenAssist® for the activity, was written to offer a reminder for the users if

necessary.

Discussion

Main Results

In this study, we demonstrated that the implementation of MyGenAssist® to the PV case documentation process provided an average 23.3% time saving on the task without any modification in the rate of answers. Whatever the experience of the workers, the use of MyGenAssist® induces time saving, although this effect is higher in non-experimented ones. Therefore, the use of the Bayer's LLM improved the efficiency of this activity. That must save dozens of hours yearly for our local PV Team which could be dedicated to other activities with higher added value. Only one short and reachable training was required to implement the use of MyGenAssist®, by presenting the changes provided in the operating mode by the tool to the users, who don't have any qualifications or skills in Informatics. Hence, we saw here that making workers use a LLM could be easy as far as they are assisted at the beginning, while other AI tools require an important training to be used daily. However, a daily use of a LLM can make the user continually improve its abilities with this tool. Therefore, LLMs seem easy to integrate in several work environments and a way for the worker to get new skills without needing a large amount of time. Thanks to its ease, all users kept using the generative AI for their activity after the end of the study.

Although we included in the linear regression model all parameters that could have an influence on the time spent on the activity to our point of view, the adjusted R-square is low (0.286). Therefore, the most part of the time spent on each case couldn't be fully explained by the considered parameters. It seems that some aspects that are specific to each and difficult to transcribe in the model are important factors too. Moreover, a 'human factor' could play a role here, as the user could spend a variable duration of time for the same task, in function of a lot of exterior parameters. Whatever explanatory variable was not included here, the average difference created by MyGenAssist® (more than 5 minutes on a task requiring about 22 minutes without its use) seems too high to be questioned by these potential 'hidden' parameters.
Other ways could have been explored to determine the effectiveness of the generative AI. Here, we made the choice to use as the main criteria the objective of the task: to get the necessary information to analyse the PV case. To our perspective, other criteria didn't seem relevant in this context. Moreover, we made the choice not to analyse the quality of the drafts written by MyGenAssist® because it was clear in our operating mode and in the training that a human assessment of the letter was mandatory before sending it out. To get a relevant analysis of the effectiveness, recipients weren't informed that the letter they received was first written with the help of a LLM: on one hand, the recipient could have had the impression that its report was "automatically" handled, which could have encouraged this latter not to answer. On the other hand, the potential curiosity created by an eventual mention of the generative AI, in a current era in which all eyes are turned to such tools, could have created a bias by making the recipient more willing to answer.

Limitations

While our study was realized on a four month-period, this latter only includes 122 cases. Even if it was enough to notice a difference in the time spent in function of the use of the tool, this has to be taken into account, particularly while analysing the answers' rate. However, this study is a first step before the extension of the use of the LLM in the PV case documentation process to all Bayer Local PV teams worldwide. The efficiency improvement noticed by the French PV Team could give fresh impetus to make other teams adopt the same principle. This will give the

opportunity to retrieve a higher amount of data concerning our question.

Comparison to Prior Work

Our study may fulfil what seems to be, to the best of our knowledge, a lack in the medical literature. Descriptions of LLMs use cases for PV exist but none of them include a measure of time saving realized thanks to this tool. A study showed that the use of Chat GPT® for writing tasks enhanced the productivity of the workers by decreasing the time required by 40%, while the quality rose by 18%[23], but didn't concern Health. Hence, our objective was to determine if the integration of the LLM in the adverse event case documentation process can improve the efficiency by reducing the time required for this GVPs-related task without decreasing the response rate from the reporters.

These first encouraging results could be an incentive to implement MyGenAssist® in other processes. In the PV field, some tasks fit well with the integration of MyGenAssist®. For example, the comparison of different versions of the same procedure with this tool can provide a rapid insight into the modifications in order in a second step to assess their impact on other quality documents. Other use cases could be found in other departments, as the task given to the LLM, which is writing letters based on a template, seems pretty reproducible in other contexts for different objectives. The results of this study show that using LLMs in pharmaceutical activities, whatever their field is, is relevant and can create improvements without losing quality, in the respect of the regulations of the GxPs activities.

Conclusions

In this study, we showed the first example of a use case for a Chat GPT-based tool, MyGenAssist®, in a PV industry department, and assessed its efficiency on a four month-period. An average 23.3% of time savings was achieved thanks to this LLM, while its implementation didn't modify the effectiveness of the task. It only required a short training to be set up. These results could be the first step to a largest use of LLMs in pharmaceutical activities.

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Conflicts of Interest

None declared.

Abbreviations

ANSM: Agence Nationale de Sécurité du Médicament et des produits de santé
AI: Artificial Intelligence
ChatGPT®: Chat Generative Pre-trained Transformer
GVPs: Good Vigilance Practices
GxPs : Good Practices
LLM: Large Language Model
PV: Pharmacovigilance

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Supplementary Files

Multimedia Appendixes

Original prompt used in French.
URL: http://asset.jmir.pub/assets/d7584eee161856d0cbfeaf25c0678451.png

Translation of the prompt used in English.
URL: http://asset.jmir.pub/assets/f794c907369ee6b556585753817e75b5.png