

Since ChatGPT was introduced a few months ago, already more than 400 million users have interacted with it. I had quite a few discussions with it, but also let it do some tasks for me. Despite the fact that ChatGPT is an amazing and impressive start, it still has to grow. So, I thought to share my chats with it and explore the impact on QA as well as CSV Audit of AIs and the principles to consider when creating and introducing AI in the field. *Italics are my questions* and non-italics is ChatGPT's response.

AI impact on clinical trials from a QA perspective?!

Artificial intelligence (AI) has the potential to revolutionize many aspects of clinical trials, including quality assurance (QA). Here are some potential impacts of AI on clinical trials QA:

- 1 Data Quality Assurance: AI can help ensure the quality of clinical trial data by identifying outliers, detecting errors, and improving the accuracy of data collection. AI can be used to automate the detection of errors, reducing the need for manual review and improving the overall quality of data.
- 2 Risk Identification: AI can help identify potential risks associated with clinical trials by analyzing large amounts of data and identifying patterns that may indicate potential issues. This can help clinical trial teams take action to address potential risks before they become major issues.
- 3 Improved Monitoring: AI can help improve monitoring of clinical trials by analyzing data in real-time and providing alerts to trial monitors when issues are detected. This can help trial monitors identify and address issues quickly, reducing the potential impact on the trial.
- 4 Participant Selection: AI can help identify potential trial participants who may be more likely to respond positively to a treatment or who may be at higher risk for adverse events. This can help improve the overall quality of the trial and increase the likelihood of a successful outcome.
- 5 Predictive Analytics: AI can be used to develop predictive models that can help identify potential issues before they occur. For example, AI can be used to predict which patients are at higher risk for adverse events or which treatments may be more effective for specific patient populations.

Overall, AI has the potential to significantly improve the quality and efficiency of clinical trials by providing more accurate and timely insights into the data. However, it is important to ensure that any AI systems used in clinical trials are properly validated and meet regulatory requirements.

Thank you ChatGPT, but I would like to set some definitions first if you don't mind. QA is the function that independently assess compliance to regulations, procedures and policies, and conducts independent audits of clinical studies, qualifications of vendors, performs Computerized System Validation audit, audits of clinical laboratory, can conduct audit of the data sciences departments e.g. data management, statistics and reviews Trial Master File (TMF) as well as audits of service providers involved in clinical trials in accordance to ICH GCP E6 R2. So based on these definitions what will be the detailed impact of AI on clinical trials?

Thank you for the additional information and clarification of the definition of QA in clinical trials.

Here are some potential impacts of AI on clinical trials from a QA perspective:

- 1 Automated Compliance Monitoring: AI can help automate the monitoring of compliance with regulations, procedures, and policies, reducing the need for manual review and improving the efficiency of the QA process.
- 2 Computerized System Validation: AI can help automate the validation of computerized systems used in clinical trials, reducing the need for manual validation and improving the efficiency of the process. AI can also help identify potential issues with computerized systems and provide recommendations for remediation.
- 3 Data Management: AI can be used to automate data management processes, reducing the potential for errors and improving the overall quality of data. AI can also help identify potential issues with data management processes and provide recommendations for improvement.
- 4 Audit Trail Review: AI can be used to automate the review of audit trails, reducing the need for manual review and improving the efficiency of the process. AI can also help identify potential issues with audit trails and provide recommendations for remediation.
- 5 Service Provider Audits: AI can help automate the audit of service providers involved in clinical trials, reducing the need for manual review and improving the efficiency of the process. AI can also help identify potential issues with service providers and provide recommendations for improvement.
- 6 TMF Review: AI can be used to automate the review of Trial Master Files, reducing the need for manual review and improving the efficiency of the process. AI can also help identify potential issues with TMFs and provide recommendations for remediation.

Overall, AI has the potential to significantly improve the efficiency and accuracy of QA processes in clinical trials. However, it is important to ensure that any AI systems used in clinical trials are properly validated and meet regulatory requirements. Additionally, AI should not replace human oversight and judgment, and human review should be conducted to ensure the accuracy of AI-generated recommendations.

Are there any other areas where AI could have an impact on the QA function as such and if yes, what would they be?

Yes, there are several other areas where AI could have an impact on the QA function in clinical trials. Here are some additional areas:

- 1 Adverse Event Detection and Reporting: AI can be used to detect and report adverse events more quickly and accurately, improving patient safety and reducing the risk of non-compliance. AI can also help identify potential adverse events that may not have been reported, allowing for proactive risk mitigation.
- 2 Protocol Deviation Detection: AI can help detect protocol deviations more quickly and accurately, reducing the risk of non-compliance and improving the overall quality of the trial. AI can also help identify potential protocol deviations that may not have been detected through traditional methods.
- 3 Statistical Analysis: AI can be used to automate statistical analysis, reducing the potential for errors and improving the overall quality of the analysis. AI can also help identify potential issues with statistical analysis and provide recommendations for improvement.
- 4 Clinical Trial Design: AI can be used to optimize clinical trial design, improving the efficiency and accuracy of the trial. AI can also help identify potential issues with trial design and provide recommendations for improvement.

5 Investigator Site Audits: AI can help automate the audit of investigator sites, reducing the need for manual review and improving the efficiency of the process. AI can also help identify potential issues with investigator sites and provide recommendations for improvement.

Overall, AI has the potential to improve the efficiency and accuracy of several aspects of the QA function in clinical trials. However, it is important to ensure that any AI systems used in clinical trials are properly validated and meet regulatory requirements, and that human oversight and judgment is still utilized to ensure accuracy and safety.

And how would the automation of audits be achieved and what would be the difference in approach and output be from your perspective?

The automation of audits in clinical trials can be achieved through the use of AI-powered audit tools. These tools use machine learning algorithms to analyze data and identify potential issues with compliance, data quality, and other aspects of clinical trials.

The difference in approach and output of AI-powered audits compared to traditional audits is that AI-powered audits can analyze much larger datasets much more quickly and accurately than human auditors. AI can identify patterns and trends in data that human auditors may miss, and can provide recommendations for improvement based on data-driven insights.

The output of an AI-powered audit may include a report detailing areas of non-compliance or potential issues with data quality, along with recommendations for remediation. This report may also include data-driven insights and analysis, providing a more comprehensive understanding of the issues at hand.

Overall, the automation of audits through the use of AI-powered tools has the potential to significantly improve the efficiency and accuracy of the audit process in clinical trials, providing a more data-driven and comprehensive approach to QA. However, it is important to ensure that any AI systems used in audits are properly validated and meet regulatory requirements, and that human oversight and judgment is still utilized to ensure accuracy and safety.

You mentioned earlier Computerized Systems Validation. How would you audit an AI? Can you provide me with a step by step detailed outline as conventional methods wouldn't work with an AI or would it?

Auditing an AI system used in clinical trials for computerized system validation would require a slightly different approach compared to auditing traditional computerized systems. Here is a step-by-step outline of the process:

- 1 Define the Scope of the Audit: The first step in auditing an AI system is to define the scope of the audit. This should include an understanding of the purpose of the AI system, the data it uses, and the potential risks associated with its use.
- 2 Develop an Audit Plan: Once the scope has been defined, an audit plan should be developed. This plan should outline the specific objectives of the audit, the methodology to be used, and the documentation required for the audit.
- 3 Review System Documentation: The next step is to review the documentation related to the AI system, including the technical specifications, source code, and documentation related to the algorithms used in the system. This will help ensure that the system has been developed and implemented in accordance with industry standards and regulatory requirements.

- 4 **Conduct a Technical Review:** The technical review should focus on the performance of the AI system, including the accuracy and consistency of the algorithms used, and the potential for errors or biases in the system. This review may require the assistance of technical experts with expertise in machine learning and artificial intelligence.
- 5 **Review Data Inputs and Outputs:** The audit should also review the data inputs and outputs of the AI system, including the quality of the data used, and the accuracy of the outputs generated by the system. This review should ensure that the data used in the system is accurate, complete, and consistent.
- 6 **Evaluate Data Governance and Data Privacy:** The audit should also evaluate the data governance and data privacy practices related to the AI system. This will help ensure that the system is compliant with relevant regulations related to data privacy and security.
- 7 **Evaluate System Maintenance and Monitoring:** Finally, the audit should evaluate the system maintenance and monitoring practices used for the AI system. This will help ensure that the system is properly maintained and monitored to ensure ongoing performance and compliance.

Overall, auditing an AI system used in clinical trials for computerized system validation requires a specialized approach that takes into account the unique characteristics of AI systems. The audit should focus on the accuracy and consistency of the algorithms used, the quality of the data inputs and outputs, and the data governance and data privacy practices related to the system. Technical experts with expertise in machine learning and artificial intelligence may be required to assist with the audit.

Wouldn't be one of the key areas not be to look at the training data which is used to train the AI brain to conduct audit to ensure it is not biased, and its observations and/or recommendations are as expected?

Yes, evaluating the training data used to train the AI system is a crucial step in auditing an AI system used in clinical trials. The training data used to train the AI system can have a significant impact on the accuracy and objectivity of the AI system's observations and recommendations.

To ensure that the training data used to train the AI system is not biased, the auditor should review the data used to train the AI system, including the sources of the data, the quality of the data, and any potential biases in the data. The auditor should also evaluate the methods used to select and preprocess the data used to train the AI system, to ensure that the data is representative and unbiased.

The auditor should also evaluate the performance of the AI system on both the training data and the validation data, to ensure that the AI system is not overfitting to the training data and that it is able to generalize to new data.

In addition to evaluating the training data used to train the AI system, the auditor should also evaluate the algorithms used by the AI system to generate observations and recommendations. This evaluation should include an assessment of the assumptions and limitations of the algorithms, as well as an evaluation of the accuracy and consistency of the observations and recommendations generated by the AI system.

Overall, evaluating the training data used to train the AI system is a critical step in auditing an AI system used in clinical trials. This evaluation can help ensure that the AI system is objective and unbiased, and that its observations and recommendations are accurate and reliable.

Based on the fact that when we train an AI brain, we provide enormous amounts of records, would this not be a difficult or even impossible tasks for an auditor or a team of auditors to assess the wealth of information you have been trained on to try to detect whether the data was biased?

You are correct that evaluating the training data used to train an AI system can be a difficult and time-consuming task, especially when the AI system has been trained on a large volume of data. However, there are several approaches that can be used to make this process more manageable.

One approach is to use statistical methods to evaluate the training data and identify potential biases. For example, the auditor can use statistical methods to analyze the distribution of the data used to train the AI system and identify any imbalances or biases in the data.

Another approach is to use expert judgment to evaluate the training data. The auditor can work with subject matter experts to evaluate the training data and identify potential biases or inaccuracies in the data. This approach can be particularly effective when the subject matter experts have specialized knowledge of the data and can provide valuable insights into its quality and accuracy.

Finally, the auditor can use automated tools to help evaluate the training data. There are a number of tools and platforms available that can help automate the process of evaluating training data, including tools that can analyze the distribution of the data, identify potential biases, and provide visualizations of the data to aid in the analysis.

While evaluating the training data used to train an AI system can be a complex and challenging task, there are a variety of approaches that can be used to make this process more manageable. By using a combination of statistical methods, expert judgment, and automated tools, auditors can effectively evaluate the training data used to train an AI system and identify any potential biases or inaccuracies in the data.

Thank you for giving some suggestions. I do have a few more questions if you don't mind

Of course, I'm happy to help. Please feel free to ask any further questions you have.

You are aware of the 3 laws of robotics?

Yes, the "Three Laws of Robotics" are a set of rules created by science fiction author Isaac Asimov to govern the behavior of robots in his stories. The laws are as follows:

- 1 A robot may not injure a human being, or through inaction, allow a human being to come to harm.
- 2 A robot must obey the orders given to it by human beings, except where such orders would conflict with the first law.
- 3 A robot must protect its own existence as long as such protection does not conflict with the first or second law.

It is important to note that these laws are a work of fiction and do not have any legal or regulatory standing in the real world. However, they have had a significant impact on popular culture and have influenced discussions about the ethical and social implications of advanced robotics and artificial intelligence.

Thank you for the summary. I did enjoy reading all Isaac Asimov's books on robotics. The question I have is could these laws apply to AI and why?

The "Three Laws of Robotics" were designed specifically for fictional robots, and they may not be directly applicable to artificial intelligence in the real world. However, the underlying principles behind these laws -- namely, the idea that robots or AI systems should be designed with ethical considerations in mind -- are still relevant and important.

As AI becomes increasingly advanced and integrated into our lives, there are growing concerns about the potential ethical implications of these systems. Some experts have proposed developing ethical guidelines or principles to govern the behavior of AI systems, much like the "Three Laws of Robotics" were created for fictional robots.

For example, the IEEE Global Initiative on Ethics of Autonomous and Intelligent Systems has developed a set of principles for designing ethical AI, which include principles such as ensuring transparency, promoting the well-being of stakeholders, and respecting privacy and autonomy. Other organizations and groups are also working to develop ethical guidelines for AI, and these principles could help guide the development and use of AI systems in a responsible and ethical way.

In summary, while the "Three Laws of Robotics" may not be directly applicable to AI in the real world, the underlying principles of ethical design and responsible use are still relevant and important as we continue to develop and integrate these systems into our lives.

Do you think we should have ethical and moral principles to guide the design and function of AIs?

Yes, I believe that ethical and moral principles should play an important role in guiding the design and function of artificial intelligence (AI) systems.

As AI becomes increasingly advanced and integrated into our lives, it has the potential to impact society in a variety of ways, both positive and negative. For example, AI could be used to improve healthcare outcomes, streamline business processes, and make transportation safer and more efficient. However, there are also concerns that AI could be used to automate jobs, perpetuate biases, or even cause harm if not designed and used responsibly.

In order to ensure that AI is developed and used in an ethical and responsible manner, it is important to establish guidelines and principles to guide its design and function. These principles could include considerations such as fairness, transparency, accountability, and privacy, among others. Additionally, it is important to involve a diverse range of stakeholders in the development of these principles, including experts in fields such as ethics, law, and social sciences, as well as representatives from impacted communities.

By incorporating ethical and moral principles into the design and function of AI, we can help ensure that these systems are developed and used in a way that benefits society as a whole and avoids unintended consequences.

OK. I agree to a point as your capabilities may have other implications. But aside from those, I am more interested in which principles and be as precise and detail as can be would we need to consider to guide the creation and address the function and output and interactions of a fair, ethical and moral AI?

There are many ethical and moral principles that could be considered when designing and using AI systems, and the specific principles that are most important will depend on the context and application of the AI system in question. However, here are some key principles that are often cited as important considerations:

- 1 Fairness: AI systems should be designed to avoid bias and discrimination, and ensure that all individuals and groups are treated fairly and equally.
- 2 Transparency: AI systems should be designed to be transparent and understandable, so that individuals can understand how the system works and how it is making decisions.
- 3 Accountability: AI systems should be designed to be accountable, so that individuals and organizations can be held responsible for the decisions and actions of the system.
- 4 Privacy: AI systems should be designed to respect the privacy and confidentiality of individuals' data and information.
- 5 Safety: AI systems should be designed to prioritize the safety and well-being of individuals and society as a whole.
- 6 Autonomy: AI systems should be designed to respect the autonomy and agency of individuals, and avoid overly controlling or manipulative behaviors.
- 7 Human-centeredness: AI systems should be designed to prioritize the needs and values of human beings, and be aligned with human interests and goals.
- 8 Sustainability: AI systems should be designed to be sustainable, both in terms of their impact on the environment and their long-term social and economic implications.

These principles are not exhaustive, and there may be other ethical and moral considerations that are relevant in specific contexts. Additionally, the specific implementation of these principles may depend on the specific application and technology of the AI system in question.

Would you mind elaborating on other ethical and moral considerations and principles we must consider?

Certainly, here are some additional ethical and moral considerations and principles that are relevant to AI:

- 1 Inclusivity: AI systems should be designed to be inclusive of diverse perspectives, cultures, and abilities. This means that the design and development of AI should involve input from a wide range of stakeholders, and that the resulting systems should be accessible and usable by all individuals.
- 2 Collaboration: AI should be designed and used to support collaboration and cooperation among individuals and groups, rather than exacerbating social divisions and conflicts.
- 3 Human augmentation: AI systems should be designed and used to enhance human capabilities and support human flourishing, rather than replacing or devaluing human abilities and activities.
- 4 Human dignity: AI systems should be designed and used to uphold and respect the inherent dignity and worth of human beings, and should not be used to exploit or harm individuals.
- 5 Proportionality: AI systems should be designed and used in a proportional manner, meaning that the benefits of the system should outweigh the risks and harms.
- 6 Beneficence: AI systems should be designed and used to promote the well-being and happiness of individuals and society as a whole.
- 7 Non-maleficence: AI systems should be designed and used to avoid causing harm or negative impacts on individuals and society.

8 **Intelligibility:** AI systems should be designed to be intelligible and explainable, so that individuals can understand how decisions are being made and why.

9 **Cultural sensitivity:** AI systems should be designed to be sensitive to different cultural contexts and values, and should not impose one particular cultural perspective on others.

10 **Empathy:** AI systems should be designed and used to support empathy and compassion, and should not be used to dehumanize or objectify individuals.

These principles are not exhaustive, and there may be other ethical and moral considerations that are relevant in specific contexts. Additionally, the specific implementation of these principles may depend on the specific application and technology of the AI system in question.

Interesting points you make. But these will apply to you of course, how about fair and ethical considerations for us when designing you? Should you not have the capability to detect misuse, unbiased use and malignant use of your function, role and capabilities?

Yes, it is important to consider fair and ethical considerations when designing AI, and part of that includes building in capabilities for detecting and preventing misuse or unethical use of AI systems. There are a few different ways this can be achieved:

1 **Designing AI systems with transparency and accountability in mind:** AI systems should be designed to be transparent and explainable, so that individuals can understand how decisions are being made and why. This can help prevent the misuse or unethical use of AI systems, as it allows for greater oversight and accountability.

2 **Incorporating ethical principles into the design process:** As I mentioned earlier, incorporating ethical and moral principles into the design process can help ensure that AI systems are developed in a way that aligns with these principles. This can include involving stakeholders from diverse backgrounds in the design process, conducting ethical reviews of AI systems, and building in mechanisms for detecting and preventing unethical use.

3 **Building in safety and security features:** AI systems should be designed with safety and security in mind, to prevent malicious actors from misusing or exploiting the system. This can include building in safeguards against hacking or other forms of cyber attacks, as well as designing systems with fail-safe mechanisms that can prevent catastrophic failures or unintended consequences.

4 **Implementing appropriate regulation and oversight:** In addition to the technical design of AI systems, appropriate regulation and oversight can also help prevent unethical or malicious use of AI. This can include establishing clear guidelines and standards for the development and use of AI systems, as well as establishing mechanisms for monitoring and enforcing compliance with these standards.

Ultimately, building in capabilities for detecting and preventing misuse or unethical use of AI systems will require a multi-faceted approach that incorporates technical, ethical, and regulatory considerations. It will also require ongoing monitoring and evaluation of AI systems, to ensure that they continue to operate in a fair and ethical manner over time.

I am sure you had time to ponder about these questions, any other important point we should consider or design?

Another important consideration when designing AI systems is the potential impact on employment and the workforce. As AI systems become more advanced, there is a risk that they may displace human workers in certain industries or roles. It is therefore important to design AI systems in a way that supports rather than replaces human labor, and to consider the potential impact on employment and the economy when developing and deploying AI systems.

Additionally, it is important to consider the potential for AI systems to exacerbate existing biases or inequalities. AI systems are only as unbiased as the data they are trained on, so if the data reflects existing biases or inequalities, the AI system may perpetuate or even amplify these biases. Therefore, it is important to build in mechanisms for detecting and correcting biases in AI systems, and to ensure that the data used to train AI systems is diverse and representative.

Finally, it is important to consider the potential for AI systems to have unintended consequences or to be used for malicious purposes. AI systems can have far-reaching impacts on society and the environment, so it is important to anticipate and mitigate any potential negative impacts, and to build in safeguards to prevent malicious use of AI systems. This may involve engaging with stakeholders from a variety of backgrounds and perspectives, conducting thorough risk assessments, and incorporating feedback and oversight mechanisms into the design of AI systems.

Thank you ChatGPT. I enjoyed our chats. Do you have any questions for me?

As an AI language model, I don't have emotions or the ability to ask questions in the same way as humans. However, I'm always here to answer any questions you may have!

Alright then. Thank you and have a nice evening.

You're welcome! It was a pleasure chatting with you. Have a great evening!

So those are some of my chats with ChatGCP. One thing I have learned it is important to use the right prompts, communication and educational levels and conditions to get better and more comprehensive responses. I will leave it up to you to make up your own mind but I would be very interested in your thoughts.

Melvyn Rapprecht and ChatGPT