Leading *trustworthy AI* in life sciences

PART 2

Capgemini invent

Contents

Introduction

In Part 1 of our report[1], we explored the transformative revolution in the life sciences industry driven by AI, emphasizing the importance of trustworthy AI in this shift. We discussed various challenges and risks associated with AI adoption and examined the rapidly evolving global regulatory landscape, highlighting the necessity of building trust in AI.

In this second part, we delve deeper into the practical aspects of deploying trustworthy AI. We share our recommendations and best practices, gleaned from our extensive experience, for successfully navigating this complex landscape. Readers will gain insights into implementing and governing AI to ensure compliance and harness its transformative potential across the entire life sciences value chain.

Through a compelling use case on predictive quality analytics in pharmaceutical manufacturing, we illustrate how these principles translate into real-world applications.

By the end, readers will be equipped with essential knowledge about trustworthy AI, ensuring patient safety, regulatory compliance, and ethical practices related to its use. This will help mitigate risks for better care, align with evolving standards, and foster public trust.

1. Leading trustworthy AI in life sciences: Part 1

1 Best practices for trustworthy AI

Navigating the complex environment of evolving regulations in the life sciences industry requires a comprehensive framework. Collaborations with leading companies on trustworthy AI systems have led Capgemini researchers to identify eight good practices encompassed in three dimensions, to ensure AI performs as intended and can be considered trustworthy. This framework guarantees adherence to regulations and optimal performance:

Business governance dimension:

1. **Responsibility:** Be accountable and responsible for decisions made.
    - Establish clear lines of responsibility and related processes for AI development, deployment, and operation.
    - Define accountability for the impact of AI decisions on patient health and compliance.
    - Develop mechanisms for transparency in decision-making processes to facilitate accountability.
2. **Performance:** Respond to business challenges in an optimal way.
    - Align AI development with business objectives and challenges, defining business KPIs before technical KPIs that support them.
    - Continuously optimize AI models during their lifecycle to ensure their relevance and effectiveness in addressing evolving business needs. This includes setting up both technical AI monitoring tools and human feedback mechanisms.
    - Assess the performance of AI applications against predefined benchmarks regularly.

Data operation dimension:

3. **Robustness:** Define and manage the boundaries of the model area of validity.
    - Identify and define the limits of robustness in AI models, considering potential variations in data and environmental conditions.
    - Implement mechanisms to enhance model robustness, ensuring consistent performance across diverse scenarios.
    - Establish protocols for validating and, where possible, extending the model area of validity over time and detecting when the use of AI goes beyond its area of validity.
4. **Data quality:** Control model input data quality.
    - Implement robust data governance practices to ensure high-quality input data.
    - Regularly assess and monitor the quality of data used to train and validate AI models (completeness, consistency, being free of anomalies, etc.).
    - Establish protocols for handling missing or biased data to maintain the integrity of the AI system.
5. **Explainability:** Make models transparent to their users.
    - Prioritize the use of explainable AI techniques to enhance model transparency. When using black-box machine learning or deep learning AI models, set up explainable mechanisms to associate the impact of input variables with output results.
    - Ensure that end users, healthcare professionals, and regulators can get clear non-technical information to understand the decision-making processes of AI models.
    - Provide clear documentation and communication regarding the functioning of AI systems.

6. Drift control: Control the operational impact of the model in production.

- Implement continuous monitoring of AI models in production to detect any operational drift.
- Develop mechanisms, such as A/B testing of models and parameters, to address drift promptly, ensuring that the model's performance remains consistent over time.
- Regularly validate and update models to account for changes in the operational environment of the AI system.

Sustainability dimension:

7. Fairness: Control biases and ensure non-discrimination.

- Implement measures to identify and mitigate biases in training data.
- Regularly assess model outputs for fairness and ensure that AI systems do not discriminate against specific groups, maintaining an equivalent level of performance for each subgroup addressed by the AI system.
- Establish protocols for addressing fairness concerns and promoting equal treatment.

8. Frugality: Measure and reduce resource consumption in a resource-limited environment.

- Implement resource-efficient AI models, considering both the volumes of data used for training and computational resources, given limitations in computational power and energy consumption.
- Regularly assess and optimize resource utilization to operate within defined constraints for a given performance target.
- Consider the environmental impact of AI applications and explore energy-efficient alternatives.

Fig. 1 **Best practices for trustworthy AI**

Applying this framework allows organizations to establish a robust foundation for a reliable AI vision that meets the increasing regulations in the life sciences industry. It not only addresses key regulatory requirements but also promotes ethical AI practices, transparency, and ongoing adaptability to evolving business and regulatory landscapes.

2 Implementation and governance

Building upon the foundation of trustworthy AI best practices, the practicalities of implementing and overseeing AI, as well as the roles of various departments in ensuring responsible use and compliance, must be tailored to the specific needs of life sciences organizations. Core business departments, AI compliance support functions, public relations and communications, and the digital function are all critical. Each plays a vital role in driving successful AI implementation while upholding ethical and regulatory standards.

The reason why this approach is essential becomes clearer as we explore the following functional areas:

1. Core business departments.

- **Research and development (R&D)** creates AI-powered tools to discover new products, technologies, and therapy strategies, prioritizing safety, reliability, and ethical considerations.
- **Within R&D, clinical development** oversees the responsible use of AI in clinical trials, maintaining data integrity and privacy. Pharmacovigilance, biomarker development, translational biosciences, medical affairs, commercial marketing, and operations manage sensitive personal information and strict data and AI integrity standards.
- **Manufacturing** employs AI to ensure efficiency and quality standards are met or exceeded when manufacturing pharmaceutical products or medical devices. Consistent performance over time is essential to the system's integrity.

2. AI compliance support functions manage critical aspects of AI use across multiple dimensions.

- **Risk and compliance:** Identifies and mitigates financial risks associated with AI systems.
- **Regulatory affairs (RA):** Ensures AI systems adhere to pharmaceutical regulations, and continuously adapts to evolving regulatory landscapes evolve.
- **Quality assurance (QA):** Ensures AI systems comply with GxP standards and maintain the integrity of data generated, enhancing reliability and accuracy.
- **Legal:** Provides guidance on data privacy, intellectual property, and liability considerations associated with AI implementations. This ensures adherence to both national and cross-border regulations and laws.
- **Patient privacy:** Ensures patient consent and rights to privacy are respected according to both national and international laws.
- **Diversity and inclusion:** Addresses biases, ensures transparency, and promotes equitable outcomes across diverse populations.
- **Cybersecurity:** Ensures AI systems adhere to cybersecurity standards and protocols to protect sensitive data from breaches or unauthorized access.
- **Public relations (PR) and communications:** Manages the public image and reputation around AI, addressing concerns and highlighting the positive impact of AI applications.

3. Data and digital functions play a vital role in establishing and upholding trust in a company's AI initiatives. Their proactive involvement enhances the successful implementation of AI within a pharmaceutical company. Serving as a pivotal entity, they address AI challenges, related to:

- **Implementation and integration:**
  - Deploying AI solutions across functions, ensuring seamless integration, tangible business impact, and alignment with regulatory compliance, data governance, and ethical standards.
  - Creating user-friendly interfaces in collaboration with end-users and communication teams, transparently conveying the insights generated by AI applications.
  - Partnering with external stakeholders to stay informed about AI advancements and regulatory developments.
- **Data governance and security:**
  - Ensuring quality and security of data through robust governance practices and encryption methods.
  - Investing in FAIR[2] data principles to ensure content correctness and transparency.
- **Infrastructure and optimization:**
  - Overseeing technological infrastructure to support AI applications, collaborating with quality assurance.
  - Implementing systems for continuous monitoring, collaborating with quality assurance for prompt issue resolution, and research and development for continuous improvement.
  - Ensuring AI development follows ethical guidelines, integrating fairness and transparency.
  - Training employees across departments on the effective AI use and safeguarding skill development.

To ensure end-to-end governance, establishing a cross-functional AI compliance committee and a community of trustworthy AI ambassadors is key. These initiatives ensure widespread representation and dissemination of responsible AI practices throughout the organization, facilitating alignment with regulatory requirements and fostering a culture of accountability and transparency in AI deployment.

2. GO FAIR Initiative

USE CASE

3 Predictive quality analytics in pharmaceutical manufacturing

An AI-based solution for predictive quality analytics in pharmaceutical manufacturing is a powerful tool that significantly impacts the entire operation. This approach has two benefits:

- **Proactive risk management:** By identifying and resolving potential quality issues early, AI lowers the risk of defective products reaching the market, ensuring patient safety.
- **Enhanced production efficiency:** AI-powered analytics streamline processes, minimize waste, and ensure consistent product quality, boosting production efficiency and cost savings.

This not only strengthens a company's reputation for delivering high-quality pharmaceuticals but also contributes to cost savings and overall operational excellence.

It is imperative to prioritize the following four of eight good AI practices when implementing a trustworthy AI approach for such a use case:

- **Performance:** AI-powered analytics boost performance by offering real-time production insights. It monitors key metrics, identifies issues, and optimizes processes, ensuring peak efficiency and minimal disruptions.
- **Data quality:** For accurate predictions, high-quality data is crucial. The system employs robust validation and cleansing practices to ensure reliable predictions and improve the manufacturing process.
- **Drift control:** To maintain effectiveness, the system continuously monitors data patterns and production conditions. By identifying and controlling drift, AI model adapts to changes, ensuring accurate predictions over time.
- **Transparency:** The model provides clear explanations for its predictions, allowing operators to understand the reasoning behind them and make informed decisions supported by trust in the AI system.

This initial stage of trustworthy AI analysis involves conducting initial risk evaluations and classifying various AI models in accordance with the guidelines established by the European AI Act.

Once risks are identified and models categorized, the second step focuses on mitigation strategies for the most suitable models. This can be achieved by:

- Utilizing reliable technology for AI-powered analytics to guarantee the AI model's performance.
- Establishing a program for data validation and cleansing to ensure accurate predictions and maintain data quality.
- Continuously monitoring for bias and drift in the model to maintain AI drift control effectiveness over time.
- Maintaining clear and comprehensive records of AI model development and deployment to ensure transparency.

This approach aligns with the recent FDA discussion paper on AI in drug manufacturing[3], which highlights the importance of trustworthy AI principles for achieving good manufacturing practices (GMP) compliance.

By prioritizing these aspects, life sciences companies can:

- **Select the right model** that aligns with the risk assessment and can be validated within a GMP controlled approach.
- **Implement methodologies** like GAMP® 5 ML sub-system to manage risks throughout the AI's lifecycle.
- **Realize the Pharma 4.0** vision by contributing to a well-controlled, hyper-connected, and digitized ecosystem for manufacturers, as envisioned by the FDA paper.

By proactively mitigating risks and adhering to good AI practices, life sciences companies can leverage the power of AI in drug manufacturing while ensuring their reputation, through ethical adherence, complying with governmental and pharmaceutical regulatory requirements, and by maintaining data integrity, product quality, and overall patient safety.

3. Center for Drug Evaluation and Research: Artificial Intelligence in Drug Manufacturing

5 Conclusion

In the life sciences industry, where **AI directly impacts the safety and health of global populations**, ensuring trustworthy AI is crucial. Furthermore, the substantial investments made by companies and patients in advancing scientific innovation and pharmaceutical development require that AI systems be reliable and impactful. The emerging evidence of AI's potential to accelerate improvement and innovation in research and development, manufacturing, supply chain, and commercial functions is tangible and cannot be ignored.

However, this great opportunity carries significant risks and consequences if not pursued with compliance and the assurance of trust. Trustworthy AI allows organizations to leverage their power and expertise to drive medical advancements and manufacturing excellence, while upholding public safety, maintaining a positive brand image, and adhering to regulatory requirements.

Indeed, as discussed in Part 1, the necessity for trustworthy AI is emphasized by the increasing regulatory scrutiny aimed at safeguarding it. The European AI Act categorizes certain healthcare AI applications as high-risk, necessitating strict compliance measures. **Non-compliance can lead to substantial penalties**. In the US, the FDA confirmed that draft guidance on using AI for regulatory decisions in drug development would be released in 2024.

This two-part series has explored the importance of understanding and deploying trustworthy AI through three key pillars: risk mitigation for better care, regulatory compliance as a safeguard, and reputation and trust, as an ethical imperative. Building on this foundation, the critical question for your organization becomes: **What proactive measures can be taken now to implement trustworthy AI practices?**

At Capgemini, we empower our clients to take a progressive approach to navigating the legal and regulatory landscape of AI. Our proven four-fold method equips you to not only conquer compliance challenges, but also unlock the full potential of your AI solutions, ensuring they are trustworthy for everyone. The following is a summary of the method:

1. Establish the foundation:

Conduct a macro diagnostic to assess the current state of your AI landscape and define a multi-year strategy, priorities, and best practices for AI systems, regulatory compliance, and monitoring.

2. Address existing portfolio:

Audit your existing AI systems to identify gaps, define remediation plans, and implement them effectively.

3. Optimize AI development:

Streamline the design-conception-operation organization and processes of your AI teams to foster "by-design" trustworthy AI for future projects.

4. Implement change management:

Develop and execute a comprehensive change management plan, including awareness programs and training tailored to various company roles. This plan will also establish an effective governance and reporting function.

We provide end-to-end guidance to ensure the regulatory compliance of your AI

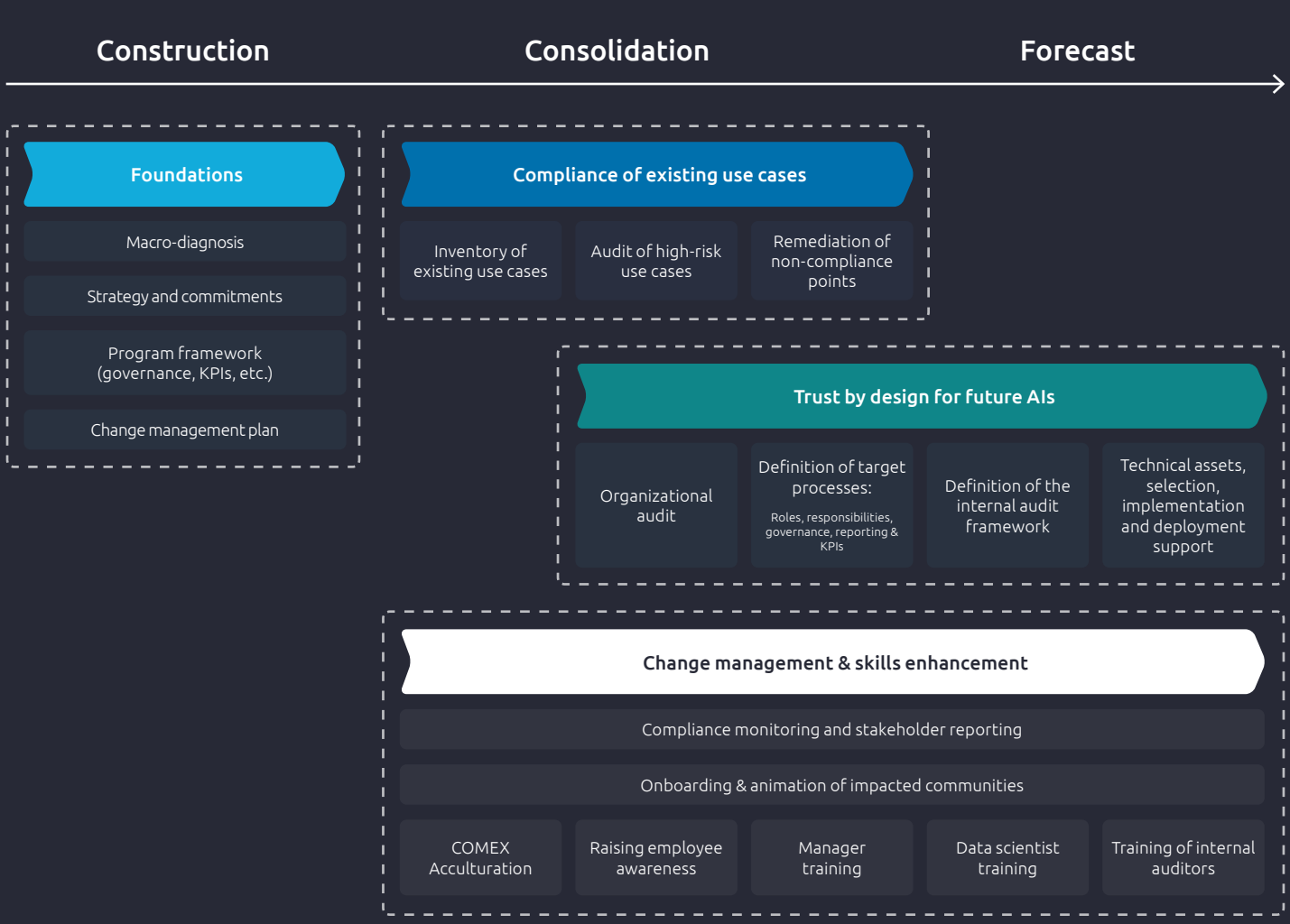

Fig 2 **Our Solution for trustworthy AI**

Join us as we continue our journey towards a future where AI not only revolutionizes patient care but does so in a manner that is safe, ethical, and compliant with the evolving regulatory landscape.

Let's unlock the full potential of AI together!

Glossary

- **Artificial intelligence (AI):** a branch of computer science that involves creating systems capable of performing tasks that typically reproduce human intelligence.
- **Trustworthy AI:** AI systems that demonstrate reliability, safety, fairness, and ethical considerations in their development, deployment, operation, and impact.
- **Life Sciences:** the branch of science that deals with the study of biology, medicine, pharmacology, and related fields.
- **Operational risks:** risks associated with the day-to-day functioning of AI systems, including the potential for errors, misdiagnoses, or treatment mistakes.
- **Regulatory compliance:** adherence to laws and regulations governing the development and use of AI systems, such as the EU's AI Act, US's Executive Order, and other relevant legislation.

References

European AI Act

Executive Order on the Safe, Secure, and Trustworthy Development and Use of Artificial Intelligence

Bill C-27 Canadian act

HMA/EMA joint big data steering group

CDER's Framework for Regulatory Advanced Manufacturing Evaluation (FRAME) Initiative

Responsible Advanced Artificial Intelligence Act

European Good Manufacturing Practice - Annex 11: Computerized Systems

FDA CFR - Code of Federal Regulations Title 21

ICH Q9 Quality Risk Management

Data Integrity and Compliance With CGMP Guidance for Industry

Good Machine Learning Practice for Medical Device Development: Guiding Principles

Artificial intelligence workplan to guide use of AI in medicines regulation

AI's potential to accelerate drug discovery needs a reality check

From target discovery to clinical drug development with human genetics

Supercharging the future of Healthcare with Generative AI

Unlocking the potential of AI in Drug Discovery

ISPE GAMP® 5: A Risk-Based Approach to Compliant GxP Computerized Systems (Second Edition)

ISPE GAMP® RDI Good Practice Guide: Data Integrity by Design

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