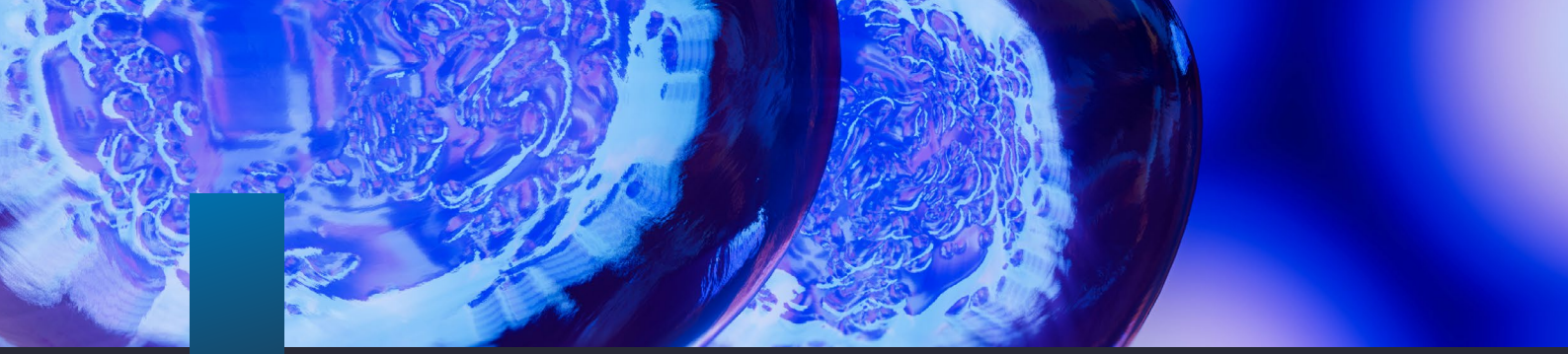
Leading *trustworthy AI* in life sciences

PART 1

Capgemini invent

Contents



Introduction to the series

In recent years, and especially since the end of 2022, there has been a tremendous upswing in excitement about the potential impact and value that artificial intelligence (AI) may provide to many industries. There's no doubt that the promise of generative artificial intelligence (Gen AI) is particularly vast for pharmaceutical companies. It's a potential game-changer for the whole industry, with the best evidence for this being that AI-intensive R&D could yield time and cost savings of at least 25–50% in drug discovery, up to the preclinical stage[1]. In a recent Nature paper, R&D teams claim that one major Californian company, thanks to its Gen AI program, now spends 60% less time than it did five years ago on developing a candidate drug up to the clinical-trial stage[2].

While interest has risen thanks to the Gen AI wave[3], questions are being asked about how to invest in AI to secure the models, ensure robustness, and maximize impact. Questions around how to avoid bias and ensure ethical use have also emerged. And now, especially in 2024, there are further questions around how to ensure compliance in the use of AI. We summarize these concepts under the banner of "trustworthy AI."

Beyond existing standards from health authorities, such as the Food and Drug Administration (FDA) and the European Medicines Agency (EMA), the upcoming European AI Act introduces a new layer of requirements. This act will ignite innovation around a library of techniques that will become commonplace on the pathway to releasing any compliant AI product, for example: red teaming, earmarking, ring-fencing against prompt-injections, fairness assessments, and robustness documentation. **Changing the game** is necessary to secure business and anticipate strong compliance requirements.
Similar trends are emerging globally with national or regional adaptations. For example, the concepts in the Responsible Advanced Artificial Intelligence Act of 2024 in the US, which is expected to become law, will also impose new changes.

Capgemini has been at the forefront of this transition, in close collaboration with clients and the European Commission; and in the building of a European Union (EU)-wide platform that can secure compliance with the AI Act.

This is the first document in our two-part series that explores how we lead and successfully deploy trustworthy AI systems – to provide impactful and reliable systems that are compliant and trustworthy in every way.

- Part 1: **From trustworthy AI to evidence-based medicine**
- Part 2: **Recommendations and best practices for deploying trustworthy AI**

In these two documents we shed light on the lessons we've learned and explain how our experience forms the basis upon which our services are deployed to leading AI clients and thinkers, globally. We hope you find this material as thought-provoking, enlightening, and impactful as our clients have.

1.https://www.nature.com/articles/s41586-023-06388-8
https://cms.wellcome.org/sites/default/files/2023-06/unlocking-the-potential-of-AI-in-drug-discovery_report.pdf
2.https://www.nature.com/articles/s41586-023-06388-8
3.https://www.capgemini.com/insights/research-library/future-of-healthcare-with-generative-ai/

1 From trustworthy AI to evidence-based medicine

The life sciences industry is adopting new technologies such as AI to enhance research, development, and diagnosis. To successfully leverage this new technology, it's crucial to ensure safety, reliability, fairness, and adherence to ethical standards. Aligning with the principles of evidence-based medicine is paramount for any company that aims to reach a patient as an end user.

The challenges and risks associated with AI adoption are why we've undertaken comprehensive analysis. By continuously monitoring legislation, pharmaceutical regulations, and conducting our own research, we aim to provide a clear picture of the current landscape, thus empowering the industry to adopt AI-assisted technology with confidence. We believe there are three key pillars that highlight the importance of trustworthy AI.

Pillar 1 – Mitigating risks for better care.

Studies show a concerning failure rate in AI implementations as a component of operational risk, posing significant hazards to patient safety. To ensure responsible AI development, implementation, and operational use, an effective risk mitigation plan must be in place.

Pillar 2 – Navigating the regulatory landscape by aligning with evolving standards.

The global regulatory landscape is rapidly evolving, with legislation such as the EU's AI Act[4], the United States EO 14110 "Executive Order on the Safe, Secure, and Trustworthy Development and Use of Artificial Intelligence"[5], and Canada's C-27 Bill[6], setting strict guidelines for the development and use of AI. Life sciences organizations must ensure their AI practices comply with these evolving standards. Failure to do so could result in legal and financial consequences, but more importantly, it could undermine public trust.

Pillar 3 – Reputation and trust, the ethical imperative.

End users and patients are increasingly wary of AI due to the ethical concerns surrounding privacy, bias, and transparency. Ignoring these concerns will erode trust in life sciences providers. By demonstrating responsible and ethical use of AI, life sciences organizations can build trust, foster positive brand perception, and ultimately deliver better care.

Building trust in AI is not just an ethical imperative; it's essential for the successful and sustainable integration of AI. By prioritizing safety, adhering to regulations, and upholding ethical standards, we can unlock the full potential of AI to revolutionize life sciences while protecting the well-being of patients and the integrity of the medical profession. This journey starts with an understanding of three foundational elements of trustworthy AI leadership:

1. Considering trustworthy AI's role throughout the life sciences value chain.
2. Understanding the nuances of AI algorithms and data sensitivity.
3. Recognizing the importance of a regulatory framework for ensuring compliance.

4.https://www.europarl.europa.eu/doceo/document/TA-9-2024-0138-FNL-COR01_EN.pdf
5.https://www.whitehouse.gov/briefing-room/presidential-actions/2023/10/30/executive-order-on-the-safe-secure-and-trustworthy-development-and-use-of-artificial-intelligence/
6.https://www.justice.gc.ca/eng/csj-sjc/pl/charter-charte/c27_1.html

2 What defines a trustworthy AI system in life sciences?

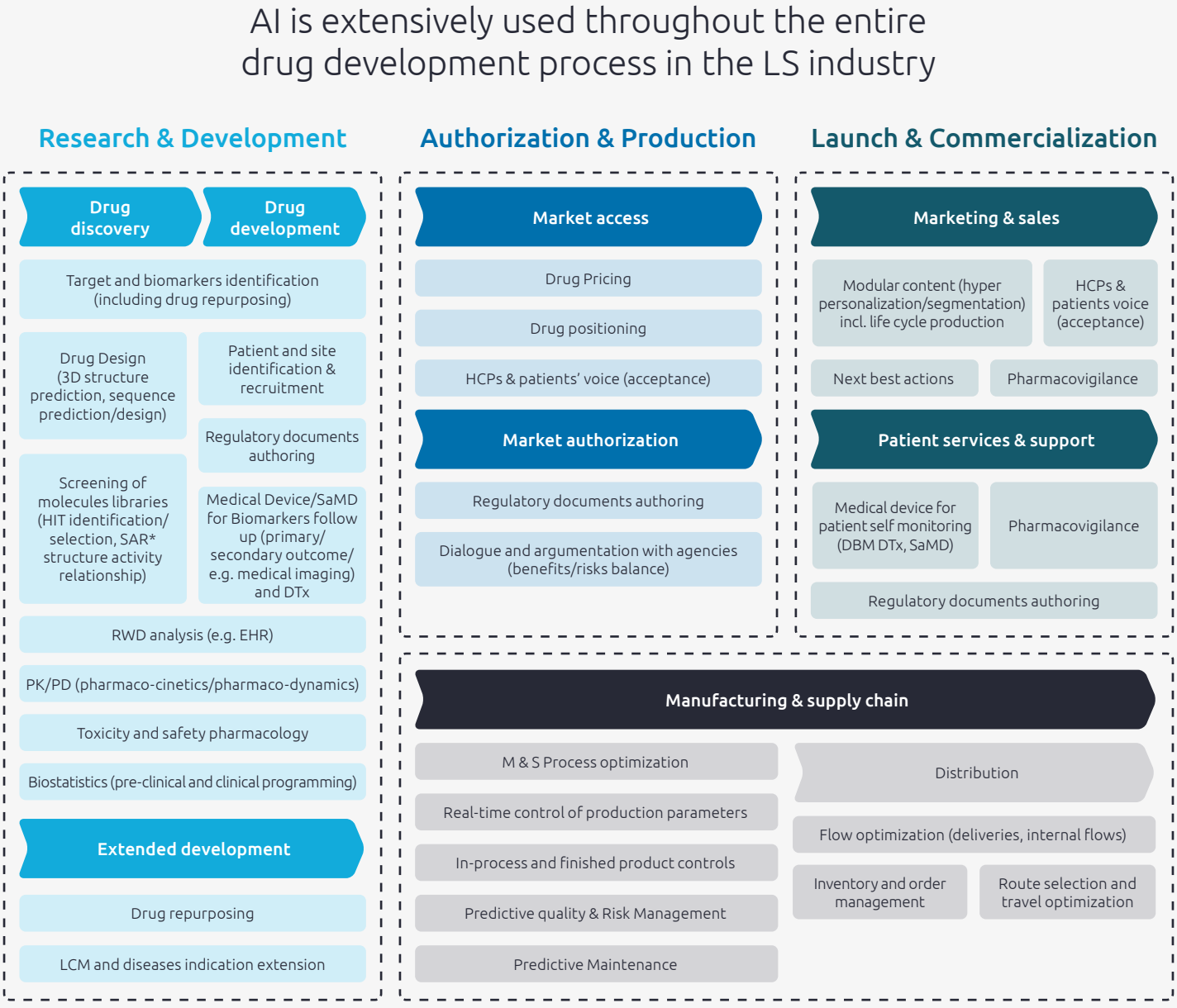


Fig. 1 **Application of AI in the life sciences industry**

The integration of AI into the pharmaceutical industry value chain undoubtedly holds immense potential (Fig. 1.0). We explored three critical uses of AI applications that underscore the pivotal roles trust and compliance play in this transformation.

1. Ethical, regulatory, and quality considerations for AI

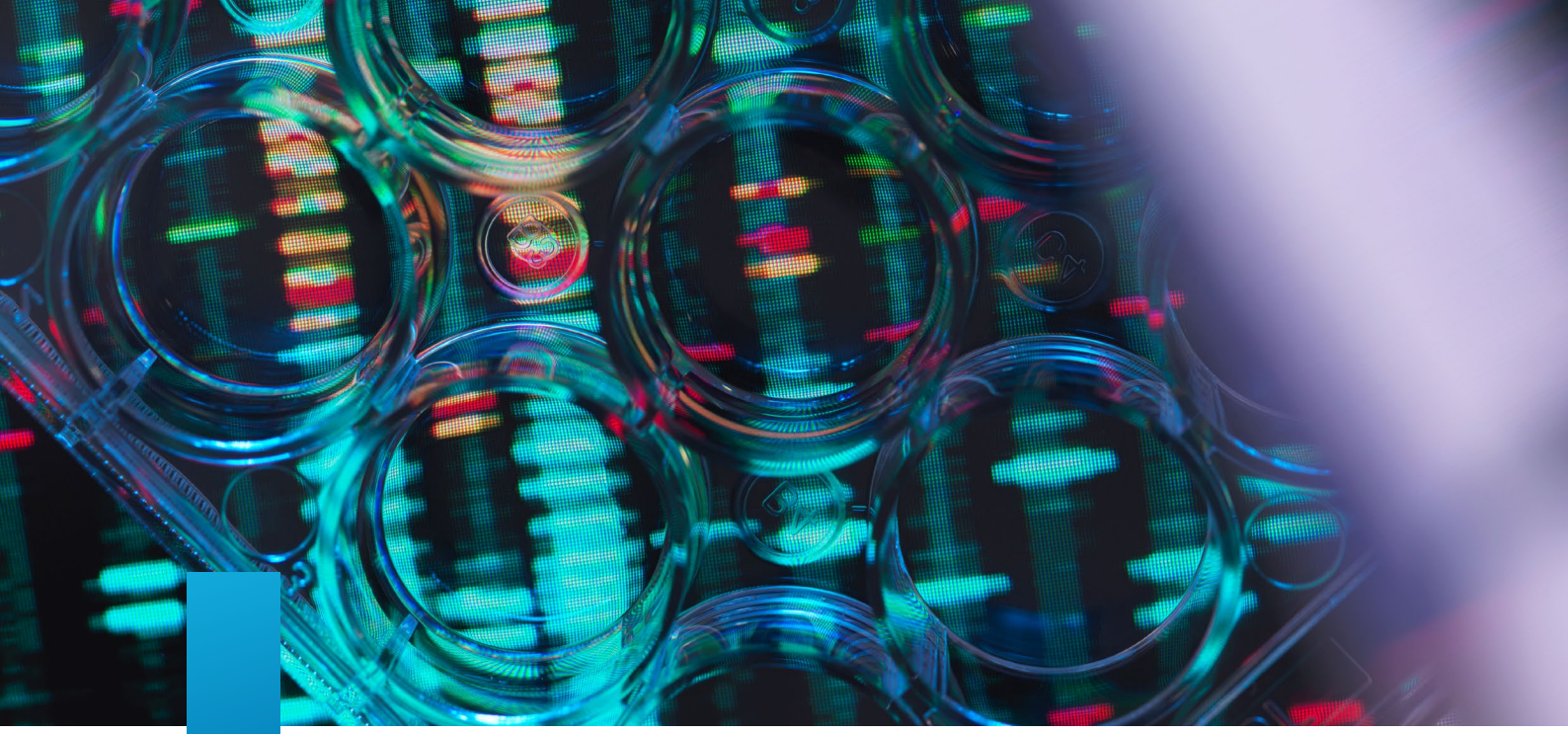
- Ethical standards for AI in **healthcare management** are crucial for **transparent** and **objective** decision-making.
- Robust **data governance** laws protect sensitive **patient data**; incorporating AI-powered encryption and access controls is required.
- Developing AI solutions aligned with **regulatory guidelines** to navigate complex requirements and ensure **compliance**, including a medical, legal, and regulatory (MLR) review of commercialized products and marketing documentation.
- Balancing AI integration with **quality assurance** practices and adherence to good manufacturing practice (GMP) standards is key.

2. AI in drug development and clinical trials

- Rigorous, ongoing testing and validation processes to ensure accurate and reliable AI models for **drug discovery**, and continuous monitoring of data quality and drift.
- Ensuring robust clinical **trials** (validity domain) and **performance** of AI algorithms while maintaining compliance with evolving regulations.

3. AI applications in precision medicine and patient care

- Identifying response **biomarkers**, ensuring that the optimal patient populations are engaged, and unbiased AI performing as expected are key to developing **translational medicine**.
- Addressing bias in AI models for **personalized medicine** through detection mechanisms is crucial to ensuring that health outcomes are equitable across race, ethnicity, and socioeconomic status.
- Implementing stringent testing, validation, and monitoring procedures is essential to preventing **misdiagnoses** and **treatment errors**.



3 Poking holes in the black box to design trustworthy AI in life sciences

The successful design of trustworthy AI hinges on **two key technical considerations**: Algorithm categorization and data sensitivity.

Across all sectors and applications, AI algorithms can generally be classified into four main groups:

1. **Rule-based algorithms:** These operate on pre-defined rules, offering transparency and predictability but limited adaptability.
2. **Machine learning (ML):** ML algorithms learn from data, improving performance over time. However, explaining their decision-making process can be challenging.
3. **Deep learning:** A subset of ML, deep learning uses complex neural networks to extract features and patterns from data. While powerful, deep learning models can be "black boxes" with limited understanding of how it reaches its conclusions.
4. **Generative AI (Gen AI):** This category encompasses algorithms that create new data, like images or text. Gen AI raises concerns about generating false outputs, or "hallucinations", which require careful review.

Data sensitivity, in terms of the level of protection required due to privacy concerns, **varies across the life sciences value chain**. Let's consider two examples:

- Sensor data used in manufacturing may require less stringent protection compared to patient data from clinical trials, which is subject to stricter privacy regulations.
- Ensuring ethical data sourcing that promotes fair representation is crucial. Historical biases in data collection need to be addressed. For instance, neglecting diverse patient groups in genome sequencing can lead to biases in AI algorithms, undermining their fairness and inclusivity.

To effectively manage related risks to **AI Algorithms** and **Data sensitivity**, future regulations like the AI Act and evolving global standards will be critical tools for life sciences companies navigating the complexities of AI design and implementation.

4 How is AI regulated in life sciences?

As more sectors of the life sciences industry adopt AI and legislative bodies struggle to keep pace with development, there are questions regarding how regulations will evolve to support responsible use. There are currently two leading initiatives from the EU and the US to establish a regulatory framework.

The EU is drafting a comprehensive framework for regulating AI across various sectors. The cornerstone of this effort is the **AI Act**, a game-changing regulation that applies to all AI systems used in Europe, regardless of origin.

The **AI Act** adopts a risk-based approach, classifying AI systems into three categories: Prohibited, high-risk, and low-risk. This determines the specific obligations placed on developers, users, and other participants in the AI lifecycle. These obligations can relate to:

System characteristics, such as data management, technical documentation, and cybersecurity

Organizational practices, such as certification, transparency, and risk assessment processes

The specific requirements will depend on the type of AI, the actor's role (private company, public body, etc.), and whether the AI falls under a high-risk category explicitly listed in Annex III of the Act (e.g., remote biometric identification, emotion recognition systems). **Actors must demonstrate compliance through documentation and communication with relevant authorities.**

The AI Act defines high-risk systems as posing a "significant risk of harm to the health, safety or fundamental rights of natural persons." Examples include those listed in Annex III. However, **even for low-risk AI, a risk assessment is mandatory to identify potential negative impacts on health, safety, or rights.** This is essential, as the high-risk categories in Annex III can be amended in the future.

Within this broader framework, the European Medicines Agency **EMA** and Heads of Medicines Agencies (**HMAs**) have launched a dedicated **AI plan for the pharmaceutical field**[7]. This plan focuses on responsible AI use in medicine regulation, aiming to benefit patients and animals while managing potential risks. It emphasizes a collaborative approach and includes:

Guidance on safe and effective AI use in regulatory processes

Encourages ongoing knowledge sharing among stakeholders

Collaborative policy development to establish a robust framework

Transparency, inclusivity, and existing expertise

Development of necessary tools for effective AI utilization

7. https://www.ema.europa.eu/en/news/artificial-intelligence-workplan-guide-use-ai-medicines-regulation

The EU's approach prioritizes transparency and inclusivity:

Ongoing public consultation to incorporate stakeholder feedback

Training and experimentation opportunities to support workforce development and responsible AI innovation

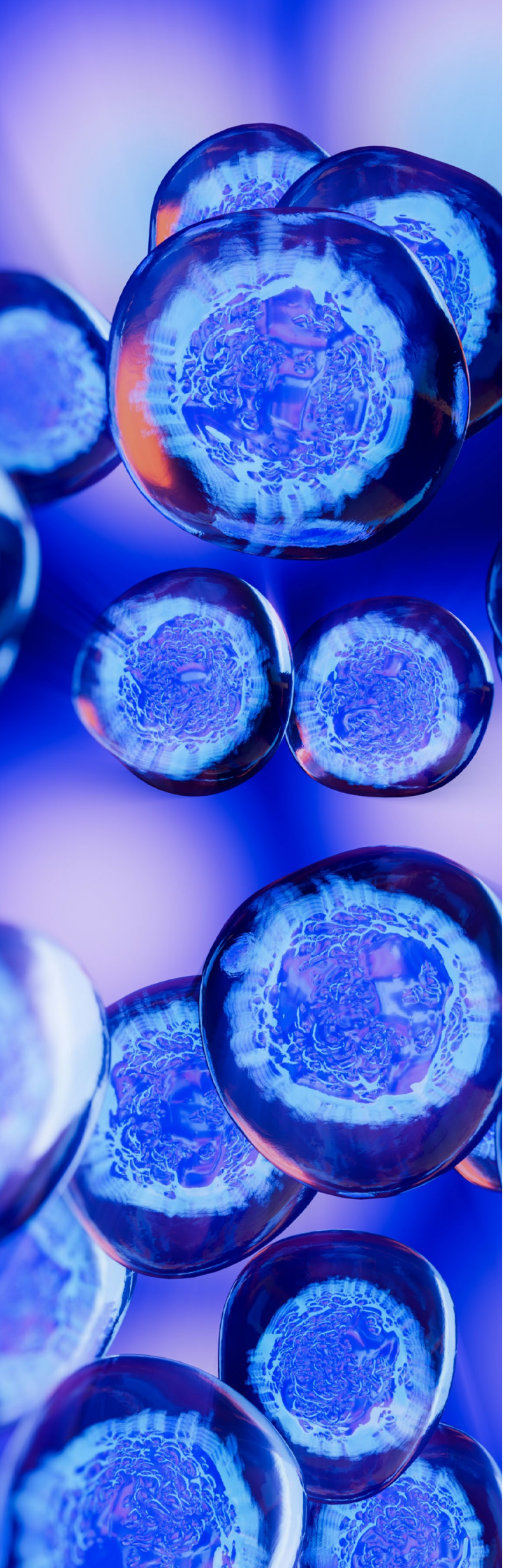
Furthermore, the plan leverages existing expertise within the EMA-HMA Joint Big Data Steering Group[8] and their experience in **data-driven medicine** regulation. This focus on data management practices ensures the ethical use of AI in pharmaceutical regulation. Additionally, workshops such as AI for Smart Regulation in a Rapidly Evolving World[9], highlight their commitment to open dialogue and collaborative brainstorming to shape the future of **AI-powered medicine regulation**.

The US is also taking a proactive approach to ensure the responsible development and use of AI. Various government bodies have published texts and recommendations on the subject. In 2022, the government introduced the Blueprint for an AI Bill of Rights. In 2023, the Algorithmic Accountability Act was introduced into Congress and President Biden signed an **Executive Order on the Safe, Secure, and Trustworthy Development and Use of AI**[10].

Unlike the EU's AI Act, which uses a risk classification system, the US focuses on specific AI systems that pose serious risks in areas such as security, the national economy, and public health. The American approach relies heavily on **risk assessments** based on how the AI systems are used. The US government requires actors to implement risk mitigation measures, such as security testing and audits, to address potential risks associated.

Initiatives like the AI Bill of Rights and the Executive Order on AI have already established comprehensive frameworks to address bias, safety issues, and data privacy. The AI Bill of Rights outlines five ethical AI principles, including anti-discrimination safeguards and transparency. The Executive Order on AI emphasizes safety, security, equity, and accountability in AI development.

8. https://www.hma.eu/about-hma/working-groups/hma/ema-joint-big-data-steering-group.html
9. https://www.ema.europa.eu/en/events/joint-heads-medicines-agencies-hma-european-medicines-agency-ema-ai-workshop-smart-regulation-rapidly-evolving-world
10. https://www.whitehouse.gov/briefing-room/presidential-actions/2023/10/30/executive-order-on-the-safe-secure-and-trustworthy-development-and-use-of-artificial-intelligence/



Mirroring these efforts, the Center for AI Policy (CAIP)[11], a US nonpartisan research organization, released "Model Legislation to Ensure Safer and **Responsible Advanced Artificial Intelligence** (RAAI)," in April 2024. It proposes a legislative framework for governing the development and deployment of advanced AI. The RAAI Act focuses on establishing transparency and explainability, mitigating algorithmic bias, promoting algorithmic safety and security, and ensuring human oversight and accountability.

The **FDA** is actively developing its position on AI, though its standpoint on Gen AI is still in progress[12]. Beyond meeting the expectations of the executive order, we can expect that upcoming FDA guidelines will closely resemble the requirements outlined in the AI Act. The FDA's current framework already encompasses a wide range of potential applications, including drug discovery, clinical research, medical device development, post-market safety monitoring, and advanced pharmaceutical manufacturing. These potential use cases include using AI and ML to scan medical literature for relevant findings, predict patient responses to treatments, model medical interventions, and improve process controls in drug manufacturing.

As one of the first deliverables from the Biden Administration's October 2023 Executive Order and in alignment with the Center for Drug Evaluation and Research (**CDER**) guidance agenda, FDA is working on a guidance for the use of AI in drug development, titled "Considerations for the Use of Artificial Intelligence to Support Regulatory Decision-Making for Drug and Biological Products"[13]. This guidance, expected to be published in 2024, is set to clarify the scope of the agency's regulation in this emerging field.

The document aimed to clarify FDA's regulatory authority over this emerging field by addressing key areas like :

- the scope of oversight,
- implementing a risk-based approach,
- ensuring transparency in documentation,
- facilitating international alignment on AI regulations,
- and exploring options for data sharing to enhance AI models.

11. https://www.aipolicy.us/work/model-legislation-release-april-2024#:~:text=The%20%22Responsible%20Advanced%20Artificial%20Intelligence%20Act%20of%202024%22%20is%20model,government%20office%2C%20and%20instructions%20for

12. They have seen more than 100 submissions using AI/ML components in 2021, indicating a significant increase in the use of these technologies. But no clear positioning on Generative AI. https://www.fda.gov/science-research/science-and-research-special-topics/artificial-intelligence-and-machine-learning-aiml-drug-development#:~:text=In%20fact%2C%20FDA%20has%20seen,100%20submissions%20reported%20in%202021

13. https://www.fda.gov/science-research/science-and-research-special-topics/artificial-intelligence-and-machine-learning-aiml-drug-development

Regarding drug manufacturing, the FDA Center for Drug Evaluation and Research (CDER) is currently implementing the **Framework for Regulatory Advanced Manufacturing Evaluation** (FRAME) initiative[14], which is representative of the FDA's intentions and roadmap. FRAME focuses on stakeholder input, evaluating existing frameworks, and aligning with international standards. Key priorities of FRAME include:

Engaging stakeholders through discussion papers and workshops to gather comprehensive feedback on advanced manufacturing technologies

Aligning US regulations with global standards through collaboration with the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH)

Ensuring existing regulations are compatible with new technologies by evaluating the current risk-based framework

Issuing guidance to clarify regulatory perspectives on advanced manufacturing

Initiatives such as FRAME and the European AI plan bring new challenges to the pharmaceutical industry, building upon the foundation set by Good Practice (GxP) regulations like Annex 11[15] and 21CFR11.10[16]. These GxP regulations establish the criteria for trustworthy electronic records and signatures, making them reliable and equivalent to paper records and handwritten signatures. Nevertheless, applying these standards to AI models, and more specifically to LLMs, presents a challenge in ensuring integrity, authenticity, and confidentiality.

While the traditional regulations require validation of computerized systems, the lack of standardized evaluation methods for LLMs makes demonstrating their reliability difficult. Given the dynamic nature of LLMs, a risk-based validation approach is more suitable. This approach involves identifying potential risks associated with LLM outputs in the context of electronic records and signatures, defining acceptable output ranges to ensure data integrity and compliance, and implementing monitoring and feedback loops to **continuously assess LLM performance**. Traditional validation methods from Factory and Site Acceptance Tests (FAT/SAT) to performance qualification might need to be supplemented with additional strategies.

The FDA's **Human-in-the-Loop** (HITL) principle[17], originally developed for medical devices, is highly relevant for validating LLM-based systems in the pharmaceutical industry. This principle emphasizes human oversight for high-risk applications, allowing experts to review and approve LLM outputs, especially when combined with pre-defined acceptable output ranges. By incorporating human expertise, organizations can ensure that LLM-generated outputs align with domain-specific knowledge and regulatory requirements.

Beyond these considerations, data integrity principles[18] present another critical challenge and need to be adapted. Models as LLMs require more focus on transparency and traceability compared to traditional systems. A potential Center of Excellence (CoE) can address this by:

Enhancing traceability and anomaly detection by documenting all decisions, processes, and outcomes associated with LLM use

Improving LLM transparency by implementing explainability and interpretability tools

14. https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/cders-framework-regulatory-advanced-manufacturing-evaluation-frame-initiative
15. https://health.ec.europa.eu/system/files/2016-11/annex11_01-2011_en_0.pdf
16. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?fr=11.10
17. https://www.fda.gov/medical-devices/software-medical-device-samd/good-machine-learning-practice-medical-device-development-guiding-principles
18. https://www.fda.gov/files/drugs/published/Data-Integrity-and-Compliance-With-Current-Good-Manufacturing-Practice-Guidance-for-Industry.pdf

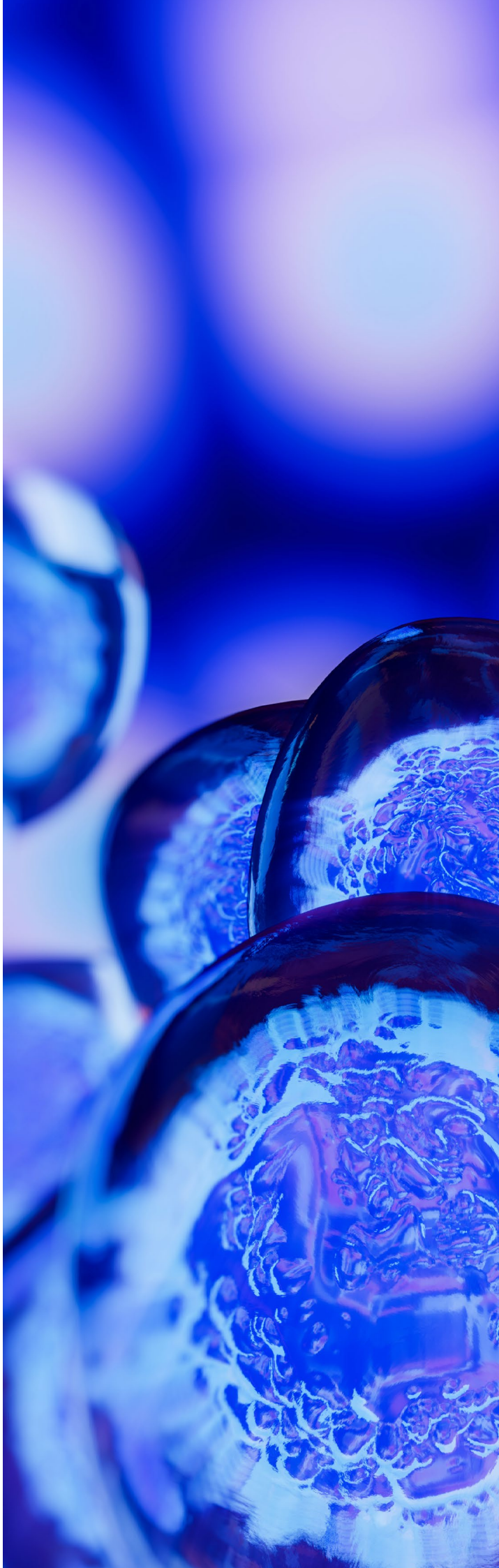
Finally, maintaining clear records of AI models development, deployment, and monitoring allows organizations to demonstrate legal and regulatory compliance, facilitate investigations, and swiftly implement corrective and preventive actions (CAPA) in case of unexpected outcomes or errors.

Recognizing the transformative impact of AI, the International Society for Pharmaceutical Engineering (ISPE)'s renowned **GAMP® 5** guide[19] reflects the changing landscape. The second edition introduces Appendix D11 on AI and ML, addressing the burgeoning use of these technologies in the pharmaceutical industry, with a strong emphasis on GxP compliance.

GAMP® 5, offers a risk-based lifecycle framework aligned with its global approach that is based on International Council for Harmonisation ICH Q9 guidance[20]. This framework focuses on data management and integrity[21] throughout the AI/ML lifecycle, from thorough business analysis and data-centric development to performance metrics and risk management. It also highlights the importance of human factors, cybersecurity, legal liability, and data governance, all crucial aspects to consider when implementing validation strategies for managing data size, quality, and iterative changes inherent in systems incorporating AI/ML algorithms.

While trustworthy AI development practices remain crucial, the GAMP® 5 methodology offers a robust framework that serves as a strong foundation for governing AI use in the pharmaceutical industry. **Indeed, we believe that an integrated approach, combining trustworthy AI good practices and GAMP® 5 guidance, provides a unified vision that facilitates evidence-based compliance with GxP regulations and adherence to emerging law, such as the European AI Act, as well as future governmental and legal mandates for AI development and use.**

19. https://guidance-docs.ispe.org/doi/book/10.1002/9781946964571
20. https://database.ich.org/sites/default/files/ICH_Q9%28R1%29_Guideline_Step4_2023_0126_0.pdf
21. https://guidance-docs.ispe.org/doi/book/10.1002/9781946964342



5 Conclusion

Building trust in AI is not only about following an increasingly well prescribed compliance pathway but rather it's about building the foundation to enable a future where AI empowers life sciences companies to more rapidly deliver safer, evidence-based medicine, and fosters more effective R&D processes. This would thereby be revolutionizing patient care and outcomes if achieved.

Thus, the need to develop trustworthy AI extends well beyond mere compliance since the critical dimensions of algorithm categorization and data sensitivity and quality, determine the risks and benefits from deploying trustworthy AI.

Building upon this thinking, in part 2 of our series, ***Recommendations and best practices for deploying trustworthy AI***, we share eight recommended practices for right-sized AI governance and organizational mechanisms that help organizations implement and manage compliant and trustworthy AI systems. Furthermore, we present a practical use case to illustrate these principles in action. **For those interested in putting this thinking to work in their own organization, this part 2 of our series can't be missed…**

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, trustworthy for all. Here's how:

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

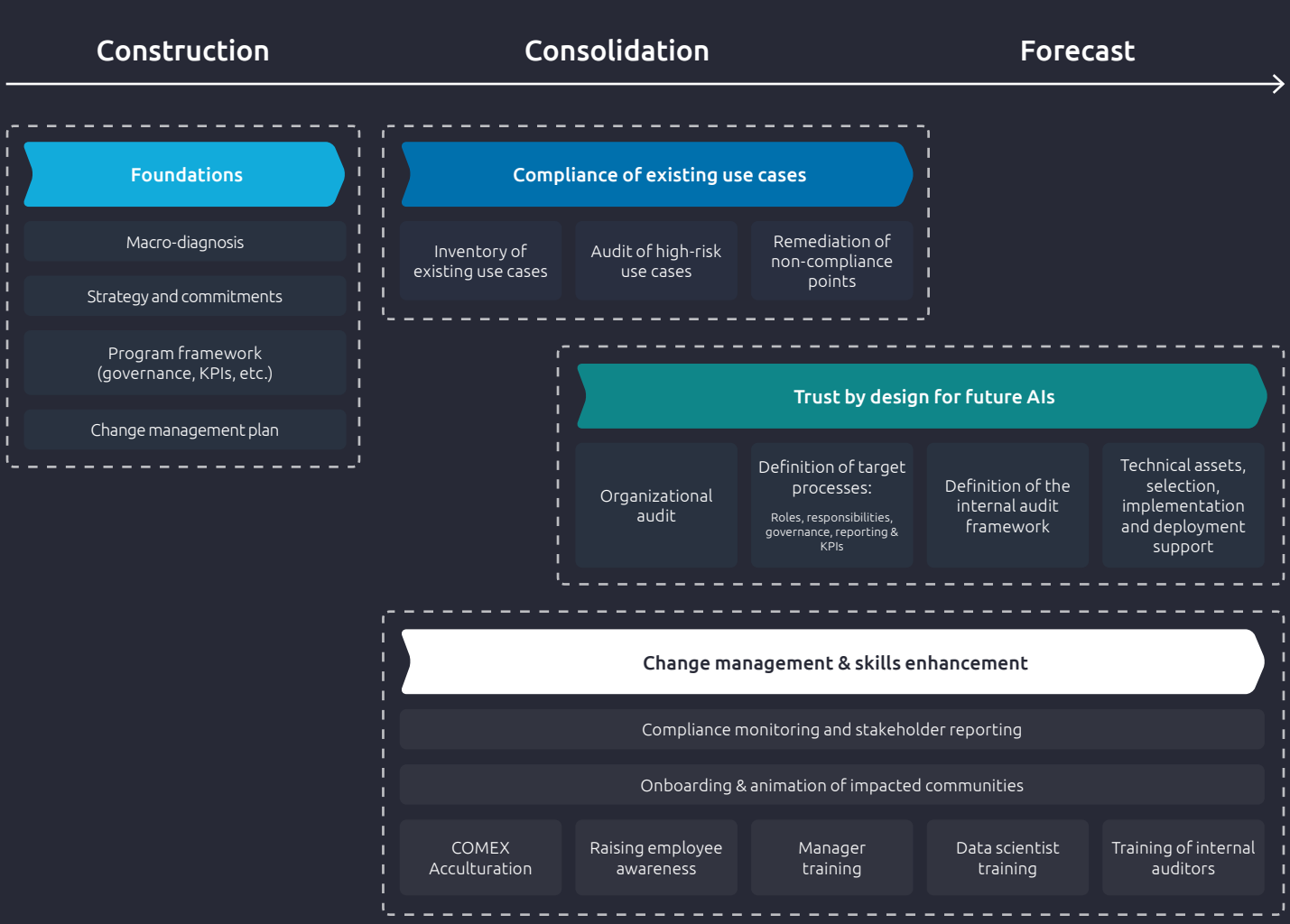


Fig 2 **Our Solution for Trustworthy AI**

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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Capgemini Invent is an integral part of Capgemini, a global business and technology transformation partner, helping organizations to accelerate their dual transition to a digital and sustainable world, while creating tangible impact for enterprises and society. It is a responsible and diverse group of 340,000 team members in more than 50 countries. With its strong over 55-year heritage, Capgemini is trusted by its clients to unlock the value of technology to address the entire breadth of their business needs. It delivers end-to-end services and solutions leveraging strengths from strategy and design to engineering, all fueled by its market leading capabilities in AI, cloud and data, combined with its deep industry expertise and partner ecosystem. The Group reported 2023 global revenues of €22.5 billion.

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