

In the Shadow of Uncertainty for the Future of Generative AI in Medicines Development: A Collaboration to Illuminate the Way

Summary Report from the *DIA 2023 Global Annual Meeting* Solution Room

Introduction

In today's dynamic landscape of medical innovation, convening a diverse array of stakeholders is critical. The transformative potential of generative AI in medicine development is undeniable, but its responsible integration requires a collaborative effort like no other. From researchers and clinicians to regulators, tech innovators, and (ultimately) patients, the convergence of all these voices is the crucible in which we forge a future of healthcare that truly serves everyone. The challenges are myriad. But we can harness the diverse recommendations and best practices of generative AI to revolutionize diagnostics, drug discovery, and patient care through collective dialogue.

A DIAMond session at the *DIA 2023 Global Annual Meeting* fully exposed the role of artificial intelligence in advancing and adding efficiency for patient benefit. Following the session, a multistakeholder group participated in a solution room to continue the discussion and explored the requirements and best practices for implementing generative AI in the pursuit of patient benefit. The multistakeholder collaboration wasn't just a conversation: It was a beginning to illuminate the path forward, one where the pursuit of innovation harmonizes with dedication to patient benefit and the betterment of the entire healthcare industry.

DIAMond Session

The DIAMond session “**Full Exposure: Artificial Intelligence to Advance, Replace, and Add Efficiency for Patient Benefit**” provided an overview of the current and future state of large language models and other AI techniques, and how they can impact the future of health. The panel discussed the differences and trade-offs between generative and other forms of AI, the latest developments and applications of GPT and other large language models in the health and life sciences domain, the key challenges and opportunities for using large language models in health-related contexts, and the regulatory and patient safety implications of generative technologies.

The session was chaired by Alison Cave (Chief Safety Officer, Medicines and Healthcare products Regulatory Agency), and participants on the panel were Hoifung Poon (General Manager, Health Futures, Microsoft), Stephen Hahn (CEO-Partner, Flagship Pioneering; Chief Executive Officer, Harbinger Health), Stacy Hurt (MBA, MHA, Patient Advocacy Ambassador, Parexel International), Johan Ordish (Head of Digital Health and Innovation Policy, Roche), and Nancy Dreyer (President, Dreyer Strategies LLC).

Solution Room

The Solution Room was envisioned as a vibrant platform for igniting meaningful conversations aimed at tackling a pressing challenge, one which resides within a specific domain, within the healthcare community. With this objective in mind, the Solution Room “**In the Shadow of Uncertainty for the Future of Generative AI in Medicines Development: Collaboration to Illuminate the Way**” was crafted as an all-encompassing forum designed to extend and deepen discussions initiated during the AI DIAMond session “**Full Exposure: Artificial Intelligence to Advance, Replace, and Add Efficiency for Patient Benefit.**”

A diverse, highly experienced group of experts spanning health regulatory authorities, industry, and innovative startups, including statisticians, epidemiologists, patient advocates, academics, and technology trailblazers, was invited to the AI Solution Room to discuss and explore the essential requisites for preparing drug development stakeholders for the future state of generative AI.

The dialogue spanned topics such as regulation, validation processes, transparency, trust, ethical considerations, and the critical issue of bias. Through this collective and interactive session, these experts meticulously mapped out a prioritized list of challenges, shared strategies to surmount these hurdles, and detailed the ideal stakeholders needed to engage in

paving the way for the future of medicine development—all in pursuit of responsible and compassionate implementation of generative AI for the patient's benefit.

Solution Room Discussion

Alison Cave (Chief Safety Officer at MHRA) chaired the Solution Room with an engaging overview of the key takeaways from the DIAMond session. DIA staff members Maria Paula Bautista Acelas and Courtney Granville provided an overview of the AI Solution Room's purpose and objectives.

The Solution Room discussion focused on the critical challenges posed by generative AI, the potential solutions, and the best practices for implementing generative technologies for patient benefit. Specifically, the discussion covered the following topics: **regulation, validation, transparency, trust, ethics, and bias**. Participants in the solution room:

- Identified the general challenges in regulation, validation, transparency, trust, ethics, and bias that need to be addressed, and prioritized a list of the most critical challenges.
- Described potential solutions and current best practices to overcome the identified challenges.
- Discussed the ideal multistakeholder collaboration.

To foster a dynamic exchange of ideas and interactive dialogue from diverse perspectives, each participant was assigned to one of five tables. Each table discussion was led by an expert: Jeremy Jokinen (Vice President and Head, Global Risk Management and International Patient Safety, Bristol Myers Squibb), Greg Ball (Safety Data Scientist and Founder of ASAP Process Consulting), Johan Ordish (Head of Digital Health and Innovation Policy, Roche), Munish Mehra (Principal Biostatistician & Executive Director, Tigermed), and Michael Meighu (Director of Consulting - Expert, Artificial Intelligence CGI, United States).

In addition, DIA distributed custom-crafted three-page workbooks to each table. These workbooks contained thought-provoking questions designed to spark open-minded discussions. Each table discussed the following questions:

What are the current challenges that need to be addressed to ensure the implementation of generative AI for patient benefit? Group the identified challenges into their respective categories (regulation, validation, transparency, trust, ethics, bias, other).

Regulation

- Reliable regulatory frameworks to ensure clarity and compliance for sustainable AI approaches, encompass scope and expectations
- Awareness of AI integration to address the lack of knowledge on effectively integrating AI into existing workflows
- Promote collaborative conversations and discussions on quality, safety, and efficacy to maximize AI's potential.

Validation

- Define validation approaches and industry standards considering regional and local factors
- Address limitations of training data, data restrictions, and assess data performance
- Keep pace with the accelerated progress of AI innovation
- Understand data provenance for enhanced generalizability.

Transparency

- Lack of representative input
- Address misinformation through training and communications
- Incorporate policies to address concerns about job security.

Trust

- Define data methodology and the accuracy of models to establish trust
 - Ensure transparency in model usage
 - Avoid undue reliance
- Build story catalogs on how people are using or have already used large language models.

Ethics

- Enhance societal awareness and stakeholder collaboration
- Maximize patient value and how patients can utilize the results
- Control patient data rights, privacy, and communication.

Bias

- Overreliance on generative AI outcomes
 - Accuracy of data
Hallucinations (precision error)
Omission (recall error)
 - Perception of bias
- Enhance “explain-ability” for efficient human verification
 - Unclear use cases.

From the above categories, select two challenges that need to be urgently addressed to prepare medicine development stakeholders for a future state of generative AI for patient benefit. For each critical challenge:

- List the opportunities or best practices that are already ongoing to overcome challenges.
- Identify the key stakeholders/partnerships that need to be involved to overcome the challenges, and how the key stakeholders can contribute.

Note: Most of the tables did not complete every question in the workbook. The following summary highlights the participants’ most commonly addressed questions.

Input 1

Prioritized Challenges to Address	Opportunities/Best Practices	Stakeholders to Involve
More Use Cases	- First, identify the problem statement and then identify the right data when developing use cases	Data scientists Patients Academia
Data and Data Sharing	- Need for data-sharing agreements - Identify the right data set for the right use - Develop trained data sets for specific use cases and then amplify their application	Medical centers Government and policy Tech or genomic industry EMR providers

Input 2

Prioritized Challenges to Address	Opportunities/Best Practices	Stakeholders to Involve
Data Access and Governance	<ul style="list-style-type: none"> - More frequent regulatory updates and guidance - Frameworks for minimum requirements - Multistakeholder collaboration for timely validation of applications 	Insurance providers Regulators Bioethics experts Clinicians
Trust and Transparency	<ul style="list-style-type: none"> - Partner with different industries to leverage available resources - Update language in informed consent for research use - Need for protocol-based education of patients and industry 	Patients Life science professionals

Input 3

Prioritized Challenges to Address	Opportunities/Best Practices	Stakeholders to Involve
Data Transparency/Validity	<ul style="list-style-type: none"> - Define data ownership - Establish incentives for sharing data - Establish valid data source - Establish patient consent which guarantees that their data won't be traceable in the future 	Healthcare organizations Patients Regulators Pharmaceutical companies Tech companies
Human/AI Partnership	<ul style="list-style-type: none"> - Help companies and individuals to embrace AI as no threat - Transform the educational system so skills enable technology 	Researchers/Academia

Input 4

Prioritized Challenges to Address	Opportunities/Best Practices	Stakeholders to Involve
Private-Public Partnerships	- Need for international alignment to understand what generative AI does	Regulators Patients
Data provenance, bias, transparency, and access	- Shared practices, data transparency, standards, regulations, internal standard operating procedures (SOPs), custom large language models (LLMs)	Tech providers Sponsors Payers Healthcare Providers Academia

Input 5

Prioritized Challenges to Address	Opportunities/Best Practices	Stakeholders to Involve
Trust	- More partnerships with sponsors and regulators - Share available tools with the public	Regulators Patients Sponsors Academics
Veracity, Fragmentation, Different Outcomes	- Establish economic incentives for data sharing - Establish draft guidance - Avoid amplification of existing bias	Caregivers Healthcare providers Researchers Journalists

Please refer to the [Global Forum](#) publication for more highlights from the Solution Room discussion.

DIA Role

During our exchange, participants passionately shared their thoughts on how DIA can engage in confronting the challenges before us while also shedding light on the promising path ahead. Insights emerging from these discussions include:

Fostering Inclusive Dialogue: One resounding call was for DIA to harness its neutral global communication channels as a vehicle for orchestrating constructive conversations. By encouraging and convening multiple stakeholder perspectives, DIA can foster an environment of informed discourse that not only enlightens but also fuels transparency as a core value.

Illuminating the Baseline: Another highlight was the need for DIA to serve as a guide for knowledge dissemination. Through the appropriate channels, DIA should diligently disseminate content that not only educates stakeholders but also enables them to grasp the foundations upon which DIA's work stands. Furthermore, these resources should be dynamic and allow stakeholders to visualize how these foundations might evolve in the future.

Empowering Innovation: Lastly, participants underscored the vital role DIA plays in empowering experts to come together and collaborate. This harmonious exchange of ideas breeds innovation, and it was widely encouraged that DIA continue to provide a robust platform for experts to unite, brainstorm, and collectively shape the future of our endeavors.

In the wake of these stimulating discussions, it is abundantly clear that DIA will continue to stand at the forefront of connecting and collaborating to bring meaningful transformation for patients' benefit.

Conclusion

The Solution Room proved to be an invaluable forum for fostering forward-thinking dialogues in our ever-evolving landscape of generative AI and served as a space where diverse perspectives converged to illuminate the challenges that this transformative technology has brought as well as the opportunities it offers. Through their dynamic exchange of ideas, stakeholders from various backgrounds revealed the importance of collaboration as a key to overcoming complex challenges. As we look to the future, one thing becomes abundantly clear: Continued collaborative conversations are not just desirable, they are essential. Through these collaborative forums, transparency is fortified, and partnerships are forged, ultimately laying the groundwork for identifying shared solutions that will shape the future of this groundbreaking field.

We extend our heartfelt gratitude to all participants for their enthusiastic engagement and candid dialogue. Your active involvement truly enriched our discussion.