

# Boosting real-world data for clinical development employing artificial intelligence and machine learning

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**Abstract.** Artificial intelligence (AI) - machine learning (ML) techniques together with the increase in vast and diverse data sets and the rise in compute power are transforming the way we investigate and understand complex systems, boost data, and perform biomedical research including biomedical engineering. First, an overview of machine learning will be given, including types of algorithms, addressable problems and a comparison with traditional methods. Second, the challenges associated with real-world data, including CT scans, will be discussed. AI/ML methodologies to tackle the challenges will be presented: How do they enable us to gain insight and to uncover pattern that were difficult to discern previously? Third, the presentation will illustrate the challenges and power of combining data sets of a variety of modalities and demonstrate the pros and cons of AI/ML approaches including state-of-the-art pre-trained transformer models for data enrichment and outcome prediction. Such approaches were used for ranking patients by their eligibility for clinical trials. Finally, challenges related to data quality, privacy, and interpretability, which must be effectively addressed to fully realize the potential of AI and ML in leveraging real-world data for knowledge discovery and advancements in biomedical research, will be highlighted.

**Curriculum.** Judith Müller earned a Master's of Science degree in physics at the RWTH in Aachen, Germany, before she has obtained her PhD in theoretical physics at McGill University in Montreal, Canada. First, she worked in the semiconductor industry for 14 years, where she modeled advanced electronic devices, specialized circuits, and developed methodologies for technology assessment and parametric yield improvements. Second, at Rosetta Design Group in the US, she provided contract R&D in computational macromolecular modeling. Third, as her interest and expertise in mathematical modeling of complex systems, data science, and machine learning continuously broadened, Dr. Müller joined GNS Healthcare, a biosimulation company based in Somerville, MA, USA, where she led a team to develop causal machine learning algorithms to extend capabilities of their proprietary REFS™ platform. Finally, as Vice President of Data Science at ConcertAI, she built and led an interdisciplinary team of data scientists and machine learning engineers to develop and deploy AI/ML solutions for clinical development using real-world oncology data. She recently joined Merck as executive director and head of AI and genomics.