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Predicting the probability of clinical trials success from AI-based approaches using multimodal data

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Please provide a brief biography for the Presenting author(s)
Nils Ternès is a statistical biomarker leader at Sanofi R&D in France where he leads the biomarker-related statistical activities on several compounds in clinical development across all phases in Oncology, Immunology and Neurology. With this position, Nils is continuously looking for data and analytical methods innovations as well as operational efficiency to ensure effective decision making, generate translational medicine insights and increase the productivity of drug development. Before joining Sanofi, Nils studied statistics applied to public health at Paris-Saclay University (MSc) and holds a PhD in Biostatistics (2016) at Gustave Roussy cancer institute on advanced penalized regression techniques for the identification of prognostic and predictive biomarkers in high-dimensional settings. With a constant interest in learning and promoting the use of ML/AI technics to support clinical development, he is now co-leading the Machine Learning workstream from the Biomarkers ESIG.

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Clinical trials are essential for the drug development lifecycle but often face uncertain outcomes due to safety, efficacy, or patient enrollment problems. It is widely known that the overall probability of clinical trial success is very limited (around 10%) and leading to unnecessary development cost and time, and most importantly unnecessary patient exposition. Predicting the probability of success of a clinical trial before it starts is therefore key for informed decision making and efficient drug development plan. Nowadays, with the spectacular breakthrough of AI/ML, there is active research in using these innovative approaches to support this goal and could be extended to drug positioning, indication prioritization or population optimization. Some recent works consider deep-learning approaches such as graphical or recurrent neural networks, or fine-tuned large language models. Benchmarks with large and multi-modal data sources are essential to achieve better prediction accuracy, such as with clinical trial information, drug chemical structure, target disease, pharmacokinetics and toxicology information, or even electronic health records. This presentation will provide an overview of current research in this hot topic, together with critical thinking, as well as some internal development. In such project, the development of fit-for-purpose benchmarks is even more critical than the AI-based model development itself. Even if several efforts have been initiated to create large clinical trial benchmarks, important improvements are still needed, and practical considerations will be shared. Bringing together expertise in AI/ML as well as in drug development and clinical research is key for project success.