HEALTHCARE

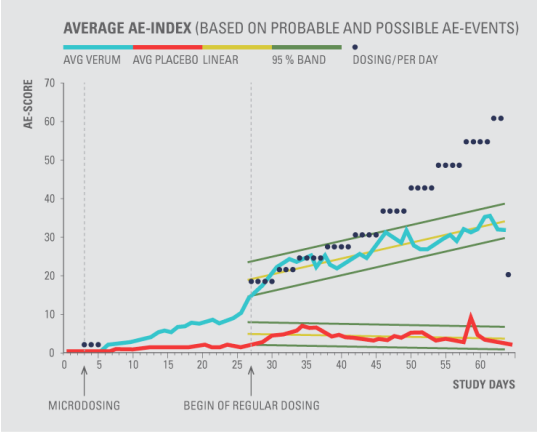
CLINICAL TRIALS

Prediction of individual side effect risk

CONTEXT

The serious progress of personalized medicine calls for improvements in today's clinical trials. Especially, the prevalence rate of study participants' individual risk for drug response, adverse events, and other side effects is a main issue in present study design.

The reason is that an early identification of these reactions and effects and the decoding of the underlying physiology can prevent study participants and – later on – patients from avoidable risk. With skillful risk stratification, we help to drive the performance and enhance the value of clinical trials. Our technology facilitates adaptive study design and optimizes the study performance by clustering the participants into relevant subgroups for the respective study conditions. Thus, the number of participants can be reduced without losing validity in terms of the intended study goal, therapeutic effect, and drug safety profile.



Early identification of differences in AE-Index delivers relevant information for patient stratification – even after micro dosing

GENERATION OF PREDICTIVE INDEX

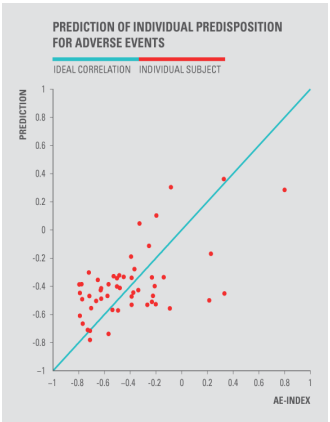
Our **Q-USD:** QLAYM UNSUPERVISED SOLUTION DISCOVERY™ technology is a fast and precise solution for the early detection of emerging effects in studies that predicts individual risk factors during study execution and at the same time, delivers predictions for subsequent study phases. Thus, **Q-USD™** reduces costs and risks, enhances the performance of adaptive study design and generates increased safety for study participants and patients.

Q-USD™ transforms blurred and noisy adverse event data into a high-precision Adverse Event (AE) Index – revealing the onset of drug related adverse events even after microdosing. The strength of the adverse events for every individual is predicted precisely (correlation between predicted and reported AE Index: 0.73).

Q-USD™ IN THE FIELD

In phase I of a clinical study for a neuroactive substance the data suggested typical compound properties. Yet, the drug failed in phase II.

For this drug, **Q-USD™** discovered that side effects can be deducted surprisingly well from just three clinical parameters right at the study start. Thus, **Q-USD™** provided early indication of side effects and prediction of individual risk and severity of adverse events. Our technology identified the relevant biomarkers and enabled the design of a theragnostics assay and patient stratification.



AE-Index enables precise prediction of individual risk of adverse events for every study participant

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