Cleveland Clinic Innovations

PRODUCT
Patient stratification software

INDICATION
- Clinical trials
- Drug discovery & development
- Drug rescue & repurposing
- Prediction of treatment response

VALUE PROPOSITION
- Patient selection for therapies & clinical trials
- Disease-biomarker driven clinical trial selection

DEVELOPMENT STAGE
MVP software has been built and tested using diabetes, epilepsy, and ulcerative colitis datasets

RELATED PUBLICATIONS

Daniel M. Rotroff, et al. A Type 2 Diabetes Subtype Responsive to ACCORD Intensive Glycemia Treatment. Diabetes Care 2021;44(6):1410–1418.

Daniel M. Rotroff, et al. Molecular Subtypes of Epilepsy Associated with Post-surgical Seizure Occurrence. Brain Communications, fcad251, 30 Sep 2023.

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CCF ref: IDFs 2019-305, 2019-330, 2022-012

Patient Stratification By Multi-modal Cluster Mining

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UNMET NEED
Almost 90% of drugs fail in clinical trials. Each clinical trial failure that ends the development of a drug costs drug companies between $0.8-1.4 billion. There is a growing appreciation that clinical trials sometimes fail to meet efficacy endpoints due to patient heterogeneity. There is a need for better patient stratification/sub-typing tools for data analysis post clinical trial to determine whether the drug truly failed or is potentially effective in a more homogenous subset of the patients. With that knowledge, the drug company can make an informed decision whether to terminate drug development or perform a clinical trial in the newly identified patient cohort.

SOLUTION
A patient stratification tool to identify patient subtypes to empower successful clinical trials and delivery of the right therapies to the right patients. The software uses machine-learning and clustering approaches on multimodal omics data and clinical data to provide clinically relevant clusters with different responses to treatment or modified risk of disease. These data enable the identification of patients that will most likely benefit from the drug, select the correct patient populations for clinical trials, and identify the disease biomarkers to design trials.

The figure below highlights how our algorithm, using two orthogonal -omics assays converged on a patient subset (top left) with a specific failure of treatment response. Importantly, this patient subtype displays significantly greater risk of seizure recurrence post epilepsy surgery. This subtype could be contraindicated for this invasive procedure that often causes cognitive deficits, while also experiencing no improvement in the disease outcome. This serves as an example for how this versatile approach can identify clinically relevant patient subtypes. Notably, we have successfully applied this to areas of type 2 diabetes polytherapy and clinical trial data for a new ulcerative colitis treatment.