Leveraging Real-World Data for EMA Qualification of a Model-Based Biomarker Tool to Optimize Type-1 Diabetes Prevention Studies

The development of therapies to prevent or delay the onset of type 1 diabetes (T1D) remains challenging, and there is a lack of qualified biomarkers to identify individuals at risk of developing T1D or to quantify the time-varying risk of conversion to a diagnosis of T1D. To address this drug development need, the T1D Consortium (i) acquired, remapped, integrated, and curated existing patient-level data from relevant observational studies, and (ii) used a model-based approach to evaluate the utility of islet autoantibodies (AAs) against insulin/proinsulin autoantibody, GAD65, IA-2, and ZnT8 as biomarkers to enrich subjects for T1D prevention.

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