Kihealth

Accelerating Diabetes Drug Development

Real-Time Beta-Cell Death Monitoring for Clinical Trials

The Challenge

Traditional diabetes trial endpoints such as HbA1c, glucose, and C-peptide are slow, indirect, and fail to directly measure active beta-cell destruction.

The Kihealth Advantage

BETA INTERCEPT™ directly measures active beta-cell apoptosis using unmethylated INS cfDNA, enabling earlier pharmacodynamic signals and improved responder identification.

Clinical Findings

Analytical validation studies demonstrated strong performance across accuracy, precision, specificity, recovery, stability, and linearity testing.

The assay achieved an average ROC AUC of 0.979 in distinguishing high-risk versus low-risk metabolic participants using average unmethylated INS cfDNA measurements across three CpG sites.

Partnership Opportunities

Kihealth is seeking collaborations with pharmaceutical companies, clinical research organizations, academic medical centers, and pediatric diabetes programs.

- Pharmaceutical companies running T1D intervention trials
- Clinical research organizations (CROs)
- Academic medical centers with T1D programs
- Pediatric diabetes research networks

Collaboration Models

- Co-development partnerships
- Clinical trial endpoint integration (Phase II/III)
- Technology licensing for companion diagnostics
- Strategic investment & Series A participation
- Academic research collaborations

Strategic Applications

01	02	03	04	05
Cohort enrichment for high-risk subjects	Adaptive trial design with real-time PD signal	Treatment monitoring and responder identification	Earlier go/no-go decisions in Phase II/III	Beta-cell preservation assessment for immune therapies

Key Advantages For Partners

625 days

Earlier pharmacodynamic signal than conventional C-peptide endpoints

Faster go/no-go	Months, not years
Lower trial cost	Fewer patients needed
Better stratification	Real-time responder ID
Regulatory path	Companion Dx strategy

www.kihealth.com

info@kihealth.com