

# 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

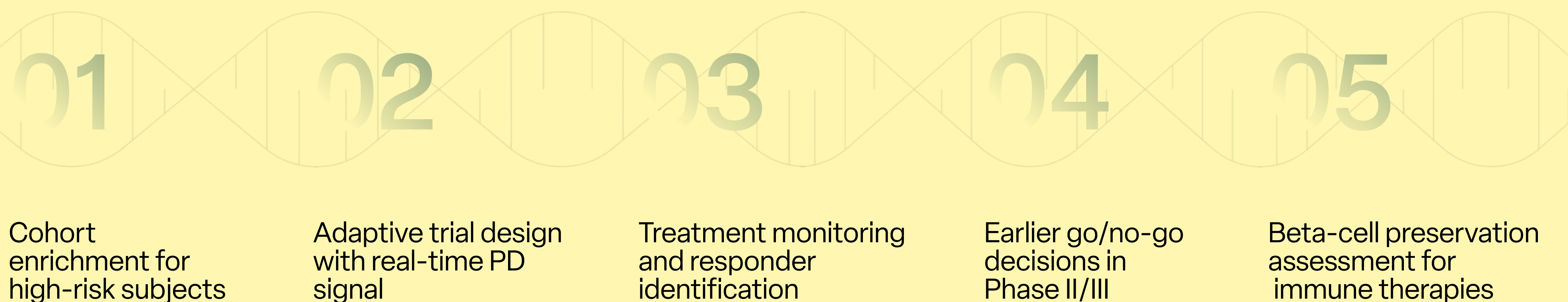


Pediatric diabetes research networks

## 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



## Key Advantages For Partners

625 days

Earlier pharmacodynamic signal than conventional C-peptide endpoints

Faster go/no-go

Lower trial cost

Better stratification

Regulatory path

Months, not years

Fewer patients needed

Real-time responder ID

Companion Dx strategy