



**U.S. FOOD & DRUG**  
ADMINISTRATION

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DATE: July 12, 2021

FROM: Kanaeko R. Ravenell, MS, Consumer Safety Officer  
Division of Inspections and Surveillance (DIS)  
Bioresearch Monitoring Branch (BMB)

THROUGH: Dennis T. Cato, Chief, BMB

THROUGH: Carrie M. Mampilly, MPH, Director, DIS

TO: Sukhanya Jayachandra, PhD, Chair  
Patricia Beaston, MD, PhD, Clinical Reviewer  
Rommel Maglalang, RPM

SUBJECT: Bioresearch Monitoring Final Discipline Review  
SPONSOR: CellTrans, Inc.  
PRODUCT: Allogeneic Human Pancreatic Islets of Langerhans (Donislecel)  
BLA: STN 125734/0

### FINAL SUMMARY STATEMENT

A Bioresearch Monitoring (BIMO) inspection was conducted for the sponsor of this original Biologics License Application (BLA) for study Protocol UIH-002. The inspection did not reveal substantive issues that impact the data submitted in the BLA.

### BACKGROUND

A sponsor inspection was conducted in accordance with FDA's Compliance Program (CP) 7348.810, Inspection Program for Sponsors, Contract Research Organizations and Monitors. The inspection assignment included specific questions concerning the information submitted in this BLA.

### PROTOCOL

Protocol UIH-002 – *Islet Transplantation in Type 1 Diabetic Patients Using the UIC Protocol, Phase 3.*

### BIMO INSPECTION SUMMARY:

No significant BIMO inspectional findings were observed during the inspection. The below table summarizes site information and outcome from the BIMO inspection:

Establishment	Location	Form 483 Issued	Final Classification
CellTrans, Inc.	Chicago, IL	Yes*	No Action Indicated (NAI)

\*CBER downgraded the Office of Regulatory Affairs (ORA)/Office of Bioresearch Monitoring Operations (OBIMO) recommended classification from VAI to NAI and ORA/OBIMO concurred with the reclassification.

### INSPECTIONAL FINDINGS

The Informed Consent (IC) did not include the complete required statement: "A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time."

However, the requirement for the above IC statement is applicable to clinical trials initiated on or after March 7, 2012. This study was initiated in 2007 so the cited statute is not applicable. CBER downgraded the inspection's classification to NAI.

### SPONSOR/MONITORING ISSUES

No significant sponsor or monitoring issues were identified during the sponsor inspection.

### FINANCIAL DISCLOSURE

The Clinical Investigator Compliance Program directs the FDA investigator to ask if and when information was disclosed about financial interests of the clinical investigators or interests of any sub-investigators, spouse(s), and dependent children, as well as if and when the information was updated. The information submitted to the BLA was verified during the inspection.

### ADMINISTRATIVE FOLLOW-UP

Should you have any questions or comments about the contents of this memo or any aspect of Bioresearch Monitoring, please contact me at (240) 402-8423.

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Kanaeko R. Ravenell  
Consumer Safety Officer