GraftAssure™ Technology

iMDx™ Insight Molecular Diagnostics

Join the GALACTIC Registry

Establishing the future of decentralized dd-cfDNA testing

In recent years, transplant programs have been seeking out monitoring that is faster, more economical, and operationally flexible. The "**G**raft**A**ssure **L**owering **A**llograft Reje**CTI**on by **C**ombination" Registry (GALACTIC), was built to answer the question: can in-house dd-cfDNA testing deliver better outcomes for programs, patients, and laboratories?

Two Part Registry

1. Send Out Testing
2. In-House Testing

Benefits for Your Program

Participating centers gain direct access to the tools and evidence needed to move toward faster, more economical in-house dd-cfDNA testing:

- **Evaluate the GraftAssureCore™ Laboratory Developed Test**: Evaluate iMDx's dd-cfDNA testing service alongside your existing send-out workflows during Part 1.
- **A pathway to in-house testing**: Part 2 offers eligible sites an optional transition to in-house testing following FDA authorization.
- **Early Access to GraftAssure™ Combination Model Score**: Experience with novel algorithm which combines the measurement of absolute and relative quantification
- **Real-world clinical evidence**: Your longitudinal data contributes directly to the clinical case for advancing transplant monitoring.
- **Publication opportunities**: Participating centers are positioned to contribute to scientific publications and presentations alongside leading transplant programs.

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The Study At a Glance

DESIGN
Observational, prospective, multi-center

FOLLOW-UP
Clinically meaningful longitudinal monitoring

ENROLLMENT
Up to 5,000 kidney transplant recipients across ~50 centers

TWO PARTS
Part 1: Centralized testing through iMDx laboratories.
Part 2: Optional in-house testing

Key Clinical Objectives

The GALACTIC Registry is designed to evaluate how comprehensive dd-cfDNA assessment may improve rejection detection, clinical decision-making, and long-term transplant outcomes.

- Improve rejection detection through the combined assessment of fractional abundance (%) dd-cfDNA, absolute (copies/mL) dd-cfDNA, and the integrated **GraftAssure™ Combination Model Score**.
- Have your site prove the clinical value of the **GraftAssure™ Combination Model Score** compared to standalone % and copies/mL dd-cfDNA measurements.
- Explore relationships between dd-cfDNA levels and outcomes including graft survival and function, re-transplantation, DSA development, and patient survival.
- Characterize the impact of longitudinal dd-cfDNA monitoring on long-term graft survival outcomes.
- Reduce hospitalization rates, rejection severity, and treatment intensity through earlier and more informed clinical intervention.

How to Join

Participation begins with an interest form submitted by your site or an iMDx representative. This is followed by CDA/NDA execution, protocol review, and a feasibility and onboarding assessment.

Ready to Participate?

Contact iMDx today to discuss logistics, protocol details, and onboarding.

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