Accelerating the Development of Molecular Diagnostics

Corporate Overview

July 2009

DGx | **Leveraging 10 years of Biomarker Development**

… looking for complex patterns that discriminate disease

GENE LOGIC

Management Highly-Experienced

- **World-Class Clinical Network**
- **Comprehensive Baseline of Human Biology**
- **Industry Standard QA/QC Metrics and Methods**
- **Established Multi-Parametric Data Analysis & Diagnostic Model Development**

in Molecular Biomarker Development

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DGx | # Core Management Team - 65 Years of Relevant Experience –

Management	Brief Vitae	Prior Industry Experience
Larry Tiffany *President &CEO*	Sr. Management, General Management & Business Development	GENE LOGIC, genetraks
Dr. Eric Eastman *CSO*	Sr. Management, Genomic Platform, Biomarker & Diagnostic Assay Development	GENE LOGIC, METRIGENIX
Dr. Doug Bigwood *SVP, Informatics*	Biostatistical Analysis & Biomarker Discovery and Validation	GENE LOGIC, Bayer

Scientific Advisory Board	
Dr. Benjamin Greenberg, UTSW Dr. Amit Bar-Or, McGill Dr. Mike Racke, OSU Dr. Avindar Nath, JHU Dr. Lisa Barcellos, UC Berkeley Dr. Mike Elashoff, Head of Biostats, CardioDx & ex-FDA	Significant Experience in: • Clinical MS/Neurology • MS Epidemiology • Diagnostic Model Building for submission to the FDA

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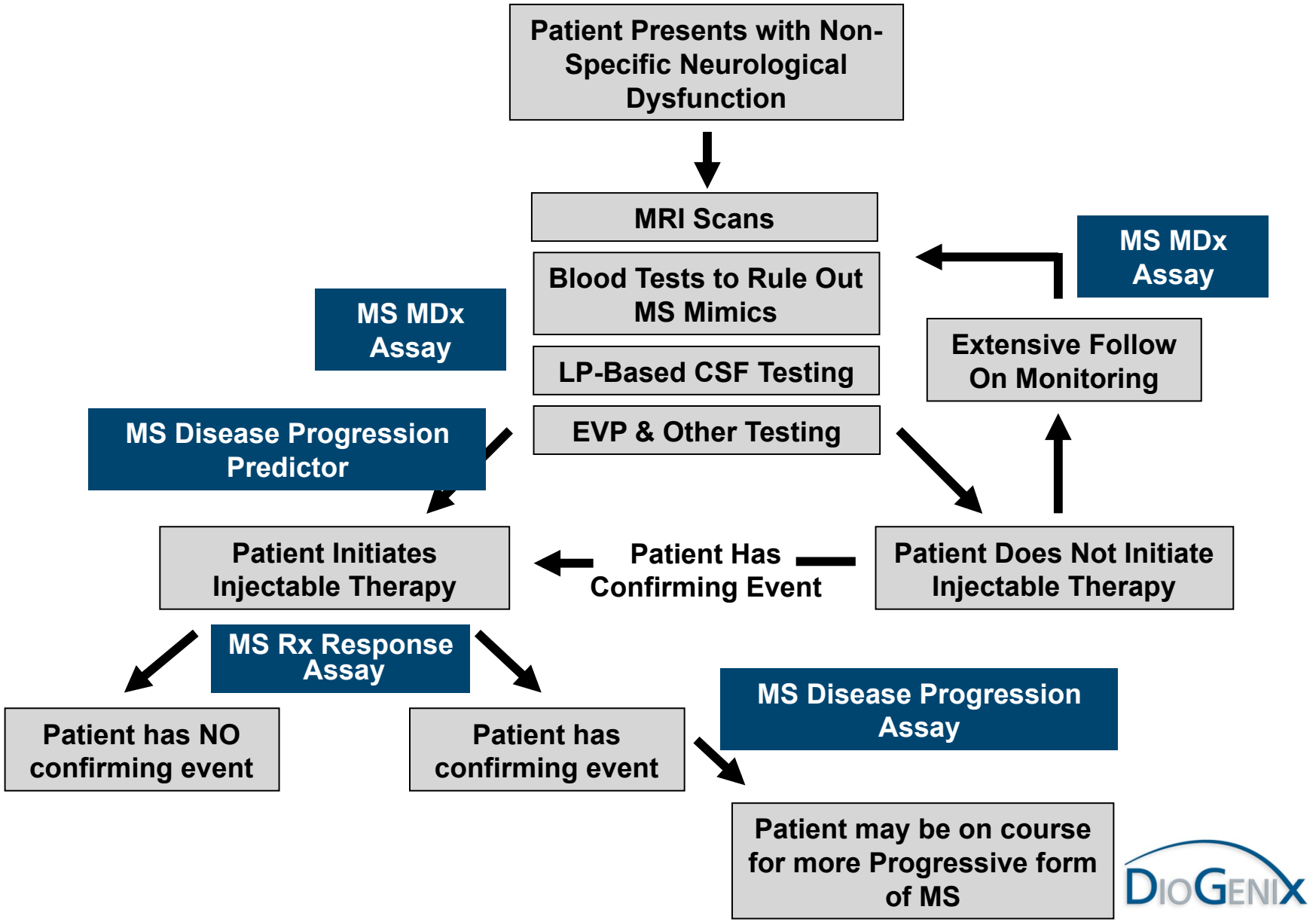
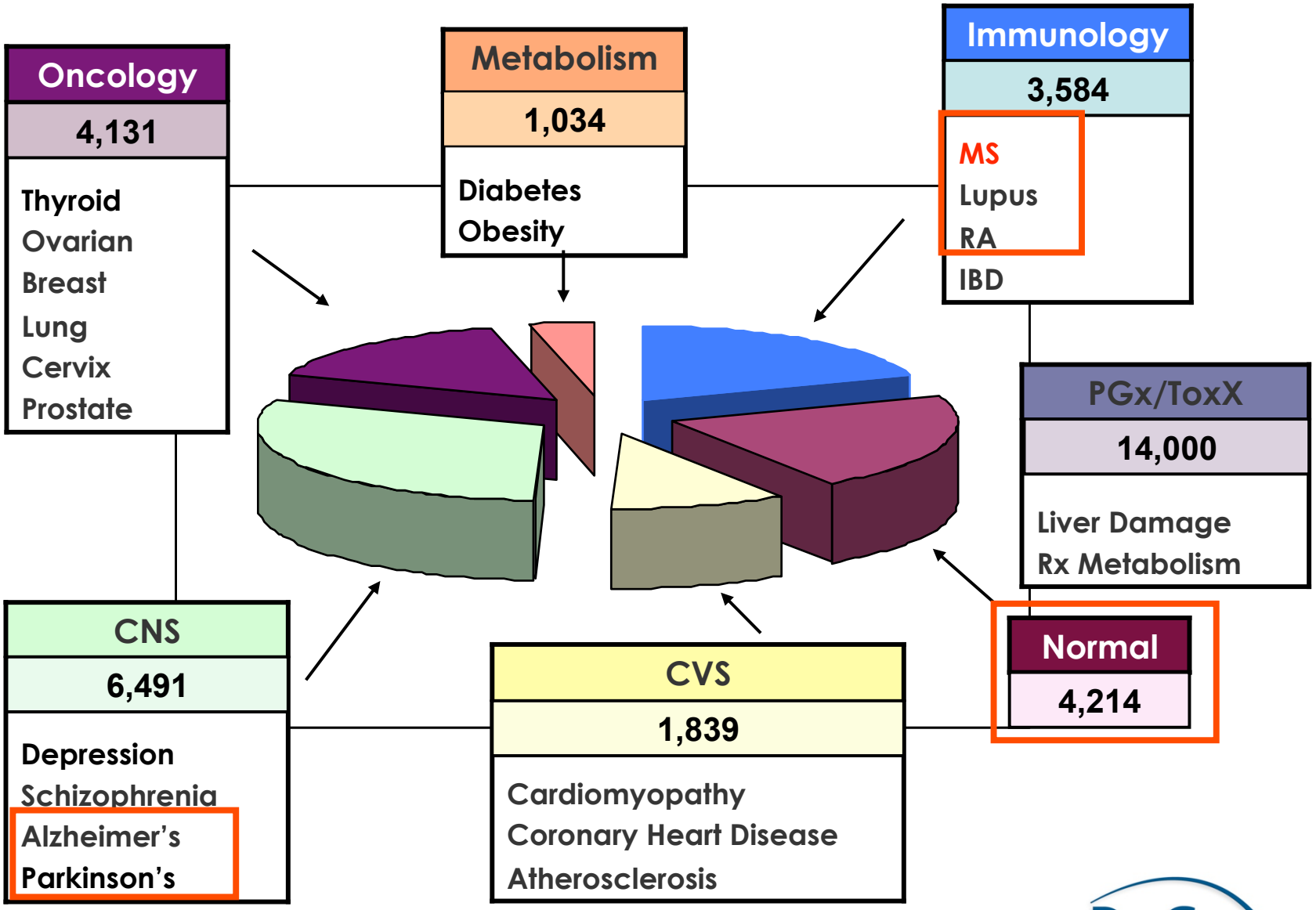
MS | Dx Inefficiency Provides Multiple Commercial Opportunities



Core Asset | Comprehensive Compendia of Human Biology provides Unique Baseline for Comparison



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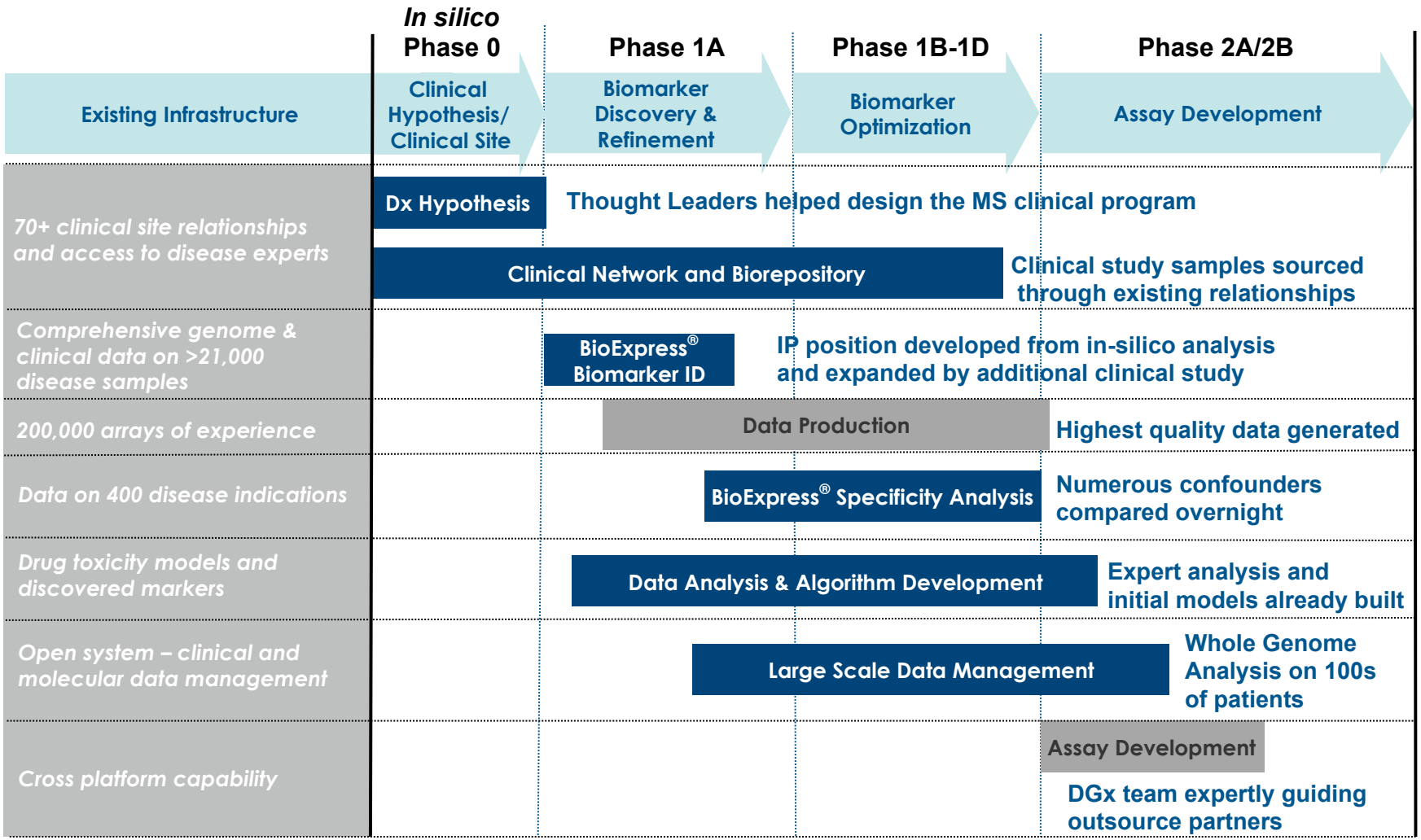
Applied to MS | Validated Dx Development Platform Leveraging an >$250M investment



Experienced in Multiplex Marker Set IP Procurement

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MS Dx | Early Development Strategy

1. ***In silico*** **Analysis using BioExpress®**
   - ✓ **Confirmed hypothesis**
   - ✓ **Filed provisional patent**
2. **Proof-of-Concept Analysis using Whole Blood Samples**
   - ✓ Comprehensive Multi-site Clinical Study
   - ✓ Excellent Discriminators Found
   - ✓ IP Estate Fortified with International Patent
3. **MS Dx Assay Development and Validation Plan**
   - ➢ Refine and Optimize MS Biomarker Sets and Models
   - ➢ Platform Selection and Assay Development (technical validation)
   - ➢ Registrational Clinical Trial (clinical validation)

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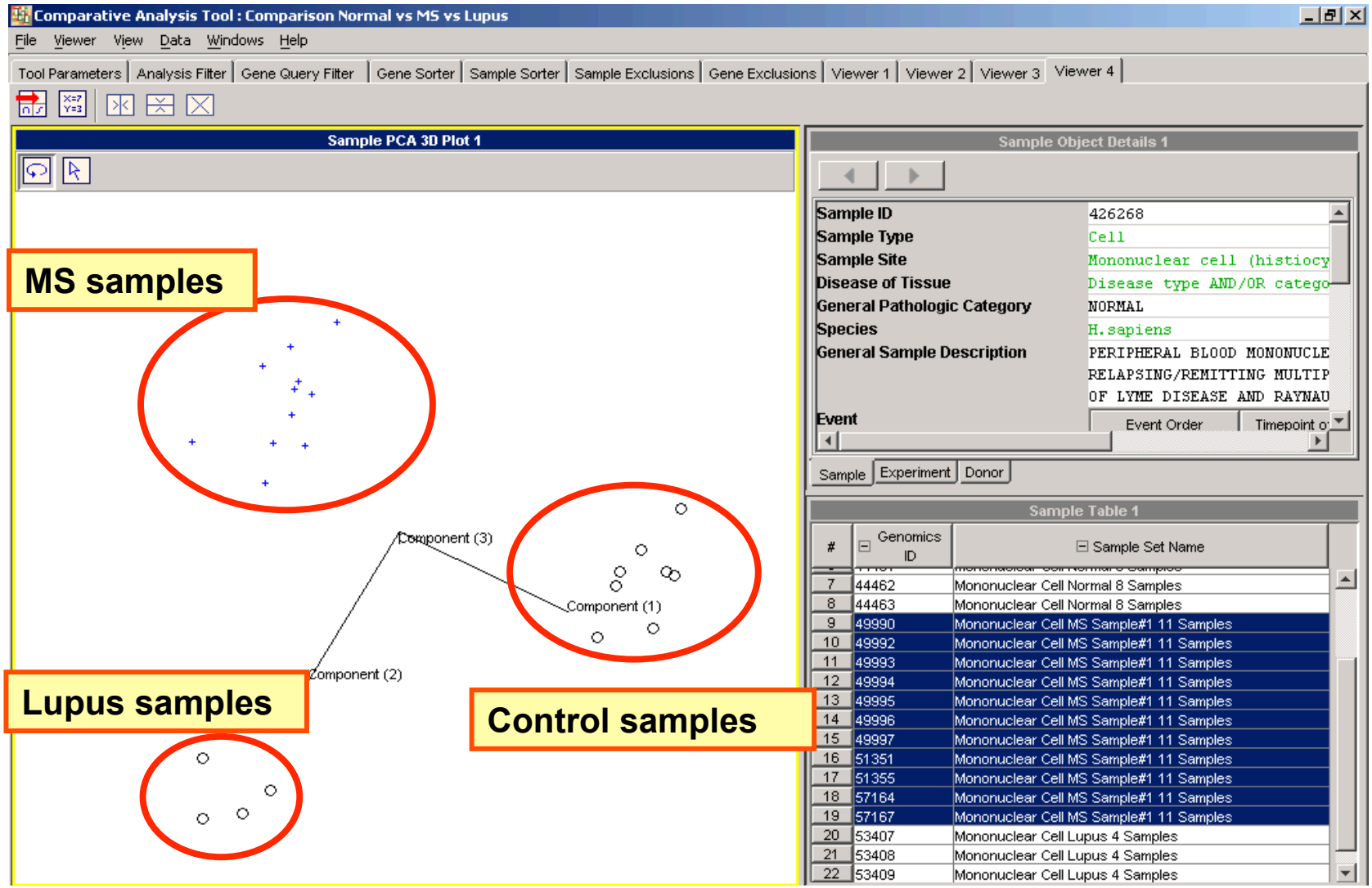
Phase 0 | **Differentiating MS, Lupus and Non-Disease Controls**



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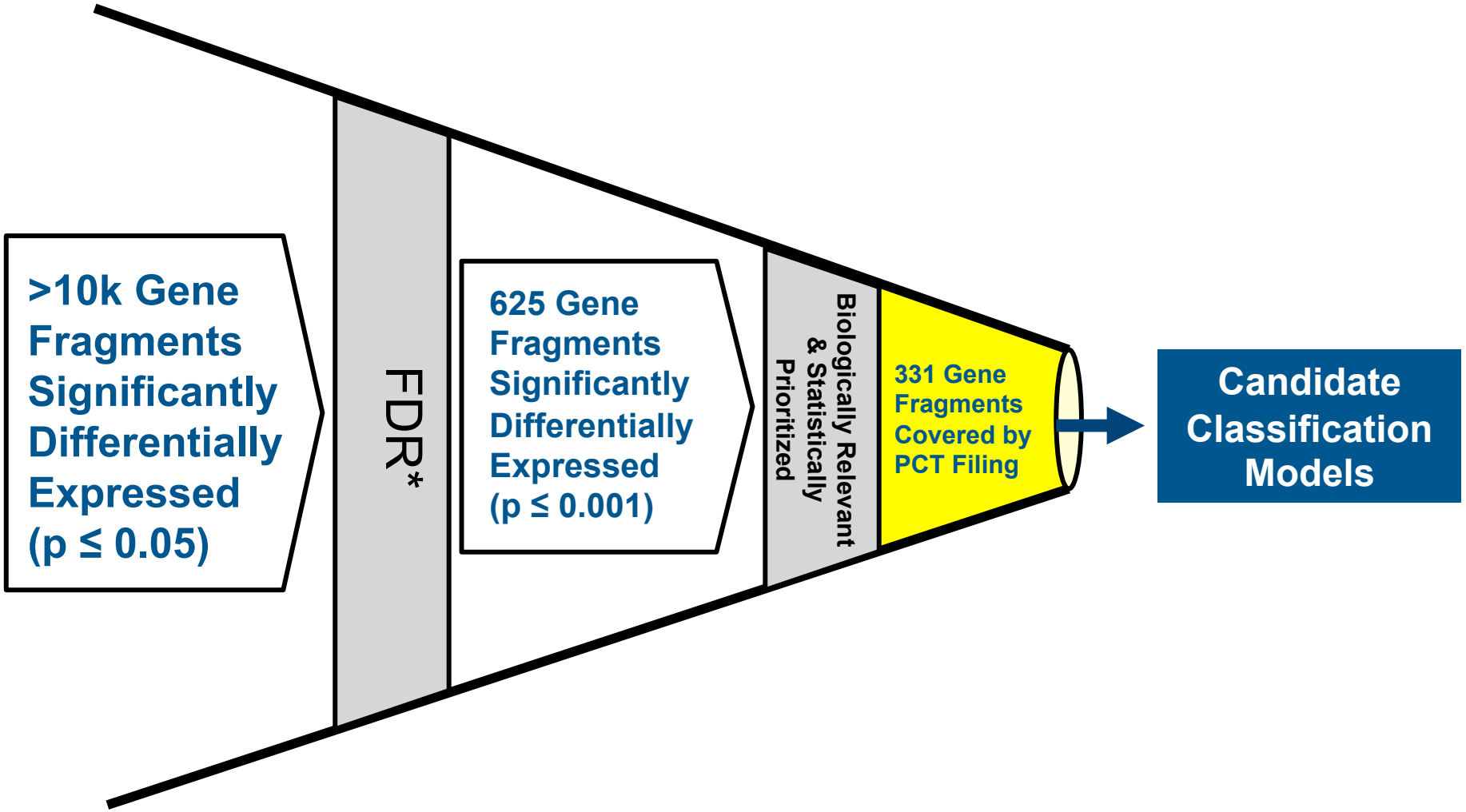
Choosing the Best Markers | **Rigorous Empirical Investigation**



***False Discovery Rate Correction**

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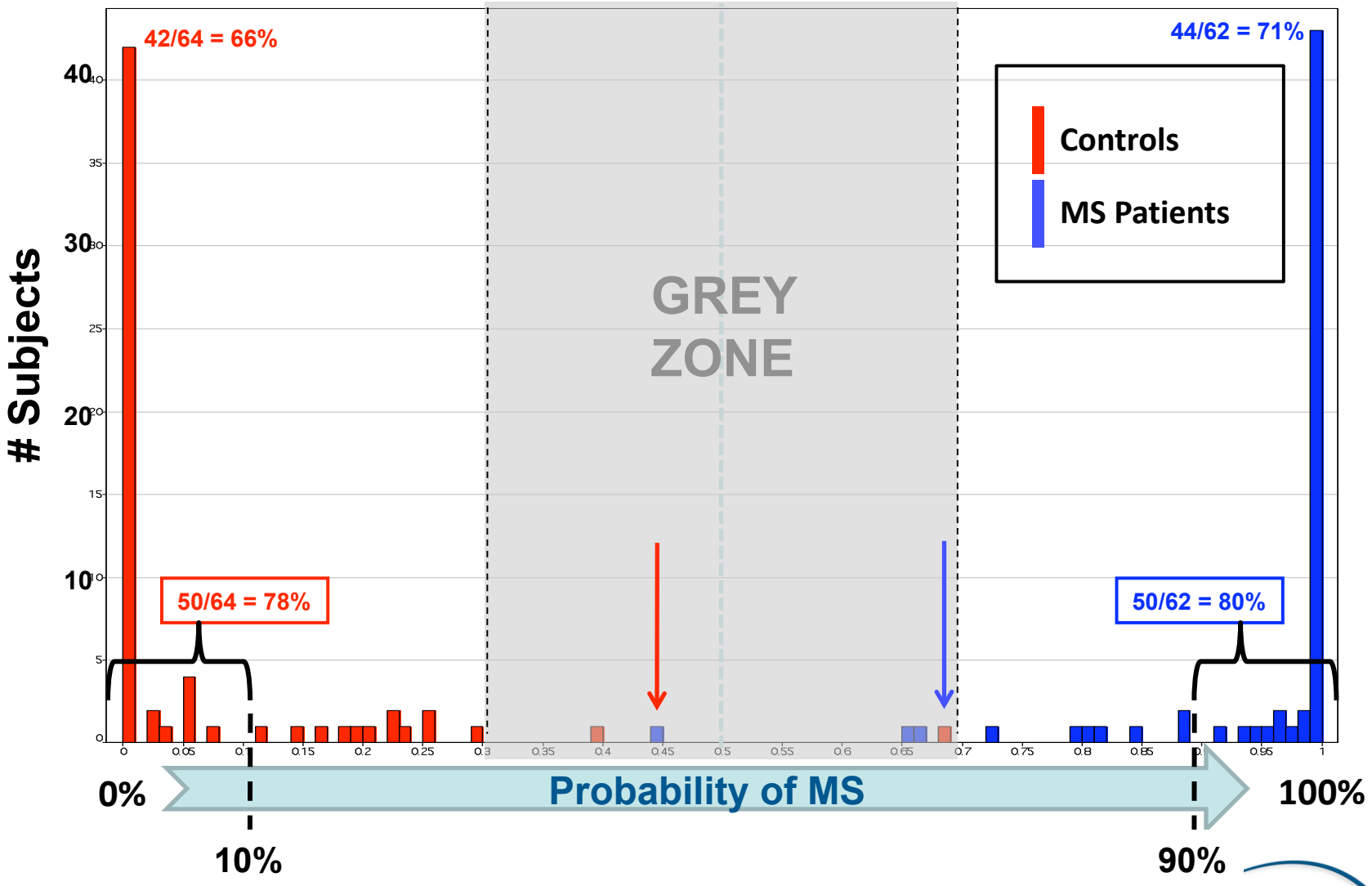
MS Dx | 7-Gene Classification Model is 99% Accurate



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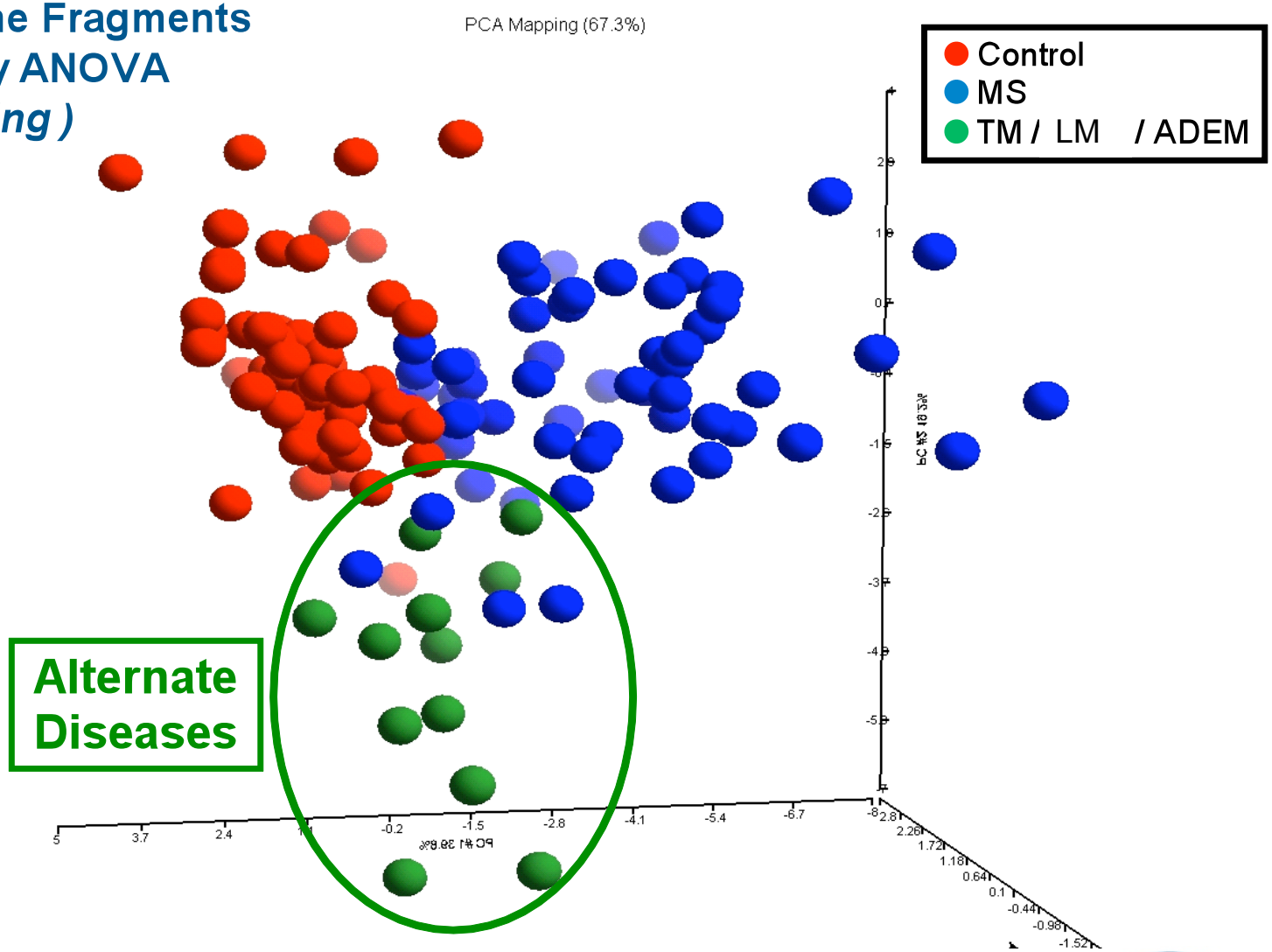
MS vs. Controls vs. Alternate Diseases

Top 50 Gene Fragments selected by ANOVA
(No Modeling)



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MS | Market Dominating Patent Position

Over 1,000 Patent Documents Reviewed

- >11,000 Marker Sequences queried (>95% identity over entire length)

Ongoing review of literature

- Comprehensive Scope - > 1,000 references investigated
- Top Academic & Commercial entities Targeted

Results

- **Few Groups have looked at *whole blood* across the entire transcriptome**
- **Most groups have used PBMCs**
- **Those that have used whole blood - small n#s**
- **Some marker overlap but NOT from a single entity**
- **Patentability of DGx Whole Blood Marker Set is High**
- **Clean International Search Report**

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MS | Development Plan

Phase	MS or CIS Samples	Other Disease Samples	Non-Disease Control Samples	Total Samples	Duration (Months)	Goal
Phase 1A (Whole Blood)	62	12	64	138	4	Qualify Initial MS Dx Signature
Specificity Study	TBP Under Confidentiality					Optimize MS Dx Signature
Steroid Effect Study						Determine "washout" period for steroid Rx
MS Therapy Effect Pilot Study						Determine affect of MS therapies on Dx Signature and Model
Assay Development (existing samples)	30	30	60	120	6	Port MS Dx Signature to commercial platform
Clinical Trial	200	100	0	300	24	Clinical Trial for FDA approval

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Key Components for Success … In Place and In Use

Experienced Management	Team has 65 Years of Relevant Experience
Lead Program	Highly Discriminatory Dx Markers targeted at >$250M Market
Resources to Support Success	$5.25M Series A
Unique Proven Assets	Validated R&D Methodology
Significant Dx IP Estate	Comprehensive International Patent Position
Virtual Company	Low overhead where vast majority of capital utilized for R&D

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www.diogenix.com