

GREAT LAKES DRUG DEVELOPMENT, INC.

A multi-disciplinary team providing
state of the art drug development solutions



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GLDD uses...

...its expertise in drug development to provide clients with knowledge (essential information and analyses) to enable early and confident decision-making

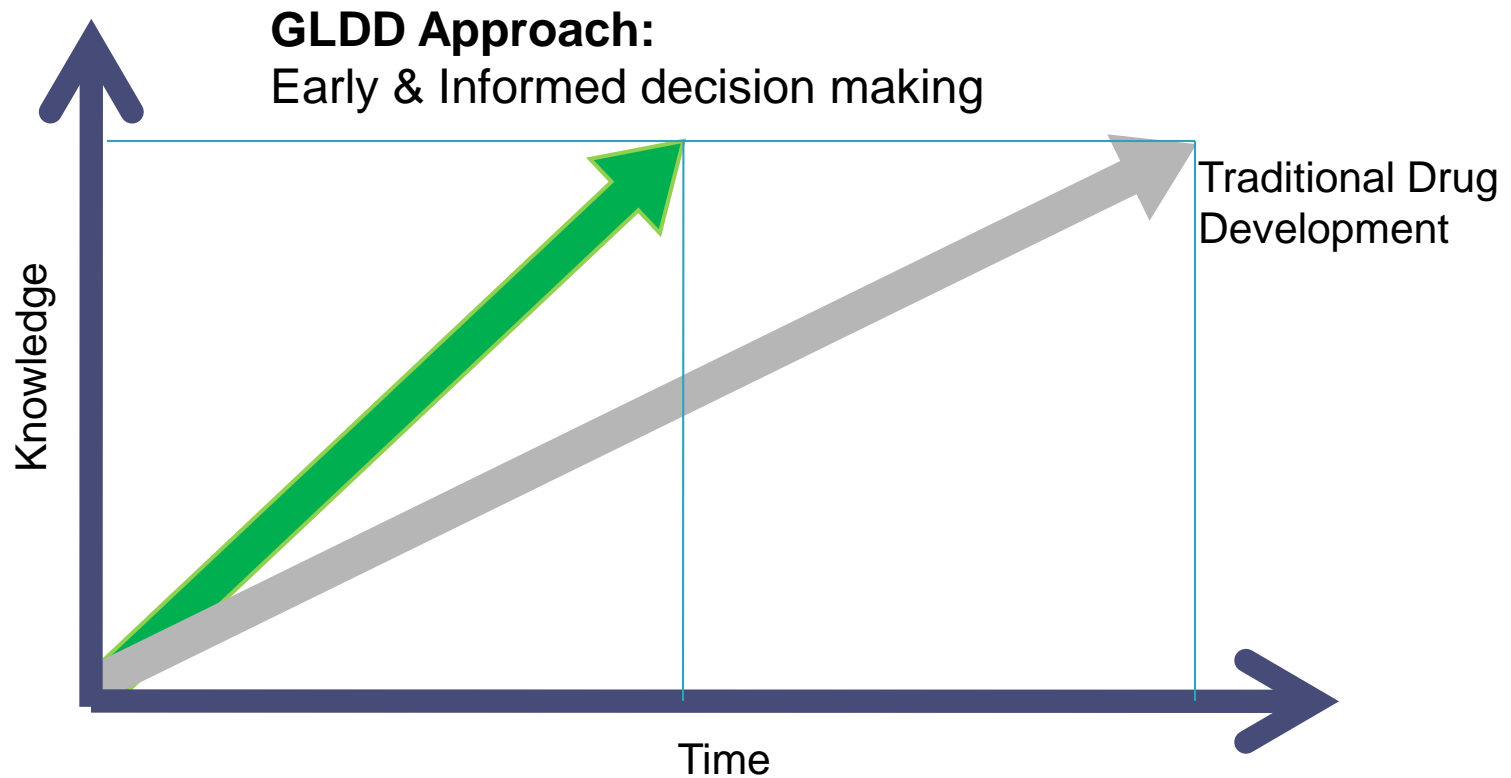


Great Lakes Drug Development, Inc.

"Bridging the Gap in Drug Development"

GLDD's adaptive drug development approach accelerates the accumulation of knowledge vs. traditional approaches

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GLDD's Adaptive Drug Development Approach

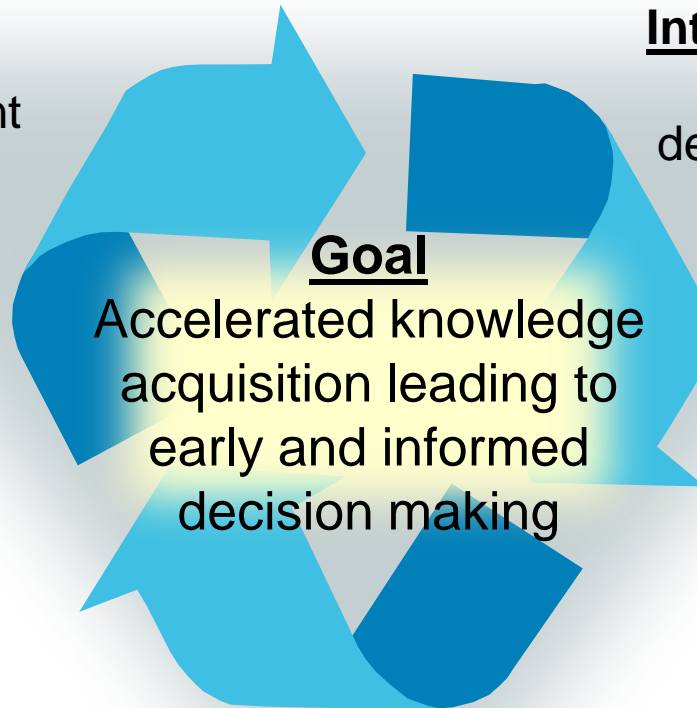
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Analyses

Continuous quantitative assessment of all relevant data converting it to knowledge

Integrated Development Plan

Strategy to address key development, commercial and scientific issues across disciplines.



Data Generation

Execution of the Integrated Development Plan through efficient operations



GLDD is a diverse team with an average of 16 years of drug development experience in large pharmaceutical and biotechnology companies

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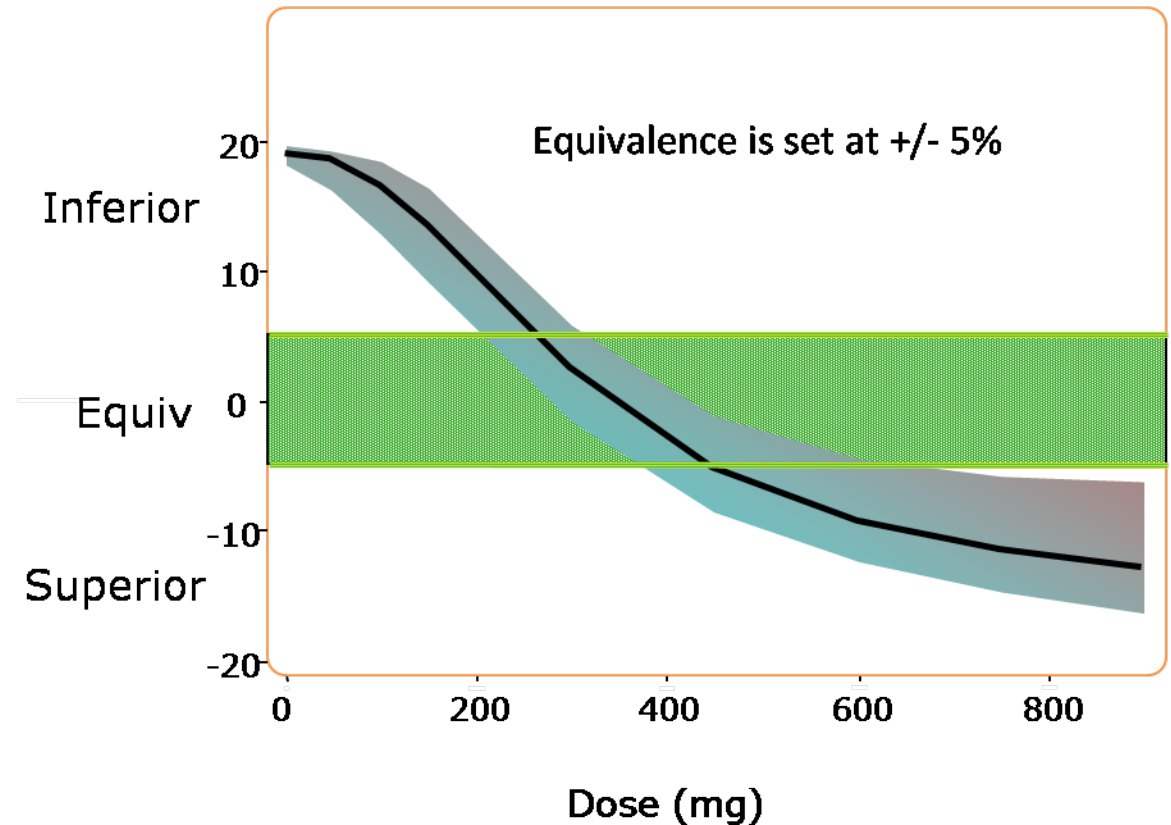


GLDD applies Quantitative Tools to Drive Informed Decisions

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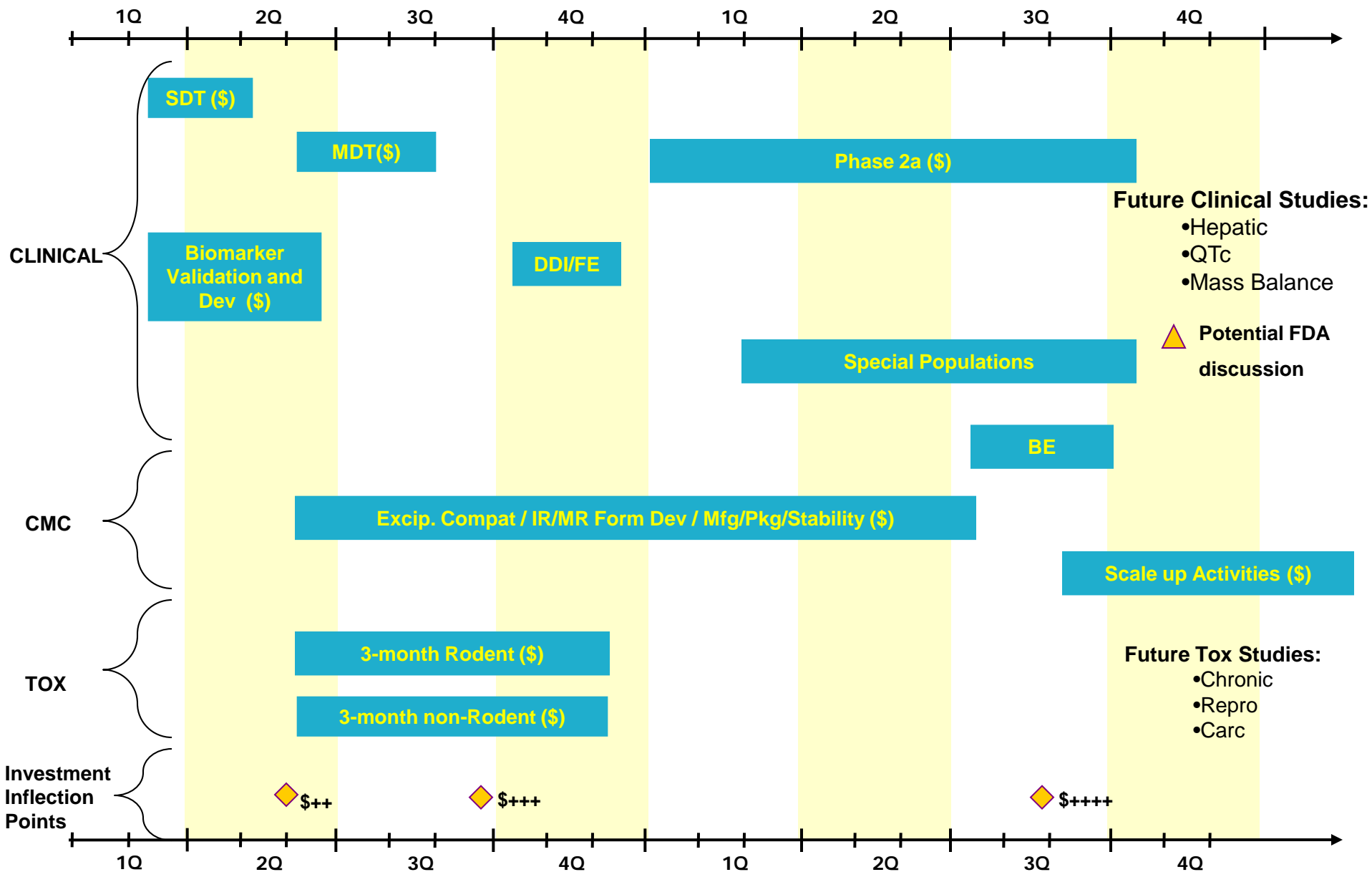
What is the probability that your drug is clinically inferior, equivalent or superior to the competition?

The answer is almost always a function of dose, regimen, patient population, and study design and duration.



Sample Integrated / Adaptive Development Timeline & Budget

(continuously updated based on new knowledge)



Broad Development Experience*

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- Anesthesia
- Biologics
- Clinical Pharmacology / special populations
- CNS / Psych
- Critical Care
- CV / Metabolism
- Dermatology
- First in Human
- Inflammation / Pain
- Oncology
- Ophthalmology
- Respiratory
- Urogenital
- Women's Health



*External TA expertise obtained as needed.

GLDD Strategic Offerings

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- Design integrated, multi-disciplinary adaptive drug development plans
- Utilize Clinical Trial Simulation (drug / disease modeling) to compare the robustness of various study designs
- Quantitative decision support
 - ▣ Modeling of pooled proprietary data
 - Including Real-time data analysis
 - ▣ Modeling of competitor data
 - ▣ Quantitative assessment (including uncertainty) of current product profile with or without comparator data
- Program reviews
- Independent assessment of key go / no-go decisions
- Regulatory strategy for products and Health Authority meetings (e.g. End-of-Phase 2a meetings)



GLDD Operational Offerings

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- Adaptive Drug Development Implementation and Project Management (project team) with the focus on knowledge and investment inflection points
 - Clinical, Non-Clinical, CMC*
- Clinical trial management and/or oversight
 - Study Management
 - Medical Monitoring / Safety
 - Vendor selection, budgets and contracts
 - Biostatistics / Programming and reporting
 - Real-time data acquisition / analysis
 - Supply chain management oversight
 - Data management*
 - Site Monitoring*
 - QA*
- Clinical, pre-clinical PK-PD and toxicokinetic analysis and reporting
- Manage regulatory communications, meetings and filings



*handled via experienced Third Party Providers

GLDD Summary

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- GLDD provides strategic and operational leadership to support drug development projects.
 - Devise efficient, integrated, development strategies focused on key decision points and value creation
 - Execute the development plan through efficient operations
 - Analyze all relevant data utilizing the latest pharmacometric techniques to guide early, informed decision making.



The above services can be tailored to meet the clients needs

Great Lakes Drug Development Inc.

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- **Dan Hartman, MD, President & Chief Executive Officer**
 - 15 years pharma experience including senior positions in Biotech and Big Pharma
- **David Hermann, PharmD, Senior Vice President of Early Development & Pharmacometrics**
 - 20 years pharma experience including Biotech, Big Pharma and Consulting
- **Kevin Hershberger, RPh, MBA, Chief Operating Officer, Dir of Business Development**
 - 14 years pharma experience including Biotech and Big Pharma
- **Don Giesecker, PharmD, Vice President Regulatory Affairs**
 - 24 years pharma experience including Biotech and Big Pharma
- **Peter Van Ess, PharmD, PhD, Vice President Clinical Pharmacology**
 - 16 years R&D experience in Academia, Biotech and Big Pharma
- **Joe Driscoll, PharmD, Senior Director Clinical Operations**
 - 21 years pharma experience in Big Pharma
- **Tom Peppard, MS, Senior Director Biostatistics and Data Operations**
 - 15 years pharma experience in Biotech and Big Pharma
- **Dan Strieter, MS, Senior Director Biostatistics**
 - 15 years pharma experience in Biotech, Big Pharma and Consulting
- **Debra Lemanski, ABA, Operations Manager & Regulatory Affairs Specialist**
 - 10 years pharma experience in Biotech and Big Pharma



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For more information, Please contact us at:

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