



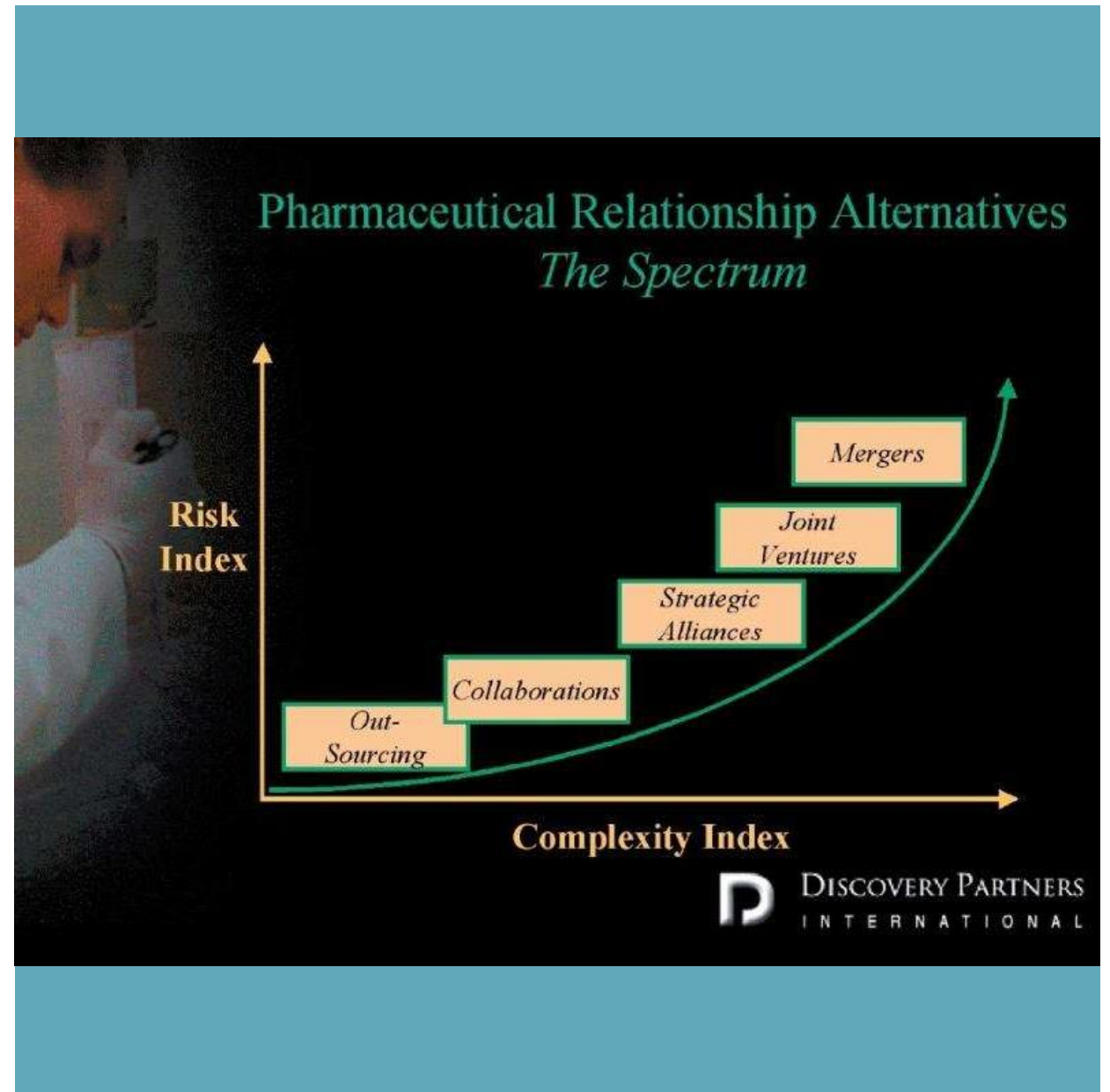
Partnering Clinical Laboratories with Pharmaceutical Companies

Clinical labs and pharmaceutical companies can partner in various ways that benefit both parties.

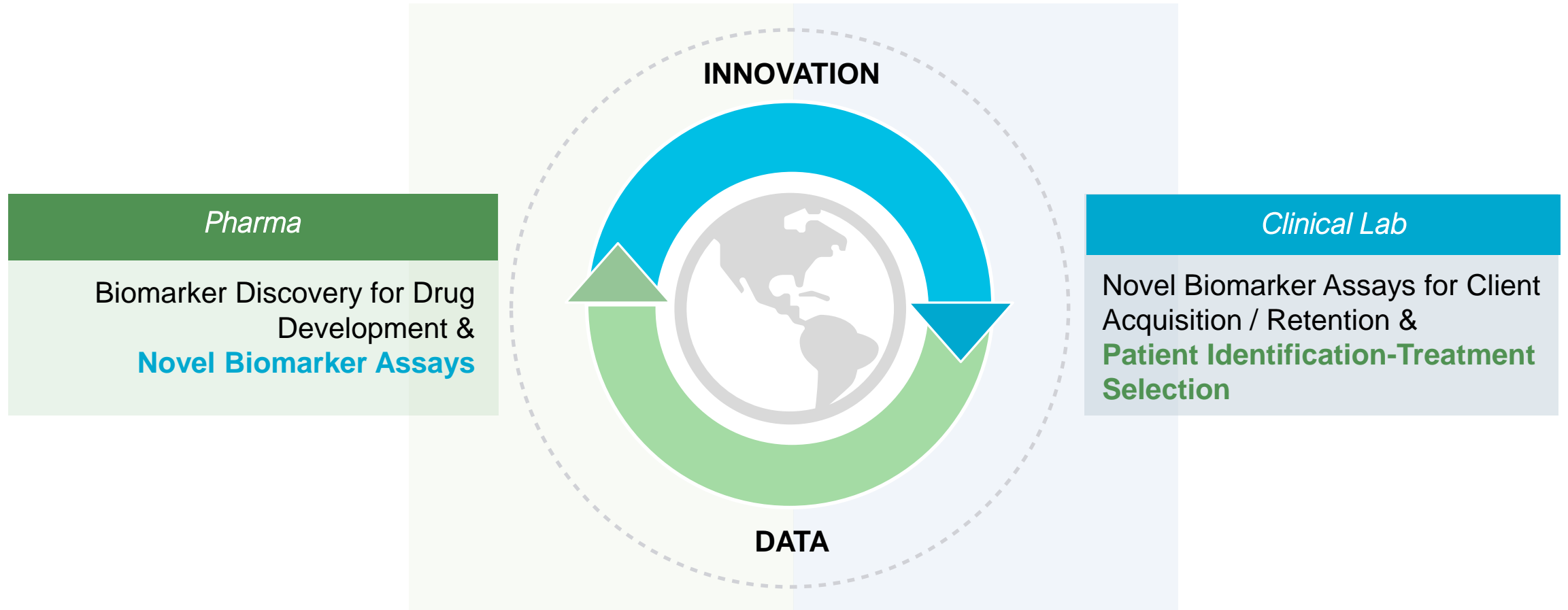
Pharma companies can contract labs to

- conduct clinical trials.
- provide testing services.
- collaborate on assay development.

Labs generate revenue, acquire specimens, and gain insights from working with pharma.



The Lab-Pharma partnership **value creation loop** drives data to fuel innovative products



Benefits for Labs



Additional revenue streams

Partnerships with pharma companies provide new revenue sources through services like clinical trials and testing.



Access to new technologies

Partnering gives labs access to pharma R&D innovations like genomic testing or other novel platforms.



Expanded testing capabilities

Partnering allows labs to validate assays, expanding the lab's testing menu and generating more data

Partnering with pharma provides valuable benefits for clinical labs including new revenue, technology access, and expanded capabilities.

Benefits for Pharma



Real-world data

Pharma companies get access to real-world data on patient selection for their products through precision medicine and R&D



Patient recruitment

Pharma companies can partner with labs to recruit patients for clinical trials



Experimental therapies

Labs provide a way for pharma to test experimental drugs and therapies

Partnering with labs gives pharma companies valuable real-world data, access to patients, and an avenue to test experimental therapies.

Types of Partnerships

- **Clinical trials**

Conducting clinical trials to test new drugs and treatments

- **Companion diagnostics**

Developing diagnostic tests to identify patients who are most likely to benefit from a specific treatment

- **Diagnostic Commercialization**

Providing services that include launching new tests, designing custom result reports, supporting reflexive or panel workflows, providing HCP education, and collaborating in the field.

- **Lab-developed tests**

Creating proprietary diagnostic tests to support clinical trials and new drug development

- **Biospecimen Repositories**

Access to specimens in the community setting from a variety of patient demographics and diversity

- **Data Partnerships**

Supporting various initiatives, including data driven HCP education, drug discovery, and longitudinal data-registry programs

Case Study: LabCorp and Pfizer

Partnering with LabCorp allows Pfizer to sequence patient tumors and identify mutations that can be targeted with Pfizer therapies. This partnership combines LabCorp's genomic profiling capabilities with Pfizer's portfolio of targeted medicines.





Case Study: Miraca Life Sciences and J&J

Serial therapeutic drug monitoring (TDM) is an effective way to personalize biologic treatments for patients living with autoimmune diseases and reduce probability of immunogenicity that can result in treatment switching.

Janssen and Miraca partnered to provide a TDM testing service to gastroenterologists, that included custom monitoring reports and a field education program. The partnership was a win-win; an additional test service to Miraca's GI clients, and a differentiator and excellence in care model for Janssen's REMICADE® patients and HCPs.

Regulatory Considerations



CLIA/CAP guidelines

Clinical Laboratory Improvement Amendments and College of American Pathologists provide quality standards for all US clinical diagnostic laboratories



FDA oversight of LDTs

FDA regulates in vitro diagnostic tests including laboratory developed tests (LDTs)



HIPAA regulations

Health Insurance Portability and Accountability Act provides data privacy and security provisions for safeguarding medical information

Regulatory oversight is essential for ensuring quality, validity and proper use of laboratory test results while protecting patient privacy.

Key Success Factors

Trust

Building trust between partners through open and honest communication.

Shared Goals

Aligning on shared goals and objectives that benefit both partners.

Transparency

Being transparent about capabilities, challenges, and opportunities.

Mutual Benefit

Structuring the partnership for mutual benefit and win-win outcomes.



Future Outlook

Partnerships between clinical laboratories and pharmaceutical companies are expected to increase over the coming years as precision medicine continues to advance.

- Precision medicine allows treatments to be tailored to individuals based on their genes, environment, and lifestyle, leading to improved patient outcomes.
- As more targeted therapies become available, partnerships will allow clinical labs to conduct genetic and biomarker testing to identify patients most likely to benefit from specific treatments.
- In rare diseases, patient identification is especially relevant as timely and accurate diagnoses are critical to access to treatment.
- Beyond diagnosis and prediction, monitoring assays are also important testing programs to successful treatment. Monitoring supports personalized treatment decisions and is sometimes required by health authorities.