



The Diagnostics of Tomorrow ADLM 2024

July 29, 2024

We are a trusted advisor to healthcare and life sciences clients, bringing global best practices and innovative solutions worldwide

Global network of **~6,400** healthcare and life sciences professionals offering diverse skills and talents

30

Countries within the global network offering key geographic-specific insights

Transaction to Transformation

Diagnostics and Life Sciences Tools and Services

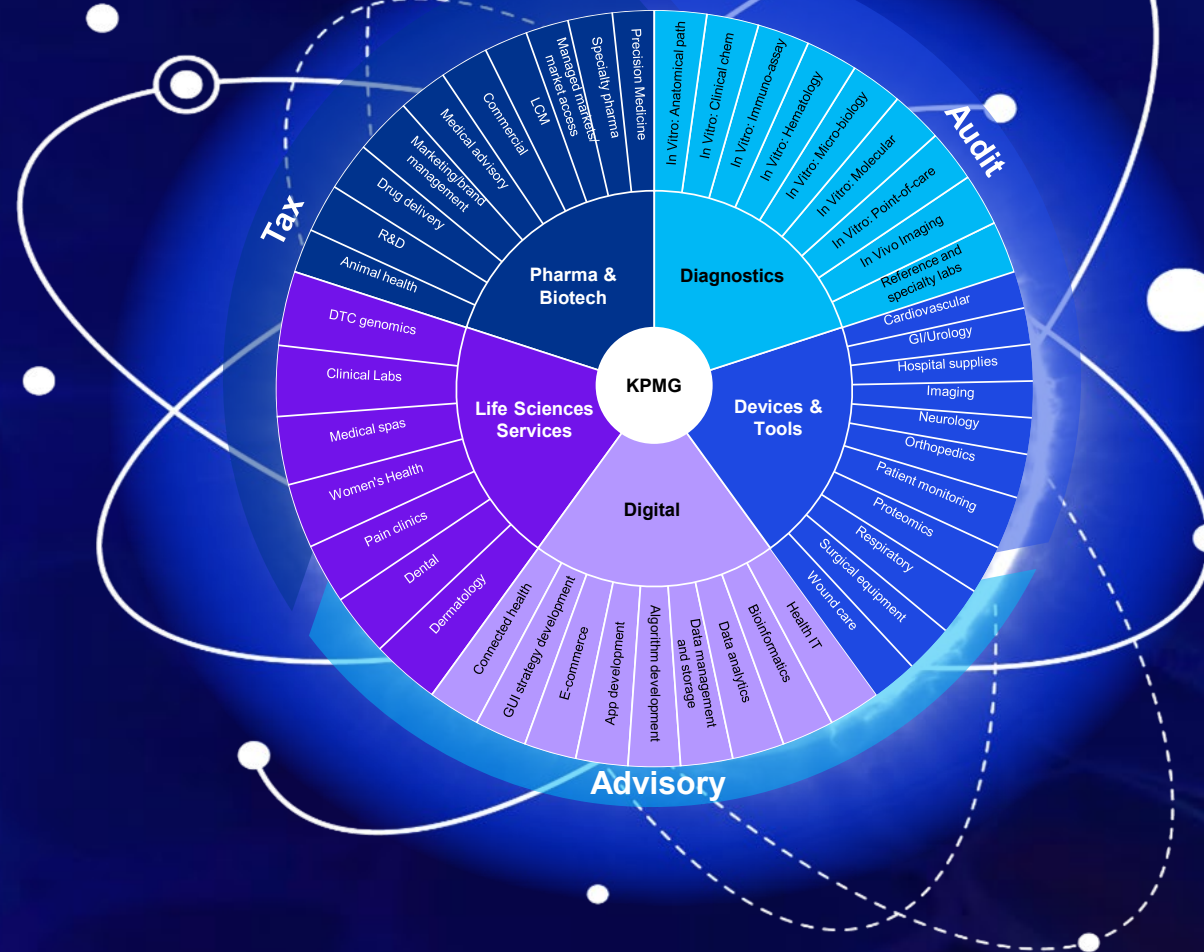
Our experience, our thought partnership, and our proprietary methodologies will take life sciences into the next frontier

Let us be your answer.

With KPMG Life Sciences, you will:

Innovate

Optimize

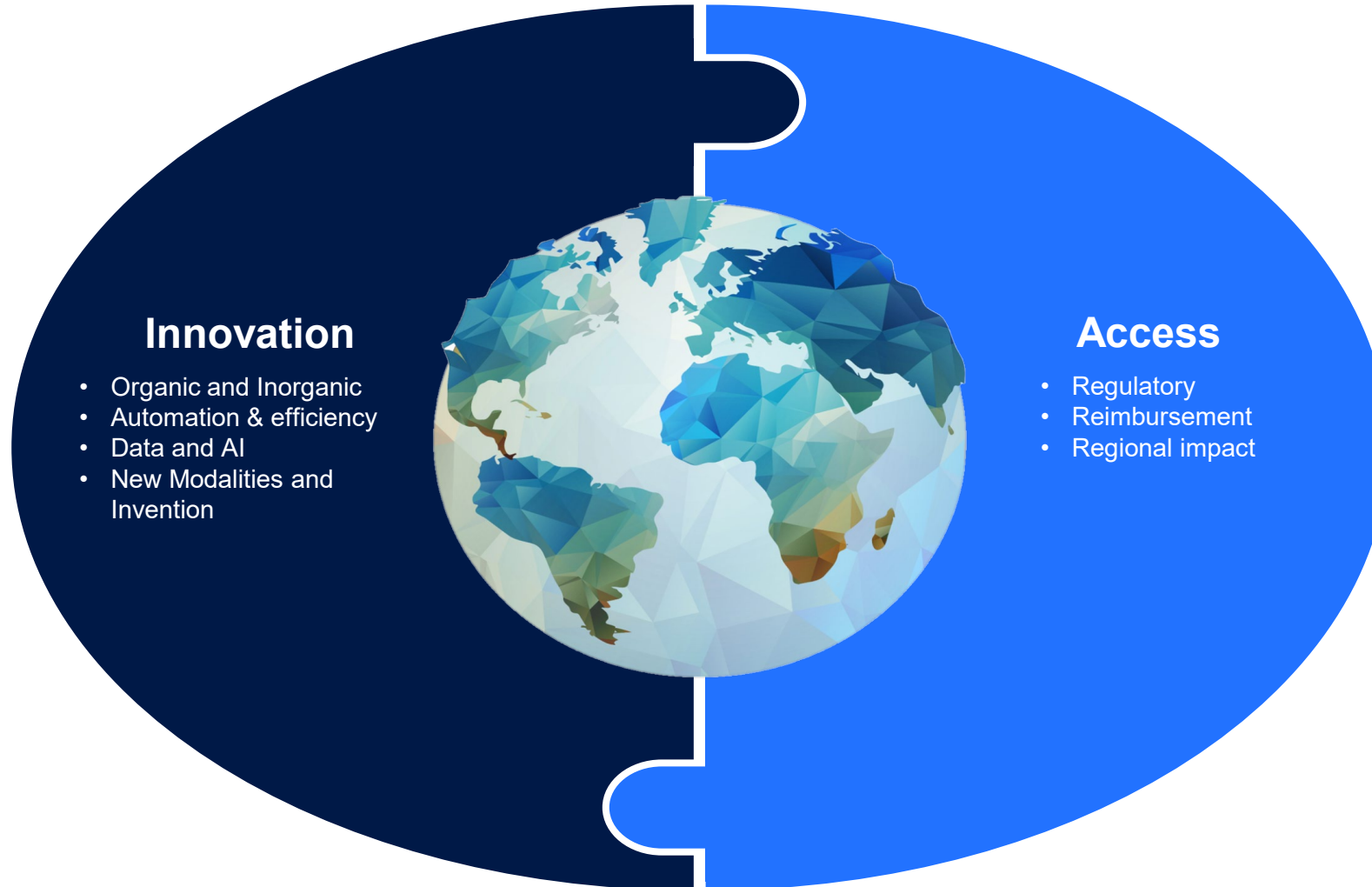


De-Risk



© 2022 KPMG LLP, a Delaware limited liability partnership and a member firm of the KPMG global organization of independent member firms affiliated with KPMG International Limited, a private English company limited by guarantee. All rights reserved.

The diagnostic laboratory medicine community is vital in providing innovation and access to patient populations throughout the globe



Inorganic deals flourished throughout diverse sub-segments of the diagnostic landscape

>100
 2023-2024 LS Dx
 Tools & Services
 Deals

	North America	>50
	Europe	>30
	APAC	>15

>60
 Diagnostic
 Product
 Deals

- Peptides
- Spatial omics platforms
- Neuro IVDs
- Consumables & reagents
- POC testing platforms
- Lab automation
- Sample logistics
- Antibodies
- Home self-test kits
- Cytometry platforms
- Liquid biopsy
- Radioscopic IVDs
- AI-protein design
- Assays
- AI/ML cancer detection
- Nano-based enrichment
- Next-gen sequencing
- Spectroscopy hardware
- Diagnostic software

>40
 Diagnostic
 Lab
 Service
 Deals

- Genetic & genomic testing
- Lab hardware maintenance
- Regulatory audit services
- Target analysis
- Prenatal testing
- Pharmacogenomics testing
- Clinical pathology
- Oncology testing
- Cold-chain storage
- Clinical immunochemistry
- Treatment monitoring



Source: KPMG Deal Advisory Analysis June 2024



From 2023-2024, innovation ranged from traditional cell biology applications to emerging molecular based tools



Cytology

Immunohistochemistry

PCR

CRISPR-based

Sequencing

scientific device laboratory



Printed and coated slide technology

MABTECH



ELIspot cytokine detection technology

3EO HEALTH



Low-cost POC rapid molecular testing

Parse BIOSCIENCES



Single cell pooled CRISPR screen kit

apton



High throughput, short-read sequencing with novel clustering

FLUXION



Fully automated, flow-based live cell imaging

Lunaphore technologies



Fully automated spatial omics and IF

QIAGEN



"Walk-away" automated digital PCR

VEDA BIO

Rapid, ambient temp. detection kits

NORTHERN NANOPORE INSTRUMENTS



Scalable, mobile, variable length nanopore sequencing

Phenomex The Functional Cell Biology Company



Single-cell phenome analysis


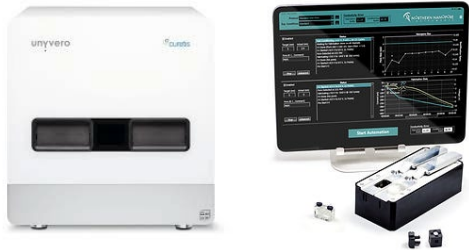


carterra



High throughput antibody characterization

Automated and digital technologies are continuing to increase efficiencies in the lab while allowing patients to track themselves resulting in an increase



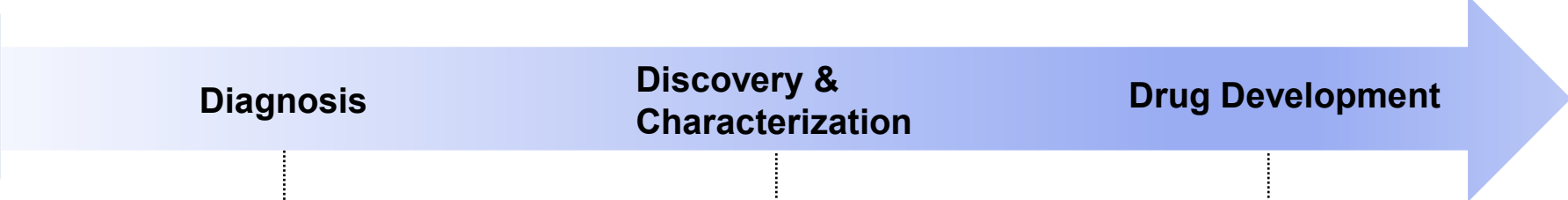
High-throughput automation	Rapid PCR-based Dx & next-generation sequencing	Digital pre-analytics and logistics	Mobile self-tracking
			
<ul style="list-style-type: none"> • High-throughput robotics and modular automation • Critical “work horses” in today’s labs • Systems becoming more sophisticated and connected • Perform advanced protocols while providing real-time feedback and data 	<ul style="list-style-type: none"> • Molecular based rapid detection for high specificity and accuracy • Expanding disease menus • Sample-to-result within minutes • Next-gen long read sequencing for instant sample identification for labs of all sizes and those on-the-go 	<ul style="list-style-type: none"> • Error free digital sample accessioning at the site of collection in the lab or in the field • Real-time courier sample tracking • Sample environment and time sensitivity monitoring all the way to site of testing 	<ul style="list-style-type: none"> • Patients can get real time diagnostics 24/7 • Devices are connected and data is tracked on smartphone devices • Can measure biometric markers like pulse, temperature, oxygen, metabolic, and now even blood proteins
<p><i>More diagnostic data is being produced in real time, faster, and in higher volume than ever before</i></p>			

Source: Company websites; KPMG Deal Advisory Analysis June 2024

Inorganic moves in AI have begun making an impact. AI is expanding not only in diagnoses but also throughout applications in discovery and development





Artificial intelligence and machine learning




Precision Medicine





GEDIcube


Acquired in 2023 by: 

- **AI technology and algorithm** combines multi-omic and multi-modal data
- Has already been validated for early **diagnosis of lung cancer in addition to 12 other cancers** including pancreatic and breast


serotiny

Acquired in 2024 by: 

- **Utilizes computational machine learning**, high-throughput cellular assays, and next-generation sequencing to design proteins
- Serotiny's therapeutic **multi-domain proteins** utilized by Tessera and Janssen pharmaceuticals


DiaGen Ai

Merged in 2024 with: **Linceis Capital**

- **Uses generative AI** in developing drugs and to design new molecules and innovate drug discovery
- **Selected by over 12 pipeline partners** including Adaptv Biosystems, Diag-Nose medica, Signalchem Biotech, and others

Source: Company websites; KPMG Deal Advisory Analysis June 2024

Mass spectrometry is still an essential analytical tool in most clinical lab flows but requires addressing the need for an easy-to-use, fully automated platform



Applications of mass spectrometry
Clinical diagnostics
Proteomics
Metabolomics
Pharmaceutical
Forensic analysis
Environmental analysis

MS services market

- OEM technical expertise
- Maintenance and repair



MS instrumentation product market



- ✓ High throughput
- ✓ Compact, benchtop
- ✓ Digital interface



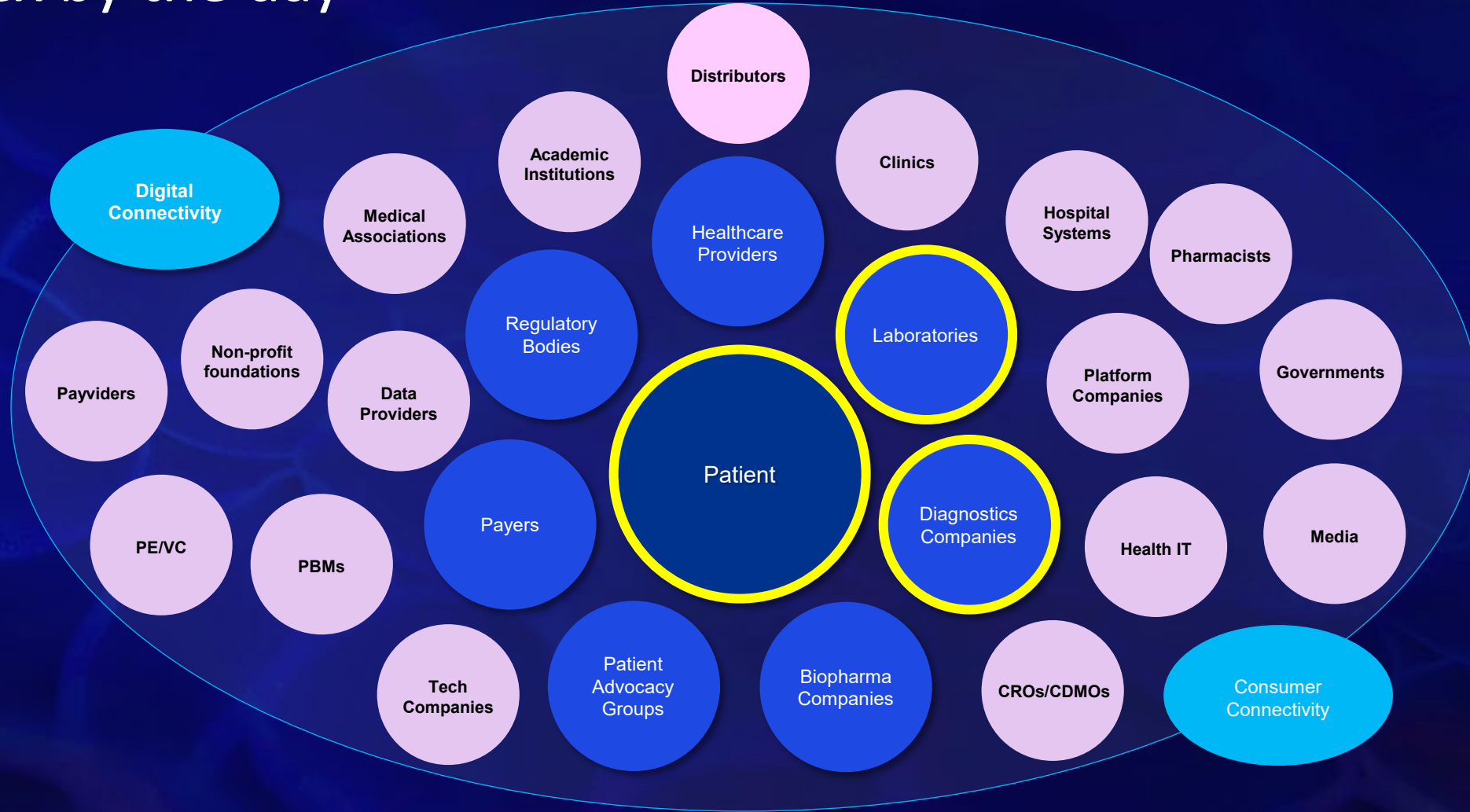
“integration of automation into the proteomics field will continue to become indispensable, providing scientists with a means to explore further”
-GM of robotics company

2024-2025
Fully automated platforms?

“Becoming more user-friendly, standardized, and accessible, a significant challenge for the industry remains the upstream bottleneck of sample preparation”
-Professor and co-director of proteomics, Academia

Source: Company websites; Genetic Engineering and Biotechnology News; KPMG analysis 2024

Despite all of this innovation, the ecosystem around diagnostics continues to expand , making access more complex by the day



Communities worldwide have faced challenges in gaining market access for diagnostic products and services



NIH collaborates with diagnostics manufacturers on obtaining authorization of multiplex tests

June 2024

illumina completes the divestiture of GRAIL

June 2024

FDA Takes Action Aimed at Helping to Ensure the Safety and Effectiveness of Laboratory Developed Tests

April 2024

European Commission welcomes adoption by EU Parliament of measures to improve the availability of in vitro diagnostics

April 2024

Everyone agrees South Korea needs more doctors — except the 9,000 doctors on strike

July 2024

The Clinical and Laboratory Standards Institute Announces the Publication of New Antimicrobial Susceptibility Testing Documents

March 2024

Regulation and policies within the diagnostic landscape impacts major global regions



“The FDA’s lab developed test rule (21 CF809) could be first check on agency’s power post-Chevron”

“The implementation of EDUAMED has made the end of 2024 a year pivotal for regulatory publications affecting the IVD space”

“EU Artificial Intelligence Act (AIA), establishes a legal framework to promote the uptake of “human centric and trustworthy” AI for medical devices, IVDs and other products”

“Mexico’s COFEPRIS 2024 plans seek promote regulatory certainty, improve confidence in its processes, and expand digitalization as a strategy to speed approvals”

“China’s NHTA moves to standardize medical consumable reimbursements is a significant step toward more equitable healthcare access.”

“ANVISA’s 3-year plan for Brazil seeks to adopt the Identification of Medicinal Products (IDMP) standard, to continue its efforts for medical device Unique Device Identification (UDI); and modernize its data platforms”

“India’s National Medical Device Policy 2023 growth strategy ensures access to patient-centric and affordable healthcare products and targets a \$50B market in the next 5 years”



....and affects the overall patient experience, as seen in our precision medicine documentary

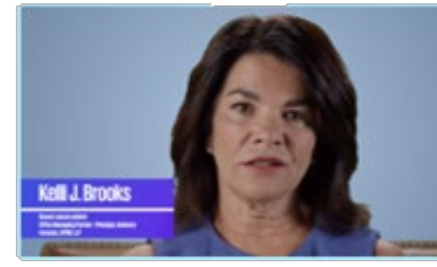
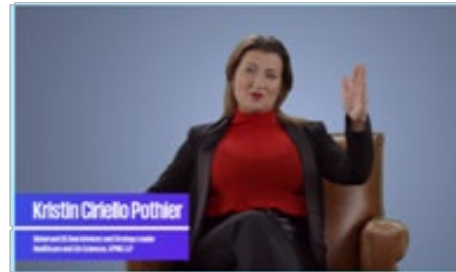
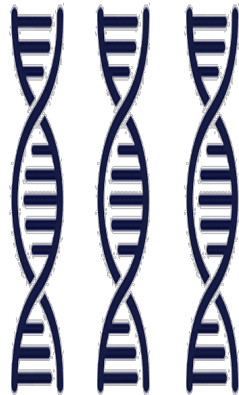


Connections in Precision Medicine

A Documentary by KPMG

Starring:
Patients, Providers, Laboratorians, Payers, and
Industry Executives

Executive Producers:
Kristin Pothier and Alasdair Milton





Speaker Introductions & Program Moderator

Kristin Pothier *Global & National Healthcare & Life Sciences Strategy Leader, Deal Advisory and Strategy, KPMG LLP*



Global IVD Market Update

Mark Girardi *Principal, Head of IVD, Diagnostic Consulting, IQVIA*
Kaitlin Vautour *Consultant, IQVIA*



Data Analytics at Work in the Clinical Lab

Dr. Gabriel M. Garcia *Clinical Innovations Specialist, TriCore Reference Laboratories*



Marci Dop *Vice President of Enterprise Lab Operations, ELLKAY*

Connections in Precision Medicine Documentary
Break/Networking Time



Deal Making in Global Life Sciences

Jessica Lin Partner, Life Sciences Strategy, KPMG LLP



Perspectives on the International Fundraising Environment for Tools and Diagnostics Companies

Christoph Brandenberger Managing Director, BGL & Company



Tony Ebert Laboratory Services & Partnership Director, Mayo Clinic



Martin Verhoef Chief Business Officer, OMAPix



Youssef Helwa CEO, FluidAI Medical



Wrap-up/closing remarks

Kristin Pothier Global & National Healthcare & Life Sciences Strategy Leader, Deal Advisory and Strategy, KPMG LLP

As we kick off ADLM 2024, how are each of us contributing to both sides of this equation in a positive way?

