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Diagnostics are no longer peripheral. They are central to delivering the full value of precision medicine

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Precision medicine increasingly depends on diagnostics that can keep pace with therapeutic innovation while remaining accessible in real-world care. Jonathan Arnold reflects on how QIAGEN approaches oncology and emerging hereditary disease programmes by aligning diagnostic development with pharmaceutical pipelines, prioritising decentralisation, and investing in technologies that support both translational insight and global deployment. The conversation offers a grounded view of how advanced diagnostics move from scientific promise to routine clinical impact.

What has shaped your career at QIAGEN, and how does that experience inform how QIAGEN approaches oncology and precision diagnostics today?

I have been with QIAGEN for nearly 12 years, and my career has consistently sat at the intersection of science, diagnostics, and commercial strategy. For more than two decades, I have worked across molecular diagnostics, companion diagnostics, and pharmaceutical partnerships, with a focus on supporting the development and global deployment of tests that guide targeted therapies. What has remained constant throughout that journey is the motivation to translate complex biology into diagnostic tools that are practical, actionable, and capable of making a real difference for patients. That sense of impact, both at an individual level and through the broader role QIAGEN plays in

healthcare globally, is what has kept me here.

In oncology and precision diagnostics, we position ourselves as a true consultative diagnostic partner to pharma rather than as a provider tied to a single technology. We take a deliberately technology-agnostic approach, developing companion diagnostics across real-time PCR (qPCR), digital PCR (dPCR), and next-generation sequencing (NGS). This allows us to tailor each diagnostic strategy to the specific needs of a clinical programme, rather than forcing a one-size-fits-all solution. Our partners come to us with a defined clinical or trial requirement, and we work closely with them to evaluate the available options, understand the trade-offs, and select the technology that best fits that programme.

Equally important is what happens beyond development. Over more than a decade, we have built strong regulatory and commercial capabilities across all major markets. That means we can support not only the development of a companion diagnostic, but also its global registration and commercialisation. When pharma partners work with us, they are looking for a partner who can operate at a global level and support market access worldwide.

How does QIAGEN balance molecular diagnostics and companion diagnostics today, and how has that balance evolved in recent years?

In oncology, our priorities are largely shaped by the development roadmaps of our pharma partners. By anchoring our planning to their clinical and biomarker strategies, we ensure that our diagnostic programmes evolve in parallel with therapeutic development rather than competing with it. In practice, companion diagnostics and in vitro diagnostic tests follow very similar regulatory and market pathways, since both must be approved and broadly accessible before they can be used in patient care. For that reason, our companion diagnostics work is fully integrated into our broader IVD development model, from early development through global regulatory submission and commercial rollout. Many of our oncology IVD programmes are therefore defined by pharma-led timelines and the need to closely align diagnostic co-development with clinical trials and drug approval pathways.

Over the past three years, an important evolution of this strategy has been our expansion beyond oncology into hereditary diseases. We observed our pharma partners investing heavily in this area, while diagnostics remained comparatively underdeveloped, creating a clear gap. We chose to invest early, recognising that diagnostics would become essential as these programmes advanced. In many ways, hereditary disease today resembles where oncology was ten to fifteen years ago,

particularly in terms of the need for education within pharma around the value diagnostics bring. A significant part of our recent effort has therefore focused on working with different teams across pharma organisations to clarify why diagnostics matter and how they support both development and clinical decision-making.

From a commercialisation perspective, we have also refined how we bring companion diagnostics to market through our Day One laboratory partner network. This network, which now includes around thirty to forty laboratories globally, has been carefully assessed for technical capability, geographic reach, and operational readiness. By engaging these partners well ahead of approval, often up to a year in advance, we enable them to prepare workflows, develop standard operating procedures, and verify assays so that testing is available at the time of drug approval. This approach addresses the long-standing gap between diagnostic approval and routine availability, which has historically delayed patient access by several months. Following this initial launch phase, we then expand availability further into regional and local hospital settings, bringing testing closer to where patient care is delivered.

What needs to happen for advanced diagnostics to move beyond leading academic centres and become a routine part of care in more regional and community-based settings?

For precision medicine to fulfil its promise, access to testing is fundamental. Today, many companion diagnostic markets remain highly centralised, particularly in the United States, where a small number of laboratories handle the majority of oncology testing. That model does not reflect how care is actually delivered, as most patients are treated locally. The resulting disconnect between centralised testing and decentralised care creates delays and limits access, which ultimately affects patient outcomes and the practical impact of innovation.

Technology has been a major driver of this centralisation. Next-generation sequencing has become the dominant approach in oncology and remains essential when broad, multiplex genomic profiling is required. At the same time, these workflows are complex, turnaround times can be long, and costs are high, which naturally concentrates testing in large, specialised laboratories. In many clinical situations, however, the diagnostic question is much more focused, and a narrower assay can deliver a faster and more practical answer.

This is where dPCR plays an important role. Digital PCR offers high sensitivity and precise absolute quantification, making it particularly well suited for targeted applications and longitudinal

monitoring, where clinicians are tracking subtle changes over time. It also brings a simpler workflow, shorter turnaround times, and economics that are closer to qPCR than to NGS. By expanding oncology assay content on QIAcuity and QIAcuityDx, our digital PCR (dPCR) platforms, we are enabling more testing to take place closer to where patient care happens. The objective is not to replace NGS, but to complement it by aligning the technology with the clinical question, which is essential if advanced diagnostics are to become a routine and accessible part of everyday care.

How are liquid biopsy and MRD testing shaping the oncology care continuum, and how do QIAGEN's recent partnerships strengthen its role in this space?

Liquid biopsy has been a major enabler for progress in oncology diagnostics. Access to tissue has always been a constraint, so the ability to work with non-invasive blood samples has opened diagnostic and monitoring use cases that were not previously practical. Minimal residual disease is a particularly strong example. By analysing circulating tumour DNA, MRD testing can detect molecular signs of residual or recurring disease months before anything is visible on imaging. That earlier signal allows care to shift from a reactive to a more proactive model, giving clinicians more time to make informed decisions around monitoring and treatment, with a meaningful impact on patient outcomes. As these tools mature, they reinforce precision medicine by supporting more timely and targeted clinical interventions.

Our collaboration with Foresight Diagnostics is focused on access and scale. Foresight's CLARITY assay is a highly sensitive circulating tumour DNA-based MRD test that has been delivered as a specialised laboratory service, primarily in the United States, with a strong focus on onco-haematology. Through this partnership, we bring the regulatory, manufacturing, and global commercial capabilities required to convert that innovation into a regulated in vitro diagnostic and companion diagnostic kit. The aim is to take an assay that originated in a highly specialised laboratory setting and make it deployable beyond a single central lab, supporting broader use in clinical trials and, over time, routine care, particularly in regions where access to advanced MRD testing remains limited.

The collaboration with Tracer Biotechnologies addresses a potential complementary dimension of dPCR for MRD testing in solid tumors. Tracer has developed assays designed to run on QIAcuity and QIAcuityDx, our digital PCR platforms, and the focus is on defining where dPCR delivers clinical value alongside next-generation sequencing. While NGS remains essential for broad genomic

profiling, there are clear use cases, particularly in longitudinal monitoring once a biomarker is established, where dPCR offers advantages in precision, turnaround time, and ease of deployment. By generating translational and clinical evidence with Tracer and our pharma partners, we aim to support more decentralised MRD testing and bring advanced monitoring closer to where patient care is delivered.

What defines a successful diagnostics-pharma partnership today, and how do those expectations shape how QIAGEN works with its partners?

When pharmaceutical companies evaluate a companion diagnostics partner, the expectations are clear and demanding. This is a complex and high-risk space, and pharma approaches it with a structured checklist. Scientific and technological depth sits at the top of that list. Partners are expected to demonstrate breadth and maturity across multiple diagnostic technologies rather than reliance on a single platform. That is where a technology-agnostic approach becomes critical, as it allows diagnostic strategies to be aligned to the specific needs of each therapeutic programme instead of forcing uniform solutions.

Regulatory capabilities are equally decisive. Regulatory expertise has taken on even greater importance in recent years, particularly in Europe with the transition from the In Vitro Diagnostic Medical Devices Directive (IVDD) to the In Vitro Diagnostic Medical Devices Regulation (IVDR), which significantly raised evidence and compliance requirements across the industry. Addressing this shift requires sustained investment and execution, including advancing IVDR certification across platforms and systems such as QIAstat-Dx and our clinical decision support software, QIAGEN Clinical Insight Interpret, to ensure reliability and continuity for our partners. Intellectula property is also important because pharma needs confidence the diagnostic has freedom to operate, whether through proprietary positions or appropriate licensing.

Ultimately, execution and trust determine whether a partnership endures. Diagnostic and therapeutic programmes are closely intertwined, which means risk is shared and collaboration must be consistent and transparent. A strong track record matters, particularly in navigating the most stringent approval pathways, such as Premarket Approval in the United States, where clinical evidence requirements are rigorous. Commercial reach completes the equation. It is not enough to develop and approve a companion diagnostic, it must also be successfully launched and supported at a global level. For me, the most meaningful measure of success is repeat business, as long-standing master collaboration agreements reflect trust built through delivery over time rather than

promise.

What are your priorities for QIAGEN’s oncology and precision diagnostics business over the next two to three years?

Our focus over the next few years is to further strengthen our role as a partner of choice for pharmaceutical companies, particularly in the development of scalable, kit-based in vitro diagnostic companion diagnostics. This is where we consistently add value, by translating complex science into diagnostic solutions that can be deployed reliably across markets. At the same time, we want to engage with pharma earlier in their development pipelines, which places greater emphasis on building capabilities that support translational research and informed decision-making at earlier stages of development.

The acquisition of Parse Biosciences fits squarely within that strategy. Parse brings scalable single-cell sequencing technology that enables gene expression analysis at the level of individual cells and at significant scale. For us, this strengthens our translational research capabilities today and creates a pathway to explore how single-cell insights could inform future diagnostic development as precision medicine continues to evolve. Alongside this, we remain firmly committed to executing in oncology while deliberately building leadership in hereditary disease, where we are still early but investing ahead of demand. Across both areas, the ambition is consistent: to combine technology breadth, global regulatory execution, and commercial reach in a way that supports durable, long-term partnerships.

How do you see hereditary disease diagnostics evolving, and what broader message would you share with the healthcare and life sciences community?

We are optimistic about hereditary disease because it allows us to apply lessons learned in oncology, particularly around access to testing. In oncology, advanced diagnostics often became highly centralised, which created a disconnect between where testing was performed and where patients received care. In hereditary disease, we have an opportunity to take a different path. By building parts of our strategy around platforms such as QIAstat-Dx, our cartridge-based, sample-to-result system, we can support simpler workflows that are easier to deploy closer to the patient, which is increasingly important for both healthcare systems and pharma partners.

More broadly, diagnostics are no longer peripheral to innovation. They are central to delivering the full value of precision medicine, shaping how patients are identified, stratified, and managed across the care continuum. Our role at QIAGEN is to work closely with partners to ensure that scientific advances are translated into robust diagnostic tools that can be launched globally and used where they matter most. That is how diagnostics move from potential to impact, and how they ultimately help improve outcomes for patients worldwide.

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