The Diagnostic Journey for Rare Disease Patients: Scaling Sustainable Solutions

June 2021
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A Letter from the Sponsor

At Alexion our mission is to transform the lives of people affected by rare disease and devastating conditions. With a nearly 30-year history in rare disease, we hear regularly from rare disease patients and their health providers how frustrating and painful they find what many have called the “diagnostic odyssey.” This term sums up the multiple years, visits, and unanswered questions that many patients must live through to reach an accurate diagnosis.

As the Global Commission to End the Diagnostic Odyssey for Children with a Rare Disease (the Global Commission1) reports, piloting and scaling technologies that leverage digital access to data is a major opportunity to help ease this burden for as many patients as possible. One way that Alexion has advanced our mission over the past five years is through stewardship of Rare Answers™, a set of research collaborations with the intent of taking on the challenges of the diagnostic odyssey. One of the major challenges that faces the creators of Rare Answers™ and other efforts designed to reduce the diagnostic odyssey encounter is the uncertain path to bring them from proof of concept to full scale.

When the Alexion team encountered the lack of a clear roadmap for scaling proven technology, we believed that the topic would benefit from greater cross-system discussion. This paper is the outcome of a workshop Alexion hosted in May 2021 by bringing together a group of leading voices from across the healthcare spectrum, including patient advocacy, clinical research, personalized medicine, venture capitalism, and payor organizations.

Our goal was to have an organized, focused discussion to identify practical, near-term “wins” to make progress in addressing the complex barriers that face those looking to bring technology solutions to shorten the diagnostic odyssey to as many rare disease patients as possible. In particular, the group worked together across 7 identified domains of the health system to answer the critical question: “What can be done in 1–3 years?”

The result was a list of short-term, high-impact approaches to chip away at the barriers between their healthcare teams and access to the best available science and information to make an informed diagnosis. We are grateful to all who attended and hope this paper will help drive this important conversation forward.

Tanisha Carino, PhD, EVP and Chief Corporate Affairs Officer, Alexion

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1 www.globalrarediseasecommission.com
Part I: Framework for Understanding System Challenges in the Diagnostic Odyssey

Identifying the Challenge

On average, it takes 4.8 years and more than 7 specialists for a rare disease patient to get an accurate diagnosis\(^2\). The diagnostic journey is not only exhausting for patients and their family members but also burdensome, costly, and inefficient for the healthcare system. Most importantly, for progressive rare diseases, that 4.8 years equates to delayed treatment and worsened outcomes. Furthermore, the Global Commission has identified the need to pilot and scale technology solutions to speed diagnosis globally as a key priority\(^3\).

Ideal State of Diagnosis for Rare Disease Patients

In an ideal world, diagnosis would occur immediately at birth or symptom onset, treatment and management of disease would be effective, precise, and prompt, and scalable solutions would be streamlined across platforms for all rare diseases. In this ideal world, a technology platform that enables safe data sharing and care coordination would result in optimal patient care. More importantly, a viable solution would include scalable platform/s among all health systems and healthcare providers.

Key Steps in the Ideal Patient Journey

Ideal rare disease patient diagnosis begins with genotypical/phenotypical symptom identification facilitated through robust technology platforms which lead to a rapid and appropriate diagnosis.

Current State of Diagnosis for Rare Disease Patients

Rare disease patients are challenged with delayed diagnosis, misdiagnosis and underdiagnosis. This is largely due to the fact that symptoms among rare disease patients overlap with those of common disorders causing clinicians to focus on the more “obvious” diseases given their

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\(^3\) The Global Commission; Global Commission Progress Update: Rare Disease Day February 2021.
education and training. When patients are not treated properly, they tend to seek answers online, which can provide counterproductive information. Simultaneously, they face constant specialist referrals, creating emotional and economic tolls for patients and their families. Lack of coverage for rare disease diagnosis and varying patient populations also create significant inequities in care. Currently, no scalable platforms are designed to help ease the diagnostic odyssey, and current options in the market lack the ability to reach all patients in need as quickly as possible.

**Key Challenges and Barriers to Scale a Diagnostic Solution**

To better understand the barriers to ensuring more patients have access to a diagnostic solution, the Avalere team conducted qualitative research with workshop participants (see full list in Meeting Summary section) to assess where there may be opportunities for the future. Conversations focused on the current state of rare disease diagnosis, including aspects of technology, timing, and workflow, and examples of fast and accurate diagnosis solutions being done at scale. The output of these discussions married with a landscape assessment of the disease space was used to develop the domains that guided the discussion at the in-person workshop. These domains form an organized method for addressing the challenge at hand and for evaluating options that seek to solve it.

<table>
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<tr>
<th>Domain</th>
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<tbody>
<tr>
<td>High Demand, Complex Needs</td>
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<tr>
<td>Clinician Education</td>
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<td>Data Maturity and Regulatory Barriers</td>
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<tr>
<td>Payment, Coverage, and Reimbursement</td>
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<tr>
<td>Adoption and Workforce</td>
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<td>Equity</td>
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<td>Sustainability</td>
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High Demand, Complex Needs
Innovation in the rare disease space continues to outpace integration into clinical practice, thus fueling demand for tools to rapidly integrate new information and evidence into decision-making. Patients have different needs when it comes to the right level of genetic information needed for rapid genomic sequencing and access to incidental findings.

Clinician Education
The accelerating cycle of discovery within the rare disease space makes it increasingly difficult for physicians to stay up to date with the literature. Physicians need to shift from a symptomatic treatment paradigm to etiology-driven treatments (genetic and proteomic methods) that involve the use of genomic and other comprehensive technologies to identify underpinning causes of disease. The shift will require providers to become more confident and better equipped to use genetic information in clinical care and be able to have discussions with patients, families, and caregivers.

Data Maturity and Regulatory Barriers
Patient privacy is a concern across the healthcare system, but unique concerns around the disclosure and use of data related to rare disease patients is paramount given the low prevalence of many rare diseases. A lack of physician data sharing and data interoperability is a continued barrier within rare disease, since patients may see multiple specialists along the diagnostic odyssey each of whom is typically unable to share previous data with new providers due to consent form limitations and privacy laws—adding unnecessary burden to the diagnostic challenge.

Payment, Coverage, and Reimbursement
Substantial barriers exist in relation to coverage, namely, payers requiring some form of savings to offset the cost of Next Generation Sequencing / Whole Genome Sequencing. Often, savings to offset high-cost diagnostics are recognized across the patient journey, which may not align with the period in which payers measure return on spend. This leads to lack of coverage, and that creates a barrier to access since patient out-of-pocket costs may be prohibitive in many circumstances—relegating the use of technologies to those patients with the means to afford access. Further, a lack of

“It’s easy to diagnose the things we already know about, but very difficult to diagnose the things we don’t.”

“Clinicians are still being taught the way we were educated 50–60 years ago, but the world has changed, and technology has changed. We need to change to align with the times, and we need to change our education system.”

“We don’t know how insurance companies are going label us if they have access to our data and know that 10 years from now, we have this disorder or that disorder.”

“When we talk to payers, in the diagnostics aspects, they are still not convinced. Clinical utility, implementation, and patient utility are three areas we get pushback. If you can go to a payer and say we have all three, the discussion will be over.”
precise reimbursement codes for most rare diseases creates an additional strain on the reimbursement process given there are only ~500 ICD-10 codes for approximately 6,000–8,000 rare diseases.\footnote{National Institutes of Health - National Center for Advancing Translational Sciences, ICD Coding for Rare Diseases}

**Adoption and Workforce**

An ever-growing shortage of geneticists, bioinformaticians, and genetic counselors make it important for the integration of technology as part of a solution if scale is to be achieved. What is needed is a technology resource that is part of the clinical workflow that provides universal insight to clinicians beyond tertiary care centers; this could afford a major step forward for the systematic diagnosis and treatment of patients with a rare disease. A technology solution that is evidence based could alleviate concerns clinicians have around misdiagnosis and liability.

**Equity**

Disparities in care for rare disease patients, like many other disease areas, continue to be a significant issue. Geographic barriers such as distance to tertiary care and genetic testing centers disproportionately impact sub-populations. Further, there is a lack of representative data in existing genetic sets from minority racial and ethnic patient populations which can result in higher rates of inconclusive diagnosis or further extension of the diagnostic odyssey for communities of color.

**Sustainability**

Individual disease patients represent a low volume, small population that is inherently challenging to the development of diagnostic and treatment solutions, specifically because the costs per patient are high and patient density is typically very low. In aggregate, however, they represent a very large and costly population that is underserved relative to those who suffer from more common diseases. A national or regional learning health system can achieve significant value by sharing data and findings across health systems, generating insights by aggregating vast sets of phenotypic, genetic, and longitudinal clinical information to mine cohorts with individual, rare genetic diseases. This learning network has the potential to share best practices among similar patient populations to produce actionable insights.

\begin{quote}
“In the future, we want to identify a genetic disease before the onset of symptoms. We would like to diagnose these diseases earlier before they become symptomatic.”
\end{quote}

\begin{quote}
“Individuals with resources have an opportunity to get an instant diagnosis. As a result, most [non-wealthy] Americans don’t have access to diagnosis options. There’s no doubt about the clinical utility. It’s now a matter of equity and justice.”
\end{quote}

\begin{quote}
“Embedding a technological solution into a health system gives you leverage to better understand the nuances of an individual system and make you a valuable partner with the providers”
\end{quote}
Part II: So, Now What?

This thoughtful and idea-provoking discussion among workshop participants (full roster found in Part IV. Meeting Summary) validated that much work still needs to be done across the identified domains. When it comes to accelerating the diagnosing of rare disease, collaborative problem-solving could not be more important. Only through innovative partnerships among patients, physicians, healthcare systems, academia, payers, pharmaceuticals, and the government can the diagnosis and treatment of rare disease address inequitable populations and be scalable to benefit patients around the country and the world.

### Rare Disease Findings

#### Rare Disease as an Example, not an Outlier
Participants noted by addressing the challenges identified, the benefits can go well beyond addressing only the needs of the rare disease community. By looking at these system level issues from the point of view of rare disease patients, we can identify and address pitfalls in the larger health care system. Repairing those problems will result in benefits for patients and providers to deliver more focused care.

#### Learning from Other Examples of Scale: Oncology and More
Oncology is more advanced than rare disease in integrating technology into diagnosis. Examples of what has worked in the cancer space that could be applied to rare disease include exploration of benefits and costs for licensing platforms to coordinate care, recognition that collaboration is critical to accelerate innovation, integration of diagnosis and management into an electronic environment that supports telehealth capabilities, use of virtual tumor boards and other advanced diagnostic technologies, and expansion of clinical trial enrollment.

#### An Issue of Adoption, not Discovery
Workshop participants were vocal in recognizing that challenges ahead are linked to application, integration, and adoption, as the science to enable more accurate diagnosis is largely in reach. Therefore, opportunities for meaningful progress by addressing sustainability, equity, adoption and workforce, payment, coverage and reimbursement, data maturity, clinician education and regulatory barriers are urgent for rare disease patients. The patient community is looking to policymakers, technology vendors, manufacturers, payers, and health systems to advance the science and provide a more timely and precise diagnosis.

### Health System Findings

#### Specific Yet Durable Framework
All healthcare discussions involve overlapping, complex systems. Using the domains identified allows for a holistic yet focused approach to identifying challenges and solutions, and a means of pivoting from “admiring the problem” to focusing on “bite-sized” parts of the solution. The domains identified are a result of rare disease specific issues, but most hold utility for characterizing many health system challenges and may be useful outside of rare disease.

#### Scale as a “Flywheel”
Scaling solutions is often an incremental approach, but one with exponential trajectories, where broader use leads to decreased costs and increased quality at greater scale. Identifying 1–2 major “leaps” for diagnostic technology adoption may be a fertile area for further discussion.

#### Need for Global Approaches
While this paper focused primarily on steps to take in the US, participants noted the issues identified are global in scope. Ample opportunity is available for further discussion that identifies approaches to implement solutions globally, while simultaneously understanding the challenges and learnings with rare disease diagnosis and scale. Collecting de-identified genetics data across all regions and races would also benefit future research into rare diseases.
Part III: Call for Action

Participants were excited about the value and shared urgency moving forward, especially appreciating the unique diversity of voices and the action-oriented nature of the conversation. Several noted this was the first of its kind of conversation, addressing critical issues where there was clear consensus on some topics and divergence on areas that require attention.

100% of participants said they would participate in a continued discussion on the diagnostic odyssey

Future Research: Although rare disease diagnosis may still feel new, diseases across the healthcare spectrum have faced similar challenges. Utilizing innovation, best practices, and health system collaborations we have seen in other areas—both healthcare and non-healthcare—it may be possible to accelerate diagnosis and spread best practices alongside the use of technology.

Policy: A sustainable approach to rare disease diagnosis necessitates an overwhelming demand for collective action among payers and other stakeholders to address coverage and payment barriers for patients (one of the largest challenges to appropriate diagnosis). Policymakers may consider a vehicle to build consensus (e.g., consortium of payers) to discuss shared benefits of genomic sequencing and viable solutions to address the problem (e.g., shared pool of genetic data).

Implementation: Urgency to engage the global community is an important factor for scaling solutions to underserved regions of the world. In many cases a patient’s life is dependent on a known solution. If individuals across the globe are working to solve for this, shared experiences and learnings have an opportunity to extend a patients’ life. Especially in the cases of technology development and implementation, finding an optimal, scalable, and accurate technology is a shared goal among stakeholders in this community.

Key Elements of an Ideal Technology Environment

This is only the beginning of the discussion, not the end. Many of the meeting participants and the individuals with whom we had an opportunity to speak noted that they would fight this battle until the patient community consistently experienced a predictable, convenient, and consistent
model of accurate diagnosis, timely treatments, and accessible medications. The joint energy to address rare disease diagnosis is the foundation for how this work will continue.

Part IV: Meeting Summary

On May 3, 2021, Avalere Health and Alexion Pharmaceuticals convened 15 individuals with strong backgrounds in rare disease, technology solutions, and venture funding to discuss The Diagnostic Journey for Rare Disease Patients and Ways to Scale Sustainable Solutions. The event featured multi-stakeholder input devoted to improving the experiences of rare disease patients and focused on the identification of optimal solutions to streamline the patient journey. The goals of the event were to generate discussion on the challenges and barriers to a scalable solution alongside opportunities to address these challenges in the short and long term that potentially will yield faster diagnoses of diseases.

**Host:** Tanisha Carino, PhD, Executive Vice President, Chief Corporate Affairs Officer, Alexion Pharmaceuticals

**Moderator:** Lisa Suennen, Lead, Digital and Technology Group Senior Managing Director, Manatt Health Leader Partner, Manatt Venture Fund

**Workshop Participants:**

**Edward Abrahams, PhD**
President, Personalized Medicine Coalition

**Uzma Atif, PhD, MPH**
Scientific Director, R&D Center for Health Equity & Patient Affairs, Chief Medical Office, Takeda; Secretariat Member, Global Commission to End the Diagnostic Odyssey for Children with a Rare Disease

**Sharon Barr, PhD**
Senior Vice President, Head of Research, Alexion

**Alan Beggs, PhD**
Director, Manton Center for Orphan Disease Research, Boston Children’s

**Joel Dudley, PhD**
Chief Scientific Officer, Tempus

**Lisa Edelmann, PhD, FACMG**
Chief Diagnostics Officer, Sema4

**Stephen Kingsmore, MD, DSc**
President/CEO, Rady Children’s Institute for Genomic Medicine

**Walter Kowtoniuk, PhD**
Venture Partner, Third Rock Ventures

**Sebastien Lefebvre**
Senior Director Data Sciences, Genomics and Bioinformatics, Alexion

**Craig Martin**
Chief Executive Officer, Global Genes

**Anna McCollister**
Head of Patient Community Engagement and Empowerment, Invitae

**Banu Sankaran, PhD**
Head of Diagnostics Strategy & Development, Alexion

**Ryan J. Taft, PhD**
Vice President, Scientific Research, Illumina Inc.

**Vanessa Vogel-Farley**
Research and Development Strategy Lead, Rare-X
Scalable Solutions Addressing Optimal Diagnosis of Rare Disease Patients: “What can be done in 1–3 years?”

Workshop participants brought energy and passion to the discussion as they contributed to conversations about areas on which they have focused to advance innovations in rare disease diagnosis. To gain perspective on getting to specific solutions, participants ranked the ideas discussed at the meeting around a few key questions.

The poll addressing which domain represents the biggest impediment to progress over the next 3 years closely mirrored findings from the primary and secondary research. Payment, coverage, and reimbursement was noted as the biggest barrier to advancing rare disease diagnosis, followed by data maturity and regulatory challenges. Of note, equity received zero votes from participants as being an impediment to progress, showcasing that equity is not only a rare disease issue. Access to equitable care clearly has an impact on the larger healthcare system.

One attendee noted, “[the] discussion is about rare disease, but really, it’s generally a structure problem about our healthcare system. [Addressing] disparities in care will not only solve rare disease challenges but also address other healthcare problems, which is a good thing because there might be bigger market incentives to solve the larger issues.”

To offset the initial question, the discussion transitioned to where there has been success. Workshop participants were polled on which area has had the greatest progress over the last 3 years. Responses highlighted that data maturity and regulatory barriers (6) ranked highest followed by the area of innovation, high demand, complex needs (3). Interestingly, the data
maturity and regulatory domain was seen by participants to be one of the largest barriers in the next 3 years as well as having made the most progress in the past 3 years.

Participants were divided into breakout groups to brainstorm and discuss actionable opportunities to address each of the barriers. Breakout conversation initially focused on the current paradigm, however, in talking through potential solutions participants were able to shift seamlessly to thinking about the optimal state of rare disease diagnosis.

### Most Actionable Opportunity to address Payment, Coverage and Reimbursement

<table>
<thead>
<tr>
<th>Action</th>
<th>Score</th>
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<tbody>
<tr>
<td>Collective action solution for and among payers</td>
<td>7</td>
</tr>
<tr>
<td>Development of diagnostic evidence</td>
<td>5</td>
</tr>
<tr>
<td>Amortizing costs for expensive treatments over time</td>
<td>3</td>
</tr>
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</table>

Workshop participants expressed an overwhelming need for a collective action among payers to address coverage and payment barriers for patients (e.g., payers coming together to align on paying for rare disease diagnosis). Specifically, there was consensus on the need to build a consortium of payers to discuss shared benefit of genomic sequencing and develop solutions to address the problem (e.g., shared pool of genetic data). Participants found consensus in the opportunity to develop new health outcomes and economic research (HEOR) studies to solidify the cost–benefit analysis for early diagnosis/treatment of rare disease pts.

### Most Actionable Opportunity: Data Maturity and Regulatory Barriers

<table>
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<th>Action</th>
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<tbody>
<tr>
<td>Rapidly persuade regulators and payers that this is economically high-value for the system and for patients*</td>
<td>11</td>
</tr>
<tr>
<td>Patient-focused HITECH act</td>
<td>4</td>
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</table>

Participants commented on the need to extend patient protections that guarantee non-discrimination and pre-existing condition coverage to move ahead with genetic sequencing. Participants identified the need for legislation giving patients’ access to their own data so codification of privacy rights can be established, similar to the HITECH act that enforces such provisions (*Discussion of barriers shifted toward reimbursement and value, which were not part of the data maturity and regulatory barriers Domain. Therefore, remaining solutions are highlighted above).*
Workshop participants agreed that it is critical to ensure physicians are engaged and know what to do with testing results. Clearer instructions are needed on how to order tests, especially at the primary-care level. Not every physician is up to date on digesting literature, so they need to be engaged through continuous medical education (CME) and other types of accreditation activities. Finally, participants wished for clear and easy-to-understand education in different formats for physicians with varying needs, especially for this patient population.

Currently, adoption is largely driven by the “fear of missing out.” The day-to-day value and financial benefit must be demonstrated for adoption to be on a scalable level, especially to physicians. The discrepancies between diagnosing and treating rare disease patients in the outpatient and inpatient settings must be considered, as there are challenges to secure approvals, technology use, etc. in the outpatient setting.

Workshop participants talked about the importance and relative scarcity of genetic counselors who are well educated to understand and interpret the complex genetic information for patients. One possible solution is that a common database can be created based on the information collected, which can be used for predictive diagnosis. Others talked about the need of having a federated data model. Advocacy on behalf of individuals is also important, especially entities not tied to payers or pharmaceutical manufacturers that can represent the patient voice.

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### Most Actionable Opportunity: Clinician Education

<table>
<thead>
<tr>
<th>Educational need</th>
<th>Score</th>
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<tbody>
<tr>
<td>Educating on when, which and what tests to order and why</td>
<td>7</td>
</tr>
<tr>
<td>Need for a clinician engagement component as part of CME</td>
<td>5</td>
</tr>
<tr>
<td>Make it easy for clinicians to understand</td>
<td>3</td>
</tr>
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### Most Actionable Opportunity: Adoption and Workforce

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<th>Adoption/Workforce need</th>
<th>Score</th>
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<tbody>
<tr>
<td>Demonstrate Financial Benefit to Institution</td>
<td>10</td>
</tr>
<tr>
<td>Demonstrate Overall Value to Clinicians (e.g., time, energy, patient satisfaction)</td>
<td>5</td>
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### Most Actionable Opportunity: High Demand, Complex Needs

<table>
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<tr>
<th>Complex need</th>
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<tbody>
<tr>
<td>Create a common database that can be used for predictive diagnosis</td>
<td>8</td>
</tr>
<tr>
<td>Standardized whole genome testing</td>
<td>4</td>
</tr>
<tr>
<td>Advocacy on behalf of individual navigating health care</td>
<td>2</td>
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### Most Actionable Opportunity: Sustainability

<table>
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<tr>
<th>Sustainability need</th>
<th>Score</th>
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<tbody>
<tr>
<td>Registries of patients</td>
<td>7</td>
</tr>
<tr>
<td>Cost avoidance demonstrated in health systems</td>
<td>5</td>
</tr>
<tr>
<td>Subsidized business model</td>
<td>3</td>
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</table>
Registries of patients with more granular ICD-10 codes and automated ways to describe phenotypes along genotypes were focal points of discussion. Participants discussed the importance of consortiums with clinicians and developers, the availability of generics, and a subsidized business model to support the expanded use of technologies to accelerate diagnosis. Implementation studies to demonstrate scaling among diagnostics are lacking.

**Most Actionable Opportunity: Equity**

- Subsidize whole genome sequencing towards clinical utility: 7
- Dedicated effort to educate disparate communities, meeting…: 3
- Recruit/incentivize communities of color to join genetic…: 3

Workshop participants stressed the importance of exploring innovative ways to make whole-genome sequencing more accessible. It is important to reduce cost at the individual or plan level. Dedicated efforts to educate patients close to their communities, such as community churches are also needed. Finally, recruiting and incentivizing communities of color to join the genetic workforce can help spread information and address current equity concerns.
Avalere is a vibrant community of innovative thinkers dedicated to solving the challenges of the healthcare system. We deliver a comprehensive perspective, compelling substance, and creative solutions to help you make better business decisions. As an Inovalon company, we prize insights and strategies driven by robust data to achieve meaningful results. For more information, please contact info@avalere.com. You can also visit us at avalere.com.

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