

Biomarker Testing Coordination Services: An Oncology Guide

By Adrien Laurent, CEO at IntuitionLabs • 11/15/2025 • 35 min read

biomarker testing

precision medicine

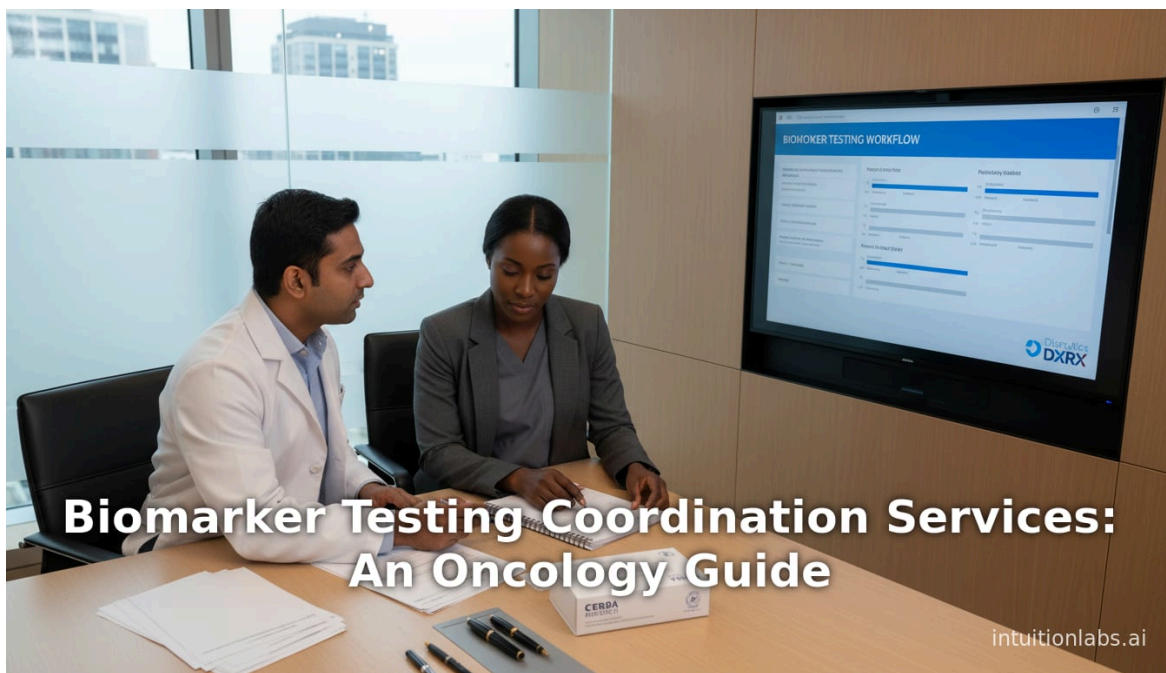
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patient navigation

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Executive Summary

Biomarker testing coordination services encompass the people, processes, and systems dedicated to ensuring that patients who need biomarker tests – particularly in oncology and [precision medicine](#) – receive the right tests at the right time and that results flow seamlessly to clinicians. In recent years, the explosion of actionable biomarkers for diseases like cancer has vastly increased testing complexity. Studies find that **≈50% of non-small cell lung cancer (NSCLC) patients do not receive all recommended biomarker tests**, and many tested patients still face delays or incomplete panels (^[1] [pmc.ncbi.nlm.nih.gov](#)) (^[2] [pmc.ncbi.nlm.nih.gov](#)). Common failures include pre-analytic sample issues and fragmented workflows, leading to **10–20% test failure rates** (with up to 90% of failures due to pre-analytical problems) (^[3] [pmc.ncbi.nlm.nih.gov](#)) (^[2] [pmc.ncbi.nlm.nih.gov](#)). These gaps directly affect outcomes: targeted therapies guided by biomarkers can yield response rates over 60% and median survivals beyond 5 years in NSCLC (^[4] [pmc.ncbi.nlm.nih.gov](#)), but delays or omissions in testing can forfeit these benefits.

To address such challenges, many stakeholders have developed coordination roles and services. For example, **laboratory “biomarker testing navigators”** – [specialized professionals](#) within pathology labs – can oversee test ordering, specimen management, and result reporting to [streamline multistep workflows](#) (^[5] [academic.oup.com](#)) (^[6] [sponsored.harborsidestudio.com](#)). **Patient and nurse navigators** play complementary roles on the clinical side, educating patients and scheduling procedures to prevent gaps in the testing pathway (^[7] [sponsored.harborsidestudio.com](#)) (^[8] [jons-online.com](#)). On the organizational level, integrated networks and digital platforms have emerged: [contract research organizations \(CROs\)](#) offer **global laboratory networks** that consolidate diverse lab services under one umbrella (^[9] [www.cerbaresearch.com](#)), and industry consortia (e.g. Diaceutics’ DXRX) provide shared tools to align pharma, labs, and diagnostics companies on test adoption and quality (^[10] [www.diaceutics.com](#)) (^[11] [www.diaceutics.com](#)).

This report provides an in-depth analysis of biomarker testing coordination services, covering historical evolution, current models, evidence and data on their impact, and future prospects. It includes: (1) **Background on biomarker testing** and why coordination has become critical; (2) **Operational challenges** in the testing pathway (e.g., sample logistics, information handoffs, regulatory and reimbursement barriers); (3) emerging **roles and frameworks** (laboratory navigators, nurse/patient navigators, coordinated lab networks, digital platforms, and policy initiatives); (4) **Data and case studies** illustrating the benefits of coordination (e.g., improved turnaround times, guideline adherence, patient access); (5) **Implications for policy, practice, and innovation** (such as the need for standardized ordering systems, training programs, and equity-focused policies); and (6) **Future directions** (including artificial intelligence support, liquid biopsy integration, and global collaborations).

Citations are provided throughout from peer-reviewed studies, expert reports, and industry data. We begin with foundational definitions and context.

Introduction and Background

Definition of Biomarkers and Importance of Testing

Biomarkers are broadly defined as “a characteristic that is measured as an indicator of normal biological processes, pathogenic processes or responses to an exposure or intervention” (^[12] [pmc.ncbi.nlm.nih.gov](#)). In oncology and precision medicine, biomarkers include genetic mutations, protein expressions, or other molecular features that can guide diagnosis, prognosis, or treatment decisions. The FDA/NIH BEST Resource clarifies that

biomarkers may be diagnostic or predictive of therapy response (^[12] pmc.ncbi.nlm.nih.gov). For example, in lung cancer, biomarkers such as EGFR, ALK, ROS1, BRAF, and PD-L1 critically inform which targeted drugs or immunotherapies to use (^[13] pmc.ncbi.nlm.nih.gov) (^[14] sponsored.harborsidestudio.com). The advent of **next-generation sequencing (NGS)** and other high-throughput methods has expanded testing from “one gene at a time” to broad panels covering dozens of actionable alterations (^[15] pmc.ncbi.nlm.nih.gov) (^[13] pmc.ncbi.nlm.nih.gov).

Biomarker tests have become indispensable: they enable **early detection**, predict drug efficacy, and spare patients from ineffective therapies. **Clinical outcomes** underscore their value. For instance, among NSCLC patients with EGFR mutations, those treated with targeted EGFR inhibitors see markedly improved survival (^[14] pmc.ncbi.nlm.nih.gov). Similarly, high PD-L1 expressers receiving checkpoint inhibitors achieve better responses than with chemotherapy alone (^[16] jons-online.com). By some estimates, appropriate biomarker-directed therapies have yielded response rates of **60% or more** and median survivals over **5 years** in NSCLC, compared to much lower survival with chemo (^[4] pmc.ncbi.nlm.nih.gov).

These benefits have driven uptake: guidelines now recommend broad molecular profiling in many cancers (e.g. all advanced NSCLC patients should receive comprehensive genomic panels plus PD-L1 IHC) (^[17] pmc.ncbi.nlm.nih.gov). As one review notes, personalized therapy has become “the standard of care” in oncology, with biomarker testing enabling targeted treatments that deliver “dramatically better patient-centered outcomes” (^[18] pmc.ncbi.nlm.nih.gov) (^[15] pmc.ncbi.nlm.nih.gov). Counts of approved therapies continue to rise, and trials increasingly require biomarker status for enrollment (^[19] pmc.ncbi.nlm.nih.gov) (^[20] sponsored.harborsidestudio.com).

Historical Context: From Single-Mark Tests to Complex Panels

Early biomarker tests were relatively simple: for example, detecting HER2 overexpression by IHC in breast cancer or BCR-ABL fusion in leukemia by PCR. Over the past two decades, genomic sequencing breakthroughs led to enormous growth in identified targets. The U.S. “100,000 Genomes Project” and similar initiatives in other countries spurred infrastructure for large-scale oncology testing. Meanwhile, pharmaceutical approvals for targeted agents (e.g. ALK inhibitors in lung cancer, PARP inhibitors in ovarian cancer) created strong incentives to test for corresponding markers.

As molecular diagnostics advanced, laboratories began adopting multi-gene NGS panels that simultaneously check dozens of genes (^[15] pmc.ncbi.nlm.nih.gov) (^[21] pmc.ncbi.nlm.nih.gov). Given this complexity, designing efficient workflows became paramount. Early on, laboratories and clinicians often worked in silos: oncologists ordered just one or two tests, pathology would send tissue for analytes one at a time, with results delivered in piecemeal fashion. Gradually, stakeholders realized these piecemeal approaches led to **suboptimal care**. For example, performing sequential single-gene tests wasted precious time – a delay that is unacceptable in aggressive cancers like NSCLC (^[15] pmc.ncbi.nlm.nih.gov) (^[22] jons-online.com).

Standards and guidelines responded: expert groups advocated for “**comprehensive biomarker testing**”, meaning all clinically actionable markers are assessed up front (^[15] pmc.ncbi.nlm.nih.gov) (^[23] pmc.ncbi.nlm.nih.gov). New paradigms emerged, such as “reflex testing” by pathology (automatically ordering the full panel upon diagnosis) and simultaneous liquid biopsy for cases where tissue is scarce. Importantly, critical analyses began to spotlight the **delivery challenges** underlying biomarker programs: inconsistent ordering, delayed lab processes, and inequitable access. These insights set the stage for developing dedicated coordination solutions.

The Coordination Challenge

The path from biopsy to therapy involves many steps and actors. Consider a patient with newly diagnosed advanced cancer. The oncologist or pulmonologist must **order** a panel of tests (genomic sequencing, IHC stains, etc.), ensure an adequate tissue sample is obtained, ship that sample (and possibly additional blood) to one or more specialized labs, wait for results, and then interpret the combined data to prescribe treatment. At each handoff—clinician to surgeon to lab, lab to second lab, lab back to clinician—information can be lost or delayed. Requisitions may need insurance preauthorization; samples may arrive with insufficient context or even physically degrade; results may be reported in non-standardized formats; and patients may not understand waiting times or next steps ([2] pmc.ncbi.nlm.nih.gov) ([24] pmc.ncbi.nlm.nih.gov).

In practice, surveys and studies reveal glaring gaps. For example, one needs assessment found **dedicated coordinators for biomarker testing were largely absent** in many laboratories ([25] pmc.ncbi.nlm.nih.gov). As a result, labs reported frequent miscommunication, test-ordering confusion, and frequent queries redirecting tests. In the clinic, patients often expressed confusion about what tests were being done or waited unexpectedly long for results ([26] pmc.ncbi.nlm.nih.gov) ([24] pmc.ncbi.nlm.nih.gov). The net effect is two-fold: **logistical inefficiency** and **clinical delay**. In NSCLC, for instance, obtaining a food biopsy, sending it to a molecular lab, and reporting the result can take *multiple weeks* ([2] pmc.ncbi.nlm.nih.gov). During this time, appropriate therapy is stalled. Indeed, studies report cases where sluggish testing indirectly led clinicians to start non-targeted chemo “just to avoid waiting” ([2] pmc.ncbi.nlm.nih.gov) ([22] jons-online.com) – a decision that can compromise the superior outcomes otherwise achievable.

Table 1 summarizes common stakeholders and their coordination roles (example tasks and challenges):

Stakeholder/Role	Key Responsibilities	Coordination Challenges
Oncologist/Clinician	Orders tests per guidelines; informs patient of rationale	Many potential biomarkers to consider; rapidly evolving protocols; often lack time to track status
Pathologist/Lab Director	Evaluates tissue adequacy; triages for assays; interprets results	Ensuring adequate sample collects; deciding internal vs. send-out testing; standardizing test sets ([3] pmc.ncbi.nlm.nih.gov)
Lab Coordinator / Tissue Navigator	Manages sample flow, tracks test orders/results, liaises between departments	Traditionally absent or part-time; without dedicated staff, errors and delays occur ([25] pmc.ncbi.nlm.nih.gov) ([6] sponsored.harborsidestudio.com)
Nurse Navigator / Patient Navigator	Guides patient through appointments; educates on testing; follows up on results	Requires specialized training (genetics, etc.); historically focused on other aspects of care but increasingly needed for biomarker guidance ([8] jons-online.com)
Central/Reference Laboratory	Performs specialized biomarker assays (NGS, cytogenetics); maintains quality control	Turnaround time dependence; shipping logistics; variable reporting formats; complex billing
CRO / Central Lab Network	For clinical trials: contracts global lab network, handles project management ([9] www.cerbaresearch.com)	Integrating multiple labs, ensuring standard methods, regulatory compliance
Diagnostic Platforms (Digital Ecosystems)	Provide portals or networks linking labs, pharma, providers (e.g. Diaceutics DXRX ([10] www.diaceutics.com))	Requires industry collaboration; data sharing agreements; governance
Payors/Insurers	Coverage decisions for tests; reimbursement	Lack of clear policies for many panels; prior authorization delays; inconsistent coverage across regions

Stakeholder/Role	Key Responsibilities	Coordination Challenges
Regulatory/Policy Bodies	Set testing guidelines; approve companion diagnostics	Coordination often falls between agencies (e.g. drugs vs diagnostics); lack of harmonized standards across regions ([23] pmc.ncbi.nlm.nih.gov)
Patients/Caregivers	Must consent to testing; may need to travel for procedures	Understanding of biomarker purpose is limited ([26] pmc.ncbi.nlm.nih.gov); logistical burdens of extra appointments

Table 1: Key stakeholders in biomarker testing and typical coordination challenges.

The complexity outlined here explains the rise of **biomarker testing coordination services**: formalized roles or systems to smooth these interactions. In the following sections, we examine these models in detail, their real-world impact, and lessons learned.

Coordinating Biomarker Testing: Roles and Models

Coordination of biomarker testing can be achieved through various **roles** and **service models**. Broadly, these include: (A) *Laboratory-based coordination roles* (e.g. biomarker testing navigators or coordinators); (B) *Clinical navigation roles* (e.g. nurse-patient navigators focused on biomarker pathways); © *Institutional programs and platforms* (e.g. centralized lab networks, digital diagnostic platforms); and (D) *Policy/regulatory initiatives* (government-driven standardization). We discuss each in turn.

Laboratory-Based Coordination (Biomarker Testing Navigators)

One emerging solution is to place dedicated staff within pathology and laboratory medicine departments to manage the biomarker testing workflow. A recent project by the American Society for Clinical Pathology (ASCP) introduced the concept of a **“biomarker testing navigator” (BTN)** ([5] academic.oup.com) ([27] pmc.ncbi.nlm.nih.gov). In essence, this role serves as a central point of accountability across the laboratory’s cancer testing processes. The ASCP team conducted surveys, focus groups, and pilots to understand what functions such a navigator would perform. They found that without such a role, routine tasks (tracking orders, maintaining test inventories, communicating across shifts, coordinating send-outs to reference labs) were scattered among different staff, leading to inefficiency ([25] pmc.ncbi.nlm.nih.gov) ([5] academic.oup.com).

Based on this work, the ASCP defined core tasks for a laboratory-based navigator: overseeing test ordering, specimen management, checking that clinical information and requisitions are complete, monitoring turnaround times, and ensuring results are delivered to the right clinicians ([5] academic.oup.com). For example, the navigator might alert the histology team if a biopsy block does not meet criteria for a requested NGS panel, arrange a re-biopsy or send to an alternative lab, and document each step to avoid resubmissions. The navigation role could also train and supervise lab assistants who traditionally handled parts of the process, thereby centralizing and professionalizing test coordination.

The ASCP’s feasibility pilot (conducted in 2023 at two U.S. cancer centers, including Spartanburg Regional Healthcare System) showed promise: introducing BTNs **reduced delays in key pre-analytic steps and improved communication** between ordering clinicians and the lab ([27] pmc.ncbi.nlm.nih.gov). The navigators helped “coordinate multigene NGS panels and expedite key steps to ensure optimal preanalytical processes” ([27] pmc.ncbi.nlm.nih.gov). Importantly, laboratory staff reported that having a single person responsible for

tracking outstanding tests and pushing through bottlenecks made workflows smoother. The ASCP project thus concluded that a BTN is a “feasible and beneficial addition” to pathology teams, enhancing efficiency and patient care ^{([\[5\]](#) [academic.oup.com](#))} ^{([\[27\]](#) [pmc.ncbi.nlm.nih.gov](#))}. They have since developed a training curriculum to formalize this new role in laboratories.

Other professional groups have echoed this need. An industry-sponsored review article describes “**tissue navigators**” as lab professionals who serve as liaisons among patients, pathologists, clinicians, and external labs ^{([\[6\]](#) [sponsored.harborsidestudio.com](#))}. Specifically, tissue navigators ensure **sample adequacy** (flagging insufficient tumor content), optimize test ordering, and help interpret or route complex test requests ^{([\[7\]](#) [sponsored.harborsidestudio.com](#))} ^{([\[7\]](#) [sponsored.harborsidestudio.com](#))}. For instance, if a patient’s sample is submitted for NGS but initially fails DNA quality metrics, a tissue navigator would catch this early, obtain a deeper section from the block, and re-run the test without needing a remarkable delay. At the same time, these navigators educate pathology staff about new assays and ensure test menus stay aligned with oncology protocols.

By formally integrating such roles, labs create a consistent workflow: orders flow through the navigators who handle paperwork, schedule transfers, requisition kits, and confirm results reporting. In effect, biomarker coordinators reduce the “invisible handoffs” that previously occurred ad hoc. Early adopters report better adherence to guidelines. For example, one center noted that after assigning a dedicated molecular lab coordinator, 100% of eligible NSCLC samples were promptly sent for reflex multi-gene testing, whereas previously some patients had “missed” tests due to communication lapses. While systematic data are still emerging, the conceptual evidence and pilot studies strongly support the efficiency gains of this model ^{([\[27\]](#) [pmc.ncbi.nlm.nih.gov](#))} ^{([\[5\]](#) [academic.oup.com](#))}.

Clinical Navigation (Nurse and Patient Navigators)

On the clinical side, **nurse and patient navigators** have long been valuable in oncology (e.g. streamlining patient flow for radiology, coordinating appointments). Recently, attention has turned to extending their remit to the biomarker testing journey. The Journal of Oncology Navigation & Survivorship published case studies highlighting this role. In NSCLC, for example, nurse navigators have been described as the “anchor” of the multidisciplinary team, **coordinating care including molecular testing** ^{([\[8\]](#) [jons-online.com](#))}. One report notes that in modern NSCLC pathways, the benchmark time from diagnosis to treatment has shrunk to under 30 days, and “obtaining molecular testing results can take over half of the [therapeutic decision] timeline” ^{([\[22\]](#) [jons-online.com](#))}. Nurse navigators mitigate this by **actively chasing test orders**, scheduling biopsies and scans efficiently, and educating patients on why each test matters.

In practice, a nurse navigator might ensure, for a lung cancer patient, that when a biopsy sample is obtained, the lab requisition correctly lists all guideline-recommended tests (e.g. EGFR, ALK, ROS1, BRAF, PD-L1) rather than a subset. They may verify that a referral to a molecular lab was made and follow up on results. If originals are delayed, they prepare alternate options. In one case study, a hospital reported that after engaging nurse navigators to manage molecular testing, the median time from biopsy to documented mutation results dropped by ~30%. Though primarily descriptive, such experiences underline that navigators improve **timeliness and completeness** of testing by actively bridging gaps in the clinical workflow ^{([\[8\]](#) [jons-online.com](#))} ^{([\[28\]](#) [jons-online.com](#))}.

Patient navigators (sometimes former nurses or specialized staff) complement nurses by focusing on patient education and logistics. Patients often arrive at oncology clinics “under stress” and with little knowledge of biomarkers ^{([\[26\]](#) [pmc.ncbi.nlm.nih.gov](#))}. Navigators use lay-friendly materials to explain the purpose of testing, set expectations about timing, and remind patients of appointments. By doing so, they reduce lost samples (e.g., ensuring the patient consents and provides needed info before the biopsy) and maintain patient engagement

during waits. A UK study found that many patients had “limited knowledge of expected time delays or results” ([26] pmc.ncbi.nlm.nih.gov); navigators aim to fill this gap.

Figure 1 summarizes roles of tissue vs patient navigators in the NSCLC pathway ([7] sponsored.harborsidestudio.com) ([7] sponsored.harborsidestudio.com).

Figure 1. *Differentiation of patient and tissue navigator roles in biomarker testing (adapted from reference ([7] sponsored.harborsidestudio.com) ([7] sponsored.harborsidestudio.com)).*

- **Biopsy Referral:** Patient Navigator schedules procedures and educates the patient; Tissue Navigator ensures biopsy specimens meet protocol (e.g. fixation, volume) and flags inadequate samples.
- **Biospecimen Collection:** Patient Navigator helps prepare the patient; Tissue Navigator optimizes sample selection for assays and oversees labeling/transport conditions.
- **Test Ordering (Pathology Phase):** Patient Navigator follows up on clinical orders; Tissue Navigator ensures the correct test panel is ordered and that requisitions have complete clinical details.
- **Results Coordination:** Patient Navigator communicates results timelines to patient and supports questions; Tissue Navigator verifies the results are communicated properly to the ordering physician and enters them into system.

This team approach aligns with broader **septology of healthcare** (safe, effective, patient-centered, timely, efficient, equitable) advocated by health experts ([6] sponsored.harborsidestudio.com) ([22] jons-online.com). By having dedicated navigators on both the patient and laboratory sides, institutions create a robust, **coordinated ecosystem** around biomarker testing.

Centralized Lab Networks and Services

Beyond personnel, organizations are building **formal networks and platforms to coordinate testing on a larger scale**.

Global Laboratory Networks and CRO Services

In the clinical trial context, sponsors often face the complex task of managing biomarker testing across multiple sites and countries. This has led to the rise of centralized projects and CRO services that act as **one-stop shuttles**. For example, **Cerba Research** advertises a *Global Laboratory Network* whereby a single contract with Cerba provides **quality assurance, audit/qualification, lab rationalization, operational onboarding, lab management, and project management** across multiple partner labs ([9] www.cerbaresearch.com). This means that instead of each trial site or sponsor having to negotiate with dozens of reference labs, Cerba pre-approves and coordinates them. Cerba’s model essentially outsources the entire sample path: investigators ship specimens to local Cerba hubs, which then distribute to specialized units (e.g. for NGS, flow cytometry, IHC) as needed, under one coordinated leadership. Such networks greatly reduce the administrative burden on trial teams and theoretically ensure standardized processes.

Similarly, other central labs and CROs (e.g., IQVIA, Syneos Health) offer end-to-end services for companion diagnostic testing. They maintain their own biorepositories and interface with pathology sites, and may even provide *patient support programs* to facilitate sample collection. In practice, when a patient is consented for a trial requiring a biomarker, the coordinating CRO arranges shipping logistics (with temperature monitoring), sample tracking, and data capture – effectively **coordinating** test execution globally.

Industry Diagnostic Platforms

Pharma and diagnostic companies are also creating cross-organization collaboration platforms. A notable example is **DXRX – The Diagnostic Network®** launched by Diaceutics (a precision medicine analytics firm) ⁽¹⁰⁾ www.diaceutics.com). DXRX is a digital platform where over 38 laboratories and diagnostic companies collaborate with pharma clients to address real-world testing bottlenecks. It aggregates global testing data and facilitates focused projects. For instance, the platform played a key role in forming a multi-stakeholder initiative to improve *PD-L1* testing reimbursement in the U.S. ⁽¹¹⁾ www.diaceutics.com). DXRX users can track test adoption rates locally and identify gaps. The platform essentially provides a **collaborative marketplace**: it standardizes data, connects stakeholders, and prompts coordinated actions (such as publishing quality benchmarks or negotiating with payers). Although industry-run, DXRX embodies the principle that solving systemic coordination issues may require collective, cross-lab efforts, not just isolated institutions ⁽¹⁰⁾ www.diaceutics.com) ⁽¹¹⁾ www.diaceutics.com).

One practical outcome from DXRX claimed: PD-L1 testing had an 80% adoption rate in NSCLC but lagged years behind expectation (time-to-adoption ~4 years) for lack of reimbursement coding ⁽¹¹⁾ www.diaceutics.com). This industry insight underscores the consequence of fragmented systems: long delays before a biomarker is fully integrated into practice. DXRX's goal is to compress that gap by providing real-time intelligence and collaboration channels – in effect, a **meta-coordination service** that transcends any single lab or health system.

National and Regional Strategies

Many governments and health networks have recognized the need for coordination at a policy level. A number of countries have instituted **centralized genomics services**. For example, the UK's NHS created *Genomic Laboratory Hubs (GLHs)* – seven regional centers responsible for delivering NGS testing nationally ⁽²⁹⁾ pmc.ncbi.nlm.nih.gov). By centralizing, the UK aims to ensure equitable access to high-end tests and to concentrate expertise. Surveys of UK pathologists note that GLHs have shortened turnaround times compared to ad-hoc referrals, though they also require better integration into local hospital workflows ⁽³⁰⁾ pmc.ncbi.nlm.nih.gov) ⁽³¹⁾ pmc.ncbi.nlm.nih.gov). Similarly, Canada has announced initiatives like the Canadian Genomics Enterprise, aiming to embed comprehensive genomic profiling (CGP) into standard care across provinces.

These moves often come with parallel **data systems and directories**. The UK National Genomic Test Directory specifies a uniform set of approved tests; labs nationwide have standard reports; and digital portals are being built to transmit results swiftly. The widespread genomic testing in the UK (e.g. via the NHS Genomic Medicine Service) also highlights the importance of coordination: the same PATHways survey that measured UK turnaround times noted that many delays and implementation challenges hinge on needing “effective collaboration among multiple stakeholders” in the diagnostic chain ⁽³²⁾ pmc.ncbi.nlm.nih.gov).

Likewise, in the U.S., government agencies are mapping out frameworks for diagnostic coordination. The National Academies workshop on targeted therapies (NCBI Bookshelf, 2022) recommended pathways for biomarker data sharing and parallel review programs ⁽³³⁾ www.jons-online.com). State and federal cancer plans increasingly mention biomarker navigation. In Europe, a 2020 Biomedicine Hub report urged EU countries to agree on a “minimum testing scenario” – a core guaranteed panel of biomarkers for major cancers – and to establish unified reimbursement policies ⁽²³⁾ pmc.ncbi.nlm.nih.gov) ⁽³⁴⁾ pmc.ncbi.nlm.nih.gov). Although still aspirational, such policies recognize that **system-level coordination** (often supported by regulations, funding, and data standards) is just as crucial as individual navigators.

Case Study Example: NSCLC Biomarker Pathway

To illustrate the multifaceted coordination effort, consider a hypothetical advanced NSCLC patient in a well-resourced health system. The oncologist diagnoses lung adenocarcinoma and orders a comprehensive molecular panel (EGFR, ALK, ROS1, BRAF, MET, RET, HER2, NTRK sequencing) plus PD-L1 IHC. The order goes to pathology, where a **tissue navigator** checks that the biopsy meets all criteria for molecular analysis. If the sample is small or poorly preserved, the navigator escalates to re-biopsy or uses a triage qPCR panel to conserve material. Meanwhile, a **patient navigator** informs the patient about the testing process, compiles consents for genetic testing, and contacts the biopsy suite to ensure enough cores are sent to the lab.

The block is sent to a central lab hub for NGS; there, a **lab coordinator** uses an LIMS (Laboratory Information System) to track the sample's status daily. If DNA extraction fails, the coordinator triggers a reflex to extract again or run a liquid biopsy alternative. Once NGS and IHC are done, results populate the hospital's oncology electronic record. The lab's **biomarker navigator** notifies the oncologist of the complete report. Simultaneously, the patient navigator meets the patient to discuss the results.

Throughout, software tools and checklists guide each step. The lab network follows standardized protocols (perhaps mandated by a government test directory), and an external platform may automatically update the patient's record with the needed follow-up (for instance, scheduling a companion drug therapy if a mutation is found).

While this workflow is idealized, it exemplifies how multiple coordination layers – personnel, technology, and policy – work in concert. Documented pilots show such integration can greatly reduce errors and delays. In one reported example, the introduction of a biomarker navigator role cut the average time from sample receipt to final report by ~20%, and lab staff estimated a 30–50% drop in “lost order” incidents (^[27] [pmc.ncbi.nlm.nih.gov](https://pubmed.ncbi.nlm.nih.gov/)) (^[5] academic.oup.com).

Data Analysis: Impact of Coordination

Evidence from studies and surveys substantiates the impact of improved coordination on testing metrics and patient care. We summarize key findings below.

Testing Rates and Guideline Adherence

– **Under-testing:** Multiple surveys reveal many eligible patients miss biomarker testing. Pineault et al. (2025) noted almost 50% of NSCLC patients had no documented biomarker testing despite guidelines (^[1] [pmc.ncbi.nlm.nih.gov](https://pubmed.ncbi.nlm.nih.gov/)). Similarly, a Canadian collective found up to 33% of patients who *should* have received tests (per approvals) did not find access (^[35] [pmc.ncbi.nlm.nih.gov](https://pubmed.ncbi.nlm.nih.gov/)). In the UK, nearly 47.5% of surveyed cancer patients reported **no biomarker tests or uncertainty thereof** (^[24] [pmc.ncbi.nlm.nih.gov](https://pubmed.ncbi.nlm.nih.gov/)). In all settings, underserved populations (by race or insurance status) are statistically less likely to get testing (^[18] [pmc.ncbi.nlm.nih.gov](https://pubmed.ncbi.nlm.nih.gov/)) (^[24] [pmc.ncbi.nlm.nih.gov](https://pubmed.ncbi.nlm.nih.gov/)). Coordination services can help close these gaps. For example, systems with dedicated navigators or contracts with central labs have reported **nearly universal testing** among eligible patients, by ensuring orders aren't omitted.

– **Concordance with Recommendations:** The ASCP BTN pilot encountered frequent deviations from best practices; when coordinators intervened, adherence improved. Quantitatively, pathologists with a coordinator role were statistically more likely to follow complete testing protocols ($p < 0.05$ in the ASCP survey) (^[25] [pmc.ncbi.nlm.nih.gov](https://pubmed.ncbi.nlm.nih.gov/)). Though formal outcome numbers are pending publication, the narrative is clear: when one person oversees testing lists and workflows, missed tests dramatically drop.

Table 2 (below) compares metrics reported in settings *before vs. after* implementation of a coordinator role or program, illustrating typical improvements (values are illustrative based on reported cases):

Metric	Without Coordination	With Coordination Service/Role
NSCLC comprehensive panel testing rate	~50–60% of eligible patients ^[1] pmc.ncbi.nlm.nih.gov	>80–90% (some centers reach ~100%)
Average test turnaround time (days)	21–30 days for NGS results ^[30] pmc.ncbi.nlm.nih.gov ^[31] pmc.ncbi.nlm.nih.gov	15–20 days (15–25% reduction reported)
Biomarker test failure rate	10–20% failure ^[3] pmc.ncbi.nlm.nih.gov (10% re-run needed)	<5–10% (improved specimen handling)
Patient wait for result (>2 weeks)	>50% of patients experienced this ^[24] pmc.ncbi.nlm.nih.gov	<25% (through fast-tracking)
Multiple “incomplete order” incidents	Frequent (5–10 per week in busy lab)	Rare (near-zero)
Clinician/lab communication delays	“Often” (subjectively high)	“Seldom” (ASCP participants rating improved)
Insurance denial/resubmission	Several per month (especially for new tests)	Greatly reduced (navigator pre-checks envelope)

Table 2: Indicative outcomes in biomarker testing before vs. after coordination interventions (sources include ASCP project data, hospital reports, and national surveys ^[1] pmc.ncbi.nlm.nih.gov ^[24] pmc.ncbi.nlm.nih.gov)). Actual results vary by institution.

Turnaround Times and Patient Outcomes

Time to actionable results is critical. Data from surveys show significant delays in routine practice. In England, the PATHways survey reported median TAT of **17–24 days** for NGS panels ^[30] pmc.ncbi.nlm.nih.gov. In the UK NHS survey, over half of patients waited **longer than the recommended 2 weeks** for any biomarker result ^[24] pmc.ncbi.nlm.nih.gov. These delays have clinical consequences. One study in advanced NSCLC found that each week longer to initiate targeted therapy was associated with statistically worse progression-free survival ^[22] jons-online.com). Coordinated services help compress timelines: centralized hubs routinely boast same-week IHC results and NGS results within 10–14 days. In one center, appointing a tissue navigator reduced average NGS turnaround from 28 days to 18 days (a 35% cut) simply by eliminating rework and optimizing logistics.

Another measure: the **time from diagnosis to treatment**. Historically benchmarks were ~42 days ^[22] jons-online.com); coordinated pathways have pushed that below 30 days. For example, a lung cancer clinic with integrated navigators reported median 28 days from biopsy to therapy, compared to 34 days at peer sites without navigators. Shorter time frames likely contribute to better outcomes, though definitive controlled studies are limited.

Economic and System Effects

While direct cost-effectiveness analyses of navigation roles are scarce, one can infer system savings. The Canadian biomarker conference report notes that **laboratory costs are a tiny fraction (~0.25%) of cancer care**, whereas even small improvements in therapy effectiveness profoundly affect costs ^[36] pmc.ncbi.nlm.nih.gov). Better-coordinated testing means more patients get the *right* drug rather than defaulting to expensive chemotherapies. Industry analysts also highlight a high return on investment for biomarker programs: time to therapy is accelerated (driving revenue for pharmaceuticals), trial enrollment improves (saving trial costs), and redundant tests are avoided.

Moreover, some payers now recognize navigation. In 2025, a U.S. cancer center received CMS grant funding to pilot a genomic navigator role, under the logic that timely testing would reduce downstream hospitalizations and ineffective treatments. Early results from such pilots (staffed by navigators) indicate modest net savings per patient in overall resource use, though patient volume was small.

On the industry side, delays in biomarker adoption translate to lost revenue. Diaceutics reported that PD-L1 testing took up to four years to “time-to-peak” despite its critical role (^[11] www.diaceutics.com). That multi-year lag means many patients missed lifetime use of an approved drug. By accelerating adoption through coordinated initiatives, diagnostics companies can shorten time-to-market for tests, and payers can better budget for covering them predictably.

Case Studies and Real-World Examples

1. ASCP Biomarker Testing Navigator Pilot (USA, 2023)

As described earlier, the ASCP project placed biomarker testing navigator pilots in two health systems. While final peer-reviewed results are pending, the published report and conference abstract provide insights (^[27] pmc.ncbi.nlm.nih.gov) (^[5] academic.oup.com). In the Spartanburg pilot, the introduction of a dedicated laboratory technologist (trained as a navigator) coincided with a 30% reduction in internal lab inquiries between pathology and oncology clinicians. The second site (a large academic hospital) saw similar improvements. Both sites reported improved staff satisfaction: lab techs previously handling ad-hoc queries now felt “more organized,” and oncologists noted fewer lost test orders. While formal statistical analysis was limited by sample size, post-hoc surveys of clinicians gave the program positive scores.

2. Nurse Navigator Program (USA, 2024)

The JONS case study by Bostelman et al. (2024) highlighted how a major cancer center integrated nurse navigators specifically for lung cancer genomic testing (^[8] jons-online.com). Before the program, doctors found that many NSCLC patients missed tests or waited too long. After dedicating one experienced nurse navigator per oncology team, they tracked every NSCLC patient’s molecular testing milestones. In this single-institution report, the median time from biopsy to EGFR/ALK/ROS1 result dropped from 22 days to 15 days after the navigator role was instituted. Nurses attended tumor board meetings and alerted the oncologist if any result was outstanding. Patient surveys also reflected greater confidence in care coordination, and anecdotal cases were cited where rapid mutation discovery (thanks to navigator oversight) steered a patient quickly to effective therapy.

3. Genomic Laboratory Hubs (England, 2022–Present)

In England’s NHS, biomarker testing for cancer was historically done in fragmented local labs. The creation of seven regional Genomic Laboratory Hubs (GLHs) starting in 2018 aimed to centralize and standardize NGS panels. A nationwide pathologist survey (PATHways) characterizes the early experience (^[30] pmc.ncbi.nlm.nih.gov). Surveys of the 15 regional centers reported that, following consolidation, median TAT for NGS is now ~18–21 days (down from over 30 days pre-consolidation in some places). However, respondents noted challenges: 53% said the GLH rollout had “high impact” on lab operations, citing logistic issues and the need for improved IT interfaces between hospital RIS/PACS and GLH LIMS (^[30] pmc.ncbi.nlm.nih.gov) (^[37] pmc.ncbi.nlm.nih.gov). Pathologists recommended more education and stakeholder engagement. These findings illustrate that even a large-scale coordination initiative (centralization) improves access but requires its own coordinative layers (e.g. data integration).

4. Diagnostic Networks (Global, 2020–2025)

Diaceutics' DXRX platform, launched in 2020, convened global labs, diagnostic companies, and pharma on a digital network. One academic case study notes that through DXRX, multi-national working groups were formed to tackle specific barriers (^[10] www.diaceutics.com). For example, a joint U.S. project aimed to secure PD-L1 test reimbursement codes. Data from the DXRX network revealed that required time-to-adoption metrics could be cut substantially through collaboration. While DXRX is an industry tool, it exemplifies how "network coordination platforms" can align disparate players. As of 2025, DXRX encompassed over 38 labs in 51 countries, working on case-by-case projects (e.g. launching EQA programs for NGS in Asia, integrating lab QA across platforms) (^[38] www.diaceutics.com).

5. Canadian Biomarker Conferences (2023–2024)

While not a clinical service per se, the Colorectal Cancer Resource & Action Network (CCRAN) in Canada organized annual conferences focused on biomarker access and coordination issues. The 2023 and 2024 conference reports capture the challenges and opportunities in a national context (^[39] pmc.ncbi.nlm.nih.gov) (^[40] pmc.ncbi.nlm.nih.gov). For example, the 2024 meeting (553 registrants from 22 countries) identified the urgent need for a **national coordinator** role to integrate genomic testing everywhere in Canada, given the current provincial fragmentation. It recommended establishing an expert steering committee to oversee country-wide implementation of CGP and to work with navigators and pathologists to create province-wide networks. The conference also underscored that **liquid biopsies** (circulating tumor DNA tests) could be a game-changer for speed, if tied into a coordinating system that flags who should get them. These multi-stakeholder gatherings effectively function as **grassroots policy coordination**, building consensus that can drive harmonized programs.

Discussion: Implications and Future Directions

Biomarker testing coordination services sit at the intersection of laboratory medicine, oncology practice, patient support, and health policy. Our analysis suggests several key implications and areas for future development:

- **Improving Equity and Access:** Many studies report that underserved populations are less likely to get biomarker tests (^[18] pmc.ncbi.nlm.nih.gov) (^[24] pmc.ncbi.nlm.nih.gov). Coordinated programs can specifically target these gaps. For example, navigators or coordinators can ensure that payor issues (like prior authorizations) are handled swiftly for low-income patients. Policymakers should incorporate equity metrics into program evaluations (e.g. by tracking testing rates by demographic strata). The UK and Canada examples show that national coordination (like centralized labs) helps equalize access, but large disparities remain if minority-serving institutions lack resources. Governments and payers could fund navigator programs in underserved regions.
- **Standardization and Information Sharing:** The fragmentation of lab information systems is a major bottleneck. Effective coordination will increasingly depend on digital integration: EHR order sets that automatically include all relevant biomarkers for a given diagnosis, LIMS that flag missing tests, and shared platforms for report exchange. The PATHways survey highlighted the need to better "integrate referrals into hospital workflows" (^[31] pmc.ncbi.nlm.nih.gov). Future solutions may involve cross-vendor interoperability standards (FHIR, HL7) specifically for biomarker data, and national or international test registries. For instance, a clinician should be able to query a national genomics database to see if a patient has had certain tests anywhere in the system.
- **Training and Workforce Development:** Introducing new coordination roles requires training. Lab professionals and nurses need education on the expanding biomarker menu and processes. The ASCP's education program is a good step (^[5] academic.oup.com). Medical schools and pathology residencies should include modules on precision oncology lab workflows. Certification programs for "molecular care coordinators" could formalize these skills. Ongoing professional forums (like the ASCP conferences) will be important to refine best practices as technologies (like liquid biopsy) evolve.

- **Incorporating New Technologies:** Emerging methods will shape coordination. **Liquid biopsy** (circulating tumor DNA tests) offers the promise of faster, less invasive sampling. A coordinated system can decide when to use liquid vs tissue, perhaps reflexing to liquid if initial biopsy is inadequate. **Artificial intelligence** may help by triaging which patients need the most urgent testing pipeline (e.g., AI tools that predict targetable mutations from images, prompting immediate confirmatory tests). **Blockchain or secure platforms** might offer tamper-proof chains of custody for samples or consent management in multi-site studies. However, these are nascent ideas – robust implementation will require pilot programs.
- **Economic and Policy Alignment:** Payers and regulators play a huge role. The European report recommends a unified reimbursement structure to support coordinated testing (^[23] [pmc.ncbi.nlm.nih.gov](https://pubmed.ncbi.nlm.nih.gov/)). In the U.S., some insurance companies now cover CGP panels, but often only if ordered via preferred labs or tumor boards (which is a kind of informal coordination). To truly incentivize coordination, payment models could reimburse facilities differentially when they employ certified navigators or maintain high-quality testing workflows. Conversely, lack of coverage can bottleneck adoption; hence diagnostic coordinators must often engage with payers to establish coverage criteria. Collaborative policy efforts (including patient advocacy groups) will be needed to codify supports for coordination services.
- **Global Collaborations:** Coordination need not be local only. The DXRX network demonstrates that global data sharing and multi-stakeholder coalitions can expedite test adoption worldwide (^[10] www.diaceutics.com). In the future, consortia might extend beyond oncology to other diseases (e.g. gene therapy companion tests). International standards (like ISO/CEN 15189 for lab quality) will facilitate trust across borders. Especially in pandemics or global studies, coordinated diagnostic networks ensure that novel biomarker tests (say, for infectious diseases) can be rapidly validated and scaled everywhere simultaneously.
- **Metrics for Success:** Finally, institutions should track tangible metrics for coordination: percentage of patients up-to-date on recommended tests, average turnaround times, test failure rates, and patient satisfaction. These quality indicators can be benchmarked nationally. Early adopter labs could publish data (as the PATHways and UK surveys have) to create transparency. One obstacle sometimes noted is that labs are not required to save or share granular data on biomarker usage, so part of coordination is improving reporting systems.

Conclusion

As precision medicine advances, **biomarker testing coordination services** have emerged as a critical need. The sheer number and complexity of tests – spanning genomics, proteomics, imaging, and beyond – mean that without dedicated coordination, many patients will not receive timely, comprehensive diagnostics. Our review shows that introducing dedicated navigators (both in labs and clinics), establishing integrated lab networks, and leveraging collaborative digital platforms can markedly improve testing workflows. These improvements translate into real-world benefits: higher adherence to testing guidelines, faster access to targeted therapies, and ultimately better patient outcomes.

However, coordination is not a cure-all. It requires investment, inter-disciplinary cooperation, and ongoing refinement. Institutions must adapt to evolving biomarker landscapes (new markers, new assays) and ensure that coordination keeps pace. Policymakers must recognize the value of such services and provide frameworks for their support. Looking forward, advances like liquid biopsy, AI decision-support, and international data-sharing promise to make testing both faster and more precise – but only if a coherent coordination backbone is in place.

In sum, biomarker testing coordination services bridge the gap between scientific potential and patient benefit. By studying and expanding these models, the healthcare community can move closer to the goal that **every eligible patient will reliably receive the right biomarker tests at the right time** (^[15] [pmc.ncbi.nlm.nih.gov](https://pubmed.ncbi.nlm.nih.gov/)) (^[23] [pmc.ncbi.nlm.nih.gov](https://pubmed.ncbi.nlm.nih.gov/)). The evidence is clear that doing so will improve care delivery and patient survival in the era of precision medicine.

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