Enhancing personalized cancer care in the community through the combined use of **navify**® Tumor Board and Mutation Profiler

Introduction

Protean BioDiagnostics, headquartered in Orlando, Florida, is a CAP/CLIA-accredited laboratory committed to developing and deploying advanced, high-quality diagnostic tools to support physicians in providing personalized care for their patients, regardless of where they live—including underserved communities.

Roche and Protean BioDiagnostics recently began a two-year collaborative research study called DelPHI (**Del**ivering **P**recision **H**ealth **I**nsights). DelPHI aims to measure the clinical impact of the use of a strategic combination of **navify** digital solutions to analyze how they can support the delivery of precision oncology to community-based oncologists.

*"**navify** Tumor Board is great for cases where we are looking for therapeutic targets and I like how it integrates data from multiple platforms (molecular, IHC, FISH, etc.)."*

Dr. Anthony Magliocco | Founder & CEO of Protean BioDiagnostics

Challenge

Providing precision oncology, personalized cancer care treatment, depends on the specific molecular (e.g. genomic) characteristics of that patient's tumor. To date, the U.S. Food and Drug Administration has approved nearly 300 targeted therapies for >30 cancer indications.[1] In addition, recent advances in molecular testing, including in the areas of immunohistochemistry and comprehensive genomic profiling, have significantly improved the availability and affordability of advanced molecular testing.

Yet, despite these advances in testing, significant challenges with uptake of precision oncology have been observed, in part due to issues of inappropriate or lack of testing, operational inefficiencies, data fragmentation and hampered access. In a recent study looking at these issues, it was determined that >60% of advanced lung cancer patients were not benefiting from precision oncology therapies for which they were potentially eligible, due to these notable gaps in clinical practice.[2]

Solution

Protean BioDiagnostics (BioDx) is a full-service clinical laboratory that generates actionable data-driven clinical insights to support timely diagnosis and targeted, personalized treatment for patients with various types of cancer at all stages. Protean BioDx performs a comprehensive pathological work-up as well as biomarker and genomic testing tailored to the patient's cancer type. To support their services, they leverage both **navify** Mutation Profiler and **navify** Tumor Board software solutions. Roche recently began a collaboration with Protean BioDx to evaluate the impact of using the above mentioned **navify** digital solutions to deliver better precision oncology to the community practices.

This research collaboration aims to:

- Improve adherence to practice guidelines
- Increase the number of patients enrolled in clinical trials
- Increase standardization of testing and improve real-world data collection

*"We are fans of the **navify** Mutation Profiler and its user interface. It is easy to navigate, create cases, and make new assays. I think it's very useful for the clinical field, as everything reported (TMB - tumor mutation burden, SNP - single nucleotide polymorphisms, amplification, fusion) has relation to a drug target or drug response"*

Dr. Anthony Magliocco | Founder & CEO of Protean BioDiagnostics

Results

The DelPHI research study set out to address the aims by leveraging a strategic combination of **navify** software solutions along the patient journey. Two patients with rare pediatric sarcomas as well as 28 patients with lung cancer were run through the program. Each tumor specimen underwent full pathologic work-up, followed by molecular testing, and interpretation, resulting in a molecularly-guided therapy plan.[3,4,5] Here's how **navify** digital solutions support the timely diagnosis and treatment planning for these patients:

- Guidelines for **navify** Tumor Board: Guided appropriate diagnostic testing and treatment options
- **navify** Mutation Profiler*: Enabled tertiary genomic data analysis leading to treatment options based on evidence tiers published in the AMP/ASCO/CAP guidelines [6]
- Clinical Trial Match for **navify** Tumor Board: Identified enrolling clinical trials matched to patient characteristics and combined protein and genomic biomarkers
- **navify** Tumor Board: Facilitated discussion and education in a virtual molecular tumor board meeting with the oncology care teams

Patient Success Story

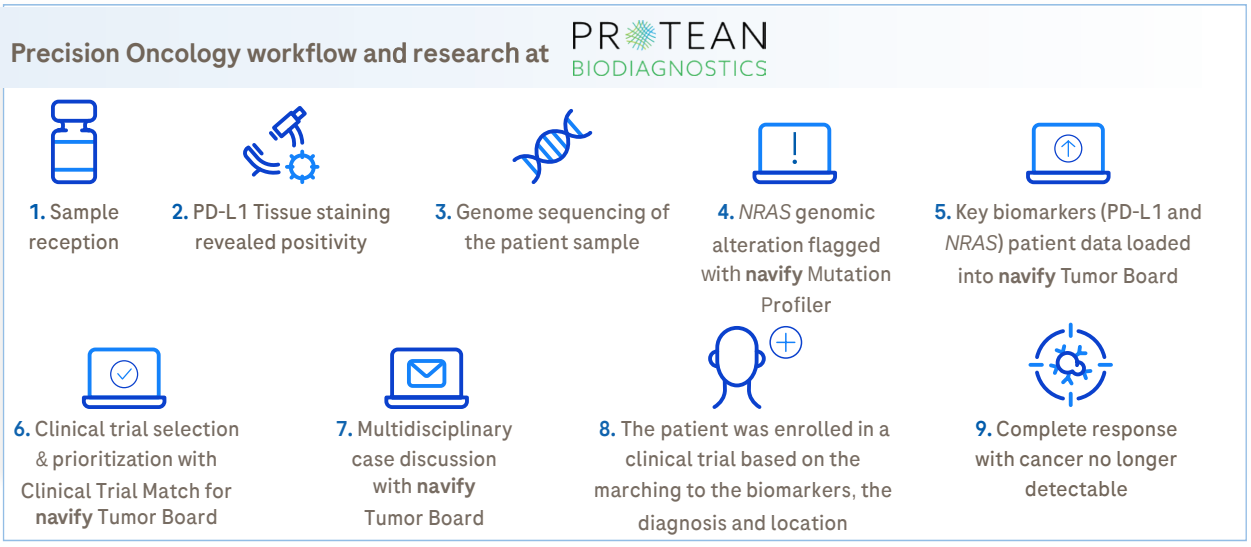
Here is a dramatic, real-life demonstration of how **navify** digital solutions aided in informing the therapies that clinicians choose to help deliver targeted, personalized care in a timely manner: A patient was diagnosed with a rare pediatric soft tissue sarcoma, called rhabdomyosarcoma, which had metastasized to the liver and bone, rendering this young patient immobile and unable to attend school anymore. Protean Biodiagnostics received a core needle biopsy, which had limited quantity of tissue, but they were able to run a pathologic work-up and perform PD-L1 staining of the specimen, revealing that the tumor was PD-L1-positive. Due to the tissue quantity limitation, a blood sample was also collected for liquid biopsy, and genomic testing was performed, and the results were run through **navify** Mutation Profiler, revealing an actionable mutation in the *NRAS* gene. The key biomarkers (PD-L1 and *NRAS*) were loaded into the **navify** Tumor Board software along with patient and tumor characteristics, as well as imaging data and pathology reports. The Clinical Trial Match module for Tumor Board yielded an enrolling clinical trial that had a perfect match to the patient diagnosis, age, and both key biomarkers mentioned above.

The holistic case was then discussed with the patient's oncology care team with the aid of **navify** Tumor Board software, which was also used to educate the patient and his family on the findings. The patient was enrolled in a clinical trial, and after 6 months of undergoing a combination of therapies targeting the two biomarkers found in his tumor, this patient had a complete response and cancer is[3] no longer detectable. He is now back in college and playing sports again.

*"Overall, I really like **navify** Tumor Board - it is helpful in managing complex cancer cases"*

Dr. Anthony Magliocco | Founder & CEO of Protean BioDiagnostics

Precision Oncology workflow and research at PROTEAN BIODIAGNOSTICS



Empowering clinical decisions that improve patients' lives. It's personal.

1. https://www.cancer.gov/about-cancer/treatment/types/targeted-therapies/approved-drug-list - accessed April 23, 2023. **2.** Sireci AN, et al. Real-World Biomarker Testing Patterns in Patients With Metastatic Non-Squamous Non-Small Cell Lung Cancer (NSCLC) in a US Community-Based Oncology Practice Setting. Clin Lung Cancer. 2023 Mar 20:S1525-7304(23)00050-5. doi: 10.1016/j.cllc.2023.03.002. **3.** Park S, et al. ST056: DelPHI: Delivering Precision Health Insights for Timely Treatment of Rhabdomyosarcoma Using Protean MAPS and NAVIFY Digital Tools. *The Journal of Molecular Diagnostics*, 24(10), 2022, S108. https:// doi.org/10.1016/S1525-1578(22)00284-7 **4.** Park S, et al. ST057: DelPHI: Delivering Precision Health Insights for Timely Diagnosis and Treatment of Epithelioid Sarcoma Using Protean MAPS and NAVIFY Digital Tools. *The Journal of Molecular Diagnostics*, 24(10), 2022, S108. https://doi.org/10.1016/S1525-1578(22)00284-7 **5.** Magliocco A, et al. J Clin Oncol 41, 2023 (suppl 16; abstr e18713). https://meetings.asco.org/abstracts-presentations/223909. **6.** Li MM, et al. Standards and Guidelines for the Interpretation and Reporting of Sequence Variants in Cancer: A Joint Consensus Recommendation of the Association for Molecular Pathology, American Society of Clinical Oncology, and College of American Pathologists. J Mol Diagn. 2017 Jan;19(1):4-23. doi: 10.1016/j.jmoldx.2016.10.002. PMID: 27993330; PMCID: PMC5707196.

* The **navify** Mutation Profiler is for Research Use Only; not for use for diagnostic procedures in the United States.

navify