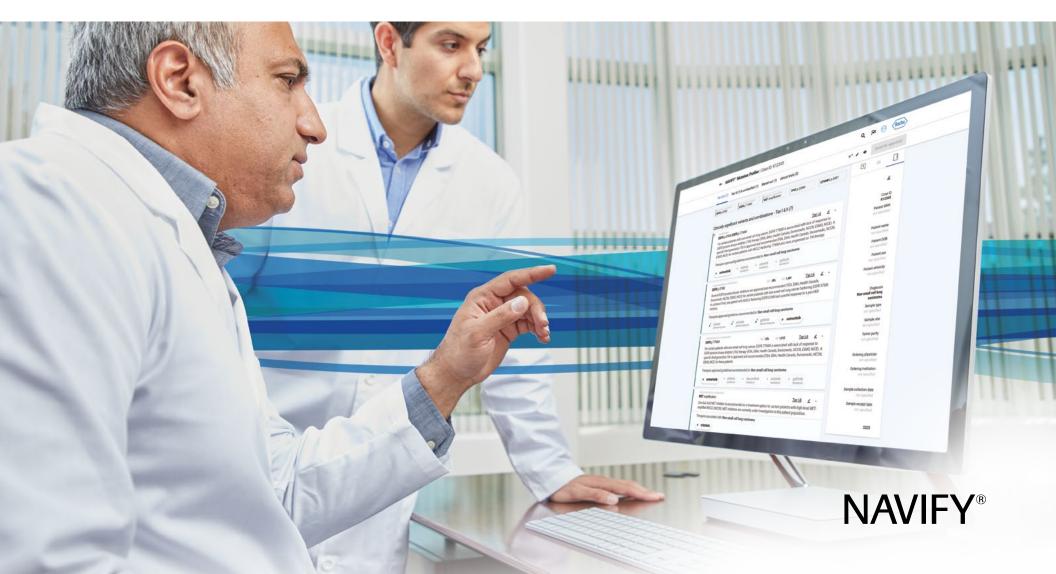


NAVIFY[®] Mutation Profiler The power to do more



Deliver more personalized healthcare

A revolutionary clinical next generation sequencing (NGS) reporting solution, NAVIFY Mutation Profiler helps clinical labs confidently, clearly and efficiently interpret the clinical significance of mutations.

Drastically reducing curation time, increasing reproducibility and automating the workflow for report generation.

With NAVIFY Mutation Profiler, labs are enabled to inform on potential personalized treatment strategies in a concise professional report for the oncologist.

Providing you the power to do more





Empowers the clinical lab with actionable information

Confidently and clearly inform on more actionable mutations and treatment options. Generate more simple and concise reports.

NAVIFY Mutation Profiler offers a richly curated and up-to-date knowledge base of genetic variants. With:

- Clinical significance for thousands of the most common variants classified in accordance with AMP guidelines
- Public annotations for millions of additional variants .
- Linking findings to actionable therapy options that are supported by . local drug-approval agencies, clinical studies and medical guidelines



Highly curated evidence-based knowledge base





- Informing oncologists on potential personalized treatment strategies
- Customizable

3

Increases lab efficiency and enables scalability

Making NGS clinical interpretation simpler. Allowing you to support more gene panels, cancers and mutations.

NAVIFY Mutation Profiler helps reduce curation time and automates report generation. **Simplifying NGS clinical interpretation with:**

- Pre-configured clinical and variant summaries that help reduce the time of interpretation
- Annotations organized in a single, focused location

A clinical lab workflow based on lab clinician input, NAVIFY Mutation Profiler offers a clean, intuitive user interface and an outstanding user experience. **Including:**

- Lab and variant analytics; with the option to opt-in for variant classification sharing
- Integrations with the LIS and EHR via APIs



Scale to your clinical lab's needs with curated gene and variant information on:



















260+ Genes

25,000+ Unique variants

260,000+ Molecular profiles



Hematologic malignancies

Breast Colorec cancer cance

Colorectal Melanoma cancer

Lung cancer

Bladder

cancer

Prostate cancer

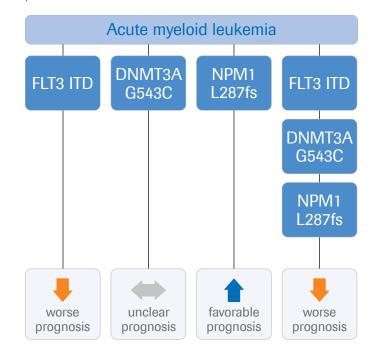
Head and neck cancer

Helps you deliver personalized healthcare

Providing a more specific understanding of the clinical implications of variant combinations. Obtaining more comprehensive results.

3	combination FLT3 p.E598_Y599insGPYVDFREYE, DNMT3A p.G543C, NPM1 p.L287fs
	Co-occurring DNMT3A mutations, FLT3 internal tandem duplications, and NPM1 mutations are associated with worse prognosis in acute myeloid leukemia (AML) (WHO). Preclinical studies support sensitivity of leukemia cells harboring DNMT3A, NPM1, and FLT3-ITD mutations to tyrosine kinase inhibitors and an MLL inhibitor.
	no approved therapies
2	combination FLT3 p.E598_Y599insGPYVDFREYE, NPM1 p.L287fs <u>Tier I-A</u> ∠ ^
	In a phase I trial, two AML patients harboring FLT3-ITD and an NPM1 mutation were sensitive to an investigational tyrosine kinase inhibitor. Preclinical studies support sensitivity of FLT3- and NPM1-mutant leukemia cells to tyrosine kinase inhibitors.
	no approved therapies
	variant present in combination FLT3 p.E598_Y599insGPYVDFREYE VAF 39% RD 109 <u>Tier I-A</u> ∠ ^
	A multikinase inhibitor (FDA, EMA, Health Canada, Swissmedic, TGA, NCCN, ESMO, NICE, eviQ), a FLT3/AXL/ALK inhibitor (FDA, EMA, Health Canada, TGA, NCCN, ESMO), and a RAF inhibitor (NCCN) are approved and recommended treatment options for certain patients with AML harboring FLT3-TD. Clinical trials support sensitivity of these patients to multiple additional tyrosine kinase inhibitors and a RAF inhibitor in combination with a CRM1 inhibitor. FLT3-TD mutations are associated with worse prognosis in AML (WHO, NCCN, ESMO, ELN) and are prognostic and predictive markers in adult and pediatric AML (CAP-ASH). FLT3 mutations are not regarded as appropriate single markers of minimal residual disease in AML (ELN).
	Therapies approved/guidelines-recommended in: Acute myeloid leukemia e gitteritinib e midostaurin e sorafenib
_	

The clinical implications for a patient differ depending on the combination of variants present versus implications as a simple function of variants in isolation. For example, the combination of FLT3 ITD, DNMT3A G543C, and NPM1 L287fs has different implications for a patient than if the former variants are present alone.





Extend the power of NAVIFY Mutation Profiler

The NAVIFY Clinical Decision Support apps ecosystem makes valuable information easily accessible so that clinical labs teams can provide more informed potential personalized treatment strategies and patient-care decisions.



NAVIFY Therapy Matcher app

Provides clinical significance of detected variants and cancer indications by:

- Informing of treatment options, if applicable, in patient indication based on publicly available information such as approved drug labels, medical guidelines and clinical trial outcomes
- Providing clinical and preclinical evidence supporting clinical significance of the variant based on publicly available information such as biomedical literature
- Engaging practitioners managing patient care and/or clinical laboratory members (e.g., molecular geneticists, clinical lab directors)
- Linking identified mutations to approved treatment options
- Obtaining treatment options based on clinical implications of variant combinations



NAVIFY Clinical Trial Matcher app*

- Easily identify clinical trial opportunities based on an individual patient's genomic alterations
- Query and present matching trials from ClinicalTrials.gov, as well as other international trial registries and private institutions
- Filter clinical trials relevant to particular variants, location, gender and desired phase



*Powered by MolecularMatch, Inc.

Trust NAVIFY Mutation Profiler for data protection



Roche recognizes the importance of incorporating privacy and security principles in our product development process and has designed NAVIFY Mutation Profiler to operate in accordance with the laws and regulations, including HIPAA (US) and GDPR (EU), of each jurisdiction where it is available.

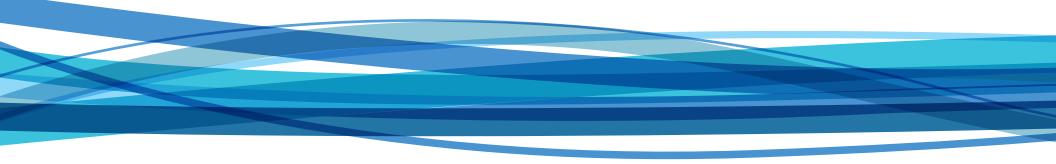


NAVIFY Mutation Profiler

The power to do more

For more information

Ask your Roche representative how NAVIFY Mutation Profiler provides your lab the power to do more. Visit https://www.navify.com/mutation-profiler/



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