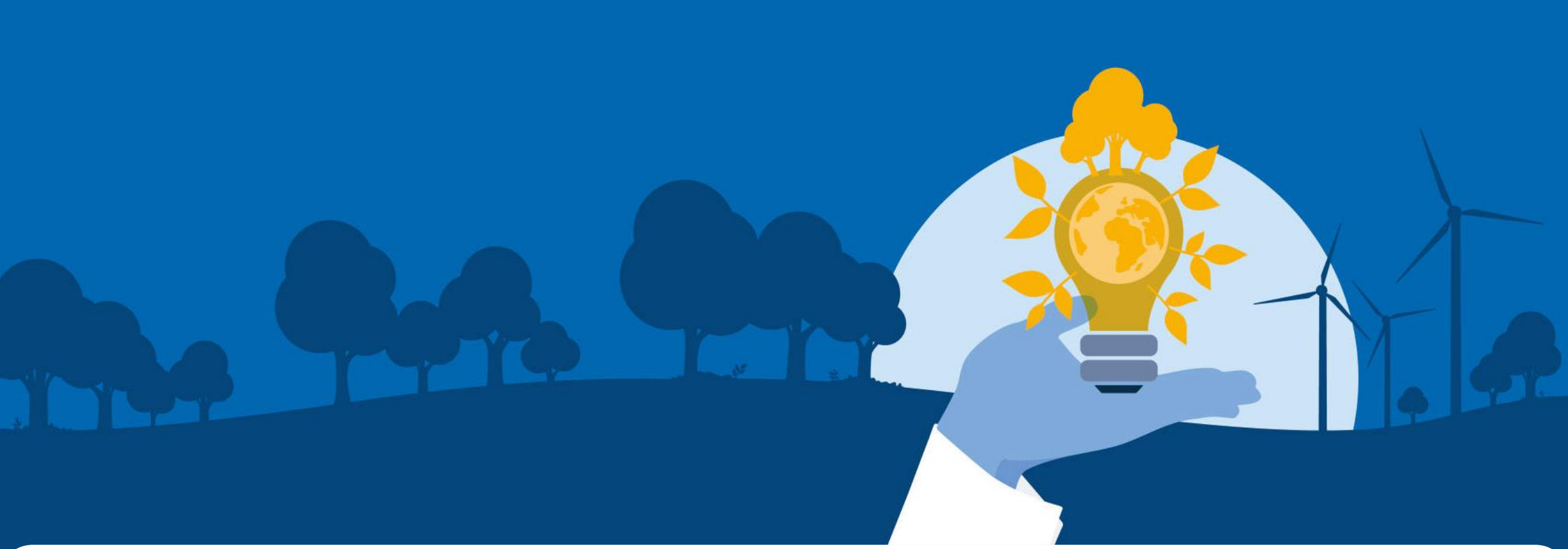
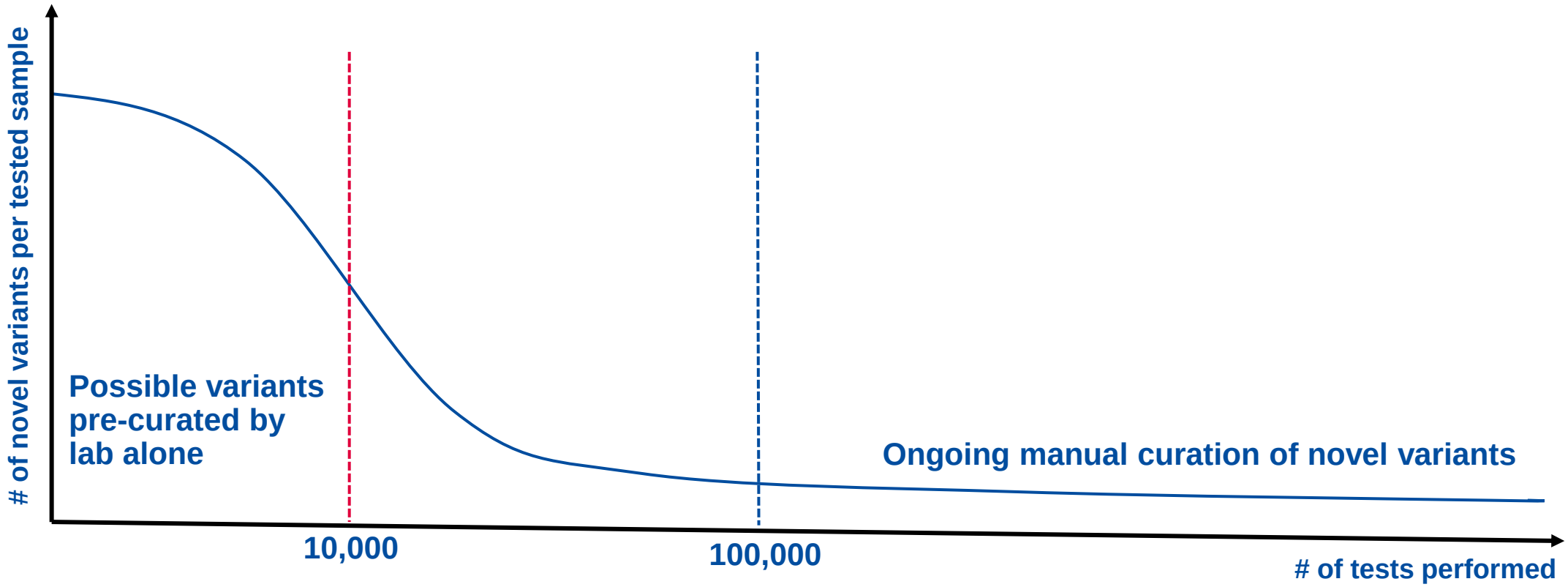


Simplify oncology NGS testing and clinical reporting for high-throughput data using QIAGEN CLC Genomics Workbench and QCI Interpret tools

Shivakumar BM, PhD
Senior Field Application Scientist, EMEA and APAC
QIAGEN Digital Insights

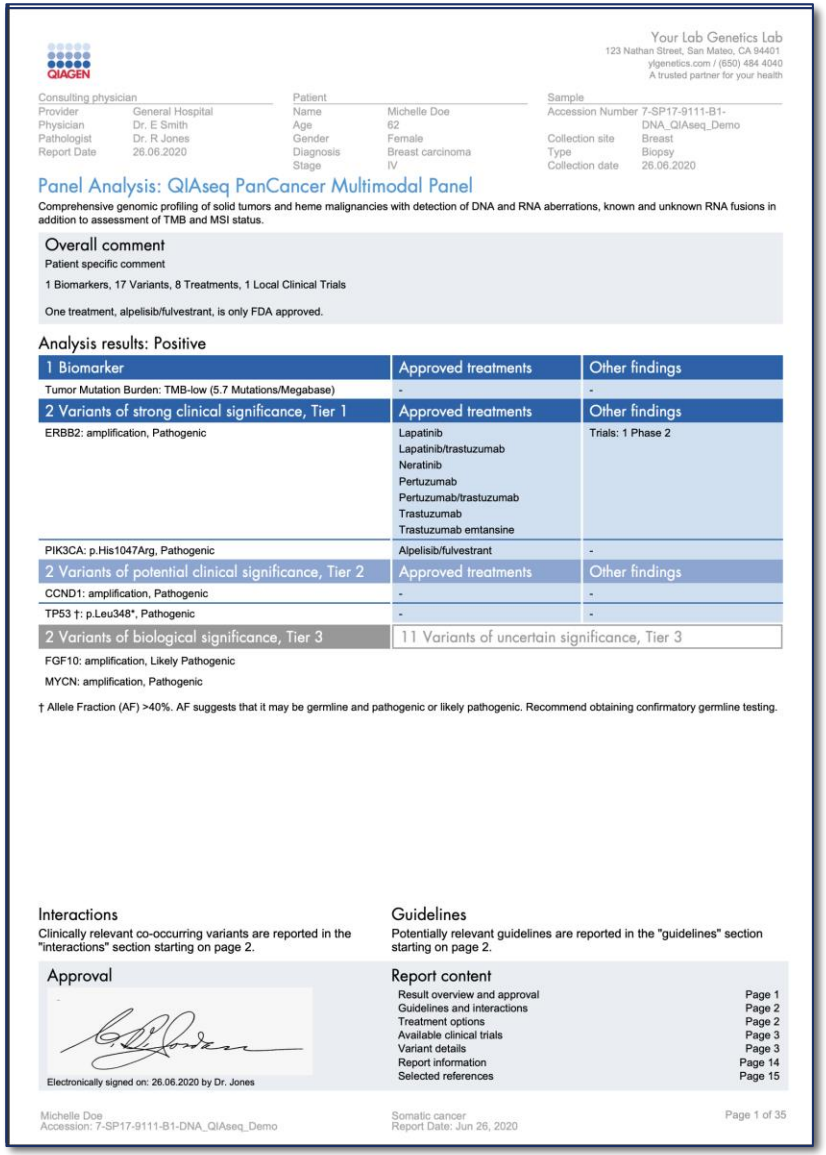
The Challenge in Large-Scale Genetic Screening

Even after >100,000 samples tested, a ~200 gene panel will continue to generate ~1-3 novel variants per sample tested*



**Based on internal QIAGEN data*

The goal of clinical genomic science



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123 Nathan Street, San Mateo, CA 94401
ylgenetics.com / (650) 484 4040
A trusted partner for your health

Consulting physician		Patient		Sample	
Provider	General Hospital	Name	Michelle Doe	Accession Number	7-SP17-9111-B1-DNA_QIAseq_Demo
Physician	Dr. E Smith	Age	62		
Pathologist	Dr. R Jones	Gender	Female	Collection site	Breast
Report Date	26.06.2020	Diagnosis	Breast carcinoma	Type	Biopsy
		Stage	IV	Collection date	26.06.2020

Panel Analysis: QIAseq PanCancer Multimodal Panel

Comprehensive genomic profiling of solid tumors and heme malignancies with detection of DNA and RNA aberrations, known and unknown RNA fusions in addition to assessment of TMB and MSI status.

Overall comment

Patient specific comment

1 Biomarkers, 17 Variants, 8 Treatments, 1 Local Clinical Trials

One treatment, alpelisib/fulvestrant, is only FDA approved.

Analysis results: Positive

1 Biomarker	Approved treatments	Other findings
Tumor Mutation Burden: TMB-low (5.7 Mutations/Megabase)	-	-
2 Variants of strong clinical significance, Tier 1	**Approved treatments**	**Other findings**
ERBB2: amplification, Pathogenic	Lapatinib Lapatinib/trastuzumab Neratinib Pertuzumab Pertuzumab/trastuzumab Trastuzumab Trastuzumab emtansine	Trials: 1 Phase 2
PIK3CA: p.His1047Arg, Pathogenic	Alpelisib/fulvestrant	-
2 Variants of potential clinical significance, Tier 2	**Approved treatments**	**Other findings**
CCND1: amplification, Pathogenic	-	-
TP53 †: p.Leu348*, Pathogenic	-	-
2 Variants of biological significance, Tier 3	11 Variants of uncertain significance, Tier 3	
FGF10: amplification, Likely Pathogenic		
MYCN: amplification, Pathogenic		

† Allele Fraction (AF) >40%. AF suggests that it may be germline and pathogenic or likely pathogenic. Recommend obtaining confirmatory germline testing.

Interactions

Clinically relevant co-occurring variants are reported in the "interactions" section starting on page 2.

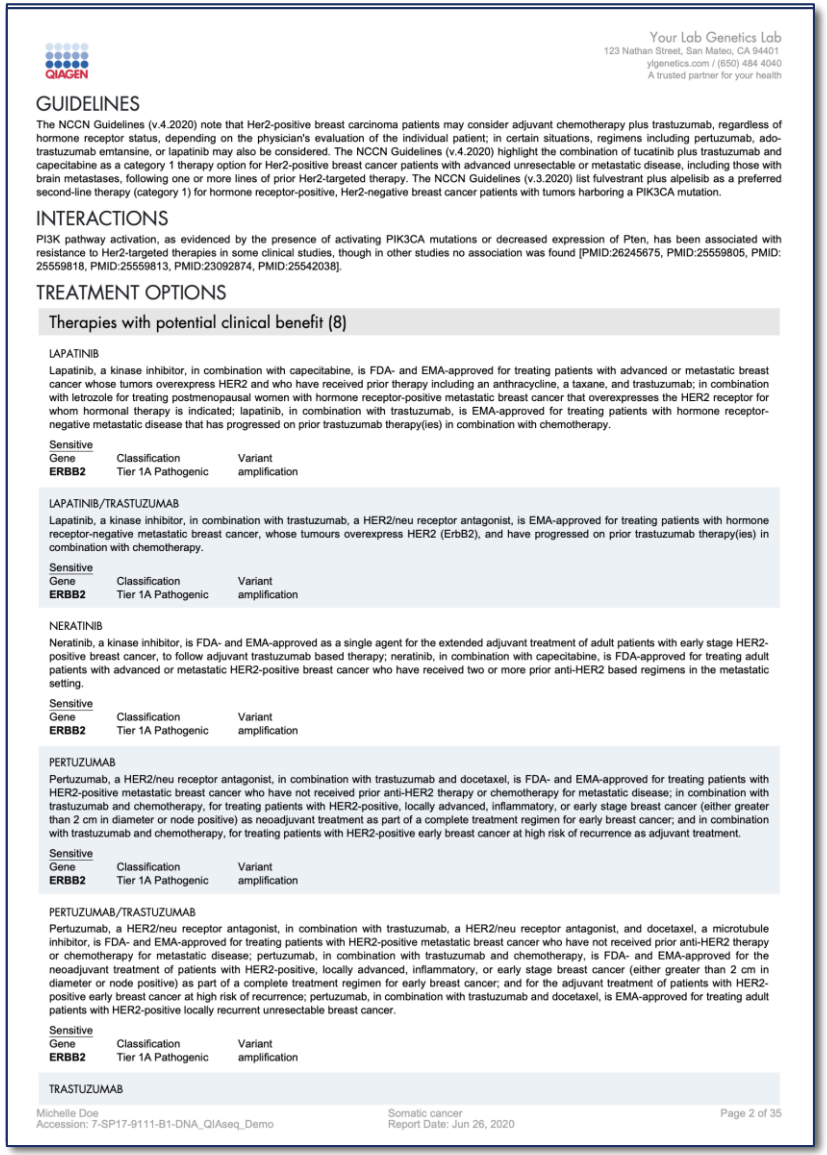
Guidelines

Potentially relevant guidelines are reported in the "guidelines" section starting on page 2.

Approval

Electronically signed on: 26.06.2020 by Dr. Jones

Report content



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GUIDELINES

The NCCN Guidelines (v.4.2020) note that Her2-positive breast carcinoma patients may consider adjuvant chemotherapy plus trastuzumab, regardless of hormone receptor status, depending on the physician's evaluation of the individual patient; in certain situations, regimens including pertuzumab, ado-trastuzumab emtansine, or lapatinib may also be considered. The NCCN Guidelines (v.4.2020) highlight the combination of tucatinib plus trastuzumab and capecitabine as a category 1 therapy option for Her2-positive breast cancer patients with advanced unresectable or metastatic disease, including those with brain metastases, following one or more lines of prior Her2-targeted therapy. The NCCN Guidelines (v.3.2020) list fulvestrant plus alpelisib as a preferred second-line therapy (category 1) for hormone receptor-positive, Her2-negative breast cancer patients with tumors harboring a PIK3CA mutation.

INTERACTIONS

PI3K pathway activation, as evidenced by the presence of activating PIK3CA mutations or decreased expression of Pten, has been associated with resistance to Her2-targeted therapies in some clinical studies, though in other studies no association was found [PMID:26245675, PMID:25559805, PMID: 25559818, PMID:25559813, PMID:23092874, PMID:25542038].

TREATMENT OPTIONS

Therapies with potential clinical benefit (8)

LAPATINIB

Lapatinib, a kinase inhibitor, in combination with capecitabine, is FDA- and EMA-approved for treating patients with advanced or metastatic breast cancer whose tumors overexpress HER2 and who have received prior therapy including an anthracycline, a taxane, and trastuzumab; in combination with letrozole for treating postmenopausal women with hormone receptor-positive metastatic breast cancer that overexpresses the HER2 receptor for whom hormonal therapy is indicated; lapatinib, in combination with trastuzumab, is EMA-approved for treating patients with hormone receptor-negative metastatic disease that has progressed on prior trastuzumab therapy(ies) in combination with chemotherapy.

Sensitive

Gene	Classification	Variant
ERBB2	Tier 1A Pathogenic	amplification

LAPATINIB/TRASTUZUMAB

Lapatinib, a kinase inhibitor, in combination with trastuzumab, a HER2/neu receptor antagonist, is EMA-approved for treating patients with hormone receptor-negative metastatic breast cancer, whose tumours overexpress HER2 (ErbB2), and have progressed on prior trastuzumab therapy(ies) in combination with chemotherapy.

Sensitive

Gene	Classification	Variant
ERBB2	Tier 1A Pathogenic	amplification

NERATINIB

Neratinib, a kinase inhibitor, is FDA- and EMA-approved as a single agent for the extended adjuvant treatment of adult patients with early stage HER2-positive breast cancer, to follow adjuvant trastuzumab based therapy; neratinib, in combination with capecitabine, is FDA-approved for treating adult patients with advanced or metastatic HER2-positive breast cancer who have received two or more prior anti-HER2 based regimens in the metastatic setting.

Sensitive

Gene	Classification	Variant
ERBB2	Tier 1A Pathogenic	amplification

PERTUZUMAB

Pertuzumab, a HER2/neu receptor antagonist, in combination with trastuzumab and docetaxel, is FDA- and EMA-approved for treating patients with HER2-positive metastatic breast cancer who have not received prior anti-HER2 therapy or chemotherapy for metastatic disease; in combination with trastuzumab and chemotherapy, for treating patients with HER2-positive, locally advanced, inflammatory, or early stage breast cancer (either greater than 2 cm in diameter or node positive) as neoadjuvant treatment as part of a complete treatment regimen for early breast cancer; and in combination with trastuzumab and chemotherapy, for treating patients with HER2-positive early breast cancer at high risk of recurrence as adjuvant treatment.

Sensitive

Gene	Classification	Variant
ERBB2	Tier 1A Pathogenic	amplification

PERTUZUMAB/TRASTUZUMAB

Pertuzumab, a HER2/neu receptor antagonist, in combination with trastuzumab, a HER2/neu receptor antagonist, and docetaxel, a microtubule inhibitor, is FDA- and EMA-approved for treating patients with HER2-positive metastatic breast cancer who have not received prior anti-HER2 therapy or chemotherapy for metastatic disease; pertuzumab, in combination with trastuzumab and chemotherapy, is FDA- and EMA-approved for the neoadjuvant treatment of patients with HER2-positive, locally advanced, inflammatory, or early stage breast cancer (either greater than 2 cm in diameter or node positive) as part of a complete treatment regimen for early breast cancer; and for the adjuvant treatment of patients with HER2-positive early breast cancer at high risk of recurrence; pertuzumab, in combination with trastuzumab and docetaxel, is EMA-approved for treating adult patients with HER2-positive locally recurrent unresectable breast cancer.

Sensitive

Gene	Classification	Variant
ERBB2	Tier 1A Pathogenic	amplification

TRASTUZUMAB

- **Alterations?**
- **Classification?**
- **Phenotypes?**
- **Guidelines?**
- **Description?**
- **In Disease Context?**
- **Treatment Options?**
- **Off-label therapy?**
- **References?**
- **Evidence?**
- **etc., etc. etc…**

→ **Interpretation**

The solution?

A NGS interpretation and reporting platform for hereditary/inherited disorder panels

Patient NGS Test Results

Today

Analyzing and interpreting hereditary panels takes hours; very time- and labor-intensive

Thousands of variants

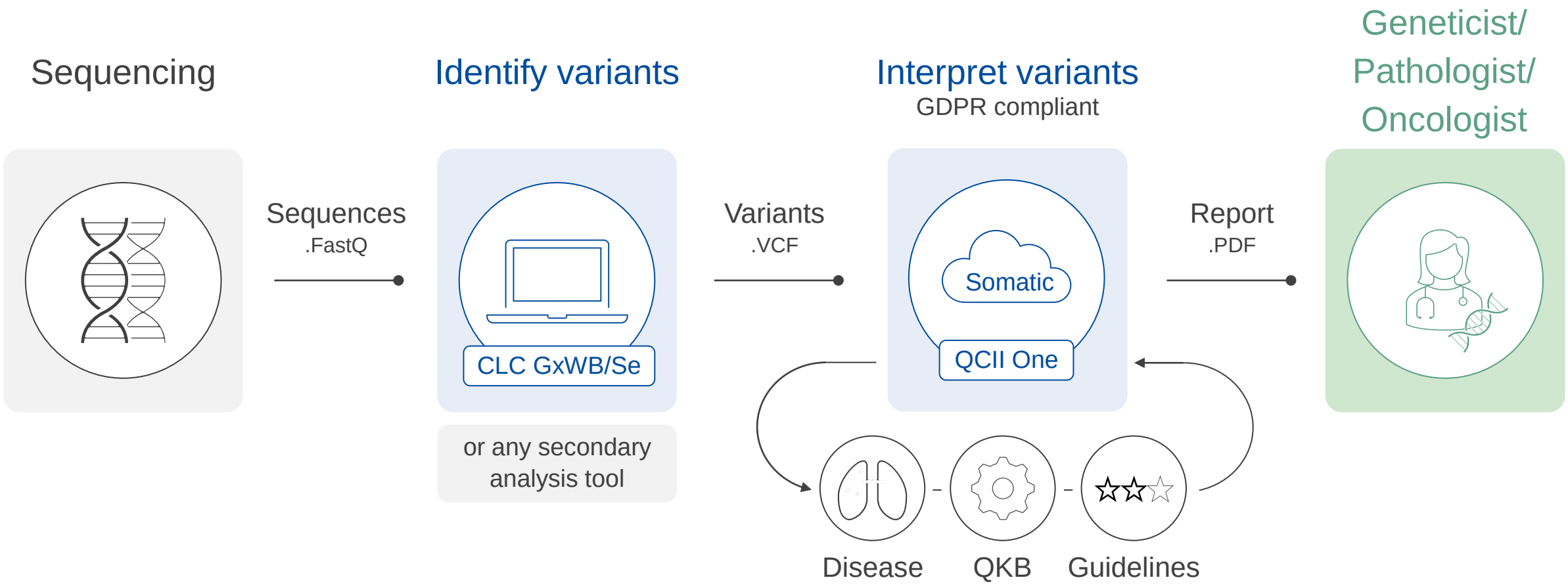
Thousands of variants must be filtered down to a subset of only the most clinically relevant

Tomorrow

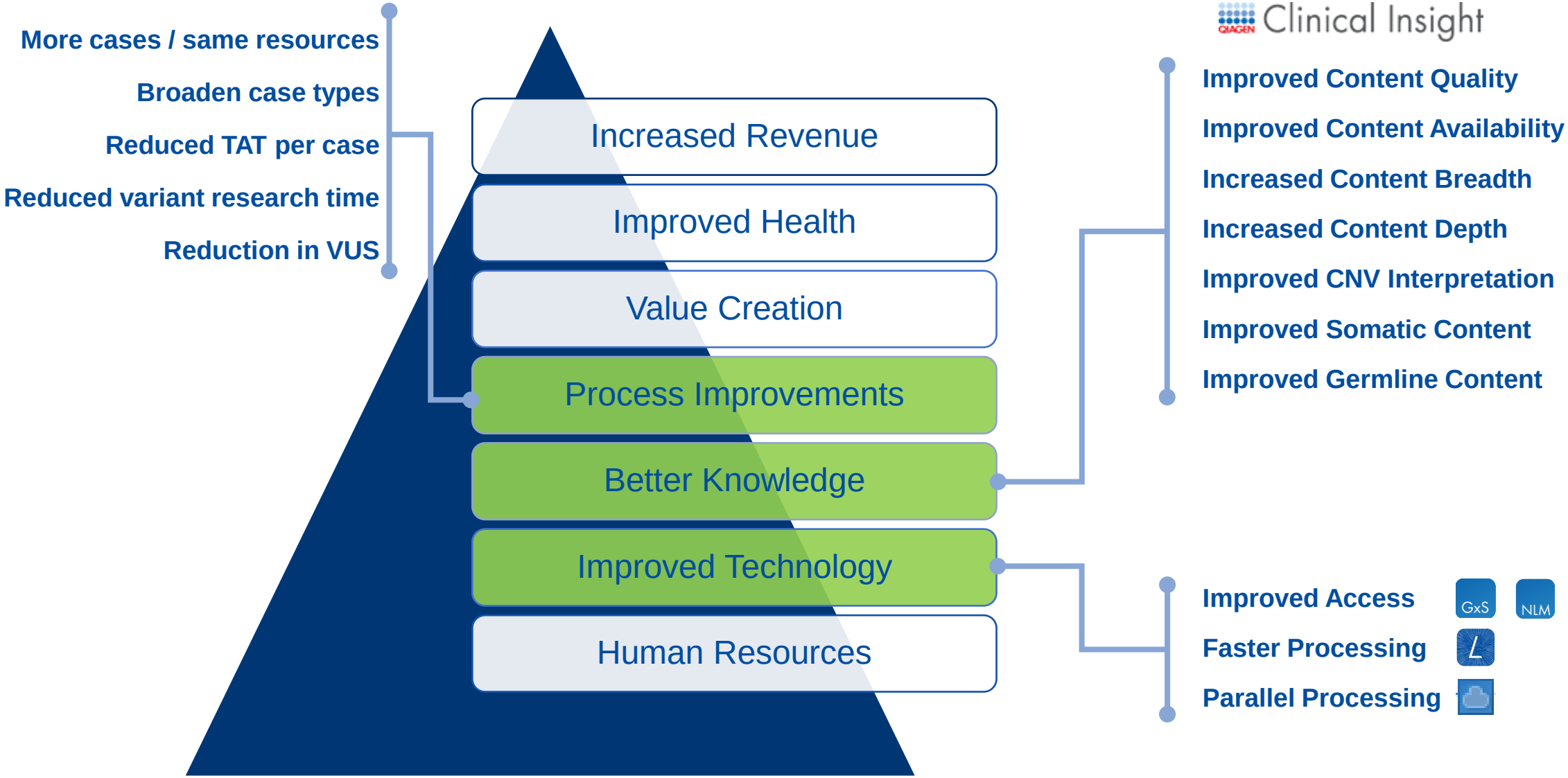
Confident assessment in minutes:

- **Automated variant analysis**
- **Evidence backed results**
- **Clinical ready reports**

Sequencing to variant reporting

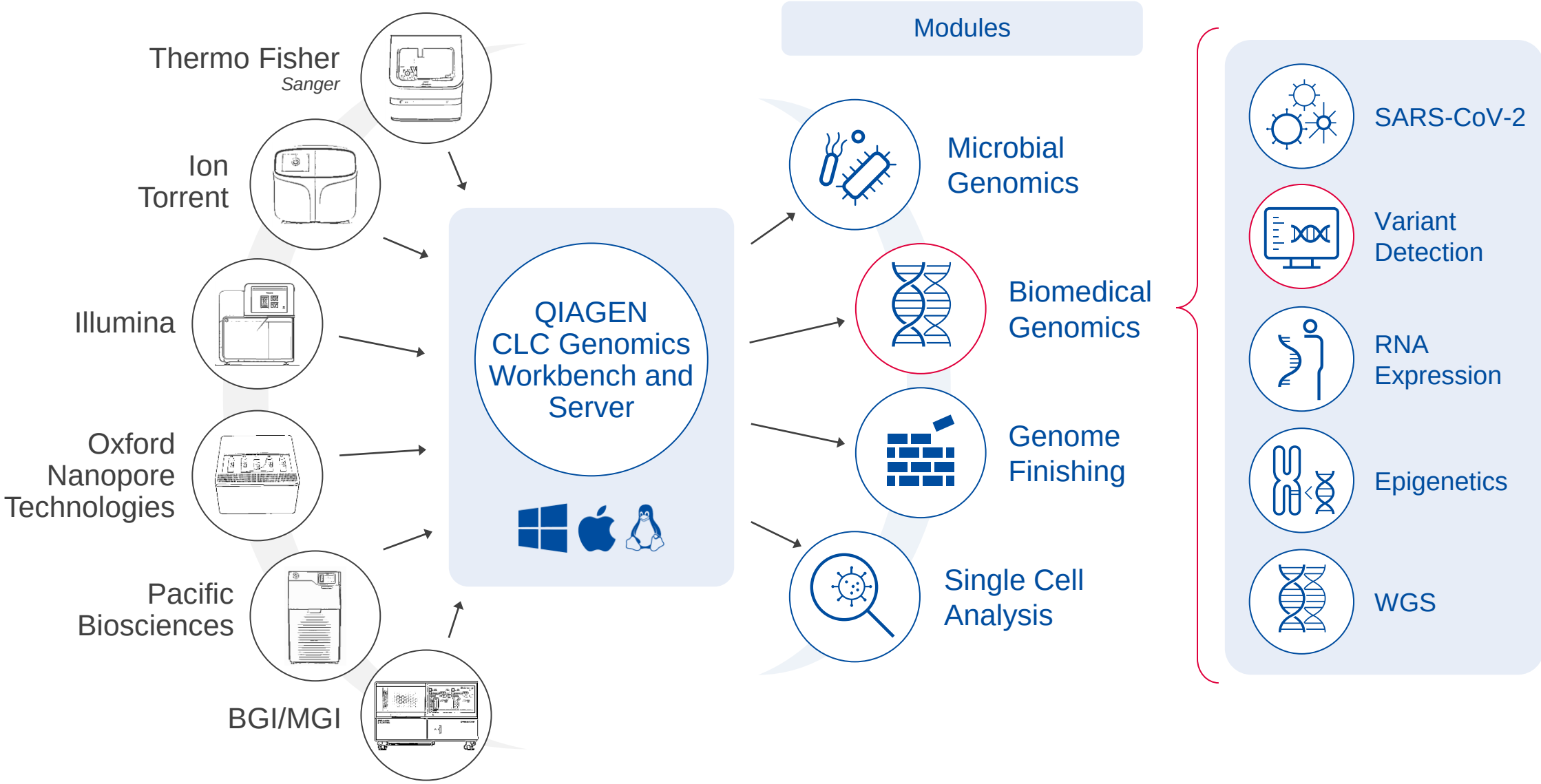


How we impact our customers to achieve their goals



CLC Genomics Workbench

A single environment for multiple applications



Reads to Results: How we have helped our customers be successful

- **Somatic QIAseq and other targeted oncology analysis and interpretation**
- **Hereditary cancer, germline testing, plus ultrafast whole exome, and whole genome analysis**
- **Targeted and whole transcriptomic secondary analysis and biological interpretation**
- **Immune repertoire and single-cell analysis**
- **Metagenomics, strain-typing, AMR and general microbiology applications**
- **SARS-CoV-2 sequencing and surveillance**

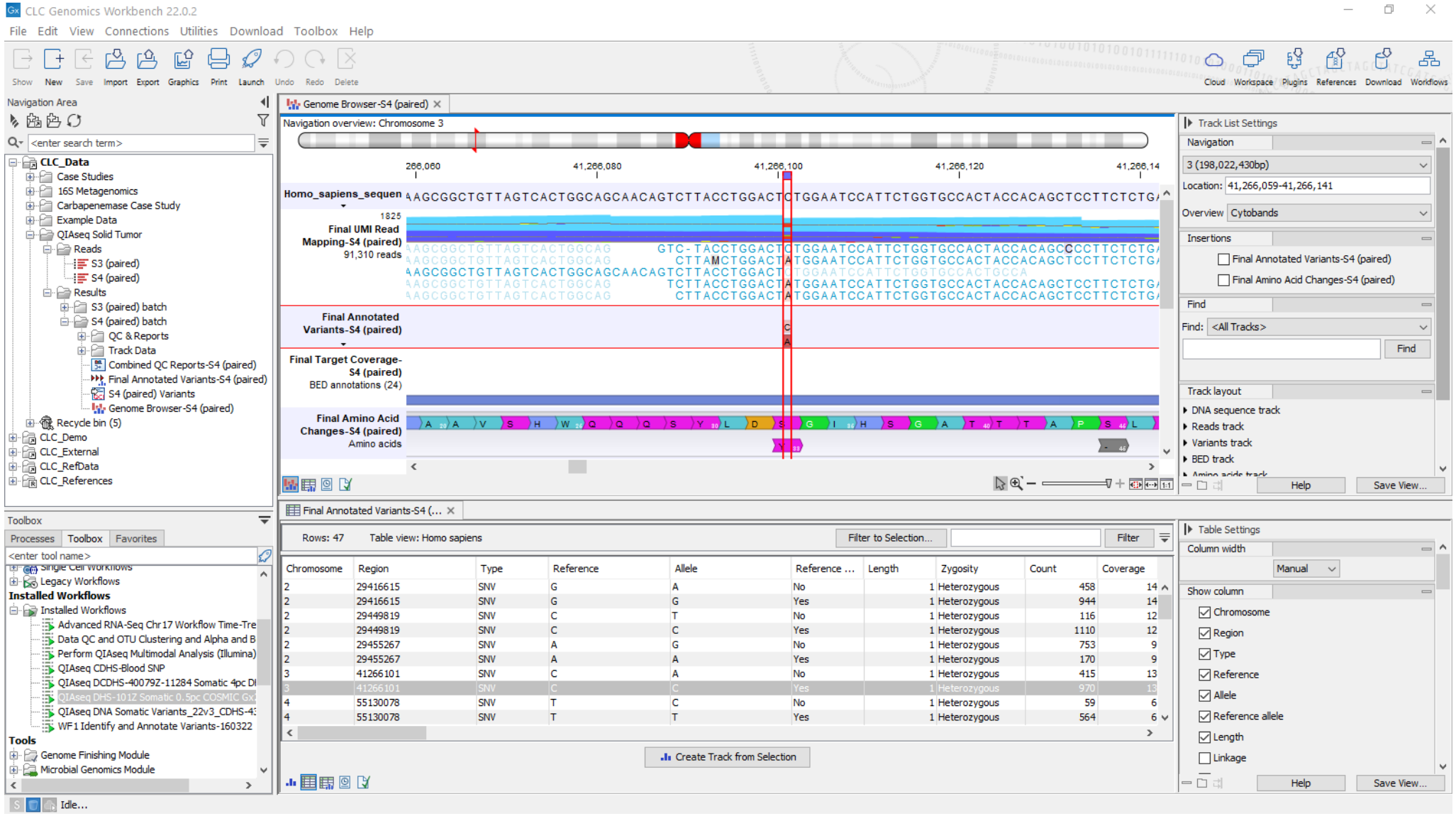
QIAGEN CLC Genomics Platform: An overview

QIAGEN CLC Genomics Workbench Premium desktop software

QIAGEN CLC Genomics Server software

QIAGEN CLC Genomics Cloud computing

QIAGEN CLC Genomics Workbench standardizes the secondary analysis of reads to VCF



QIAGEN CLC Genomics Workbench features

Cross-platform desktop genomics application with a graphical user interface

User-friendly interface

Interactive visualizations to facilitate analysis

Ready-to-use and customizable workflows

- For automated processing
- For sharing with colleagues

Modular design to add plugins

Developed under quality standard ISO 9001:2015 certification

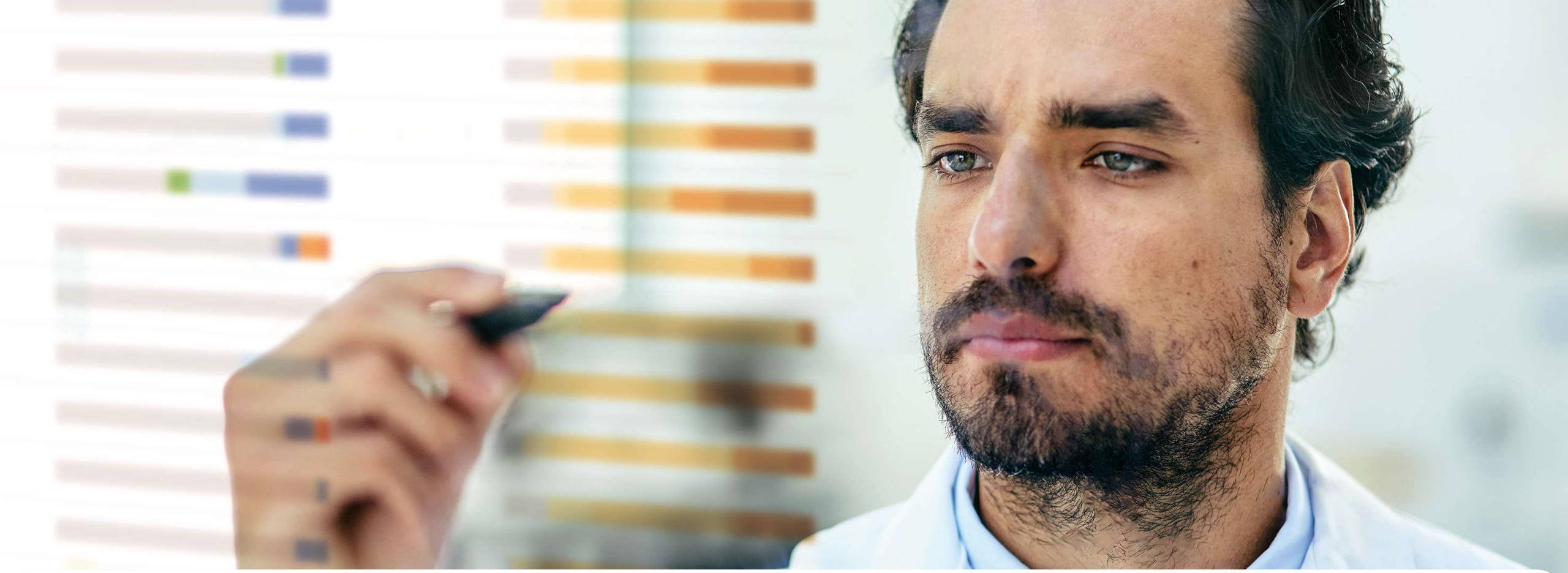
Works on Windows, Mac and Linux

Works with reads from most platforms (Illumina, Ion Torrent, Oxford Nanopore, Pacific Biosciences, BGI/MGI)

Scalable to high-throughput settings

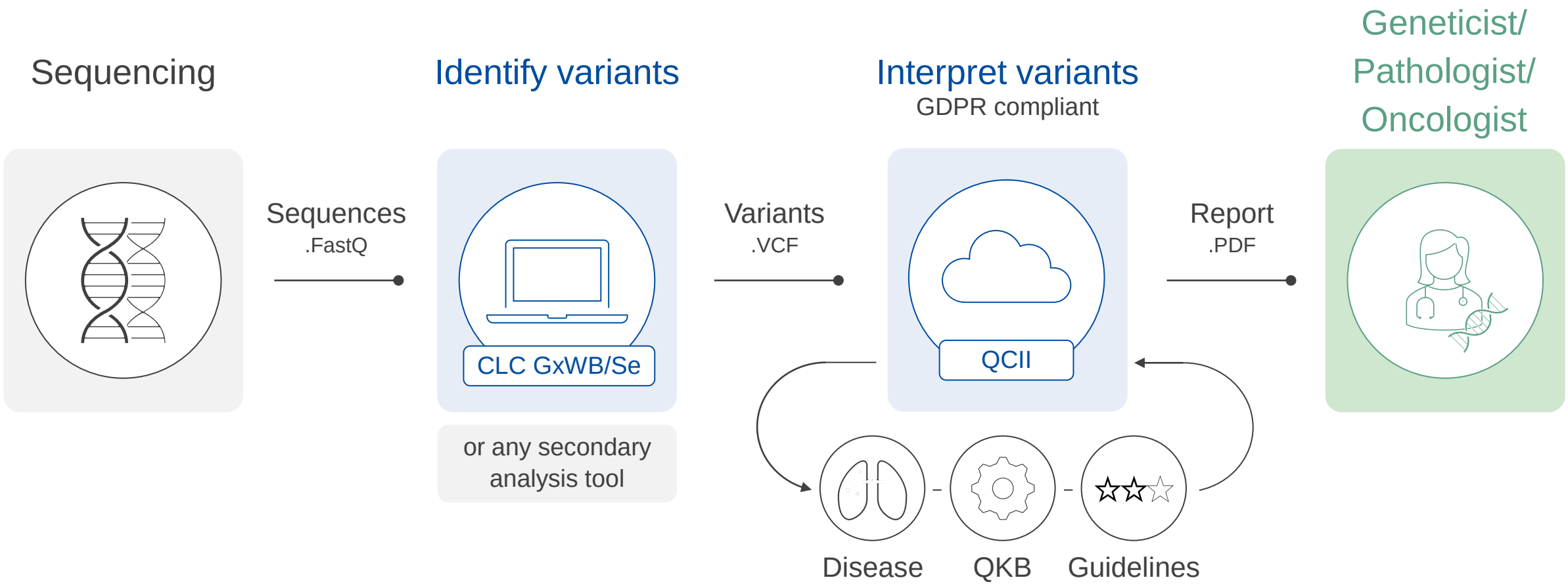
Fully documented and supported

GMP ready: Audit-log, user management, file provenance and history on all output files



QIAGEN CLINICAL INSIGHT (QCI-I)

Sequencing to variant reporting



QIAGEN Knowledge Base

Manual curation

Clinical cases, studies, literature et al. curated by 200+ certified professionals

AI curation

AI-driven integration of published data

21Y+

QIAGEN Knowledge Base

ISO9001 & ISO13485

Somatic only

Expert curation

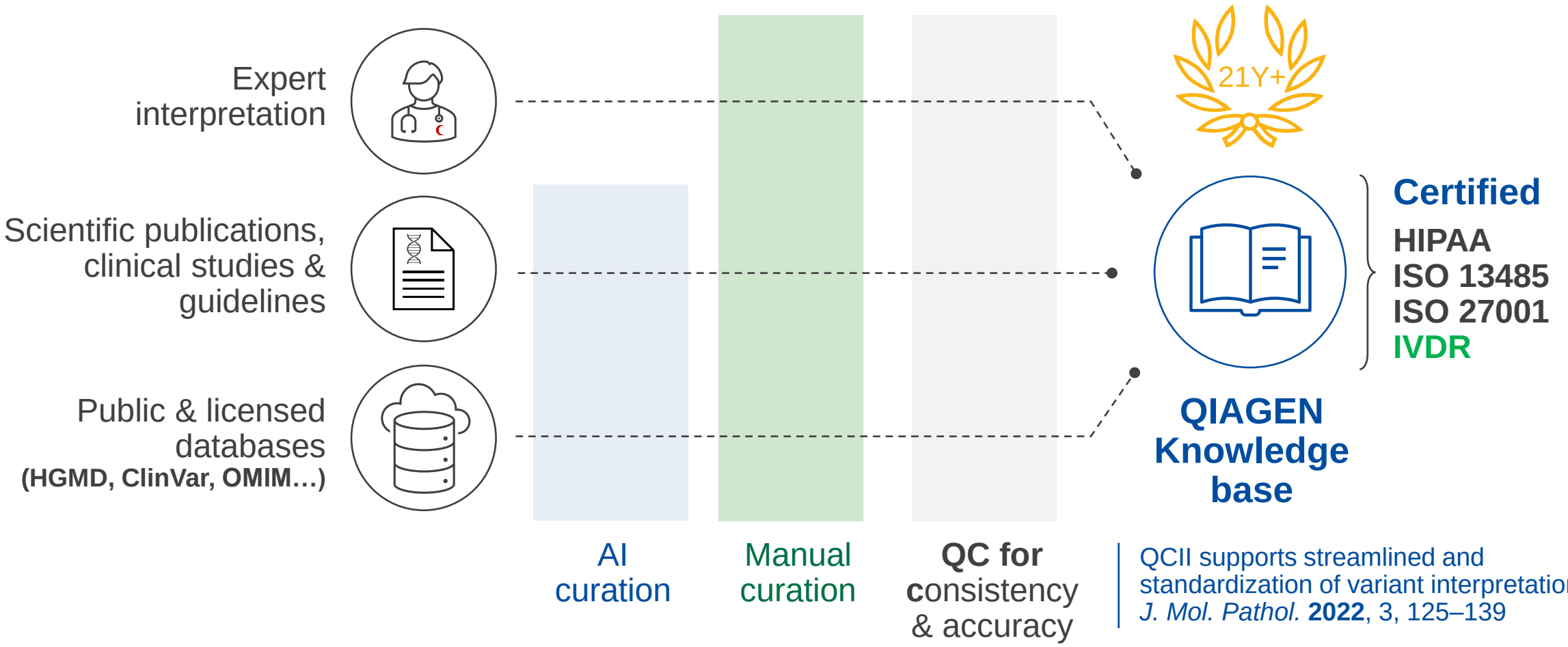
Real clinical cases reviewed by oncologists

Machine curation

In-silico prediction
40+ third party databases
Gene models
(MANE Select, RefSeq, ENSEMBL)

Disease classes:	76,000+
Curated genes:	1,400+
Unique findings:	21 M+
Curated variant findings:	9 M+
New curated variants/month:	5,000+

Trusted content



QCII supports streamlined and standardization of variant interpretation: *J. Mol. Pathol.* **2022**, 3, 125–139

Key features of QKB

- Automatic updates of variant actionability, pathogenicity and functional consequence
- Benefit from instant prioritization of clinically relevant variants, for each patient case
- For every variant in any gene, in any phenotype:
  - ACMG pathogenicity and AMP actionability classifications
  - Molecular function
  - Incidence in disease
  - Review of potentially incidental findings
  - Cancer-relevant prognostic and diagnostic evidence
  - Cancer-relevant treatments (sensitive/resistant)
  - Open and recruiting local clinical trials
- Knowledge updated weekly

Somatic interpretation made easy in a few steps

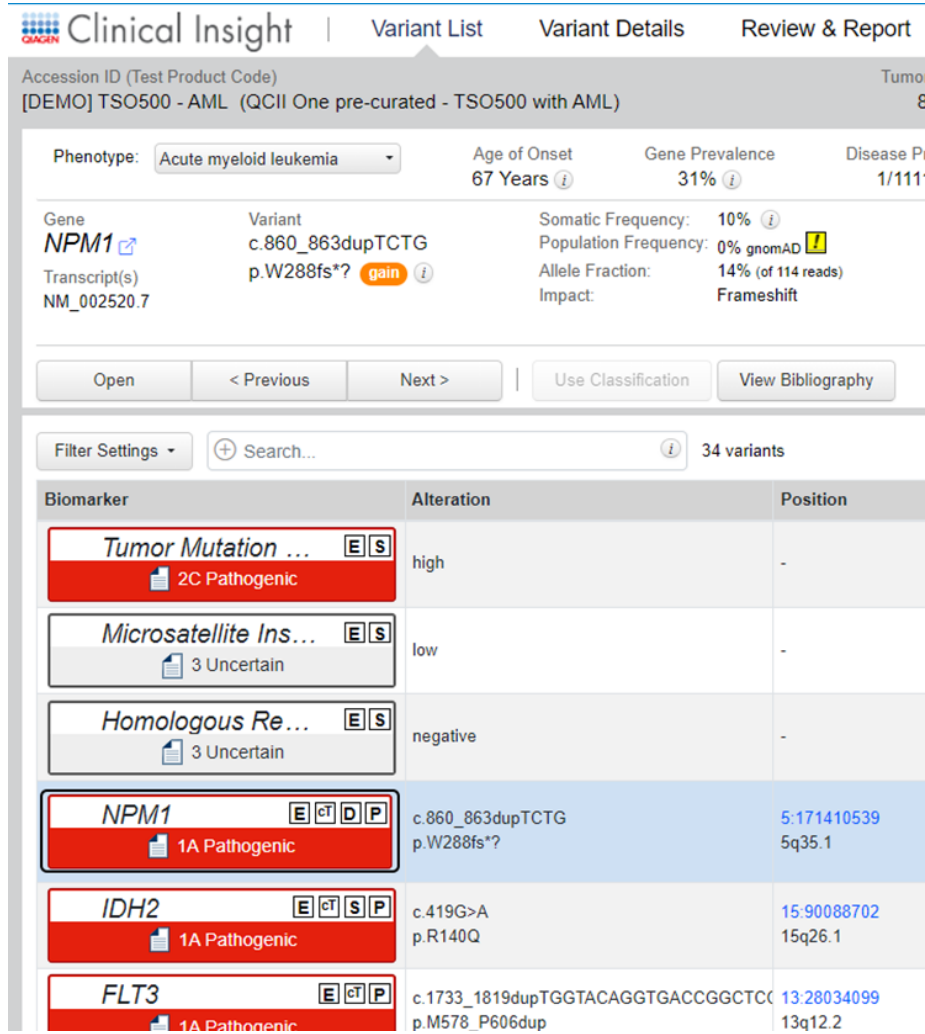
1. Upload variants and patient information (.VCF)

Automatic computing of the assessment
(ACMG & AMP compliant)

2. Review evidences and assess classification

3. Submit for Expert interpretation

4. Sign out & print the report (.PDF)



Copy of [DEMO] TSO500 - AML (QCII One pre-curated - TSO500 with AML)

Tumor Content	Age	Sex	Ethnicity	Diagnosis	Stage	TMB Score
80%	67	Female	Caucasian	Acute myeloid leukemia	IIB	11.5 Mut/Mb

Phenotype: Acute myeloid leukemia

Age of Onset	Gene Prevalence	Disease Prevalence
67 Years	31%	1/11111

Gene: *NPM1*
Transcript(s): NM_002520.7
Variant: c.860_863dupTCTG
p.W288fs*? gain

Somatic Frequency: 10%
Population Frequency: 0% gnomAD !
Allele Fraction: 14% (of 114 reads)
Impact: Frameshift

Computed Classification: Tier 1A Pathogenic Acute myeloid leukemia

New Assessment: Tier 1A **Pathogenic** for Acute myeloid leukemia
Reportable

Open | < Previous | Next > | Use Classification | View Bibliography

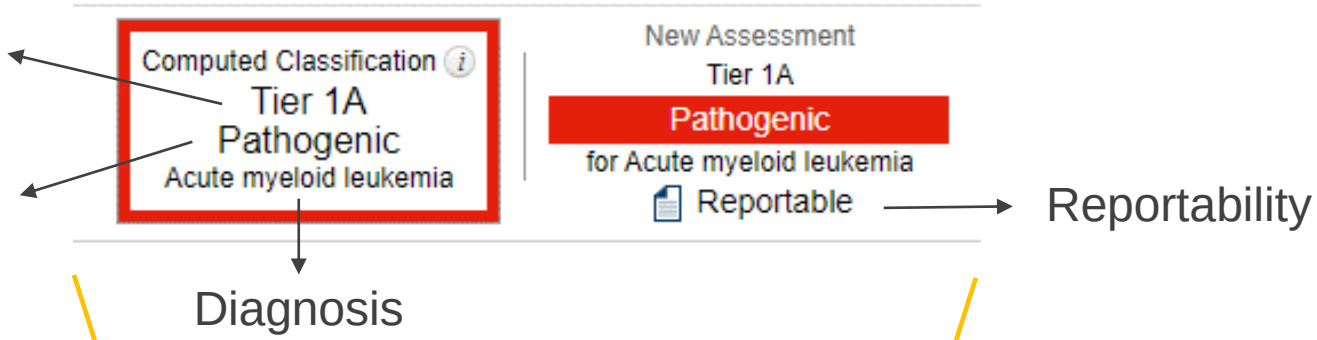
Filter Settings | Search... | 26 variants | 1 | View Settings

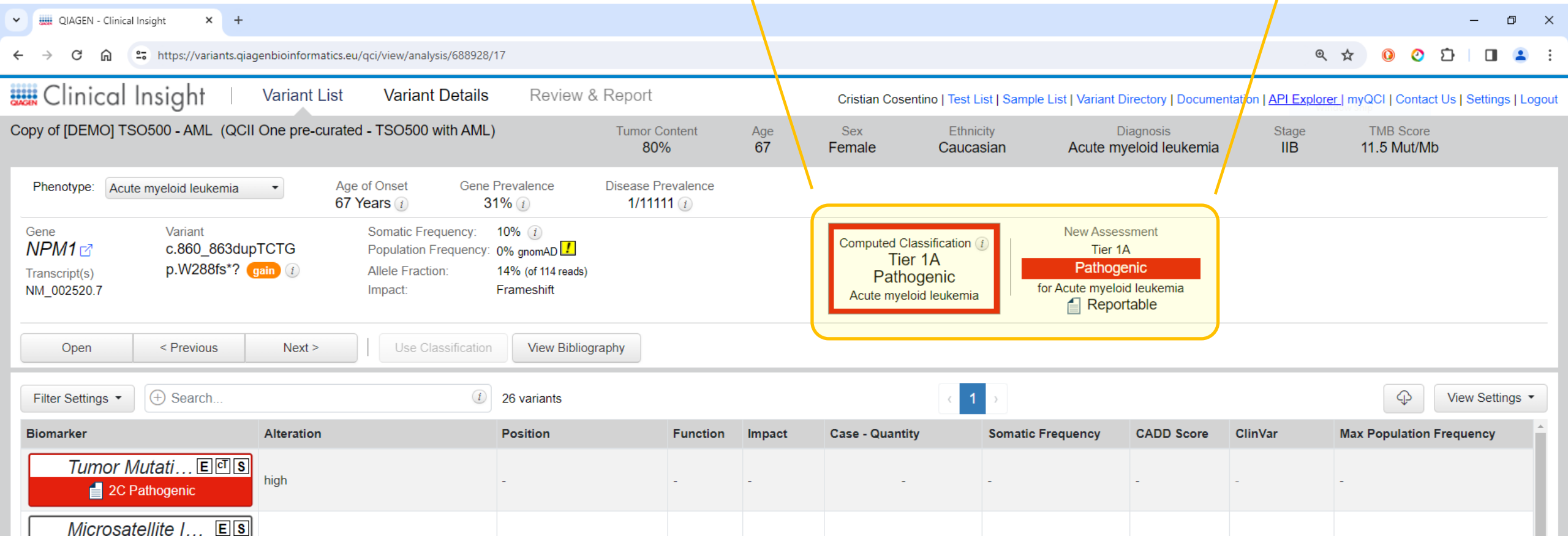
Biomarker	Alteration	Position	Function	Impact	Case - Quantity	Somatic Frequency	CADD Score	ClinVar	Max Population Frequency
Tumor Mutati… E cT S 2C Pathogenic	high	-	-	-	-	-	-	-	-
Microsatellite I… E S 3 Uncertain	low	-	-	-	-	-	-	-	-
Homologous … E S 3 Uncertain	negative	-	-	-	-	-	-	-	-
NPM1 E cT D P 1A Pathogenic	c.860_863dupTCTG p.W288fs*?	5:171410539 5q35.1	gain	Frameshift	14% (of 114 reads)	10%	33	P(3)	0% gnomAD
1A *IDH2* E cT S P	c.419G>A p.R140Q	15:90088702 15q26.1	gain	Missense	34% (of 161 reads)	2.40%	29.3	P(9), LP(5)	0.0288% gnomAD (Ashkenazi Jewish)
FLT3 E cT P 1A Pathogenic	c.1733_1819dupTGGTACAGGTGACCGG p.M578_P606dup	13:28034099 13q12.2	gain	In-Frame	25% (of 146 reads)	0.0014%	-	-	0% gnomAD

Computed classification

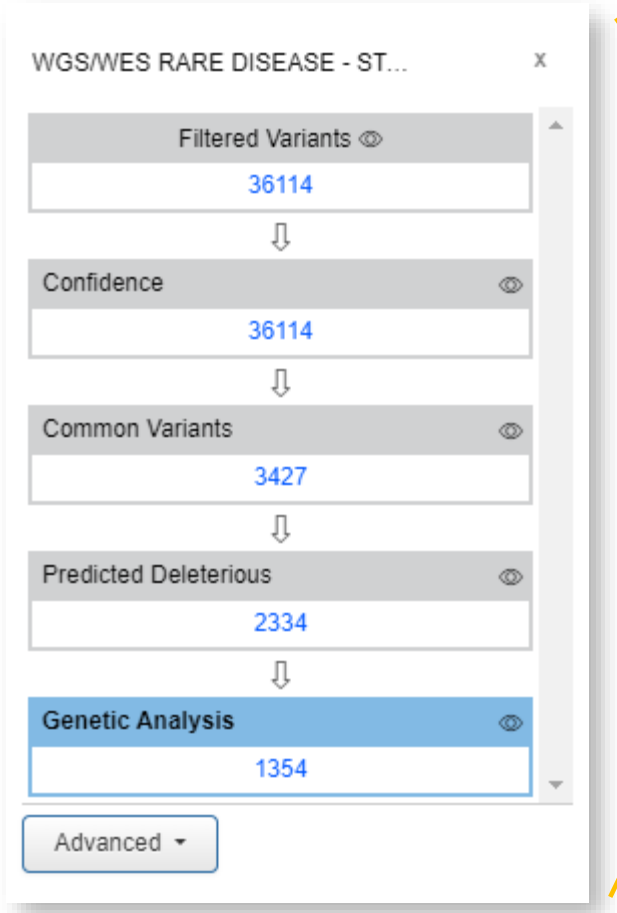
Classification by Actionability
(AMP/CAP/ASCO guidelines)

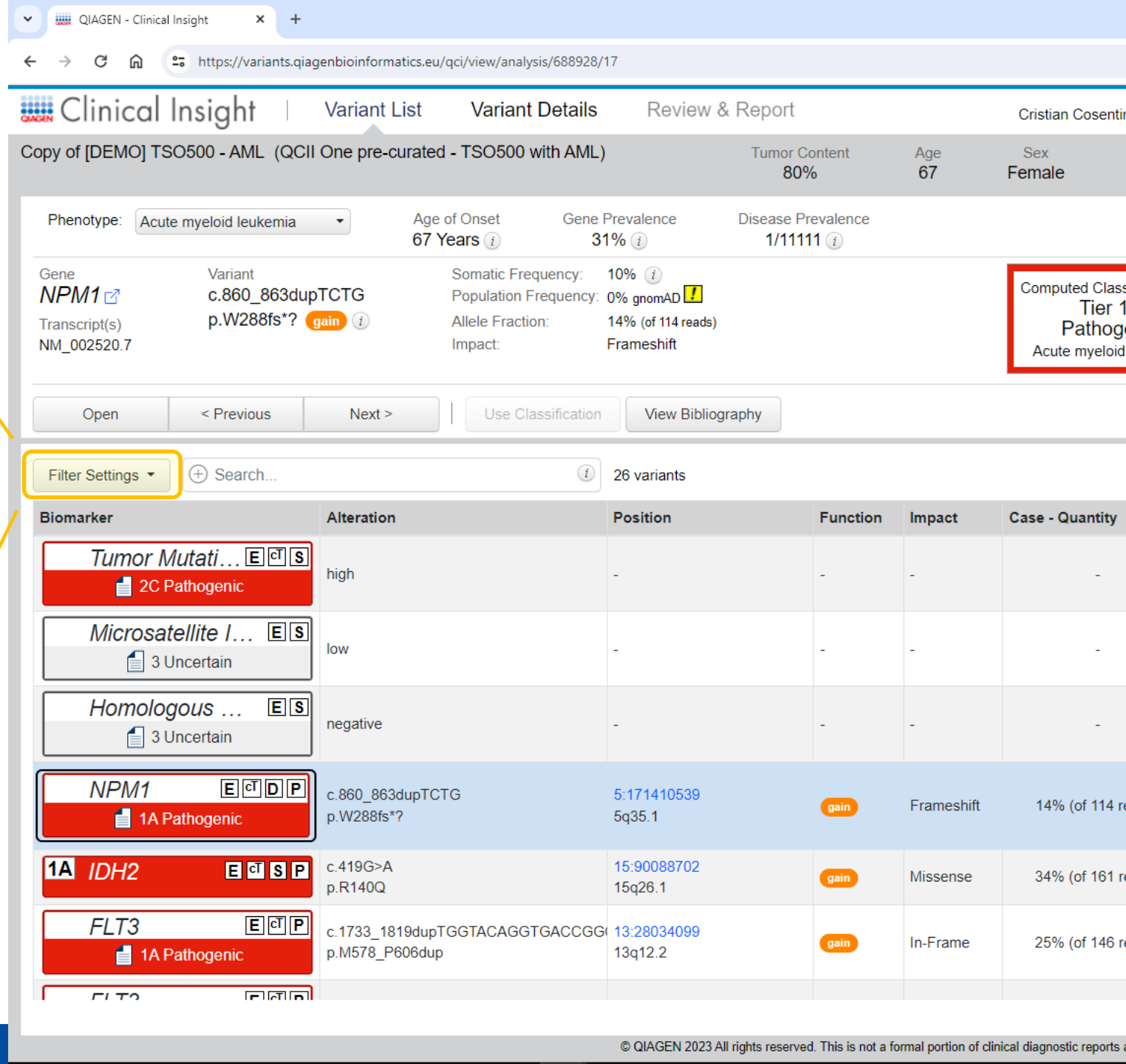
Classification by Pathogenicity
(ACMG guidelines)



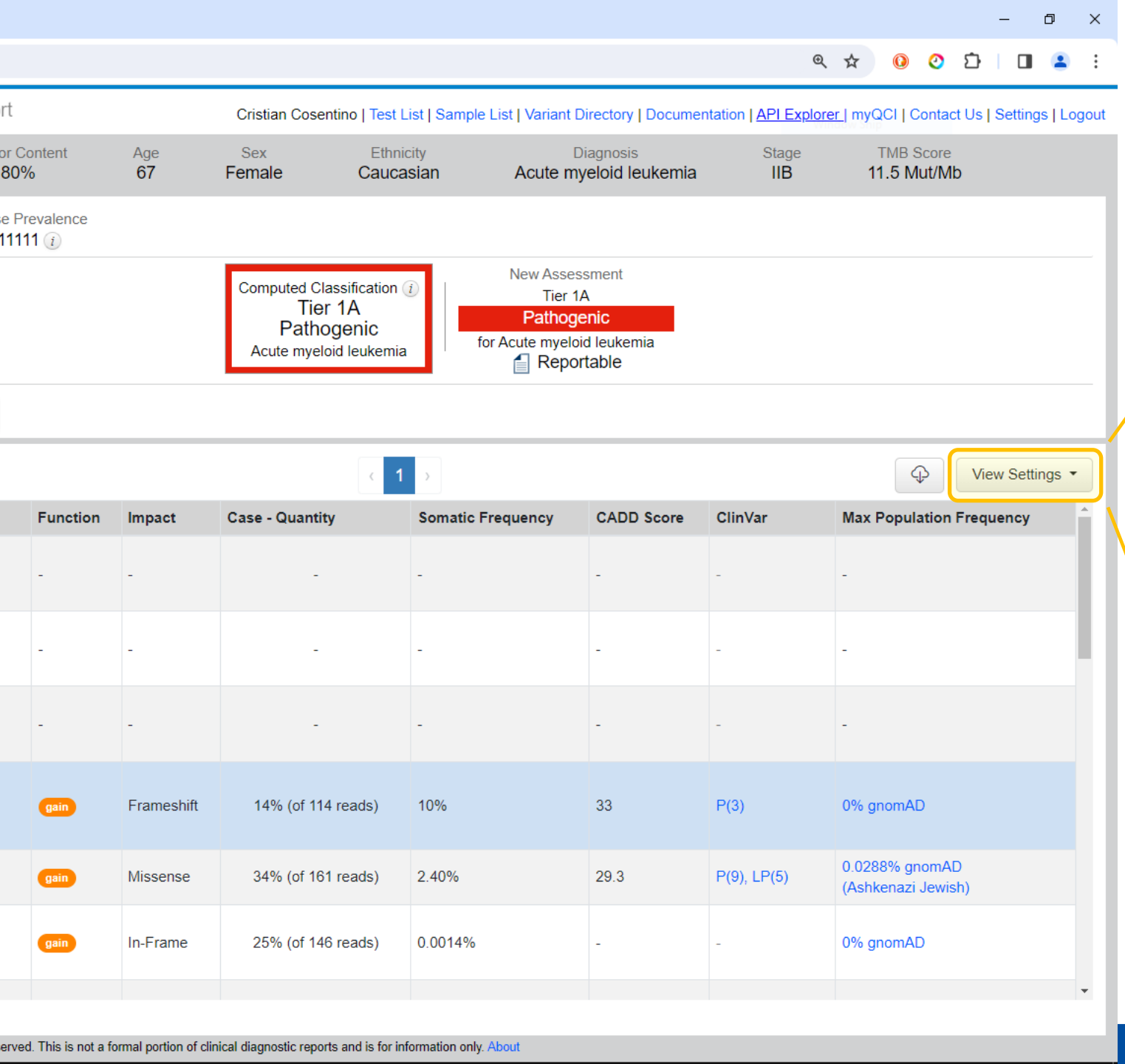


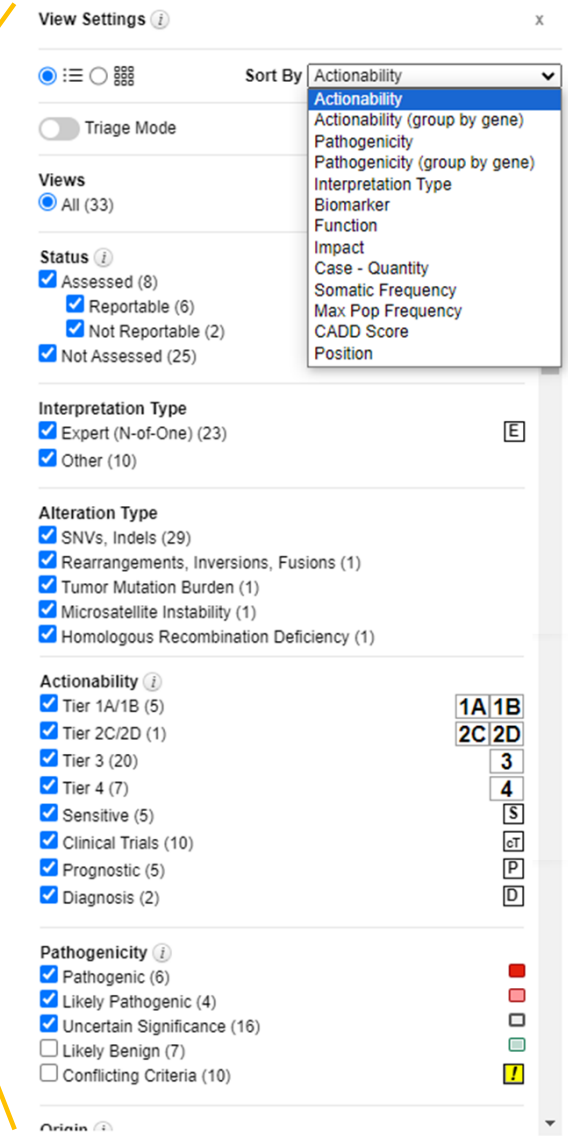
Filter cascade

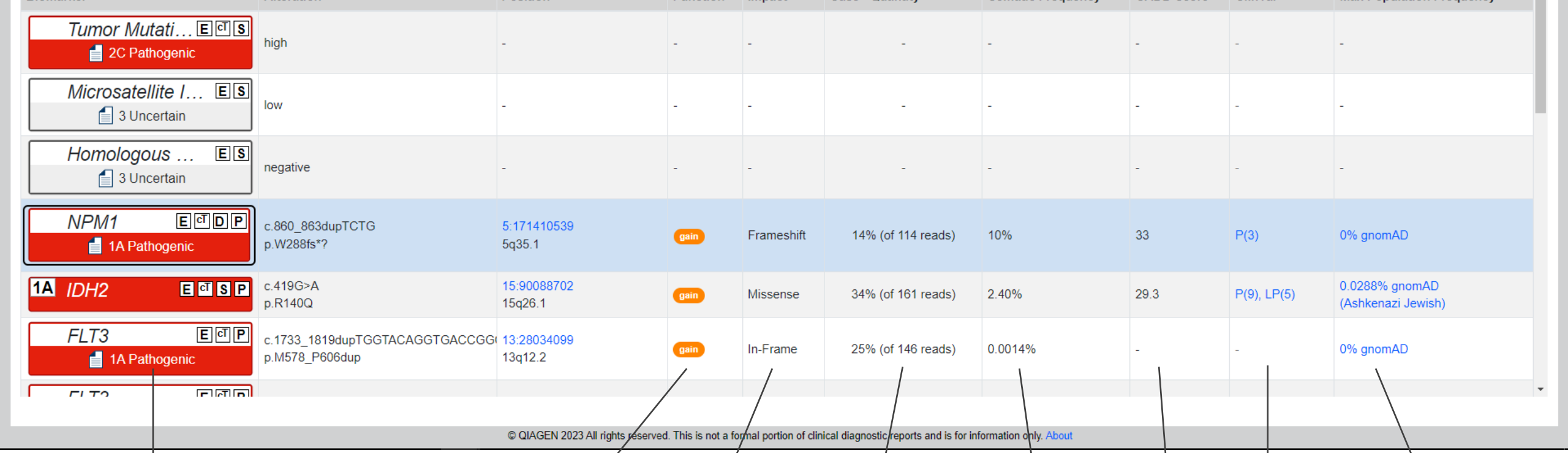




View settings







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NPM1 E cT D P — 1A Pathogenic	c.860_863dupTCTG p.W288fs*?	5:171410539 5q35.1	gain	Frameshift	14% (of 114 reads)	10%	33	P(3)	0% gnomAD
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Computed classification of a given variant

Effect of the mutation on gene function

Impact of the mutation

Allele frequency (over coverage in number of reads)

COSMIC variant frequency

In-silico computed CADD score

ClinVar reports

gnomAD population frequencies

Comprehensive visualization of the variant assessment

Accession ID (Test Product Code)	Tumor Content	Age	Sex	Ethnicity	Diagnosis	Stage	TMB Score
[DEMO] TSO500 - AML (QCII One pre-curated - TSO500 with AML)	80%	67	Female	Caucasian	Acute myeloid leukemia	IIB	11.5 Mut/Mb

Phenotype: Acute myeloid leukemia

Age of Onset: 67 Years | Gene Prevalence: 31% | Disease Prevalence: 1/11111

Gene: *NPM1*
Transcript(s): NM_002520.7

Variant: c.860_863dupTCTG
p.W288fs*? gain

Somatic Frequency: 10%
Population Frequency: 0% gnomAD
Allele Fraction: 14% (of 114 reads)
Impact: Frameshift

Computed Classification: Tier 1A Pathogenic Acute myeloid leukemia

New Assessment: Tier 1A Pathogenic for Acute myeloid leukemia Reportable

Variant List | < Previous | Next > | Use Classification | View Bibliography

Assessment

Actionability For This Diagnosis

		Criteria ID	Evidence	Rationale
x	Biomarker included in professional guidelines is prognostic for this diagnosis	1A-P	3	Add
x	Biomarker included in professional guidelines is diagnostic for this diagnosis	1A-D	2	Add
x	Biomarker is prognostic for this diagnosis based on well-powered studies	1B-P	3	Add
x	Biomarker serves as an inclusion criterion for one or more clinical trials	2C-CT	8	Add
x	Biomarker is plausibly prognostic for this diagnosis based on case studies	2D-P	6	Add

+ Add Criterion

Pathogenicity For Acute Myeloid Leukemia

		Criteria ID	Strength	Evidence	Rationale
x	Well-established in vitro or in vivo functional studies supportive of a damaging effect on the gene or gene product (Strong)	PS3	Strong	4	Add
x	The prevalence of the variant in affected individuals is significantly increased compared with the prevalence in controls [odds ratio = 57885.00; 95% confidence interval = (2524.95, 1327025.08); FET 2-tail p-value < 0.0001; affected individual count = 2; Note: Small number of affected individuals with variant.] (Strong)	PS4	Strong	1	Add
x	Absent from controls (or at extremely low frequency if recessive) in gnomAD [In these sources of population frequency data, this variant's frequency is 0% or <= 0.001%] (Moderate)	PM2	Moderate	-	Add
x	Multiple lines of computational evidence support a deleterious effect on the gene or gene product [CADD = 33.0] (Supporting)	PP3	Supporting	-	Add
x	Reputable source recently reports variant as pathogenic, but the evidence is not available to the laboratory to perform an independent evaluation (Supporting)	PP5	Supporting	2	Add

+ Add Criterion

Actionable information

Quick reportability

Treatments

Clinical trials

Prognostic outcomes

Filter by location

Filter by source

▼ Treatment Information

Treatments Report All Showing | Unreport All Showing Change Phenotype To: All Cancers 5 treatment(s) ineligible

Treatment	Response	Evidence	Specificity	Indication	References
daunorubicin	Sensitive	3	NPM1 mutation positive	Acute myeloid leukemia with recurrent genetic abnormalities	...
cytarabine/daunorubicin	Sensitive	3	NPM1 mutation positive	Acute myeloid leukemia	Clinical Studies
cytarabine/daunorubicin	Not Established	3	NPM1 mutation positive	Acute myeloid leukemia	Clinical Studies
decitabine	Not Established	3	NPM1 mutation positive	Acute myeloid leukemia	Clinical Studies

▼ Clinical Trials

Clinical Trials Report All Showing | Unreport All Showing Change Phenotype To: All Cancers 5 trials(s) ineligible

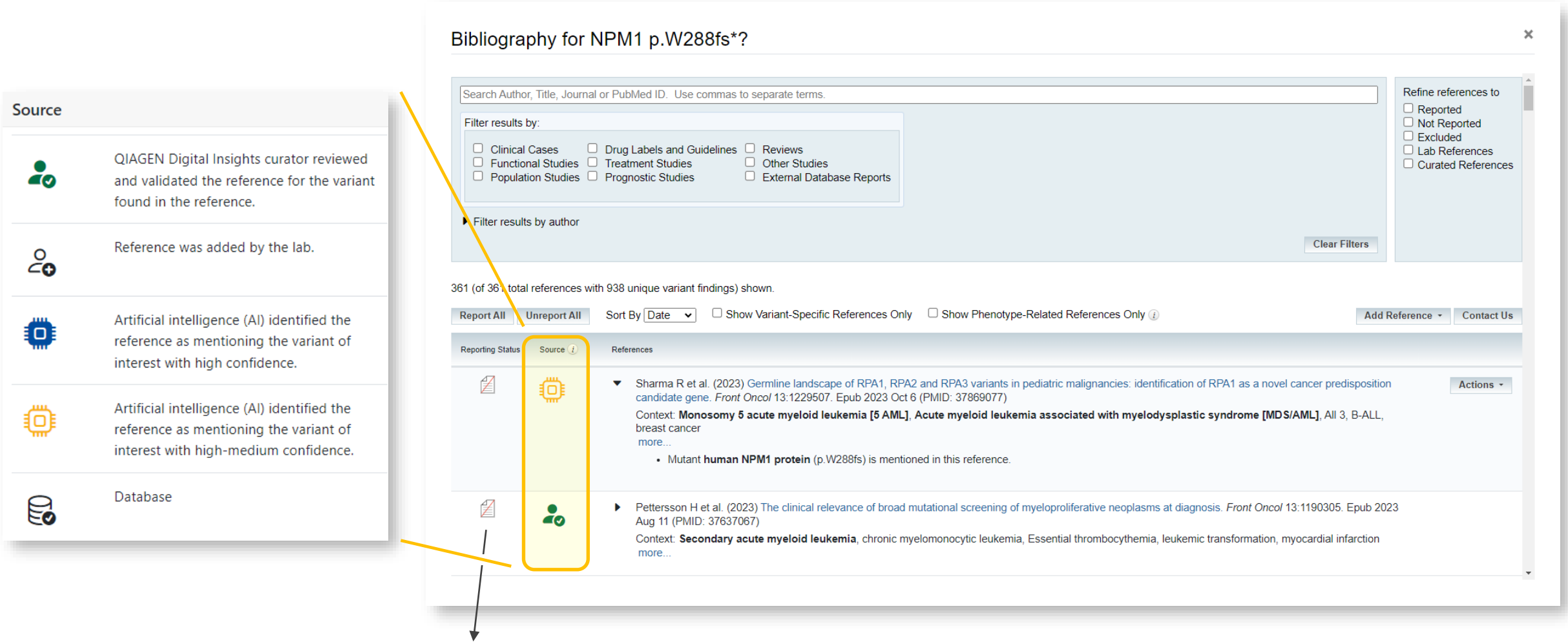
Treatment	Specificity	Study Title	Closest Location	FDA Phase	Reference
revumenib, cobicistat	NPM1 mutation positive	A Phase 1/2, Open-label, Dose-Escalation and Dose-Expansion Cohort Study of SNDX-5613 in Patients With Relapsed/Refractory Leukemias, Including Those Harboring an MLL/KMT2A Gene Rearrangement or Nucleophosmin 1 (NPM1) Mutation	University of Colorado, Aurora, Colorado, 80045, United States	Phase 1/Phase 2	NCT04065399

▼ Prognostic Outcomes

Report All Showing | Unreport All Showing Change Phenotype To: All Cancers

Prognosis	Outcome/Endpoint	Evidence	Specificity	Indication	References
favorable	clinical prognosis	1A	NPM1 mutation positive	Acute myeloid leukemia	ESMO, ...
favorable	response rate	1A	NPM1 mutation positive	Acute myeloid leukemia	...

Extended curated biography



Quick reportability of the information

Accession ID (Test Product Code)	Tumor Content	Age	Sex	Ethnicity	Diagnosis	Stage	TMB Score
[DEMO] TSO500 - AML (QCII One pre-curated - TSO500 with AML)	80%	67	Female	Caucasian	Acute myeloid leukemia	IIB	11.5 Mut/Mb

450 Days
System rec'd 2022-08-29

In Review
Current State

Change State | Expert Interpretation Complete | Sign Out | Preview Report | Label Report

Marked Reportable	3 Biomarkers	3 Variants	6 Treatments	3 Clinical Trials	4 Prognostic Outcomes	209 References

⚠ This analysis contains 6 unassessed variants with conflicting criteria.

Signing out of the final report

Overall Interpretation

Positive | Presumed Positive | Inconclusive | Presumed Negative | Negative | Omit Interpretation

Add Overall Comment

Report Comment:

Guidelines: The 2017 ELN recommendations place AML patients with wild-type NPM1 plus a high allelic ratio of FLT3-ITD (greater than or equal to 0.5) in the adverse risk category, while patients with mutated NPM1 plus a high allelic ratio of FLT3-ITD, as well as patients with wild-type NPM1 plus a low allelic ratio of FLT3-ITD (less than 0.5), are placed in the intermediate risk category.; AML patients with mutated NPM1 and a low allelic ratio of FLT3 are placed in the favorable risk category [PMID:27895058]. These guidelines additionally state that midostaurin plus standard chemotherapy may be considered for both induction and consolidation therapy in AML patients aged 18-60 years with an activating FLT3 mutation [PMID:27895058]. AML with mutant NPM1 is recognized as a subtype of AML with recurrent genetic abnormalities in the WHO classification of myeloid neoplasms and acute leukemia [PMID:27069254]. The 2017 ELN recommendations place AML patients with wild-type NPM1 plus a high allelic ratio of FLT3-ITD (greater than or equal to 0.5) in the adverse risk category, while patients with mutated NPM1 plus a high allelic ratio of FLT3-ITD, as well as patients with wild-type NPM1 plus a low allelic ratio of FLT3-ITD (less than 0.5), are placed in the intermediate risk category.; AML patients with mutated NPM1 and a low allelic ratio of FLT3 are placed in the favorable risk category [PMID:27895058].

Interactions: NPM1 mutations in the presence of FLT3-ITD, as reported here, have been associated with intermediate prognosis in the case of a high allelic ratio of FLT3-ITD, and with favorable prognosis in the case of a low allelic ratio of FLT3-ITD in AML [PMID:27895058, PMID:26551637, PMID:23377436, PMID:27416910]. The results of studies examining the effects of combined IDH2 and NPM1 mutations have been mixed. One study of 398 AML patients reported that the favorable prognostic impact of NPM1 mutations may be limited to patients who also harbor IDH1 or IDH2 mutations. However, another study of 805 AML patients reported that IDH2 mutations were associated with reduced relapse-free survival and overall survival in the context of cytogenetically normal AML with NPM1 mutations but without FLT3-ITD. Thus, additional studies are required to clarify the prognostic significance of co-occurring NPM1 and IDH2 mutations in AML [PMID:22417203,

Edit

Reportable Biomarkers

Acute Myeloid Leukemia

Biomarker	Actionability	Expert Interpretation	Pathogenicity	References

Expert curation

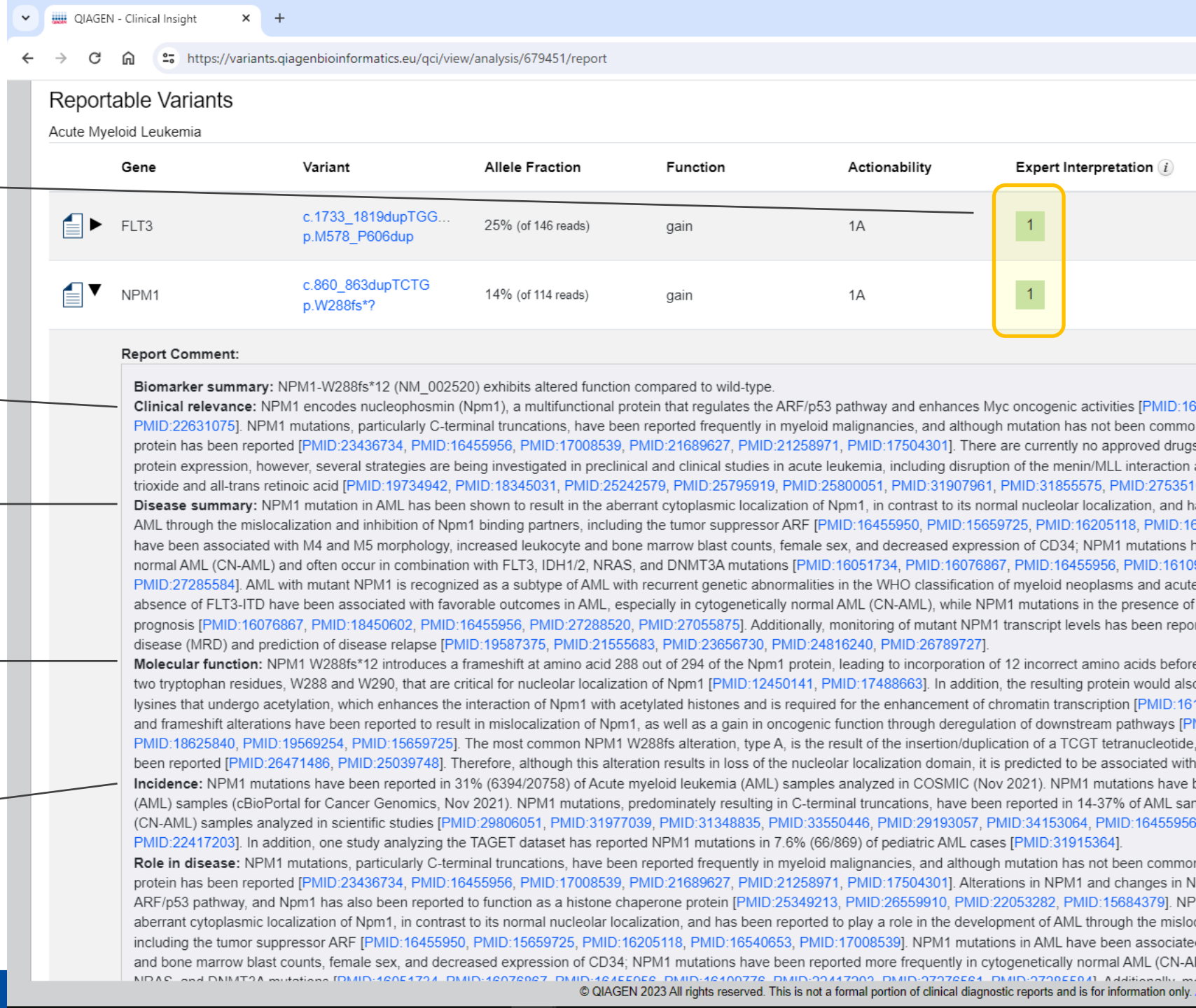
Second opinion from practicing oncologists

Available clinical information on the gene

Correlation of the gene with the disease

Molecular effects of the specific variant in the disease

Statistics on the recurrence of the gene in diseases
(COSMIC, cBioPortal)



Awaiting approval of IVDR certification

QIAGEN Digital Insights announces QCI Interpret to support In Vitro Diagnostic Regulation (IVDR) in Europe

April 11, 2023

- **QIAGEN Redwood City receives ISO 13485:2016 certification for its Medical Devices and Quality Management Systems based on the QCI Interpret product**
- **QCI Interpret is awaiting approval as an IVDR under (EU) 2017/746**
- **Enabling the continued use of QCI Interpret, a product used to process over 3 million NGS patient test cases for oncology and hereditary diseases, beyond 2025 in the European Union**

Redwood City, California, April 11, 2023 – QIAGEN Digital Insights, the bioinformatics division of QIAGEN, today announced it is progressing towards its goal of getting its clinical decision support platform, QIAGEN Clinical Insights Interpret (QCI Interpret), certified under the new In Vitro Diagnostic Regulation (IVDR). QIAGEN Redwood City, the development site of the QCI Interpret platform, has successfully received ISO 13485:2016 certification for its Medical Devices and Quality Management Systems based on the QCI Interpret product. The company is awaiting approval of QCI Interpret as an IVDR medical device under the current regulation (EU) 2017/746 based on formal submission of the technical documentation.

ISO 13485:2016 is an internationally recognized quality standard to ensure the consistent design, development, production, installation, and sale of medical devices that are safe for their intended

QCII interprets WGS data at the Danish National Genome Center

Danish National Genome Center selects QIAGEN for variant interpretation in oncology genome sequencing

June 13, 2023

- **Denmark one of the first countries to implement whole-genome sequencing (WGS) as a standard-of-care for oncology and to adopt QCI Interpret to support the national initiative**
- **QCI Interpret to be used at testing sites throughout Denmark to provide evidence-based variant interpretation and reporting results**
- **With QCI Interpret, authorized staff from labs across Denmark can interpret WGS data consistently and efficiently while meeting data privacy and security requirements**

Simplify oncology NGS testing and clinical reporting for high-throughput data using QIAGEN CLC Genomics Workbench and QCI Interpret tools

Venlo, the Netherlands, and Redwood City, California, June13, 2023 (GLOBE NEWSWIRE) -- QIAGEN (NYSE: QGEN; Frankfurt Prime Standard: QIA) today announced that its variant interpretation and reporting software, QIAGEN Clinical Insight (QCI) Interpret, is being deployed as a part of a national initiative in Denmark to offer sequencing-based solutions for cancer patients.

The QCI Interpret solution was chosen by the Danish National Genome Center to provide interpretation of oncology results generated from whole-genome sequencing (WGS) data. The initiative is part of a larger personalized medicine strategy that aims to provide WGS as the standard-of-care for relevant patient groups throughout Denmark.

Security, compliance and data priva of QIAGEN® Digital Insights hosted

Summary

QIAGEN Digital Insights applications are hosted in tier 4 data centers strategically located to ensure world-class performance, continuous availability and the highest levels of security for our customers. The data centers are SSAE SOC 1 Type II / Soc 2 Type II and ISO27001 compliant, certified annually by external auditors (audit reports available upon request).

Exceed industry standards

QIAGEN Digital Insights provides hosting capabilities intended to exceed industry standards. The data center footprint extends worldwide, with a presence in 17 key markets in North America, Europe and Asia. The infrastructure has been designed for built-in redundancy with secondary locations for disaster recovery.

Full redundancy

The hosting environment provides fully redundant internet connections and network infrastructure designed to support QIAGEN's rapid growth and expanding need for hosting capabilities. The data center facility provides N+1 minimum redundancy with an uninterruptable power source (UPS) as well as additional power generation, cooling and humidity control.

Advanced

The highly secur
physical securit
closed-circuit re
are protected w
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and out of the c
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QIAGEN Digita
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application and
Information Por
certified and co
Regulation (CFR
plans (CAPS) a
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and policy upd
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technical and p
mandates.

EU-U.S. Data Privacy Framework (DPF) and UK Extension, and the Swiss-U.S. DPF

QIAGEN Digital Insights is a certified member of the Privacy Shield initiative and in compliance with the EU-U.S. Data Privacy Framework (DPF) and UK Extension, and the Swiss-U.S. DPF. QIAGEN Digital Insights has certified its privacy practices as consistent and compliant with the EU-U.S. DPF and UK Extension, and the Swiss-U.S. DPF as set forth by the U.S. Department of Commerce regarding the collection, use and retention of personal information from European Union member countries and Switzerland. QIAGEN Digital Insights has certified that it adheres to the EU-U.S. DPF and UK Extension, and the Swiss-U.S. DPF of notice, choice, onward transfer, security, data integrity, access and enforcement. To learn more about the EU-U.S. DPF and UK Extension, and the Swiss-U.S. DPF, and to view our certification page, please visit https://www.dataprivacyframework.gov/s/. Data is managed with respect and integrity and is only accessible by those with required business justification. QIAGEN Digital Insights supports and maintains internal and external policies that enforce the primary components of the EU-U.S. DPF and UK Extension, and the Swiss-U.S. DPF.

Compliance and audit

- HIPAA
- ISO 9001 / Quality Management Systems (QIAGEN Ingenuity® Pathway Analysis (IPA®), Omicsoft)
- ISO 13485 / Quality Management System (QCI)
- General Data Protection Regulation (GDPR)
- EU-U.S. DPFa nd UK Extension, and the Swiss-U.S. DPF
- Data Center / ISO 27001, SSAE SOC 1 Type II / SOC 2 Type II

Meshed architecture

The hosted environment is b
architecture based on multi
routers, switches, firewalls a
enterprise storage have bee
capacity to withstand failur
uptime. Multiple carriers pr
redundant routes into the d
services are also used for c
Security (TLS) of all QIAGE
customer data. All administr
and originate from individu
defined access controls and
privacy and business justific
monitored, and all access fo
management process and b
is monitored 24/7 from mu
and externally by third-part

QIAGEN Digital Ins management solutio

QIAGEN Digital Insights le
leading solutions for system
and automation as shown i

Services
Single sign-on and user management
Database monitoring and management services
Server monitoring and reporting
Storage area network and storage management

QIAGEN Digital Insights protection practices

In order to secure customer data, QIAGEN Digital Insights has put in place the following data protection practices:

- Physical security: Servers reside in a high-security facility utilizing 24-hour guards, picture ID access, proximity cards, video surveillance, biometrics, and a locked dedicated cage with restricted access.
- Perimeter defense: QIAGEN Digital insights protects its network perimeter with multi-layered firewalls and proactively monitors the infrastructure with intrusion detection systems. Logs are monitored to identify security threats.
- Secure connection: Secure connection via HTTPS only via TLS1.2, TLS1.3 protocol.
- Internal security: All data is protected against compromise from server-to-server communication with multiple internal firewall layers, network address translation, port redirection, IP masquerading and non-routable addressing.
  - To shield in-transit data sessions from eaves-dropping attacks, QIAGEN Digital Insights employs 256-bit AES TLS encryption on all customer data
  - Data sharing between hosted instances is not permitted nor enabled
  - Data deletion is controlled by data originator (owner) and can be deleted any time
  - All physical, technical and administrative safeguards align and comply with CFR45

QIAGEN Digital Insights enforces strong data retention policies and ensures all customer data can and will be permanently deleted from the environment.

- User authentication: User authentication requires username and password for application login. Password creation requirements: (12 character minimum, at least 1 number and letter, uppercase / lower case, special character, no dollar sign). User is provided a "password strength meter" when selecting a password. Accounts are locked following five failed login attempts. Authentication is completed using email-based 2FA and SAML 2.0-based SSO.
- Data and database security: QIAGEN Digital Insights deploys redundant enterprise-class disk arrays to protect the QCI systems from disk failure and delayed data replication for protection from data corruption and disasters. QIAGEN's proprietary database security model prevents cross-account data leakage.
- Server operating system security: QIAGEN Digital Insights hardens all servers by removing unnecessary accounts, services, protocols and processes. Patch levels are maintained according to recommendations of its vendors.
- Data backups: The QIAGEN Digital Insights hosted applications replicate data to local and remote disks. All PII / PHI data are encrypted with 256-bit AES standards. Rotational incremental and full backups take place multiple times per day.

Thank you