

USE EXPLORATION

Discover End-to-End Applications for the Clinically Driven, Real-World Oncology Data in **Cohort Builder** from NeoGenomics



Cohort Builder is changing the way that development and commercial teams answer strategic questions and build more impactful biomarker programs from pre-clinical to post-launch surveillance. In this document, we will explore real-world use cases for generating insight across the drug development lifecycle with the ultimate goal of accelerating precision medicine.

TECHNOLOGICAL ADVANCES have put information at our fingertips in all facets of life. Services such as Google, Siri, and Alexa ensure no question goes unanswered for more than a few seconds. We believe this should also be the case for Oncology lab data. Whether you're a clinical lead, a commercial marketing manager, or a data analyst, you are regularly faced with questions about the current landscape of oncology biomarker testing. Having a clear understanding of testing algorithms and their implications to the patient journey and treatment paradigms is critical.

The need to make more informed, strategic, evidenced-based decisions across the entire precision medicine development lifecycle drove us to develop Cohort Builder, an online subscription-based application that gives our client partners access to real-world, de-identified testing data from the largest oncology lab in the US.

Cohort Builder leverages the largest volume oncology testing lab and provides access to NeoNucleus[™], a real-world database developed to drive better, faster precision medicine outcomes.

Following are examples of real-world applications for Cohort Builder that will enable you to explore its capabilities and see its value at different stages of the drug development lifecycle.

Preclinical

SCENARIO #1

An R&D team from a fortune 500 pharmaceutical company seeks to understand the prevalence of KRAS G12C and STK11 co-mutations in non-small cell lung cancer (NSCLC) to inform Phase 1 trial design.

COHORT BUILDER SOLUTION

With a few clicks, users within the R&D team can filter the >1.9 million de-identified patient results within NeoNucleus by tumor type, mutation status by gene and variant classification. The team can easily perform an annual analysis of results from the >15,000 lung cancer patients tested for KRAS mutations through NeoGenomics to understand the percentage of patients that also harbor STK11 mutations. They can then examine pathogenic variants versus variants of unknown significance as well as differences by gender, age and geographic distribution. The team can also look at other tumor types to understand the prevalence of these co-mutations outside of lung cancer.

REAL-WORLD VALUE

This data provides the evidence required to optimize the design of trial cohorts and enrollment targets.

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>1.9M

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FIG. 1

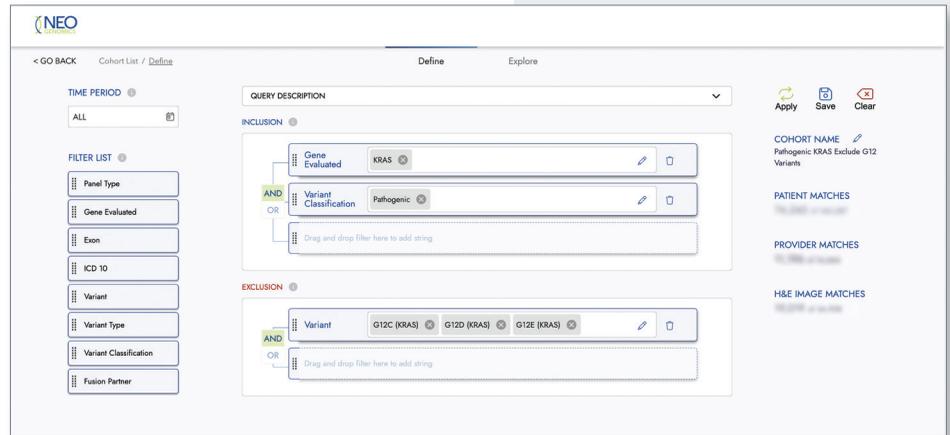


FIG. 2

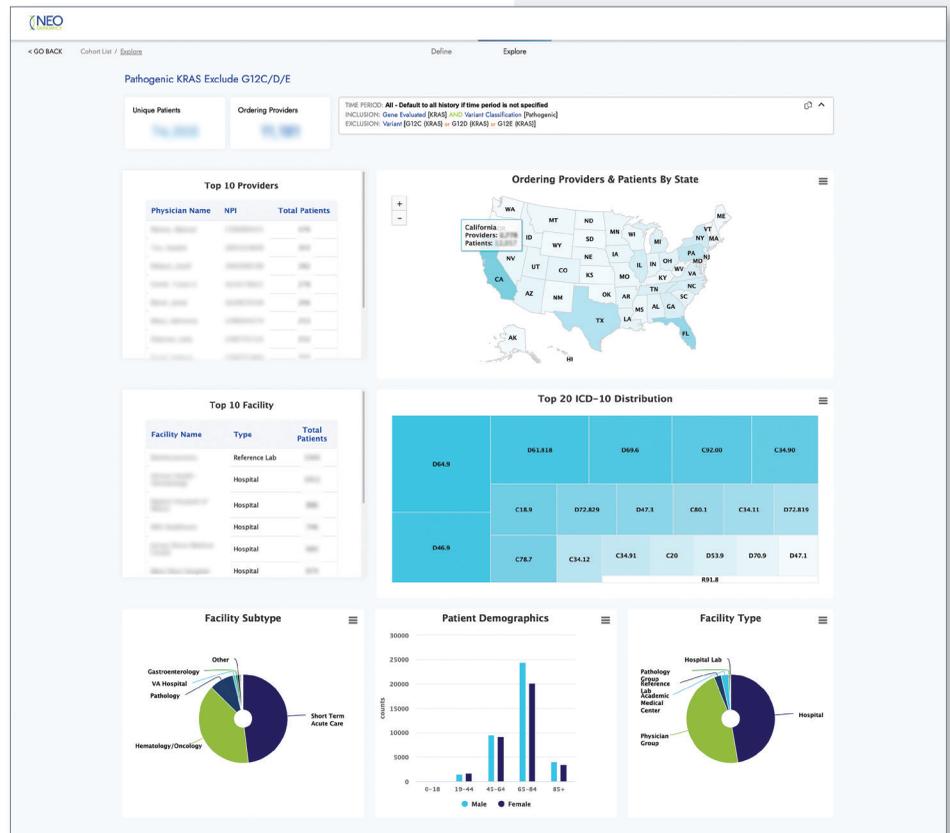


FIG. 1 Cohort Builder's drag and drop function allows users to create cohorts by diagnosis, test or panel performed, and mutation result, as patient counts update in real time.

FIG. 2 Data visualizations within the Cohort Builder explore page allow for real time analysis of variables of interest.

Preclinical

SCENARIO #2

The computational pathology team within the pharmaceutical company is beginning development work on an artificial intelligence (AI) algorithm to predict *KRAS* mutations from H&Es of NSCLC patients. In order to train its algorithm to recognize the relevant cellular features from an H&E, the team needs to source hundreds of images with known *KRAS* mutation status (both positive and negative).

COHORT BUILDER SOLUTION

In addition to mining test result data from NeoNucleus™ Cohort Builder pulls in counts from our repository of >1 million whole slide images to determine in real time how many H&Es are available for NSCLC patients with and without *KRAS* mutations. The computational pathology team can then request access to these images through a NeoPixel contract.

REAL-WORLD VALUE

As a leading provider of whole slide images in the US, access to this image count directory accelerates access to the required images and associated metadata for digital pathology AI initiatives.

IN ADDITION TO MINING TEST RESULT DATA FROM NEONUCLEUS™ COHORT BUILDER ALLOWS USERS TO BROWSE COUNTS FROM A REPOSITORY OF

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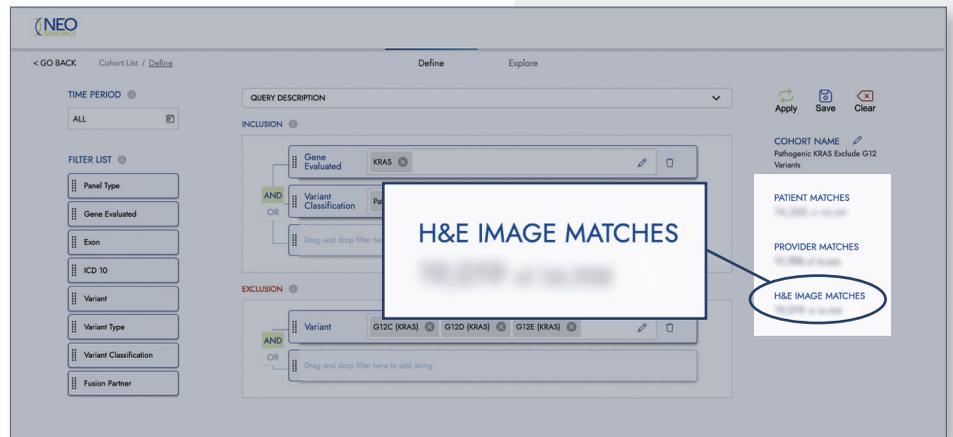


FIG.3 As cohorts are created, Cohort Builder provides a real time count of the number of H&Es available for that cohort.

Phase 1–3: clinical trials

SCENARIO

Following initial trial design, the Clinical Trial Lead is tasked with identifying trial sites with the highest likelihood of enrollment based on patient volumes.

COHORT BUILDER SOLUTION

Through Cohort Builder, users can drill down into the total patients counts for specific criteria—in this case, NSCLC cancer patients harboring both *KRAS* G12C and *STK11* mutations—to the facility and provider level. By visualizing “hotspots” of patients that meet the clinical-trial criteria and providing counts by ordering facility and provider, pharma sponsors can identify potential clinical trial sites and principal investigators who are already treating these patients in-house.

REAL-WORLD VALUE

Pharmaceutical organizations can bring the trial to patients versus spending time and resources bringing the right patients to the trial.

FIG. 4

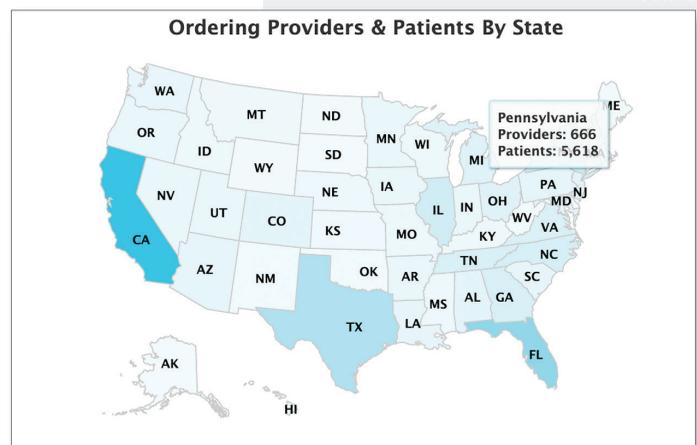


FIG. 5

Top 10 Facility

Facility Name	Type	Total Patients
Reference Lab	Reference Lab	1,000
Hospital	Hospital	800
Hospital	Hospital	600
Hospital	Hospital	500
Hospital	Hospital	400
Hospital	Hospital	300
Hospital	Hospital	200

FIG. 4 Cohort Builder visualizations include geographical distribution of providers with patients in the cohort of interest.

FIG. 5 Cohort Builder provides a list of the highest volume ordering facilities that have patients in the cohort of interest.

Pre-launch

SCENARIO

As the therapy advances to late-stage clinical trials, the commercial team works to understand the landscape into which the therapy will launch so they can prepare impactful sales and marketing strategies.

COHORT BUILDER SOLUTION

Cohort Builder helps commercial teams develop a deep understanding of the current biomarker-testing landscape and any hurdles that will need to be removed prior to launch by answering pressing pre-launch questions, such as:

- How many patients are currently tested (and equally as important, not tested) for KRAS G12C and STK11?
- What are current testing algorithms – panel vs. single gene?
- What is the real-world positivity rate of KRAS G12C mutations with and without STK11 co-mutation?
- What types of providers are testing (and not testing) for KRAS G12C and STK11 today?
- What is the total available market and what can we anchor our forecast on?

Given that >80% of ordering facilities that send testing to NeoGenomics are based in the community setting, NeoNucleus data is more representative of real-world trends that are happening outside of academic medical settings. Access to this real-time, real-world de-identified lab data provides a more accurate assessment of the current landscape and enables more appropriate allocations of budget and resources in program planning.

REAL-WORLD VALUE

Cohort Builder can serve as a springboard for linking lab data to other external data sets such as medical/Rx claims and EMR data through tokenization, which enables a better understanding of the patient journey and treatment patterns in the tested population.

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80%
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FIG. 6

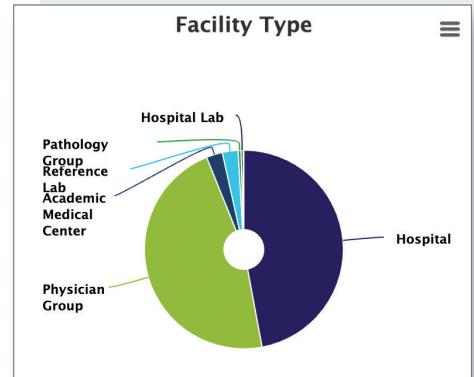


FIG. 7

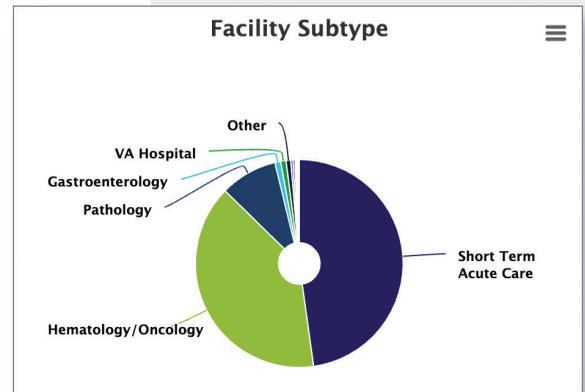


FIG. 8

Top 20 ICD-10 Distribution

D64.9	D61.818	D69.6	C34.90	C92.00	C18.9		
D46.9	C78.7	D72.829	C80.1	D47.3	C34.91	C34.12	
	C34.11	C20	D72.819	R91.8	C18.7	D53.9	D70.9

FIG. 6 Cohort Builder data visualization includes a break down of ordering facility type.

FIG. 7 Further breaking down facility by subtype provides a look at the specialty of institutions from which orders for the test of interest are being sent to NeoGenomics.

FIG. 8 Diagnosis code break down helps to further stratify patients in the cohort of interest.

Commercial launch*

SCENARIO

The biomarker-driven targeted therapy becomes FDA approved and commercially available, and brand teams are tasked with driving both biomarker and therapy awareness at the provider level.

COHORT BUILDER SOLUTION

Through real-time access to NeoNucleus, brand teams and commercial marketing managers can identify providers that have therapy-eligible patients, allowing for a tailored, targeted and relevant treatment message. This can help them optimize field team resources and ensure that provider-level communication is beneficial and actionable.

REAL-WORLD VALUE

Cohort Builder accelerates connections between the field team and the provider to ensure informed decisions are made within the treatment window and without the delay associated with many test signal or trigger alert programs.

Post-launch surveillance*

SCENARIO

The pharma company recognized a gap in testing and deployed a number of biomarker education programs at the time of commercial launch. It is interested in tracking the impact of these initiatives on testing behavior.

COHORT BUILDER SOLUTION

Cohort Builder allows users to compare historical data with real-time data to track testing trends over time. The brand team or supporting data analytics team can look at *KRAS* testing rates prior to the targeted therapy launch and track changes prospectively on a weekly, monthly or annual basis to understand whether their biomarker programs have moved the needle. They are also able to look at this at a facility level to identify the need to expand or contract their programs in certain regions.

REAL-WORLD VALUE

In addition to answering targeted questions around a single biomarker, Cohort Builder helps track overall changes in the lung cancer landscape, keeping pharma teams at the forefront of evolving testing and treating dynamics in their spaces.

* Contact a Data Strategy Consultant to discuss the various levels of service available for Cohort Builder for commercial applications.

FIG. 9

Physician Name	NPI	Total Patients
John, Michael	1234567890	450
Jane, Susan	0987654321	380
Robert, David	2345678901	320
Emily, Tracy A.	3456789012	280
Mark, David	4567890123	250
Michelle, Jennifer	5678901234	220
Thomas, John	6789012345	200
David, Alex	7890123456	180

FIG.9 Cohort Builder provides a list of the highest volume ordering providers that have patients in the cohort of interest.

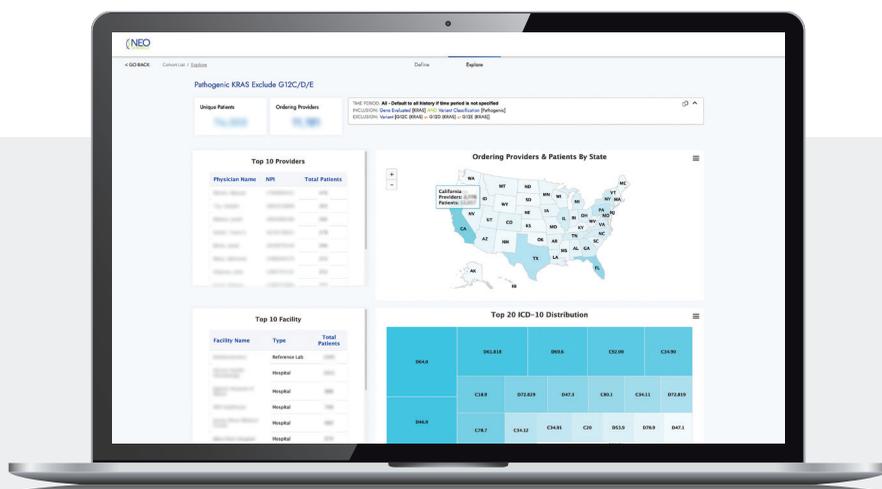
COHORT BUILDER USE EXPLORATION

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Let Cohort Builder work for you

Wherever your precision medicine programs are in the development lifecycle, Cohort Builder will provide meaningful insights for better, faster outcomes.

Request a demo today to learn more about how you can harness the power of having real-world lab data at your fingertips.



To connect with a Data Strategy Consultant on the various subscription levels available for Cohort Builder, email: informatics@neogenomics.com

INFORMATICS RESOURCES:

Learn more about Cohort Builder and download the fact sheet at cohort-builder.com

Explore insights from NeoNucleus in our latest Lite Paper: *Using Real-World Data Insights to Improve Biomarker Testing in Lung Cancer* at neogenomics.com/lung-cancer-testing-litepaper

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