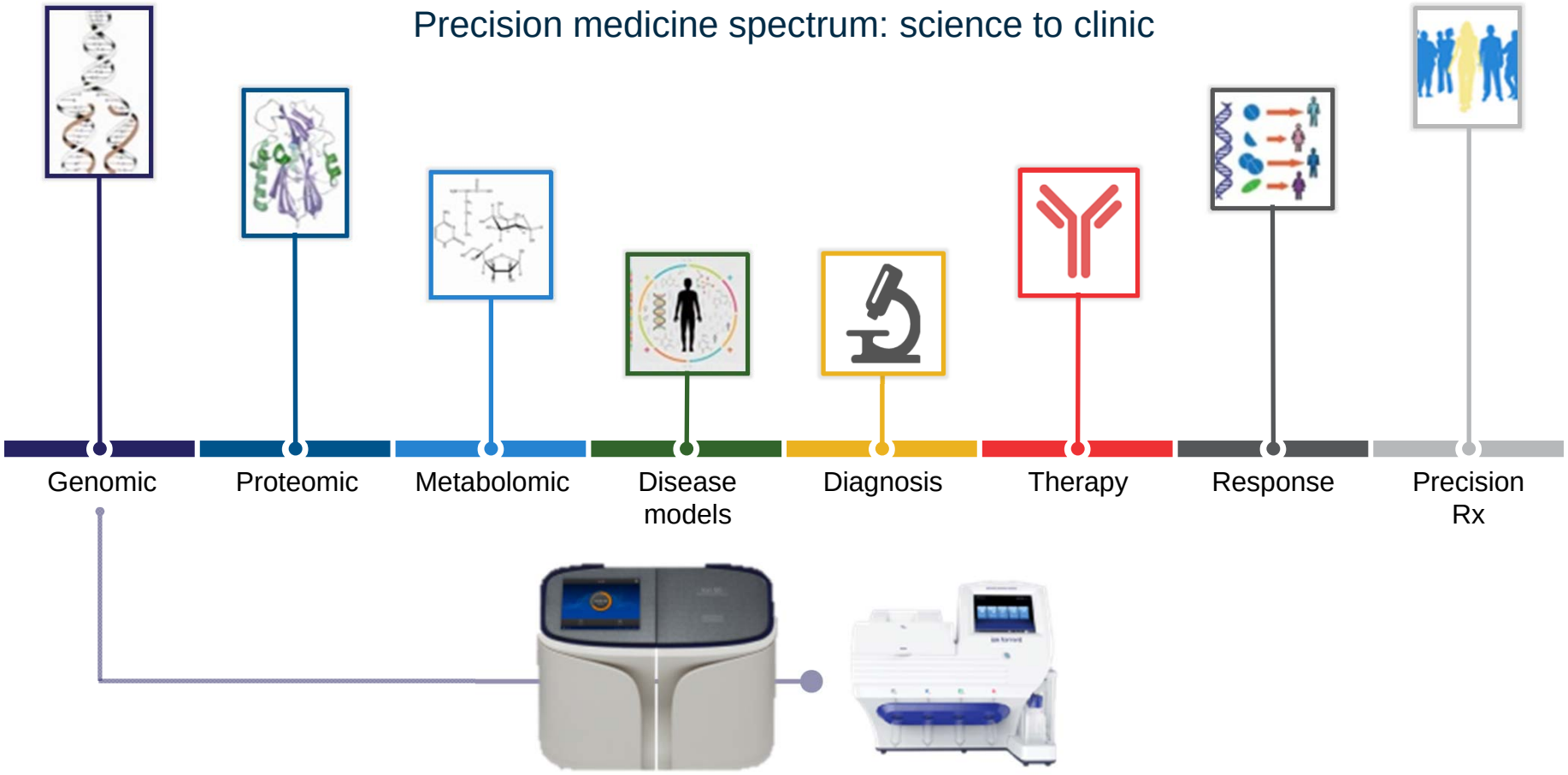
ThermoFisher SCIENTIFIC

Pioneer the Path to Precision Genomics with Ion Torrent Next-Generation Sequencing

Asia Chang
Sr. Director Product Management, Oncology
2016/10/28

Ion Torrent NGS Research Tools—Helping to Advance Progress Toward Precision Medicine

Precision medicine spectrum: science to clinic



For Research Use Only. Not for use in diagnostic procedures.

ThermoFisher SCIENTIFIC

Simplest and Fastest Workflow

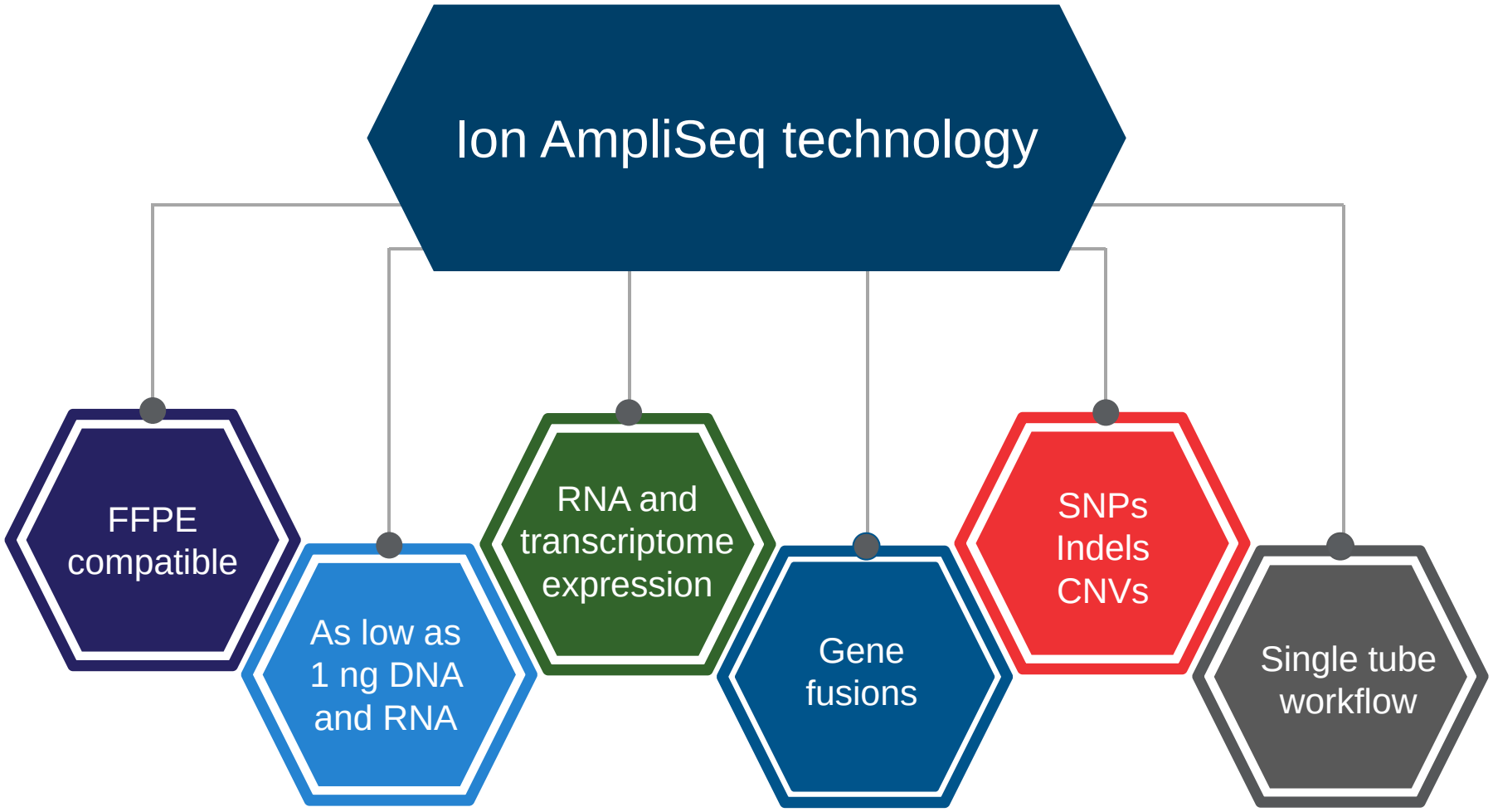
Simple **Scalable** **Supported** **Fast**

Ion AmpliSeq™ technology	Ion Chef™ System	Ion S5™ System Ion PGM™ System	Ion Reporter™ software

For Research Use Only. Not for use in diagnostic procedures.

ThermoFisher SCIENTIFIC

The Foundation of Ion Torrent NGS Solutions for Oncology Research

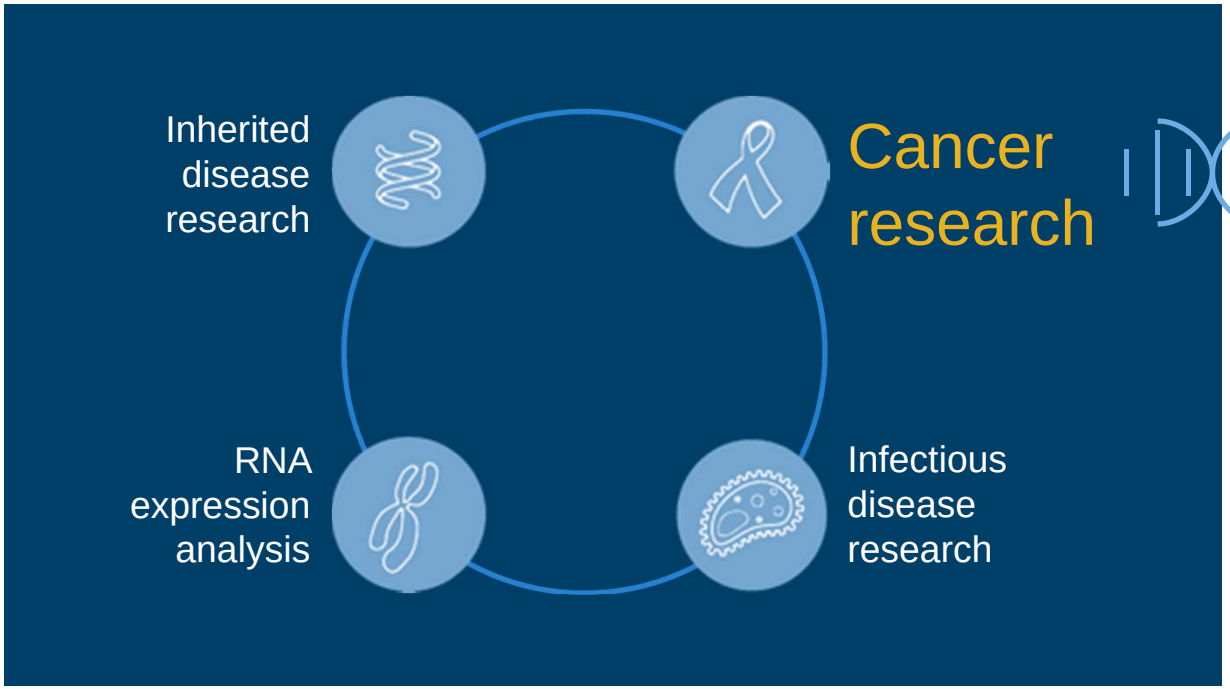


For Research Use Only. Not for use in diagnostic procedures.

ThermoFisher SCIENTIFIC

Multiple Application Areas, Unlimited Panel Options

Low sample input and formalin-fixed, paraffin-embedded (FFPE) compatibility make Ion AmpliSeq technology an excellent tool for cancer research applications.



Quantity ~~not~~ sufficient

ThermoFisher SCIENTIFIC

Our Portfolio for Cancer Research Founded on Ion AmpliSeq Technology

Discovery → Translational research → Routine research sample analysis

Ion AmpliSeq Panels

- Predesigned panels
- Flexible custom panels using Ion AmpliSeq™ Designer

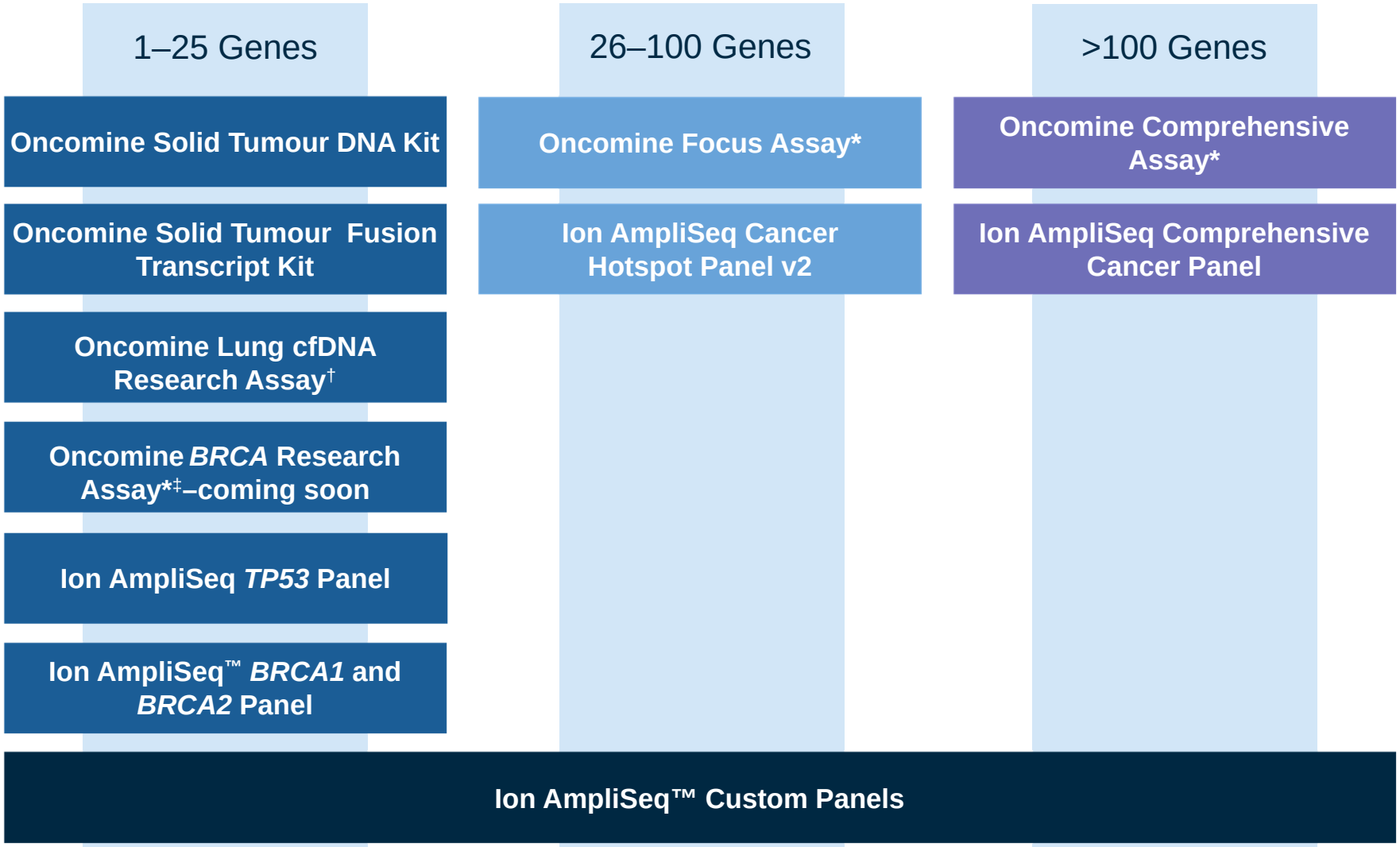
Oncomine Assays

- Curated content
- Optimized protocols based on validation with clinical research samples
- Enhanced manufacturing QC and bioinformatics
- Dedicated field support

For Research Use Only. Not for use in diagnostic procedures.

ThermoFisher SCIENTIFIC

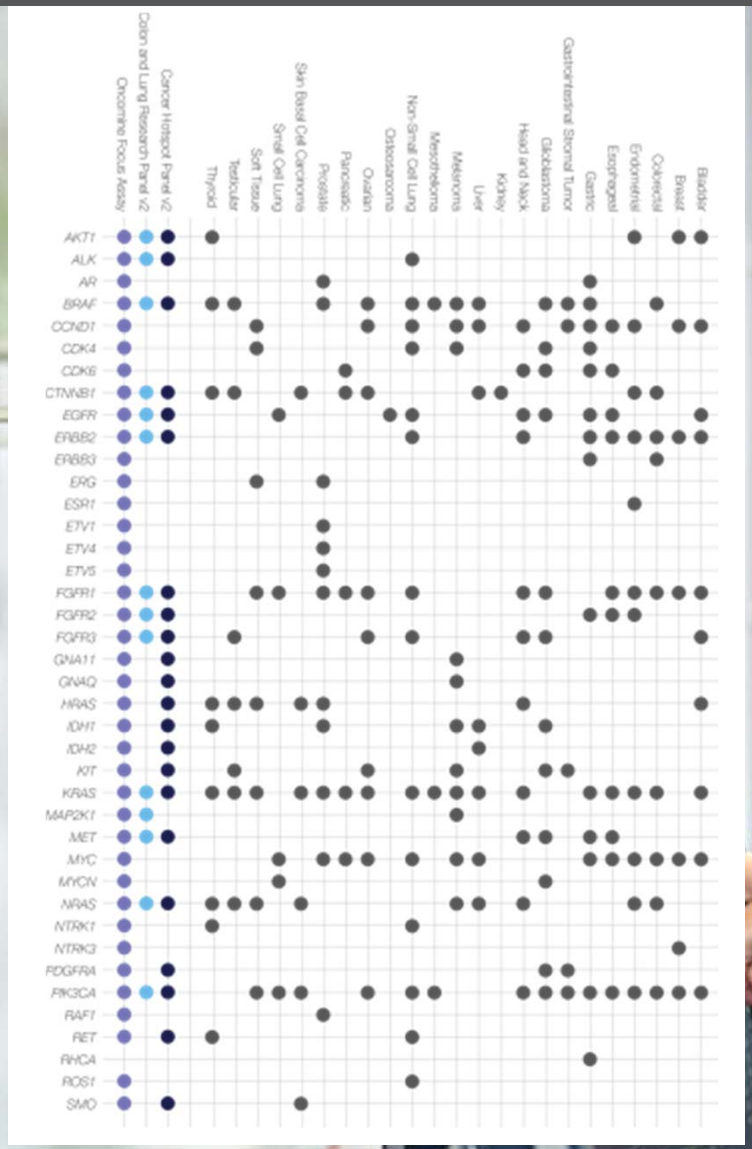
Ion AmpliSeq and Oncomine Products—Options for Oncology Research



* Based on AmpliSeq technology
† Based on Tag Sequencing technology
‡ The content provided herein may relate to products that have not been officially released and is subject to change without notice. For Research Use Only. Not for use in diagnostic procedures.

ThermoFisher SCIENTIFIC

Select Your Assay

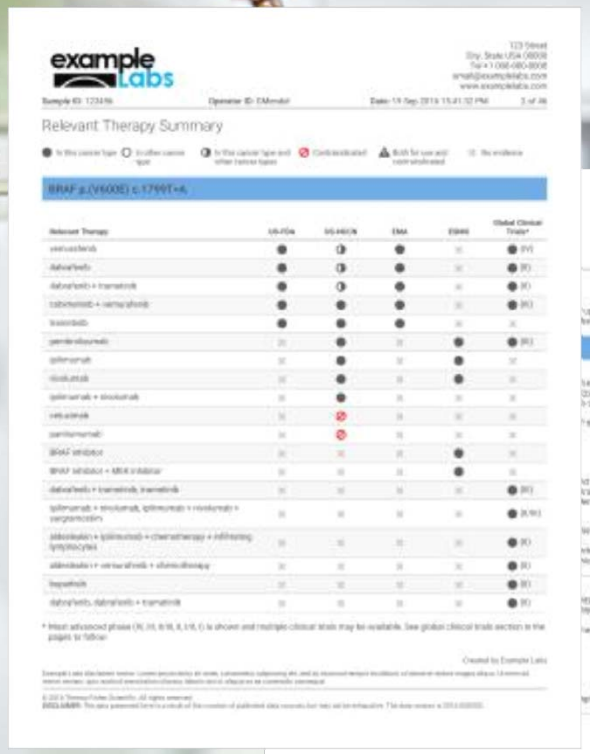


For Research Use Only. Not for use in diagnostic procedures.

ThermoFisher SCIENTIFIC

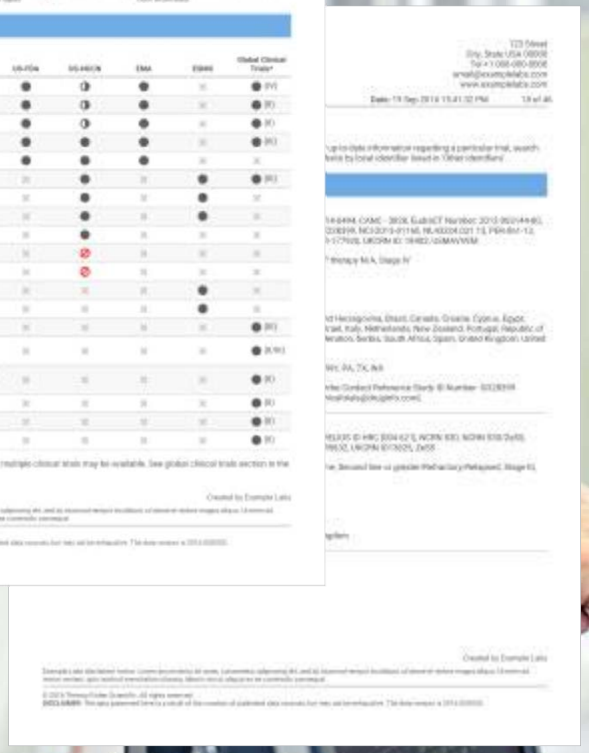
Summarize Your Data in a Customizable Report

Example readouts from the Oncomine Knowledgebase Reporter


example Labs

Relevant Therapy Summary

BRAF p.(V600E) c.1799T>A;

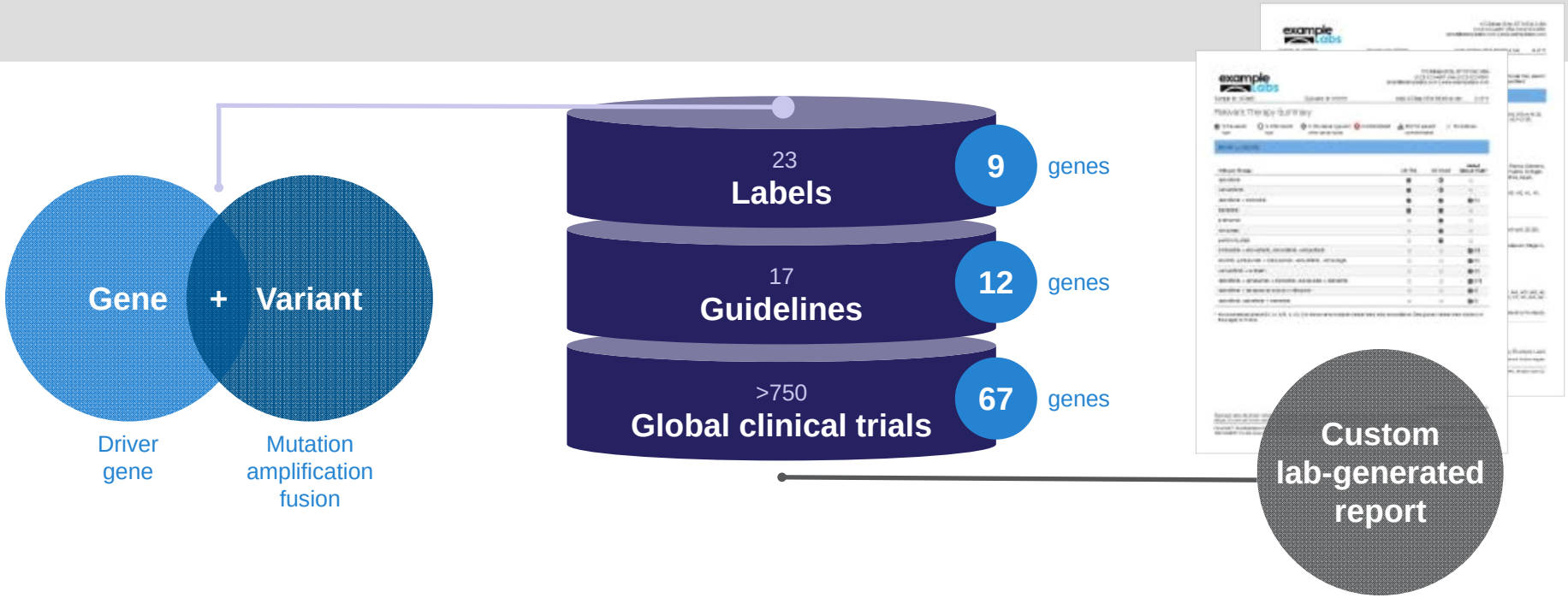


For Research Use Only. Not for use in diagnostic procedures.

ThermoFisher SCIENTIFIC

Uncover More with Oncomine Knowledgebase Reporter

- The Oncomine Knowledgebase Reporter offers associated evidence for labels, guidelines, and clinical trials
- Customizable reports help simplify your data results



For Research Use Only. Not for use in diagnostic procedures.

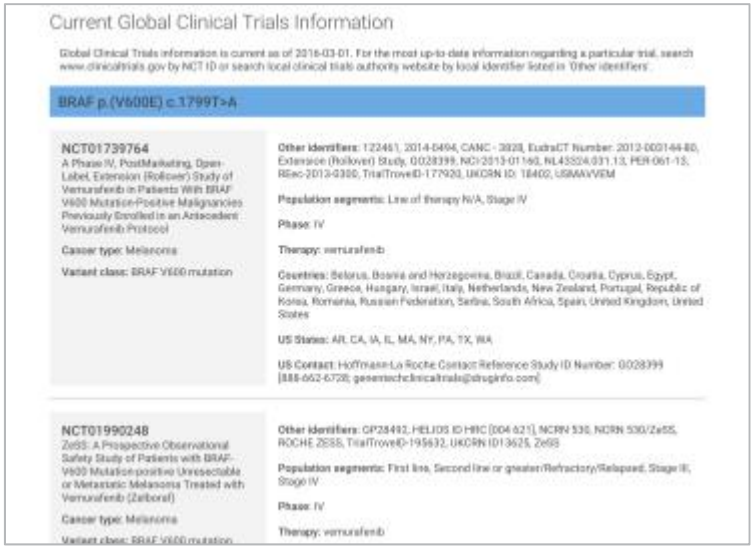
ThermoFisher SCIENTIFIC

Oncomine Knowledgebase Reporter—Custom Lab-Generated Report

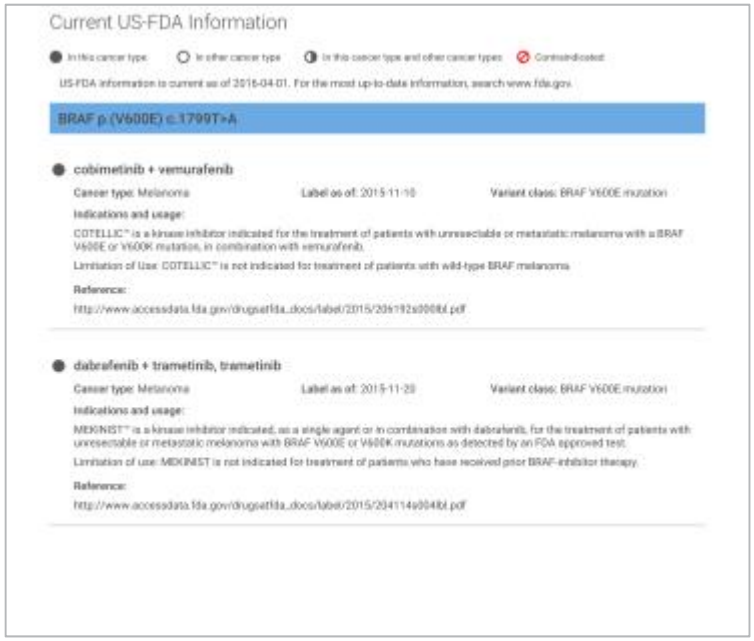
Relevant therapy summary for research purposes

Variant summary table

Current global clinical trials



Current US-FDA information



For Research Use Only. Not for use in diagnostic procedures.

ThermoFisher SCIENTIFIC

Exciting Menu Expansion for Oncology Research in Development

Peripheral monitoring/cell-free DNA research

Oncomine Lung cfDNA Research Assay†‡

New!

Oncomine™ Breast cfDNA Research Assay†‡

Coming soon

Oncomine™ Colon cfDNA Research Assay†‡

Coming soon

Immune response gene expression research

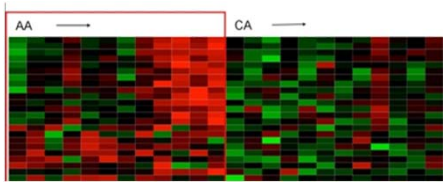
Oncomine™ Immune Response Research Assay*

Coming soon

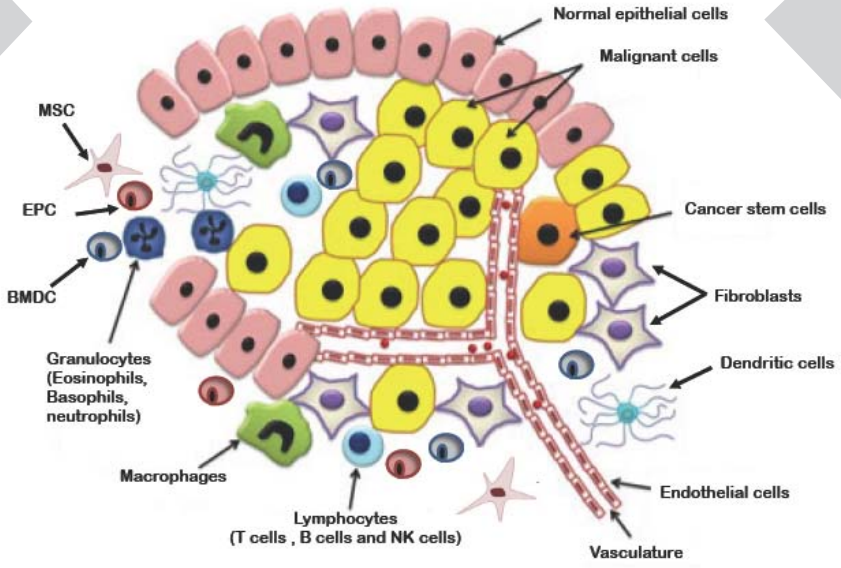
* Based on AmpliSeq technology
† Based on Tag Sequencing technology
‡ The content provided herein may relate to products that have not been officially released and is subject to change without notice. For Research Use Only. Not for use in diagnostic procedures.

Oncomine™ Immune Response Research Assay*

Oncomine™ Immune Response Research Assay*



- Tumor Infiltrating Lymphocyte level
- Low expressors



Potential to respond

Low chance of responding

ThermoFisher SCIENTIFIC

Oncomine Flagship Assays for Cancer Research

Oncomine Comprehensive Assay

143 Genes

NCI-MATCH Clinical Trial

For more information, refer to:

http://www.cancer.gov/about-cancer/treatment/clinical-trials/nci-supported/nci-match

http://www.cancer.gov/research/key-initiatives/precision-medicine

Oncomine Focus Assay

52 Genes

In development: multi-gene NGS companion Dx test

In cooperation with pharma partners

For Research Use Only. Not for use in diagnostic procedures.

ThermoFisher SCIENTIFIC

NCI-MATCH Trial—Molecular Analysis for Therapy Choice

Technology chosen for study:
Ion PGM System and Oncomine Comprehensive Assay*

Objectives:

- Study the effectiveness of genomics-informed targeted treatment strategies
- Demonstrate the use of a standardized NGS assay and platform across multiple independent clinical sequencing sites
- Use **one standardized test** for stratification into **many clinical trials**

http://www.cancer.gov/about-cancer/treatment/clinical-trials/nci-supported/nci-match
http://www.cancer.gov/research/key-initiatives/precision-medicine

* For Research Use Only. Not for use in diagnostic procedures.

NCI-MATCH Trial—Overview

Protocol and selected technology:

- Phase I: 3,000 samples stratified in 10 treatment arms
- Using Thermo Fisher Scientific assay >4,000 variants across 143 genes
- Testing at 4 central laboratories using a robust, standardized protocol

- 192 active sites
  - 2/3 community hospitals
  - 1/3 academic institutions
- 796 approved sites

Collaboration:

- Partnership between NCI and multiple pharma companies

http://www.cancer.gov/about-cancer/treatment/clinical-trials/nci-supported/nci-match

NCI-MATCH—Interim Evaluation

Phase I results published June, 2016

- **795 samples submitted in the first 3 months**
  - Far surpassing original estimate of 50 samples/month
- Of 739 core needle biopsies, **87% were successfully sequenced**
  - Industry standard ~80% success rate
  - Of the 13% not sequenced, a high percentage were necrotic and devoid of any viable nucleic acid material
- Of the **optional fine-needle aspirate (FNA) samples** submitted, **97% were successfully sequenced**
- **Phase II will require submission of FNA samples and is projected to increase the sequence success rate from 87% to 98.6%**

http://ecog-acrin.org/nci-match-eay131-researchers

NCI-MATCH Trial Update, June, 2016: Next Steps

The MATCH trial has resumed after a planned pause for interim scientific analysis. Based on high interest and success, the scope for Phase II has significantly increased.

- **Expanding to 24 treatment arms**
  - Originally 10 treatment arms
- **Expanding enrolment to 5,000**
  - Originally 3,000
- **Increasing testing capacity by adding Ion S5™ XL systems***
  - Was 50 samples/month—now, 100 samples/week
  - Turn around time: sample-to-results in 14 days
- Phase II study is projecting a 23% match rate
- FNA samples (optional in Phase 1) are now required to address the high percentage of core biopsies found necrotic and devoid of any viable material

* The Ion S5 XL System is For Research Use Only. Not for use in diagnostic procedures.

Our Ion Torrent NGS Platforms

Ion PGM System

- Minimal sample input
- Fast turnaround times
- Small panels, microbial genomes

Ion Chef System

- Automated library prep, template prep, and chip loading
- 30-minutes total set up time for library and template prep

Ion S5 System

- Simple set up <15 min
- Plug-and-play reagents
- Scalable throughput

For Research Use Only. Not for use in diagnostic procedures.

Our Vision for the Future

In development, a universal companion diagnostic test

ThermoFisher SCIENTIFIC

Our Vision for the Future: A Universal Diagnostic (Dx) Product

Universal means:

- At product launch: one CDx validated for selection of therapy A, B, & C
- In the future: new clinical trials validate the same CDx for more therapies, D, E, F

Oncomine Universal Dx Test

One companion diagnostics (CDx) test
multiple and increasing drug indication

One test

Many answers to inform patient management decisions and indication of multiple treatments

For investigational use only.
The content provided herein may relate to products that have not been officially released and is subject to change without notice.

ThermoFisher SCIENTIFIC

A Mission We Are Proud of

We enable our customers to make the world healthier, cleaner, and safer.

ThermoFisher SCIENTIFIC