Bringing NGS Testing In-House

PierianDx

Eric Loo, MD
Assistant Professor, Pathology & Lab Medicine, Dartmouth-Hitchcock

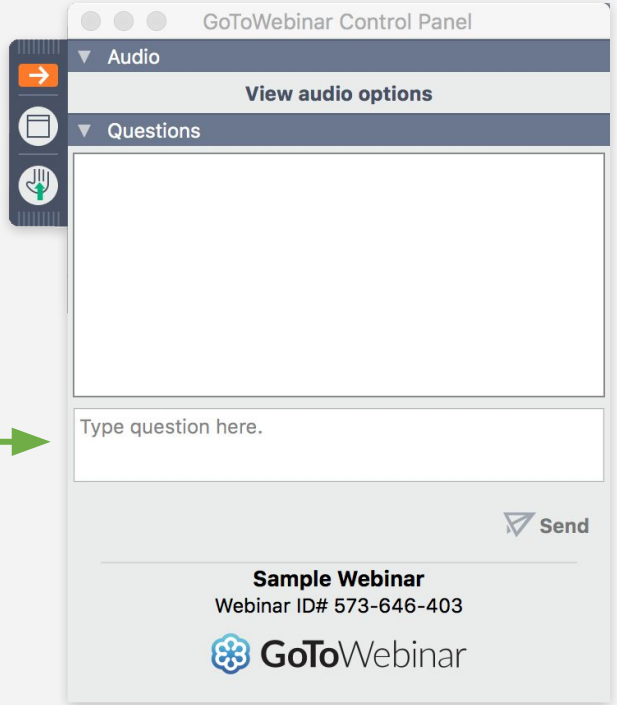
Rakesh Nagarajan, MD, PhD
Executive Chairman and Founder, PierianDx

Dartmouth-Hitchcock

We Want to Hear from You

How to Submit Questions

Type questions here



Bringing NGS In-House

Today's Topics

1. Market Dynamics
2. The Business Case
3. Critical Competencies
4. Blueprints for Success
5. Dartmouth Case Study
6. Reimbursement

Crossing the Chasm

Market Dynamics

The Inflection Point

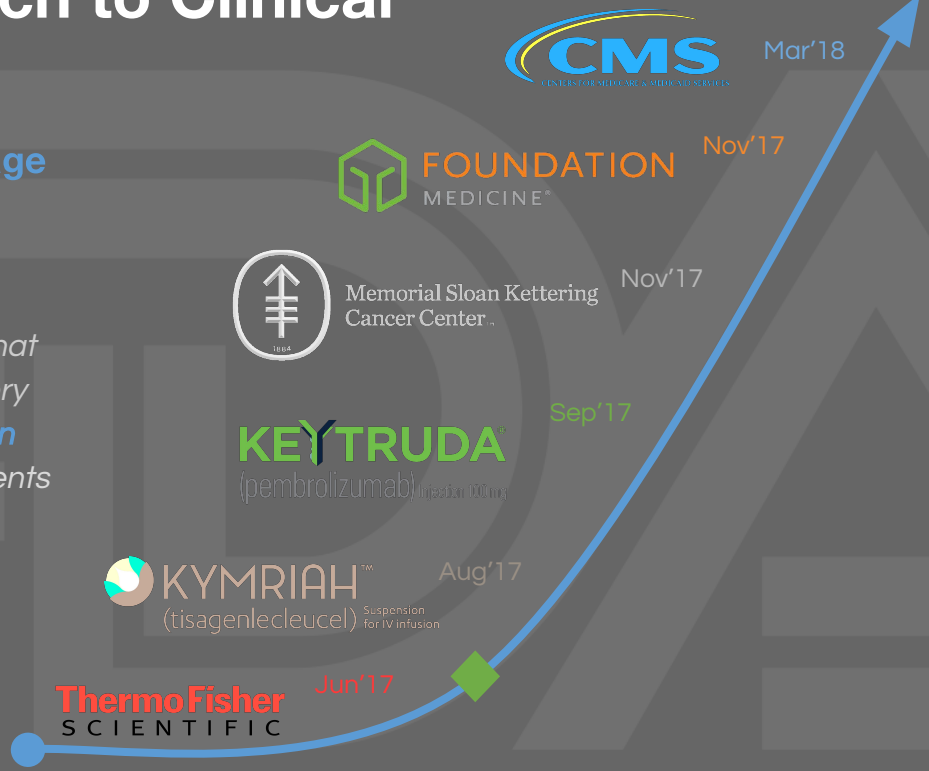
From Research to Clinical

CMS National Coverage

NGS Reimbursement

*CMS finalized a **National Coverage Determination** that covers diagnostic laboratory tests using **Next Generation Sequencing (NGS)** for patients with advanced cancer.*

CMS.gov



FDA Approval

Somatic Cancer Tests

Oncomine Dx, MSK-IMPACT, and FoundationOne CDx are the **first NGS tumor profiling assays** to gain FDA approval.

Immunotherapy

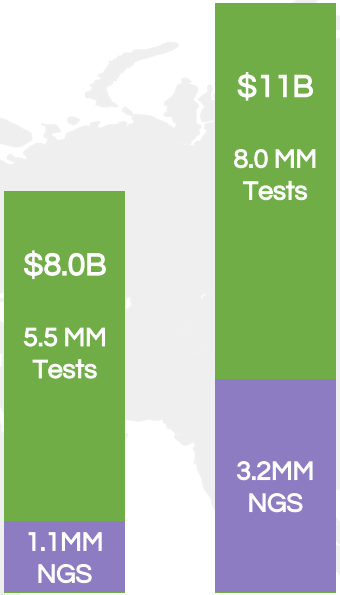
Merck's Keytruda is the **first immunotherapy treatment** approved for all solid tumors based on a genomic biomarker.

Gene Therapy

Kymriah is the **first gene therapy** approved in the US, to treat children with advanced leukemia.

Strong Growth Underway

US Genomic Testing Market



12-15% per annum revenue growth

20% NGS in 2017
40% NGS in 2020

2017 Figures

Clinical genetic testing labs

% of total commercial vs. hospital

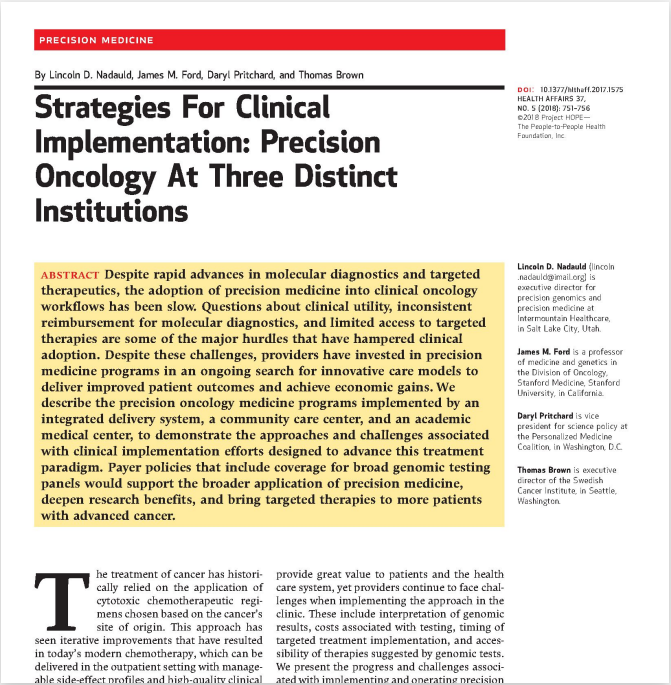
% of somatic testing among 4 labs vs all other labs
Quest, LabCorp, Genomic Health, Foundation Medicine

Source: Epstein Health

Insourcing Makes Cents

The Business Case

Leadership Strategies



PRECISION MEDICINE

By Lincoln D. Nadauld, James M. Ford, Daryl Pritchard, and Thomas Brown

Strategies For Clinical Implementation: Precision Oncology At Three Distinct Institutions

DOI: 10.1377/hlthaff.2017.1575
HEALTH AFFAIRS 37,
NO. 5 (2018): 751–756

ABSTRACT Despite rapid advances in molecular diagnostics and targeted therapeutics, the adoption of precision medicine into clinical oncology workflows has been slow. Questions about clinical utility, inconsistent reimbursement for molecular diagnostics, and limited access to targeted therapies are some of the major hurdles that have hampered clinical adoption. Despite these challenges, providers have invested in precision medicine programs in an ongoing search for innovative care models to deliver improved patient outcomes and achieve economic gains. We describe the precision oncology medicine programs implemented by an integrated delivery system, a community care center, and an academic medical center, to demonstrate the approaches and challenges associated with clinical implementation efforts designed to advance this treatment paradigm. Payer policies that include coverage for broad genomic testing panels would support the broader application of precision medicine, deepen research benefits, and bring targeted therapies to more patients with advanced cancer.

Lincoln D. Nadauld (lincoln.nadauld@gmail.org) is executive director for precision genomics and precision medicine at Intermountain Healthcare, in Salt Lake City, Utah.

James M. Ford is a professor of medicine and genetics in the Division of Oncology, Stanford Medicine, Stanford University, in California.

Daryl Pritchard is vice president for science policy at the Personalized Medicine Coalition, in Washington, D.C.

Thomas Brown is executive director of the Swedish Cancer Institute, in Seattle, Washington.

The treatment of cancer has historically relied on the application of cytotoxic chemotherapeutic regimens chosen based on the cancer's site of origin. This approach has seen iterative improvements that have resulted in today's modern chemotherapy, which can be delivered in the outpatient setting with manageable side-effect profiles and high-quality clinical

provide great value to patients and the health care system, yet providers continue to face challenges when implementing the approach in the clinic. These include interpretation of genomic results, costs associated with testing, timing of targeted treatment implementation, and accessibility of therapies suggested by genomic tests. We present the progress and challenges associated with implementing and operating precision

Intermountain Healthcare

Control

Integrated Delivery System

Insourcing has allowed Intermountain to "**control all genomic and associated clinical data** and has reduced turnaround time and lowered costs."

Providence St. Joseph Health

Institutional Learning

Community Care Center

"Clinical and molecular information from patients who undergo NGS testing is included in a centralized, **longitudinal data registry** used for **clinical treatment decision support and research.**"

Stanford Cancer Institute

Competitive Advantage

Academic Medical Center

Stanford program not only improves patient outcomes but also support its efforts to "**improve its position in the clinical marketplace.**"

The Molecular Lab

A Key Strategic Asset

Institutional Learning

Control

Competitive Advantage

ROI of Insourcing

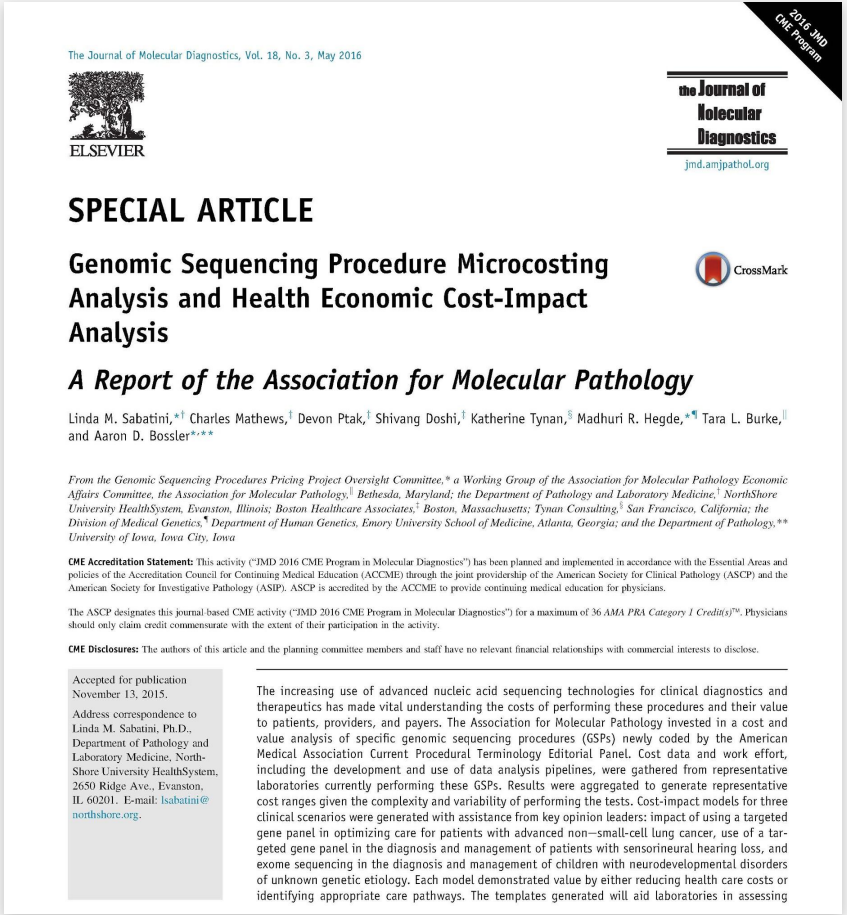
1. Improved patient care
2. Enablement of precision medicine
3. Empowers critical competencies
4. Opens new digital revenue streams (IP, data, clinical trials)
5. Operating cost savings vs. send-outs
6. Ongoing cost control of acute care

Assessment of Value

Costs & Health Economics

AMP Study Investigated 5 Genomic Sequencing Procedures (GSP) Codes

CPT	Application	# of Genes
81430	Hearing Loss	>60
81470	XLID	>60
81445	Solid Tumor	5-50
81455	Solid Tumor, Heme	>50
81415	Exome	All



2016 JMD CME Program

The Journal of Molecular Diagnostics, Vol. 18, No. 3, May 2016

ELSEVIER

the Journal of Molecular Diagnostics

jmd.amjpathol.org

SPECIAL ARTICLE

Genomic Sequencing Procedure Microcosting Analysis and Health Economic Cost-Impact Analysis

A Report of the Association for Molecular Pathology

Linda M. Sabatini,*† Charles Mathews,‡ Devon Ptak,‖ Shivang Doshi,‡ Katherine Tynan,§ Madhuri R. Hegde,*¶ Tara L. Burke,‖ and Aaron D. Bossler*,**

From the Genomic Sequencing Procedures Pricing Project Oversight Committee, a Working Group of the Association for Molecular Pathology Economic Affairs Committee, the Association for Molecular Pathology,† Bethesda, Maryland; the Department of Pathology and Laboratory Medicine,‡ NorthShore University HealthSystem, Evanston, Illinois; Boston Healthcare Associates,‡ Boston, Massachusetts; Tynan Consulting,§ San Francisco, California; the Division of Medical Genetics,¶ Department of Human Genetics, Emory University School of Medicine, Atlanta, Georgia; and the Department of Pathology,** University of Iowa, Iowa City, Iowa*

CME Accreditation Statement: This activity ("JMD 2016 CME Program in Molecular Diagnostics") has been planned and implemented in accordance with the Essential Areas and policies of the Accreditation Council for Continuing Medical Education (ACCME) through the joint providership of the American Society for Clinical Pathology (ASCP) and the American Society for Investigative Pathology (ASIP). ASCP is accredited by the ACCME to provide continuing medical education for physicians.

The ASCP designates this journal-based CME activity ("JMD 2016 CME Program in Molecular Diagnostics") for a maximum of 36 *AMA PRA Category 1 Credit(s)™*. Physicians should only claim credit commensurate with the extent of their participation in the activity.

CME Disclosures: The authors of this article and the planning committee members and staff have no relevant financial relationships with commercial interests to disclose.

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Address correspondence to Linda M. Sabatini, Ph.D., Department of Pathology and Laboratory Medicine, NorthShore University HealthSystem, 2650 Ridge Ave., Evanston, IL 60201. E-mail: lsabatini@northshore.org.

The increasing use of advanced nucleic acid sequencing technologies for clinical diagnostics and therapeutics has made vital understanding the costs of performing these procedures and their value to patients, providers, and payers. The Association for Molecular Pathology invested in a cost and value analysis of specific genomic sequencing procedures (GSPs) newly coded by the American Medical Association Current Procedural Terminology Editorial Panel. Cost data and work effort, including the development and use of data analysis pipelines, were gathered from representative laboratories currently performing these GSPs. Results were aggregated to generate representative cost ranges given the complexity and variability of performing the tests. Cost-impact models for three clinical scenarios were generated with assistance from key opinion leaders: impact of using a targeted gene panel in optimizing care for patients with advanced non–small-cell lung cancer, use of a targeted gene panel in the diagnosis and management of patients with sensorineural hearing loss, and exome sequencing in the diagnosis and management of children with neurodevelopmental disorders of unknown genetic etiology. Each model demonstrated value by either reducing health care costs or identifying appropriate care pathways. The templates generated will aid laboratories in assessing

Genomic Sequencing Procedure (GSP)

Microcosting Analysis

Sabatini et al

Table 3 GSP Microcost Summary Data

	Protocol	1	2	3	4	5	6	7	8	9	10	11	12	13
	Procedure	5-50 gene tumor panel					>50 gene tumor	XLID panel*	Hearing loss panel*	Hearing loss panel		Exome sequencing		
Variable	Average batch size	5	5	6	7	8	6	8	9	8	8	10	8	5
Total preanalytics/ analytics consumables cost	DNA extraction	6	12	10	8	5	10	6	6	5	8	3	8	3
	Library preparation	208	217	182	159	163	477	466	196	158	181	420	276	432
	Sequencing	85	92	76	137	180	279	124	365	788	985	315	989	806
Total preanalytics/ analytics equipment cost	DNA extraction	0	0	0	0	0	4	10	3	1	0	3	0	10
	Library preparation	3	2	10	1	8	13	2	2	3	9	1	17	2
	Sequencing	6	8	7	18	21	109	14	113	102	94	136	104	64
Total preanalytics/ analytics labor cost	DNA extraction	4	6	13	14	3	10	5	3	1	4	3	4	7
	Library preparation	9	8	23	18	7	30	28	11	12	0	38	22	45
	Sequencing	4	20	7	18	2	19	1	5	2	1	5	0	2
Total bioinformatics/data analysis/ reporting cost		86	243	66	110	131	699	160	66	671	256	163	1670	659
Total validation maintenance overhead cost		287	300	195	198	56	298	99	280	207	354	410	300	398
Total assay cost, per sample		699	908	589	682	578	1948	914	1048	1949	1890	1499	3388	2428

All costs reported in US dollars. 0 values indicate costs <$1.
*As part of a consolidated genetic panel workflow.
GSP, genomic sequencing procedure; XLID, X-linked intellectual disability.

Total Avg. Cost per Sample

81445: 5-50 Gene Tumor Panel

$690

81470: >60 Gene XLID

$910

81430: >60 Hearing Loss

$1500

81455: >50 Gene Tumor Panel

$1950

81415: Exome Sequencing

$2300

Ex. Non-Small Cell Lung Cancer (NSCLC)

Health Economic Analysis

Current Care

EGFR and ALK Mutational Analysis

- Targeted
- Clinical Trial (Targeted)
- Non Targeted
- Hospice

GSP Care

GSP (81445) 5-50 Gene Tumor Panel

- Targeted Therapy
- Clinical Trial Selection
- Non Targeted Selection
- Hospice Care

$2.7 Million anticipated savings for a health plan covering 1 million lives

Use of Targeted Therapy

6%	13%
$1.1MM	$2.3MM

Use of Nontargeted Therapy

83%	20%
$8.4MM	$2.2MM

Adverse Events

207	138
$ N/A	$N/A

% of Patients Eligible for Clinical Trial

4%	54%
$?	$2.7MM

% of Patients Entering Hospice

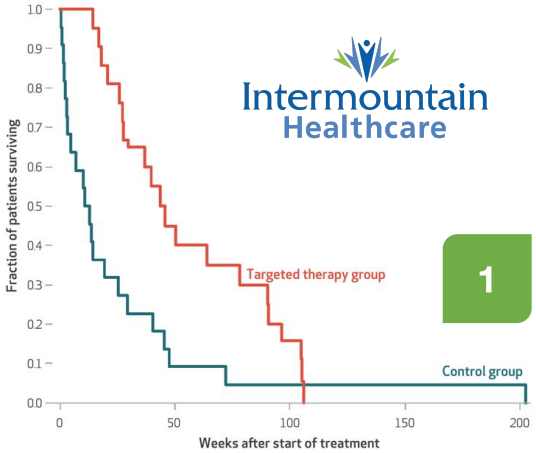
7%	13%
$?	$.06MM

Total Cost

$10.2MM	$7.5MM

Growing Body of Evidence

More NGS Value Studies



Overall Survival:
25.8 weeks vs. 51.7 weeks

Cost Savings:
$733 per week of survival

1. Nadauld et al. *Strategies for clinical implementation: precision oncology at three distinct institutions.* Health Affairs, 2018

2

Cost effectiveness of 34 gene NGS panel for melanoma

8900 Patients diagnosed with melanoma per year in US

$79.5 million annuals savings

155 quality-adjusted life years

2. Li et al. *Cost effectiveness of sequencing 34 cancer-associated genes as an aid for treatment selection in patients with metastatic melanoma.* Mol Diagn Ther. 2015.

2018 ASCO ANNUAL MEETING

NGS Most Cost-Effective for NSCLC

3

		Sequential	Exclusionary	Panel	NGS
CMS	Total Cost	$3,721,368	$3,584,177	$4,331,295	$2,190,499
	Savings	$1,530,869	$1,393,678	$2,140,795	
Private Pay	Total Costs	$747,771	$624,178	$871,211	$620,369
	Savings	$127, 402	$3,809	$250,842	

3. Pennell, et al. Economic impact of next generation sequencing vs sequential single-gene testing modalities to detect genomic alterations in metastatic non-small cell lung cancer using a decision analytic model. Abstract. ASCO 2018

Seize the Opportunity

Critical Competencies

Build Strategic Capabilities

Overcome Top Challenges

Scarcity of informatics expertise

Rapidly changing
nature of technologies

Validation of
clinical testing protocols

Expense of implementation

Amount of data to curate

Difficulty of getting first
"application" deployed

Crawford et al. *The business of genomic testing: a survey of early adopters.* Genetics in Medicine 2014

> *"In the "new molecular biology" excellence in analytics and data will be the source of long-term clinical value.*

Frank Ingari

"Precision Medicine by the Numbers"
Precision Medicine World Conference 2018

In Our Experience

Blueprint for Success

Pioneers of Precision Medicine

Leaders in Clinical Genomics

PieranDx originated at WashU in 2011

25+ Assay Validations

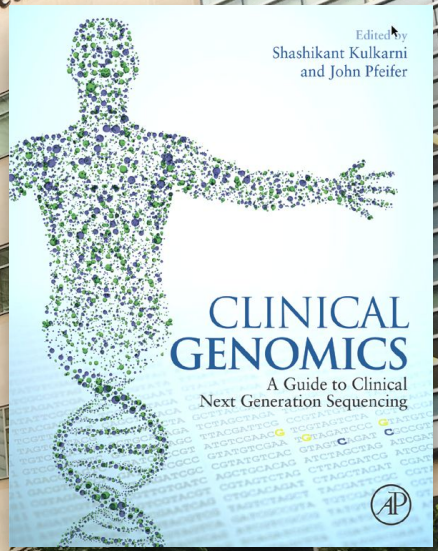
150 Unique NGS Panels Deployed

1,080 Somatic Genes Curated

1,130 Diseases Tested

Productized Software and Services

Operate Independent CLIA Lab



PierianDx

Washington University in St. Louis

All Bases Covered

Implemented Assays

ARCHER®

Agilent Technologies

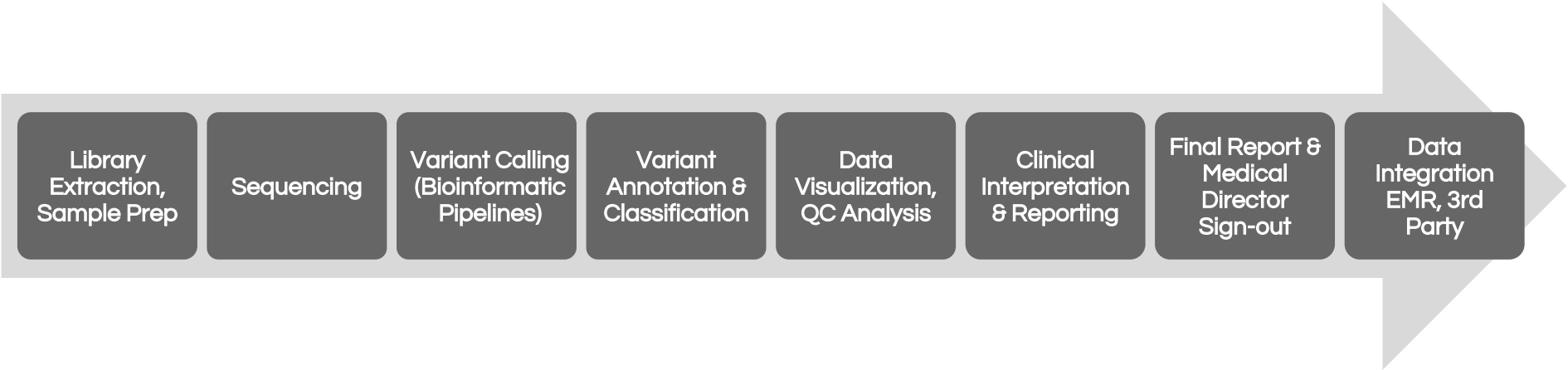
ThermoFisher SCIENTIFIC

illumina®

	Assay	Vendor
Amplicon	VariantPlex Myeloid	Archer
	VariantPlex BRCA1/BRCA2	Archer
	TruSight Myeloid	Illumina
	TruSight Tumor 15	Illumina
	TruSight Tumor 26	Illumina
	TruSeq Cancer Amplicon (TSCA)	Illumina
	BRCA1/BRCA2 (AFP2 assay)	Illumina
	Oncomine (OCA) v2/3	Thermo Fisher
	Ion AmpliSeq™ Cancer HotSpot	Thermo Fisher
Hybridization Capture	Agilent probes	Agilent
	Agilent/IDT probes	Agilent/IDT
	TruSight Tumor 170	Illumina
	TruSight Cancer	Illumina
	Ion AmpliSeq™ Inherited Cancer	Thermo Fisher
Haloplex Molecular barcodes/UMIs	Agilent Haloplex Technology	Agilent
Somatic Fusions	FusionPlex ALK/RET/ROS	Archer
	TruSight RNA fusion	Illumina
Whole Exome Clinical Exome	Agilent SureSelect	Agilent
	TruSight One	Illumina

Take Complete Control

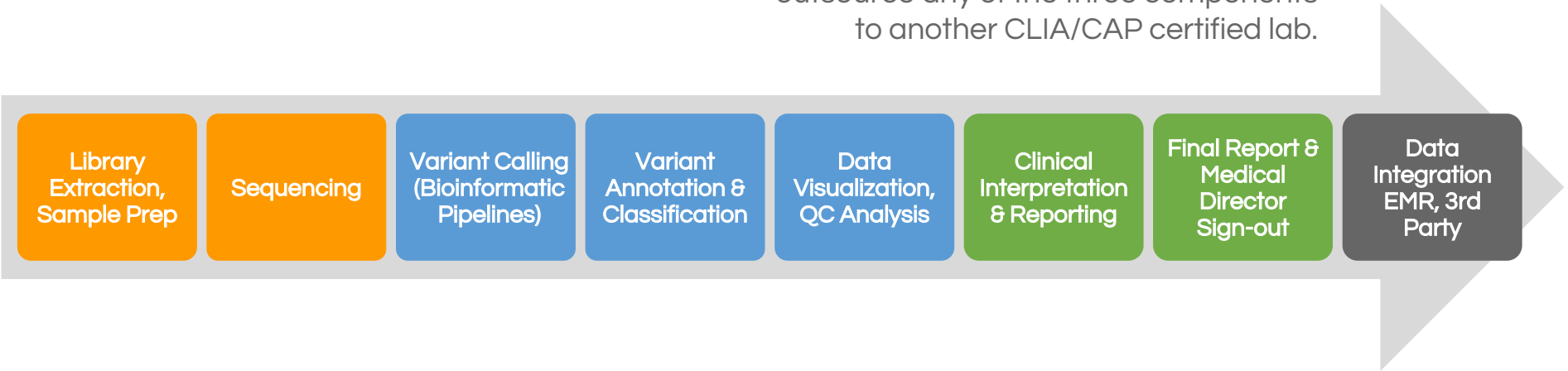
Insource the Entire Clinical Workflow



Take an Economical, Modular Approach

CAP Distributive Model

A CLIA/CAP certified lab is allowed to outsource any of the three components to another CLIA/CAP certified lab.



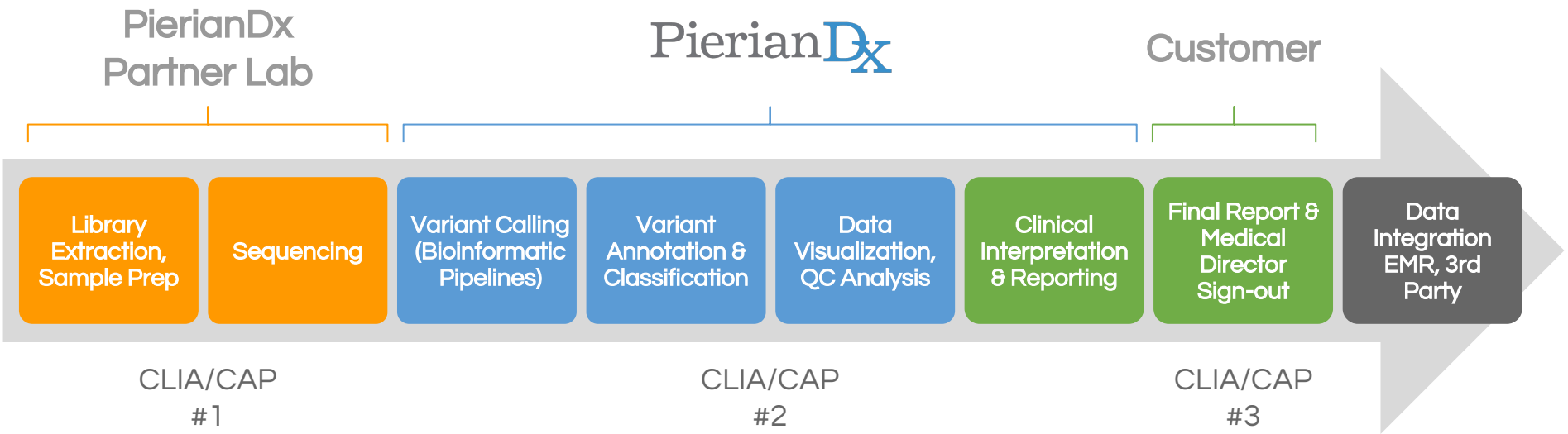
Wet Lab Dry Lab Professional

CAP ACCREDITED
COLLEGE of AMERICAN PATHOLOGISTS

Clinical Laboratory Improvement Amendments

CAP Distributive Model in Action

Multi-Lab Example



Wet Lab Dry Lab Professional

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Clinical Laboratory Improvement Amendments

PierianDx Gateway Lab Services

Validated, Turnkey Assays

Indication	# of Genes
Solid Tumors	122
Heme Disorders	54
Breast Tumors	42
CNS Tumors	48
Genitourinary Tumors	50
Head and Neck Tumors	41
Melanoma	38
Thoracic Tumors	36

3rd Party Bill Available

Indication	# of Genes
Myeloid	65
Lymphoid	61

Indication	# of Genes
Inherited Cancer	94

Indication	# of Genes
Cardiomyopathy	91

Know the Guidelines

Checklist Item	
Minimum # of variants assessed per type to achieve certain confidence level	✓
Assess limitations by variant type (e.g. max length of indels detected by the assay)	✓
Determine acceptance and rejection criteria based on analytical validation	✓
Determine lower limit of detection as a function of coverage and variant allele fraction	✓

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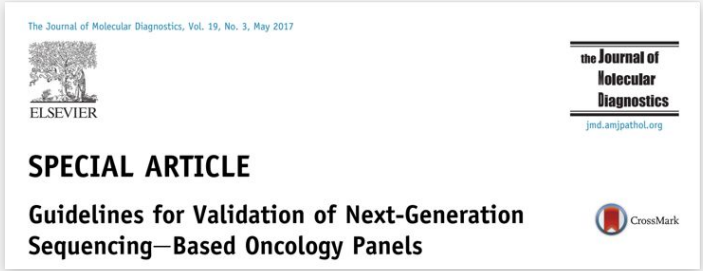
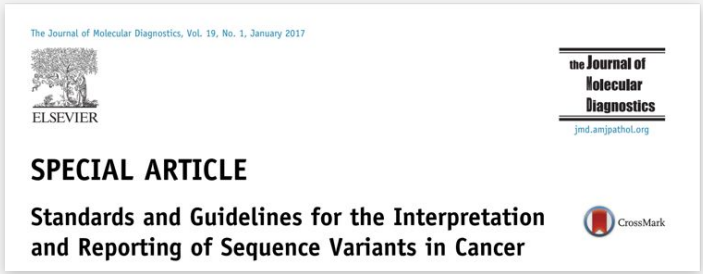
COLLEGE of AMERICAN PATHOLOGISTS

Clinical Laboratory Improvement Amendments

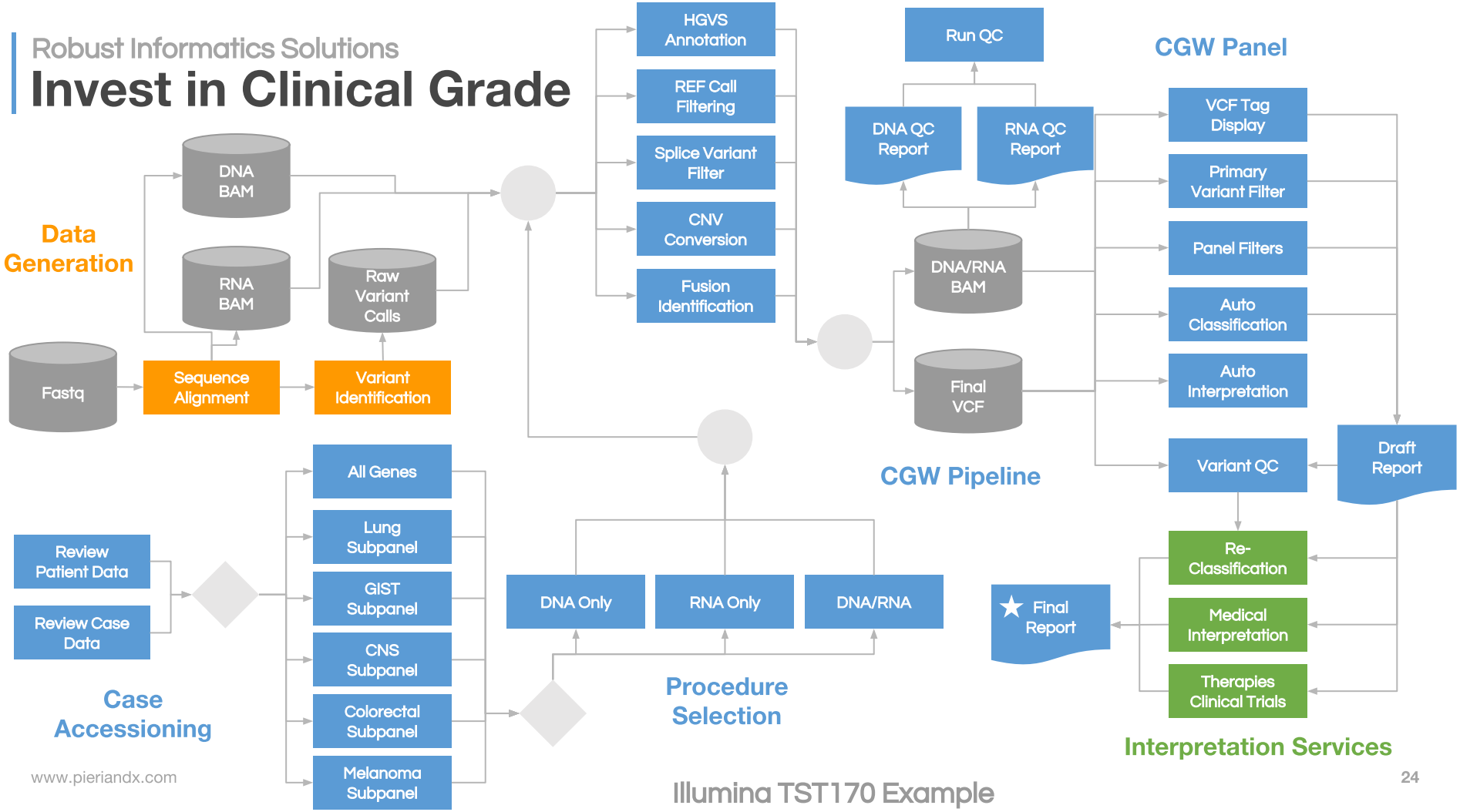
New in 2017





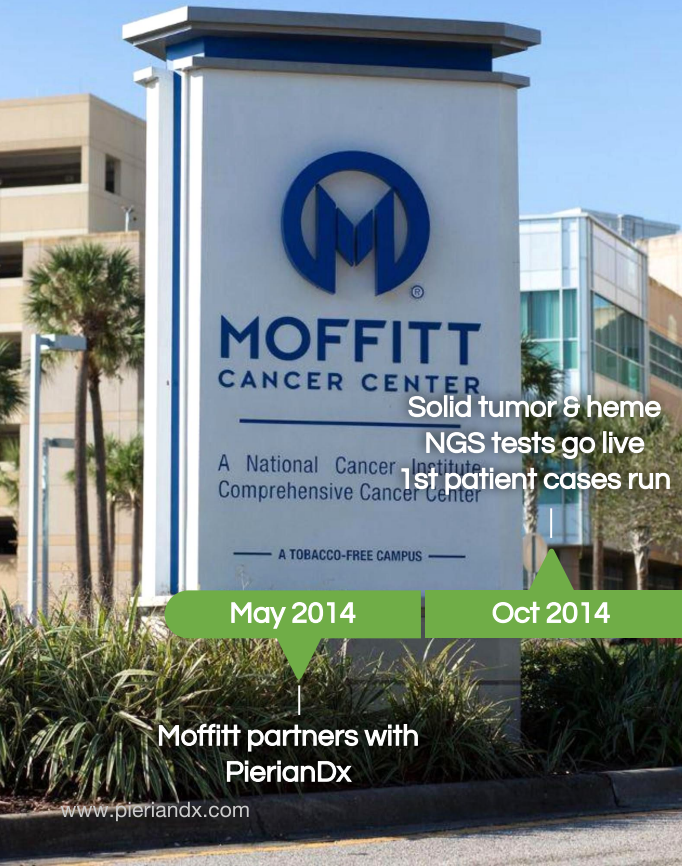
Robust Informatics Solutions

Invest in Clinical Grade



Putting it All Together

Insourcing Success



"Working with **PierianDx** has been an **ideal partnership**. They have been with us since the early onset of our program, providing both the **technology** and **services** that allowed us to **ramp our program much faster**."

— Dr. Anthony Magliocco
Exec. Director, Esoteric Laboratory Services

May 2014 — Moffitt partners with PierianDx

Oct 2014 — Solid tumor & heme NGS tests go live; 1st patient cases run

Nov 2015 — #18 Best Hospitals U.S. News National Cancer 2015-16; PierianDx Lab Services added, increases Moffitt's capacity

Jan 2016 — NGS informatics upgraded

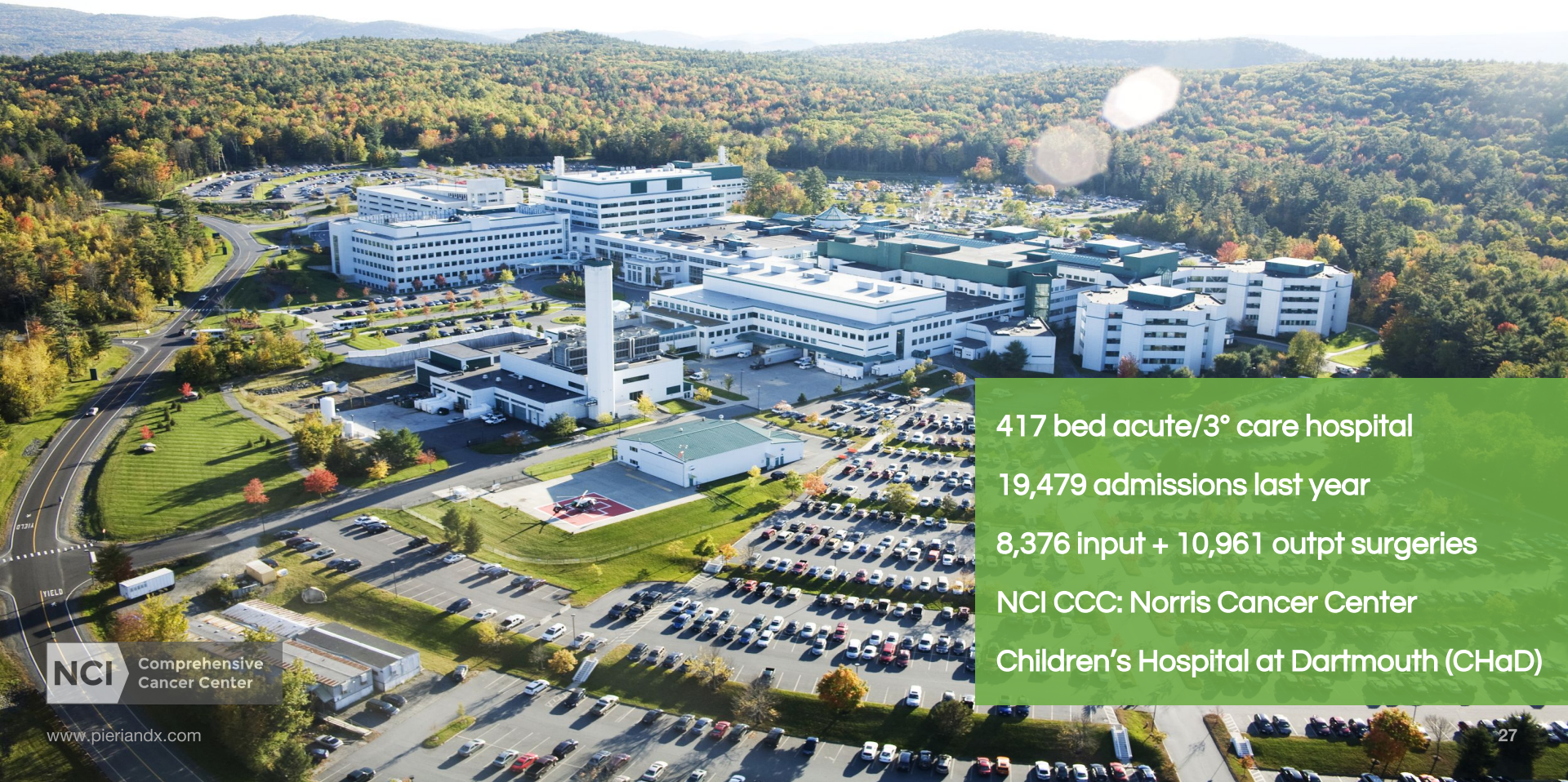
Jan 2017 — #9 Best Hospitals U.S. News National Cancer 2017-18; Interpretation Services added

Today — >120,000 enrolled in Total Cancer Care Study; First TST 170 assay validated for clinical use

Dartmouth-Hitchcock

Case Study

Dartmouth-Hitchcock



417 bed acute/3° care hospital

19,479 admissions last year

8,376 input + 10,961 outpt surgeries

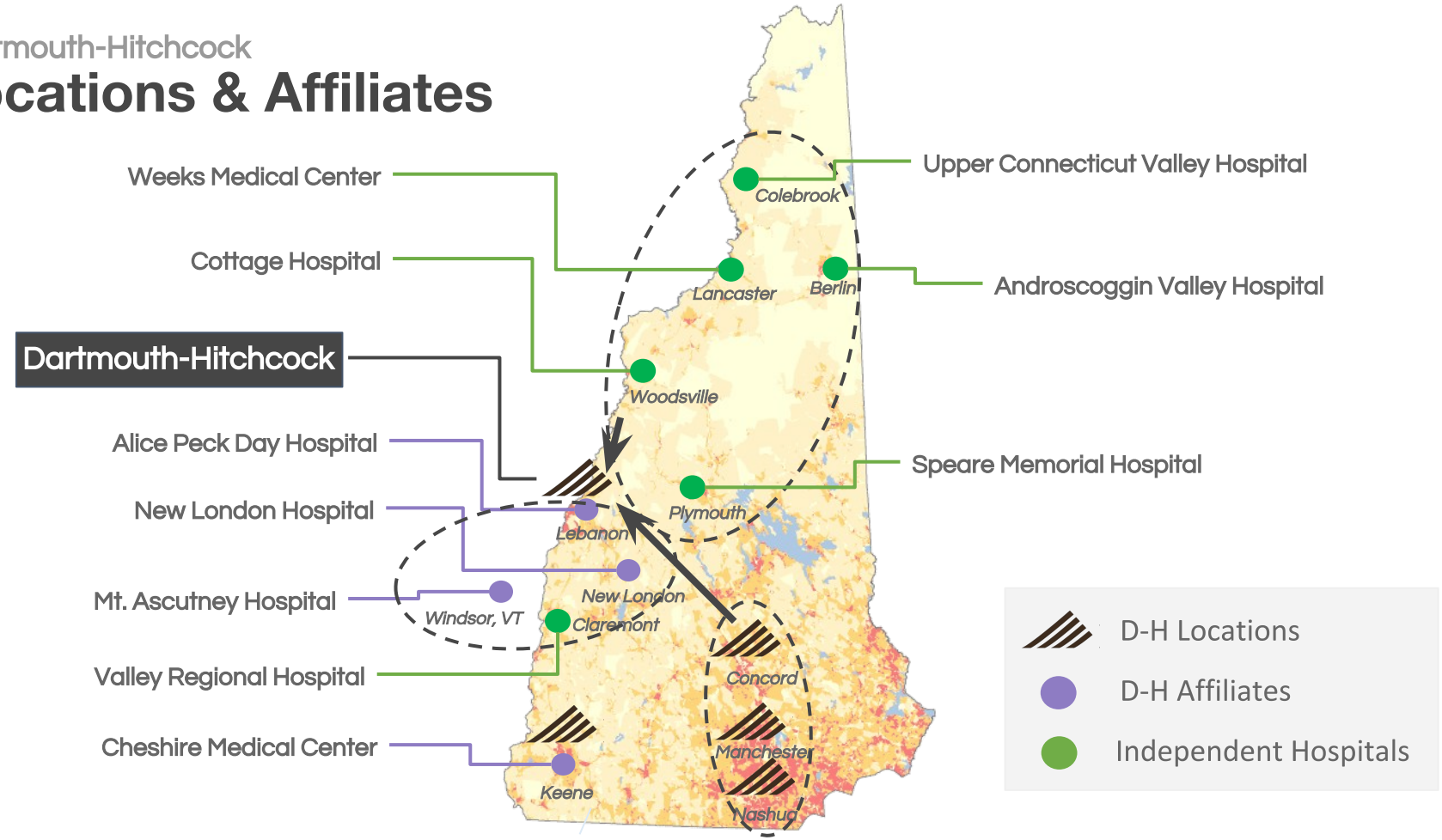
NCI CCC: Norris Cancer Center

Children's Hospital at Dartmouth (CHaD)

NCI Comprehensive Cancer Center

Dartmouth-Hitchcock

Locations & Affiliates



Why Invest in NGS?

Reasons for In-House NGS

Academic Mission

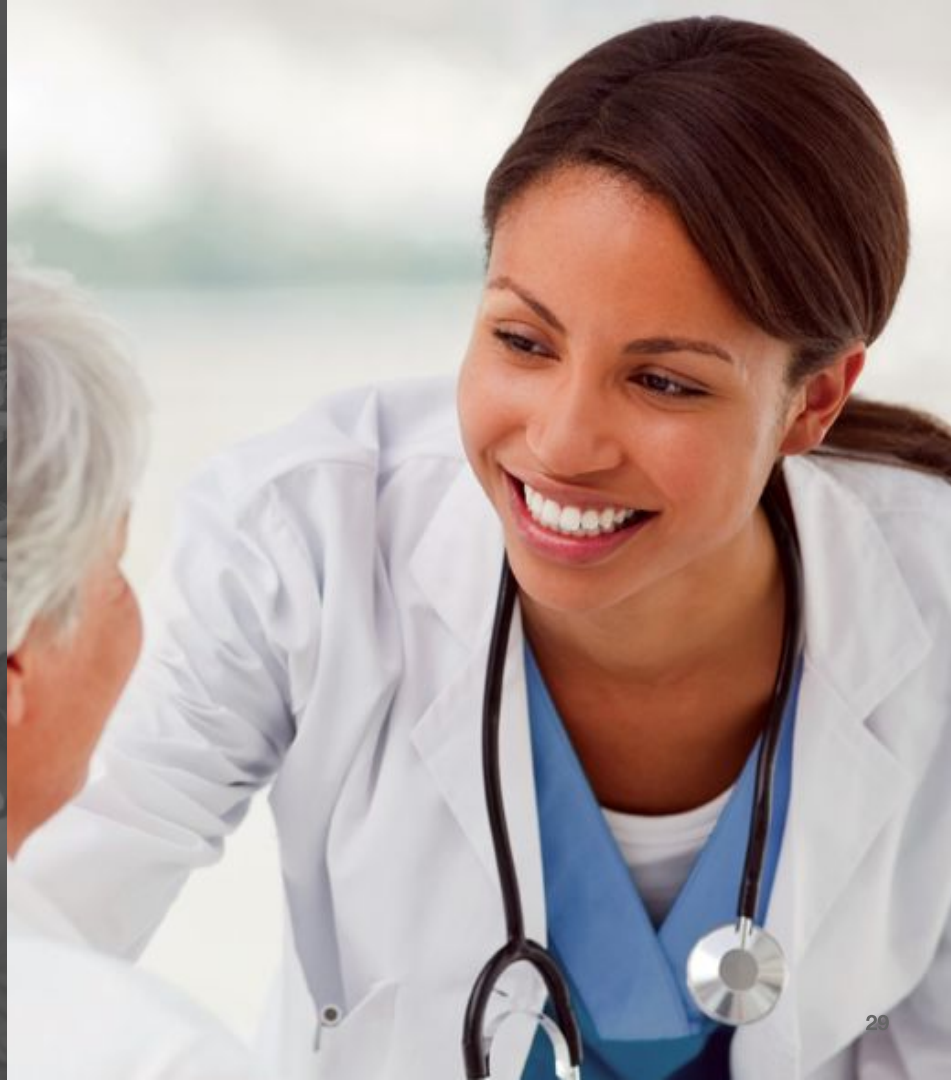
Advance health through research and education

Clinical Mission

Oncologists are going to order and use testing results

Would have to provide access internally or externally

Question: Can we make it for less than what we "buy" it for?



Clinical Genomics & Advanced Technology (CGAT)

Driving In-House Volumes

Goals

Keep send-out volume <5% of total

Keep send-out expense <7-8% of total lab expenses

Plan

Make vs. Buy

Test utilization

Aggressive contracting with reference labs

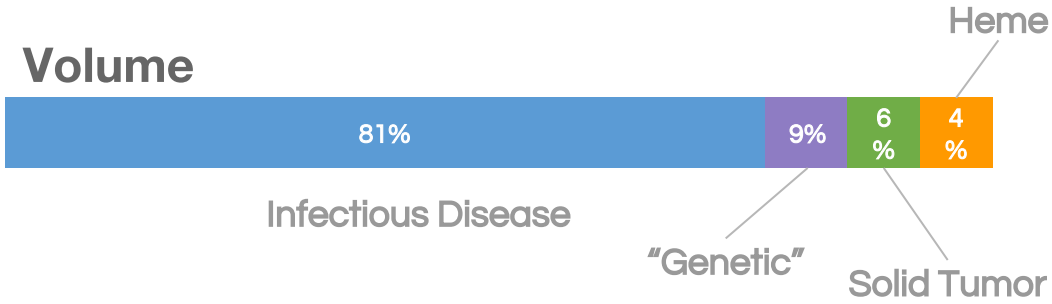
Disciplines	CMS Reportable	CMS Non-Reportable
Chemistry	4,300,000	0
Hematology	418,544	30,627
Microbiology	240,000	2,711
Anatomic Pathology	229,247	1,110
Transfusion Medicine	31,492	0
Point of Care	25,000	390,000
CGAT	23,636	0
Chemistry - Special	7,506	24,407
Flow-Cytometry	3,375	17,210
Cytogenomics	2,301	0
'16 Total DHMC Vol.	**43,981,101**	**466,065**

CGAT Testing

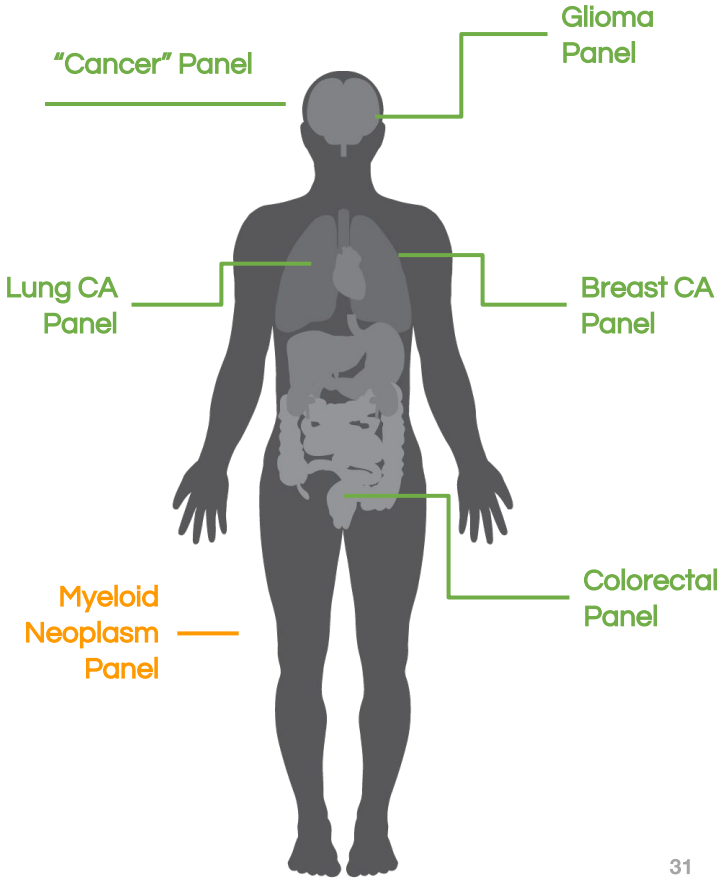
Assay Breakdown

Type

Volume



NGS Assay Panels



Make vs. Buy

Less Costly to "Make" In-House

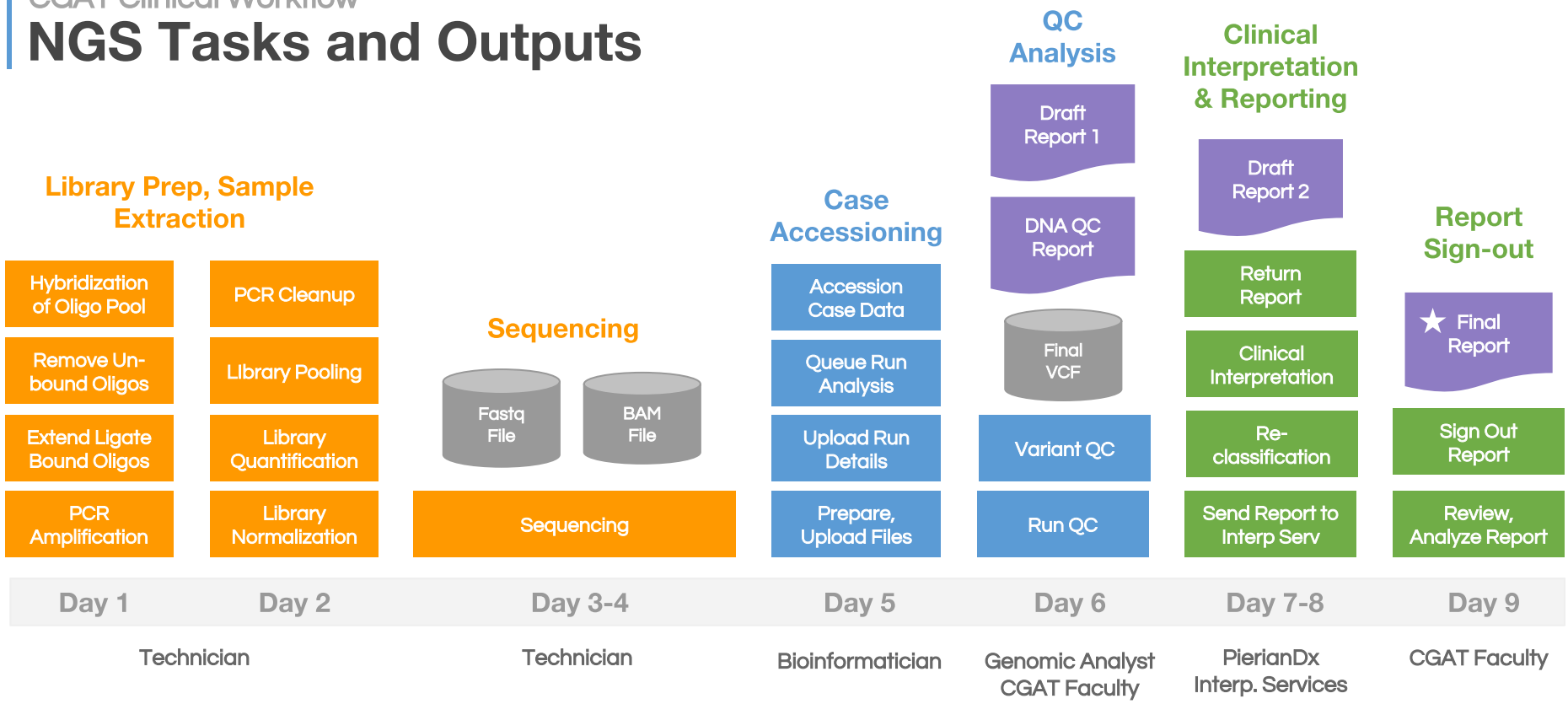
CPT Code	NGS Assay	Direct Variable	Complete Cost	"If Sent Out"	NGS Volume YTD
81445 vs 81450	Myeloid	~$600	~$2,000	~$2,700	**122**
81445 vs 81445	Lung CA	~$300	~$800	~$1,400	**219**
81445 vs 81445	Melanoma	~$300	~$800	~$1,500	**60**

		Total DV	Total CC	Total "ISO"	Tot. Vol: 401
81445 vs 81450	Myeloid	~$75,000	~$215,000	~$325,000	
81445 vs 81445	Lung CA	~$70,000	~$175,000	~$300,000	
81445 vs 81445	Melanoma	~$20,000	~$50,000	~$90,000	
		~$165,000	**~$440,000**	**~$715,000**	
	Savings	76.79%	**38.57%***	←	
		To Lab	**To Institution**		

*Dollar figures were altered for confidentiality. Savings are accurate.

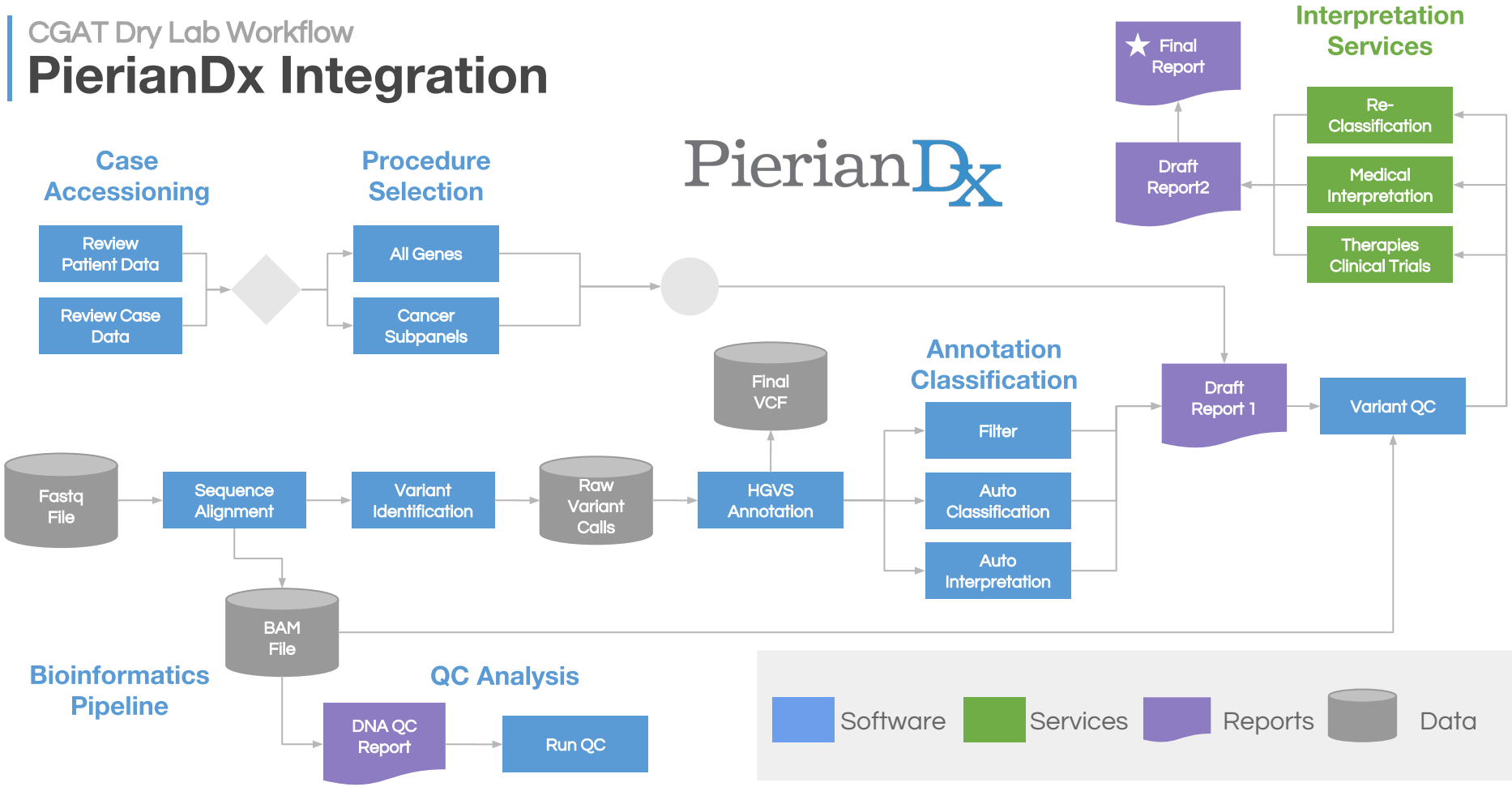
CGAT Clinical Workflow

NGS Tasks and Outputs



CGAT Dry Lab Workflow

PierianDx Integration



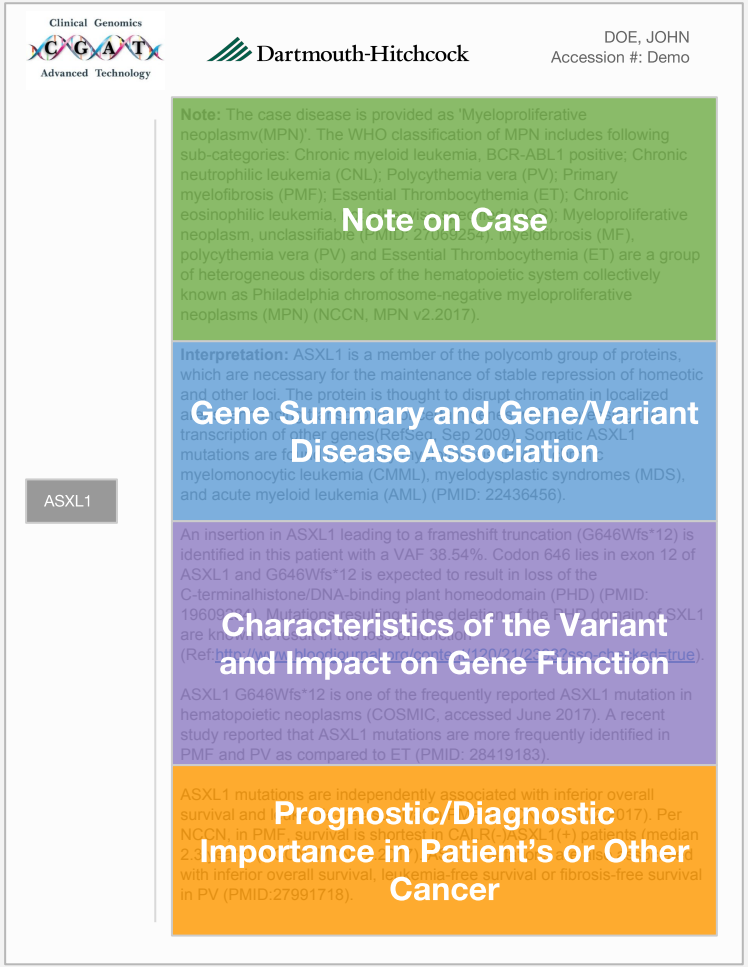
Uniformity of Reports

“Group Sign-Outs”

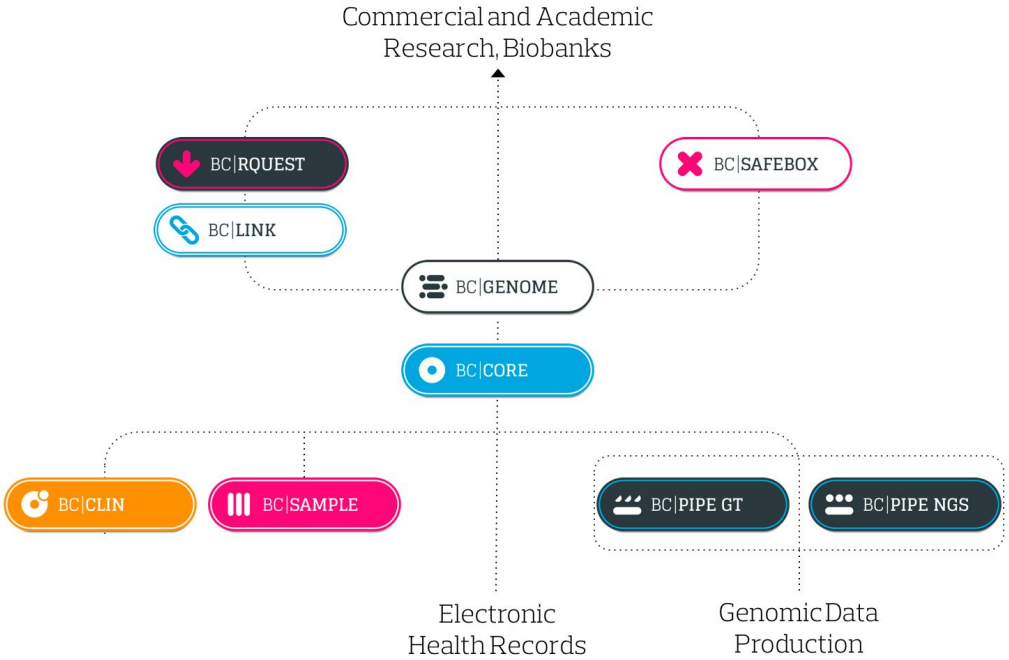
We try to maintain a uniform structure to the interpretation to keep uniformity in reports across signout pathologists.

We are in the process of creating “canned” comments for recurring scenarios.

Not shown are sections 5: Approved/Emerging Therapies) and 6: Concluding Remarks or Other Comments).



DHMC Long Term Vision



BC Platforms

DHMC Biobank

Managed by Pathology Dept

Pair genomic data to all banked specimens for research and collaboration

BC Platforms

Research / Industry collaboration

Sample & clinical data management

Genotype knowledge base for pharma

NGS Takes a Team Effort

Invest in People

Technical staff

Administration

Management

Ideally: 3 clinical lab scientists

Ideally: At least 2 bioinformaticians

IT support staff

Molecular genetics boarded physicians and scientists

Advanced Technologies

Invest in Equipment

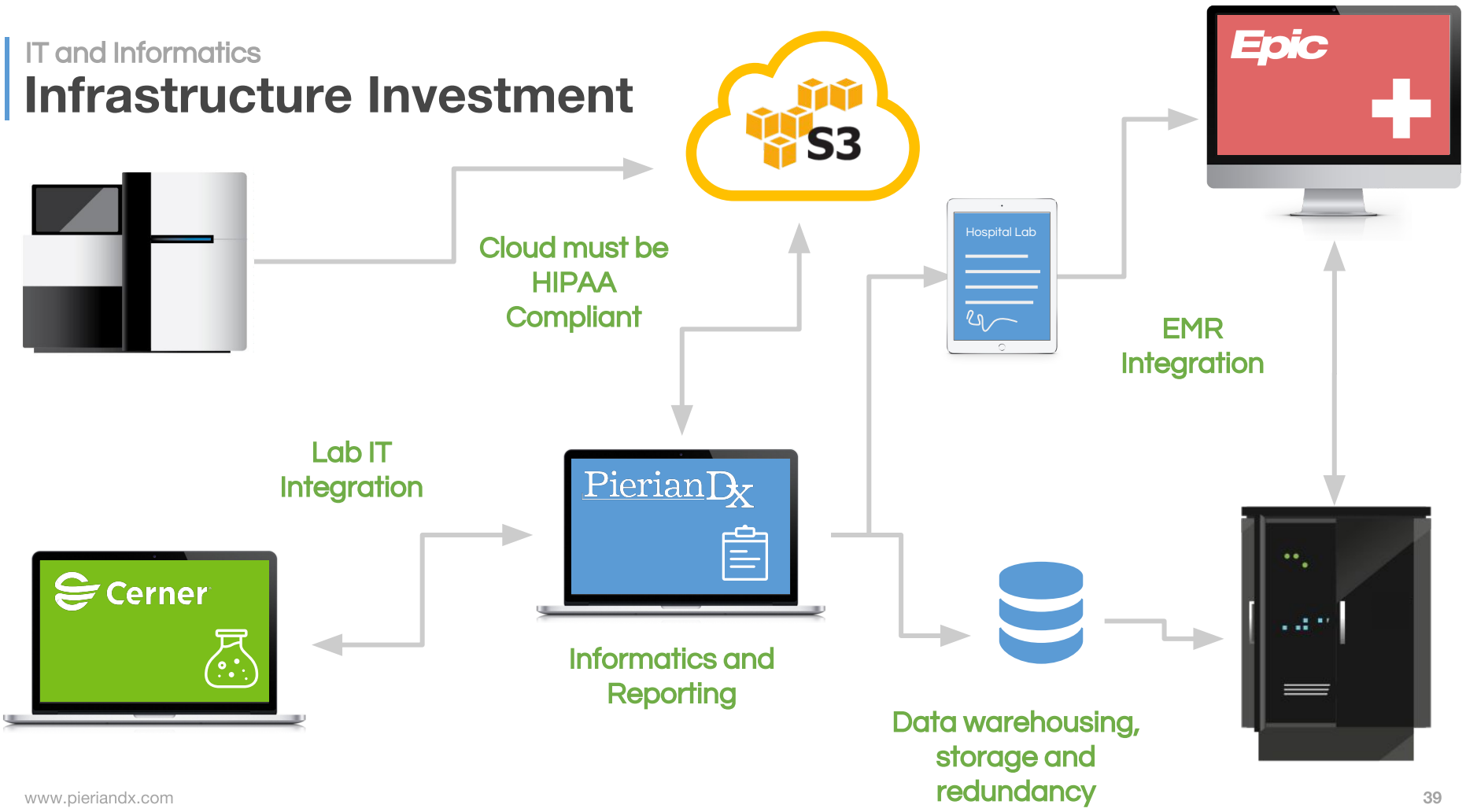
NGS Sequencers

CGAT is using reagent rental

Hard Capital Equipment

E.g. machines for extraction, RT-PCR, robots to automate portions such as library prep, etc

Infrastructure Investment



In Summary

CGAT Experience

Key Learnings

In-house testing met educational mission and made financial sense

Could be feasible if specimen volumes are high enough

It IS an investment (money, time, personnel, IT resources, etc)

Not everything in the pipeline needs to be done in-house

Remaining Challenges

Can keep pace with 'wet-lab' work, but explosion of data is difficult to manage

Need more staff positions, but not granted due to institutional budgetary constraints

And...

The Elephant in the Room

Reimbursement

Issues and Considerations

Medicare

MolDX Program*

Other Regional MAC LCDs

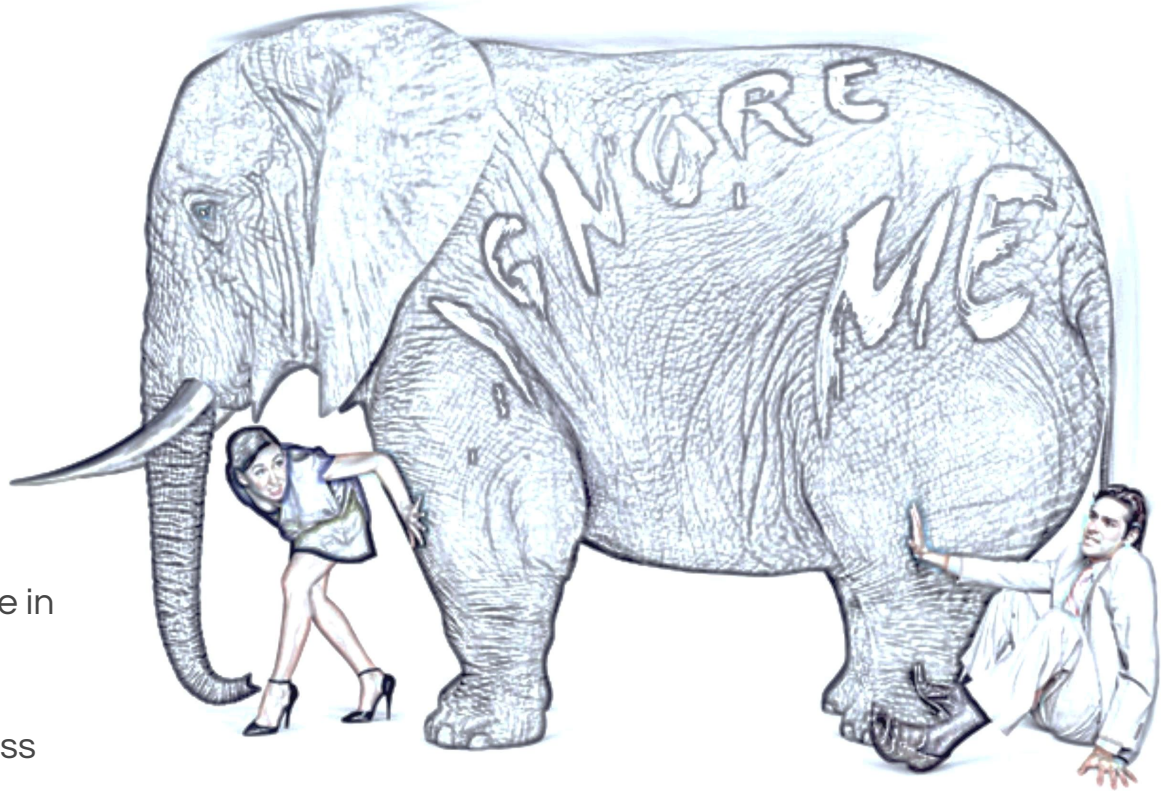
CMS National Coverage Decision

Private Insurers

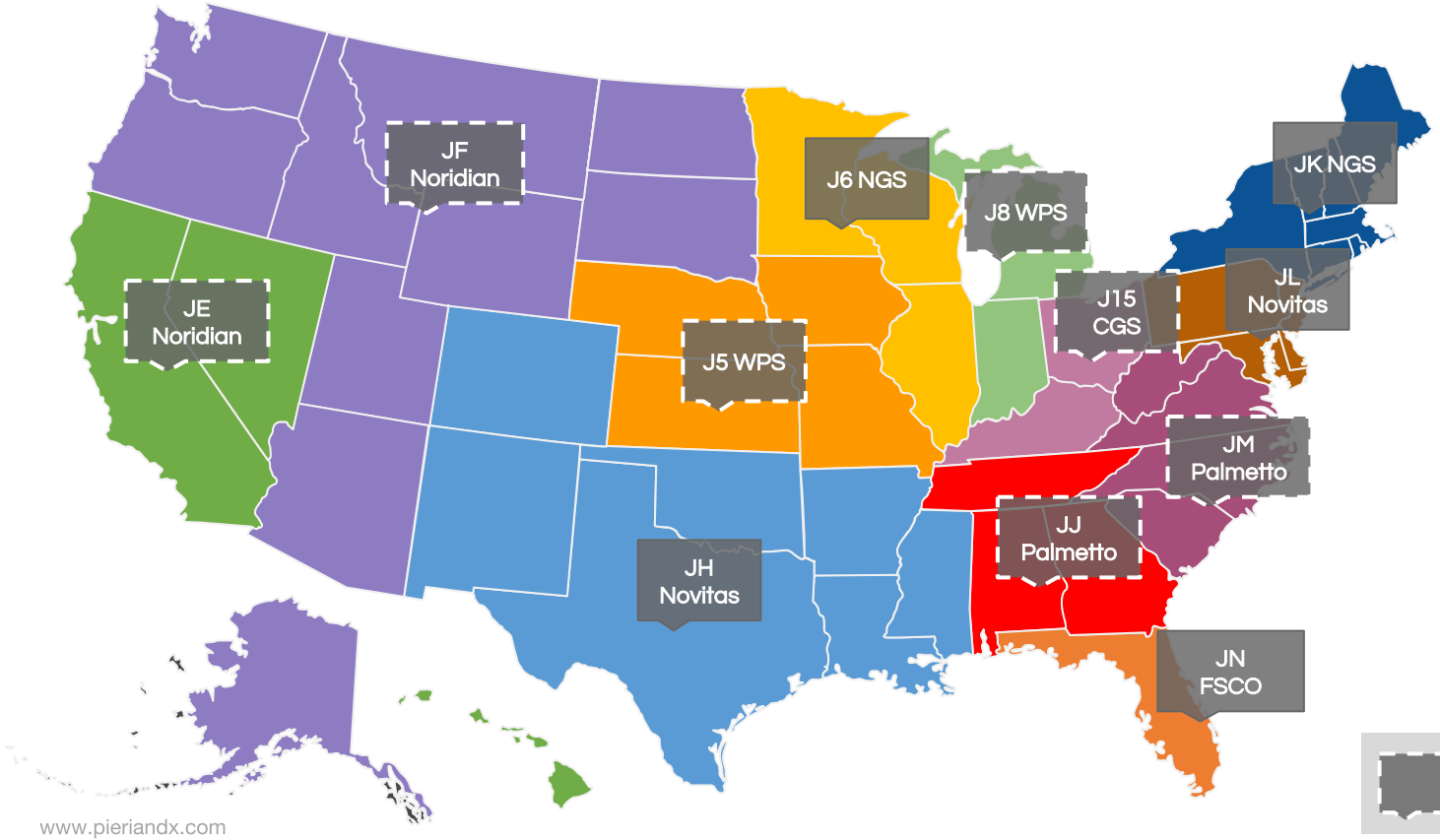
Major health plans utilize laboratory benefits management (LBM) programs

Insurers realizing they lack the expertise in this field to rein in fraud & abuse

Potential cost-savings in driving business to preferred in-network labs



Medicare Administrative Contractors



All labs performing MolDX testing and submitting claims to Medicare are affected

Palmetto GBA maintains "Master Edit File" that's updated weekly and distributed to participating MACs.

Participating Palmetto MACs

AMA Codes

Molecular Pathology

MolDX, CPT 8000 Series, "Z-Codes"

If in a jurisdiction with MolDX and want to submit a MDT claim, you're going to need a "Z-code"

Z-code = unique identifier for your lab's assay

If assay is a LDT, getting registered can be rather onerous

Code Category/Description	'18 MolDX CPT Code Range
Tier 1	81105-81112, 81120-81121, 81161-81383
Tier 2	81400-81408
Genomic Sequencing Procedures	81410-81471
Molecular Multianalyte Assays	81490-81595
MAAA Admin. Codes	All Codes
Immunology	86152-86153
PLA	All Codes
Cytology	88120-88121
Not otherwise classified (NOC)	81479, 81599, 84999, 85999, 86849, 87999, 88199, 88299, 88399, and 89398

Rev Cycle Management

Conifer Health Solutions

Revenue cycle management services

Generate list of denials → ID insurance groups to target

Work with payers to determine the patient subset where auth is needed

Team for submitting prior-auth requests for lab-generated testing

Run test cases to ID the true turnaround time for authorization

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CGAT

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Bing Ren
Laura Tafe

Clinical Genomics

CGAT

Advanced Technology

@DHMC_CGAT

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Northwestern Medicine

Cedars-Sinai

The University of Alabama at Birmingham

The University of Vermont Medical Center

TriCore Reference Laboratories

NorthShore University HealthSystem

Adventist Health System

Dartmouth-Hitchcock

The George Washington University Washington, DC

Seattle Children's

Augusta University Medical College of Georgia

Wake Forest Baptist Medical Center

Human Longevity, Inc.

Carolinas HealthCare System

Alpha Genomix Laboratories

Nicklaus Children's Hospital

HackensackUMC

PathGroup
Physician Centered. Patient Focused.

ARUP Laboratories

Cancer Genetics Incorporated
Empowering Personalized Cancer Treatment

PerkinElmer

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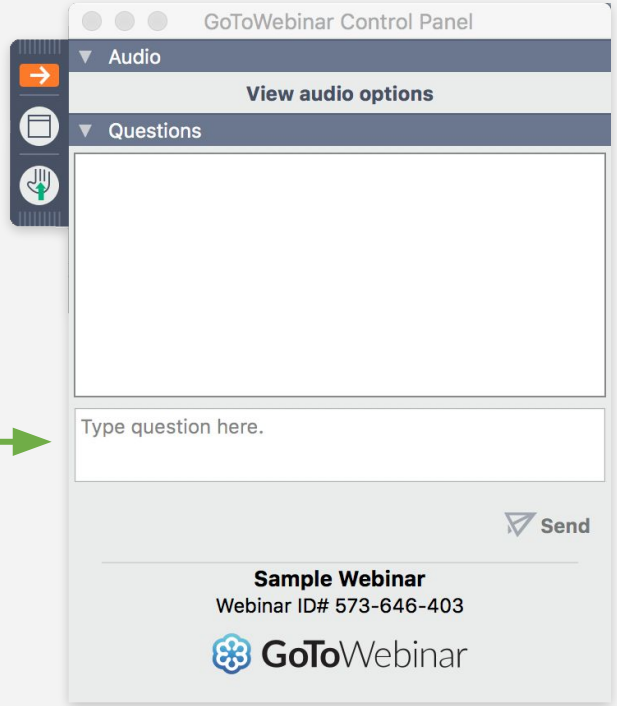
Thank You

Q&A



Type questions here

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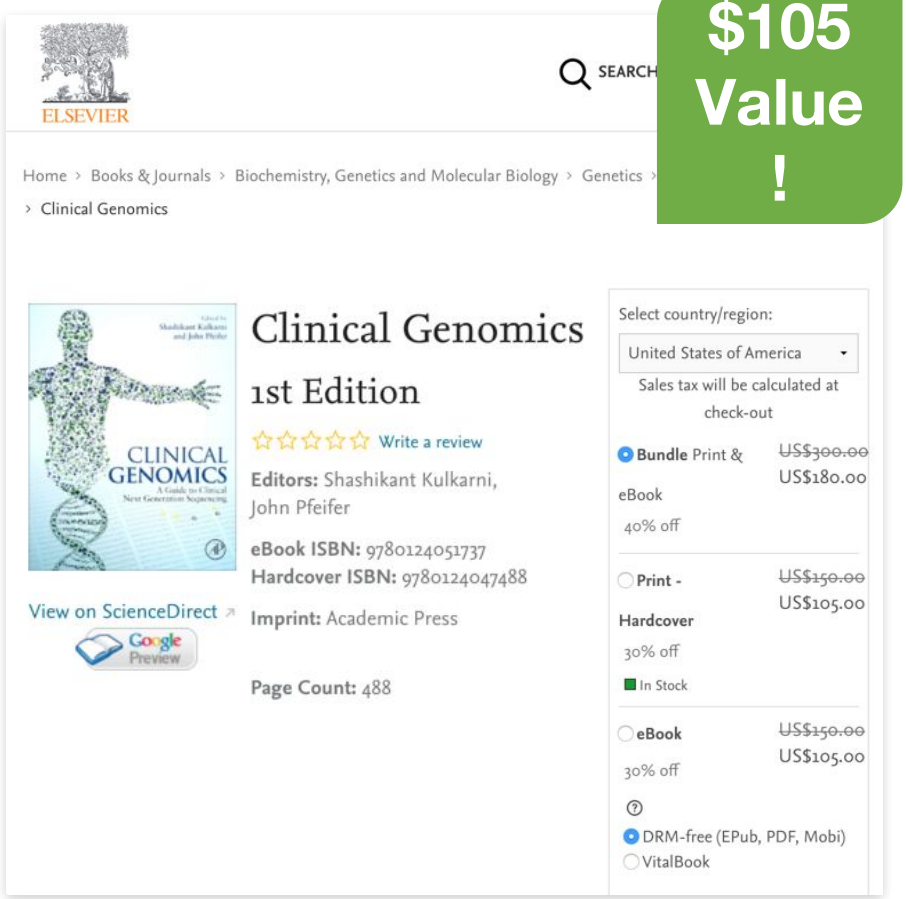

*Limit to the first 10 who qualify