Northwell Health Laboratories: Value, Outcomes, Precision Medicine

James M Crawford, MD, PhD jcrawford1@northwell.edu

Executive Director and Senior Vice President for Laboratory Services,

Northwell Health

Professor and Chair, Pathology/Lab Medicine

Hofstra Northwell School of Medicine

Manhasset, NY



Disclosures

- ClaraPath (start up from Cold Spring Harbor Laboratories)*
 - 2015: Scientific Advisory Committee
- Northwell Health Genomics Alliance (with OPKO Health)
 - 2015: President of LLC



What is Laboratory "Value"?

- "Value generation" is in the eyes of who is paying for it:
 - Hospital-based testing: Hospital-Health System-Payer
 - Ambulatory testing: Health System-Payer
 - ABN*/Co-Pay/Balance bill: Consumer
- Listen to the people who need our services:
 - What are their needs? Are we meeting them?
 - Is our lab testing doing any good for the patient?
 - Can we prove it?
- Write your story
- Tell your story



So how does a Laboratory deliver "Value"?

- Support health system Financial Outcomes
- Improve Health System Revenue: Documentation and Coding
- Provide lower cost services: or will someone else do it instead?
- Support Value-based Payment: meeting contractual metrics
- Support Risk-based Payment: Coordinating care at lower cost
- Improve Patient Access: Patient-centered care
- Improve Patient and Provider Experience: Are you a "good lab"?
- Actually improve Patient Outcomes? Can you quantify it?
- Help drive health system Strategies

Leverage the Information you are already generating, demonstrate your impact on Outcomes (of whatever nature), and make sure that you are publicizing your Accomplishments



Northwell Health



Reference laboratory (9% of ambulatory market)

450+ practice locations

21 Hospitals (27% of regional market)

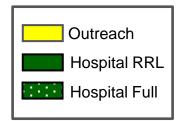
>4M patient encounters per year

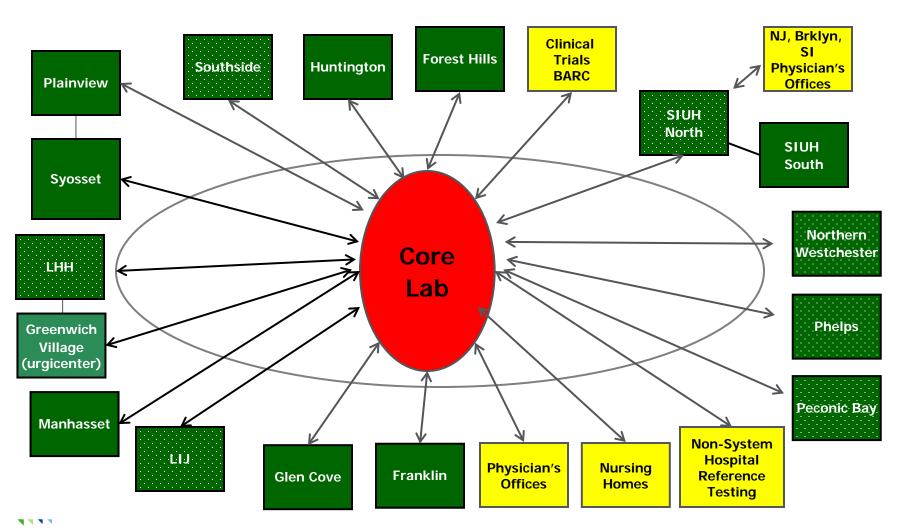
Free-standing Emergency Room

Network of SNFs, AmbSurg, UrgiCenters



Northwell Health Laboratory System





Plus: 32 Patient Service Centers, in-office phlebotomy, home draw, network support of PQLs

Northwell Health Laboratories

Chair/SVP/ED VP

Senior Leadership Group

System Managers

Hospital Laboratories

Medical Director Admin Director

n = 15

Core Laboratory

Financial Services
Logistics
Quality
Continuing Ed
LIS/Informatics
Procurement
Sales/Marketing
Phlebotomy/PSC
Business
Development

Divisions

Blood Banking Transfusion Med

Infectious Disease Diagnostics

Point-of-Care Testing

Hematopathology

Cytopathology

Pediatric Pathology

Autopsy Pathology

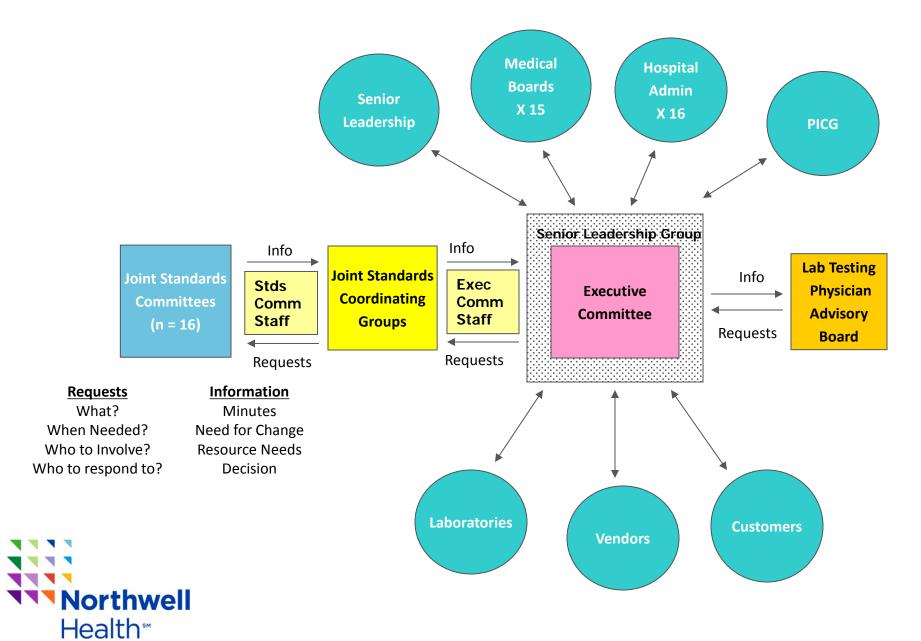
Joint Standards

BB/TM
Central Processing
Charting
Chemistry
Cytopathology
Education
Hematology
Histology
LIS
Infectious Disease Molecular Path Cytogenetics
Path Assistants
Phlebotomy
Point-of-Care
Safety
Surgical Pathology
Validation

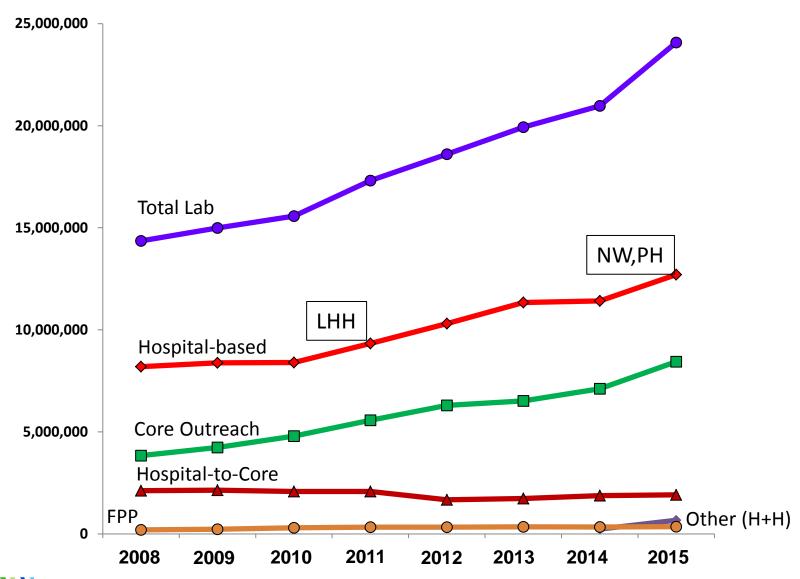
Laboratory Process Improvement Coordinating Group (PICG)

Northwell Health

Joint Standards Committee Process

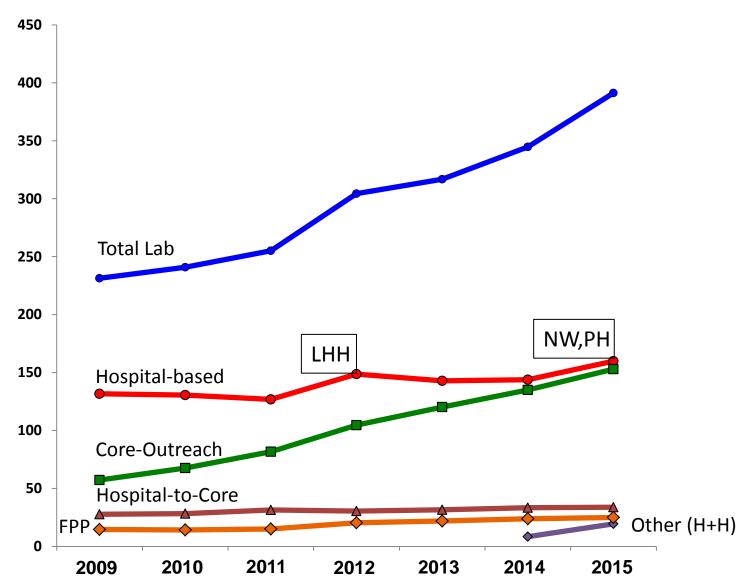


Northwell Health Laboratory Service Line (volumes)



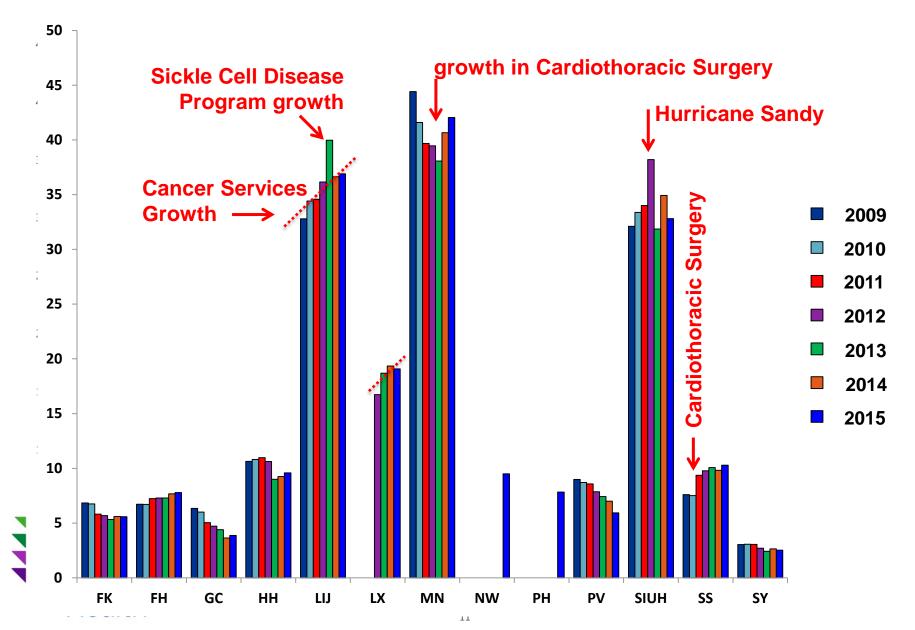


Northwell Health Laboratory Service Line (\$M)

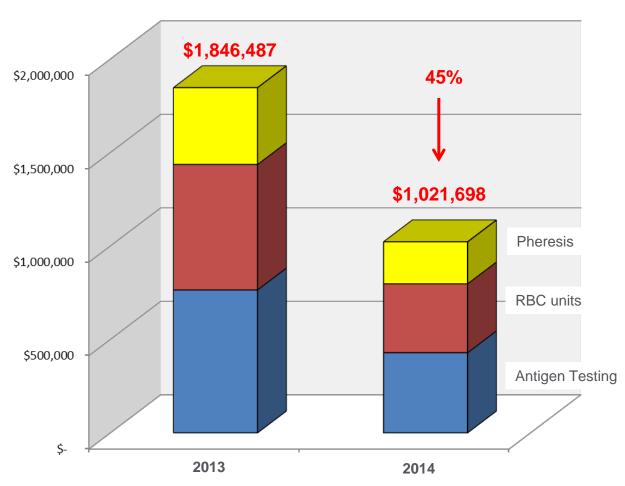




Hospital Laboratory Costs (\$M)



Blood Product Management: CCMC Sickle Cell Disease



Phase 1: Product
Standardization

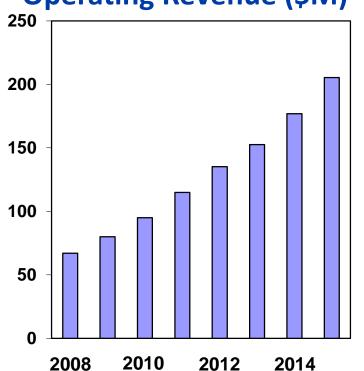
Phase 2: Standardized clinical criteria for use

Phase 3: Product selection:

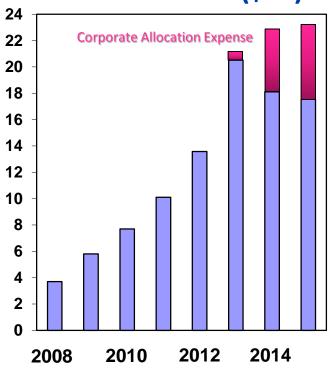
- "Deep" Ag typing of units
- Health IT to track unit Ag and recipient reactivity
- Administration of pretyped units only

Northwell Health Laboratories (Core Lab)

Operating Revenue (\$M)



Net Revenue (\$M)



2015 Contribution to health system – Laboratory Service Line

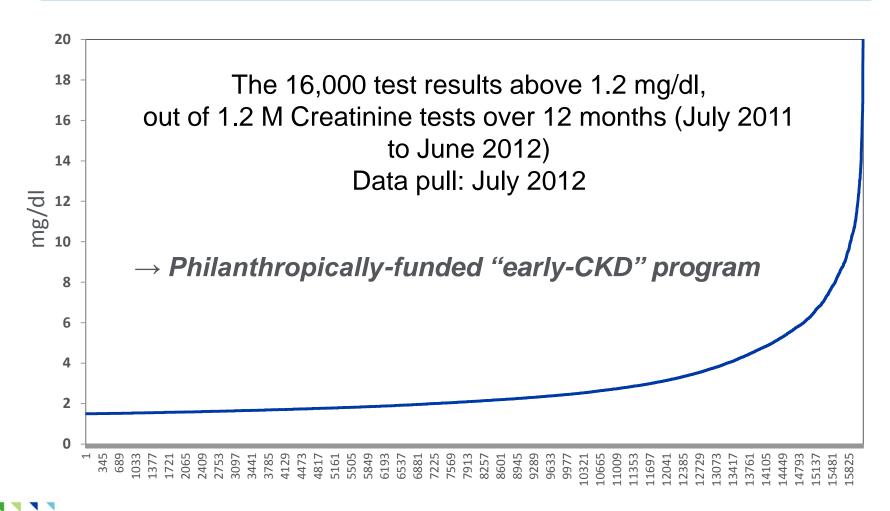
Core Laboratories: Actual \$17.5 M
Corporate Allocation Expense:Actual \$4.8 M
Hospital Laboratories: To Budget \$2.9 M favorable
Pathology Department: Actual (\$0.3 M)

NET CONTRIBUTION

\$24.9 M

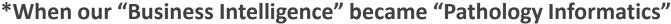


Chronic Kidney Disease Management*



Northwell

Health™



Pathology Informatics

- Est. in 2013; a "group", not "division" (n = 8 and growing)
- Works intimately with LIS team (n = 30 and growing)
- CMIO and CIO for Laboratory Service Line
 - CMIO: works with clinical stakeholders throughout system
 - CIO: accountable to enterprise IT (CIO, OCIO)
- Design and build infrastructure Internal and External
- LDW*: architecture, programmers, analysts, project manager
- Data integration from multiple systems throughout enterprise
 - "Owning" deliverables from laboratory environment
- Delivery platforms, both as internal and external builds
- Return-on-Investment: within first year but to health system. (Benefit does not derive to Laboratory Service Line)



Blood Culture Fill Volume



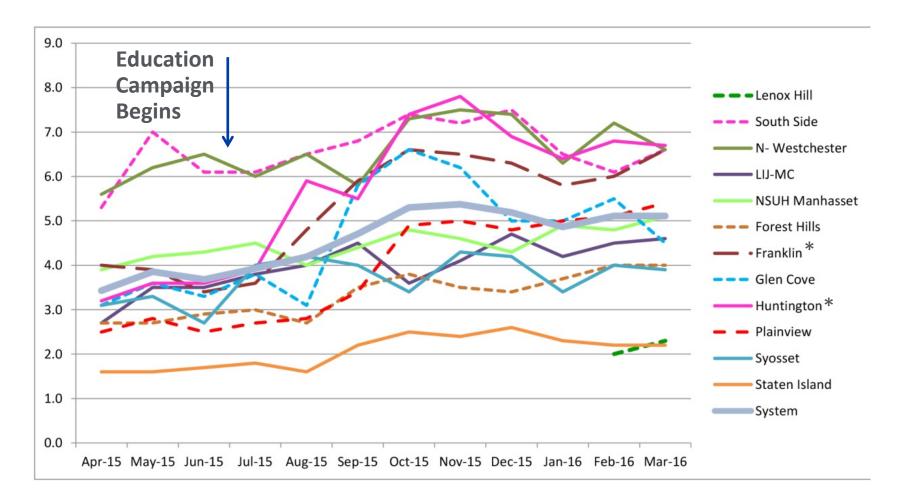


Fill volume:

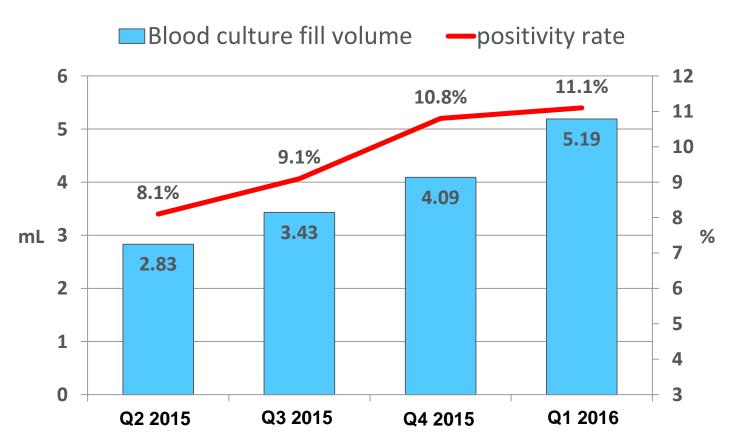
Optimal is 8 – 10 mL

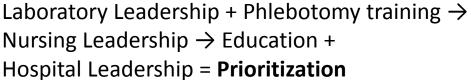
Maximum is 10 mL Minimum is 3 mL

System Quality Initiative Blood Culture Fill Volumes



System Quality Initiative Blood Culture Fill Volumes







Interprofessional Council: Lab, Nursing

Goal: To provide leadership in system-wide initiatives requiring interprofessional collaboration*

- 2014: Blood Glucometer implementation
 - On-label → Off-label validation
 - 13,000 personnel trained
- 2015: Blood product administration standardization
 - Risk Assessment and risk mitigation (19 hospital sites)
- 2015 2016: Phlebotomy standardization
 - Governance (Phlebotomists 30% of draws, Other 70%)
 - Best practices (e.g., Blood Culture bottles)
 - Procurement, Bar Coding, Work Flow

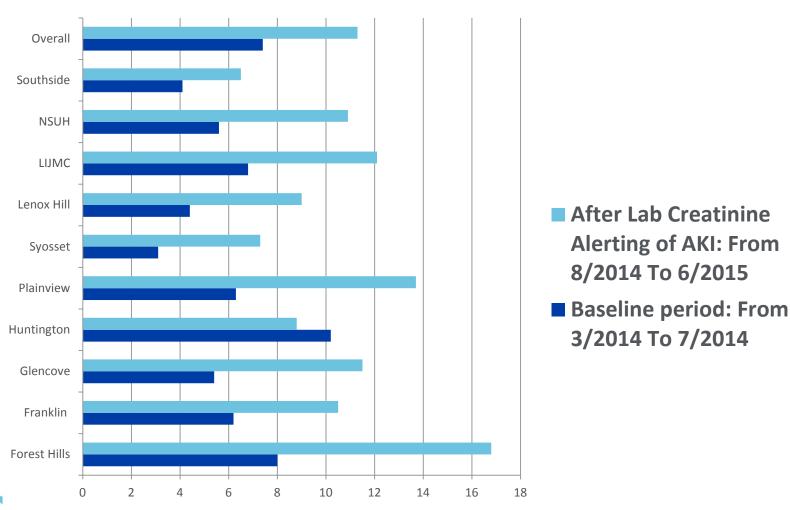


Acute Kidney Injury

- AKI affects 5-7 % of all hospitalized patients and majority of patients are cared for by non-nephrologists
- AKI is under-recognized and under-diagnosed:
 - 6 to 30 fold increase in in-hospital mortality
 - Average LOS is increased by 3 to 7 days
 - Hospitalization costs increased by \$4,000 to \$10,000/day/patient
 - \$10B in annualized costs throughout the U.S.
- Lab instituted a "delta creatinine" Alert pilot program:*
 - 50% relative rise OR 0.3 mg/dl rise: detects 99.8% of AKI patients
 - 7:00 AM daily notification to CMO → distributed to units
 - Pilot initiated at Forest Hills Hospital (250 beds) Jan 1, 2014
 - Alert triggered 5,185 times in 6m = 40 times per day
 - Clinical rounding identified 20 pts per day = 8% of admissions



System-wide Identification of AKI



Percentage of all cases with a secondary DRG diagnosis of AKI
Northwell (Medicare FFS and HMO only)

Health™

Enhanced Inpatient Reimbursement*

- The system-wide AKI capture rate has increased from 7.4 % (in July 2014) to 12.9 % (in July 2015) since the daily lab AKI reporting and education program for physicians began
- Average revenue increase per DRG with secondary diagnosis of AKI is \$700
- Secondary diagnosis of AKI /month in 2014 (avg.): n = 615
- Secondary diagnosis of AKI / month in 2015 (avg.): n = 930
- Increase in secondary diagnosis of AKI from 2014: n = 315
- Increased in reimbursement / month because of secondary diagnosis of AKI= 315 x 700 = \$ 220,500
- Increase system reimbursement for 2015 = ~ \$ 2.65 million



*Capturing correct disease severity through correct coding (note: system lead = Gerard Brogan, MD)

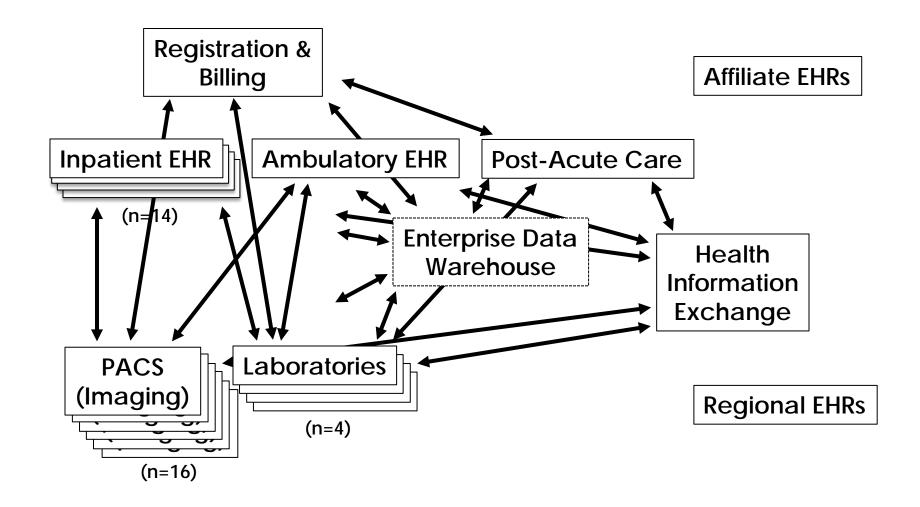
Utilization - Heat Maps - LDW alone

#	Ordered Test	Total	Doc 1	Doc 2	Doc 3	Doc 4	Doc 5	Doc 6	Doc 7	Doc 8	Doc 9	Doc 10	Doc 11	Doc 12	Doc 13	Doc 14	Ooc 15	Doc 16	Doc 17	Doc 18	gini coef
	Total	100%	17	% 11	% 10%	6 99	6 80	% 7'	% 7%	6%	6%	5%	4%	4%	2%	2%	2%	1%	0%	09	
1	Glycosylated Hemoglobin	9931	1.0	60 0.0	<mark>00</mark> 1.6	8 0.0	0 2.0)5 3.0	0.00	0.00	0.00	0.00	0.00	2.14	1.81	2.38	0.00	0.00	2.13	1.4	5 0.56
2	Vitamin D 25 Hydroxy	5469	0.	74 2.8	37 1.1 ₀	4 0.0	0 1.1	4 1.1	1.98	0.09	0.84	0.00	0.00	1.15	0.77	1.11	0.00	0.77	0.54	0.7	0.45
3	LEAD	4851	0.0	0.5	75 0.8	1 1.7	6 0.5	51 0.0	0.75	1.52	1.16	2.30	3.74	1.29	1.46	0.62	3.49	2.26	0.00	0.0	0.48
4	HHC Quantiferon-TB Gold	4365			98 1.4	8 1.8			1.11	1.70	2.13	0.44	0.00	1.04	2.59	0.40	0.33	0.78	3 2.76	2.4	0.43
5	Order Comment	1127	2.:		0.0	7 1.4			36 0.19	2.03	0.40	2.22			0.11	0.04	0.18	0.00	0.71	0.0	0.59
	Tubes Received	1111	2.4						0.21	2.01	0.38	2.12	1.38	0.34	0.11	0.04	0.18	0.00	0.72	0.0	0.58
	HHC HIV AG/AB Screen by CMIA	1094								2.47	0,02	0.00	0.00		0.00	0.16	0.00	0.00			
8	HPVHR MRNA	1087	0.		_	0 1.4	0.0	0.0	0.00	1.00	1.40		0.00	0.00	0.00	0.00	11.63	0.73		0.0	0.81
9	Viral Load	838	0.0	<mark>00</mark> 2.				_	0.03	4.79	1.32	0.00	0.00	0.00	0.00	0.90	0.00	2.84			
	Antinuclear AB	736				0.0	0 2.1	1.0)4 0.95	0.05	1.97	1.67			0.50	0.89	0.75	0.00	1.09	2.2	6 0.46
	Vitamin D 1,25 Dihydroxy	666								3.26	0.95			-	1.67	0.33	0.00	0.34			
	Benzo QuaNT Ur Confirm	587			0.0	0.0		_ /	0.00	1	0.00	0.00			0.00	0.00	0.00	1.35	_		
	HHC HPVGENO	503		21 0.0	0.0			_ \	00 6.79		0.00	0.00			0.00	7.61	0.00	0.00			
	Blood Culture	493		9.2	2 <mark>7</mark>	0.0			0.00	0.00	0.00	0.00			8.00		0.00	0.00			0.94
15	Hepatitis C RNA Quant	429	0.0	00 2.8	0.0	0 1.7	5 0.0	0.0	0.03	2.13	4.00	0.00	3.88	0.00	0.00	0.00	0.00	3.43	0.00	0.0	0.72
16	Vitamin B1	391	3.	_				0.0	1.26	0.00	0.04	1.87			0.00	0.11	0.51	0.00			0.82
	H.Pylori AG Stool	349								2.17	2.06		2.42	0.00	0.00	0.00	0.00	1.95		0.0	0.72
	HLX CFTR Results	326									4.24				2.65	0.13	0.00	4.17			0.73
	Testosterone Free and Total	321					2 1.2	26 0.6		0.70	1.69		0.16	1.02	0.00	0.54	2.66	4.94	0.00	0.0	0.50
	Hepatitis B Surface Antibody, Quant	313									0.62				0.00	0.00	0.00	0.00			
21	Vitamin B6	271			_			_			0.06				0.00	0.00	0.00	0.00	0.00	0.0	0.89
22	Transglutaminase IgA	253	1.0	0.0	37 0.6	7 1.8	0.7	0.9	0.12	0.68	1.25	3.07	2.93	0.00	0.00	0.00	2.38	0.00	0.00	0.0	0.59
	Cyclic Citrullinated Peptide AB	250									0.56		0.51	0.22	0.00	0.00	0.00	0.00			0.54
	Herpes Simplex 1/2 Ab IGG	244							0.00		0.65		0.00	1.78	1.52	1.78	0.00	11.13	0.00		0.71
25	Fecal Occult Blood Immuno	217	0.0	0.0	<mark>)0</mark> 2.7	6 0.0	0.0	0.0	0.00	0.00	0.08	0.00	0.00	5.02	2.28	11.83	0.23	22.43	0.00	0.0	0.84

→ Utilization Management, Gaps-in-Care, Quality Measures, Outcomes

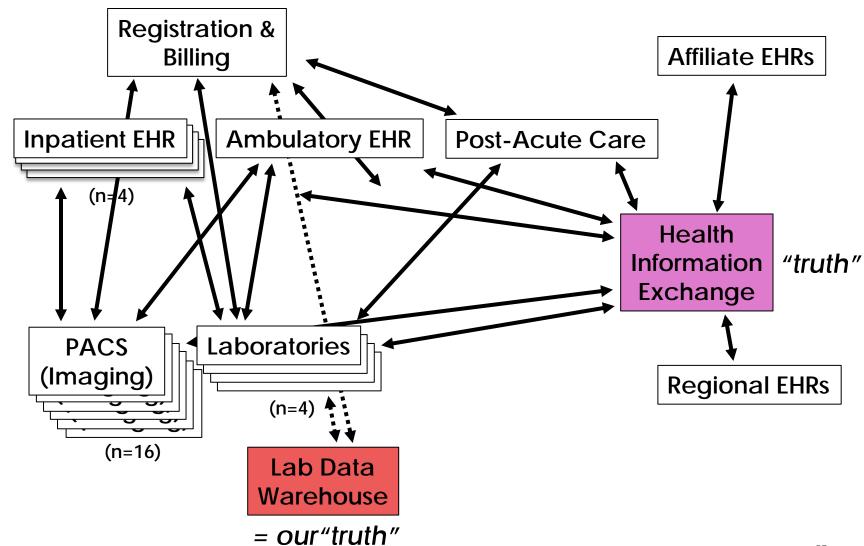


Enterprise Data*

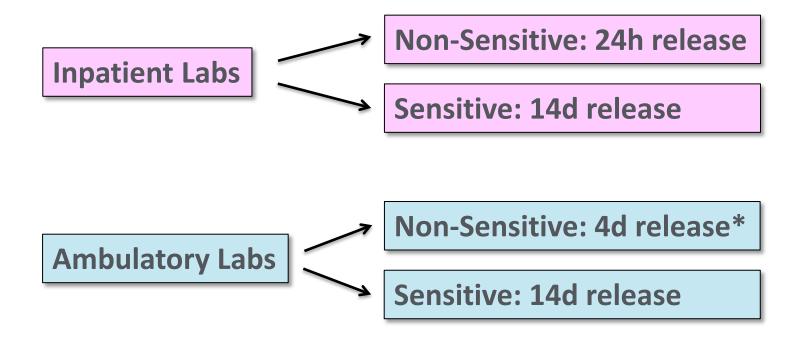


^{*}Northwell Lab's worm's eye view of the Northwell Health System

Northwell Lab's approach



Patient Portal: "Follow-my-Health"

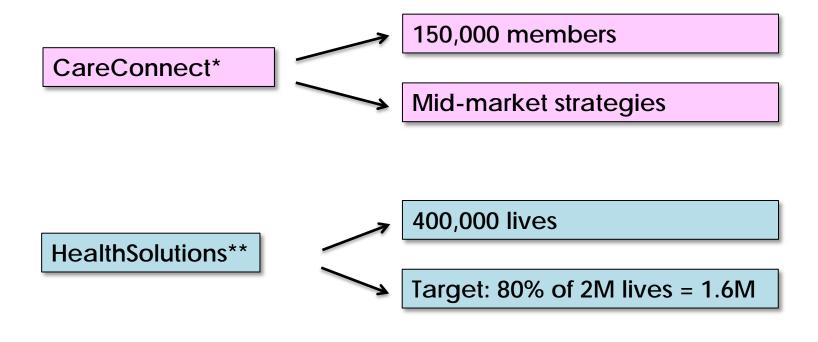




*with "look-back" data

26

Insurance* & Coordinated Care**



Core Competencies: Clinical "Population Health" data

Laboratory data & analytics

Claims and Utilization data

Pro-active Risk Assessment

Pro-active Care Coordination

LDW plus other data sources



Formation of a Joint Venture

Northwell Health Labs

- Central "Core" Laboratory
- 12 Hospital Based Labs
- \$300 Million Annual Operating Budget
- Approx. 1600 FTE's
- 18 Million Billable Tests/year
- Not-for-Profit Health System
- Focus on Patients, Community and Education

Health & Hospitals

- 4 "Core" Laboratories
- 11 Hospital Based Labs
- \$260 Million Annual Operating Budget
- Approx. 1400 FTE's
- 16 Million Billable Tests/year
- Public-Benefit Corporation
- Focus on Patients, Community and Education





Vision

Shared Consolidated Core Laboratory

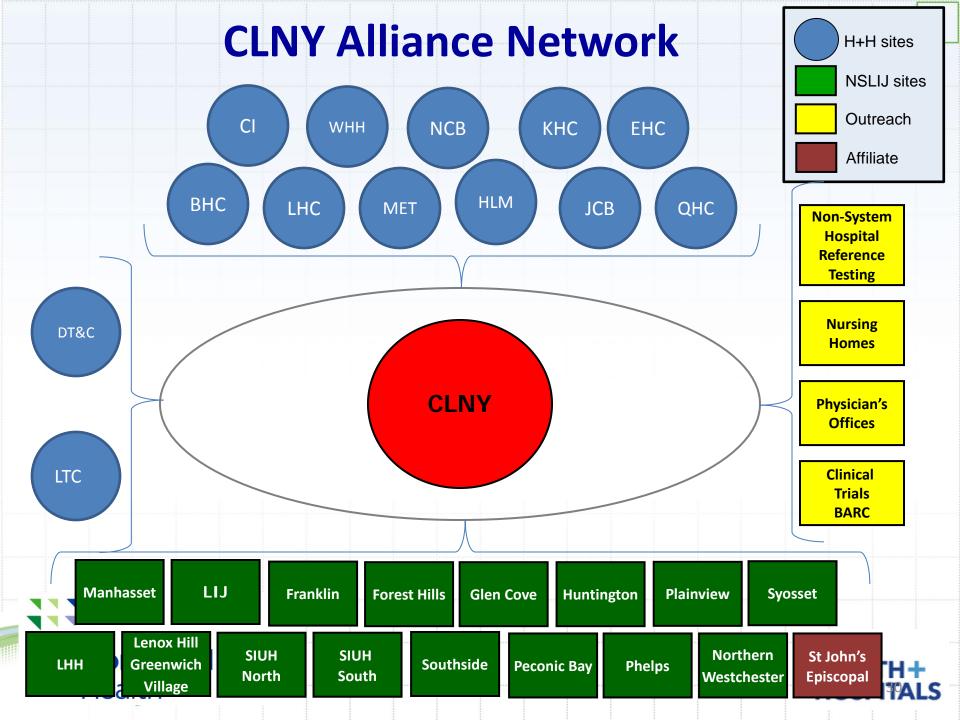
- Standardized Equipment across all Laboratories
- Standardized Information System
- Standardized SOP's through Joint Standards program
- Standardized Quality Program
- Seamless Integration of Laboratory Services

Increased Quality and Depth of Service

Decrease Cost: H+H and NSLIJ are projected to see combined >\$40M savings annually by 2018







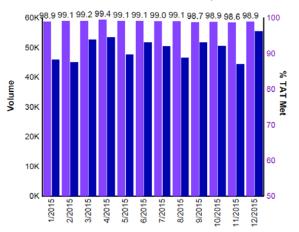




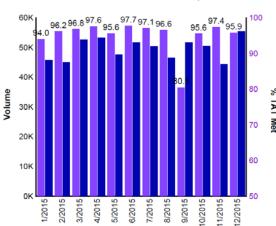
Northwell Health HHC Quality Metrics

January - December 2015

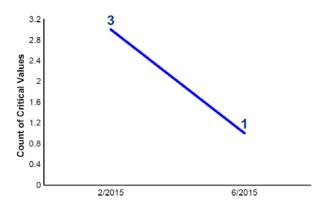
In-house Overall TAT%, 2015



Sendout Overall TAT%, 2015

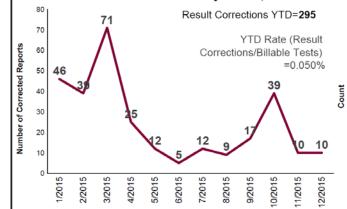


* Critical Values not called within 15 minutes of result by month, 2015

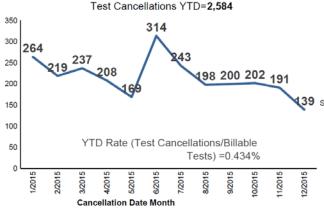


Received (in lab) Time Month

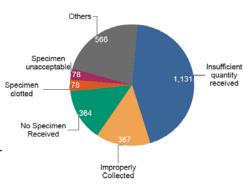
Result Corrections by Month, 2015



Test Cancellations by Month, 2015



Top 5 Reasons for Test Cancellation, 2015



Jan-15 Feb-15 Mar-15 Apr-15 May-15 Jun-15 Jul-15 Aug-15 Sep-15 Oct-15 Nov-15 Dec-15 YTD 51,722 50,487 Billable 45,828 45.004 52,659 53,376 47,649 50,458 46,593 51,708 44,347 55,427 595,258

Notes:

Inhouse % Turnaround Time (TAT) met = Inhouse met / Inhouse total Sendout % Turnaround Time (TAT) met = Sendout met / Sendout total * Critical values show count where TAT: Resulted to Time of 1st Call exceeded 15 min

Tests

Northwell: Enterprise-level Genomics

- Cancer: ~ 16,000 unique cancer patients cared annually*
 - Cancer Genomics: detects "actionable" (diagnostic, prognostic, therapeutic) gene variants that impact patient management
 - Hereditary Cancer Genetics: screening and counseling for patients with a strong personal and family history
 - 5-10% of all cancer is hereditary
 - Approximately 9% of women who present for a mammogram meet criteria for hereditary breast and ovarian genetic testing
- Prenatal Diagnosis: ~40,000 live births annually*
 - Non-invasive perinatal screening (NIPS) → Cell-free DNA
 - Carrier screening
 - Prenatal microarray
- Pediatric & Adult Genetics
 - Cardiomyopathy, epilepsy, mitochondrial disorders, etc.



* 1.1% of 1.7M newly-diagnosed cancer patients/yr 1.0% of 3.96M live births/yr in U.S.

Meeting the Needs of the Competitive Market















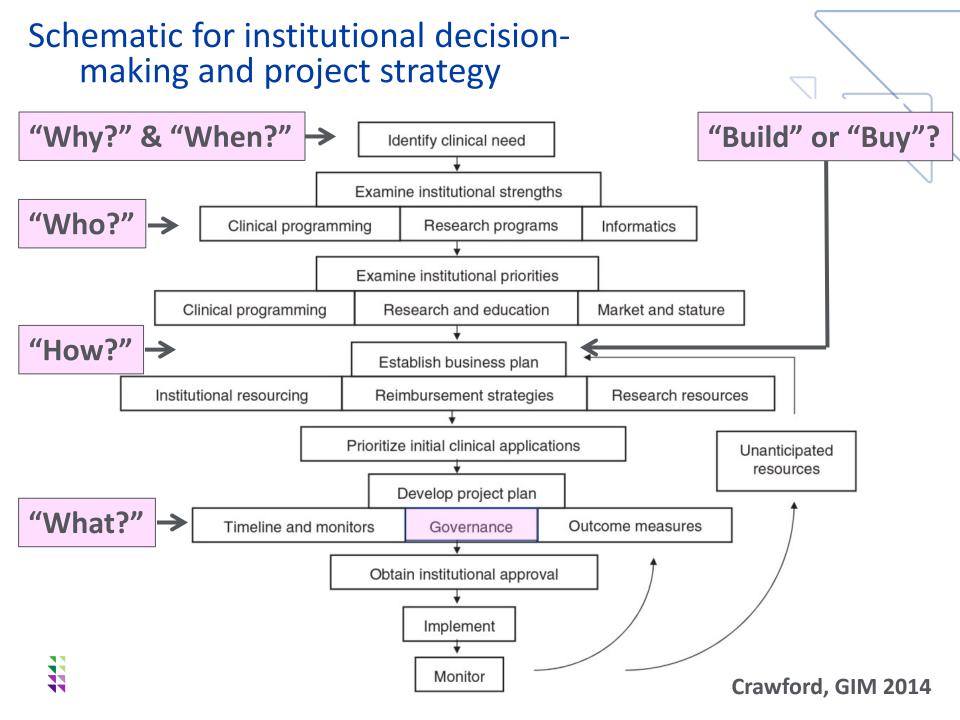
Columbia University
College of Physicians
and Surgeons



Weill Cornell Medical College

Genomics as an essential element of brand identity and market presence





A Joint Venture: Why?

- The strengths of Northwell Health:
 - These are our patients: they and their families live here
 - We have a mature delivery system for total care
 - We have clinical data that no one else has (if we collect it)
- Why partner (as opposed to build)?
 - We don't have the time to do a build
 - Our respective assets are complementary
- Intended outcomes:
 - Immediate alignment of respective expertise of the partners
 - Delivery of cost-effective laboratory testing
 - Creation of disciplined clinical pathways for use of genomic testing
 - Achievement of value: for our patients, in our marketplace



Genomics Partner



- Cancer
- Maternal Fetal
- Pediatric Genetics
- Adult Genetics

Northwell Health Laboratories







Genomics: Essential Questions

- Testing: "The right testing on the right patient, at the right time"
 - Cancer Genomics: ab initio or in extremis?
 - Hereditary Cancer Genetics: oncologists, medical geneticists, PCP?
 - Prenatal Genetic Testing: for at risk or for all pregnancies?
 - Pediatric Genetics: peds geneticists, generalists?

Utility:

- Is clinical care actually informed by Genomic information?
- Do patients do better for having had Genomic testing?

Cost:

thwell Health*

- Is this just a costly lab test?
- Or, is the total cost-of-care lower for having had such testing?
- Are we willing to take the financial risk?
 - → Institutional account; Northwell takes responsibility for testing

Due Diligence: Selecting a Partner

April – Aug 2013: 4 months to schedule a meeting (only time)

2 initial site visits

Sep – Dec 2013: Drafting of Request for Qualifications (RFQ)

Jan – Mar 2014: By invitation: deadline for RFQ applications

Apr – Jun 2014: Internal review of RFQ applications

Jul – Oct 2014: Site visits to five candidate partners

• Nov 2014 – Apr 2015: Development of Letter of Intent

Apr – Dec 2015: Development of Business Agreements

Jan 2016: Launch



Partner Laboratory



Clinical Testing

BioReference

Target Markets:

- Physician Offices
- Health Facilities
- Jails and Prisons
- FQHCs
- **Key Services:**

key Services:

- Automated, High Volume, Routine Testing
- HIV, HepC and Other Molecular Tests
- GCI Informatics
- Heart Health
- Regulatory Reporting

Oncology



Target Markets:

- Hematologists
- Oncologists
- Hospital Pathologists
- Academic Medical Institutions

Key Services:

- OnkoSight Targeted NGS
- Hematologic and solid tumors
- Array CGH for lymphoid disorders
- Complete Special Coagulation laboratory
- Clinical trial studies
- New assay developments in areas such as Thyroid

Women's Health



Target Markets:

- Obstetricians
- Gynecologists

Key Services:

- Image Directed Paps
- HPV Genotyping
- GenPap STI Testing
- Non-Invasive PreNatal
- Reproductive Genetics NGS Carrier Testing (Inherigen)
- Prenatal Cytogenetics
- Special Coagulation Studies

Inherited Disorders



Target Markets:

- Geneticists
- Medical Centers
- Children's Hospitals
- Clinicians with Specialties Affected by Genetics

Key Services:

- DNA Sequencing
- aCGH Array Testing
- NextGen Sequencing
- Whole Exome Sequencing



BioReference Genomic Capabilities

Oncology (NGS)

- Actionable panels for myeloid disorders (37 genes) and solid tumors (31 genes), site-specific panels for MDS, AML, MPNs, lung, colon, melanoma
- Inclusive of: FLT3, NPM1, BRAF, KIT, EGFR, KRAS, NRAS, PDGRA

Oncology (Mutation Analysis)

JAK2, MPL515, NPM1, BRAF, ALK, ROS

Hereditary Cancer (Genetic Screening)

- BRCA Testing: BRCA1/BRCA2/Ashkenazi;
- Site-Specific: HBOC, CRC, Endometrial, Melanoma, Pancreatic, Renal
- Management Panels (only genes associated with management guidelines)
- Comprehensive Cancer Panel (32 genes)

Pharmacogenomics (Mutation Analysis)

• UGT1A1, CEBPA, Warfarin, P450 2C19 (Plavix), DPD (5-FU)

Prenatal (NIPT, Array, Carrier)

 44 tests: NIPT, Comprehensive Carrier Screen Panels, AJ-focused panels, individual carrier screens

Pediatric and Adult Genetics

 122 tests for Rare Constitutional Disorders: Cardiomyopathy, Epilepsy, Mitochondrial Disorders, etc.



BioReference Laboratory Locations

- Elmwood Park, NJ: Oncology & Women's Health NGS
 - >10 years genomic testing
 - Genomics lead by Dr. Robert Daber, Ph.D.
 - Thought leader in cancer genomics,
 - Previously served as the Technical Director of Clinical Genomics at UPenn, where he pioneered the implementation of NGS in oncology by building one of the earliest CAP/CLIA NGS diagnostic labs in the U.S.
- Gaithersburg, MD: GeneDx (NGS for Rare Disorders, Cancer)
 - Industry leaders for inherited disorders
 - Founded by Sheri Bale, Ph.D.
 - Authored ACMG guidelines on interpreting sequence variants and clinical laboratory standards for next-generation sequencing



Joint Venture Structure

- Strategic Alliance: The master agreement
- Laboratory Service Agreement (LSA): Laboratory Testing
 - Genetic Counseling: Test selection; Test interpretation
 - Basic Genomics: standard reporting
 - Enhanced Genomics: Northwell signs out the reports
 - Genomic Tumor Boards, strategic teaching
- Limited Liability Corporation (LLC): The Joint Venture
 - Generation of Knowledge: Collect our Data
 - Goal: "Developments"
- Fair Market Value
 - On-site Genetic Counselors (as arranged)*



Joint Venture Fundamental Principles

- [Patient Data]: Patient information on the Requisition
- [Test Results]: either through Basic or Enhanced Genomics
- [Clinical Data]: The "clinical metadata" (pre- & post-test)
- Intellectual Property
 - De-identified data: [Patient Data] and [Test Results]
 - Northwell-centric Knowledge Base:[Patient Data] + [Test Results] + [Clinical Data]
 - Potential Developments:
 - Software Analytics
 - Databases
 - Actual Knowledge



Protections

Northwell-centric Knowledge Database

- Northwell Data: Is "ours" to use for any unrelated purposes
 - Note: [Patient Data] and [Test Results] enter into BRLI deidentified database, in keeping with industry standards

NHGA* Tests

OPKO/BioReference Genomics Database



Protections

Northwell-centric Knowledge Database

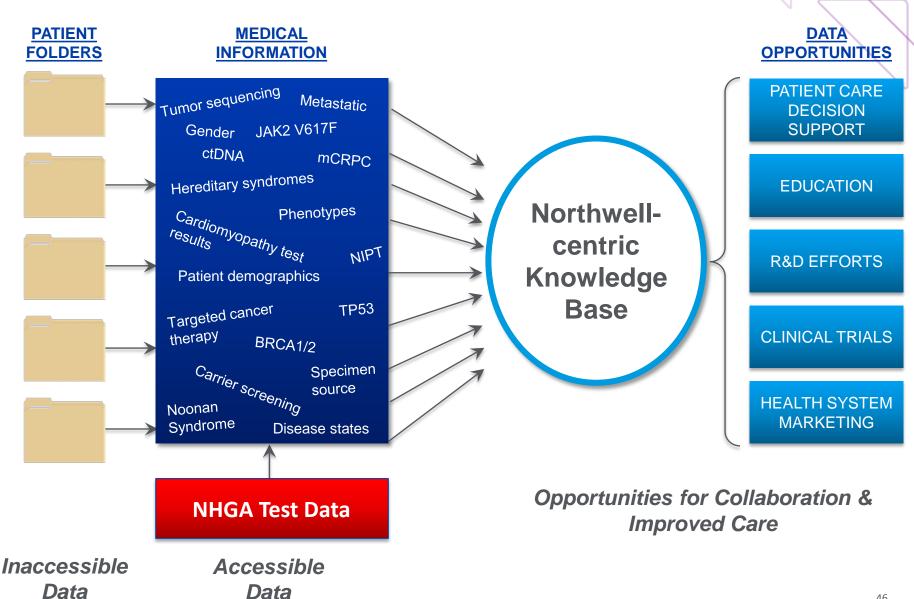
- Northwell Data: Is "ours" to use for any unrelated purposes
 - Note: [Patient Data] and [Test Results] enter into BRLI deidentified database, in keeping with industry standards
- [LLC Developments]: Licensed from LLC if "mature"
- Exclusivity
 - Excluded: named Northwell affiliations
 - Geography: designated exclusivity for "Strategic Alliances"
 - Allows for alliance partners from non-competing geographic regions

NHGA* Tests

OPKO/BioReference Genomics Database



Joint Venture Knowledgebase



Current Status (1st Quarter 2016)

ITEMS COMPLETED

- ✓ Governance of "Northwell Health Genomic Alliance"
- ✓ "Master" IT interface built with BRLI
- √ 1st group constitutional tests built and activated (02/18)
- ✓ Testing for Cancer
 Genetics Risk begun
- ✓ Testing for Carrier Screening begun

ITEMS IN PROGRESS

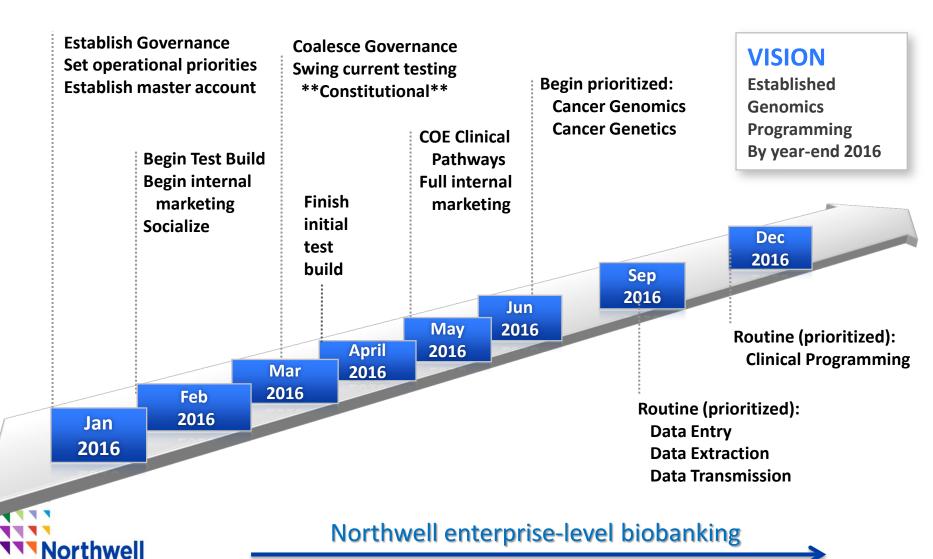
- Prioritized extended test build: constitutional, somatic
- "Cancer Genomics Governance Group"
- "Cancer Genomics Research Committee"
- IRB application for databasing under LLC
- Due diligence on Patient Consents (for research)
- [Cancer Genetics Counselor] practice activation
- Marketing "sweep" of ambulatory OB, Oncology practices
- Due diligence on hospital-based ordering (LHH, SIUH....)
- Swinging Anatomic Pathology test ordering to BRLI
- Establishing "Benefits Investigation" for revenue cycle

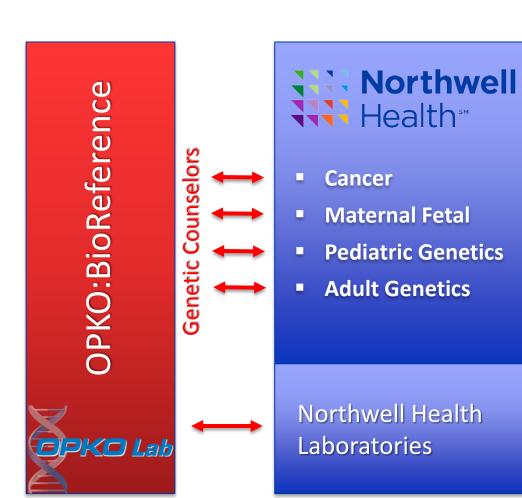


NHGA: Target Deliverables 2016

Health™











Are the Northwell Labs delivering "Value"?

•	Support health system Financial Outcomes	V
•	Improve Health System Revenue	V
•	Provide lower cost services	V
•	Support Value-based Payment	V
•	Support Risk-based Payment	V
•	Improve Patient Access	V
•	Improve Patient and Provider Experience	V
•	Actually improve Patient Outcomes?	V
•	Help drive health system Strategies	V

This is an infinite space.

There is plenty of room for humility.

Do not take your status for granted for a minute.



jcrawford1@northwell.edu



