

Doing the Math for Genetic Counseling and Clinical Trials

*Please stand by. The webinar will
begin shortly.*

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Kelly Hall

Kelly Hall is the VP of Program Development at InformedDNA, the nation's largest independent provider network of genetics specialists. She leads the efforts with Oncology Programs to implement a turnkey solution for providing risk assessment and genetics counseling in a cost effective and compliant manner as well as Hospital Laboratories to develop a utilization management program to reduce send out costs. Prior to joining InformedDNA, Kelly was a member of the Senior leadership team at several Cancer Centers and Oncology Programs around the country including 14 years at Moffitt Cancer Center in Tampa, FL. She was a member of the NCCN Best Practices Committee working with Cancer Centers to develop benchmarks and share data in oncology operations. Kelly received her MBA from the prestigious George Washington University and has extensive experience in strategic planning, financial analysis and program implementation focused in the Oncology setting.

Brian Sevier, PhD

Brian Sevier, PhD, Associate Director, UFHealth Cancer Center – Clinical Trials Office, leads a multidisciplinary team of administrators, research coordinators, and data managers across a broad geography, in addition to managing a team of regulatory staff and contract administrators, IT staff, and other support team members. He has served as a research administrator at UF for over 15 years, including university-wide and college level leadership in contracts & grants administration. He has held leadership and committee membership at the National Council of University Research Administrators (NCURA) as an active member since 2005. He has managed complex grants and research agreements at the department, center, college and university level. As the Associate Director, he oversees the business operations of the CTO, assists in authoring and contributing to center and core grant proposals, and serves on multiple UF committees dedicated to clinical research administration and compliance. He also serves as the Clinical Research liaison to the ACOS Committee on Cancer at UFHealth and UFHealth Cancer Center at Orlando Health. He has managed the UFHealth Cancer Center CTO since late 2012..



Board-certified Genetic Counseling for Your Patients



- Review external pressures around the offering of genetic counseling to oncology patients
- Compare 3 models for providing genetic counseling
 - Employment
 - Referral to local GC
 - Outsource to InformedDNA

National Guidelines Recommend Genetic Counseling

Recommendation: Women whose family history is associated with an increased risk of BRCA1 or BRCA2 gene mutations **be referred for genetic counseling** and evaluation for BRCA testing.



The U.S. Preventive Services Task Force

Individuals with Cigna-administered coverage will be **required to receive pre-testing genetic counseling** from an independent board-certified genetic counselor or clinical geneticist for three hereditary conditions – breast and ovarian cancer (BRCA), colorectal cancer syndromes, and Long QT syndrome. This will provide these individuals with the opportunity to become fully informed about these complex genetic tests.



CIGNA Genetic Counseling Requirement

STANDARD 2.3 Risk Assessment and Genetic Counseling

**Cancer risk assessment, genetic counseling,
and testing services are provided to
patients either on-site or by referral,
by a qualified genetics professional.**



- Implement Risk Assessment at New Patient Intake (All New Analytic Cases)
- Refer for Genetic Counseling when indicated
- Evaluate and track numbers and address barriers if they exist
- Refer for Genetic Testing when indicated
- Report to Cancer Committee on volumes – risk assessment, counseling, testing

Standard 2.16 Cancer risk assessment, genetic counseling and genetic testing services are provided or referred

“Cancer risk assessment and genetic counseling is performed by a cancer genetics professional who has extensive experience and educational background ... Educational seminars offered by commercial laboratories about how to perform genetic testing are not considered adequate training for cancer risk assessment and genetic counseling.”

“Cancer risk assessment and genetic counseling involve pre- and post-test counseling.”

Family History of Breast Cancer: Required Preventive Services

Covered Preventive Services for Women:

- BRCA counseling about genetic testing for women at higher risk
- Breast cancer chemoprevention counseling for women at higher risk



Understanding the Affordable Care Act:
About the Law

Preventive Services Covered under the Affordable Care Act

If you have a new health insurance plan or insurance policy beginning on or after September 23, 2010, the following preventive services must be covered without your having to pay a copayment or co-insurance or meet your deductible. This applies only when these services are delivered by a network provider.

- Reveals rampant inappropriate ordering of genetic tests
 - ❖ Vast majority of physicians believe genetics is important to clinical practice, <25% feel comfortable discussing genetic test results with patients
 - ❖ Extraordinarily high rate of incorrect test ordering among non-genetics professionals at Cleveland Clinic
 - ❖ New system-wide policy dictates that all genetic tests must be ordered in concert with a genetics expert

Ray, Turna. "Cleveland Clinic Explores Issues Associated with Integrating Genomics into Healthcare." *GenomeWeb*. N.p., 30 Mar. 2011. Web. 28 May 2014.

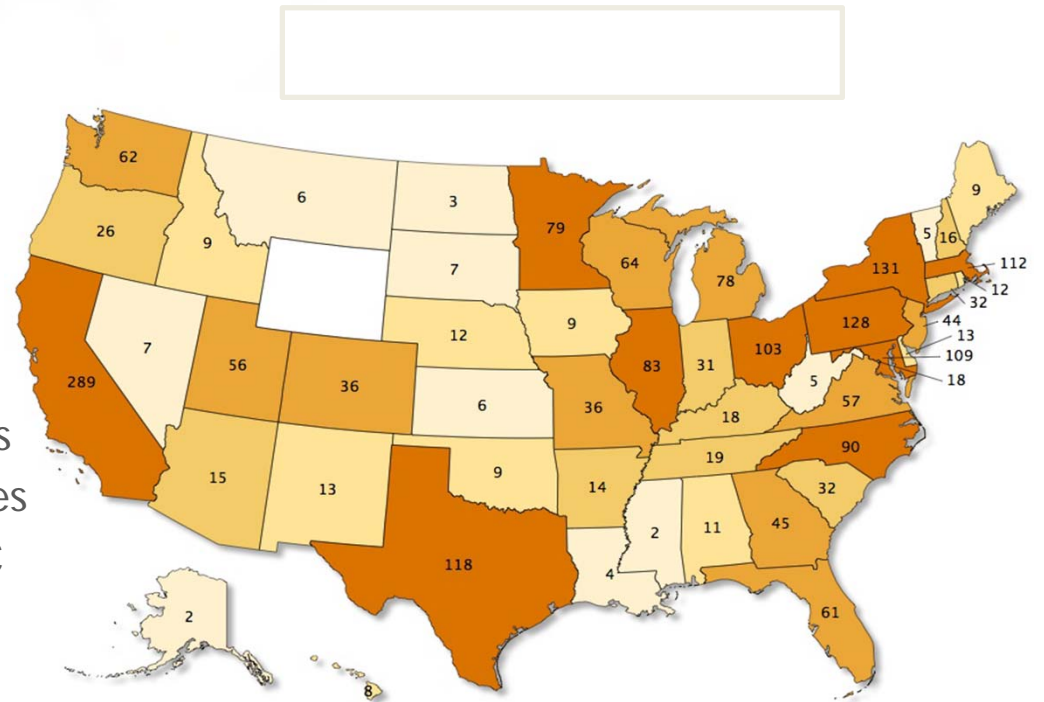
- More than 50 cases, most involving physicians
- Growth trend in lawsuits
- Failing to:
 - take an adequate family history
 - recommend the appropriate testing
 - refer to a genetic counselor or geneticist
 - interpret the test results correctly
 - interpret the test results in a timely manner
 - recommend the appropriate risk mitigation strategies
 - discuss at-risk family members based on test results



Lindor RA, Marchant GE
ASCO 2012

Current GC Landscape

- Fewer than 3,000 practicing GCs in U.S.
- Only 29% specialize in cancer
 - ❖ Majority work in academic centers
 - ❖ Most CGCs located near large cities
 - ❖ Most patients wait weeks for a GC appointment



Many oncologists have insufficient access to cancer GC

3 Models for consideration

- Employment
- Refer to another provider
- Outsource to InformedDNA

- Volumes

- The mean capacity of a Genetic Counselor is 300 cases per year *
- Estimate your volumes for diagnosed patients :
 - (a) Annual Breast cases x 14%
 - (b) Annual Ovarian cases x 100%
 - $((a)+(b))/.8$ = Estimated total annual genetic counseling volumes
- Consider number of cases who would/should be considered expedited cases (surgical or treatment decision is pending)

* NCCN Survey of Genetic counselor productivity

- Finances

- Cost to recruit and retain an FTE
 - How many do you need?
 - Ave Salary is \$74,000*
- Wait times for an appointment
 - Delays in getting to surgery
 - Right care doesn't happen at the right time
- Lost margin if you risk losing a case to competition
 - Ave Net Revenue \$1,100 to \$3,100 per case **

* NSGC 2014 Survey ** Oncology Management Consulting Group

- **Finances**

- Program Fees

- Costs for managing scheduling, billing etc...
 - Costs for Annual Program at InformedDNA

- Billing opportunities

- Very few programs bill for genetic counseling
 - Hospitals on UB92
 - With MD supervision on HCFA

- Downstream Revenue

- Breast MRI (approximately 40% meet criteria)
 - Family members

300 Cases	Employment	Outsource
Start Up	\$ 10,000	\$ 4,500
Salary and Benefits	\$ 100,458	\$ -
Program Fee	\$ -	\$ 17,000
Clinical Services		\$ 87,900
Total Cost	\$ 110,458	\$ 109,400

Cost Comparison

150 Cases	Employment	Outsource
Start Up	\$ 10,000	\$ 4,500
Salary and Benefits	\$ 100,458	\$ -
Program Fee	\$ -	\$ 9,500
Clinical Services		\$ 43,950
Total Cost	\$ 110,458	\$ 57,950

- Employment of FTE
 - Face to Face option
 - Costly to maintain and impacted by turnover
- Refer out
 - No direct costs
 - Seen as not full service provider
 - Risk of losing patients
- Outsource to InformedDNA
 - Full service, turnkey solution
 - Cost similar to employment/scalable



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Doing the Math for Clinical Trials

Is there any room for margin?

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ACoS COC

- What can be counted:
 - Treatment-related clinical trials
 - Cancer prevention and cancer control
 - Prevention
 - Early detection
 - QOL / Supportive Care trials
 - Economics of Care
 - Biorepositories
 - Patient Registries

SPECIFICATIONS BY CATEGORY

Programs meet the clinical trial accrual percentage that is specified for their accreditation category.

MINIMUM REQUIRED AND COMMENDATION CLINICAL TRIAL ACCRUAL PERCENTAGES FOR EACH CATEGORY		
Category	Minimum Required Percentage* Accrual to Clinical Trials	Commendation Percentage* Accrual to Clinical Trials
Integrated Network Cancer Program	6	8
NCI-designated Comprehensive Cancer Center Program	20	30
Academic Comprehensive Cancer Program	6	8
Veterans Affairs Cancer Program	2	4
Comprehensive Community Cancer Program	4	6
Community Cancer Program	2	4
	Note: Until 2015, programs seeking initial accreditation in this category are exempt from the accrual percentage at the first survey.	
Hospital Associate Cancer Program	Exempt	2
Pediatric Cancer Program	30	40
Freestanding Cancer Program	2	4

*Of the number of annual analytic cases.

<https://www.facs.org/quality-programs/cancer/coc/standards>

Agenda

- Measuring Profit
- Calculating Expenses
- Revenue Sources
- Balancing profit vs. “feel good”
 - Pharma vs. Cooperative Group
- “must haves”
- Other Considerations

Measuring Profit

- Simply stated

Revenues – Expenses = Net Income

Measuring Profit

- Calculating total revenues
 - What is funded by the study/sponsor
 - What is funded by the subject/insurance
- Calculating total expenses
 - What costs are associated directly to the operation of the study
 - What costs are associated directly with the operation of the clinical trials program/office (CTO)

Calculating Expenses

- Operational expenses – the cost of doing business
 - Space
 - Computers
 - Paper
 - Printing
 - Office supplies
 - Salaries not allocable to a study
 - Freezers
 - Centrifuges
 - Dry ice*
 - Collection tubes*
 - Shipping materials*

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* - could be study related

Calculating Expenses

- Study-related expenses
 - Salaries that are allocable to a protocol
 - Study coordinator time
 - Data manager time
 - PI/provider time
 - Costs for non-routine services
 - Yes routine services can still be billed out

Calculating Expenses

- As a hospital/practice - what will you charge your own clinical trials program??
 - Cost of time and materials?
 - When the CTO needs a non-routine CBC, will you charge them for the blood-draw, and the tube(s), and the lab services?
 - Our hospital charges a “research” rate to the academic operation for the conduct of clinical trials

Revenue Sources

- Study funded revenues
 - Administrative start-up
 - Regulatory services (pass through)
 - Per subject revenues (from the sponsor)
 - Services that are not routine or standard of care
 - Visits that are not routine or standard of care

Revenue Sources

- Start-up
 - Determination of scientific feasibility
 - PI administration fee
 - Administrative/Financial processing fee
 - Investigational Pharmacy startup

Revenue Sources

- Regulatory
 - IRB coordinator salary support
 - Pass through for using IRB Services
 - negotiate that the sponsor must pay your IRB expenses and add a 5-10% administrative fee for processing and reconciling payments
 - OSR/IND Reports
 - SAE's
 - ICF or IB revisions

Revenue Sources

- Patient funded revenues
 - Rarely in oncology will you find a study where all services are study funded
 - Medicare Coverage Analysis
 - Routine Services (i.e. standard of care) – billable
 - If its not a routine service, the sponsor should pay for it!

Balancing Profit vs “feel good”

- Industry sponsored vs. NCI Cooperative Group studies
 - Industry provides the greatest opportunity to make a margin – find the compromise between speed/efficiency and leaving something on the negotiating table.
 - Cooperative Groups are underfunded, BUT almost all services are considered routine. There is no negotiation process, there is a flat funding rate per subject enrolled.

Pharma/Industry Studies

- Charge start-ups
- Track every activity, and be sure you are compensated for them – don't subsidize big pharma
- Find your comfort zone on margin/mark-up
 - How much are you paying for your services (Medicare rate), so what will you charge your sponsors?

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Cooperative Group Studies

- Funding Fact Sheets (non-negotiable)
- There are no start-ups
- There are only per subject enrollment payments (highly delayed)
- Large proportion of study time points are for routine services, so you can still recover the costs!
- We try to negotiate best/subsidized rates for hospital-provided services
 - i.e. Investigational Pharmacy admin and dispensing fees

“must haves”

- PI Champion!!!!
- Billing system controls (routine vs non)
 - Isolate research bills before you bill insurance or the patient
- Tumor registry
- Regulatory oversight – institutional IRB and central IRB’s
 - You are missing out if you don’t take advantage of external IRB’s
- All services must be committed to research...not just the Oncology service line
 - Cardiology, Pathology, Radiology, Pharmacy, NURSING

Other Considerations

- Study selection process – don't open everything!
- Inclusion/Exclusion criteria – do you really have those patients?
- Data mining tools in the EMR – don't query the patients....but query the diagnoses and treatment data!
- Buy a CTMS – or have one heck of a savvy system to track every subject, every visit, and every invoiceable item

Questions

- Any questions not addressed here may be emailed to solutions@oncologymgmt.com
- OMC Group will compile questions and answers and distribute to webinar registrants

Thank You!

Sincere thanks to all of you for joining us today. We hope that you will keep OMC Group in mind when consulting needs arise in the future.

**Financial and
Market Analysis**

**New Center
Development**

**Hospital/
Physician
Integration**

**Strategic
Planning**

**Implementation
and Interim
Leadership**

**Performance and
Financial
Benchmarking**

**Operational
Assessments**

**Revenue Cycle
Reviews**

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