Hot Topics

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Learning Objectives

- Learn about new services and processes for conducting clinical research at USF
- Reinforce select prior trainings and revisit lessons learned in the interim
- Discuss current hot topics at USF with particular focus on accrual

Training is Now Entered in GEMS

- The USF OCR is pleased to announce that documentation of training for attendance at the CRC meetings since July 2011 are now being entered into GEMS
- Note: Your supervisor cannot view your training in GEMS. Be sure to provide a copy of your trainings to your supervisor prior to your performance evaluation!

OCR Recruiting July 2012

- A Clinical Research Coordinator position in the OCR will be posted on the USF HR website July 2012
- Please tell your colleagues who may be interested in joining the OCR team
- Position works as a centralized resource on a fee for service basis

Pick Up/Drop Off Boxes at STC

- For document delivery to and from USF Health OCR
- 6th Floor STC
  - North side of STC (TGH side)
  - Cubicle shared with USF IRB
  - Drop boxes and signage easily visible when exiting elevators
  - Boxes located on top of beige file cabinets
- Documents will be picked up/dropped off by OCR staff throughout the week and on request by phone (4-3336) or email (OCR@health.usf.edu)

OCR Pick Up/Drop Off Boxes at STC

Quest Charge Master

- USF Purchasing has signed a Master Research Testing Agreement with Quest including receipt of a Charge Master
- Pricing can be obtained from your PL when budgeting a study
- An "Amendment of Agreement" form will be completed for each study
- Amendment forms are obtained from Joyce A. Harshbarger at Quest joyce.a.harshbarger@questdiagnostics.com
- Amendment forms are forwarded for execution to Lazara Stinnette at USF Purchasing lstinnette@usf.edu

FDA Audit?

- Immediately notify the USF IRB and the OCR of
  - Any audit or site visit by the FDA
  - Any correspondence received from or sent to the FDA
  - Any sanctions or actions taken against the Investigator, the Sponsor, or the research
- This includes research which has been reviewed and approved by an IRB other than the USF IRB
- Best practice: Notify for all audits, not just FDA

Internal Form Tips

- When should the IF be completed?
  - Study is approved by IRB *and*
  - Contract is fully executed
- What must be attached?
  - Final Budget and Contract
  - Financial Management Plan from eCOI module if there is a financial COI with the research
  - ROAD if there is outside activity that is or could be perceived as conflicting with the research
  - Nepotism Memo if there are any relatives or related persons participating in the research

Internal Form Tips, cont.

- Project Type = Pharmaceutical Contract
- Funding Source = For-Profit Corporation (sometimes Nonprofit Org)
- Indirect Cost Rate = 30%
  - Use the rate that was negotiated in your budget
  - Get the budget numbers from your PL
  - Full Federal Indirect Cost = No
    - Reason = Industry sponsored clinical research study

ClinCard: Lessons Learned

- Travel Module has been deactivated
- Two methods available for travel reimbursement
  - Fixed price travel reimbursement
  - Tiered model approach
- Both methods are entered via manual payment method
- Sites must request User IDs through OCR, not directly from GreenPhire

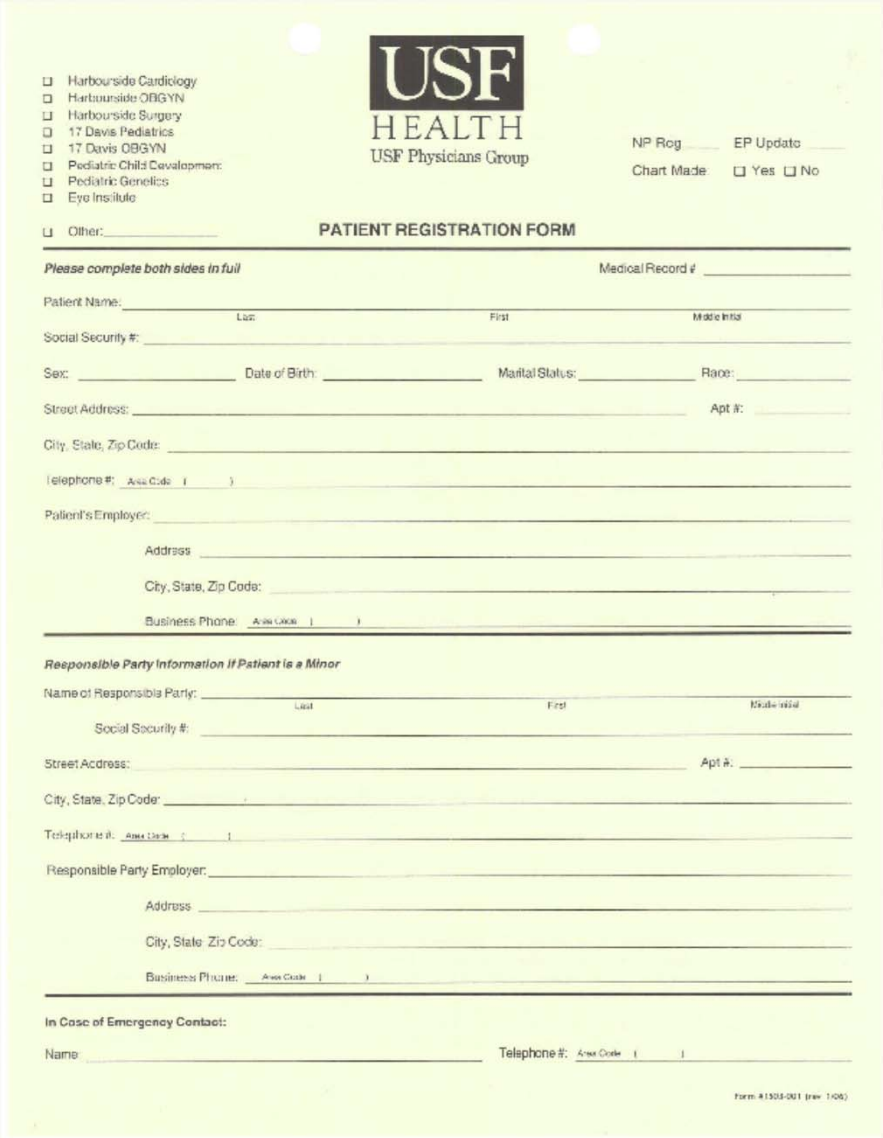
ClinCard: Important Reminders

- Study participant must be in receipt of their ClinCard or present in clinic prior to funds being loaded
  - See CCHIP #017 revised June 1, 2012
  - Gift cards cannot be mailed
- If there is a change in payment schedule or in $ amount per visit, site must notify OCR so study can be modified in system prior to participant's visit.
  - Include a copy of the revised Consent Form
- OCR compares participant payments to the budget and the IC, especially for manual payments

Patient Registration Form

- Completed for all study participants who do not already have a USFPG medical record number
- Must be completed prior to the participant being seen in the clinic
- Completed form is submitted to
  - Ellen Pastizzo epastizz@health.usf.edu
  - cc Billie Lee blee@health.usf.edu

Patient Registration Form



- ☐ Harbourside Cardiology
- ☐ Harbourside OBGYN
- ☐ Harbourside Surgery
- ☐ 17 Davis Pediatrics
- ☐ 17 Davis OBGYN
- ☐ Pediatric Child Development
- ☐ Pediatric Genetics
- ☐ Eye Institute
- ☐ Other:

USF HEALTH
USF Physicians Group

NP Reg ____ EP Update ____
Chart Made ☐ Yes ☐ No

PATIENT REGISTRATION FORM

Please complete both sides in full

Medical Record # _____

Patient Name: _____ (Last / First / Middle Initial)

Social Security #: _____

Sex: _____ Date of Birth: _____ Marital Status: _____ Race: _____

Street Address: _____ Apt #: _____

City, State, Zip Code: _____

Telephone #: Area Code ( ) _____

Patient's Employer: _____

Address _____

City, State, Zip Code: _____

Business Phone: Area Code ( ) _____

Responsible Party Information if Patient is a Minor

Name of Responsible Party: _____ (Last / First / Middle Initial)

Social Security #: _____

Street Address: _____ Apt #: _____

City, State, Zip Code: _____

Telephone #: Area Code ( ) _____

Responsible Party Employer: _____

Address _____

City, State Zip Code: _____

Business Phone: Area Code ( ) _____

In Case of Emergency Contact:

Name _____ Telephone #: Area Code ( ) _____

Form A1503-001 (rev 1-06)

Issues with Contract and IC Language

- Subject injury language in the contract and the informed consent must be congruent
- OCR verifies language in both documents is consistent
- Some sponsors are insisting that
  - They are not responsible for the payment of subject's medical bills in the event of injury if the subject is not compliant
  - Third parties (insurance) must be billed first before the sponsor is accountable to reimburse for costs related to AEs
- OCR, General Counsel and DSR are working to establish USF's policy/position on payments for research related injury
- Priority – hold the study participant harmless (principal of Justice)
  - Some discussion R/T "reckless or intentional" non-compliance

CTSI Division of Health Informatics & Decision Making

- Will provide information on patient populations that are eligible for a study protocol
- Provide USF and National statistics of incidence and prevalence
- Data is used to complete site selection questionnaire from sponsor/CRO
- Provides more realistic enrollment projections based on EMR data
- Contact: Athanasios Tsalatsanis at atsalats@health.usf.edu

Science and Business of Clinical Trials

- = ENROLLMENT (eligible) PATIENTS
- Without (adequate) patient accrual
  - A scientific/clinical question of interest cannot be answered
  - No revenue to support clinical research
- Everyone loses
  - Sponsor, PI, USF, patients, public

New Process in July: Accrual Tracking & Monitoring

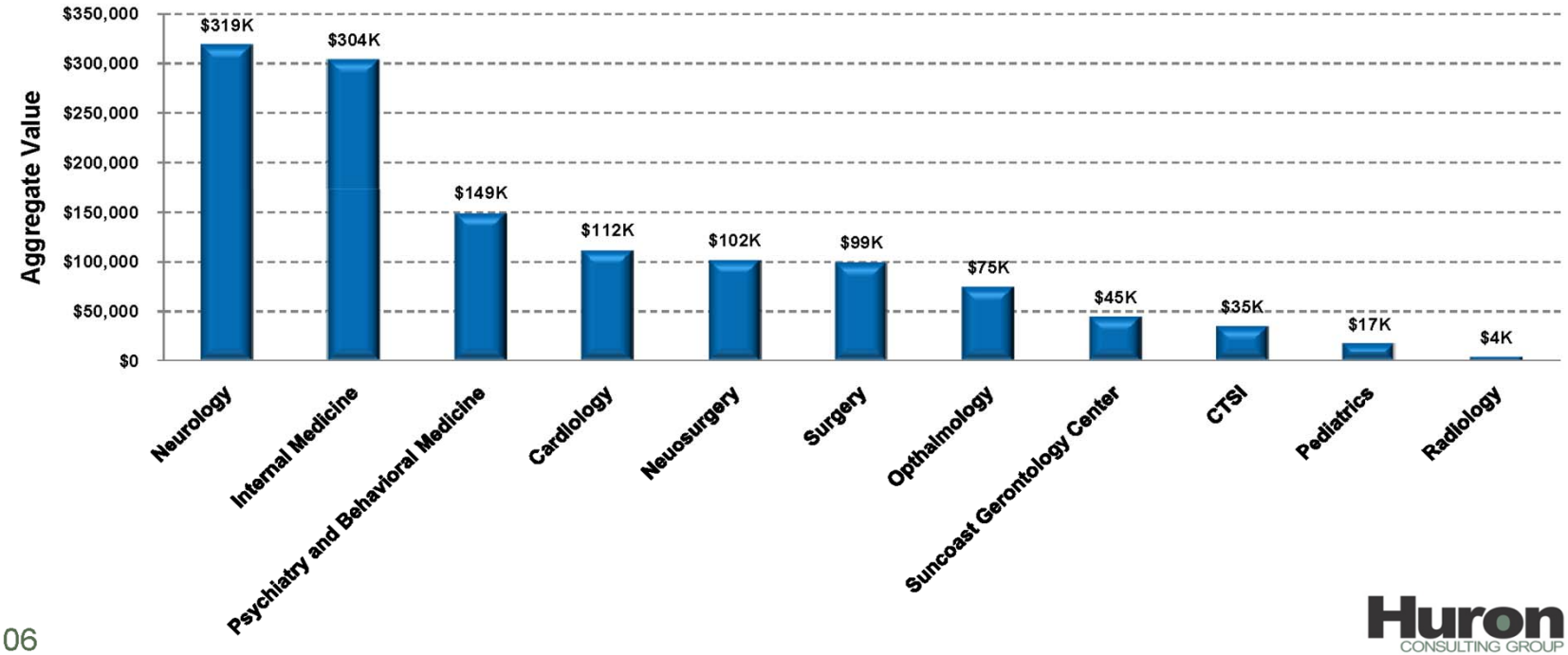
- Identification of enrollment start dates
  - Contract executed
  - IRB approval achieved
  - Sponsor approval
  - If TGH, receipt of TGH approval letter
- Will be looking at studies that are open but have no accrual
  - Is the study really viable? Does it need to be closed?
  - How to avoid futile studies?
- How to increase enrollment for all studies?

Closed Clinical Trial Data

Impact of One Additional Patient

- USF would earn $1.26 million if one additional patient was enrolled on each study closed during FY2009.
  - Indirect (at 27%): $340,000
  - Direct: $920,000

Revenue Potential by Department From One Additional Patient Per Study



Huron CONSULTING GROUP

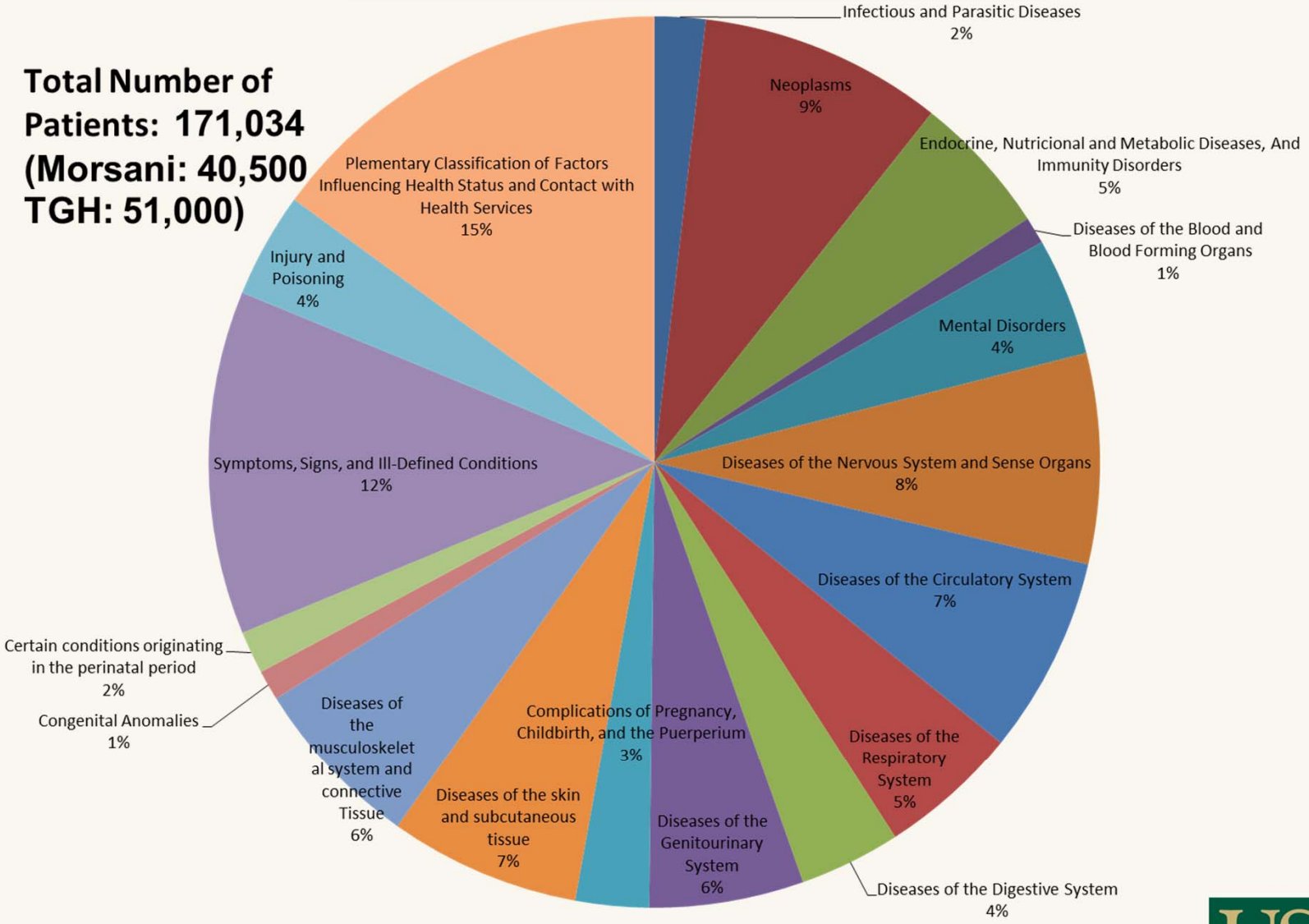
Summary of Accrual Data – USF Studies March 2011 through January 2012

Name	# of Projects	# of Screen Fails	# of Participants Enrolled	Total Visits
Cardiology	1	0	0	0
CTSI	4	5	3	21
Internal Medicine	22	13	66	169
Neurology	18	15	34	185
Ophthalmology	2	0	0	0
Otolaryngology	1	9	33	47
Pediatrics	7	0	164*	183
Psychiatry	7	3	12	56
Suncoast Gerontology	3	0	6	31
Surgery	7	3	26	28
Total	72	48	344	720

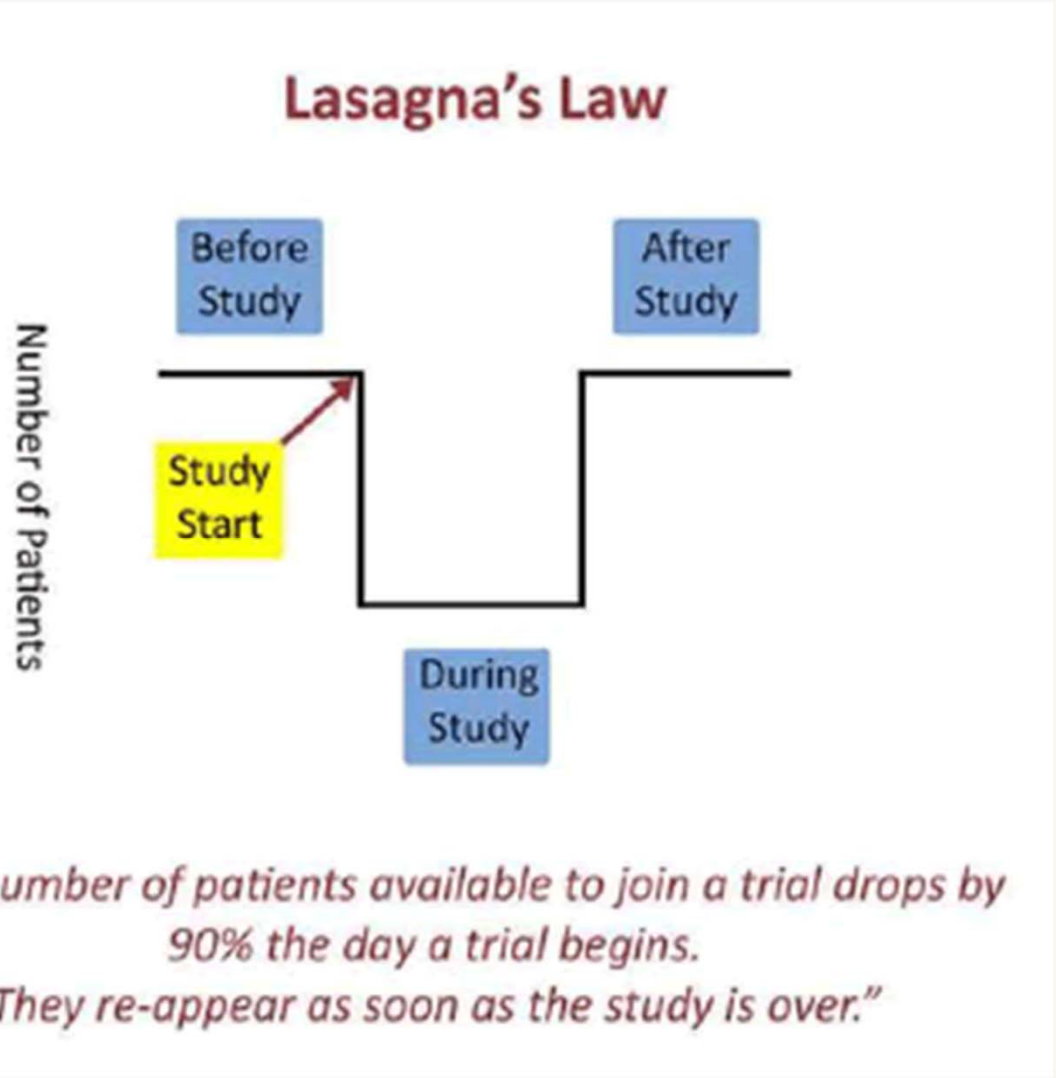
* Both trials and registry data included

Number of patients seen by USF physicians in 2011

Total Number of Patients: 171,034 (Morsani: 40,500 TGH: 51,000)



Where are the patients?
Lasagna Law of Recruitments in Clinical Trials



Accrual Problems: Contracting Failures

- As of January 31, 2012, 72 open studies/29 with no enrollment (40%)
- 20 (1 in 5) contracts inactivated/terminated before execution
- Significant staff time (OCR and department) spent on these studies
- These studies slow down the process for successful studies
- Before moving forward, PIs should assess his/her study population and the importance of the study question & availability of other resources for successful recruitment
- Obtaining information on patient populations that are eligible for the study protocol
  - Health Informatics

#1 Reason For Poor Accrual : Patient's Perspective

- Awareness of trials
- Opportunity to participate
- Acceptance of trial participation

➢ Opportunity to participate = most common group of barriers

Ford JG, et al. Knowledge and access to information on recruitment of underrepresented populations to cancer clinical trials. Evidence Report / Technology Assessment No. 122. AHRQ Publication No. 05-E019-2. Rockville, MD. Agency for Healthcare Research and Quality. June 2005.

Improving Accrual

- New PI Target – 10 / Current – 15
- Patient Recruitment
  - Clinical studies recruitment materials placed at STC, Morsani, CMS and Byrd
- Continuation of Florida Clinical Trials project
  - Matching patients to trials
- Recent demo of The Patient Recruiting Agency™ (TPRA)

Questions, Concerns, Comments?