Approaches to Implementation: EAPathways, Genomics, TAPUR and the Levine Cancer Institute Experience

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CHANGING THE COURSE OF CANCER CARE

Levine Cancer Institute

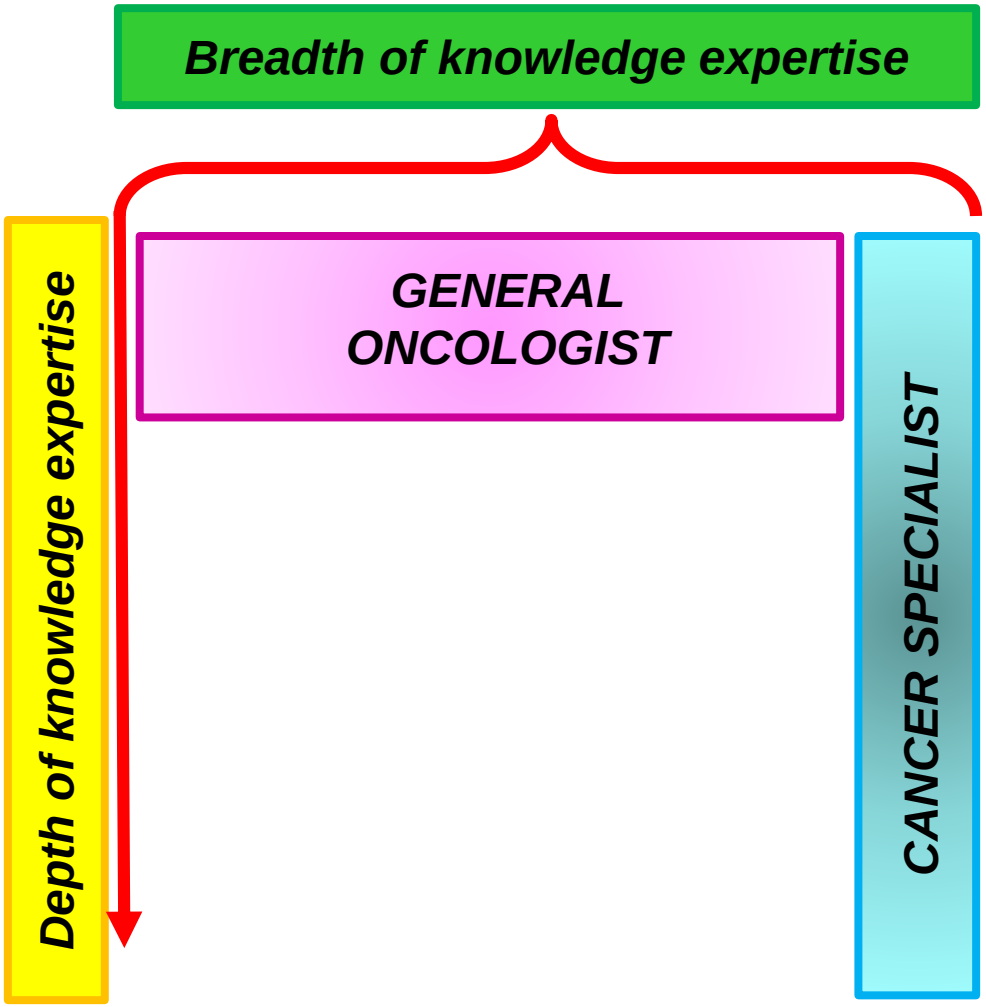
Challenges for Providers in Delivering Patient Care

- ❑ Cancer is a complex disease
- ❑ Advancing technology
  - Molecular testing
  - New drugs and indications
- ❑ Research trial opportunities/discussion
  - How can we keep track of everything?
- ❑ Documentation
  - Encounter, Billing

Challenges in Community-Based Practice

- ❑ >80% patients are seen and treated in Community-based clinics
- ❑ Most are generalists
  - All solid tumors and hematology
- ❑ Busy clinics
  - Majority of patients are seen and treated close to home
- ❑ More pressures
  - Documentation, Billing, Prior authorizations
- ❑ Resource Challenged

General Oncologists and Specialists



- Specialists have focused depth of knowledge
- Generalists have broad knowledge, but less depth

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Challenges to Conducting Clinical Research

- ❑ Accrual
- ❑ Accrual
- ❑ Accrual
- ❑ Blood and tissue collection
- ❑ Regulatory Burden
- ❑ Expediting site activation
- ❑ Providers time

Attempts to Streamline Eligibility Criteria

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JOURNAL OF CLINICAL ONCOLOGY

SPECIAL ARTICLE

Modernizing Eligibility Criteria for Molecularly Driven Trials

Edward S. Kim, David Bernstein, Susan G. Hilsenbeck, Christine H. Chung, Adam P. Dicker, Jennifer L. Ersek, Steven Stein, Fadlo R. Khuri, Earle Burgess, Kelly Hunt, Percy Ivy, Suanna S. Bruinooge, Neal Meropol, and Richard L. Schilsky

Edward S. Kim, Jennifer L. Ersek, and Earle Burgess, Levine Cancer Institute, Carolinas HealthCare System, Charlotte, NC; David Bernstein, Suanna S. Bruinooge, and Richard L. Schilsky, American Society of Clinical Oncology, Alexandria, VA; Susan G. Hilsenbeck, Dan L. Duncan Cancer Center, Baylor College of Medicine; Kelly Hunt, University of Texas MD Anderson Cancer Center, Houston, TX; Christine H. Chung, Johns Hopkins University School of Medicine, Baltimore; Percy Ivy, National Cancer Institute, Bethesda, MD; Adam P. Dicker, Sidney Kimmel Medical College and Cancer Center at Thomas Jefferson University, Philadelphia, PA; Steven Stein, Novartis, East Hanover, NJ; Fadlo R. Khuri, Winship Cancer Institute, Emory University, Atlanta, GA; and Neal Meropol, University Hospitals Case Medical Center, Seidman Cancer Center, Case Comprehensive Cancer Center, Case Western Reserve Univer-

A B S T R A C T

As more clinical trials of molecularly targeted agents evolve, the number of eligibility criteria seems to be increasing. The importance and utility of eligibility criteria must be considered in the context of the fundamental goal of a clinical trial: to understand the risks and benefits of a treatment in the intended-use patient population. Although eligibility criteria are necessary to define the population under study and conduct trials safely, excessive requirements may severely restrict the population available for study, and often, this population is not reflective of the general population for which the drug would be prescribed. The American Society of Clinical Oncology Cancer Research Committee, which comprises academic faculty, industry representatives, and patient advocates, evaluated this issue. Evaluation results were mixed. Most physicians agreed that excessive eligibility criterias slow study enrollment rates and prolong the duration of enrollment; however, this hypothesis was difficult to validate with the data examined. We propose the organization of a public workshop, with input from regulatory bodies and key stakeholders, with the goal of developing an algorithmic approach to determining eligibility criteria for individual study protocols, which may help guide future investigators and companies in streamlining eligibility criteria in the era of molecularly driven therapy.

J Clin Oncol 33:2815-2820. © 2015 by American Society of Clinical Oncology

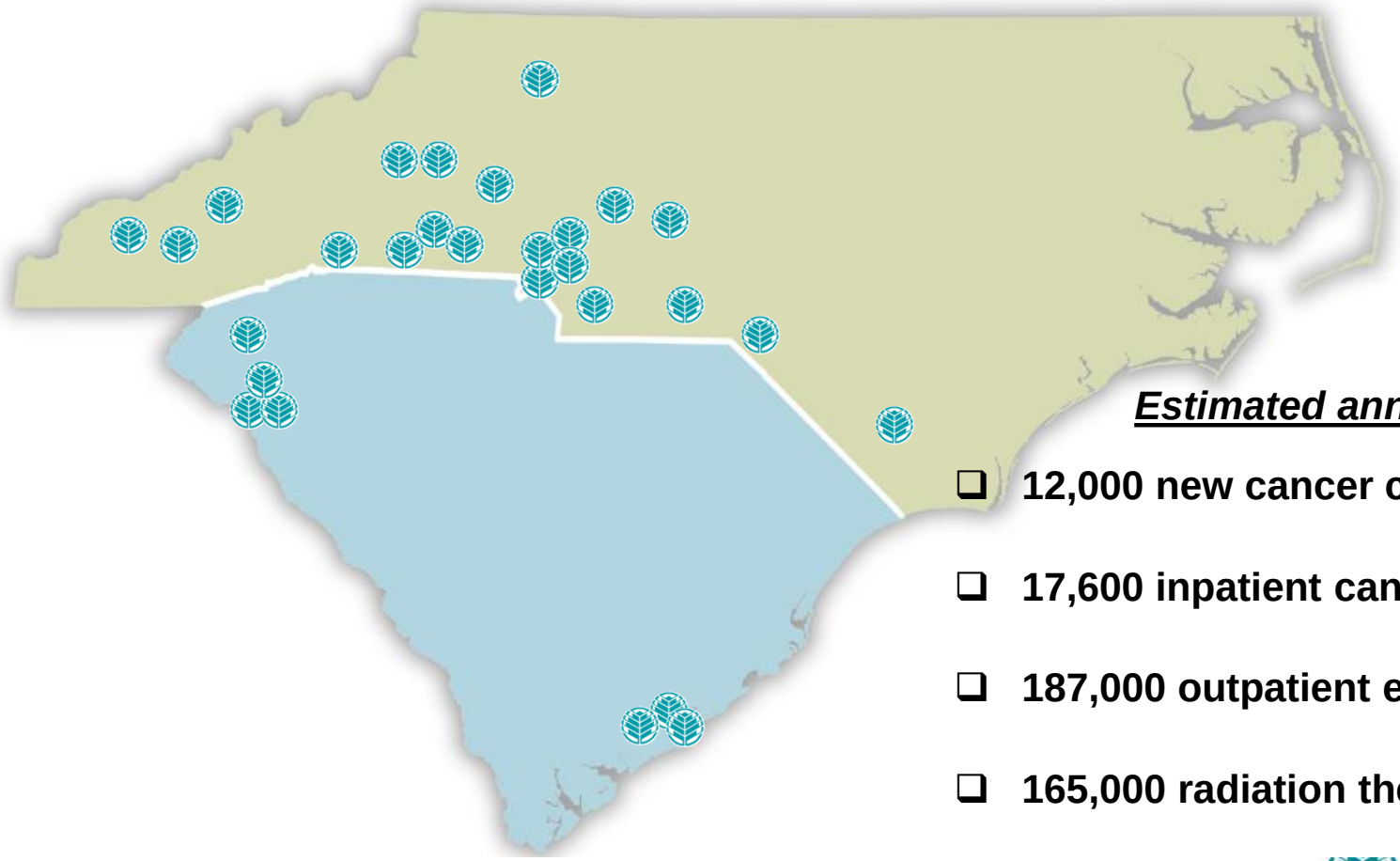
- ASCO Cancer Research Committee
- Meetings with FDA and other interested parties to address this issue
- Need concrete plans to fix

er Institute

Clinical Treatment Pathways

- Help with clinical decision making
- Cost containment
  - FDA on-label therapy
- Quality and best practice
- Clinically acceptable
- What would you NOT want to see done to a patient prior to seeing them as a referral
- Encourage treatment close to home and only travel when there is an unmet need or higher level of specialty

Carolinas HealthCare System



Estimated annual volume:

- ❑ **12,000 new cancer cases**
- ❑ **17,600 inpatient cancer admissions**
- ❑ **187,000 outpatient encounters**
- ❑ **165,000 radiation therapy treatments**

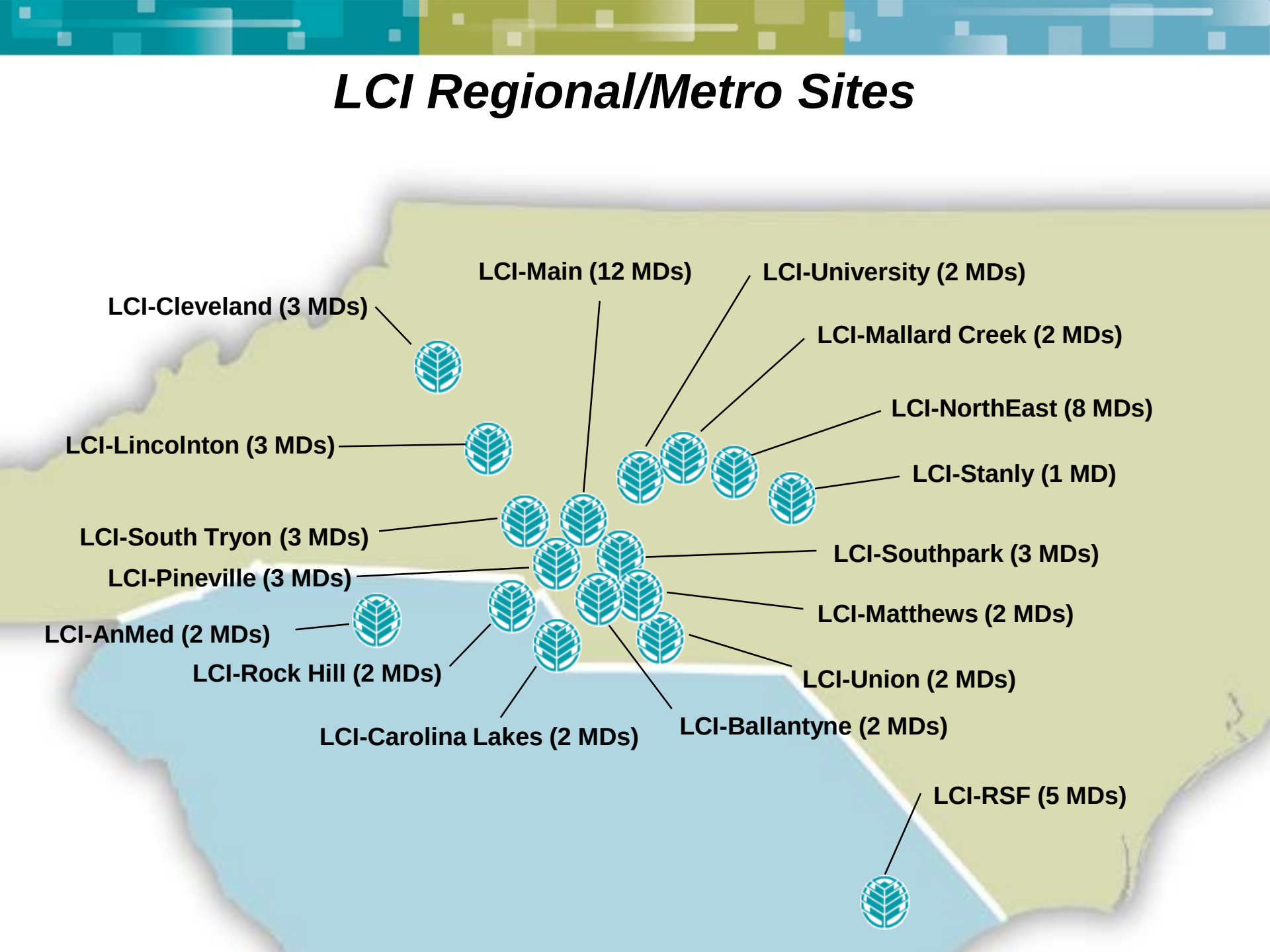
Levine Cancer Institute

Levine Cancer Institute

Derek Raghavan, MD
President, Levine Cancer Institute

- Started with 3 community practices (27 MDs)
- Phase I Clinical Trials Unit
- Bone Marrow Transplant Unit
- Biostatistics Department
- Biospecimen Repository
- Patient Navigation
- Goals
  - Patient services, Access, Ease
  - Clinical trials access

LCI Regional/Metro Sites



Rationale for Creating LCI EAPathways

- Tumor boards already existed
- Different private practice groups and some individual tumor boards at different venues
- How to *integrate* expertise for the general medical oncologist
- There are usually *several* appropriate ways to treat a patient and a *few* that are considered not appropriate
- 3 local private practices were merged into LCI faculty
- How to find “unity” among providers

LCI Clinical Pathways: EAPathways

- Development initiated in Fall 2013; Tested Jan 2015; Activated May 2015
- Promotes consistent treatment across a system with general oncologists
- Alerts clinical teams about system clinical trials
- Study coordinators focus on specific trials and patient-related activities
- Tracks data on
  - Trial inquiries; Pathway enrollments; Why no trial or pathway enrollment
- Nimble: Close to “real-time” edits on pathways and trials (24 hrs)
- Email communication

Patient Treatment Guidelines and Pathways

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Treatment Guidelines & Pathways

Disease Sites

- Acute Myeloid Leukemia
- Bladder
- Breast
- Colorectal
- Colorectal
- Gastric
- Hepatocellur
- Lung

Guidelines & Pathways
Non-Small Cell
Small Cell

Clinical Trials	Status ▼	Notes
SWOG 0819	Open	Accepting New Patients
Carboplatin + nab-paclitaxel	Open	Accepting New Patients

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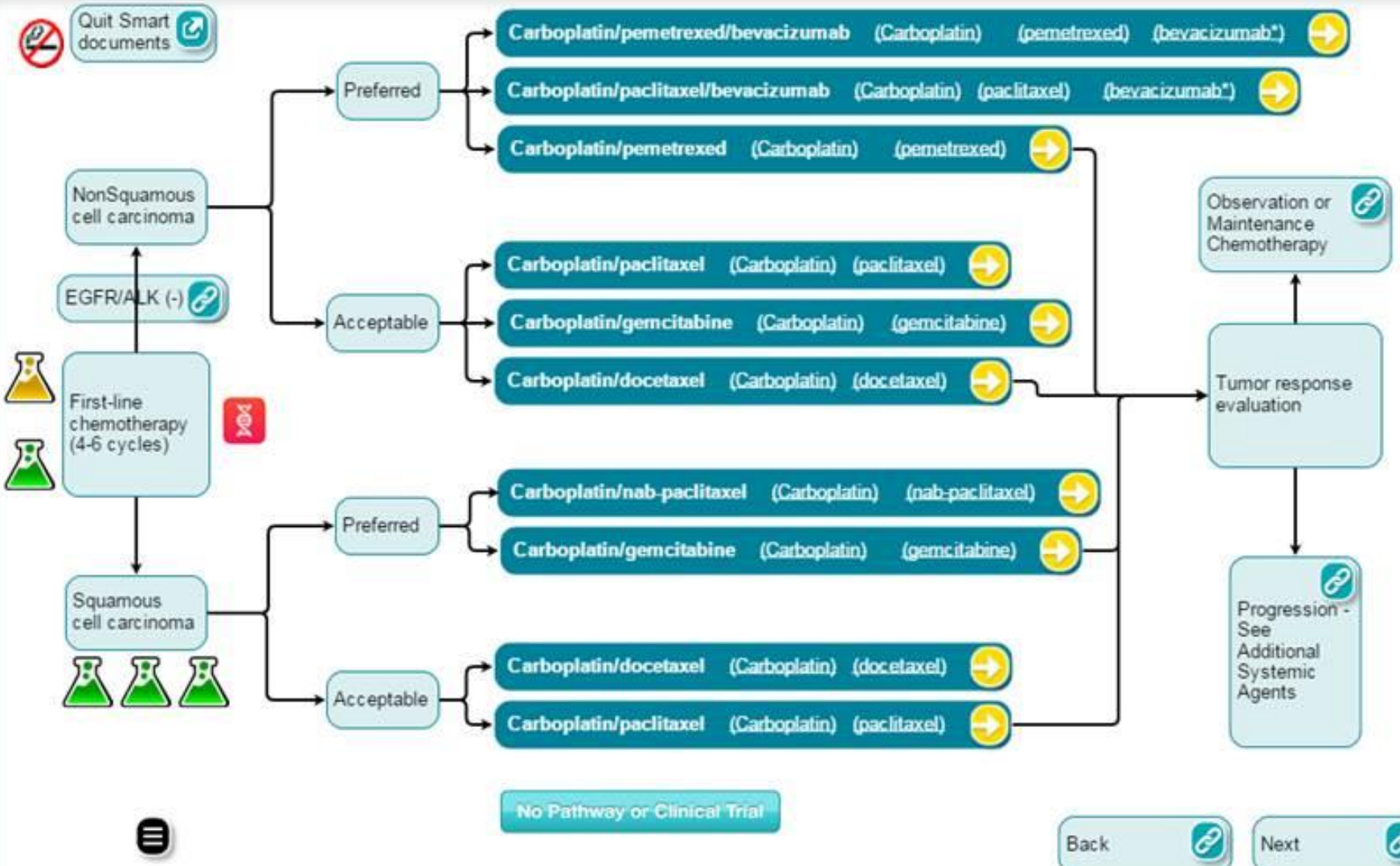
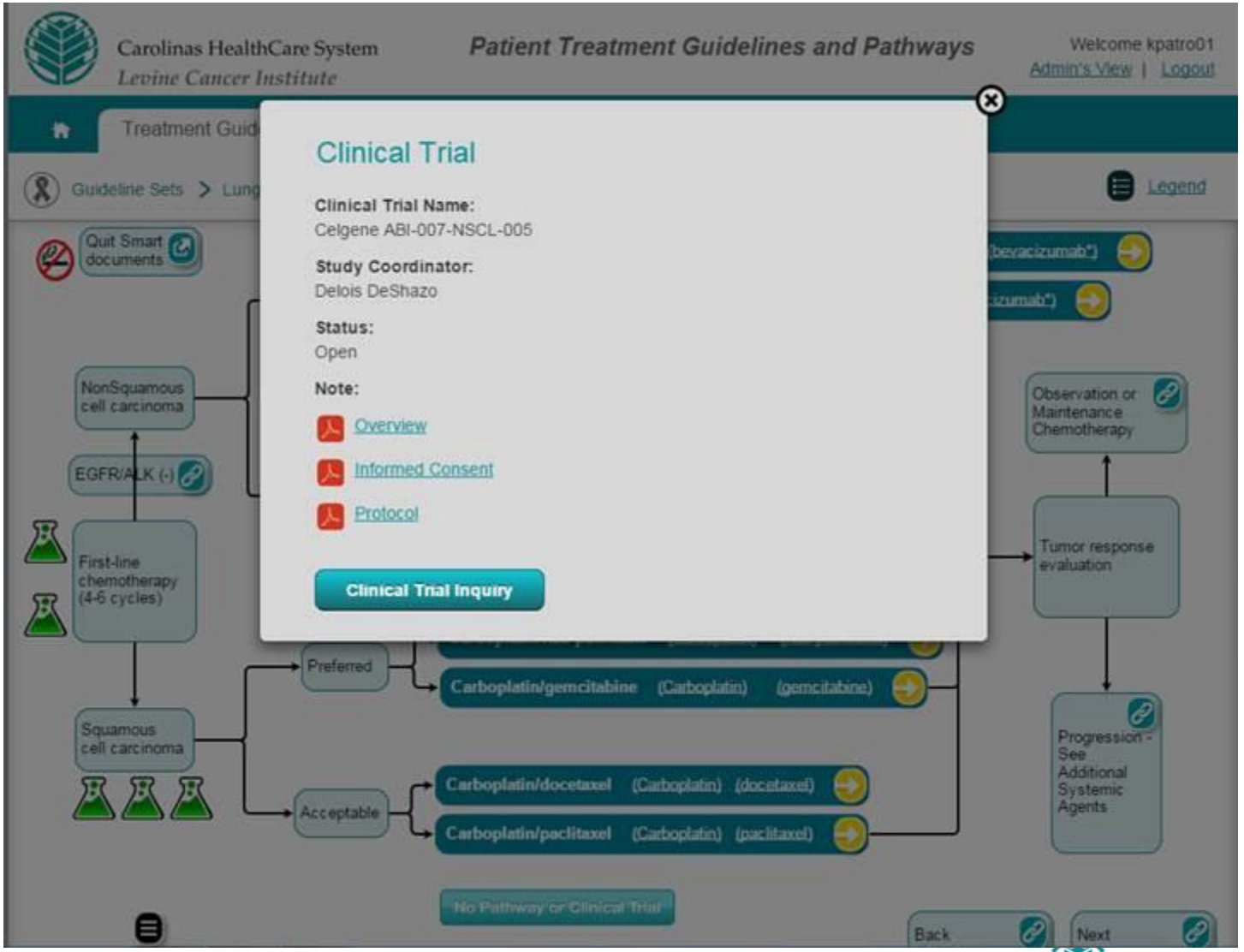
Lung/Thoracic > Non-small cell lung cancer > **Metastatic First Line Chemotherapy**

Previous | Legend




Carolinas HealthCare System
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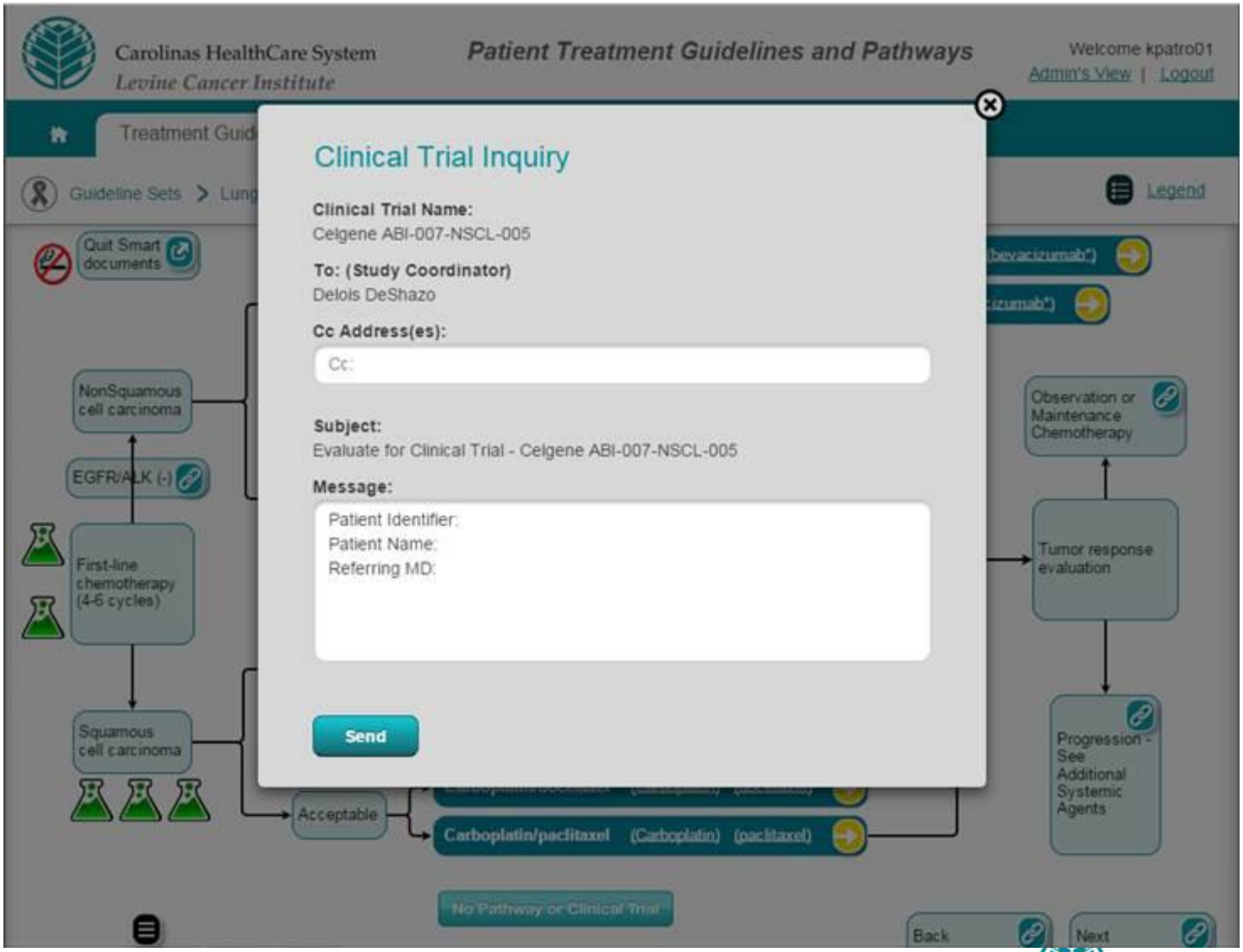
Patient Treatment Guidelines and Pathways
Welcome kpatro01
Admin's View | Logout
Treatment Guid
Guideline Sets > Lung
Legend
Quit Smart documents
Clinical Trial
Clinical Trial Name:
Celgene ABI-007-NSCL-005
Study Coordinator:
Delois DeShazo
Status:
Open
Note:
Overview
Informed Consent
Protocol
Clinical Trial Inquiry
NonSquamous cell carcinoma
EGFR/ALK (-)
First-line chemotherapy (4-6 cycles)
Squamous cell carcinoma
Preferred
Carboplatin/gemcitabine (Carboplatin) (gemcitabine)
Acceptable
Carboplatin/docetaxel (Carboplatin) (docetaxel)
Carboplatin/paclitaxel (Carboplatin) (paclitaxel)
Observation or Maintenance Chemotherapy
Tumor response evaluation
Progression - See Additional Systemic Agents
No Pathway or Clinical Trial
Back
Next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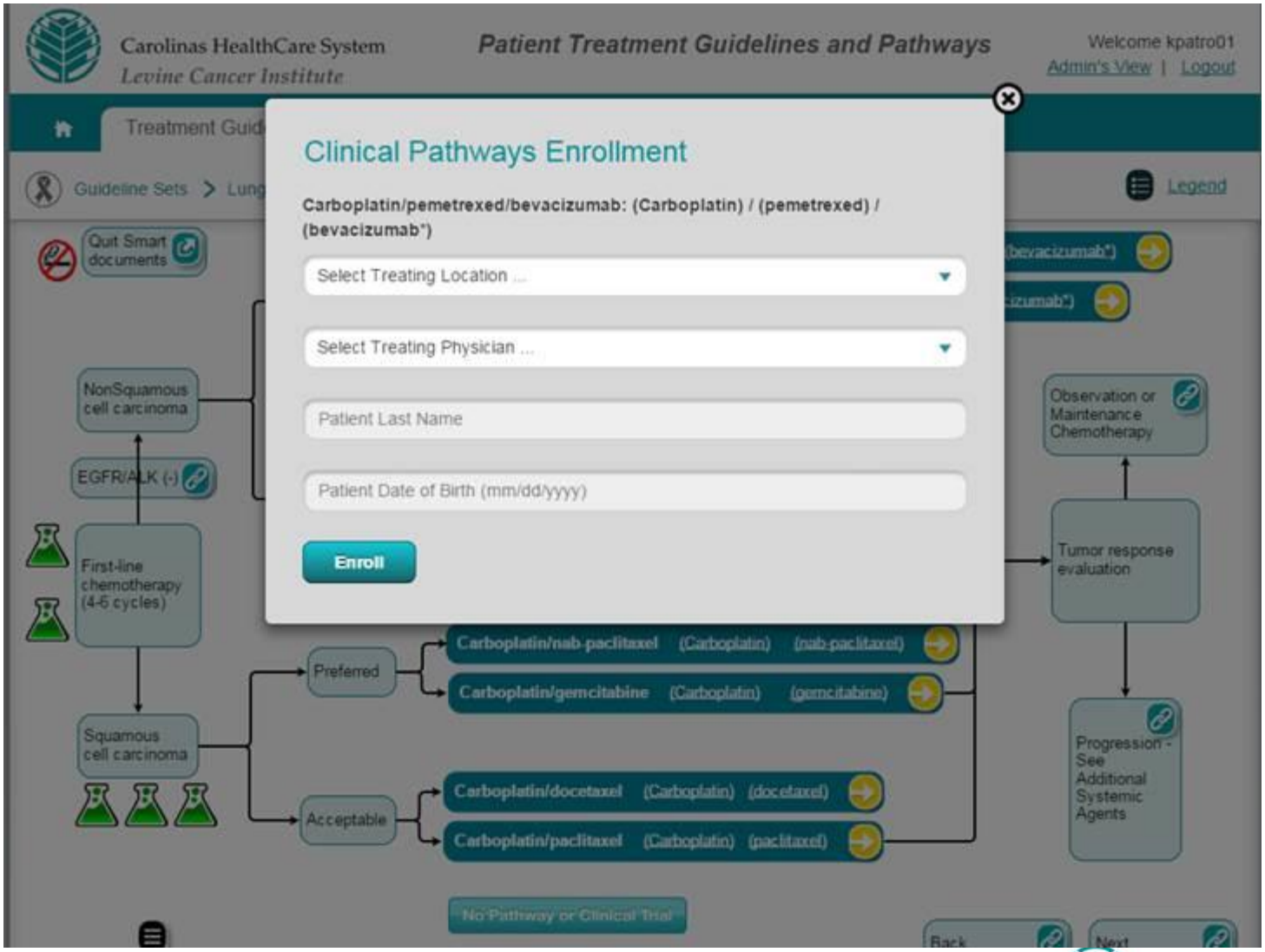
Clinical Trial Name:
Celgene ABI-007-NSCL-005
To: (Study Coordinator)
Delois DeShazo
Cc Address(es):
Cc:
Subject:
Evaluate for Clinical Trial - Celgene ABI-007-NSCL-005
Message:
Patient Identifier:
Patient Name:
Referring MD:
Send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Treatment Guid
Guideline Sets > Lung
Legend
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Clinical Pathways Enrollment
Carboplatin/pemetrexed/bevacizumab: (Carboplatin) / (pemetrexed) / (bevacizumab*)
Select Treating Location ...
Select Treating Physician ...
Patient Last Name
Patient Date of Birth (mm/dd/yyyy)
Enroll
NonSquamous cell carcinoma
EGFR/ALK (-)
First-line chemotherapy (4-6 cycles)
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Acceptable
Carboplatin/nab-paclitaxel (Carboplatin) (nab-paclitaxel)
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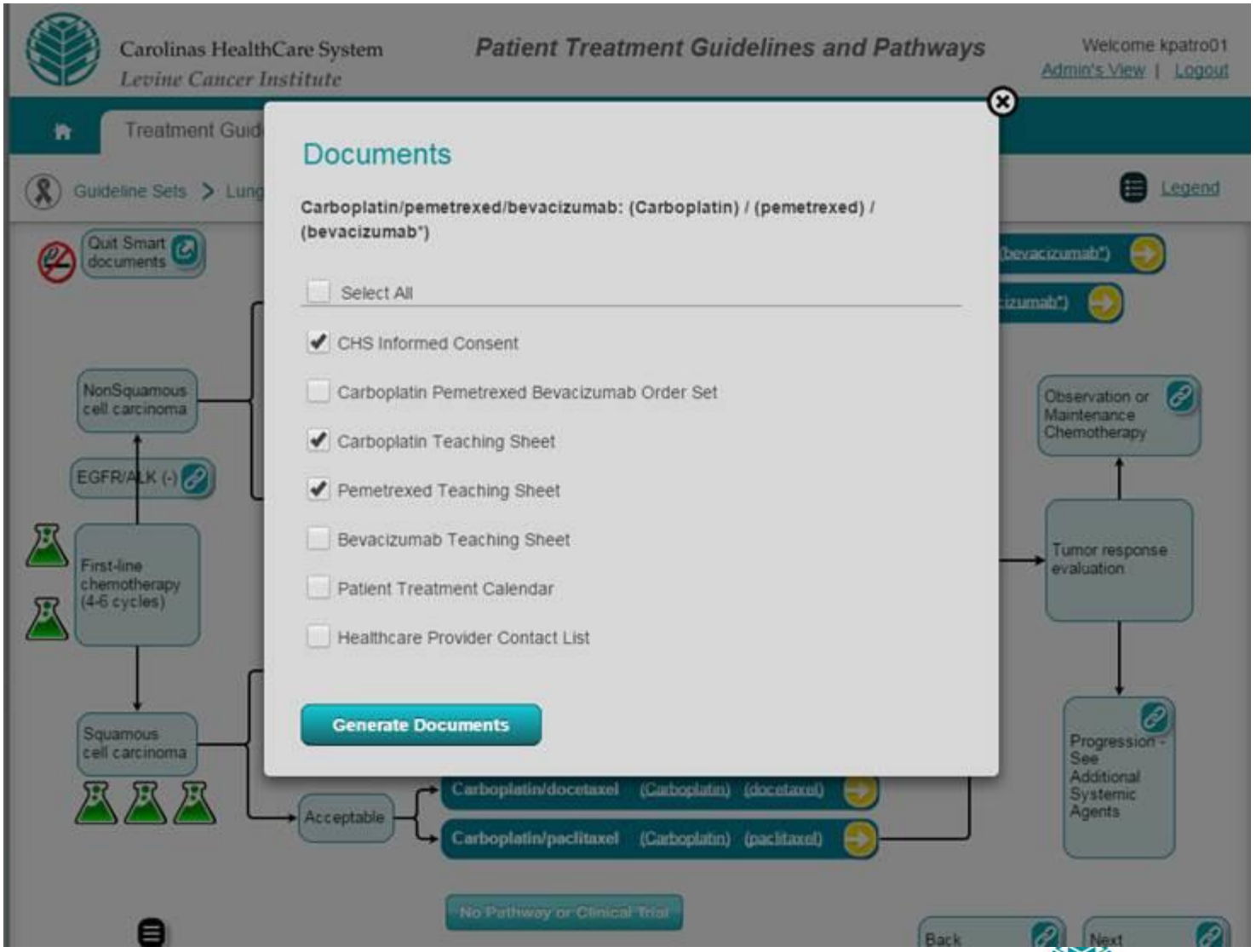
Carolinas HealthCare System
Levine Cancer Institute
Patient Treatment Guidelines and Pathways
Welcome kpatro01
Admin's View | Logout
Treatment Guid
Guideline Sets > Lung
Legend
Quit Smart documents
Documents
Carboplatin/pemetrexed/bevacizumab: (Carboplatin) / (pemetrexed) / (bevacizumab*)
Select All
CHS Informed Consent
Carboplatin Pemetrexed Bevacizumab Order Set
Carboplatin Teaching Sheet
Pemetrexed Teaching Sheet
Bevacizumab Teaching Sheet
Patient Treatment Calendar
Healthcare Provider Contact List
Generate Documents
NonSquamous cell carcinoma
EGFR/ALK (-)
First-line chemotherapy (4-6 cycles)
Squamous cell carcinoma
Acceptable
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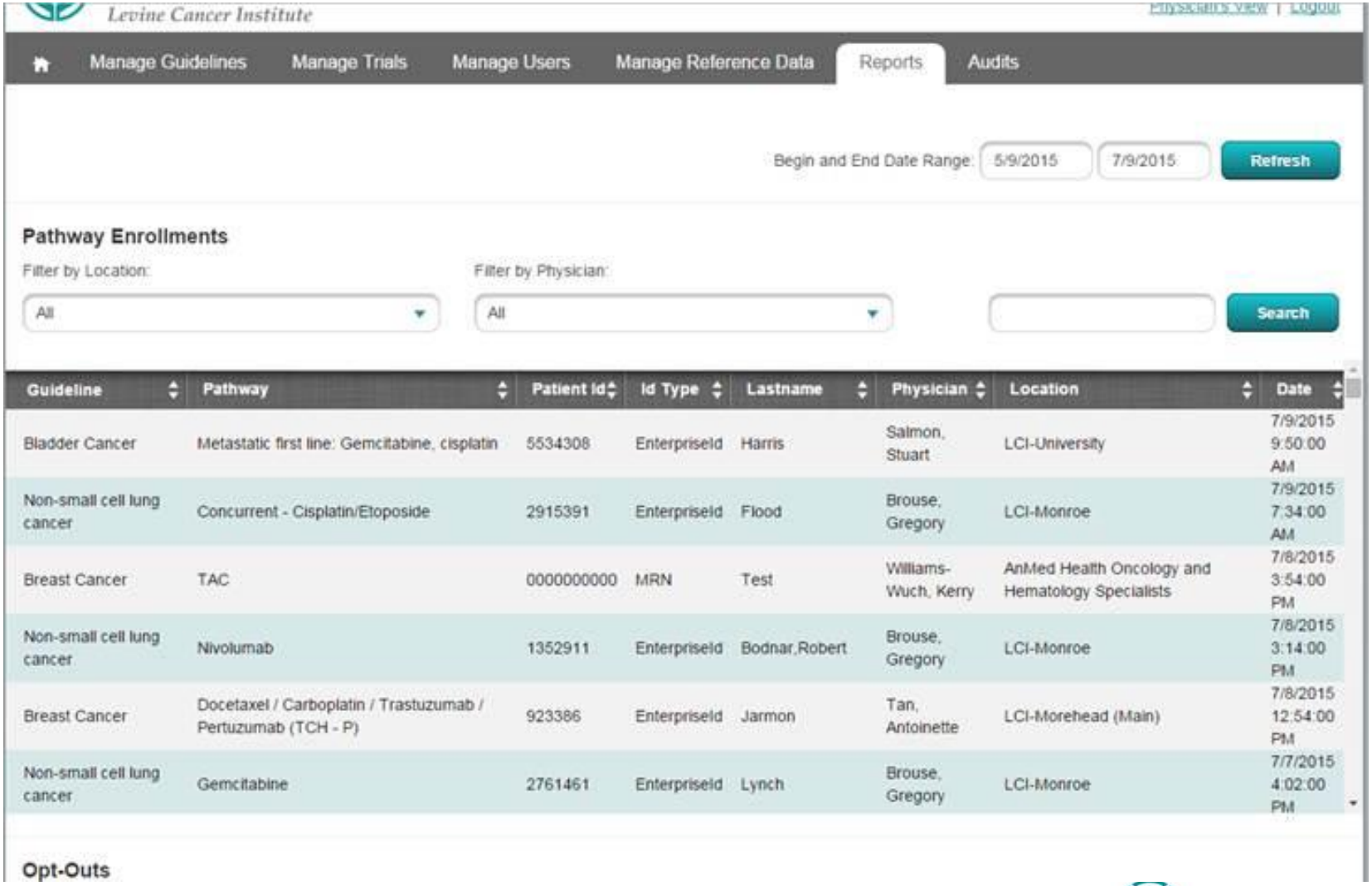
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Physician's View | Logout
Manage Guidelines
Manage Trials
Manage Users
Manage Reference Data
Reports
Audits
Begin and End Date Range:
5/9/2015
7/9/2015
Refresh
Pathway Enrollments
Filter by Location:
All
Filter by Physician:
All
Search
Guideline
Pathway
Patient Id
Id Type
Lastname
Physician
Location
Date
Bladder Cancer
Metastatic first line: Gemcitabine, cisplatin
5534308
EnterpriseId
Harris
Salmon, Stuart
LCI-University
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Concurrent - Cisplatin/Etoposide
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LCI-Monroe
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LCI-Morehead (Main)
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Non-small cell lung cancer
Gemcitabine
2761461
EnterpriseId
Lynch
Brouse, Gregory
LCI-Monroe
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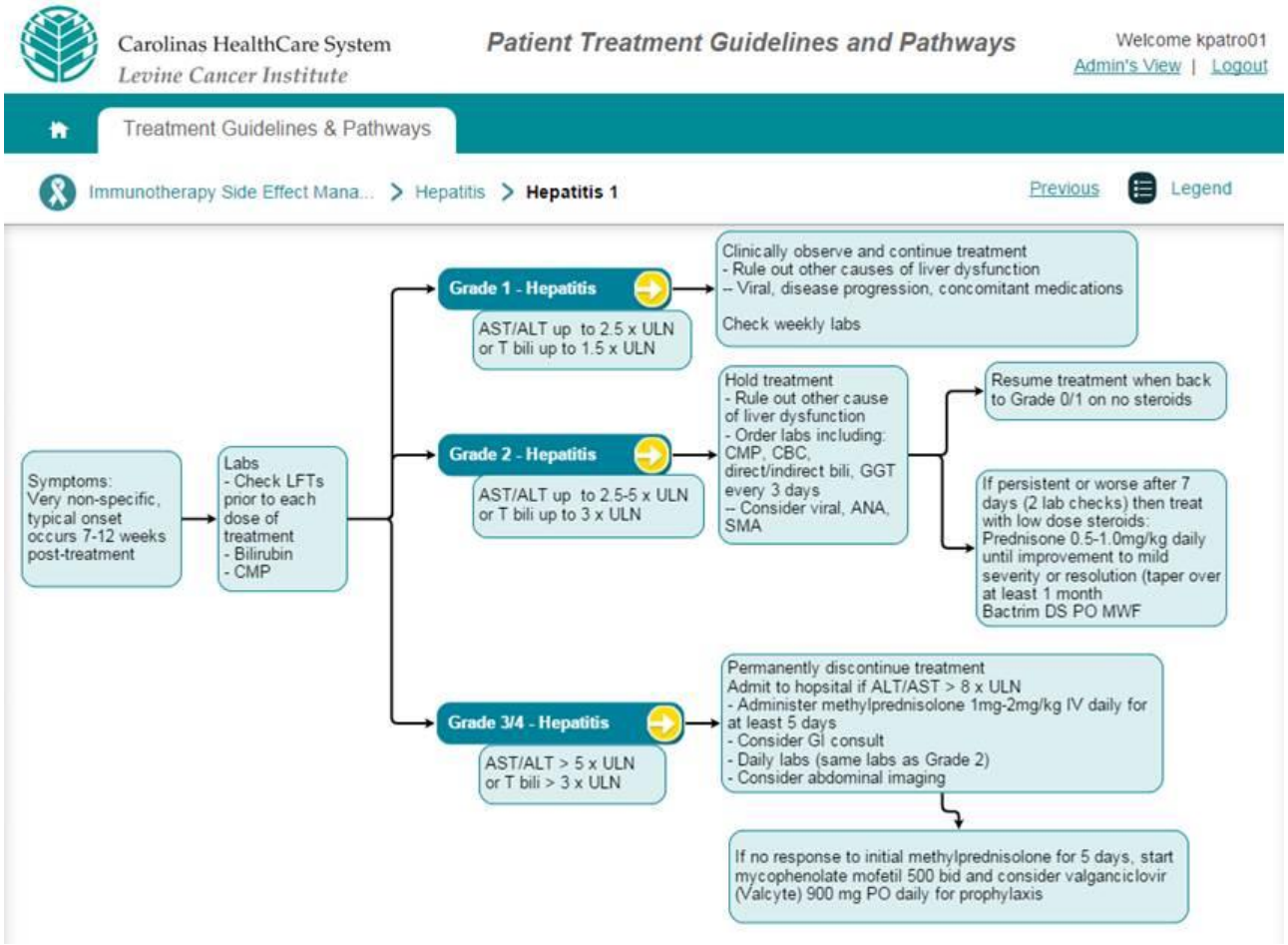
Opt-Outs

- ***Immunotherapy Side Effect Management***
- ***Hepatitis***



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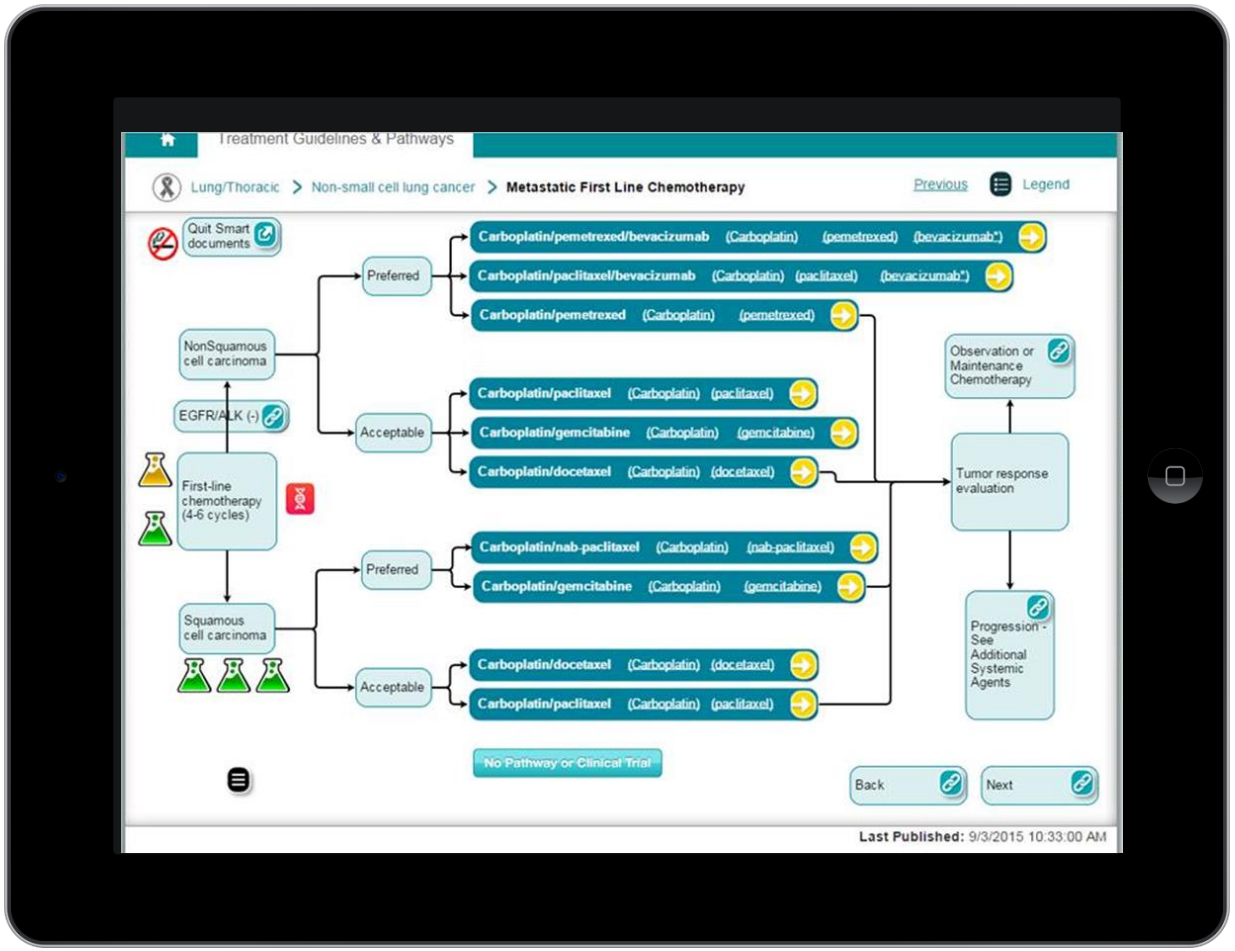

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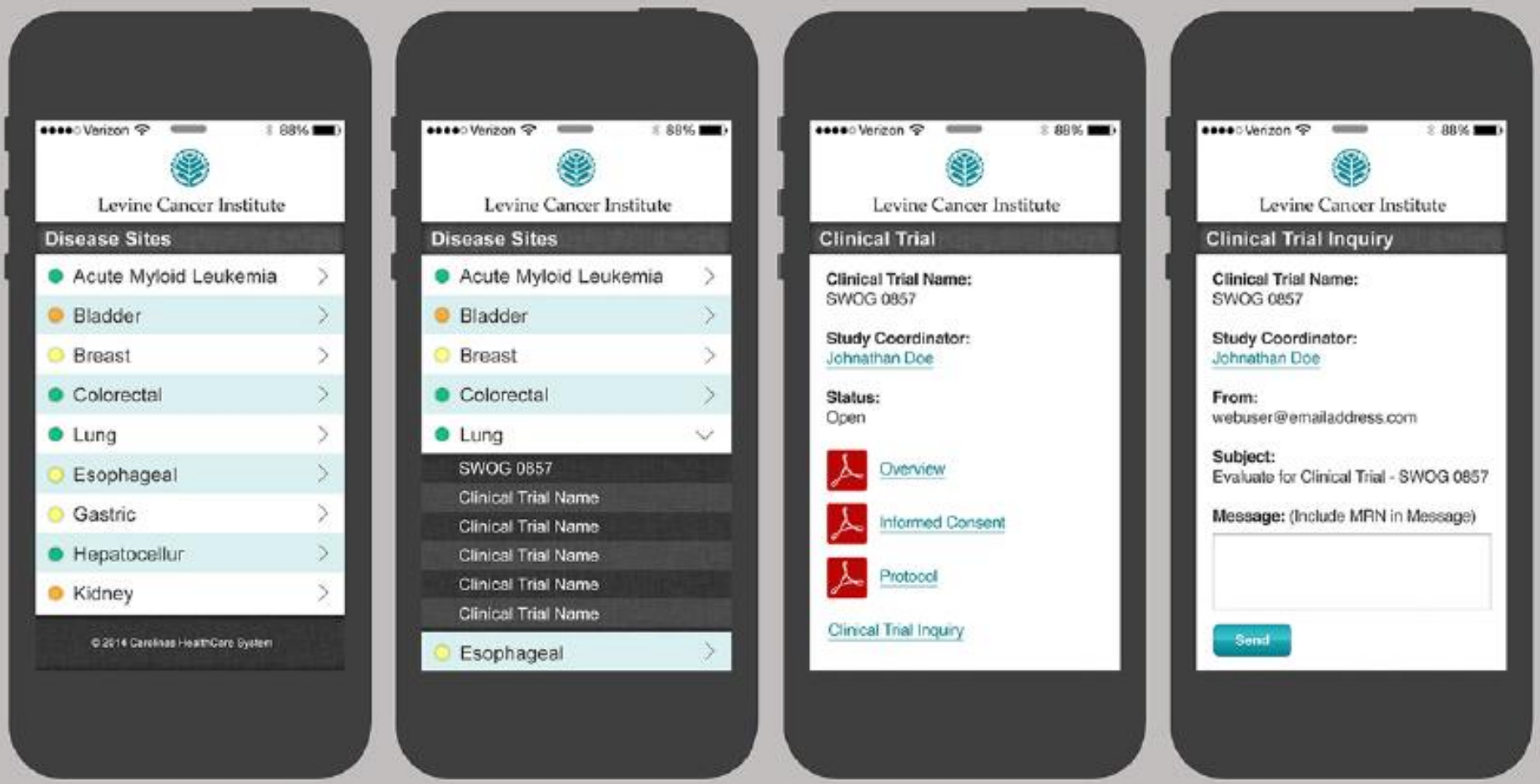

TAPUR

Targeted Agent and Profiling Utilization Registry Study

American Society of Clinical Oncology

The Targeted Agent and Profiling Utilization Registry (TAPUR) Study

- **Primary Objectives (PI Schilsky):**
  - To describe the anti-tumor activity and toxicity of commercially available, targeted anti-cancer drugs prescribed for treatment of patients with advanced solid tumors, B cell NHL or MM with a known genomic variant.
  - To facilitate patient access to commercially available, targeted anti-cancer drugs of potential efficacy for treatment of patients with an advanced solid tumor, B cell NHL or MM with a known genomic variant.

ASCO Targeted Agent and Profiling Utilization Registry (TAPUR) Study (Schilsky)

- Great fit for community-based systems
- Provides access for patients to drugs
- Molecular tumor board to help with decision-making
- Reduces the need for generalists to speculate or hypothesize
- Prospectively study drug and targets
- AstraZeneca, Bristol-Myers Squibb, Eli Lilly and Company, Genentech, Pfizer

EAPathways, Genomics, TAPUR: Conclusions

- **Patient-centered**
  - Treat close to home (minimize travel inconveniences)
  - Pathways are to help generalists, not specialists
  - Strategy, Transparency, Inclusiveness, Disclosure
  - Consistency of diagnosis/treatment/follow-up/molecular testing etc.
- **Genomic testing at appropriate points of care**
- **Integration of Research Efforts (TAPUR)**
  - Direct Notification/Communication
  - Specimen Collection

Thank you for your attention!

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