FDA-ASCO
Geriatric Oncology Workshop

Session 3. Leveraging research designs for real-world patients: Real-world evidence

November 6, 2017

ASCO’s CancerLinQ®: Real-world insights to drive quality improvement and discovery

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ASCO & CancerLinQ

- Leading professional organization representing physicians caring for those with cancer
- >44,000 members from 100+ countries
- Mission: Conquering cancer through research, education, and promotion of the highest quality patient care

- Not-for-profit subsidiary of ASCO
- Dedicated staff and governing board
- Mission: Empowering the oncology community to improve quality of care and patient outcomes through transformational data analytics
Getting to the data

1.7MM people diagnosed with cancer in the US

97% of patient data locked away in unconnected files and servers
Unlock, assemble, and analyze de-identified cancer patient medical records

Uncover patterns to generate knowledge

Measure and benchmark quality of care

Provide guidance by identifying the best evidence-based course of care
Overview of CancerLinQ data assets and flows
CancerLinQ progress to date

- **110** practices/cancer centers (92 signed BAAs)
- **30** implementations in progress
- **37** active sites
- **12** source systems represented
- **~2,500** oncologists
- **>550K** active cancer patient records
What is CancerLinQ Discovery™?

An extension of CancerLinQ’s QI-focused database designed to support hypothesis-based research

1. Key structured data elements → additional editorial/curation effort to ensure that those data elements exist in a canonical form
2. Uses natural language processing and manual curation to extract additional data from unstructured data
3. Initial area of focus: non-small cell lung cancer
4. Third parties can submit data requests to the CancerLinQ Discovery Research & Publications Committee for approval
Data Access Process

Submit Request
- Two part process: data request form & online upload and submission
- Initial CancerLinQ Discovery™ request screening

High-level Data Sufficiency Review
- CancerLinQ Discovery™ data availability & quality check — data fit for purpose
- Initial project data specifications and cost estimates determined

CancerLinQ Discovery™ Research & Publications Committee Review
- Full review and consensus decision making process
- Committee may request additional information from data requester

Decision on CancerLinQ Discovery™ Request
- Requester notified of decision on submitted data request
- Successful requests move forward to identify contract terms, project cost, and provisions of data
Selected adjuvant trials from the literature

- **MOSAIC (JCO 2009)** – 5FU/leucovorin +/- oxaliplatin
  - Stage II/III colon cancer
  - Median age FOLFOX4 arm = 61
  - Age > 65 = 35.6% (pts > age 75 not eligible)
  - **CLQ median age = 68**
  - **CLQ age 60-80 = 52%**

- **CheckMate 238 (NEJM 2017)** – nivolumab vs. ipilimumab
  - Stage IIIB, IIIC, or resected Stage IV melanoma
  - Median age (range): nivo = 56 (19-83), ipi = 54 (18-86)
  - Age > 75: nivo = 3.8%, ipi = 2.9%
  - **CLQ median age = 64**
  - **CLQ age >70 = 36%**

- **IALT (NEJM 2004)** – cisplatin-based chemo vs. observation
  - Stage I-IIIA non-small cell lung cancer s/p resection
  - Median age (range) chemo arms = 59 (27-77)
  - **CLQ median age = 71**
Limitations of real-world evidence in studying the geriatric population

• Data limited to what is available in the EHR source
• Many important oncologic concepts not captured in structured data fields
• Elements of geriatric assessment domains sparsely represented:
  ▪ Functional status ×
  ▪ Cognitive function ×
  ▪ Comorbidities ✔ as ICD9/10 codes
  ▪ Psychological state ×
  ▪ Nutritional status ×
  ▪ Social support ✔ marital status alone
• Outcomes of importance to older adults (e.g., impact of Rx on function or cognition) can only be obtained through curation