FDA-ASCO
Geriatric Oncology Workshop

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

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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 though 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

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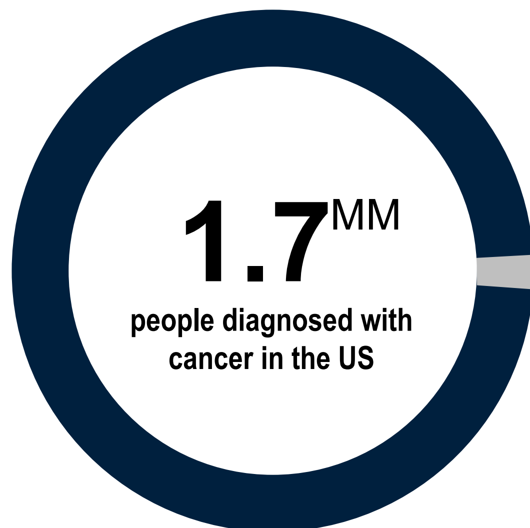
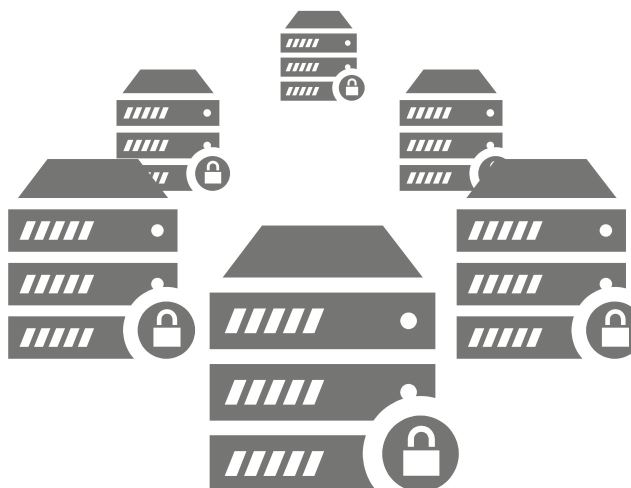
Getting to the data



97%

of patient data locked away in unconnected files and servers



QI

Measure and benchmark quality of care

Research

Unlock, assemble, and analyze de-identified cancer patient medical records

QI

Provide guidance by identifying the best evidence-based course of care

Research

Uncover patterns to generate knowledge

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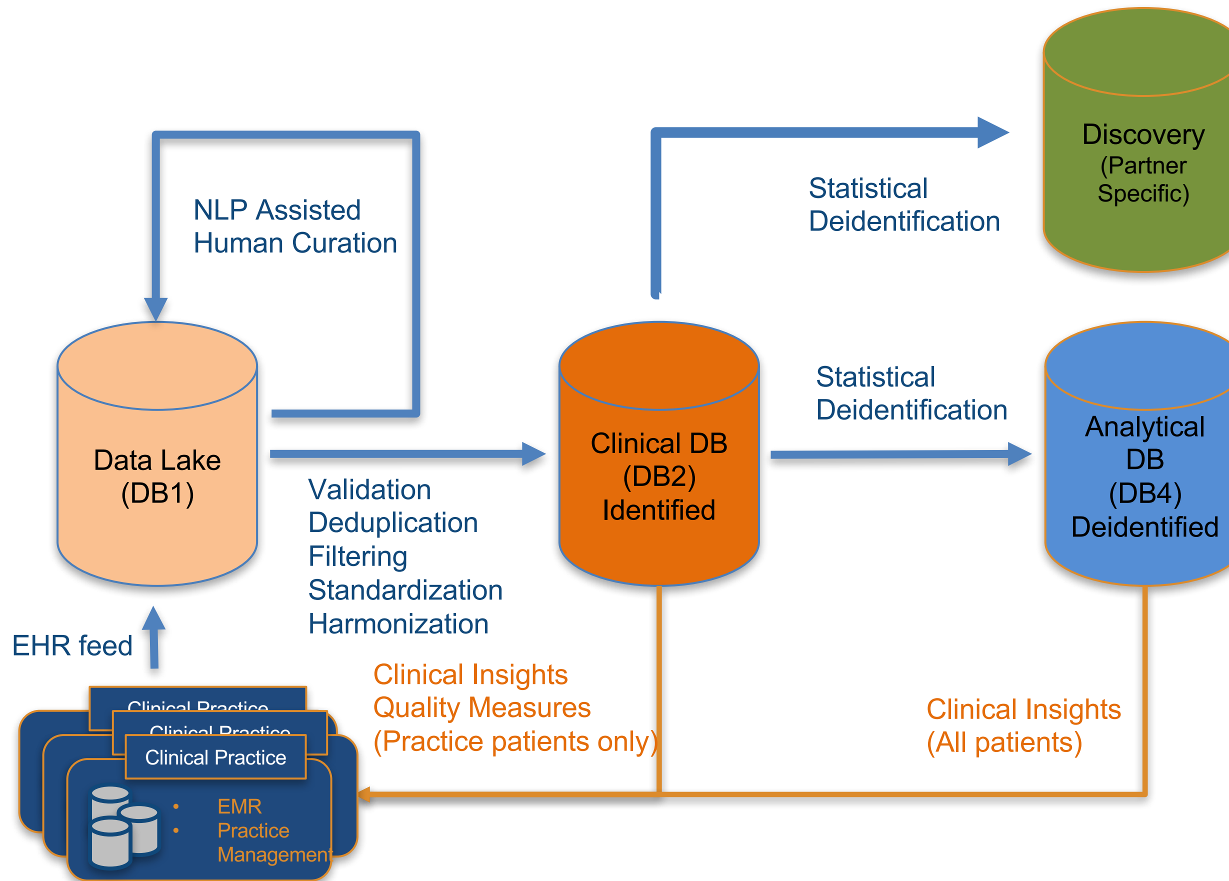
Overview of CancerLinQ data assets and flows



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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

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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

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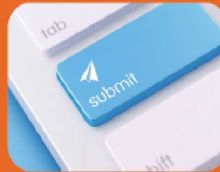
www.cancerlinq.org/research-database

ASCO CANCERLINQ DISCOVERY

Data Access Process



Submit Request

- Two part process: data request form & on-line upload and submission
- Initial CancerLinQ Discovery™ request screening

High-level Data Sufficiency Review

- CancerLinQ Discovery™ data availabilty & 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

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Selected adjuvant trials from the literature

- MOSAIC (JCO 2009) – 5FU/leucovorin +/- oxaliplatin
  - Stage II/III colon cancer
  - Median age FOLFOX4 arm = 61 **CLQ median age = 68**
  - Age > 65 = 35.6% (pts > age 75 not eligible) **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) **CLQ median age = 64**
  - Age ≥ 75: nivo = 3.8%, ipi = 2.9% **CLQ age >70 = 36%**
- IALT (NEJM 2004) – cisplatin-based chemo vs. observation
  - Stage I-III 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