Unlocking Real World Evidence from the Electronic Health Record

Emily Castellanos, MD MPH National Cancer Policy Forum July 29-30th, 2024



Disclosures

Dr. Emily Castellanos is an employee of Flatiron Health, which is an independent subsidiary of the Roche Group.

- Stock ownership in Roche



Flatiron network of U.S. oncology clinics and academic hospitals

OUR NETWORK:

Community Oncology Clinics

Practices and MSOs

Hospitals & Health Systems

Including Academic Medical Centers

3.6M +

Active patients

2,900+

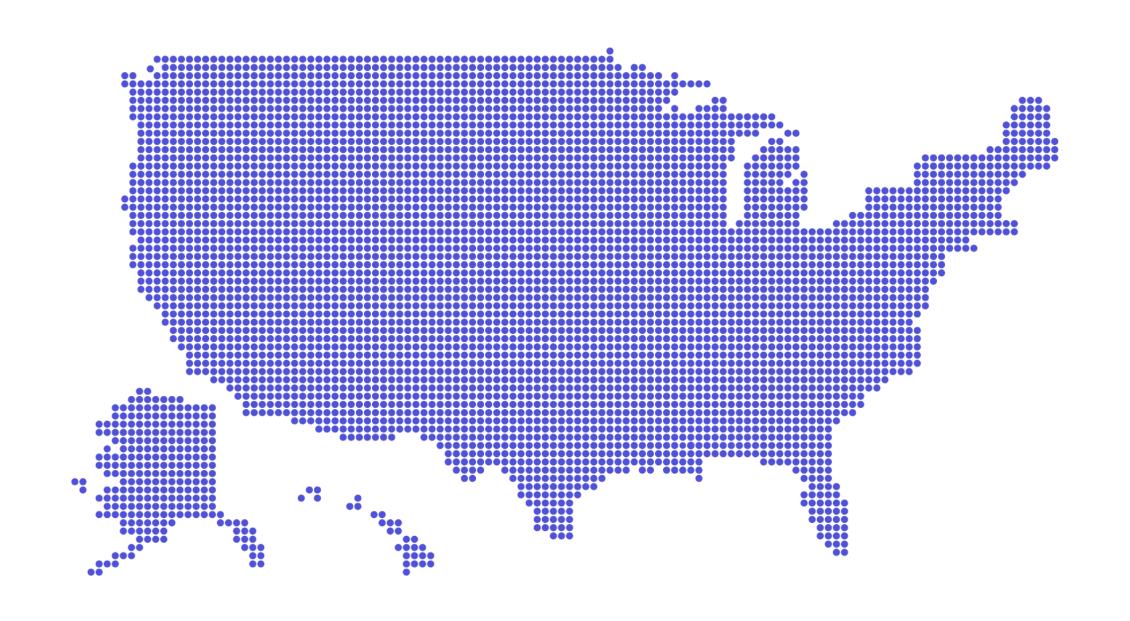
Clinicians

300+

Cancer Clinics

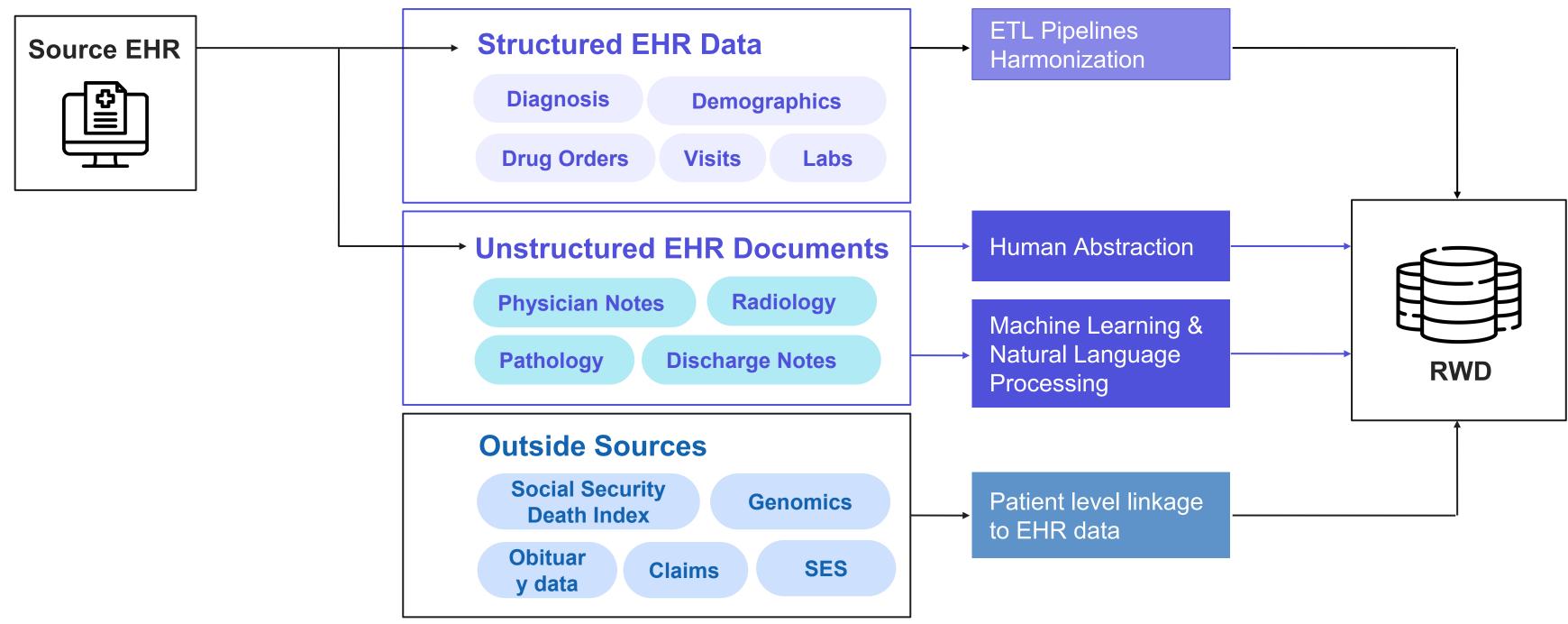
800+

Unique Sites of Care



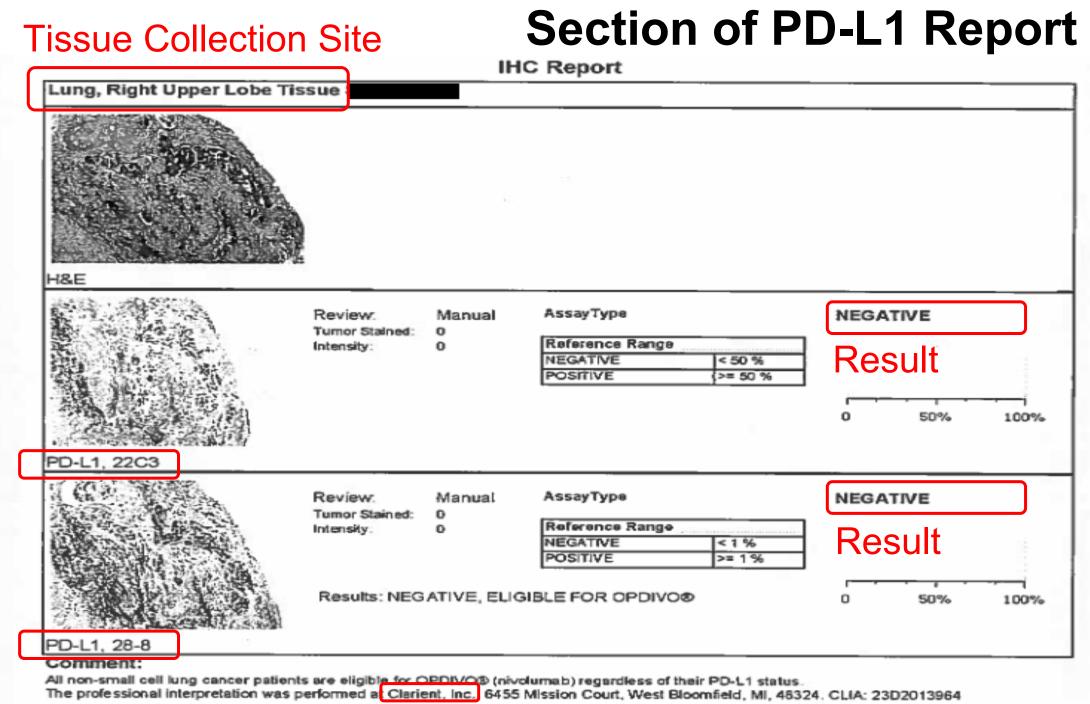


EHR-based RWD exists in structured and unstructured formats, and can be combined with non-EHR data





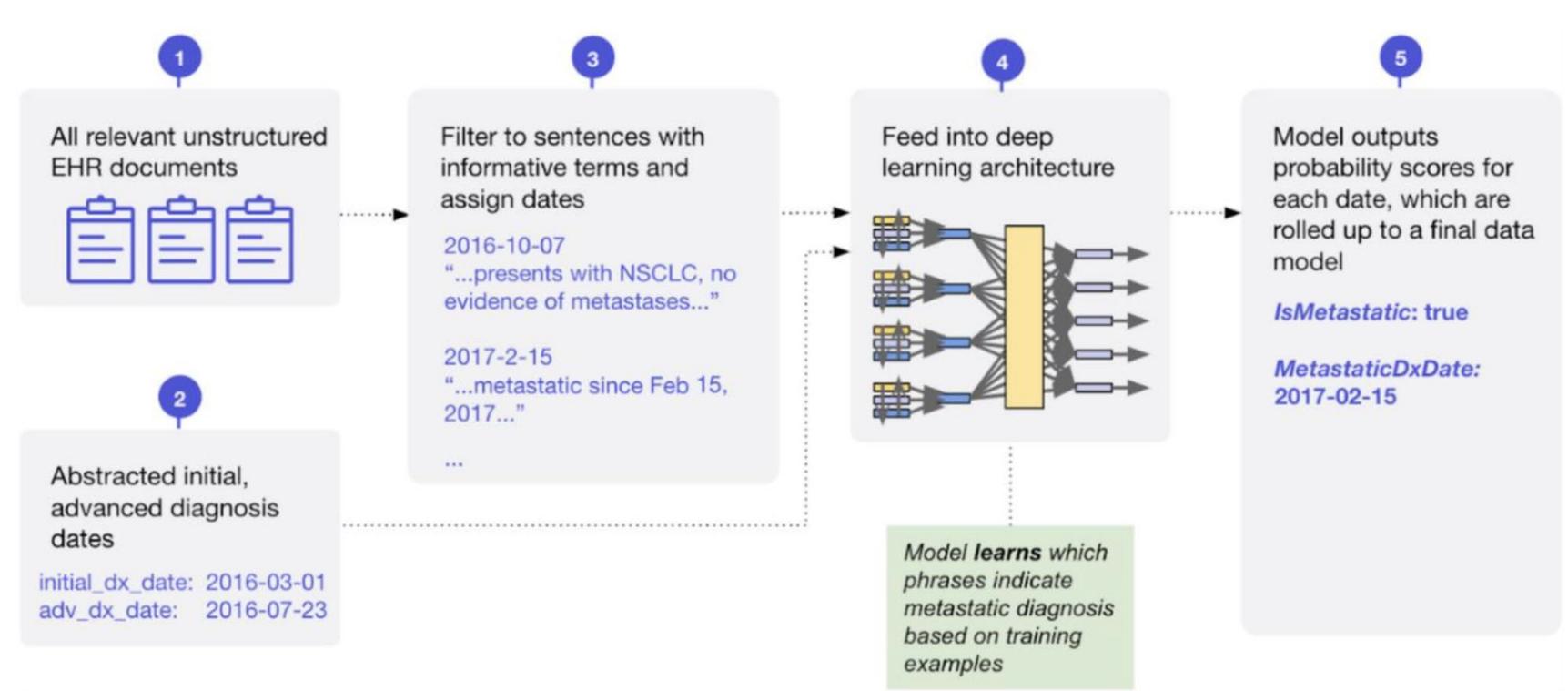
Abstraction of unstructured data can provide critical, complex clinical information, but is resource intensive



Example data elements:

- Test status
- Test result
- Date biopsy collected
- Date biopsy received by laboratory
- Date result received by provider
- Lab name
- Sample type
- Tissue collection site
- Type of test (e.g., FISH)
- Assay / kit (e.g., Dako 22C3)
- Percent staining & staining intensity

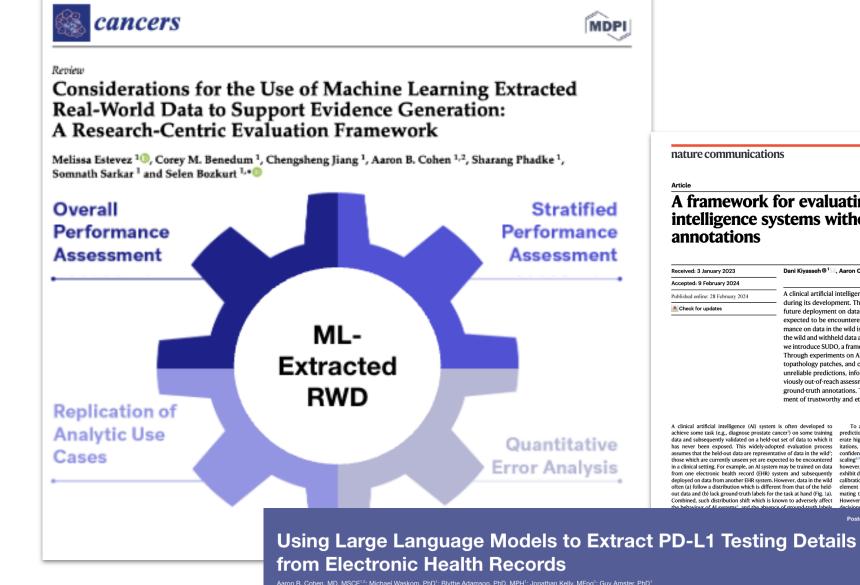
ML/Al technology can unlock scale





Challenges for the future

- Finding the right balance between human and technology
- Continuing to innovate by developing novel capabilities to improve accuracy and scale



nature communications A framework for evaluating clinical artificial intelligence systems without ground-truth annotations Accepted: 9 February 2024 A clinical artificial intelligence (AI) system is often validated on data withhel Check for updates future deployment on data in the wild; those currently unseen but are expected to be encountered in a clinical setting. However, estimating performance mance on data in the wild is complicated by distribution shift between data in the wild and withheld data and the absence of ground-truth annotations. Here we introduce SUDO, a framework for evaluating AI systems on data in the wild. Through experiments on AI systems developed for dermatology images, hisopathology patches, and clinical notes, we show that SUDO can identify unreliable predictions, inform the selection of models, and allow for the pre viously out-of-reach assessment of algorithmic bias for data in the wild without ground-truth annotations. These capabilities can contribute to the deployment of trustworthy and ethical AI systems in medicine.

®Raising the Bar for Real-World Data in Oncology: Approaches to Quality Across Multiple Dimensions ACCOMPANYING CONTENT RPOSE Electronic health record (EHR)-based real-world data (RWD) are integral to ncology research, and understanding fitness for use is critical for data users Complexity of data sources and curation methods necessitate transparency into how quality is approached. We describe the application of data quality dimensions in curating EHR-derived oncology RWD. METHODS A targeted review was conducted to summarize data quality dimensions in

rameworks published by the European Medicines Agency, The National Institute for Healthcare and Excellence, US Food and Drug Administration, Duke-Margolis Center for Health Policy, and Patient-Centered Outcomes Research Institute. We then characterized quality processes applied to curation of Flatiro Health RWD, which originate from EHRs of a nationwide network of academic and community cancer clinics, across the summarized quality dimensions.

RESULTS The primary quality dimensions across frameworks were relevance (including subdimensions of availability, sufficiency, and representativeness) and reli ability (including subdimensions of accuracy, completeness, provenance, and timeliness). Flatiron Health RWD quality processes were aligned to each dimension. Relevancy to broad or specific use cases is optimized through data set size and variable breadth and depth. Accuracy is addressed using validation indirect benchmarking, and verification checks for conformance, consistency and plausibility, selected on the basis of feasibility and criticality of the variable to the intended use case. Completeness is assessed against expected source procedures, and auditable metadata; and timeliness by setting refresh fre

Development of high-quality, scaled, EHR-based RWD requires integration of systematic processes across the data lifecycle. Approaches to quality are optimized through knowledge of data sources, curation processes, and use case needs. By addressing quality dimensions from published frameworks, Flatiron

Fine-tuned LLMs accurately extracted complex biomarker testing details and results from unstructured clinical documents

- complex PD-L1 test details from the EHR despite considerable rariability in cancer type, documentation, and time.



Ref: Estevez et al. Cancers 2022; Castellanos et al. JCO CCI 2024; Kiyasseh et al, Nature Communications 2024; Cohen et al, ISPOR **Annual Meeting 2024**

Thank you

Questions? Email ecastellanos@flatiron.com

