Opportunities to Leverage Electronic Health Records in Clinical Evidence Generation

Incorporating Integrated Diagnostics into Precision Oncology Care: A Workshop National Cancer Policy Forum

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Disclosures

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Equity interest in Roche

The Problem for Diagnostics

- **Research**: Diagnostic modalities historically lack investment to ensure optimal evidence generation
- **Complexity**: Advances in technology are driving a wealth of new diagnostic tools
- **Decision making**: These tools often enter the clinic with incomplete guidance for their use
  - Clinicians may not know what to order
  - Clinicians may not know how to interpret results

For every patient…

Screening
Who should I screen?
How should I screen them?

Treatment
What biomarker can guide therapy?

Diagnosis
What is the best test?

Follow Up
What is the best surveillance strategy?

Test Performance
Sensitivity/Specificity/PPV/NPV
Cost
Convenience
Interpretability

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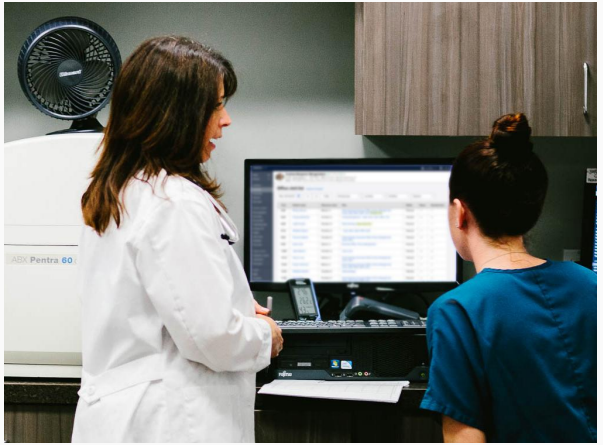
Then

Now



EHRs were not built for research

However…

- **Rich source** of patient-level data
- **Integrate** multiple data sources
- **Real-time** documentation
- **Digital** information
- Key component of **point-of-care workflow**
- **Representative** of all patients

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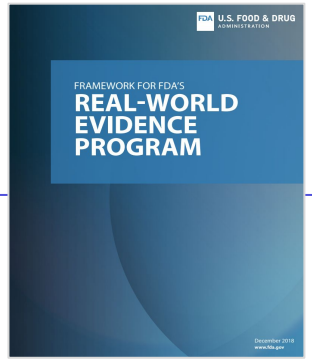
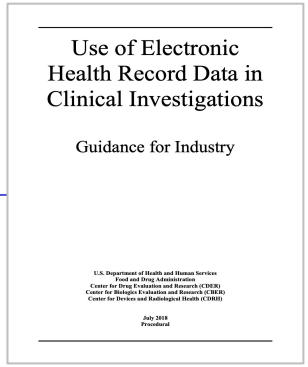
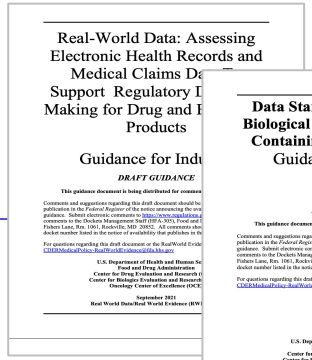
Recent FDA Draft Guidances Outline Key Considerations in Using EHR/Real-World Data for Research

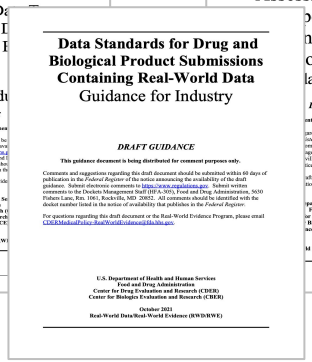
2018

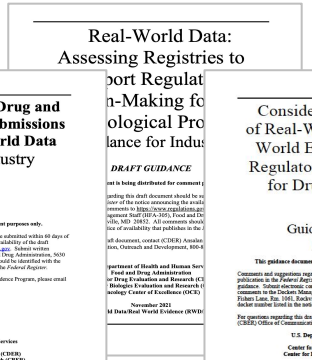


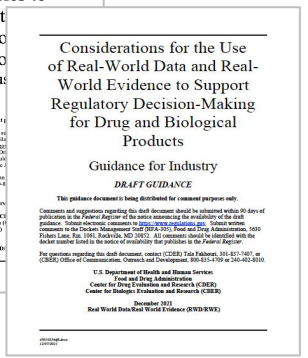


2021

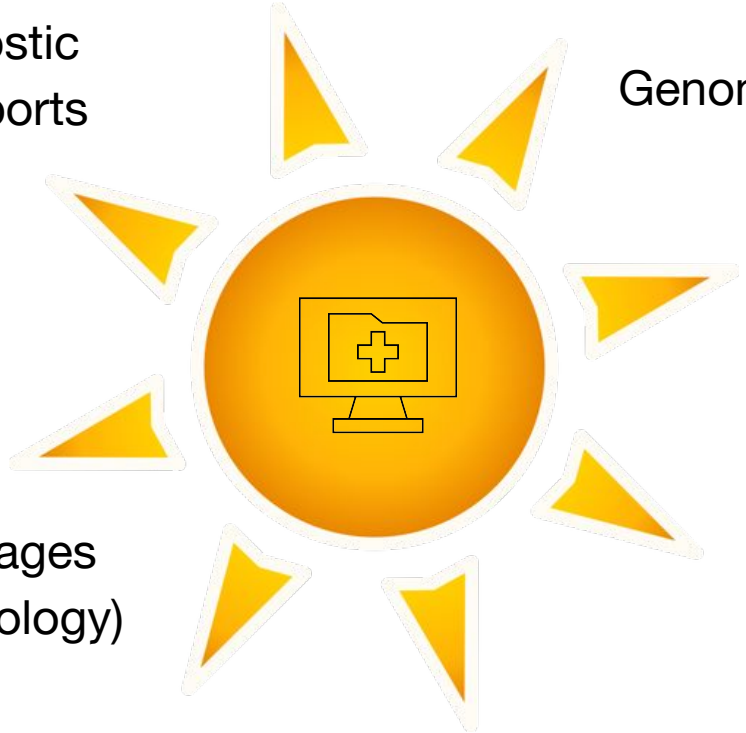








The EHR as a Platform for Integrating Evidence



Diagnostic test reports

Genomic data

Patient reported data

Insurance Claims

Wearables

Diagnostic Images (radiology/pathology)

SES / SDoH / Geocoding

Mortality

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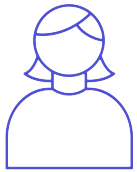
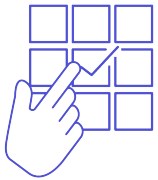
“Table Stakes” for use of EHRs in Integrating Evidence



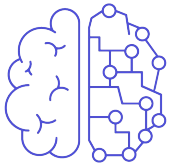
Privacy framework that respects patients



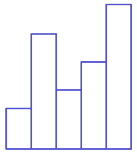
Curation capabilities for structured & unstructured data

Real-time EHR data access

Linkage / tokenization for data not documented in the EHR



Careful application of ML and NLP

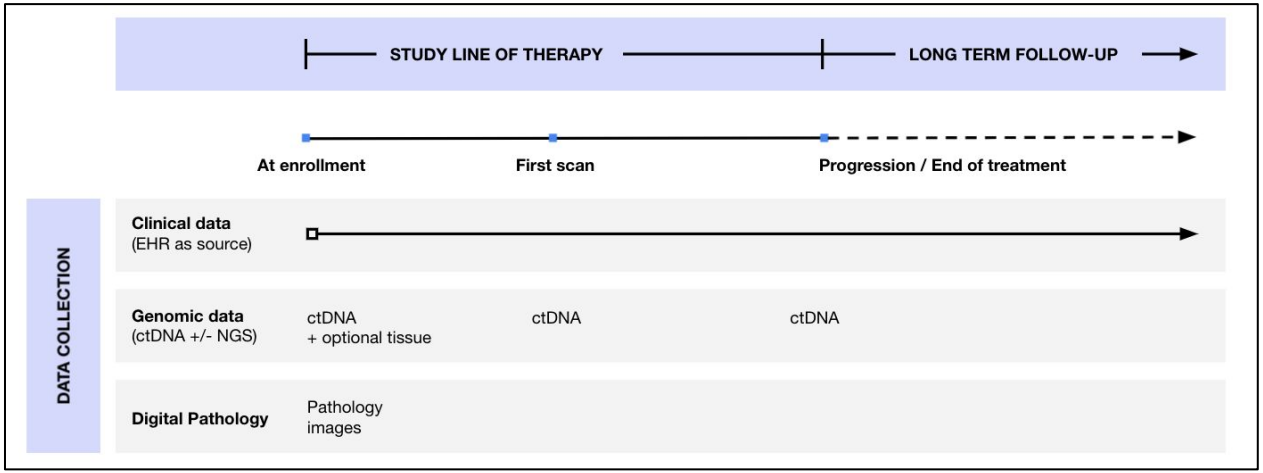


Relentless appetite for context-specific characterization of data quality and fitness-for-purpose

“Passively” collected data is not always enough

- **Routinely collected** data may not be fit-for-purpose to address all evidence gaps
  - Missingness, selection / confounding biases, causal inference, outcome measurement, exposure variability
- **Intentionally collected** data can be implemented to support specific research questions, e.g.
  - Non-routine diagnostic / monitoring tests
  - Prespecified testing modalities or intervals
  - Patient-reported outcomes

Case Study: A Prospective Clinico-genomic Study in Patients with Advanced Lung Cancer

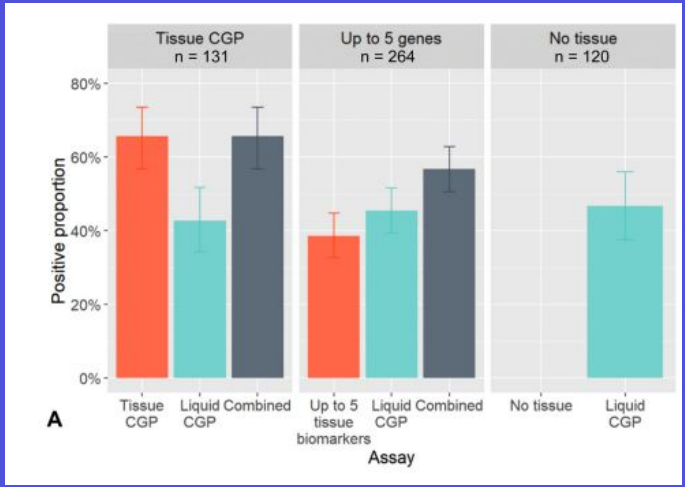


- ~1000 patients enrolled to “low interventional” study
- Tech-enabled ascertainment
- Centralized EHR-based data collection and processing
- Routine + intentional data collection

Lu MW et al. ASCO 2020; Schwartzberg LS et al. J Thoracic Oncol,
Chiang A et al. WCLC, 2022; Bourla A. J Precision Med, 2022

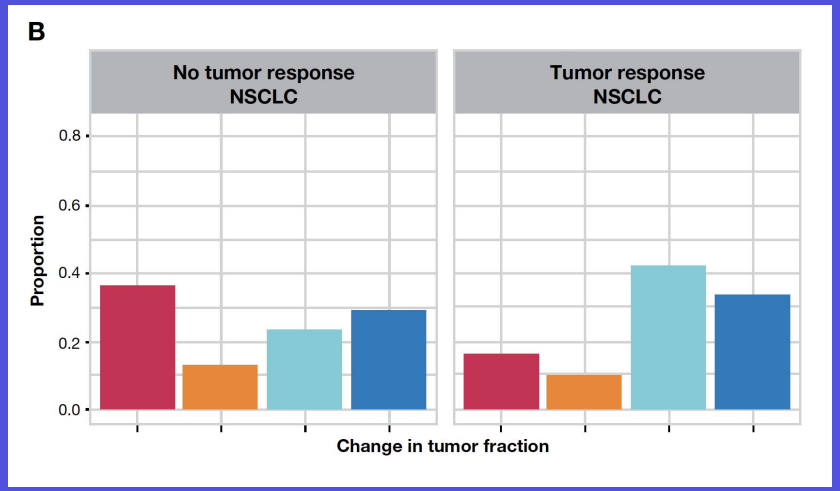
Insights from a Prospective Real-World Study on an EHR-Based Platform in Patients with NSCLC

Complementary Roles for Tissue- and Blood-Based Genomic Profiling



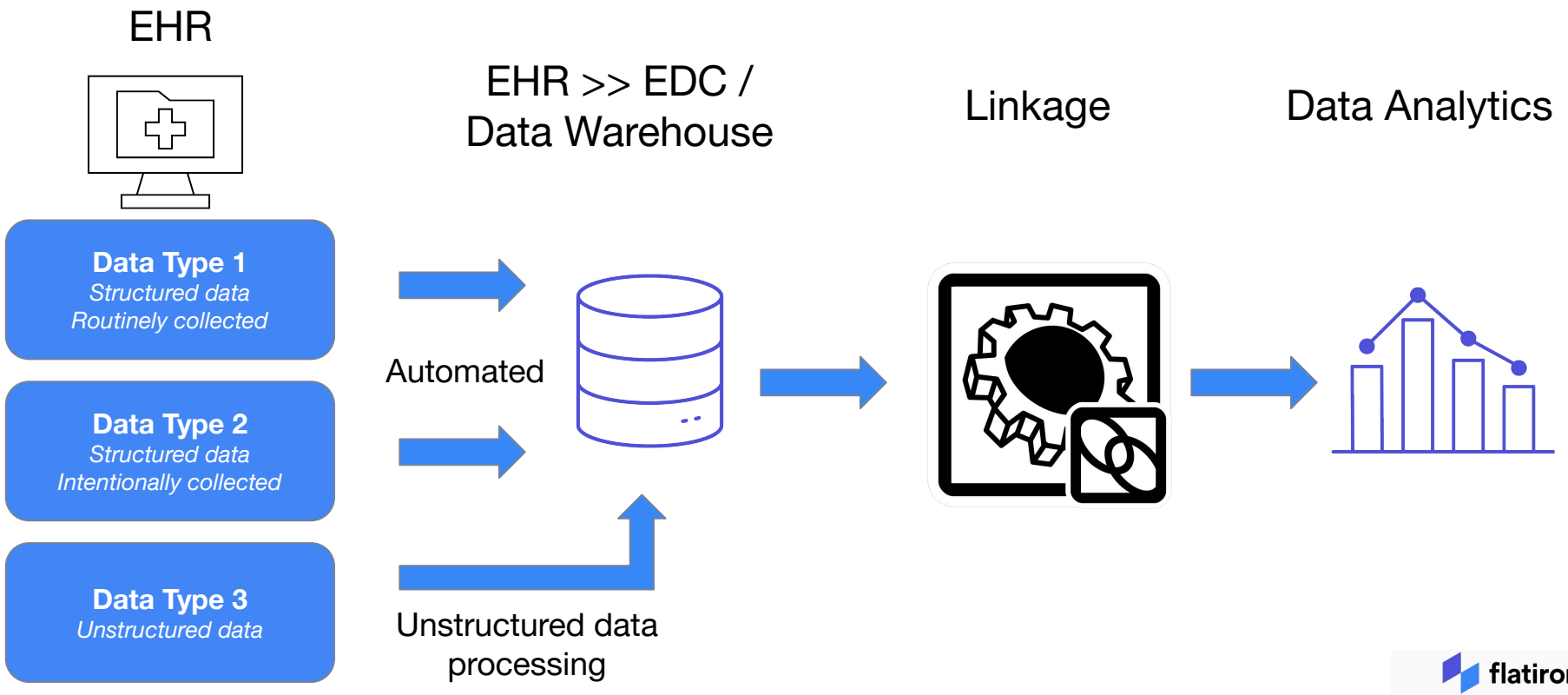
LS Schwatrzberg et al. JTO Clinical and Res Reports, 2022

Association of ctDNA with rwResponse



Chiang AC et al, WCLC, 2022

Getting from EHR to Evidence:
What does this mean operationally?



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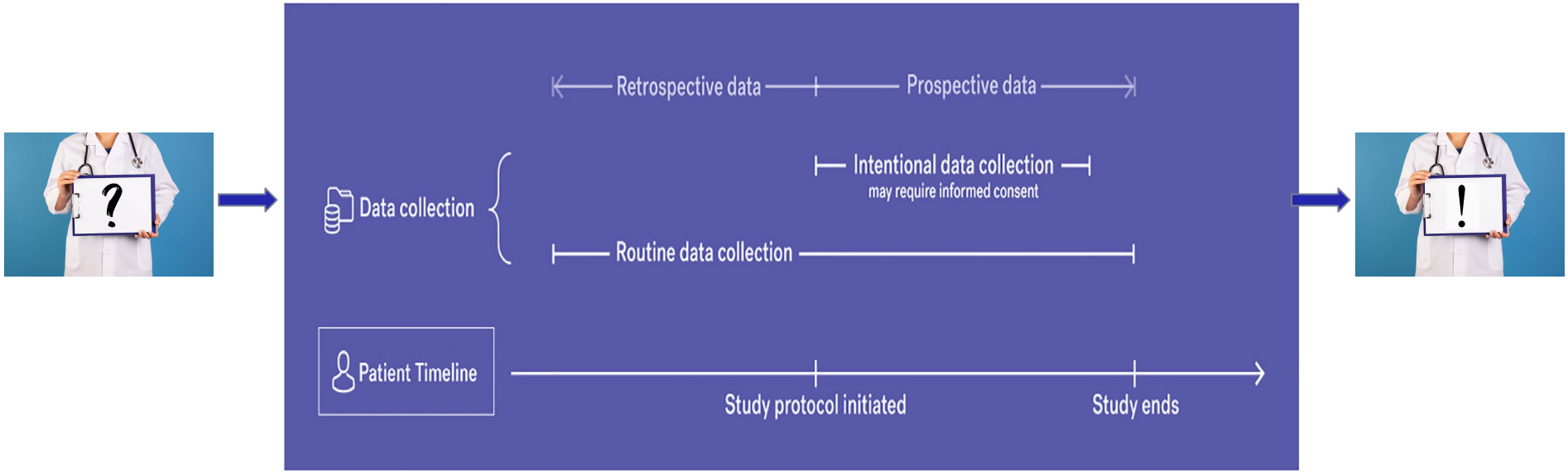
A platform for real-time learning



Bourla and Meropol, Digital Health, 2021

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Tools Exist Today

- ML-based cohort selection / automated patient ascertainment
- Structured and unstructured data processing
- Research-oriented data collection tools embedded in EHR
- Automated transfer of EHR > EDC
- Tokenization and linkage of EHR-based data with external sources


Thank You
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