

# Leveraging electronic health records to narrow the divide between research and practice

National Cancer Policy Forum Opportunities and Challenges for Using Digital Health Applications in Oncology: A Virtual Workshop

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## The Challenge

Traditional evidence generation platforms cannot meet the demand for evidence in oncology Clinical trials remain the gold standard, but:

- Current clinical trials infrastructure is cumbersome, costly, and inefficient
- Patients must often travel to participate in research
- Traditional clinical trials are infeasible for rare populations
- Patients enrolled in clinical trials are often not representative of overall cancer population
- Historically, real-world data sources have been most appropriate for hypothesis generation

# A solution:

# EHR-based platforms for the integration of research and practice

# What has changed?

#### Supply

Health Information Technology for Economic and Clinical Health (HITECH) Act

Privacy and Security Provisions

(Subtitle D of Title XIII of Division A of the American Recovery and Reinvestment Act (ARRA) of 2009)





#### Demand



#### COVID-19 and the Need for a National Health Information Technology Infrastructure

FREE

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JAMA. 2020;323(23):2373-2374. doi:10.1001/jama.2020.7239

# Policy FDA U.S. FOOD & DRUG FRAMEWORK FOR FDA'S **REAL-WORLD EVIDENCE** PROGRAM

#### 21st Century Cures Act

EHR-based technologies can enable real-time assessment of treatment patterns and outcomes Case Study: PD-1 Inhibitors in Patients with Advanced Non-Small Cell Lung Cancer



How can a real-world data infrastructure support evidence generation in the context of clinical trials?



Case Study: Clinical Trial Patient Ascertainment (aka "Trial Matching")

- Requires digitization of eligibility criteria
- Key criteria not currently available in oncology records as structured data
- Novel analytic approaches can help

	TOTAL, N	Metastatic, n		Non-Metastatic, n			Sensitivity, %	Specificity, %	PPV, %	NPV,
		High-Likely	Likely	Likely	High-likely	Unknown, n				
Overall	66,532	7964	9543	8207	40,111	707	82.4	95.5	89.3	94.0
Tumor type										
Bladder Ca.	3268	132	574	1475	889	198	61.5	97.6	92.4	88.
Breast Ca.	22543	1342	1231	0	19970	0	84.5	98.6	89.3	97.
CRC	10589	1261	1707	728	6893	0	84.5	96.3	90.8	93.
Melanoma	7748	109	1698	1478	4362	101	70.2	96.5	90.8	89.
NSCLC	13554	3013	3151	3490	3492	408	84.0	86.4	87.3	88.
Prostate Ca.	6074	1363	1016	704	2991	0	92.6	93.4	89.5	95.
RCC	2756	744	166	332	1514	0	88.1	95.9	91.9	93.

Machine Learning can be applied to identify patients with metastatic disease (Kirshner et al. ASCO 2020)

# Case Study: Association of FDA Label Restriction with Treatment Patterns in Patients with Bladder Cancer

The value of real-time assessment



Parikh RB et al. JAMA. 2019

## Learnings during a pandemic



Bobby Green, Flatiron Health, "ASCO-ONS Webinar Series: May 28, Data Insights on the Impact of COVID-19 Pandemic on Cancer Care," May 28, 2020. An opportunity for decentralized clinical trials

- Patient data may be collected in real time
- Centralized data collection is feasible
- Telemedicine can scale

# Case Study: A Prospective Clinico-genomic Study in Patients with Advanced Non Small Cell or Small Cell Lung Cancer



#### Primary objective: feasibility

- Secondary objective: ctDNA biomarker exploration
- "Routine" and "Intentional" data collection
- Clinical, genomic, and imaging data

#### Lu MW et al. ASCO 2020.

Bridging the chasm between research and practice



### Interventional Research

## Key Requirements

- Common data model
- Interoperability
- Transparent adherence to regulatory and ethical frameworks
- Data quality standards
- Stakeholder collaboration

Thank you

