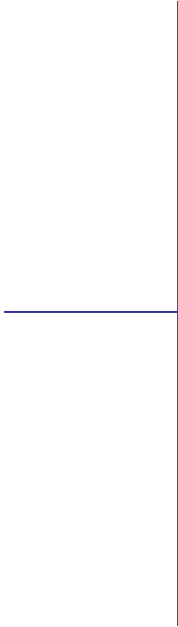


Marrying Connected Platforms and Data Science to Change the Paradigm of RWE Generation

Deepti Jaggi, PharmD, MBA
President & Chief Medical Officer, Clinakos Inc.

Agenda



21st Century Cures Act

Current Methodologies and Gaps

Proposed Solution

Case Studies

Enabling a Better Patient Outcome Everyday



The 21st Century Cures Act



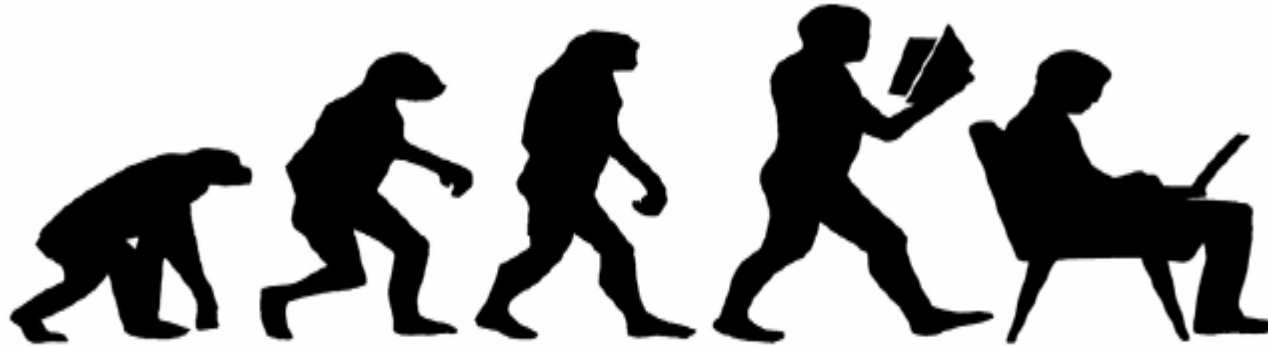
Real World Data (RWD)- “Fit for Use”

Complete
Connected
Granular
Structured
Longitudinal
Integrated
Quality

Real World Evidence (RWE)- Relevant Study Designs

Source: Framework for FDAs Real World Evidence Program, Dec 2018

Patient Data Has Evolved Over the Years



Account Level Data

Raw Sales
No link to HCP
No regimen information
Across all indications

Prescriber Profiles

Specialty pharmacy data
Across all indications
Masking
No regimens or disease information

Claims Data

Some linking
Hospitalizations
Links to HCP
What happens when patient changes insurance?

EMR Data

Holy grail?
Rich insights on diagnosis
One physician or HC system
What about co-morbidities and outcomes?

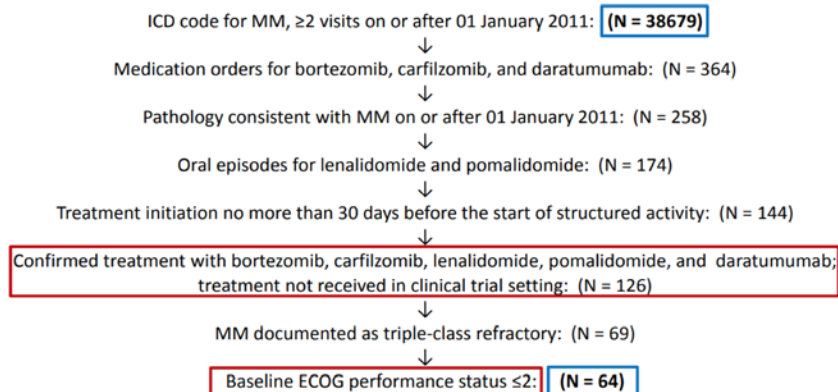
Integrated Patient Data

Diagnoses
Meds, Labs
Hospitalizations
Others- devices, wearables, questionnaires, PROs



But There are Issues with Current RWD Approaches

KS-50039: Flatiron (FHAD) Population



www.fda.gov

Abbreviations: FHAD = Flatiron Health Analytic Database; ECOG = Eastern Cooperative Oncology Group

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KS-50039: Baseline Characteristics



Parameter	FHAD (N = 64)	STORM (N = 122)
ECOG Status, n (%)		
Missing	20 (31.3)	3 (2.5)
0	4 (6.3)	37 (30.3)
1	33 (51.6)	71 (58.2)
2	7 (10.9)	11 (9.0)
Carfilzomib, pomalidomide, and daratumumab refractory prior to index date, n (%)		
# prior regimens before index date, median	5	7
Daratumumab as last line prior to index date, n (%)	43 (67.2)	58 (47.5)
Stem cell transplant prior to index date, n (%)	38 (59.4)	102 (83.6)

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Source: FDA ODAC February 2019

A New Paradigm is Needed

A rocket is shown launching from the bottom left, leaving a long, bright white trail of smoke and fire. The rocket is heading towards the upper right, where a large, blue, textured planet or moon is visible. The background is a solid blue color.

Prospectively select patients you'd like to follow

Get complete 360° medical data on those patients

Join the data

Analyze

Case Studies

Thank You



2225 East Bayshore Rd., Suite 200

Palo Alto, CA 94303

www.clinakos.com

deepti.jaggi@clinakos.com