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The Power Behind the Cure

From Real World to Real Evidence

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The RWE Landscape

TriNetX

CLINERION
Real World Data Solutions

inato

CPRD

AETION

Concerto
HealthAI

Clinical Pharmacology & Therapeutics

State of the Art

When and How Can Real World Data Analyses Substitute for Randomized Controlled Trials?

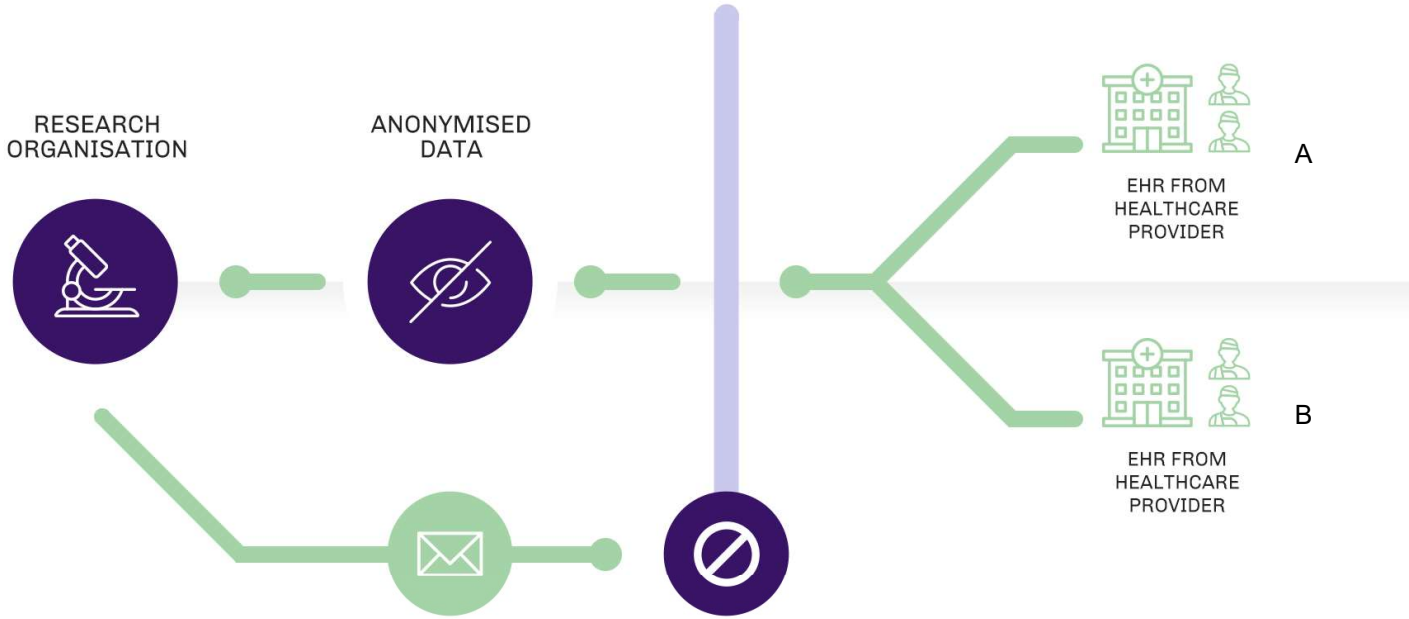
Jessica M. Franklin, Sebastian Schneeweiss

Volume 102, Issue 6
Innovative Clinical Trial Design
December 2017
Pages 924-933

The core problem

Anonymisation of data prevents patients and their clinicians from being centrally engaged

Consequently, individual sites are burdened with managing studies and associated manual patient interactions, with huge cost, time and capacity impacts



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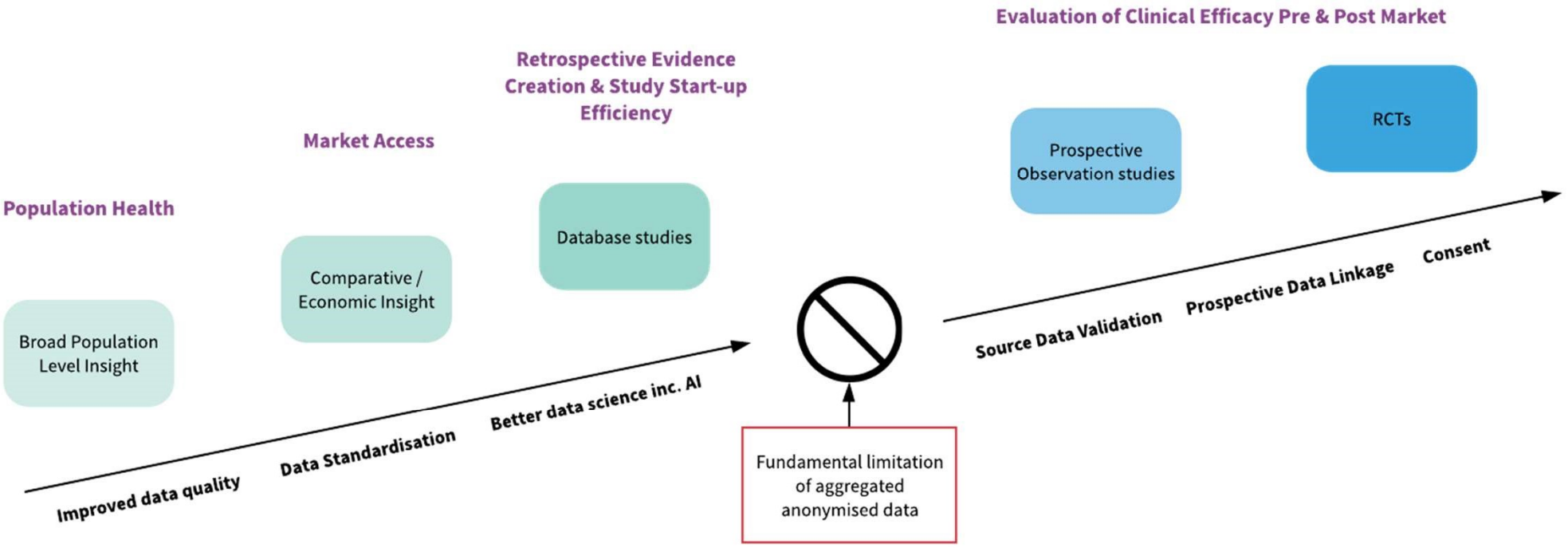
FDA View on RWE

“

The potential lack of up-front transparency, especially in retrospective observational study design and conduct, coupled with the fact that retrospective analyses in electronic datasets can be conducted multiple times relatively inexpensively with varying study design elements, makes it possible to conduct numerous retrospective studies until the desired result is obtained and then submit only favorable results as if they were the result of a single study with a prespecified protocol.

Limitation of Real World Data



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uMed uses EHR data to unlock *automated* end-to-end research capability

Rapid case finding
& e-consent

FIND Patients

Remotely captures data from the patient and links to real-time electronic health records

GATHER data

Monitors patients and sites in real-time across and international network

MANAGE studies

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Oxford COVID Testing Study

- Identification of high risk cohorts (Elderly & comorbid)
- Automated engagement, screening and e-consent on behalf of recognised GP
- Link e-PRO data to EHR outcomes for long term follow up and re-targeting

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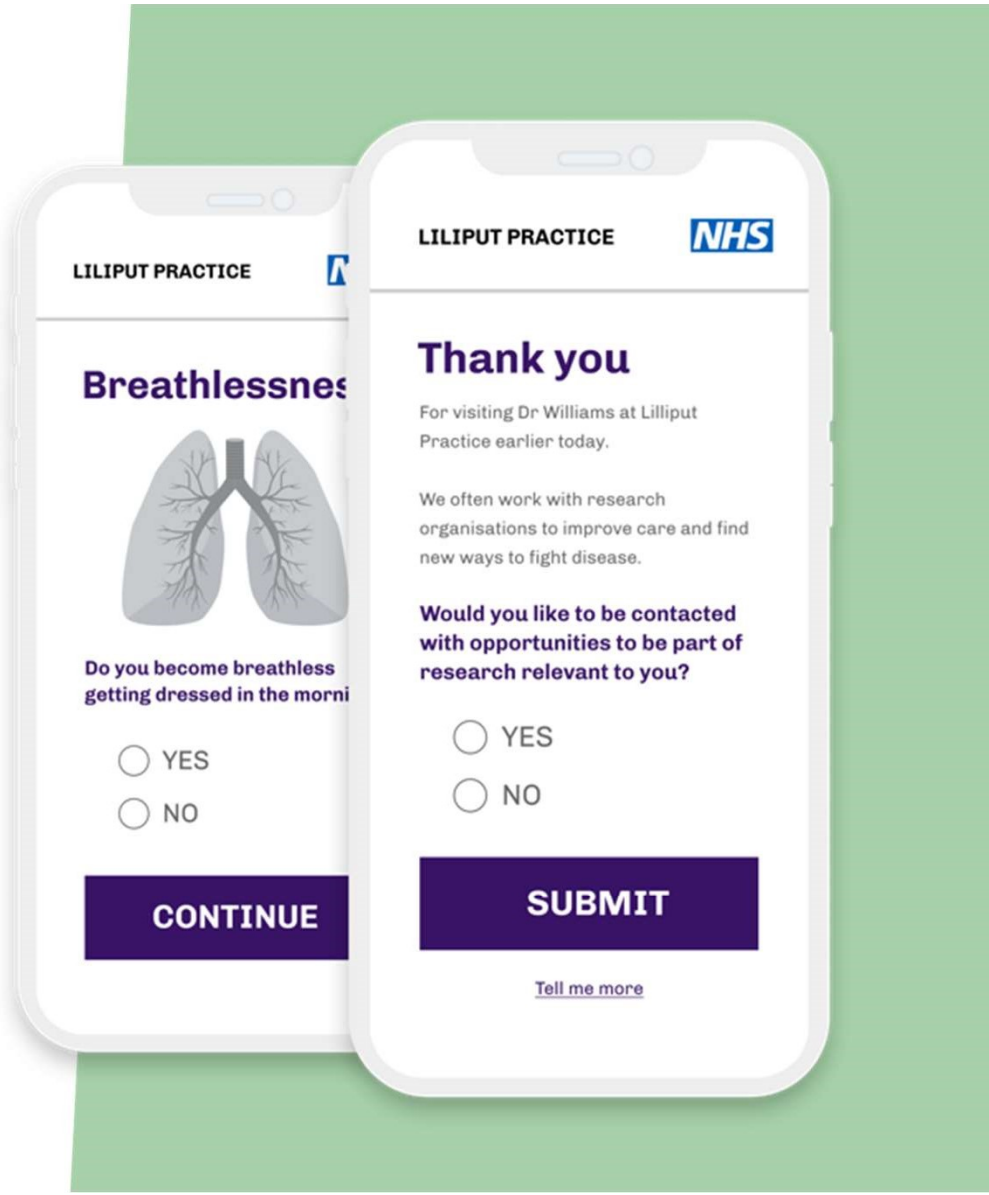

Beyond RWE to Integrated Clinical Evidence

From Discovery…

- Identification of rare disease patients
- Remote consent to home genomic testing
- Linkage of genomic data to EHR/ePRO

…To Post-Market

- Case finding of patients on a specific immunotherapy
- Automated engagement for consent & ePRO
- Linkage to EHR record with source data validation

+ re-engage study cohort and access outcome data beyond study period

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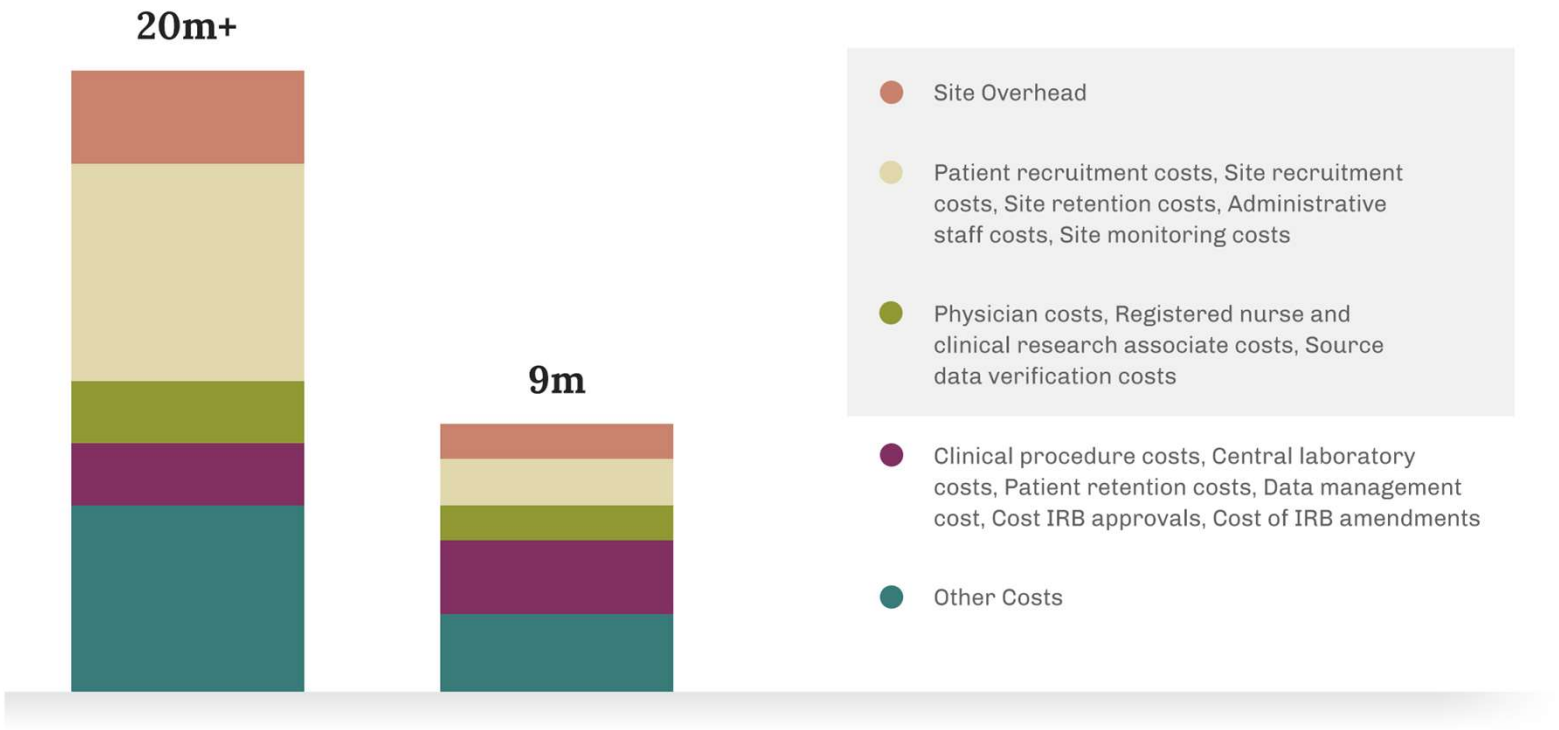
Disruptive Efficiency

Removing manual ‘site-level’ process to radically reduce cost and time of studies



*Data from a report to U.S. Department of Health and Human Services by Sertkaya et al (2014)

UMED'S GLOBAL NETWORK

- **800,000** patients across 74 UK sites today
- 1st US Health System live in H1 2020 = **2M more** patients
- EHR Partnership providing access to further **30M+ UK patients**

VALIDATION

Multiple studies with world leading institutions including:

- ✓ Oxford University
- ✓ Queen Mary's University of London

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HEALTH SCIENCES
Medical Sciences Division

Queen Mary
University of London

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