CardinalHealth™

Unlocking the potential of routine patient health records for RWE

A RWE reality check

May 15, 2025

Speakers

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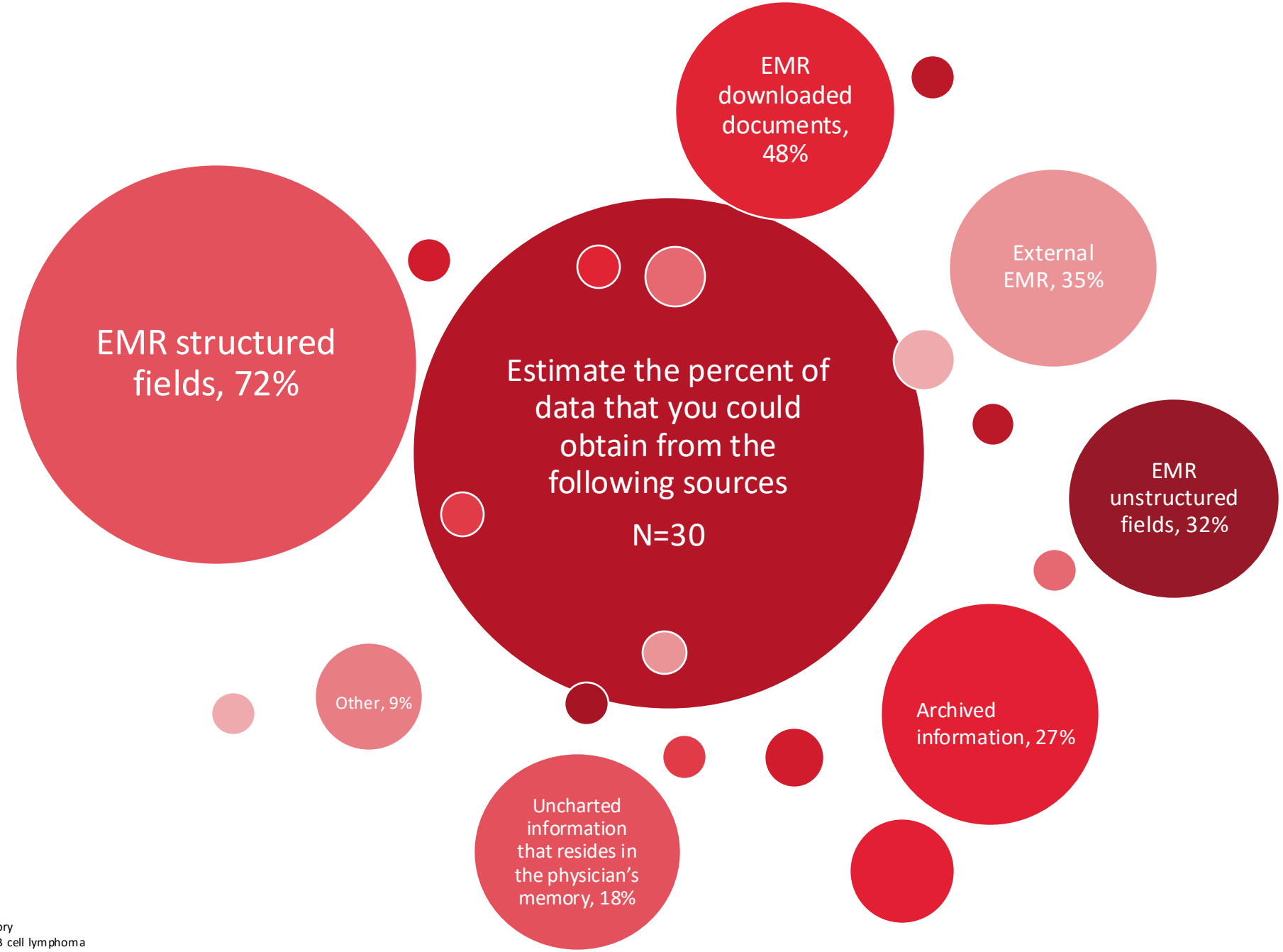


r/r: relapsed, refractory
DLBCL: Diffuse large B cell lymphoma

Craig, C. ONC (2025). Oncology Provider Extended Network Feasibility ONC 2025#1; DLBCL. [Unpublished raw data] Cardinal Health.

Feasibility example: AML Patients

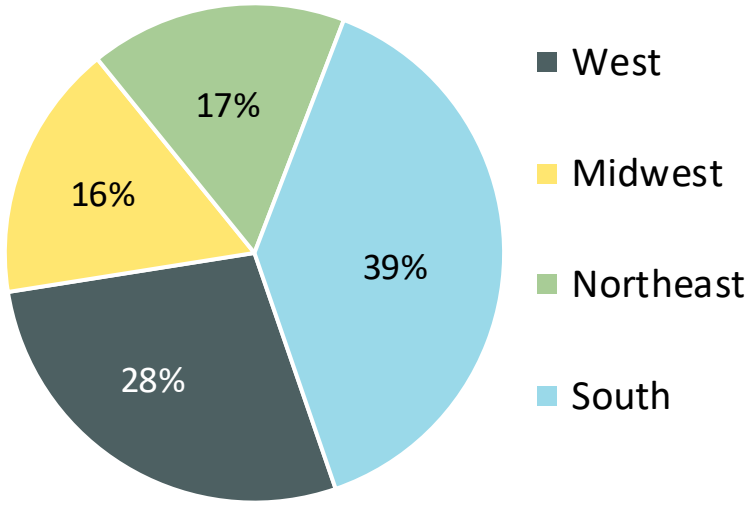
Respondent demographics

Among the **41 physicians** who responded, **36 (88%)** reported having personally treated or managed patients with **acute myeloid leukemia (AML)** in the past year

Board Certified/Eligible Medical Specialty	
Medical oncology	97%
Hematology	78%
Radiation oncology	0%
Gynecological oncology	0%
Pediatric hematology/oncology	0%
Surgical oncology	0%
Other	0%

Primary practice setting	
Solo practitioner	0%
Small private community practice (2-5 physicians)	28%
Medium-sized private community practice (6-10 physicians)	31%
Large private community practice (>10 physicians)	25%
Community practice owned by an academic center	6%
Academic medical center	8%
Affiliated teaching hospital	3%
VA/military hospital/DoD	0%
Other	0%

Region of primary practice



*Total > 100 due to rounding; **17% of total from private community practices owned by a hospital

DISCLAIMER: Patient counts are self-reported estimates and may be under or over reported. Reported patient counts may include clinical trial participants. Physicians are not compensated for their responses.

**Note: base sizes may be reduced due to removal of outliers.*

Data from Cardinal Health Oncology feasibility assessment. February 2024.

AML Patients

Of the 950 AML patients, the following were **ineligible for intensive chemotherapy and had the following mutation**:

Mutation:	# of Physicians Reporting	Total # of Patients	Average # of Patients per Provider	SD of # Patients per Provider	Range *(min-max)*
FLT3 (FLT3-ITD or FLT-TKD)	32	185	5.8	5.3	1-20
IDH1 or IDH2	32	161	5	4.5	1-15
All others (no actionable mutations/unknown mutational status)	32	371	11.6	7.3	1-30

ROID	Question	Value	PSET
ONC04052	FLT3	30	Academic medical center
	IDH1/2	15	
	Others	55	
ONC00032	FLT3	24	Medium-sized private community practice (6-10 physicians)
ONC11013	FLT3	25	Medium-sized private community practice (6-10 physicians)
ONC00448	IDH1/2	25	Small private community practice (2-5 physicians)
ONC00261	Others	40	Community practice owned by an academic center

S3_2 (n=35) Of those AML patients, approximately how many were ineligible for intensive chemotherapy and had the following mutation
*1 outlier removed for S3_1 > 84; 2 removed for `FLT3` > 23; 1 removed for `IDH1/2` > 19; 1 removed for `Others` > 34

DISCLAIMER: Patient counts are self-reported estimates and may be under or over reported. Reported patient counts may include clinical trial participants. Physicians are not compensated for their responses.
**Note: base sizes may be reduced due to removal of outliers.*

Data from Cardinal Health Oncology feasibility assessment. February 2024.

AML Patients

Of the 185 AML patients with FLT3 mutations and ineligible for intensive chemotherapy, the following **induction therapies** were reported:

Treated with:	# of Physicians Reporting	Total # of Patients Treated	Average # of Patients per Provider	SD of # Patients per Provider	Range *(min-max)*
HMA monotherapy	9	15	1.7	1	1-4
Gilteritinib + HMA	16	42	2.6	2.6	1-8
Sorafenib +/- HMA	4	12	3	2.2	1-6
Venetoclax + HMA	23	65	2.8	2.5	1-12
Venetoclax + LDAC	8	20	2.5	1.9	1-6
Other	1	1	1	-	1-1

ROID	Question	Value	PSET
ONC04052	Gilt	8 (25%)	Academic medical center
	Ven + HMA	23 (75%)	
ONC00032	HMA mono	16 (65%)	Medium-sized private community practice (6-10 physicians)
	Ven + HMA	8 (35%)	
ONC11013	Gilt	3 (10%)	Medium-sized private community practice (6-10 physicians)
	Ven + HMA	5 (20%)	
	Ven + LDAC	3 (10%)	
	Other	15 (60%)	
ONC00461	Gilt	15 (100%)	Large private community practice (>10 physicians)
ONC00816	Ven + HMA	18 (90%)	Community practice owned by an academic center

S3_3 (n=32) Of those AML patients with FLT3 mutations and ineligible for intensive chemotherapy, approximately what percentage were treated with the following as induction therapy *1 outlier removed for S3_1 > 84; 2 removed for `FLT3` > 23; 1 removed for `Gilt` > 13; 1 removed for `Ven + HMA` > 13

DISCLAIMER: Patient counts are self-reported estimates and may be under or over reported. Reported patient counts may include clinical trial participants. Physicians are not compensated for their responses.

**Note: base sizes may be reduced due to removal of outliers.*

Data from Cardinal Health Oncology feasibility assessment. February 2024.

AML Patients

Of the 161 AML patients with IDH1/2 mutations and ineligible for intensive chemotherapy, the following **induction therapies** were reported:

Treated with:	# of Physicians Reporting	Total # of Patients Treated	Average # of Patients per Provider	SD of # Patients per Provider	Range *(min-max)*
HMA monotherapy	4	5	1.3	0.5	1-2
Enasidenib +/- HMA	18	41	2.3	1.8	1-6
Ivosidenib +/- HMA	19	44	2.3	1.6	1-6
Venetoclax + HMA	18	52	2.9	2.1	1-8
Venetoclax + LDAC	4	6	1.5	0.6	1-2
Other	1	8	8	-	8-8

ROID	Question	Value	PSET
ONC04052	Enas	2 (15%)	Academic medical center
	Ivo	2 (10%)	
	Ven + HMA	11 (75%)	
ONC00448	HMA mono	4 (15%)	Small private community practice (2-5 physicians)
	Enas	3 (10%)	
	Ivo	5 (20%)	
	Ven + HMA	8 (30%)	
	Ven + LDAC	6 (25%)	
ONC00461	Ivo	12 (100%)	Large private community practice (>10 physicians)

S3_4 (n=32) Of those AML patients with IDH1/2 mutations and ineligible for intensive chemotherapy, approximately what percentage were treated with the following as induction therapy *1 outlier removed for S3_1 > 84; 2 removed for `IDH1/2` > 19; 1 removed for 'Ivo' > 9

DISCLAIMER: Patient counts are self-reported estimates and may be under or over reported. Reported patient counts may include clinical trial participants. Physicians are not compensated for their responses.

**Note: base sizes may be reduced due to removal of outliers.*

Data from Cardinal Health Oncology feasibility assessment. February 2024.

AML Patients

Of the 371 AML patients with no actionable mutations/unknown mutational status and ineligible for intensive chemotherapy, the following **induction therapies** were reported:

Treated with:	# of Physicians Reporting	Total # of Patients Treated	Average # of Patients per Provider	SD of # Patients per Provider	Range *(min-max)*
HMA monotherapy	17	55	3.2	2.8	1-12
LDAC	4	11	2.8	2.4	1-6
Glasdegib + LDAC	4	11	2.8	2.9	1-7
Gemtuzumab ozogamicin monotherapy	4	6	1.5	0.6	1-2
Venetoclax + HMA	30	236	7.9	5.4	1-20
Venetoclax + LDAC	7	20	2.9	1.7	1-5
Other	0	0	-	-	-

ROID	Question	Value	PSET
ONC04052	Ven + HMA	55 (100%)	Academic medical center
ONC00261	HMA mono	4 (10%)	Community practice owned by an academic center
	Glas	16 (40%)	
	Gem	8 (20%)	
	Ven + HMA	8 (20%)	
	Ven + LDAC	4 (10%)	
ONC00032	HMA mono	16 (55%)	Medium-sized private community practice (6-10 physicians)
ONC10967	Ven + HMA	24 (80%)	Large private community practice (>10 physicians)

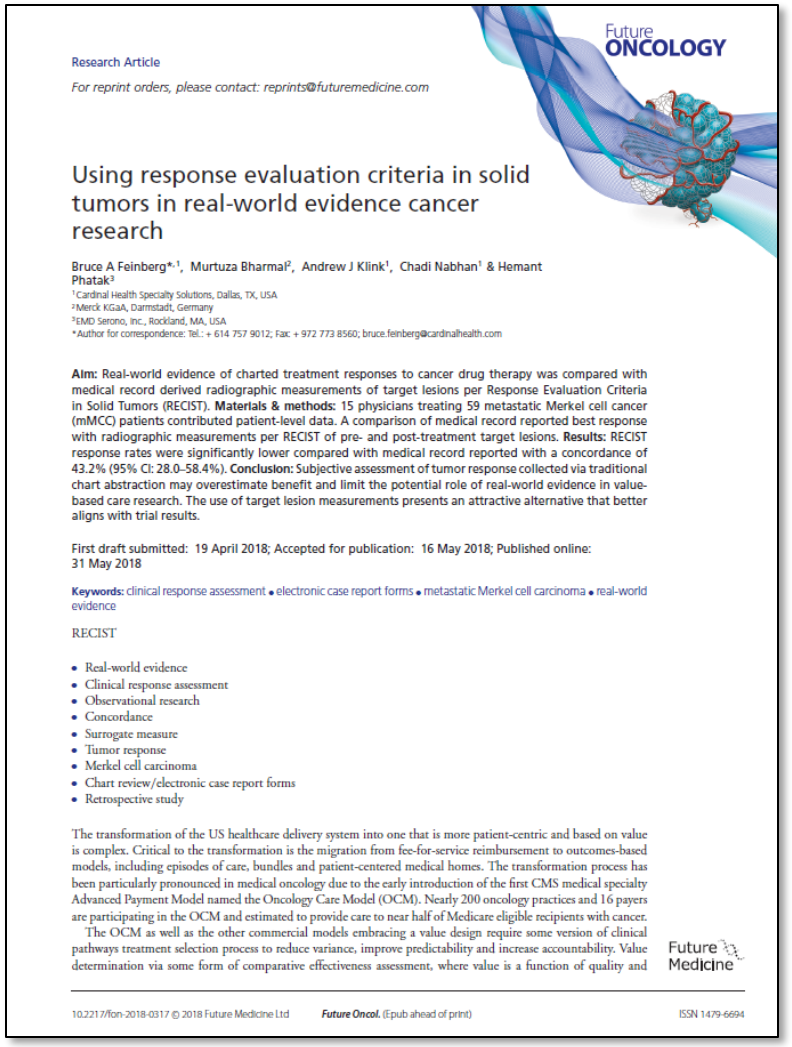
S3_5 (n=32) Of those AML patients with no actionable mutations/unknown mutational status and ineligible for intensive chemoth erapy, approximately what percentage were treated with the following as induction therapy *1 outlier removed for S3_1 > 84; 1 removed for `No/Unkn own mut` > 34; 1 removed for 'HMA mono' > 14; 1 removed for 'Ven + HMA' > 23

DISCLAIMER: Patient counts are self-reported estimates and may be under or over reported. Reported patient counts may include clinical trial participants. Physicians are not compensated for their responses.

**Note: base sizes may be reduced due to removal of outliers.*

Data from Cardinal Health Oncology feasibility assessment. February 2024.

rwRECIST



Future ONCOLOGY

Research Article

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Using response evaluation criteria in solid tumors in real-world evidence cancer research

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Aim: Real-world evidence of charted treatment responses to cancer drug therapy was compared with medical record derived radiographic measurements of target lesions per Response Evaluation Criteria in Solid Tumors (RECIST). **Materials & methods:** 15 physicians treating 59 metastatic Merkel cell cancer (mMCC) patients contributed patient-level data. A comparison of medical record reported best response with radiographic measurements per RECIST of pre- and post-treatment target lesions. **Results:** RECIST response rates were significantly lower compared with medical record reported with a concordance of 43.2% (95% CI: 28.0–58.4%). **Conclusion:** Subjective assessment of tumor response collected via traditional chart abstraction may overestimate benefit and limit the potential role of real-world evidence in value-based care research. The use of target lesion measurements presents an attractive alternative that better aligns with trial results.

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Keywords: clinical response assessment • electronic case report forms • metastatic Merkel cell carcinoma • real-world evidence

RECIST

- Real-world evidence
- Clinical response assessment
- Observational research
- Concordance
- Surrogate measure
- Tumor response
- Merkel cell carcinoma
- Chart review/electronic case report forms
- Retrospective study

The transformation of the US healthcare delivery system into one that is more patient-centric and based on value is complex. Critical to the transformation is the migration from fee-for-service reimbursement to outcomes-based models, including episodes of care, bundles and patient-centered medical homes. The transformation process has been particularly pronounced in medical oncology due to the early introduction of the first CMS medical specialty Advanced Payment Model named the Oncology Care Model (OCM). Nearly 200 oncology practices and 16 payers are participating in the OCM and estimated to provide care to near half of Medicare eligible recipients with cancer.

The OCM as well as the other commercial models embracing a value design require some version of clinical pathways treatment selection process to reduce variance, improve predictability and increase accountability. Value determination via some form of comparative effectiveness assessment, where value is a function of quality and

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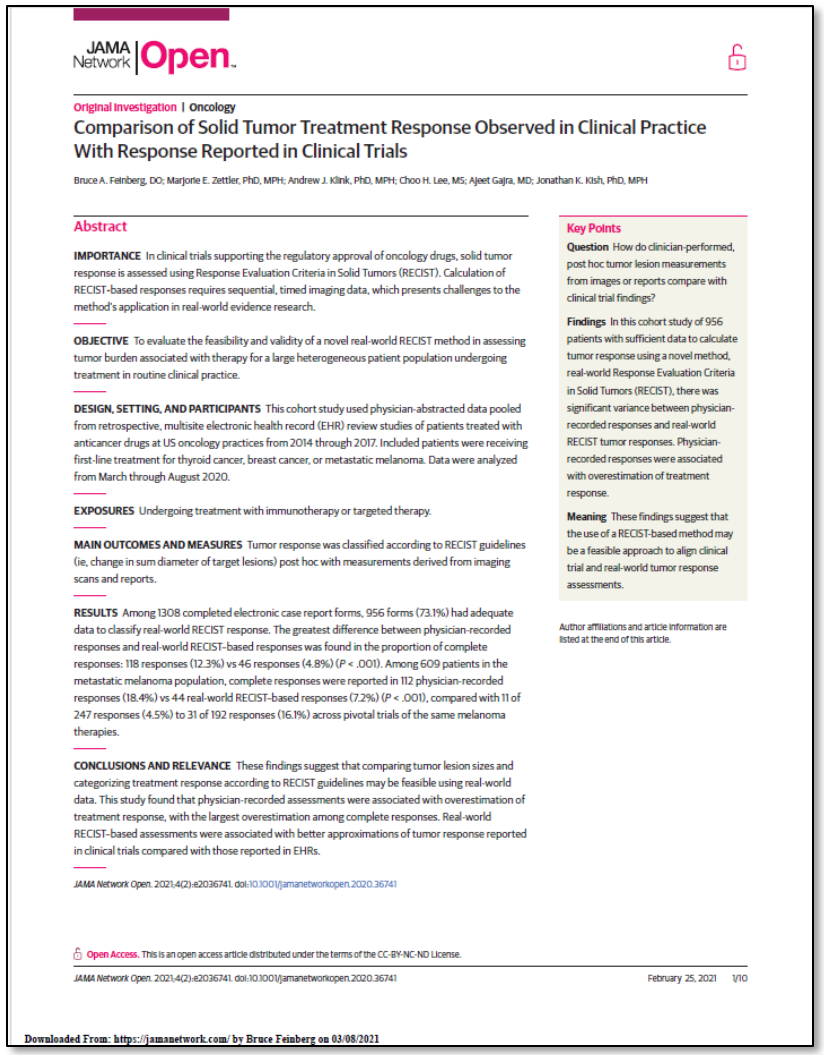
Table 3. Treatment response by assessment method.

RECIST criteria (n)	Physician-reported best response (n)				
	CR	PR	SD	PD	Total
CR	0	3	0	0	3
PR	2	13	0	0	15
SD	0	8	3	1	12
PD	0	10	1	3	14
Total	2	34	4	4	44

CR: Complete response; PD: Progressive disease; PR: Partial response; SD: Stable disease.

Feinberg, B. A., Bharmal, M., Klink, A. J., Nabhan, C., & Phatak, H. Using Response Evaluation Criteria in Solid Tumors in Real-World Evidence Cancer Research. *Future Oncology*, *14*(27), 2841–2848. https://doi.org/10.2217/fon-2018-0317

Validating physician-charted response



JAMA Network Open.

Original Investigation | Oncology

Comparison of Solid Tumor Treatment Response Observed in Clinical Practice With Response Reported in Clinical Trials

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Abstract

IMPORTANCE In clinical trials supporting the regulatory approval of oncology drugs, solid tumor response is assessed using Response Evaluation Criteria in Solid Tumors (RECIST). Calculation of RECIST-based responses requires sequential, timed imaging data, which presents challenges to the method's application in real-world evidence research.

OBJECTIVE To evaluate the feasibility and validity of a novel real-world RECIST method in assessing tumor burden associated with therapy for a large heterogeneous patient population undergoing treatment in routine clinical practice.

DESIGN, SETTING, AND PARTICIPANTS This cohort study used physician-abstracted data pooled from retrospective, multisite electronic health record (EHR) review studies of patients treated with anticancer drugs at US oncology practices from 2014 through 2017. Included patients were receiving first-line treatment for thyroid cancer, breast cancer, or metastatic melanoma. Data were analyzed from March through August 2020.

EXPOSURES Undergoing treatment with immunotherapy or targeted therapy.

MAIN OUTCOMES AND MEASURES Tumor response was classified according to RECIST guidelines (ie, change in sum diameter of target lesions) post hoc with measurements derived from imaging scans and reports.

RESULTS Among 1308 completed electronic case report forms, 956 forms (73.1%) had adequate data to classify real-world RECIST response. The greatest difference between physician-recorded responses and real-world RECIST-based responses was found in the proportion of complete responses: 118 responses (12.3%) vs 46 responses (4.8%) ($P < .001$). Among 609 patients in the metastatic melanoma population, complete responses were reported in 112 physician-recorded responses (18.4%) vs 44 real-world RECIST-based responses (7.2%) ($P < .001$), compared with 11 of 247 responses (4.5%) to 31 of 192 responses (16.1%) across pivotal trials of the same melanoma therapies.

CONCLUSIONS AND RELEVANCE These findings suggest that comparing tumor lesion sizes and categorizing treatment response according to RECIST guidelines may be feasible using real-world data. This study found that physician-recorded assessments were associated with overestimation of treatment response, with the largest overestimation among complete responses. Real-world RECIST-based assessments were associated with better approximations of tumor response reported in clinical trials compared with those reported in EHRs.

Key Points

Question How do clinician-performed, post hoc tumor lesion measurements from images or reports compare with clinical trial findings?

Findings In this cohort study of 956 patients with sufficient data to calculate tumor response using a novel method, real-world Response Evaluation Criteria in Solid Tumors (RECIST), there was significant variance between physician-recorded responses and real-world RECIST tumor responses. Physician-recorded responses were associated with overestimation of treatment response.

Meaning These findings suggest that the use of a RECIST-based method may be a feasible approach to align clinical trial and real-world tumor response assessments.

Author affiliations and article information are listed at the end of this article.

JAMA Network Open. 2021;4(2):e2036741. doi:10.1001/jamanetworkopen.2020.36741

Table 1. Treatment Response by Assessment Method, Overall Patient Population

Physician-recorded responses	Real-world RECIST responses, No. (%)				Total physician-recorded responses
	CR	PR	SD	PD	
CR	43 (36.4)	65 (55.1)	6 (5.1)	4 (3.4)	118 (12.3)
PR	2 (0.4)	470 (82.3)	67 (11.7)	32 (5.6)	571 (59.7)
SD	1 (0.7)	20 (14.1)	109 (76.8)	12 (8.5)	142 (14.9)
PD	0 (0)	7 (5.6)	23 (18.4)	95 (76.0)	125 (13.1)
Total real-world RECIST-based responses	46 (4.8)	562 (58.8)	205 (21.4)	143 (15.0)	956 (100)

Feinberg, B. A., et al. Comparison of Solid Tumor Treatment Response Observed in Clinical Practice With Response Reported in Clinical Trials. *JAMA network open*, *4*(2), e2036741. https://doi.org/10.1001/jamanetworkopen.2020.36741

Matching endpoints

CLINICAL CANCER RESEARCH | CLINICAL TRIALS: IMMUNOTHERAPY

RE-MIND: Comparing Tafasitamab + Lenalidomide (L-MIND) with a Real-world Lenalidomide Monotherapy Cohort in Relapsed or Refractory Diffuse Large B-cell Lymphoma

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ABSTRACT

Purpose: Tafasitamab, an Fc-modified, humanized, anti-CD19 monoclonal antibody, in combination with lenalidomide, demonstrated efficacy in transplant-ineligible patients with relapsed/refractory (R/R) diffuse large B-cell lymphoma (DLBCL), in the single-arm, phase II L-MIND study (NCT02399085). RE-MIND, a retrospective observational study, generated a historic control for L-MIND to delineate the contribution of tafasitamab to the efficacy of the combination.

Patients and Methods: Data were retrospectively collected from patients with R/R DLBCL treated with lenalidomide monotherapy for comparison with tafasitamab + lenalidomide-treated patients (L-MIND). Key eligibility criteria were aligned with L-MIND. Estimated propensity score–based Nearest Neighbor 1:1 Matching methodology balanced the cohorts for nine prespecified prognostic baseline covariates. The primary endpoint was investigator-assessed best overall response rate (ORR). Secondary endpoints included complete response (CR) rate, progression-free survival (PFS), and overall survival (OS).

Results: Data from 490 patients going through lenalidomide monotherapy were collected; 140 qualified for matching with the L-MIND cohort. The primary analysis included 76 patients from each cohort who received a lenalidomide starting dose of 25 mg/day. Cohort baseline covariates were comparable. A significantly better ORR of 67.1% (95% confidence interval, 55.6–77.5) was observed for the combination therapy versus 34.2% (23.7–46.0) for lenalidomide monotherapy [odds ratio, 3.89 (1.90–8.14); $P < 0.0001$]. Higher CR rates were achieved with combination therapy compared with lenalidomide monotherapy [39.5% (28.4–51.4) vs. 13.2% (6.5–22.9)]. Survival endpoints favored combination therapy. Lenalidomide monotherapy outcomes were similar to previously published data.

Conclusions: RE-MIND enabled the estimation of the additional treatment effect achieved by combining tafasitamab with lenalidomide in patients with R/R DLBCL.

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Note: Supplementary data for this article are available at Clinical Cancer Research Online (http://clincancerres.aacrjournals.org/).

Clinicaltrials.gov identifier: NCT04450328.

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Clin Cancer Res 2021;27:6124–34

doi: 10.1158/1078-0432.CCR-21-1471

Introduction

Diffuse large B-cell lymphoma (DLBCL) is the most common aggressive subtype of non–Hodgkin lymphoma, with more than 18,000 cases diagnosed in the United States every year (1). Although 50% to 60% of patients might be cured with first-line chemo-immunotherapy, the prognosis in relapsed or refractory (R/R) disease is poor, with long-term remission being achieved in a minority of cases following high-dose chemotherapy (HDC) and autologous stem-cell transplantation (ASCT; ref. 2). In an analysis of 244 patients who relapsed after anthracycline-based first-line therapy for DLBCL from 2002 to 2012, median overall survival (OS) in 141 patients unable to undergo ASCT was 6.8 months from first relapse, with a 2-year OS rate of 19% (3).

Although options for patients with R/R DLBCL have historically been limited with poor rates of response, recent studies have shown more promise. Overall response rates (ORR) of 52% [95% confidence interval (CI), 41–62; ref. 4] and 82% (95% CI, 72–89; ref. 5) have been associated with chimeric antigen receptor (CAR) T-cell therapy in this population, and an ORR of 45% [including a complete response (CR) rate of 40%] was observed with the combination of polatuzumab vedotin plus bendamustine and rituximab in transplant-ineligible patients (6).

The immunomodulatory agent lenalidomide is also an option, although not approved, in the United States and the European Union (EU), with or without rituximab, especially in the ASCT-ineligible

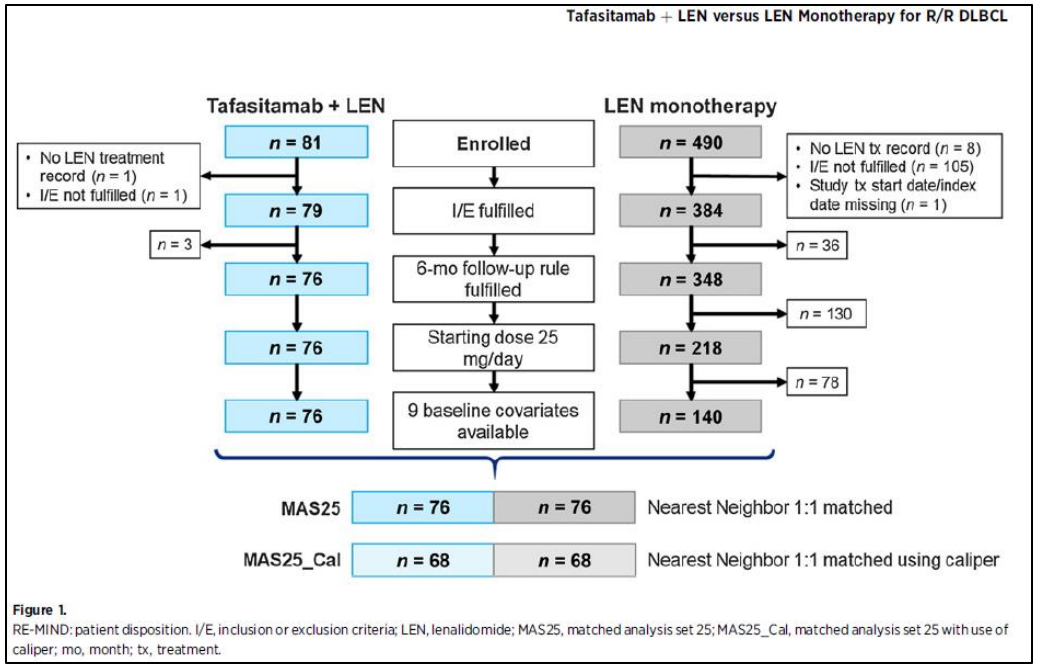

Figure 1.
RE-MIND: patient disposition. I/E, inclusion or exclusion criteria; LEN, lenalidomide; MAS25, matched analysis set 25; MAS25_Cal, matched analysis set 25 with use of caliper; mo, month; tx, treatment.

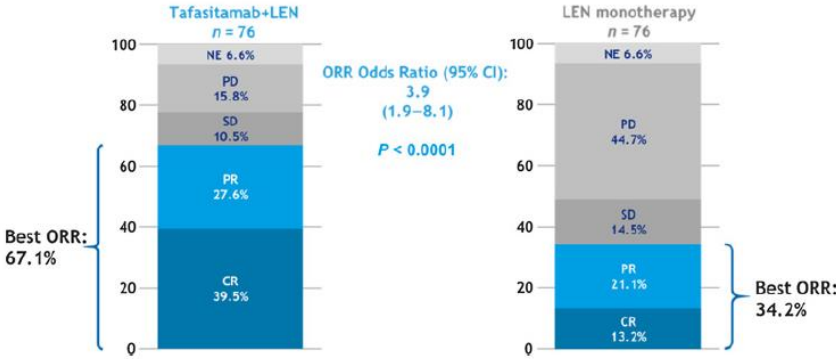

Figure 3.
Primary endpoint: Best ORR (investigator assessed; MAS25). CI, confidence interval; CR, complete response; LEN, lenalidomide; MAS25, matched analysis set 25; NE, not evaluable; ORR, overall response rate; PD, progressive disease; PR, partial response; SD, stable disease.

Zinzani, P. L., et al. RE-MIND: Comparing Tafasitamab + Lenalidomide (L-MIND) with a Real-world Lenalidomide Monotherapy Cohort in Relapsed or Refractory Diffuse Large B-cell Lymphoma. *Clinical cancer research : an official journal of the American Association for Cancer Research*, *27*(22), 6124–6134. https://doi.org/10.1158/1078-0432.CCR-21-1471

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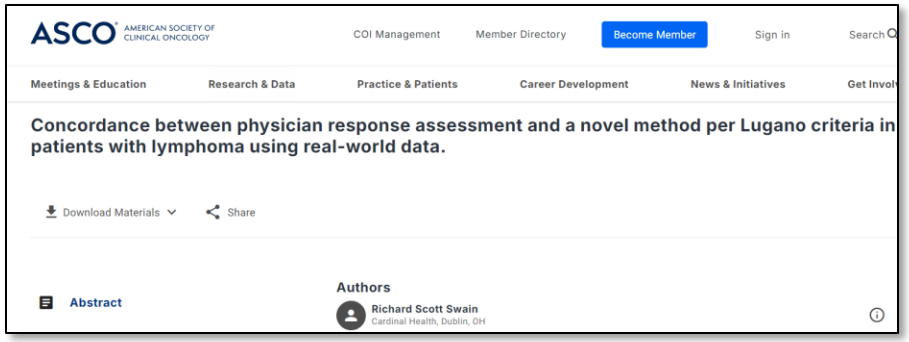


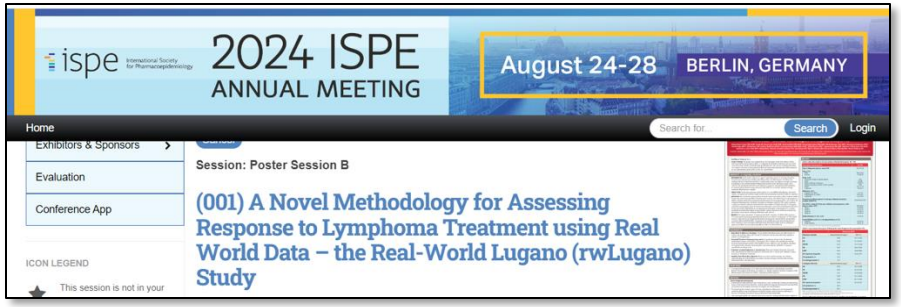
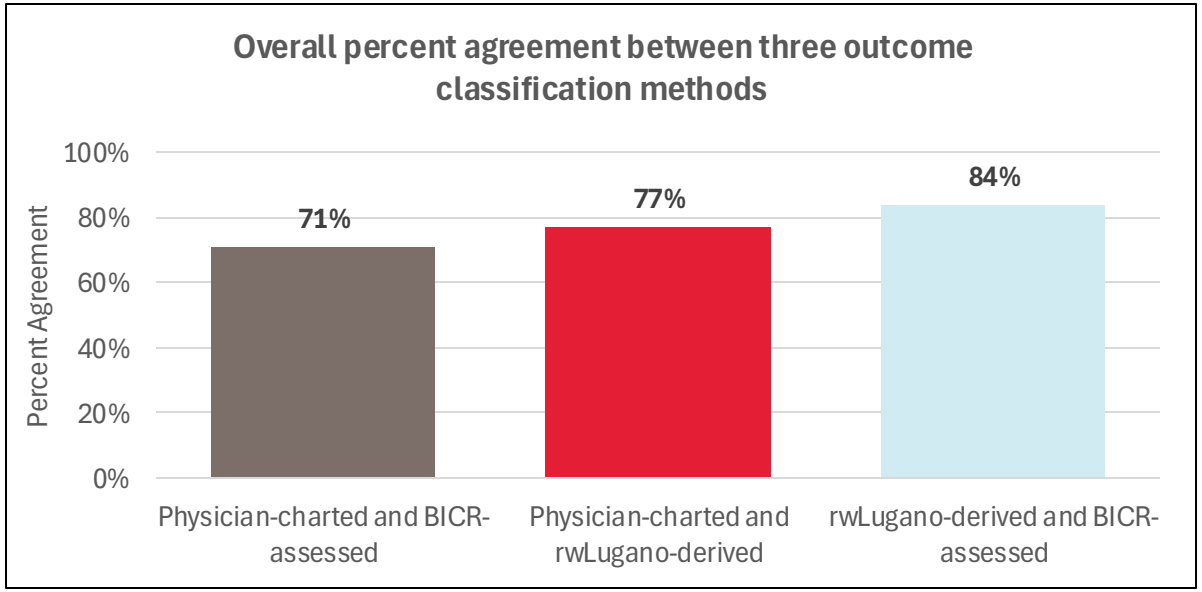


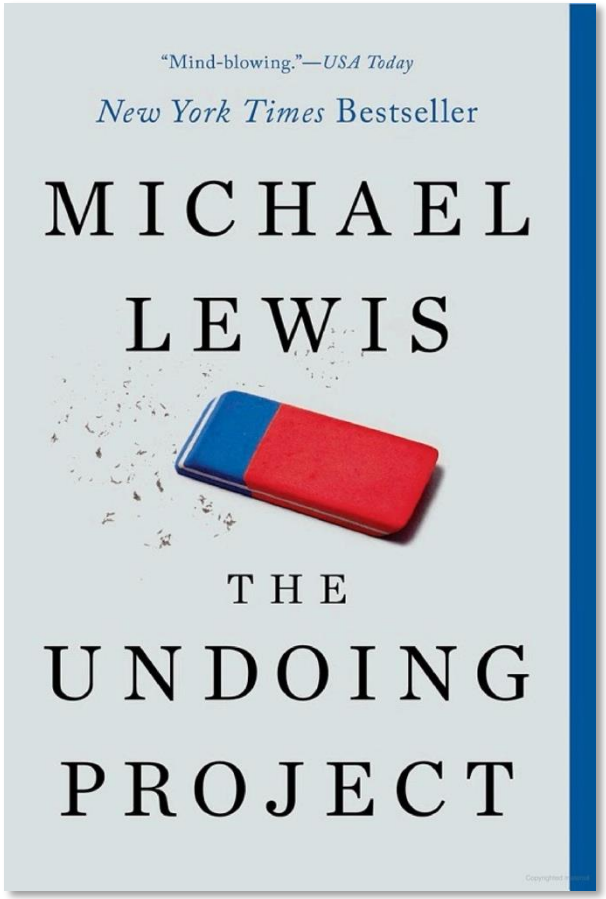
Table 3. Initial Treatment Response Assessment Per Method

Response type, n (%)	Physician-charted (N = 178)	rwLugano-derived (N = 178)	BICR-adjudicated (N = 178)
CR	113 (63.5%)	145 (81.5%)	148 (83.1%)
PR	56 (31.5%)	25 (14.0%)	22 (12.4%)
SD/NR	5 (2.8%)	3 (1.7%)	1 (0.6%)
PD	4 (2.2%)	5 (2.8%)	7 (3.9%)
ORR*	169 (94.9%)	170 (95.5%)	170 (95.5%)

*ORR is sum of patients with CR or PR divided by number of total evaluable patients.
Acronyms: BICR, blinded independent central review; CR, complete response; ORR, objective response rate; PD, progressive disease; PR, partial response; SD/NR, stable disease/no response.



Swain, RS, et al. A Methodologic Solution to Missing Deauville Scores Using Imaging Report Data to Classify Lymphoma Treatment Response in Real-World Data. ISPOR US. May 2024



COMMENTARY

Real-World Evidence and the Behavioral Economics of Physician Prescribing

Bruce Feinberg, DO

ABSTRACT

The projections for the rising cost of healthcare have spurred robust dialogue, and among the many targets for cost control are specialty drugs. An important question thus becomes: Are behavioral economic factors driving physician prescribing? This article presents a review of leading behavioral economic theories and their application to the results of an Oncology Medical Home pilot that reversed incentives from drug administration to patient care. A host of these theories may explain the irrational economic actors in regard to physician prescribing, including heuristics, framing, and defaults. Ultimately, the complex interplay of behavioral economics may result in reimbursement methodology alternatives to the prevailing fee-for-service payment system having less impact on prescribing behavior than has been conjectured.

Am J Manag Care. 2017;23(4):254-256

The projections for the rising cost of healthcare have spurred robust dialogue from every sector of the healthcare economy.[1,2] Among the many targets for cost control are specialty drugs, distinguished clinically by their route of administration, synthesis or bioengineering, mechanism of action, and cost itself.[3] This terminology likely originated from payers who designated these drugs for special attention, not only because of price, but also the need for distinctive handling or particular patient monitoring.[3] Although there are examples of competition emerging to ramp down prices to more acceptable levels (eg, pharmacy benefit manager negotiations for hepatitis C drugs), stakeholders (eg, policy makers, insurance carriers) and nongovernmental groups (eg, the American Society of Clinical Oncology) are seeking other market-based solutions.[2]

The fee-for-service (FFS) payment system has been identified as one of the main drivers of rising healthcare costs; the more that is done for patients, the larger the reimbursement to the healthcare provider.[1] In the FFS model, providers may directly purchase the drugs they administer to patients in their in-office infusion suites from manufacturers and/or wholesalers, then bill the payer for cost plus margin.[4,5] Many argue that this "buy-and-bill" model encourages physicians to overprescribe, creates incentives for price inflation, and thereby drives up the costs of patient care.[6] A few studies have even suggested that providers' choices of drug treatment can be affected by reimbursement, resulting in their overutilization of more costly brands rather than less expensive brands or generic alternatives.[7] Such suggestions draw the ire of providers who believe the portrayal of patient care as being driven solely by financial incentives and behavioral economics is insulting, demeans their professional integrity, and is inconsistent with real-world evidence that demonstrates highly variable regional resource utilization, as well as few differences in prescribing patterns among community, staff model, and academic physicians when controlling for these geographic variances.[8]

Atul Gawande wrote in his *New Yorker* article, "The Cost Conundrum," that "[h]ealth-care costs ultimately arise from the

Journal of the National Comprehensive Cancer Network

Behavioral Economics and the Future of Biosimilars

Chadi Nabhan, MD, MBA, and Bruce A. Feinberg, DO

The expanded use of biologic agents in cancer has contributed substantially to the continued rise in US healthcare costs. Recent statistics show biologics accounting for 62% of the $18.5 billion USD total Medicare Part B drug spending, exerting additional pressure for drug-savings measures.[1] Some experts have proposed that biosimilars could mitigate this continued upslope through competing market prices relative to their reference product. This is especially relevant because many patents for biologics are expiring within the next 5 years, including those for 4 of the top 10 drugs by cost.[2] Such bending of the cost curve would require robust acceptance of biosimilars by the prescribing oncologists and the patients they treat.

Biosimilars contain a highly similar version of the active substance of an already approved biologic agent, referred to as the "reference product."[3] Regulatory agencies such as the FDA allow at least 1 of the approved indications for the reference product to be listed as an indication for the biosimilar, but the FDA mandates that safety, efficacy, dosing, route of administration, and immunogenicity are established first.[3] In addition, the FDA allows extrapolation of safety and efficacy data from one biosimilar indication to another after rigorous requirements are fulfilled.[4] These requirements are meant to assure clinicians that extrapolation is safe and effective. Extrapolation is a cost-saving measure welcomed in a resource-constrained environment that recognizes limitations of conducting expensive confirmatory randomized studies for every indication in every disease stage.[4]

Behavioral economics is a discipline that combines insights from psychology, economics, judgment, and decision-making to better understand, predict, and potentially change human behavior. Tversky and Khaneman[5] launched the field with a series of experiments that confirmed that people are often irrational economic actors. The authors proposed that such irrational behavior relied on a limited number of heuristic principles, which reduce the complex intellectual tasks of assessing probabilities and predicting values to simplified judgment operations. These heuristics, however, can lead to serious erroneous biases in decision-making that may have significant impact on healthcare reform.

Behavioral Economics of Oncologists' Prescribing

Biosimilars are entering healthcare markets at a time when fee-for-service reimbursement methodologies are rapidly being replaced with value-based care models in which prescribers share financial risk. These new reimbursement models challenge our understanding of physicians' decision-making and prescribing preferences. The proposed dissolution of simplistic rational economics (ie, the more you do or prescribe, the more you are paid) and replacement with complex models that compare clinical and financial outcomes of providers with those of both historical benchmarks and providers' peers may have broad consequences on physician prescribing.

If providers were rational economic actors, then biosimilar adoption could play a significant role in such financial outcome models given projections of (±30%) cost differences with their reference brands.[2] Behavioral economics healthcare research, albeit limited, suggests that neither patients nor providers are rational economic actors due to numerous inherent biases in their decision-making.[6] Researchers have be-

Lewis M. The Undoing Project.
Feinberg B. Real-world evidence and the behavioral economics of physician prescribing. *American Journal of Managed Care. 2017 April;23(4):254-256*
Nabhan C, Feinberg BA. Behavioral Economics and the Future of Biosimilars. Journal of National Comprehensive Cancer Network. 2017 Dec;15(12):1449-1451.

Matching the patient

Identifying the seen and unseen

The criteria:

- Long hair
- Recently bought a heavy metal album or attended a heavy metal concert
- Wears spikes or chains
- Knows the words to Fade to Black

Who we expected:

All images created using Microsoft Copilot

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Who we expected:

Who we got:

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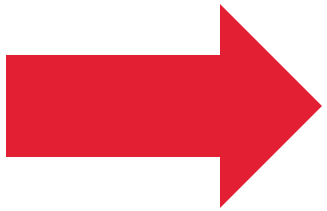


The criteria:

- Castrate resistant prostate cancer
- Recently started a PARP Inhibitor or Docetaxel
- Failed to respond to radiation
- Suffers from depression

All images created using Microsoft Copilot

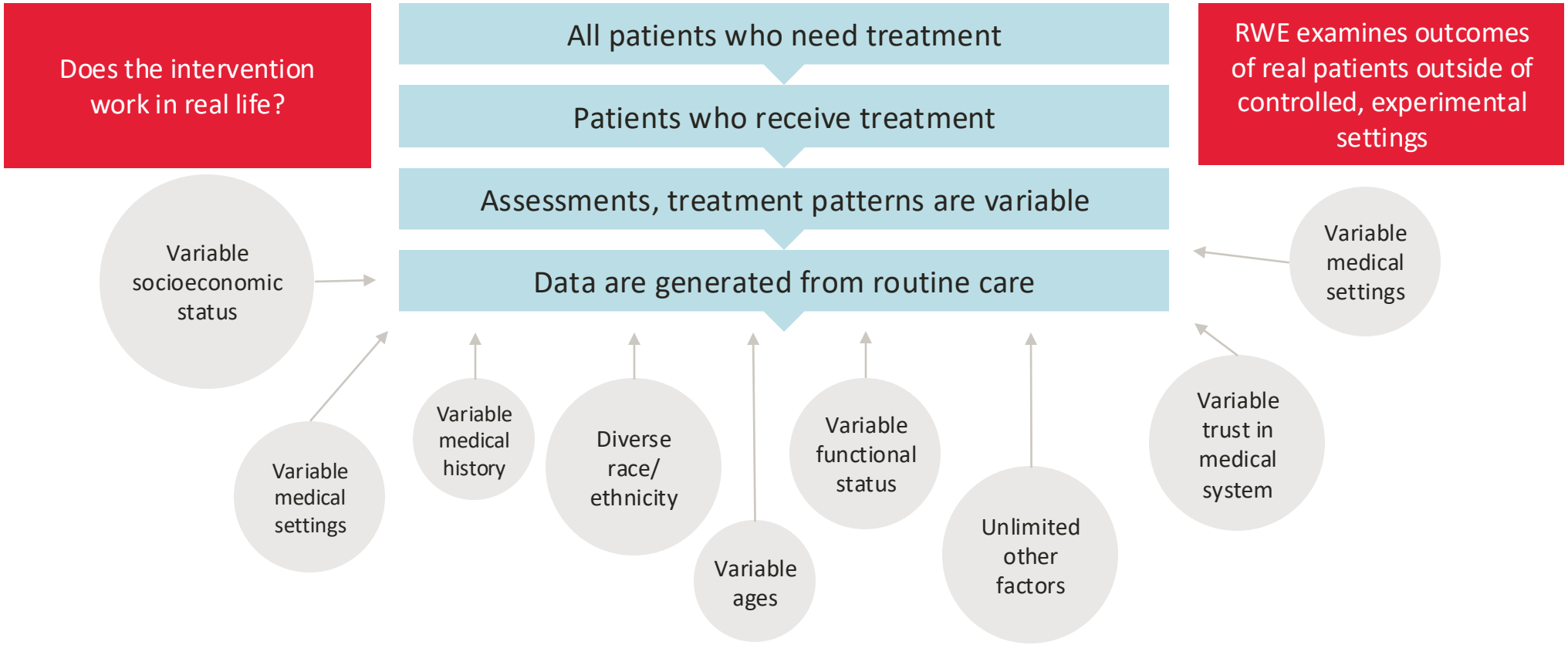
How representative and generalizable is real-world data (RWD)

Source: https://gis.cdc.gov/Cancer/USCS/#/NationalPrevalence/

RCTs = randomized controlled clinical trials
SEER = Surveillance, Epidemiology, and End Results Program

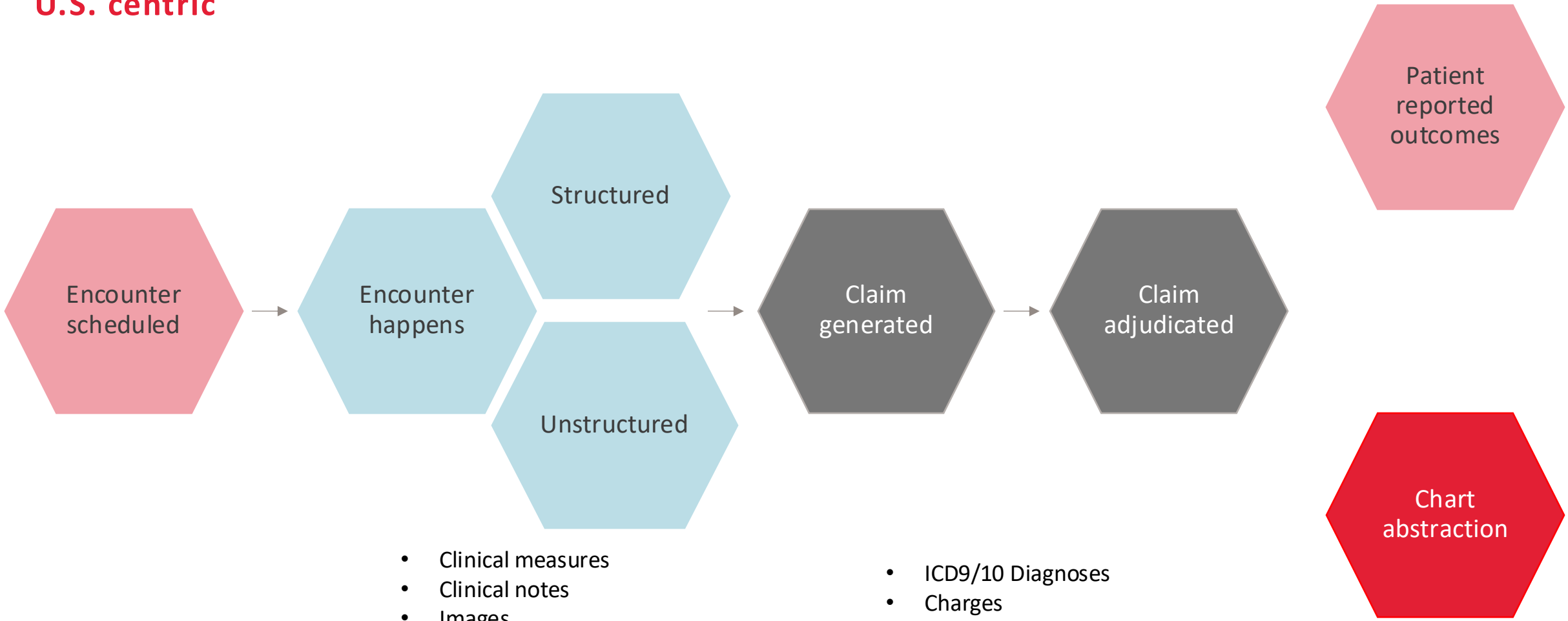
Methods

Real-world evidence (RWE)



Real-world evidence data lifecycle – Simplified

U.S. centric



- Clinical measures
- Clinical notes
- Images
- Problems/Diagnoses
- Prescriptions written
- Medications dispensed

- ICD9/10 Diagnoses
- Charges
- Paid
- Prescriptions filled

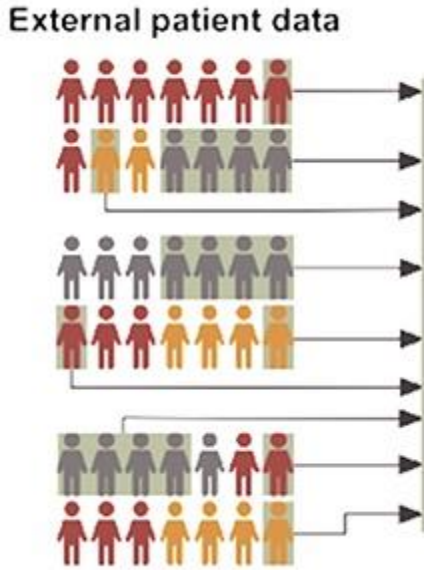
Synthetic controls

Harnessing what has already been collected

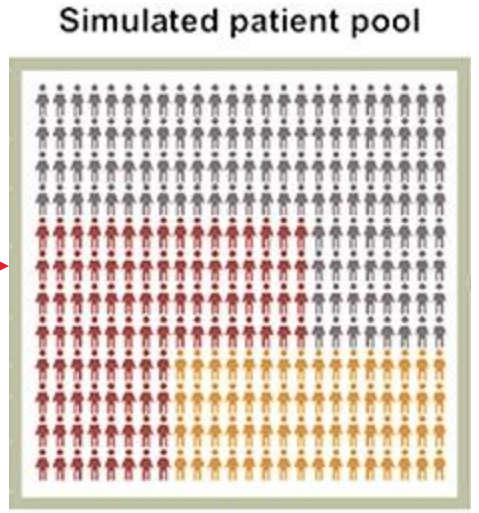
Clinical Trial 1

Clinical Trial 2

Clinical Trial 3



Sampling, Weighting

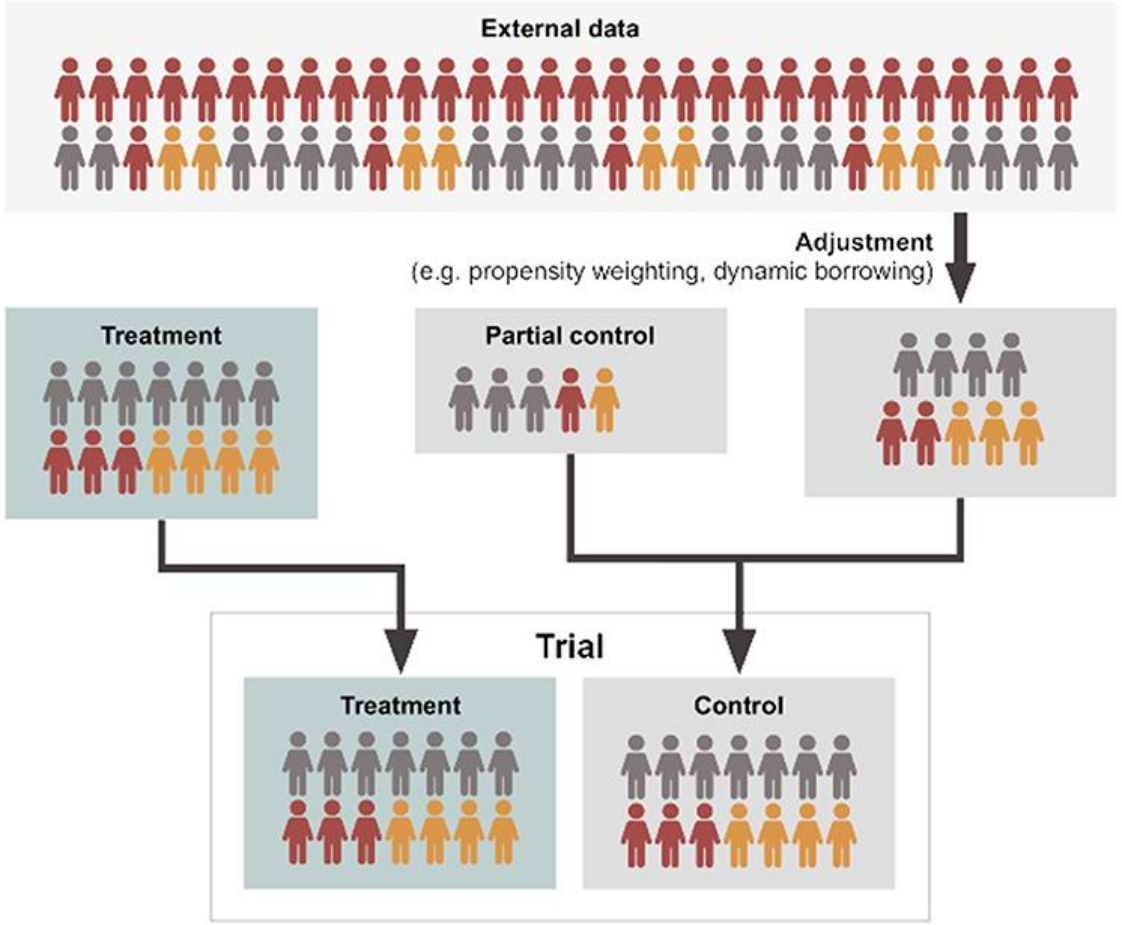


Source: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7218288/

External controls

Borrowing from existing data and matching to trial criteria

- Strong use case for real-world data(RWD)
- Highly dependent on the quality of the data collected and similarity to original criteria
- Dramatically reduces spend and time to recruitment



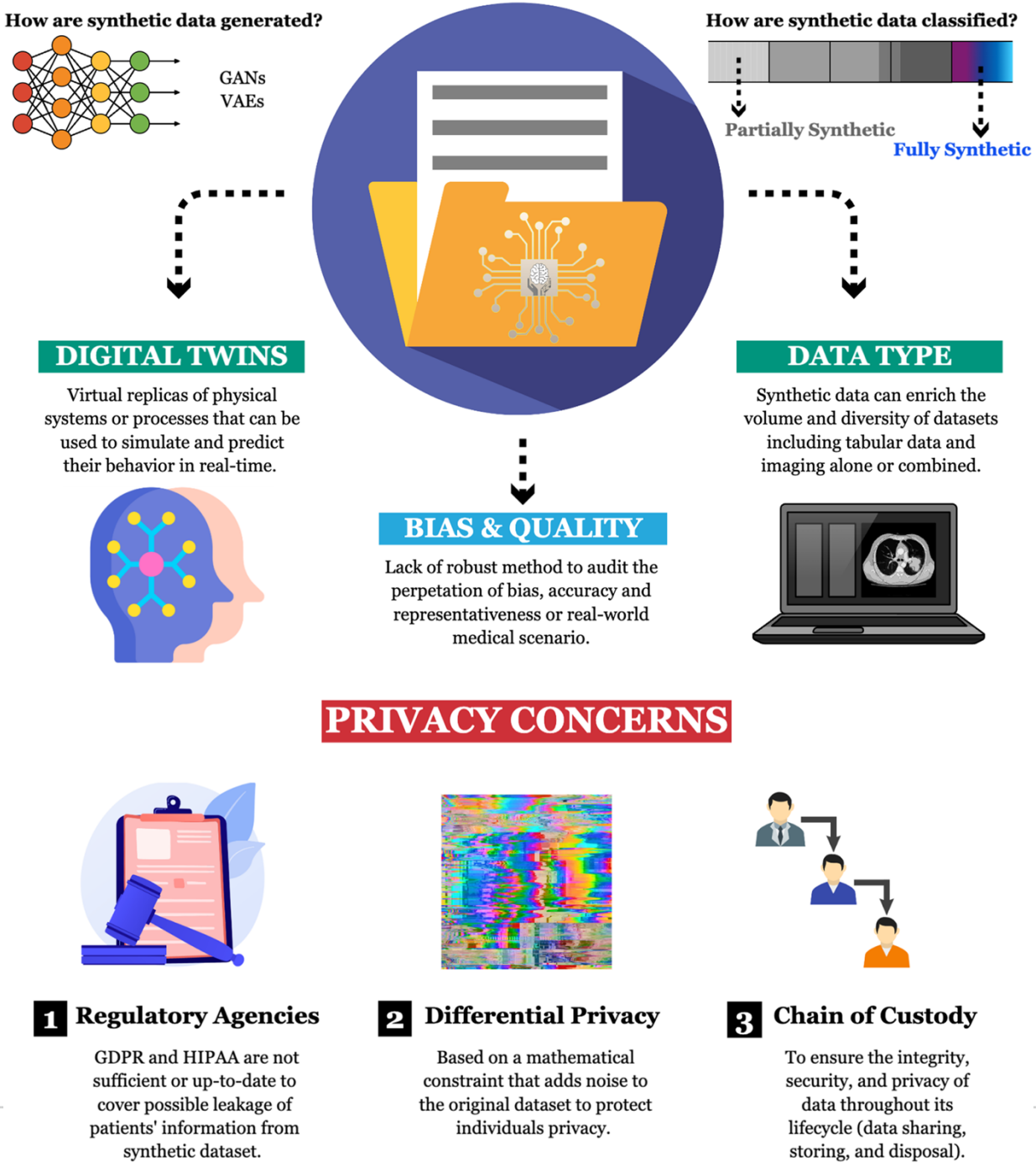
Source: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7218288/

Future of controls:

AI driven true synthetic controls

Synthetic data

Definition (*by the Royal Society and Alan Turing Institute*): data that has been generated using a purpose-built mathematical model or algorithm, with the aim of solving a (set of) data science task(s).



Source: https://www.nature.com/articles/s41746-023-00927-3

Q&A

If we don’t get to your question, please visit us at **Booth 1407**