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Physician-Led Chart Abstraction (PLCA) in Oncology: Advancing FDA Fit-for-Use Real-World Data for HEOR Decision-Making

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BACKGROUND

- Regulatory agencies emphasize "fit-for-use" in real-world data (RWD), where reliability and relevance are core considerations for generating decision-quality real-world evidence (RWE).[1]
- In oncology, electronic health record (EHR)-derived data are often incomplete, as key variables are captured in unstructured sources and fragmented across care settings, thereby challenging this data source as fit-for-use.[2,3]
  - Missingness impacts both reliability and relevance affecting interpretability and introducing bias.4
- FDA guidance recommends to pre-specify, justify, and mitigate missing data, including analytic approaches used and their limitations.[4]
- Physician-led chart abstraction (PLCA) may help address these gaps by leveraging the treating physician's knowledge of and access to disparate data sources across a patient's journey, thereby reducing missingness and enabling more complete and clinically meaningful capture of oncology endpoints.

OBJECTIVES

- To determine whether specialty PLCA produces RWD meeting FDA "fit-for-use" standards for regulatory-grade evidence.
- To assess unique data elements of interest not available in EHR or claims datasets.

METHODS

- A systematic synthesis was conducted across retrospective, non-interventional PLCA studies in oncology/hematology, leveraging an internal archive of studies published from March 2020 to June 2025.
- Eligible studies featured U.S.-based PLCA from practice and hospital EHRs, as well as primary source lab and imaging findings, into standardized electronic case report forms, rigorous quality control, and study selection was guided by principles from PRISMA 2020, with key elements of systematic identification and screening applied to identify eligible studies.
- The primary outcome was pooled missingness rates for key HEOR-relevant variables categories (demographics, treatment patterns, clinical characteristics, outcomes, safety, utilization, and unique insights).

RESULTS

- Four studies (follicular lymphoma, HER2+ breast cancer, high-risk myelofibrosis, hepatocellular carcinoma) were included, with PLCA by board-certified oncologists/hematologists at an array of geographically diverse practice settings (i.e., both community and academic, dispersed across the U.S.).
- PLCA demonstrated high completeness for core HEOR variables: demographics, treatment patterns, adverse events, and clinical characteristics (aggregate means per category >98% complete).
- Despite greater outcomes variability, aggregate completeness remained >90%.
- PLCA demonstrated high capture of "why-level" insights (e.g., rationale for treatment, eligibility for subsequent lines) rarely available in claims/automated EHR extractions (100%).
- Missingness was transparently reported, consistent with FDA guidance.

Table 1. Study Characteristics for Physician-Led Chart Abstraction Studies in Oncology

Study	Disease / Population of Interest	Summary of Research Objectives	Summary of Inclusion Criteria	N Physicians	N Charts	Mean Charts per Physician	Geographic Breakdown of Physician Practice US Location[a]	Physician Specialty	Physician Setting	Published Reference
1	R/R DLBCL	Describe clinical characteristics, treatment patterns and outcomes of real-world patients who received at least one administration of tafasitamab for the treatment of R/R DLBCL and utilization patterns of tafasitamab and concomitant lenalidomide.	Adult patients diagnosed with R/R DLBCL, initiated treatment with tafasitamab in second- to sixth-line treatment for DLBCL after October 21, 2020 at age 18 years or older, had four months of follow up since tafasitamab initiation unless deceased during that time.	24	181	7.54	South: 41.67% Northeast: 20.83% West: 20.83% Midwest: 16.67%	Hematology/oncology: 20.83% Medical oncology: 16.67%	Community: 83.33% Academic: 16.66%	Saverno et al., 2024[5]
2	HER2-low or IHC 0 expression mBC	Describe biomarker testing patterns, clinical characteristics, treatment patterns, and outcomes of real-world patients with HER2-low or IHC 0 expression mBC.	Adult patients diagnosed with HER2-low or IHC 0 expression mBC, received at least two or three lines of systemic therapy for mBC (depending on HR+ status), including chemotherapy, with the first line initiated between February 19, 2016 and December 31, 2018, and with specific biomarker testing results as detailed in published literature.	33	444	13.45	South: 33.33% West: 27.27% Northeast: 24.24% Midwest: 15.15%	Hematology/oncology: 57.58% Medical oncology: 51.52% Hematology: 9.09%	Community: 81.82% Academic: 18.18%	Mehta et al., 2025[6]
3	Myelofibrosis	Describe clinical characteristics and outcomes of real-world myelofibrosis patients who initiated fedratinib after prior ruxolitinib failure.	Adult patients diagnosed with PMF, post-ET MF, or post-PV MF, initiated treatment with fedratinib after August 16, 2019, received prior treatment with ruxolitinib at age 18 or older, and had spleen assessed at time of initiation of fedratinib by palpation.	24	150	6.25	South: 33.33% West: 33.33% Midwest: 16.67% Northeast: 16.67%	Hematology/oncology: 91.67% Medical oncology: 16.67%	Community: 91.67% Academic: 8.34%	Marrone et al., 2024[7]
4	Advanced HCC	Describe/compare clinical characteristics, treatment patterns, HCRU, and outcomes of real-patients treated in the first-line with atezolizumab plus bevacizumab or a TKI for unresectable/advanced HCC and estimate rates of clinically-significant toxicities.	Adult patients diagnosed with unresectable/advanced HCC, initiated first-line systemic treatment with atezolizumab plus bevacizumab or a TKI (sorafenib or lenvatinib) after June 1, 2020, had eight or more months of follow up following first-line therapy initiation unless deceased during that time.	36	263	7.31	South: 38.89% Northeast: 22.22% West: 19.44% Midwest: 19.44%	Hematology/oncology: 77.78% Medical oncology: 38.89%	Community: 77.78% Academic: 22.22%	Klink et al., 2022[8]

ET=essential thrombocytopenia; DLBCL=diffuse large B-cell lymphoma; HCC=hepatocellular carcinoma; HCRU=healthcare resource utilization; HER2=Human Epidermal Growth Factor Receptor 2; HR+=hormone receptor positive; mBC=metastatic breast cancer; MF=myelofibrosis; PMF=primary myelofibrosis; PV=polycythemia vera; R/R=relapsed or refractory; TKI=tyrosine kinase inhibitor; US=United States

[a]Midwest included IA, IL, IN, KS, MI, MN, MO, ND, NE, OH, SD, WI; Northeast included CT, DE, MA, ME, MD, NH, NJ, NY, PA, RI, VT; South included AL, AR, DC, FL, GA, KY, LA, MS, NC, OK, SC, TN, TX, VA, WV; West included AK, AZ, CA, CO, HI, ID, MT, NM, NV, OR, UT, WA, WY.

Table 2. Completeness and Missingness of Data Elements

Category	Data Element	Study 1 R/R DLBCL (N=181) Completeness (%)	Study 2 HER2-Low or IHC 0 Expression mBC (N=444) Completeness (%)	Study 3 Myelofibrosis (N=150) Completeness (%)	Study 4 Advanced HCC (N=263) Completeness (%)	Aggregate Completeness (Mean % Across Studies)	Aggregate Missingness Due to Unknown/Unavailable/ By Design (Mean % Across Studies)
Patient Demographics and Baseline Characteristics	**Mean[a] %**	**98.23%**	**98.70%**	**100%**	**98.16%**	**98.87%**	**1.13%**
	Age	100%	100%	100%	100%	100%	0%
	Race	93.92%	97.50%	100%	96.60%	97.01%	2.99%
	Ethnicity	99.45%	96.00%	100%	96.20%	97.91%	2.09%
	Insurance payer	97.79%	100%	100%	100%	99.45%	0.55%
	Region of residence	100%	100%	100%	100%	100%	0%
Treatment Patterns and Lines of Therapy	**Mean[a] %**	**100%**	**98.70%**	**100%**	**100%**	**100%**	**0%**
	Index therapy	100%	100%	100%	100%	100%	0%
	Dates of index therapy	100%	100%	100%	100%	100%	0%
	Dose modifications occurred during index therapy (yes/no)	100%	100%	100%	100%	100%	0%
	Total number of lines of therapy	100%	100%	not collected[b]	100%	100%	0%
	Therapy sequences	100%	100%	not collected[b]	100%	100%	0%
Clinical Characteristics and Disease Burden	**Mean[a] %**	**99.07%**	**98.70%**	**100%**	**100%**	**99.74%**	**0.26%**
	Date of diagnosis	100%	100%	100%	100%	100%	0%
	Disease stage/type at initial diagnosis	100%	99.30%	100%	100%	99.83%	0.18%
	Sites of metastases	not collected[b]	100%	not collected[b]	100%	100%	0%
	Performance status	100%	100%	100%	100%	100%	0%
	Comorbidity index could be calculated	100%	100%	100%	100%	100%	0%
	Biomarker results, among tested patients[c]	100%	100%	100%	100%	100%	0%
	Lab values at initiation of index therapy[d]	94.47%	not collected[b]	100%	100%	98.45%	1.55%
Outcomes	**Mean[a] %**	**100%**	**95.70%**	**-**	**64.63%**	**87.27%**	**12.73%**
	Disease response to index line of therapy[e]	100%	95.70%	not collected[b]	64.63%	87.27%	12.73%
AEs and Safety During Index Therapy	**Mean[a] %**	**-**	**-**	**100%**	**100%**	**100%**	**0%**
	Incidence of AEs	not collected[b]	not collected[b]	100%	100%	100%	0%
	Start dates of AEs	not collected[b]	not collected[b]	100%	100%	100%	0%
	CTCAE grade/severity of AE	not collected[b]	not collected[b]	100%	100%	100%	0%
	AE ongoing/resolution status	not collected[b]	not collected[b]	not collected[b]	100%	100%	0%
	Relationship of AE to index therapy (e.g., AE resulted in dose modification or discontinuation)	not collected[b]	not collected[b]	100%	100%	100%	0%
Healthcare Utilization	**Mean[a] %**	**-**	**-**	**100%**	**100%**	**100%**	**0%**
	Number of hospitalizations during index therapy	not collected[b]	not collected[b]	100%	100%	100%	0%
	Number of ER visits during index therapy	not collected[b]	not collected[b]	100%	100%	100%	0%
Unique Insights	**Mean[a] %**	**98.34%**	**98.87%**	**100%**	**100%**	**99.39%**	**0.61%**
	Calculated risk or staging score at initiation of index line of therapy	93.37%	not collected[b]	100%	100%	97.79%	2.21%
	Rationale for initiation of index line of therapy	100%	not collected[b]	100%	100%	100%	0%
	Rationale for dose modifications[f]	not collected[b]	100%	100%	100%	100%	0%
	Rationale for discontinuation of index line of therapy	100%	100%	100%	100%	100%	0%
	Cause of death	100%	96.61%	100%	100%	99.15%	0.85%

AE=adverse event; AFP=alpha-fetoprotein; BCL2=B-cell lymphoma 2; BCL6=B-cell lymphoma 6; CALR=calreticulin; CTCAE=Common Terminology Criteria for Adverse Events; DLBCL=diffuse large B-cell lymphoma; ER=emergency room; FISH/ISH=fluorescence in situ hybridization/in situ hybridization; HCC=hepatocellular carcinoma; HER2=Human Epidermal Growth Factor Receptor 2; IHC=immunohistochemistry; JAK2=Janus kinase 2; LDH=lactate dehydrogenase; LFT=liver function test; mBC=metastatic breast cancer; MPL=myeloproliferative leukemia protein; MYC=myelocytomatosis; PD-L1=programmed death-ligand 1; R/R=relapsed or refractory; TMB=tumor mutational burden

[a]Means were calculated out of studies where data points were collected, omitting studies where the data were not collected due to not being deemed relevant for the disease studied and/or not needed to achieve study objectives.
[b]Data point was not collected in this study as it was not deemed relevant for the disease studied and/or was not needed to achieve study objectives.
[c]Biomarkers assessed for completeness included MYC, BCL2 and BCL6 translocation (assessing double hit or triple hit) for study 1, HER2 by FISH/ISH and IHC for study 2, JAK2, CALR and MPL for study 3, and AFP, TMB and PD-L1 for study 4.
[d]Lab values assessed for completeness included LDH for study 1, platelets and hemoglobin for study 3, and LFT and bilirubin for study 4.
[e]Given the heterogeneity of reporting approaches across the studies, response data was considered "complete" for a patient if the patient's physician provided at least one data point for patient's best or initial response to index line of therapy.
[f]Rationale for dose modification was considered complete for a patient if the patient's physician provided at least one data point for rationale for dose increase, dose decrease or dose interruption, depending on which dose modification(s) was/were queried in the study.

LIMITATIONS

- PLCA cannot fully overcome fragmented care, institution-specific documentation practices, and variable access to external systems.
- Selection bias can arise from physician network participation and site characteristics.
- Study objectives and designs were not inclusive of all data points of interest.

CONCLUSIONS

- PLCA demonstrated enhanced data completeness, contextual validity, and contemporaneity relative to conventional RWD sources, supporting FDA and HEOR expectations for reliability and relevance in regulatory-grade evidence.
- Integrating dispersed documentation and expert judgement, PLCA supports fit-for-use datasets for complex endpoints and enables context-rich analyses for economic modeling, comparative effectiveness, and outcomes research.
- Future work should benchmark PLCA against automated pipelines and formalize quality control taxonomies to further advance HEOR practice.

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Abbreviations: EHR, electronic health record; FDA, U.S. Food and Drug Administration; HEOR, health economics and outcomes research; HER2, Human Epidermal Growth Factor Receptor 2; PLCA, physician-led chart abstraction; RWD, real-world data; RWE, real-world evidence; US, United States

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