Availability and Feasibility of Real-World Data from a Large US Multi-payer Claims Database to Support Regulatory Decision-making for Biosimilars

C-033

Pamala A. Pawloski,[1] Scott M. Myers,[2] Catherine M. Lockhart[1]

1. Biologics and Biosimilars Collective Intelligence Consortium, Alexandria, VA, USA,
2. PearlDiver Technologies, Colorado Springs, CO, USA.

OBJECTIVE

To identify and describe the availability of relevant data variables in administrative claims to support regulatory decision-making for biosimilars using adalimumab and insulin glargine as use cases

METHODS

- A retrospective feasibility assessment of the PearlDiver claims database to determine the variable availability to support regulatory decision-making
- PearlDiver, a large, national multi-payer claims database, containing 174 million lives from 1/1/2010-12/31/2023
- Data included the International Classification of Diseases, Ninth and Tenth Revisions (ICD-9/10), Common Procedure Terminology (CPT), and National Drug Codes (NDC)
- The index date is defined as the first reference product dispensation, with a 183-day lookback
- Variables to assess the adalimumab and insulin glargine test cases were compiled from published clinical trials

RESULTS

- Demographic information (**Table 1, Table 3**) was readily available and consistent across reference and biosimilar users, as well as patients who switched treatment.
- Outcome measures were available for events or characteristics that are medically attended or have specific codes such as infection and hypoglycemia (**Table 2, Table 4**)

ADALIMUMAB

Table 1. Demographic Characteristics of US adults receiving adalimumab 2020-2023

Characteristic	Reference	Biosimilar	Switchers	Total
Number of unique individuals	361,281	987	866	363,134
Age in years, median [IQR]	49 [37-59]	50 [38-59]	48 [36-57]	49 [37-59]
Age group				
18-40 years	112,150 (31.0)	295 (29.9)	284 (32.8)	112,779 (31.1)
41-60 years	172,169 (47.7)	486 (49.2)	432 (49.9)	173,099 (47.7)
61+ years	76,962 (21.3)	206 (20.9)	150 (17.3)	77,256 (21.3)
Female Sex	244,086 (67.6)	644 (65.2)	536 (61.9)	245,266 (67.5)
Diagnosis				
Rheumatoid arthritis	120,427 (33.3)	258 (26.1)	267 (30.8)	87,081 (24.0)
Psoriasis / psoriatic arthritis	33,716 (9.3)	149 (15.1)	127 (14.7)	72,934 (20.1)
Inflammatory bowel disease	54,479 (15.1)	292 (29.6)	188 (21.7)	147,924 (40.7)
Ankylosing spondylitis/axial spondyloarthritis	16,092 (4.5)	279 (28.3)	277 (32.0)	52,986 (14.6)
Rheumatoid arthritis	120,427 (33.3)	*	*	2,209 (0.6)

Table 2. Adverse Events of US adults receiving adalimumab 2020-2023

Adverse Event	Reference	Biosimilar	Switchers	Total
Upper Respiratory Infection	74,562 (20.6)	198 (20.1)	181 (20.9)	74,941 (20.6)
Rash	99,183 (27.5)	256 (25.9)	234 (27.0)	99,673 (27.4)
Nausea	126,334 (35.0)	324 (32.8)	295 (34.1)	126,953 (35.0)
Tuberculosis	2,884 (0.8)	*	*	2,897 (0.8)
Fungal Infection	66,244 (18.3)	162 (16.4)	163 (18.8)	66,569 (18.3)
Sepsis	25,935 (7.2)	31 (3.1)	37 (4.3)	26,003 (7.2)
Lymphoma	1,546 (0.4)	*	*	1,549 (0.4)
Hepatosplenic T-cell Lymphoma	*	0	0	*

INSULIN GLARGINE

Table 3. Demographic characteristics of US adults receiving insulin glargine 2020-2023

Characteristic	Reference	Biosimilar	Switchers	Total
Number of unique individuals	1,421,390	1,143,303	357,051	2,921,744
Age in years, median [IQR]	63 [52-72]	58 [48-67]	57 [48-65]	58 [48-66]
Age group				
18-40 years	150,417 (10.6)	162,907 (14.2)	46,876 (13.1)	364,245 (12.5)
41-60 years	484,956 (34.1)	492,529 (43.1)	166,774 (46.7)	1,152,213 (39.4)
61+ years	786,017 (55.3)	487,867 (42.7)	143,401 (40.2)	1,405,286 (48.1)
Female Sex	718,168 (50.5)	595,726 (52.1)	181,804 (50.9)	1,495,698 (51.2)
Diagnosis				
Type 1 diabetes mellitus	218,388 (15.4)	338,606 (29.6)	64,512 (18.1)	612,053 (21.0)
Type 2 diabetes mellitus	983,155 (69.2)	695,165 (60.8)	255,309 (71.5)	1,927,329 (66.0)
Diabetes, type unspecified	219,847 (15.5)	109,532 (9.6)	37,230 (10.4)	382,362 (13.1)

Table 4. Adverse Events of US adults receiving insulin glargine 2020-2023

Adverse Event	Reference	Biosimilar	Switchers	Total
Hypoglycemia	43,305 (3.6)	50,750 (4.4)	12,099 (3.4)	108,552 (3.7)
Nocturnal hypoglycemia	NA	NA	NA	NA
Symptomatic hypoglycemia	NA	NA	NA	NA
Nausea	201,434 (14.2)	198,331 (17.3)	60,434 (16.9)	472,621 (16.2)
Nasopharyngitis	6,968 (0.5)	7,896 (0.7)	2,305 (0.7)	17,897 (0.6)
Rash	60,404 (4.2)	59,803 (5.2)	18,360 (5.1)	143,274 (4.9)
Allergic reaction	2,362 (0.2)	2,386 (0.2)	730 (0.2)	5,622 (0.2)
Insulin antibodies (immunogenicity)	3,050 (0.2)	3,602 (0.3)	1,187 (0.3)	8,315 (0.3)
Hypertension	809,972 (57.0)	678,417 (59.3)	211,740 (59.3)	1,728,331 (59.2)

- The most common payer type differed between products, with adalimumab coverage coming most often from pharmacy benefit managers (PBMs, 22.2%), while insulin glargine was most commonly covered by Medicare (35.0%).
- The mean time to the first product switch was 1,177 days for adalimumab users, and 1,450 days for insulin glargine users.

Table 5. Feasibility Assessment of PearlDiver Claims Database of US adults receiving adalimumab and insulin glargine 2020-2023

Data Field	Rate of Data Missingness (%)	Data Field	Rate of Data Missingness (%)
Patient Age	0.002	Claim Code (ICD/CPT/NDC)	0
Patient Sex	0.001	Claim Date	0
Patient Race	100	Insurance Product Name	7.407
Patient Geography (3-digit zip code)	0.729	Payer Name	<0.001
Laboratory Test Results	100	Charge Type	0
Vital Signs	100	Provider Specialty	3.915
Patient Mortality	100	Reimbursement	1.465

Database STRENGTHS

- The database includes more than 174 million covered lives from a national multi-payer data source with longitudinal closed claims spanning 13 years.
- Variables with administrative codes (e.g., ICD) are readily available and reliable

Database LIMITATIONS

- The data lag is approximately 24 months, and it is unknown if data feasibility for regulatory decision making is influenced by payer type, this should be explored in future studies.
- Patient race, vital signs, laboratory test results, and mortality are unavailable, whereas codes for procedures, tests, and medications indicating clinical care are readily available

CONCLUSIONS

- RWD from administrative claims data is reliable and consistent in identifying demographics, exposures, and some outcomes
- The data are associated with a time lag following clinical care administration that may impact timeliness of research
- Some variables such as laboratory results, vital signs, mortality, and patient reported data are unreliable or unavailable, and complementary data sources may be required to supplement regulatory decision-making

ACKNOWLEDGEMENTS

- This project is fully supported by a cooperative agreement (Award #1U01FD008041) with the Food and Drug Administration (FDA) of the U.S. Department of Health and Human Services (HHS). The contents are those of the authors and do not necessarily represent the official views of, nor an endorsement by, FDA/HHS or the U.S. Government.
- The authors wish to thank our collaborative partners for this cooperative agreement at the University of Verona, Italy, and University of Southern Denmark

REFERENCES

- Considerations in Demonstrating Interchangeability With a Reference Product Guidance for Industry. 2019.
- ICH Official web site : ICH. 2025. https://www.ich.org/page/multidisciplinary-guidelines#14-1. Accessed December 23.
- Determining Real-World Data's Fitness for Use and the Role of Reliability. 2026. https://healthpolicy.duke.edu/publications/determining-real-world-datas-fitness-use-and-role-reliability. Accessed April 28.
- Research, Center for Drug Evaluation and. 2025. Real-World Data: Assessing Electronic Health Records and Medical Claims Data To Support Regulatory Decision-Making for Drug and Biological Products. FDA. March 2.
- Gatto, Nicolle M., Ulka B. Campbell, Emily Rubinstein, Ashley Jaksa, Pattra Mattox, Jingping Mo, and Robert F. Reynolds. 2022. The Structured Process to Identify Fit-For-Purpose Data: A Data Feasibility Assessment Framework. *Clinical Pharmacology & Therapeutics* 111: 122–134. https://doi.org/10.1002/cpt.2466.