



Feasibility of Reconstructing Survival Outcomes from Unstructured Electronic Medical Records under Japan's Next-Generation Medical Infrastructure Act: A Historical Cohort Study of Atezolizumab in Non-small Cell Lung Cancer

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Abstract

Background and objective As the use of real-world evidence (RWE) expands, evaluating whether Japanese real-world data (RWD) can reproduce clinical trial findings is crucial. This study aimed to determine whether pseudonymized medical information collected under the Next-Generation Medical Infrastructure Act could reconstruct a patient cohort comparable to the Japanese subgroup of the OAK trial and to evaluate progression-free survival (PFS) and overall survival (OS) in patients with non-small cell lung cancer (NSCLC) treated with atezolizumab.

Methods We conducted a historical cohort study using the Millennium Medical Record database. Medical information collected between 1 October 2015, and 31 October 2022 was utilized, and the study itself was conducted from September 2023 to February 2024. Patients treated with atezolizumab for NSCLC were identified, and eligibility criteria from the OAK trial were applied. Effectiveness outcomes were extracted from unstructured electronic medical record text by trained abstractors through manual review of the medical records, ensuring robustness of the assessments.

Results A total of 75 patients were analyzed. The median PFS was 3.5 months (95% CI 2.3–8.9), comparable to the 4.2 months (95% CI 2.8–4.4) reported in the OAK trial's Japanese subgroup. Subgroup analyses showed numerical distance, with shorter PFS in patients with advanced stage and poor performance status, consistent with clinical expectations. Median OS was not reached, likely due to censoring from untracked hospital transfers.

Conclusions This study demonstrated the feasibility of extracting PFS from unstructured text in RWD, yielding results comparable to clinical trials. While OS estimation faced challenges due to tracking limitations, future integration with the National Database under the revised law is expected to enhance accuracy, paving the way for using this infrastructure to generate external control arms.

1 Introduction

As the use of real-world evidence (RWE) expands in Japan [1–3], it is increasingly important to evaluate how well domestically available real-world data (RWD) sources can reproduce findings from clinical trials [4, 5]. The Next-Generation Medical Infrastructure Act provides a legal framework for collecting, processing, and supplying pseudonymized medical information with standardized procedures [6] that ensure data quality and traceability. Although RWD generated under this framework has the potential to complement randomized controlled trials (RCTs), empirical

evidence assessing its ability to reproduce trial-derived outcomes remains limited [7].

Japan's Next-Generation Medical Infrastructure Act is a law that promotes the secure use of medical data for research, innovation, and healthcare improvement. It was enacted in 2017 and came into force in 2018 to support the development of a modern, data-driven healthcare system in Japan while protecting personal privacy. Under the Act, hospitals and medical institutions may provide patient information to government-certified operators. These operators are responsible for processing the data into anonymized or pseudonymized forms in which individuals cannot be readily identified. The processed data can then be made available to approved users including researchers, universities,

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Key Points

This study demonstrates that survival outcomes can be successfully reconstructed from unstructured electronic medical records using the database established under Japan's Next-Generation Medical Infrastructure Act.

The research shows that real-world results for lung cancer treatment can closely reflect clinical trial outcomes, proving the feasibility of generating robust real-world evidence (RWE) from this legally regulated domestic data source.

These findings suggest that the infrastructure provided by the Act is a viable and reliable tool for future medical assessments and regulatory science applications in Japan.

pharmaceutical companies, and medical device developers. The main purpose of the Act is to accelerate medical progress. By combining healthcare data from many institutions, researchers can study disease patterns, compare treatment outcomes, and evaluate the effectiveness of medical interventions in real-world settings. This supports areas such as personalized medicine, drug discovery, AI-based diagnostics, preventive care, and evidence-based policymaking.

An important feature of the Act is its privacy protection framework. Only certified organizations may handle the data, and they must comply with strict requirements regarding cybersecurity, governance, and compliance. Patients are informed that their data may be used and are generally given an opt-out right, meaning they can request exclusion from data sharing. The Act was revised in 2023 to expand its usefulness. The amendment introduced broader use of pseudonymized information and promoted stronger data linkage with public databases and other healthcare resources. This change is expected to improve the use of real-world data in clinical research and regulatory review. Overall, the Next-Generation Medical Infrastructure Act is a key part of Japan's healthcare strategy. It seeks to balance two important goals: encouraging innovation through large-scale medical data use and maintaining public trust through strong safeguards for privacy and transparency.

The use of RWD, particularly for the construction of external control arms (ECAs), has attracted increasing interest as a complementary approach in clinical development when randomized controlled trials are difficult to conduct. Regulatory authorities have emphasized that the acceptability of RWE depends on whether the data are fit for purpose, with particular attention to relevance and reliability for the regulatory question of interest. In the USA, the US Food and Drug Administration (FDA) has outlined methodological

expectations for externally controlled trials, including the need to address bias and confounding, ensure alignment of outcomes and timeframes, and maintain transparency in study design and analysis, as well as clarifying the use of RWD within the Investigational New Drug framework [8, 9]. In Europe, the European Medicines Agency (EMA) continues to recognize randomized controlled trials as the standard for evidence generation, while promoting the use of RWD and RWE across the medicinal product lifecycle through regulatory initiatives such as the DARWIN EU network [10]. Although harmonized European guidance on ECAs remains under development, ongoing efforts by regulatory authorities reflect an evolving framework for the appropriate use of RWD in regulatory decision-making [11].

The aim of this study is to determine whether pseudonymized medical information collected under the Next-Generation Medical Infrastructure Act can be used to reconstruct a patient cohort comparable to the Japanese subgroup of an international RCT, and to evaluate treatment outcomes using survival analysis as the primary analytical approach. Specifically, we identified key eligibility criteria and baseline characteristics from the RCT and applied them to the real-world dataset to create a comparable cohort. We then conducted time-to-event analyses, including survival time and event occurrence from treatment initiation, to assess whether real-world outcomes reflected patterns observed in the clinical trial population.

This research is significant for several reasons. In many international multicenter trials, the number is relatively small, limiting the precision and interpretability of subgroup analyses. Demonstrating that real-world data can be used to approximate these subgroups and support survival analyses provides an important opportunity to supplement clinical evidence for Japanese patients [12]. Furthermore, evaluating the feasibility of applying survival analysis to data collected under the Next-Generation Medical Infrastructure Act offers foundational insights into the potential regulatory use of such data.

The findings of this study contribute to understanding the utility of Japan's legally regulated RWD for future applications in regulatory science, including the development of external control arms, health technology assessment (HTA), and broader RWE-based assessments.

2 Methods

In this study, we conducted a case count survey targeting drugs that have already been marketed following approval applications, including international joint clinical trials. The target drug was atezolizumab (recombinant), which was approved in January 2018 at a dose of 1200 mg for unresectable advanced/recurrent non-small cell lung cancer. As

a result of the sample size survey, 75 cases were extracted from 12 facilities and used as research subjects. Furthermore, as a subgroup analysis, we extracted a patient group that met the exclusion criteria in the international joint clinical trial (OAK trial) and conducted comparative studies. In this study, medical information collected between 1 October 2015 and 31 October 2022 was utilized. The study itself was conducted over a 6-month period from September 2023 to February 2024.

OAK trial is a randomized, controlled, open-label, international, phase 3 trial investigating atezolizumab monotherapy versus docetaxel in previously treated patients with locally advanced or metastatic NSCLC. The primary endpoint was overall survival, and secondary endpoints included investigator-assessed progression-free survival [13].

Survival analyses were conducted using structured and text data extracted from electronic medical records. Progression-free survival (PFS) was defined as the time to progression disease (PD) according to RECIST version 1.1 or death from any cause, and overall survival (OS) as the time to death from any cause. The event date for OS was extracted from the “date and time of death” column within the structured data of the electronic medical records. The event date for PFS was determined on the basis of RECIST version 1.1 as the entry date in the medical records where “PD” or “exacerbation” was explicitly documented in the

text data. The determination of “PD” or “exacerbation” for non-small cell lung cancer was performed by trained abstractors through manual review of the medical records, ensuring the robustness of the assessments.

This study was approved by the institutional review board at each participating facility for appropriate use of pseudonymized medical data under the Next-Generation Medical Infrastructure Act. Data extraction and anonymization were performed following institutional approval. The anonymized dataset was stored on secure computing servers with implemented cybersecurity protocols to ensure data confidentiality and integrity throughout the analysis. Statistical analyses were conducted in a dedicated analysis environment with controlled access.

2.1 Statistical Analysis

The continuous and categorical variables were expressed as median values (with range) and frequencies, respectively. Survival curves were analyzed using the Kaplan–Meier method and the log-rank test. A Cox proportional hazard model was performed to estimate the hazard ratio with 95% confidence intervals (CIs). Analyses were performed using Python 3.8.5 [14] and the lifelines 0.27.8 [15] survival analysis library running on Python. Atezolizumab initiation was defined as day 0. OS was measured from the first day of

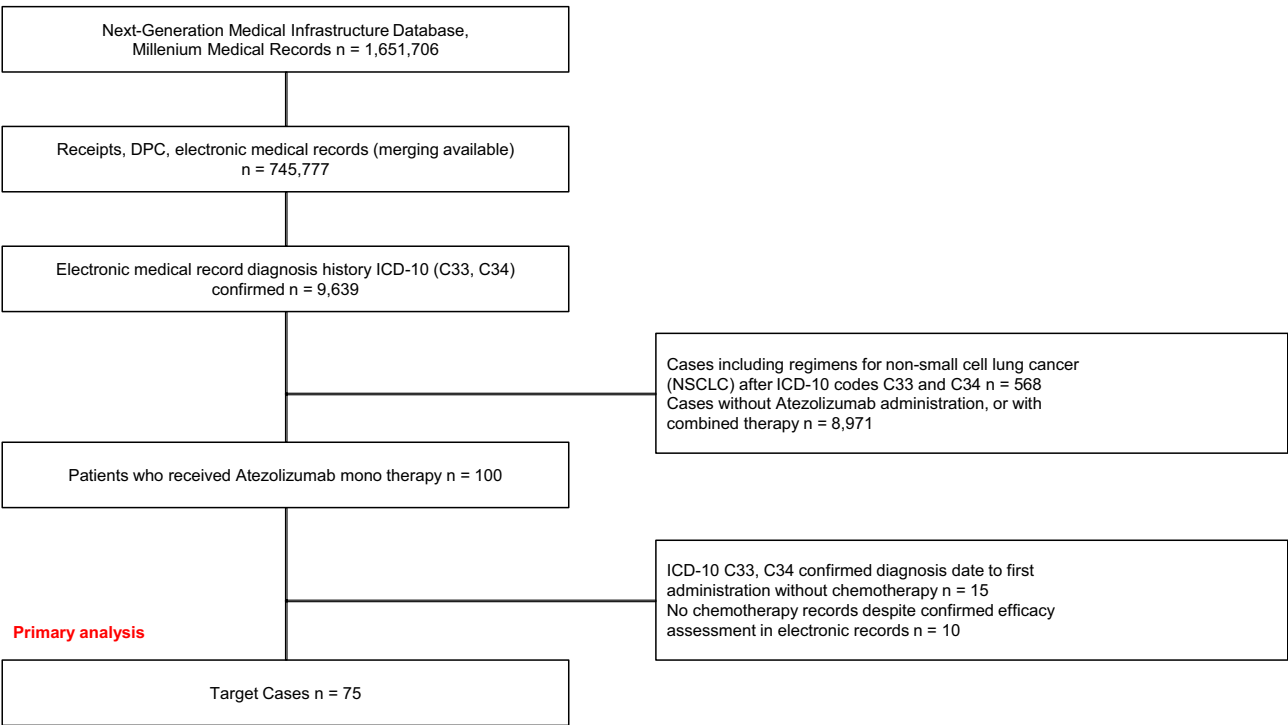


Fig. 1. Patient selection criteria

Table 1 Baseline and clinical characteristics

Characteristics	Analysis set (n=75)	OAK study[15] (n=36)
Observation period (months)	10.2 (0.2–49.0)	NA
Age	71 (32–86)	64 (33–77)
Sex		
Male	50	19
Female	25	17
BMI (kg/m ²)	21.9 (16.12–29.88)	NA
ECOG-PS		
0	30	12
1	25	24
2	5	0
≥ 3	3	0
Unknown	12	0
Stage		
≤ 2	8	NA
3	9	NA
4	51	NA
Unknown	7	NA
Histology		
Squamous	4	8
Non-squamous	71	28
EGFR mutation status		
Positive	17	8
Negative	44	28
Unknown	14	0
PD-L1 expression status		
TPS <1%	25	25
1% ≤ TPS ≤ 49%	10	6
TPS ≤ 50%	9	5
Metastasis		
Liver	4	NA
Bone	16	NA
Albumin (g/dL)	3.7 (2.4–4.5)	NA
CRP (mg/dL)	0.8 (0.07–15.6)	NA
LDH (U/L)	222 (121–456)	NA
WBC (/mm ³)	6780 (2950–17520)	NA
Neutrophils(/mm ³)	4630 (2392–10862)	NA
Lymphocytes (/mm ³)	1263.5 (260–5266)	NA
Monocytes (/mm ³)	586.5 (204–1546)	NA
Platelets (10 ³ /μL)	292.5 (132.5–530.0)	NA
NLR	3.1 (1.2–14.0)	NA
LMR	2.5 (0.5–6.4)	NA
PLR	236.6 (74.4–533.8)	NA
Treatment lines of atezolizumab		
2nd	25	27
3rd	21	9
≥ 4th	29	0
Atezolizumab treatment duration (Days)	64 (1–1406)	NA

NA not reported

Data are median (range), or frequencies

BMI body mass index, CRP C-reactive protein, ECOG-PS Eastern Cooperative Oncology Group-Performance Status, LDH lactate dehydrogenase, LMR lymphocyte-to-monocyte ratio, NLR neutrophil-to-lymphocyte ratio, TPS tumor proportion score, WBC white blood cells

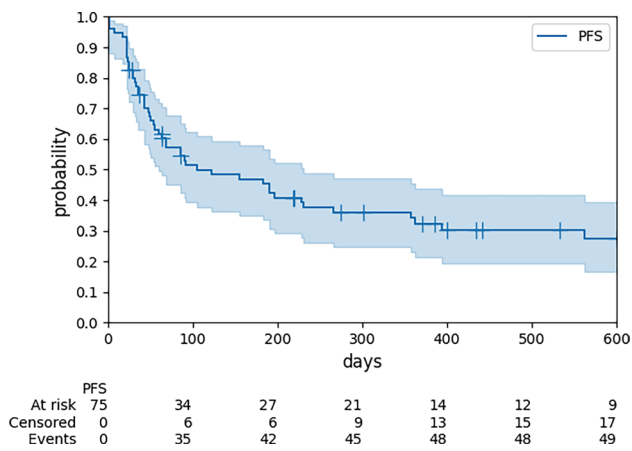


Fig. 2 Progression-free survival

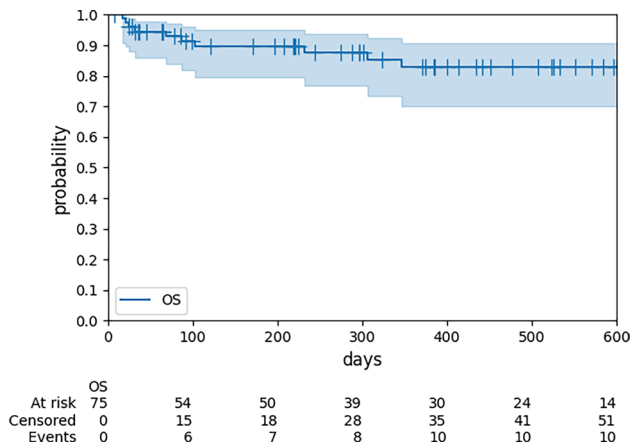


Fig. 3 Overall survival

treatment until death from any cause. PFS was defined as the time from the first day of treatment to tumor progression or death from any cause. Patients lost to follow-up (e.g., due to transfer to another facility) were censored. A p -value < 0.05 was considered statistically significant.

3 Results

3.1 Patient

To reconstruct a patient cohort comparable to the Japanese subgroup of an international RCT, the primary analysis set of 75 patients was selected through the following procedure from 1,651,706 cases registered in the Millennium Medical Record database maintained by the Life Data Initiative

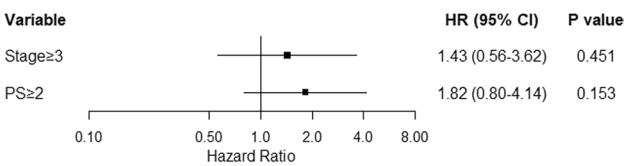


Fig. 4 Forest plot based on the univariate Cox proportional hazard model

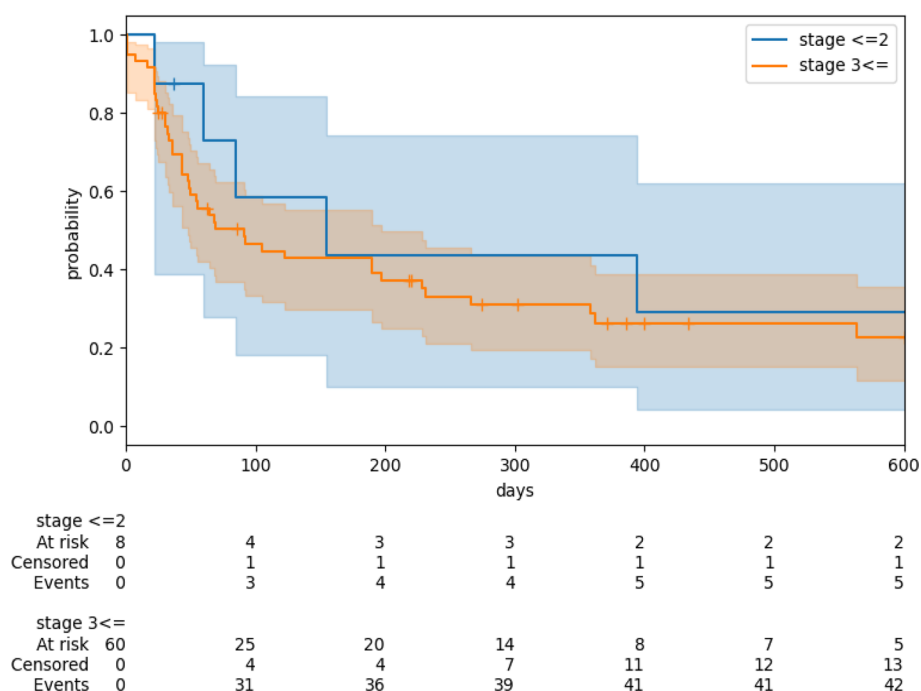
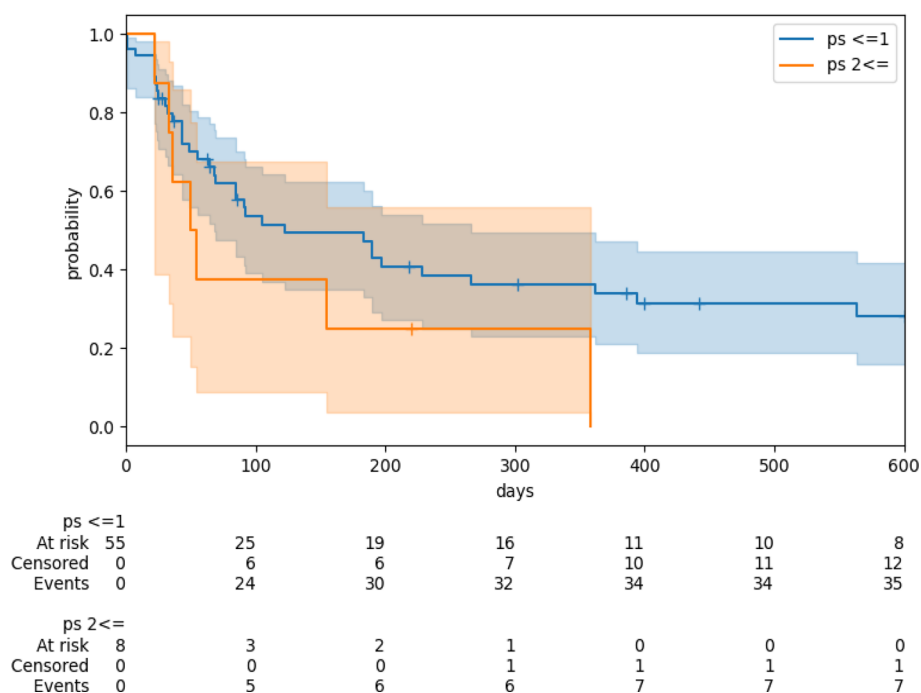
(LDI), a certified pseudonymized medical data handling operator under the Next-Generation Medical Infrastructure Act of Japan.

First, the study population was narrowed down to 745,777 cases from 12 medical institutions where all 3 data sources utilized in this study—medical claims (receipts), Diagnosis Procedure Combination (DPC) survey data, and electronic medical records—were available and could be linked at the patient level. Second, the cohort was restricted to 9639 cases with a diagnosis code of ICD-10 C33/C34. Third, the selection was further limited to 100 cases that had received atezolizumab monotherapy and had no prior prescription history of treatments for small cell lung cancer (irinotecan, etoposide, nogitecan, and amrubicin). Finally, after excluding cases with missing chemotherapy records for atezolizumab or inconsistencies in diagnosis dates, 75 cases were selected as the primary analysis set (Fig. 1).

Table 1 summarizes the baseline and clinical characteristics of these 75 patients, including demographic information, disease stage, and treatment-related variables. The baseline characteristics of the Japanese subgroup in the OAK trial [16] are presented in Table 1 for comparison.

3.2 Progression-Free Survival and Overall Survival

The median PFS was 3.5 months (95% CI 2.3–8.9), demonstrating feasibility of survival time analysis and curve plotting (Fig. 2). The median OS was not reached, as the survival rate remained above 50% throughout the observation period. The 1-year survival rate was 83.0% (Fig. 3). The median PFS was 155 days in patients with stage ≤ 2 disease, compared with 91 days in those with stage ≥ 3 disease (hazard ratio: 1.43; 95% confidence interval: 0.56–3.62; $p = 0.45$). The difference was not statistically significant (Figs. 4 and 5). The median PFS was 122 days in patients with ECOG performance status ≤ 1 , compared with 54 days in those with ECOG performance status ≥ 2 (hazard ratio: 1.82; 95% confidence interval: 0.80–4.14; $p = 0.15$). The difference was not statistically significant; a numerical distance toward reduced PFS was observed in patients with poor ECOG performance status (Figs. 4 and 6). In the OAK trial, the median

Fig. 5 PFS stratified by disease stage**Fig. 6** PFS stratified by ECOG performance status

PFS was 4.2 months (95% CI 2.8–4.4), and the median OS was 21.3 months (95% CI 11.0–not estimable) [16].

4 Discussion

This study demonstrated the feasibility of generating survival curves and analyzing PFS using integrated medical data, with a median PFS of 3.5 months. When compared

with the median PFS of 4.2 months (95% CI 2.8–4.4) reported for 36 Japanese patients in the OAK trial (intention-to-treat population) [16], our results support the applicability of real-world data

for estimating survival functions. Despite the inherent limitations of observational studies,

such as potential selection bias and immortal time bias, the methodology used in this study

shows potential for broader applications in real-world data analysis.

The OS analysis revealed a 1-year survival rate of 83.0%, although the median OS was not reached due to the high survival rate observed throughout the period. A comparison with the OAK trial, which reported a median OS of 21.3 months (95% CI 11.0–not estimable) for 36 Japanese patients, provides context for our findings.

Furthermore, the internal validity of our dataset is supported by the subgroup analyses. Although statistical significance was not reached due to the limited sample size, the trends observed—specifically shorter PFS in patients with advanced disease stages or poorer ECOG performance status—were consistent with established clinical knowledge. This alignment with expected clinical courses suggests that the extracted cohort effectively reflects the characteristics of the target population, reinforcing the reliability of the data for assessing treatment progression.

The revised Next-Generation Medical Infrastructure Act (effective April 2024) enables linkage with external databases such as the National Database, which includes death notifications. Future integration is expected to improve OS accuracy by incorporating post-transfer mortality data.

Achieving complete outcome tracking through such linkage is a critical step toward broader regulatory applications. With improved accuracy in survival outcomes, this infrastructure could eventually support the generation of external control arms for single-arm trials, particularly for rare cancers or specific molecular subgroups, thereby accelerating drug development and approval processes in Japan.

5 Limitations

First, it is important to acknowledge that the OS outcomes in this study may be subject to overestimation. This potential bias arises from the tracking limitations of the Millennium Medical Record system, particularly its inability to capture deaths occurring after patients have been transferred to another institution. Second, the sample size of this study was relatively small, consisting of 75 patients in the primary analysis set. This limited number of cases is due to our strict application of selection criteria to isolate patients receiving atezolizumab monotherapy within a legally regulated database, which reduced statistical power for the subgroup analyses. Although this cohort size is larger than the Japanese subgroup in the OAK trial ($n = 36$), the findings should be interpreted with caution, and larger multi-database studies are warranted to confirm these results.

6 Conclusions

This study explored the feasibility of evaluating cancer treatment effectiveness—specifically PFS and OS—by integrating claims data, DPC data, and electronic medical records (EMRs) collected under Japan's Next Generation Medical Infrastructure Act. The focus was on extracting and estimating PFS and OS-related information from unstructured free-text within EMRs.

The research demonstrated the potential for building a fast and precise evaluation process using anonymized medical data. It also clarified which effectiveness metrics are currently assessable and which are not, emphasizing the importance of prior validation before implementing artificial intelligence (AI)-based systems.

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Author Contributions All authors contributed to the study conception and design. Yosuke Nishida and Suguru Nozue were responsible for data provision under the Next-Generation Medical Infrastructure Act. Masahiko Nakatsui received and managed the data. Data analysis was performed by Yosuke Nishida, Suguru Nozue, Yukinori Sakata, Yuki Nakagami, and Masahiko Nakatsui. Rika Okamoto provided expert advice on regulatory and pharmaceutical matters. Rika Abe and Yasushi Okuno provided scientific advice and guidance throughout the research. Yosuke Nishida, Mie Azuma, Yukinori Sakata, and Masahiko Nakatsui designed the overall research framework. All authors contributed to writing the manuscript and approved the final manuscript.

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Data Availability The data used in this study were obtained from the Millennium Medical Record database and are managed by an authorized operator under the Next-Generation Medical Infrastructure Act.

Code Availability Statistical analyses were conducted using Python, and the results were verified by R. The code consists of standard procedures and is not publicly available.

Declarations

Competing Interests Yosuke Nishida was an employee of NTT DATA Corporation at the time of the study. Suguru Nozue is an employee of NTT DATA Corporation. Yukinori Sakata and Mie Azuma are employees of Eisai Co., Ltd. The authors have no other relevant financial or non-financial interests to disclose.

Consent to Participate The LDI data were collected by the opt-out consent process per the Next-Generation Medical Infrastructure Law, and the use of LDI data for this study was approved by the review board of LDI (application no.: 2023_MIL_0005).

Consent to Publish The LDI data were collected by the opt-out consent process per the Next-Generation Medical Infrastructure Law, and the use of LDI data for this study was approved by the review board of LDI (application no.: 2023_MIL_0005).

Ethical Approval This study was performed in line with the principles of the Declaration of Helsinki. Approval was granted by the Review Board of Life Data Initiative, a certified operator under the Act on Anonymized Medical Data and Pseudonymized Medical Data That Are Meant to Contribute to Research and Development in the Medical Field (Next-Generation Medical Infrastructure Act) (application no.: 2023_MIL_0005).

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