

NON-INTERVENTIONAL/LOW-INTERVENTIONAL STUDY REPORT ABSTRACT

Title: Post-Authorisation Active Surveillance Study of Myocarditis and Pericarditis Among Individuals in Europe Receiving the Pfizer-BioNTech Coronavirus Disease 2019 (COVID-19) Vaccine

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Keywords: Pfizer-BioNTech COVID-19 vaccine; database study; active surveillance study; post-conditional approval safety study; non-interventional study.

Rationale and background: The Pfizer-BioNTech COVID-19 vaccine, tozinameran (Comirnaty®), a novel mRNA-based vaccine, was authorised for use in several countries including the United States and European Union, for the prevention of COVID-19. The European Medicines Agency (EMA) safety committee (Pharmacovigilance Risk Assessment Committee [PRAC]) confirmed the risk of myocarditis and pericarditis following vaccination with the mRNA COVID-19 vaccines, Comirnaty and Spikevax, which has been added to the product information for these two vaccines.

Both the EMA and the United States Food and Drug Administration (FDA) requested that Pfizer-BioNTech evaluate the clinical course and risk factors associated with myocarditis and pericarditis following vaccination with the Pfizer-BioNTech COVID-19 vaccine. To do so, this study used data from the Pfizer-BioNTech Study, C4591021, entitled *Post Conditional Approval Active Surveillance Study Among Individuals in Europe Receiving the Pfizer-BioNTech Coronavirus Disease 2019 (COVID-19) Vaccine* which estimated the risk of prespecified adverse events of special interest (AESIs), including myocarditis and pericarditis, among individuals who had received at least one dose of the Pfizer-BioNTech COVID-19 vaccine and among individuals who have not received any COVID-19 vaccine. This non-interventional study (NIS) was designated as a post-authorisation safety study (PASS) and was a commitment to the European Medicines Agency (EMA) and a post-marketing requirement to the FDA.

Research question and objectives: The research question was: 'What is the clinical course of myocarditis and of pericarditis cases after being vaccinated with the Pfizer-BioNTech COVID-19 vaccine in European countries?'

Primary study objective:

To determine the clinical course (natural history) of myocarditis and pericarditis cases after being vaccinated with the Pfizer-BioNTech COVID-19 vaccine in European countries.

Secondary study objective:

To examine and identify potential risk factors for myocarditis and pericarditis, such as age, sex, Pfizer-BioNTech COVID-19 vaccination status, vaccine doses received, i.e., first, second and third doses), and history of COVID-19, using a cohort study design.

Study design: This was a retrospective cohort study that included individuals in six data sources from five European countries who received at least one dose of the Pfizer-BioNTech COVID-19 vaccine, as well as individuals who did not receive a COVID-19 vaccine. For the primary objective (natural history) the study was conducted in two cohorts of individuals: one with a first diagnosis of myocarditis during the study period and the second with a first diagnosis of pericarditis during the study period. For the secondary objective (risk factors for myocarditis and pericarditis) the study evaluated risk factors in three dose-specific matched vaccinated and unvaccinated cohorts.

Setting: The source population included all individuals registered in six electronic healthcare data sources in Europe: Pédianet, IT; PHARMO Institute for Drug Outcomes Research (PHARMO), NL; Norwegian Health Registries (NHR), NO; EpiChron Research Group on Chronic Diseases at the Aragon Health Sciences Institute (EpiChron), ES; Sistema d'Informació per el Desenvolupament de la Investigació en Atenció Primària (SIDIAP), ES and CPRD (Clinical Practice Research Datalink) Aurum (UK).

The study period included the following calendar time by data source:

- Pédianet (family paediatrician diagnoses) between 26 February 2021 and 31 December 2022;
- PHARMO (general practitioner data, with partial linkage to hospital data) between 6 January 2021 and 30 June 2023 and (hospital data) between 6 January 2021 and 31 December 2022;
- NHR (general practice, outpatient specialist and hospital discharge diagnoses) between 1 January 2021 and 14 January 2023;
- EpiChron (general practice and emergency room, hospital discharge diagnoses) between 27 December 2020 and 31 July 2023;
- SIDIAP (general practice and hospital discharge diagnoses) between 1 January 2021 and 30 June 2023;
- CPRD Aurum (general practice recorded data) between 2 December 2020 and 7 June 2023.

Outcomes, treatments and diagnostic methods were identified in the data sources with algorithms based on codes for diagnoses and treatments. A sample of myocarditis and pericarditis cases were validated for level of diagnostic certainty (LOC) using modified Brighton Collaboration case definitions and a study-specific natural history questionnaire to collect information.

Results:

The source population captured 34.47 million individuals from all data sources. In this population, 5,674 cases of myocarditis and 10,655 cases of pericarditis were identified during the study period. Approximately 45% of cases were not eligible to be included in the disease cohorts, often because of prior vaccination with a non-Pfizer-BioNTech COVID-19

vaccine. A total of 3,142 myocarditis cases and 5,966 pericarditis cases were included in the final disease cohorts.

Validation

A subset of approximately 990 (considering masking) myocarditis and 1,250 pericarditis cases were sampled for validation from the cohorts for the primary and secondary study objectives across all sites. For myocarditis, 19% were classified as Level 1 (definitive) and 36.2% were classified as Levels 1–3 (definite, probable, and possible), 35% were classified as level 4 (had a diagnostic code but insufficient data for Levels 1–3). The highest number of definitive cases came from NHR. In all data sources combined 10% of cases were not myocarditis cases (Level 5); but none were classified as such in NHR and CPRD Aurum, so the false positive rate was higher in SIDIAP, EpiChron and PHARMO. The positive predictive values (PPVs) for the combined Levels 1–3 ranged from 0% (Pedianet) to 75% (EpiChron). For combined Levels 1–4 the PPVs ranged from 50% (PEDIANET) to 100% (CPRD Aurum and NHR).

For pericarditis, 20% were Level 1, with highest percentages in Pedianet, EpiChron and SIDIAP. A total of 38.6% were Level 1–3 combined, 9.9% were not cases. The PPVs for combined Levels 1–3 ranged from 5.3% (CPRD Aurum) to 80% (Pedianet). The PPVs for combined Levels 1–4 ranged from 73% (SIDIAP) to 100% (CPRD Aurum/NHR).

Validated cases were used in sensitivity analyses.

Natural history: Characteristics at first diagnosis and comparisons between vaccinated and unvaccinated individuals.

Overall, 1,821 of the 3,142 myocarditis cases were vaccinated with Pfizer-BioNTech-COVID-19 vaccine prior to diagnosis (58.0%), and 3,701 of the 5,966 pericarditis cases (62.0%). In >90% of vaccinated cases, onset occurred >14 days after the last dose. Most had received two doses and a few had received three. Myocarditis mostly occurred >22 days after the second dose.

The median age was higher in vaccinated individuals (except in PHARMO); in NHR and SIDIAP, with a difference of between 11–14 years. Comorbidity prevalence over the prior 10 years was higher in vaccinated cases, particularly for cardiovascular and respiratory diseases. Medication use in the prior year was frequent, especially antibiotics, NSAIDs, and analgesics, with higher use in vaccinated individuals. Prior non-COVID-19 vaccinations varied by data source; CPRD Aurum showed high rates due to a longer lookback period. Few women were pregnant at diagnosis. Between 15–35% of myocarditis cases had ≥1 hospitalisation in the prior year and most had ≥1 GP visit. COVID-19 recording varied and was highest in CPRD Aurum (>50%) and lowest in NHR, with lower recording in 2023. In the two weeks before myocarditis, about 10% had a hospital visit and 0–15% had an emergency room visit.

Individuals with pericarditis had more frequent prior hospitalisations, especially in NHR (43%). Emergency room visits were common in databases that contained such information like EpiChron and CPRD Aurum. Most had ≥1 GP visit in the prior year, with more visits



among vaccinated individuals. Healthcare use in the two weeks before pericarditis diagnosis was low.

Natural history: Comparison of vaccination and treatment after diagnosis in vaccinated and unvaccinated cohorts

Many individuals with myocarditis were subsequently re-vaccinated with a COVID-19 vaccine after diagnosis. This ranged from 17.3% of vaccinated individuals in EpiChron to 40% in PHARMO. Among individuals who were unvaccinated at diagnosis, 35% to 73% were vaccinated with a COVID-19 vaccine afterwards. Similar patterns were observed for individuals with pericarditis.

In the 365 days post-diagnosis, vaccinated and unvaccinated individuals with myocarditis commonly received antibiotics, beta-blockers, ACE inhibitors/ARBs, and diuretics, but these data were not restricted to new use of these medicines. Few received invasive treatments and pacemaker, or defibrillator use was rare, based in natural history questionnaire data. Individuals with pericarditis frequently received colchicine, NSAIDs, and antibiotics. Invasive treatments (in data sources where this was available) were rare, with only 1.72% in EpiChron who had a pacemaker. Pericardial drainage was the most frequent non-pharmacological treatment in NHR and EpiChron.

Natural history: Outcomes following the diagnosis of myocarditis and pericarditis

The table below shows the 12-month crude and adjusted relative risks of select outcomes in vaccinated and unvaccinated individuals with myocarditis and pericarditis at baseline. The crude risks did not adjust for potential differences between vaccinated and unvaccinated individuals. Vaccinated individuals were older with a median age difference of up to 14 years depending on data source and they had a higher proportion of comorbid conditions at baseline. Moreover, prevalent chronic conditions that were highly common at baseline such as heart failure and arrhythmia were not excluded in the Kaplan Meier analyses for these outcomes. To explore the impact of confounding on observed differences between vaccinated and unvaccinated individuals at baseline *post-hoc* Cox-regression analyses adjusting for age, gender, and comorbidity scores were undertaken. The results of these analyses showed that the adjusted hazard ratios for all the prespecified outcomes in this study decreased compared to the crude hazard ratios and did not indicate a substantial difference between individual who had been vaccinated with the Pfizer BioNTech COVID-19 vaccine at first diagnosis of myocarditis or pericarditis, compared with those who were unvaccinated.

Table. Summary of the 12-month unadjusted risk for selected outcomes in the myocarditis and pericarditis cases who were vaccinated and unvaccinated at first diagnosis, with unadjusted and adjusted comparisons

Outcome	Myocarditis				Pericarditis			
	Vaccinated	Unvaccinate d	HR crude	HRadj.* (95% CI)	Vaccinated	Unvaccinate d	HR crude	HRadj.*
Hospitalisation	%	%			%	%		
PHARMO	NA	NA	NA	NA	NA	NA	NA	NA
NHR	82.21	82.71	1.01 (0.87-1.17)	1.04 (0.90-1.20)	85.27	82.96	1.04 (0.94- 1.15)	0.96 (0.86-1.06)
EpiChron	85.33	82.93	1.02 (0.70-1.50)	0.99 (0.66-1.49)	51.14	60.93	0.79 (0.60-1.02)	0.66 (0.50-0.86)
SIDIAP	67.10	63.30	1.09 (0.90-1.31)	0.77 (0.64-0.91)	70.07	60.34	1.34 (1.19-1.50)	1.07(0.94-1.20)
CPRD Aurum	13.71	12.99	1.11 (0.76-1.63)	1.04 (0.69-1.56)	12.74	12.93	0.98 (0.75-1.29)	0.92 (0.70-1.20)
Death								
PHARMO	2.53	4.51	0.55 (0.23-1.35)	0.40 (0.16-1.01)	2.78	7.74	0.36 (0.04-3.17)	0.25 (0.03-1.74)***
NHR	7.72	5.77	1.38 (0.76-2.52)	0.74 (0.39-1.40)	5.16	2.29	2.09 (1.15- 3.81)	1.06 (0.57-1.98)**
EpiChron	16.54	5.01	3.60 (0.82-15.79)	3.25 (0.7-14.9)***	10.27	5.34	1.90 (0.83-4.38)	1.13 (0.47-2.74)
SIDIAP	11.43	8.25	1.30 (0.77-2.19)	0.66 (0.36-1.22)	8.93	5.73	1.60 (1.10-2.33)	0.84 (0.56-1.26)
CPRD Aurum	2.21	1.57	1.31 (0.43-3.91)	0.89 (0.28-2.85)	2.19	0.71	3.06 (1.14-8.25)	0.90 (0.69-1.19)
Heart failure\$								
PHARMO	3.39	5.73	0.58 (0.27-1.23)	0.51 (0.24-1.07)	5.64	18.49	0.28 (0.06-1.25)	0.21 (0.03-1.36)***
NHR	20.22	17.42	1.15 (0.81-1.63)	0.92 (0.64-1.32)	13.80	7.73	1.83 (1.30-2.57)	1.14 (0.80- 1.62)
EpiChron	21.63	17.30	1.31 (0.54-3.15)	0.78 (0.29- 2.11)	15.85	9.87	1.65 (0.90-3.05)	0.99 (0.54-1.81)
SIDIAP	15.82	16.78	0.96 (0.65-1.42)	0.68 (0.46-1.01)	26.80	13.64	2.11 (1.67-2.66)	1.18 (0.92-1.52)
CPRD Aurum	9.72	9.992	0.94 (0.60-1.47)	0.83 (0.53-1.29)	3.02	2.88	1.09 (0.62-1.91)	0.69 (0.38-1.26)
Cardiogenic shock								
PHARMO	0.33	1.08	0.30 (0.03- 2.72)	0.27 (0.03-2.28)***	0	0	NE	NE
NHR	1.10	0.74	1.49 (0.30-7.40)	1.67 (0.34-8.13)***	0.43	0.18	2.34 (0.28-19.42)	2.01 (0.28-14.6)
EpiChron	1.33	0	NE	NE	1.99	0.75	2.66 (0.32-22.0)	3.14 (0.43-23.2)
SIDIAP	3.30	7.09	0.41 (0.20-0.87)	0.40 (0.19-0.82)	1.35	1.58	0.87 (0.39- 1.93)	0.77 (0.33-1.84)
CPRD Aurum	0	0.29	NE	NE	0	0	NE	NE



Table. Summary of the 12-month unadjusted risk for selected outcomes in the myocarditis and pericarditis cases who were vaccinated and unvaccinated at first diagnosis, with unadjusted and adjusted comparisons

Outcome	Myocarditis				Pericarditis			
	Vaccinated	Unvaccinated	HR crude	HRadj.* (95% CI)	Vaccinated	Unvaccinated	HR crude	HRadj.*
Fulminant myocarditis								
PHARMO	0.99	2.17	0.46 (0.12-1.72)	0.44 (0.12-1.56)	NR	NR	NR	NR
NHR	4.48	4.46	1.00 (0.50- 2.00)	0.93 (0.47-1.81)	NR	NR	NR	NR
EpiChron	2.57	0			NR	NR	NR	NR
SIDIAP	3.01	6.72	0.40 (0.18-0.86)	0.39 (0.18-0.83)	NR	NR	NR	NR
CPRD Aurum	2.75	2.59	1.06 (0.46-2.46)	1.01 (0.45-2.27)	NR	NR	NR	NR
Arrhythmia\$								
PHARMO	5.205	5.10	0.77 (0.38-1.58)	0.71 (0.35-1.45)	7.98	2.08	7.93 (0.92-68.6)	4.45 (0.46-42.8)***
NHR	15.40	16.76	1.06 (0.73-1.54)	0.91 (0.61-1.34)	12.10	12.29	1.18 (0.90-1.56)	0.85 (0.64-1.14)
EpiChron	3.89	2.86	0.85 (0.19-3.68)	0.75 (0.16-3.55)***	6.65	5.83	1.02 (0.47-2.20)	0.58 (0.24-1.41)
SIDIAP	4.83	2.88	1.58 (0.82-3.05)	1.18 (0.57-2.44)	8.44	5.64	1.82 (1.32-2.51)	1.01 (0.72-1.43)
CPRD Aurum	3.36	3.83	0.98 (0.43-2.44)	0.75 (0.33-1.69)	3.03	2.90	1.17 (0.66-2.07)	0.79 (0.44-1.42)

HR: hazard ratio estimated through Cox-regression. Vac, vaccinated; Unvac, unvaccinated; NA: not available; NE: not estimable; \$ analyses did not exclude prevalent cases of arrhythmia and heart failure that were highly prevalent at baseline, posthoc analyses were conducted to exclude them.*adjusted for age. age2. Charlson index and CDC score.**adjusted for age. age2. and Charlson index due to non-convergence with CDC score added as well; ***adjusted for age. age2 only due to non-convergence. NA: not available; NR: not relevant, NE not estimable

Risk factors for myocarditis and pericarditis (secondary objective)

The population for the secondary objective included matched vaccinated and unvaccinated individuals for each dose of the Pfizer-BioNTech COVID-19 vaccine. For dose 1, 14.3 million vaccinated individuals were eligible and matched, for dose 2 12.8 million and for dose 3 4.1 million vaccinated individuals.

For this report, individuals aged 80+ were inadvertently excluded from the risk factor analyses and, therefore, the results can be generalised only to individuals aged up to 79 years old. Cardiovascular disease, immunological conditions, and infections were common risk factors for myocarditis in all data sources. The association between the Pfizer-BioNTech COVID-19 vaccine and myocarditis varied by dose and data source. Generally, no increased risk was observed after dose 1, while highly imprecise associations were observed after dose 2, with some indication of interaction with age. For pericarditis, results were heterogeneous with broad confidence intervals. In confirmed cases, associations with the vaccine appeared stronger but remained highly imprecise.

Table. Summary table of the association between Pfizer-BioNTech vaccine by dose and occurrence of myocarditis or pericarditis

		Myocarditis			Pericarditis		
Data source	Pfizer-BioNTech	Dose 1 OR (95%CI)	Dose 2 OR (95%CI)	Dose 3 OR (95%CI)	Dose 1 OR (95%CI)	Dose 2 OR (95%CI)	Dose 3 OR (95%CI)
Univariate analysis (all cases)							
PHARMO	Vaccine	1.4 (0.5–3.8)	12.0 (1.6–92)	NA	1 (0.1-16)	NE	NE
NHR	Vaccine	0.6 (0.3–1.4)	1.1 (0.4–2.7)	0.6 (0.2–1.5)	0.8 (0.5–1.4)	1.3 (0.8–2.1)	0.4 (0.2–0.8)
EpiChron	Vaccine	1 (0.1–16.0)	2.0 (0.2–22.1)	NE	1.4 (0.4, 4.4)	7 (0.9, 56.9)	NE
SIDIAP	Vaccine	1 (0.2, 5.0)	1.1 (0.5, 2.6)	NE	1.5 (0.8, 2.6)	1.1 (0.6, 2.1)	1.5 (0.2, 9.0)
CPRD	Vaccine	1.5 (0.6–3.7)	4.8 (1.6–14.0)	1 (0.2–5.0)	1.6 (0.7, 3.6)	0.6 (0.3, 1.1)	1.2 (0.4, 3.9)
Multivariate logistic regression with interaction (all cases)							
PHARMO	Vaccine	1.0 (0.3–3.1)	9.0 (1.1–71.1)		NE	NE	NE
	age 15-30 & vaccinated	4.0 (0.3–46.9)	NE		NE	NE	NE
NHR	Vaccine	0.6 (0.2–1.5)	0.9 (0.3–2.6)	0.7 (0.2–1.9)	0.7 (0.4–1.5)	1.3 (0.7–2.3)	0.3 (0.1–0.6)
	age 15-30 & vaccinated	1.1 (0.1–8.5)	2.3 (0.3–17.3)	0.5 (0.0–6.0)	2.6 (0.7–10.1)	4.5 (0.9–22.2)	NE
EpiChron	vaccine	NE	NE	NE	1.2 (0.4–3.9)	7 (0.9–56.9)	NE
SIDIAP	vaccine	NE	NE	NE	1.7 (0.8–3.5)	1.1 (0.5–2.5)	1.5 (0.3–9.0)
	age 15-30 & vaccinated				0.9 (0.2–3.4)	3.2 (0.7–14.3)	NE
CPRD	Vaccine	2.7 (0.7–10.1)	5.0 (0.6–43.1)	1 (0.2–5.0)	0.8 (0.3–2.2)	0.3 (0.1–0.6)	1.3 (0.3–4.7)
	age 15-30 & vaccinated	0.3 (0.0–1.9)	0.9 (0.1–11.0)	NE	10.6 (1.0–108.9)	3.3 (1.0–11.6)	0.8 (0.0–17.1)
Definite cases only							
PHARMO	Vaccine	NE	NE	NE	NE	NE	NE
NHR	Vaccine	0.7 (0.1–4.0)	3 (0.3–28.8)		0.8 (0.2–3.4)	5.0 (1.1–22.9)	NE
EpiChron	Vaccine	NE	NE	NE	0.5 (0.1–2.7)	2 (0.2–22.1)	

Table. Summary table of the association between Pfizer-BioNTech vaccine by dose and occurrence of myocarditis or pericarditis

Data source	Pfizer-BioNTech	Myocarditis			Pericarditis		
		Dose 1 OR (95%CI)	Dose 2 OR (95%CI)	Dose 3 OR (95%CI)	Dose 1 OR (95%CI)	Dose 2 OR (95%CI)	Dose 3 OR (95%CI)
SIDIAP	Vaccine	NE	NE	NE	NE	NE	NE
CPRD	Vaccine	NE	NE	NE	NE	NE	NE

OR: odds ratio; NA: not available; NE: not estimable.

Discussion and conclusions:

The main objective of this study was to describe the clinical course of myocarditis and pericarditis after being vaccinated with at least 1 dose of the Pfizer-BioNTech COVID-19 vaccine in comparison to those that develop these conditions without being vaccinated with a COVID-19 vaccine.

Conclusions from this study are that myocarditis and pericarditis were infrequent events and occurred more frequently in males. Myocarditis was mainly diagnosed with cardiovascular magnetic resonance and echocardiogram, but this information could not always be obtained from the electronic health records, because these procedures were conducted in the hospital setting. For pericarditis, an echocardiogram was often performed based on information reported for validated cases. Invasive non-pharmacological treatments were rarely recorded. Most individuals received medicines, although it was not possible to know the reason for the prescription. Individuals with myocarditis often received antibiotics and cardiovascular medications (B-blockers, ACE inhibitor or ARB, cardiac glycosides or calcium channel blockers and diuretics), although the latter were less frequently used in younger individuals. Individuals with pericarditis were mostly treated with colchicine and NSAIDs. Treatment patterns did not differ between cases who had been vaccinated with Pfizer-BioNTech COVID-19 vaccine and those who were unvaccinated.

Many individuals who developed myocarditis or pericarditis received one or more doses of a COVID-19 vaccine after diagnosis. This was higher for those who were unvaccinated at the time of diagnosis. Most of those who were vaccinated received a mRNA-based COVID-19 vaccine.

The 12-month crude and adjusted relative risks of prespecified outcomes after diagnosis differed across data sources and within data source between vaccinated and unvaccinated individuals. Individuals with myocarditis and pericarditis were youngest in CPRD Aurum, and oldest in NHR, which is likely due to the COVID-19 vaccination campaigns, that prioritised older individuals and began with the AstraZeneca COVID-19 vaccine in the UK, and with the Pfizer-BioNTech COVID-19 vaccine in the Netherlands. The 12-month risks of clinical outcomes showed that



serious outcomes were rare, except for heart failure, which could be explained by the high prevalence of heart failure at baseline.

The crude differences in outcomes observed between vaccinated and unvaccinated individuals within data sources was mostly due to increased age and higher rate of comorbidities in the vaccinated group compared to the unvaccinated, and high prevalence of potentially pre-existing disease, which was not excluded for some conditions, e.g. heart failure and arrhythmia. Within data sources, vaccinated individuals were much older than the unvaccinated, with a 13–14-year median age difference between vaccinated and unvaccinated in NHR and SIDIAP, respectively. Vaccinated individuals had proportionately more comorbidities. Due to these differences in baseline risk, *post-hoc* analyses were conducted with adjustment for age and comorbidity scores. The adjusted results showed that the 12-month risk ratio for each of these outcomes did not differ between those who were vaccinated and unvaccinated at the time of diagnosis.

Only a subset of cases of myocarditis and pericarditis could be validated because of practical feasibility. The level of certainty that could be assigned depended largely on the data that could be accessed to validate cases. In data sources that had access to original hospital records, the level of certainty was much higher than in data sources that could only review information recorded by the GPs. Importantly, the clinical course did not differ between cases classified as definitive (Level 1) compared with all cases.

The analyses for risk factors for myocarditis or pericarditis after one, two or three doses of the Pfizer-BioNTech COVID-19 vaccine indicated that age, cardiovascular and immunological conditions as well as infections were general risk factors for myocarditis mostly after dose 1. Odds ratios between myocarditis and Dose 2 of the Pfizer-BioNTech COVID-19 vaccine varied across data sources and although the estimates were imprecise, there was a suggestion of effect modification by age.

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