

Leveraging open data and machine learning enhanced data extraction for clinical trials insight

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Abstract

Open databases such as ClinicalTrials.gov provide valuable information about clinical trials for specific diseases or drugs, including data from protocol and study results.

However, some information is not always directly provided in a structured format in protocol descriptions (dosage, frequency, and route of drugs) or in results (type of group).

These limitations makes it challenging to extract information and fully leverage open data for clinical projects analysis. Machine learning tools like Med7 and BioBERT allow extraction and mapping of this information, making exploitation of data easier over a larger number of clinical trials and reducing human error and efforts.

These processes allow multiple use cases such as extracting adverse event data for meta-analytic risk modeling, gathering data to produce tables, or providing a landscape of clinical trials over time with a data visualization dashboard.

Thus, making data extraction and monitoring easier unlocks numerous use cases for clinical trial analysis, automation, and exploration.

Goal

The aim of this is to monitor and analyze the landscape of clinical trials for specific diseases and drugs. It primarily leverages data from open public databases (ClinicalTrials.gov and PubMed) and machine learning models/AI to extract additional information from non-structural data, enabling more comprehensive analysis and insights.

These data allow for multiple use cases we have in our company such as:

- Providing a landscape of clinical trials over time
- Gathering data to produce custom tables and data visualizations
- Extracting adverse event data for meta-analytic risk modeling

Landscape of clinical trials for Asthma disease with trial.gov data for Asthma

ClinicalTrials.gov

Search Results

Viewing 1-100 out of 4802 studies

Showing results for: **Asthma**

[+ Synonyms of conditions or disease \(3\)](#)

Card View

Table View

Sort studies by **Relevance**

None Selected  								 	
☐	Study Title	NCT Number	Status	Conditions	Interventions	Sponsor	Study Type		
☐ 1	Bikram Yoga and Asthma	NCT00410098	Unknown status	• Asthmatics	• Behavioral: Bikram Yoga	Hadassah Medical Organization	Interventional		
☐ 2	Effects of p38 Inhibitor AZD7624 in Corticosteroid Resistant Asthma	NCT02753764	Completed	• Corticosteroid Resistant (CR) Asthmatics	• Drug: AZD7624 • Drug: prednisone • Drug: Placebo	National Jewish Health	Interventional		
☐ 3	Effects of Costovertebral Joint Mobilization on Respiratory Function in Asthmatic Patients	NCT06133985	Completed	• Asthmatic	• Other: Costovertebral mobilizations + Conventional PT • Other: Conventional treatment	Riphah International University	Interventional		
☐ 4	Cardiopulmonary Fitness in Children With Asthma Versus Healthy Children	NCT04650464	Completed	• Asthmatic		University Hospital, Montpellier	Observational		
☐ 5	Laura Mitchell's Relaxation Versus Papworth Exercise in Asthmatic Patient	NCT05915845	Recruiting	• Asthmatic	• Other: Laura Mitchell's Relaxation technique • Other: Papworth exercise	Riphah International University	Interventional		

4802 studies for Asthma

Question:

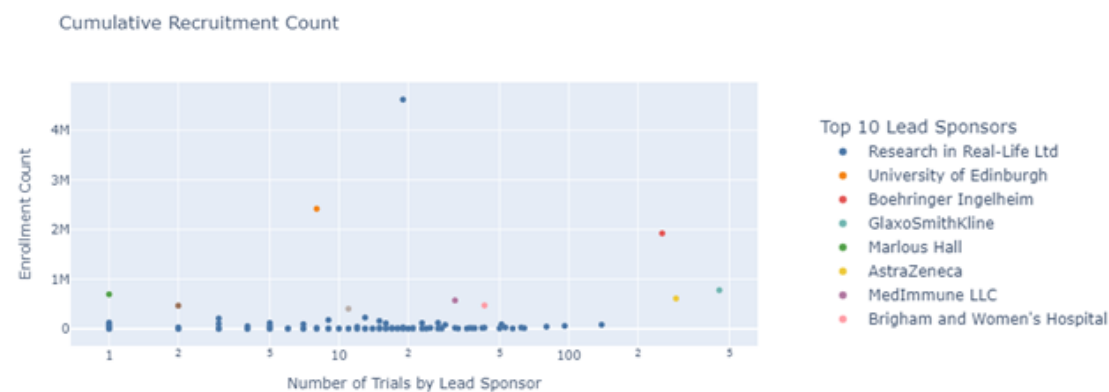
- How many clinical trials and at which phase ? status?
- What is the study design of these trials?
- Which big pharmas have the most clinical trials and patient recruited for a disease or a drug?

Landscape of clinical trials for Asthma disease with trial.gov data for Asthma

A

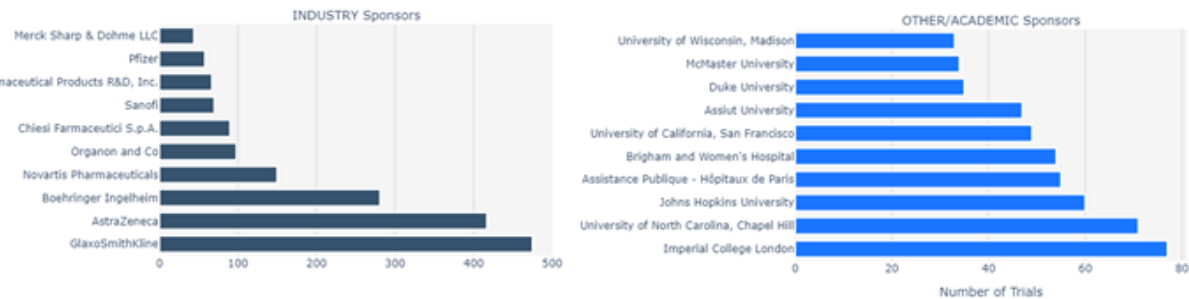


B



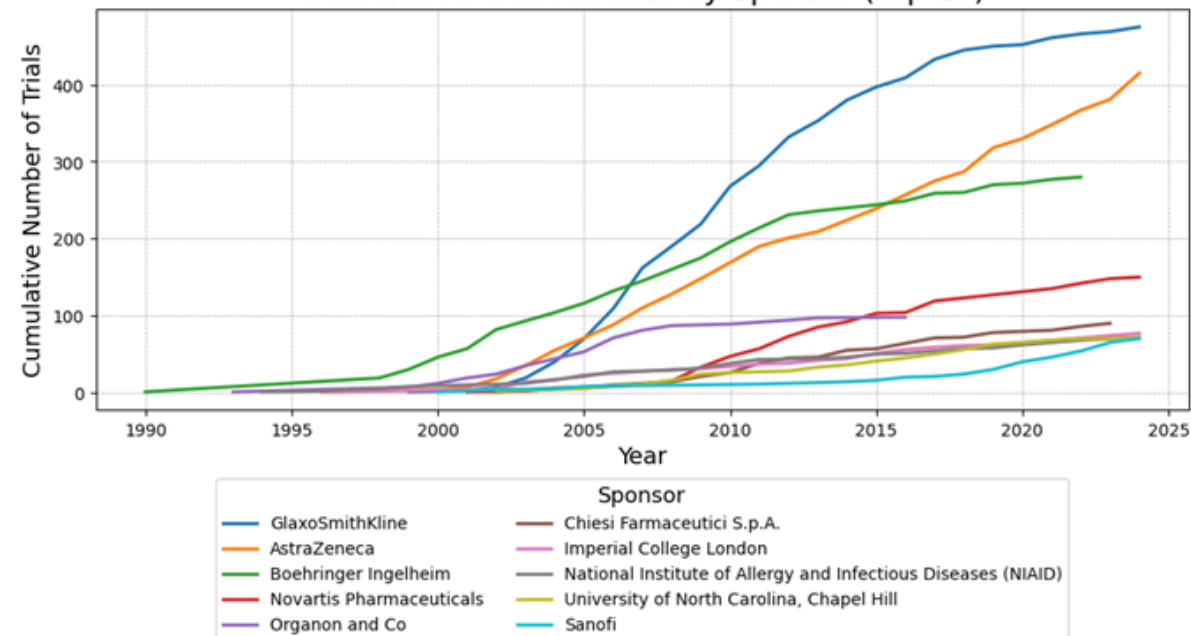
D

Top 10 Sponsors

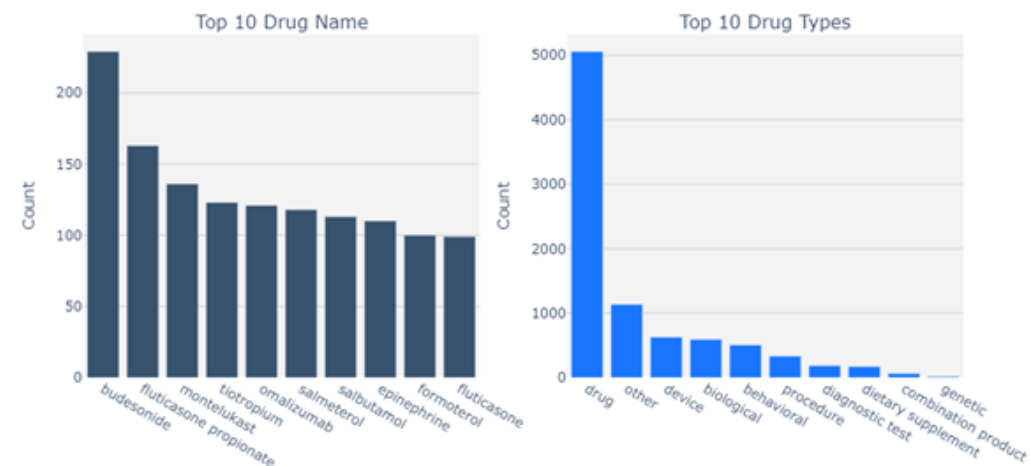


C

Cumulative Trial Number by Sponsor (Top 10)



E



Citation data retrieved from the PubMed database for clinical trials using the drug Vedolizumab.

ClinicalTrials.gov

PubMed®

On this page

[Study Overview](#)

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[Publications](#)

[Study Record Dates](#)

[More Information](#)

Publications

General

These publications are provided voluntarily by the person who enters information about the study and may be about anything related to the study.

- [Loftus EV Jr. Clinical epidemiology of inflammatory bowel disease: Incidence, prevalence, and environmental influences. Gastroenterology. 2004 May;126\(6\):1504-17. doi: 10.1053/j.gastro.2004.01.063. !\[\]\(15cb01d00100e773a50f80002909e9a5_img.jpg\)](#)
- [M'Koma AE. Inflammatory bowel disease: an expanding global health problem. Clin Med Insights Gastroenterol. 2013 Aug 14;6:33-47. doi: 10.4137/CGast.S12731. eCollection 2013. !\[\]\(d8d739ecb1ddc47a32a7c3d18f26efef_img.jpg\)](#)
- [Ng SC, Shi HY, Hamidi N, Underwood FE, Tang W, Benchimol EI, Panaccione R, Ghosh S, Wu JCY, Chan FKL, Sung JJY, Kaplan GG. Worldwide incidence and prevalence of inflammatory bowel disease in the 21st century: a systematic review of population-based studies. Lancet. 2017 Dec 23;390\(10114\):2769-2778. doi: 10.1016/S0140-6736\(17\)32448-0. Epub 2017 Oct 16. Erratum In: Lancet. 2020 Oct 3;396\(10256\):e56. doi: 10.1016/S0140-6736\(20\)32028-6. !\[\]\(ce2e1352a90071ca4ea4a7fe9e1defae_img.jpg\)](#)
- [Niewiadomski O, Studd C, Hair C, Wilson J, McNeill J, Knight R, Prewett E, Dabkowski P, Dowling D, Alexander S, Allen B, Tacey M, Connell W, Desmond P, Bell S. Health Care Cost Analysis in a Population-based Inception Cohort of Inflammatory Bowel Disease Patients in the First Year of Diagnosis. J Crohns Colitis. 2015 Nov;9\(11\):988-96. doi: 10.1093/ecco-jcc/jjv117. Epub 2015 Jun 30. !\[\]\(e6686070ceb4e1e22108b54add5bfad9_img.jpg\)](#)
- [Bewtra M, Su C, Lewis JD. Trends in hospitalization rates for inflammatory bowel disease in the United States. Clin Gastroenterol Hepatol. 2007 May;5\(5\):597-601. doi: 10.1016/j.cgh.2007.01.015. Epub 2007 Mar 26. !\[\]\(138be6a573fed23aa50961b158f92310_img.jpg\)](#)
- [Colombel JF, Sandborn WJ, Reinisch W, Mantzaris GJ, Kornbluth A, Rachmilewitz D, Lichtiger S, D'Haens G, Diamond RH, Broussard DL, Tang KL, van der Woude CJ, Rutgeerts P, SONIC Study Group. Infliximab, azathioprine, or combination therapy for Crohn's disease. N Engl J Med. 2010 Apr 15;362\(15\):1383-95. doi: 10.1056/NEJMoa0904492. !\[\]\(f91fe3b717172eea3b574487fce9cacb_img.jpg\)](#)
- [Gisbert JP, Marin AC, Chaparro M. The Risk of Relapse after Anti-TNF Discontinuation in Inflammatory Bowel Disease: Systematic Review and Meta-Analysis. Am J Gastroenterol. 2016 May;111\(5\):632-47. doi: 10.1038/ajg.2016.54. Epub 2016 Mar 22. !\[\]\(b353dcf0515c723ba6b847c3713de412_img.jpg\)](#)

[Gastroenterology](#) 2004 May 126(6):1504-17. doi: 10.1053/j.gastro.2004.01.063.

Clinical epidemiology of inflammatory bowel disease: Incidence, prevalence, and environmental influences

Edward V Loftus Jr ¹

Affiliations [+ expand](#)

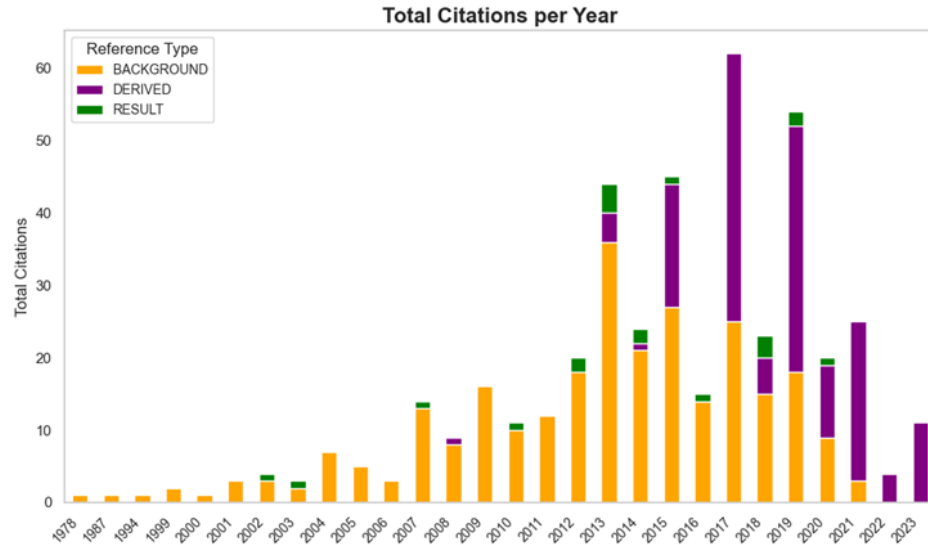
PMID: 15168363 DOI: 10.1053/j.gastro.2004.01.063

Journal date, date of publication, authors

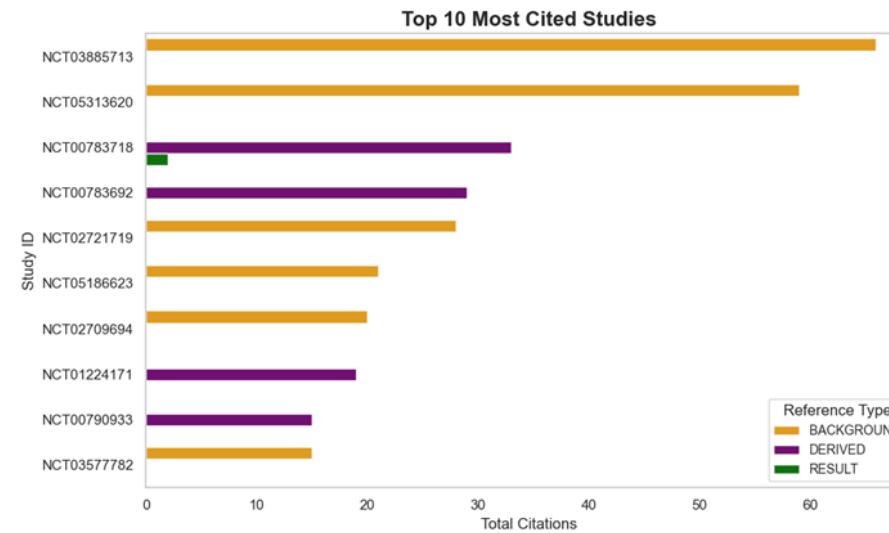
Publication for study NCT03885713

Citation data retrieved from the PubMed database for clinical trials using the drug Vedolizumab.

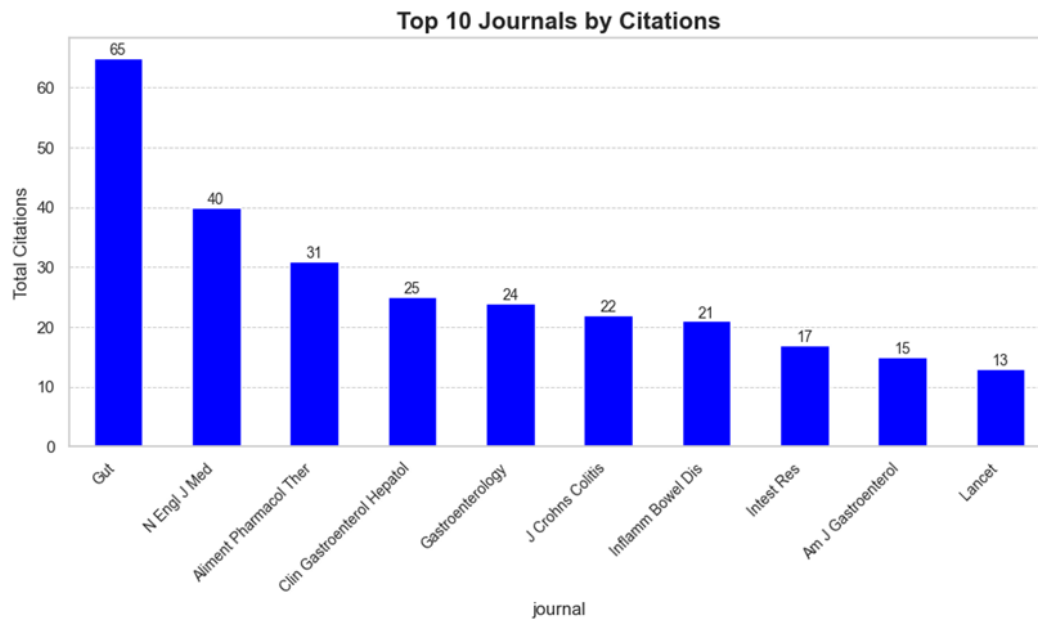
A



C



B



Citation data retrieved from the PubMed database for clinical trials using the drug Vedolizumab.

(A) Total number of citations per year, grouped by reference type.

(B) This figure shows the top 10 most cited studies, grouped by reference type, based on their ID.

(C) This figure displays the top 10 journals ranked by their total number of citations. The data helps identify the journals in which the clinical study is published.

Arm description and Adverse events in the result section for study

A

Participant Group/Arm ①	Intervention/Treatment ②
Experimental Alirocumab SC Q2W Alirocumab SC every 2 weeks (Q2W) from baseline (day 1) through week 10 during the double-blind treatment period Starting at week 12, and continuing through week 22, participants will receive open-label alicumab SC Q2W	Drug: Alirocumab • Alirocumab SC Q2W • Other Names: ◦ PRALUENT® ◦ REGN727 ◦ SAR236553
Experimental Placebo SC Q2W Matching placebo SC Q2W from baseline through week 10 during the double-blind treatment period Starting at week 12, and continuing through week 22, participants will receive open-label alicumab SC Q2W	Drug: Alirocumab • Alirocumab SC Q2W • Other Names: ◦ PRALUENT® ◦ REGN727 ◦ SAR236553 Drug: Placebo • Matching placebo SC Q2W

Arm description and Adverse events in the result section for study NCT03156621

(A) Title and description of arm in protocol section
(B) Title and description of result group in result section
(C) Adverse event data with numatrisk (total number of patient per group) and numaffected (number of patient experiencing at least once the corresponding AE)

B

Arm/Group Title	DB Placebo (DBTP)	DB Alirocumab 150 Q2W (DBTP)	DB Placebo (OLTP)	DB Alirocumab 150 Q2W (OLTP)
Arm/Group Description	Participants received matching placebo subcutaneously (SC) every 2 weeks (Q2W) from baseline (Day 1) through Week 10 during the double-blind treatment period.	Participants in this arm received alirocumab 150 milligrams (mg) SC Q2W from baseline (Day 1) through Week 10 during the double-blind treatment period.	Participants received matching placebo subcutaneously (SC) every 2 weeks (Q2W) from baseline (Day 1) through Week 10 during the double-blind treatment period. Starting at Week 12, and continuing through Week 22, all participants received open-label alirocumab SC Q2W	Participants in this arm received alirocumab 150 milligrams (mg) SC Q2W from baseline (Day 1) through Week 10 during the double-blind treatment period. Starting at Week 12, and continuing through Week 22, all participants received open-label alirocumab SC Q2W

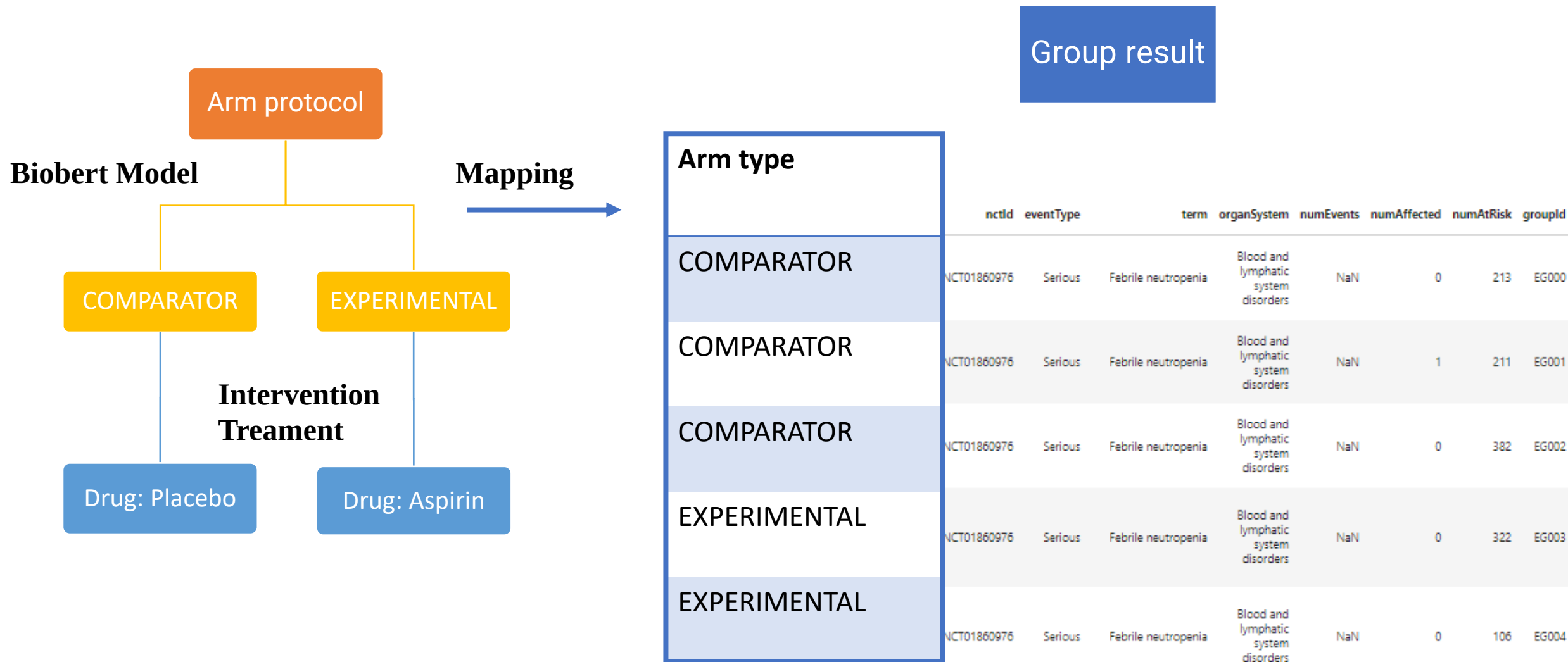
C

Other (Not Including Serious) Adverse Events								
Frequency Threshold for Reporting Other Adverse Events	5%							
Arm/Group Title	DB Placebo (DBTP)		DB Alirocumab 150 Q2W (DBTP)		DB Placebo (OLTP)		DB Alirocumab 150 Q2W (OLTP)	
	Affected / at Risk (%)	# Events	Affected / at Risk (%)	# Events	Affected / at Risk (%)	# Events	Affected / at Risk (%)	# Events
Total	4/24 (16.67%)		8/45 (17.78%)		2/24 (8.33%)		4/45 (8.89%)	
Gastrointestinal disorders								
Diarrhoea ^{†1}	0/24 (0.00%)	0	3/45 (6.67%)	3	0/24 (0.00%)	0	1/45 (2.22%)	1
Infections and infestations								
Nasopharyngitis ^{†1}	0/24 (0.00%)	0	2/45 (4.44%)	3	1/24 (4.17%)	1	3/45 (6.67%)	4
Upper respiratory tract infection ^{†1}	2/24 (8.33%)	3	2/45 (4.44%)	2	0/24 (0.00%)	0	0/45 (0.00%)	0
Nervous system disorders								
Headache ^{†1}	2/24 (8.33%)	8	2/45 (4.44%)	2	1/24 (4.17%)	2	1/45 (2.22%)	1

† Indicates events were collected by systematic assessment

1 Term from vocabulary, MedDRA (22.0)

Arm description and Adverse events in the result section for study



Arm description and Adverse events in result Mapping with Biobert

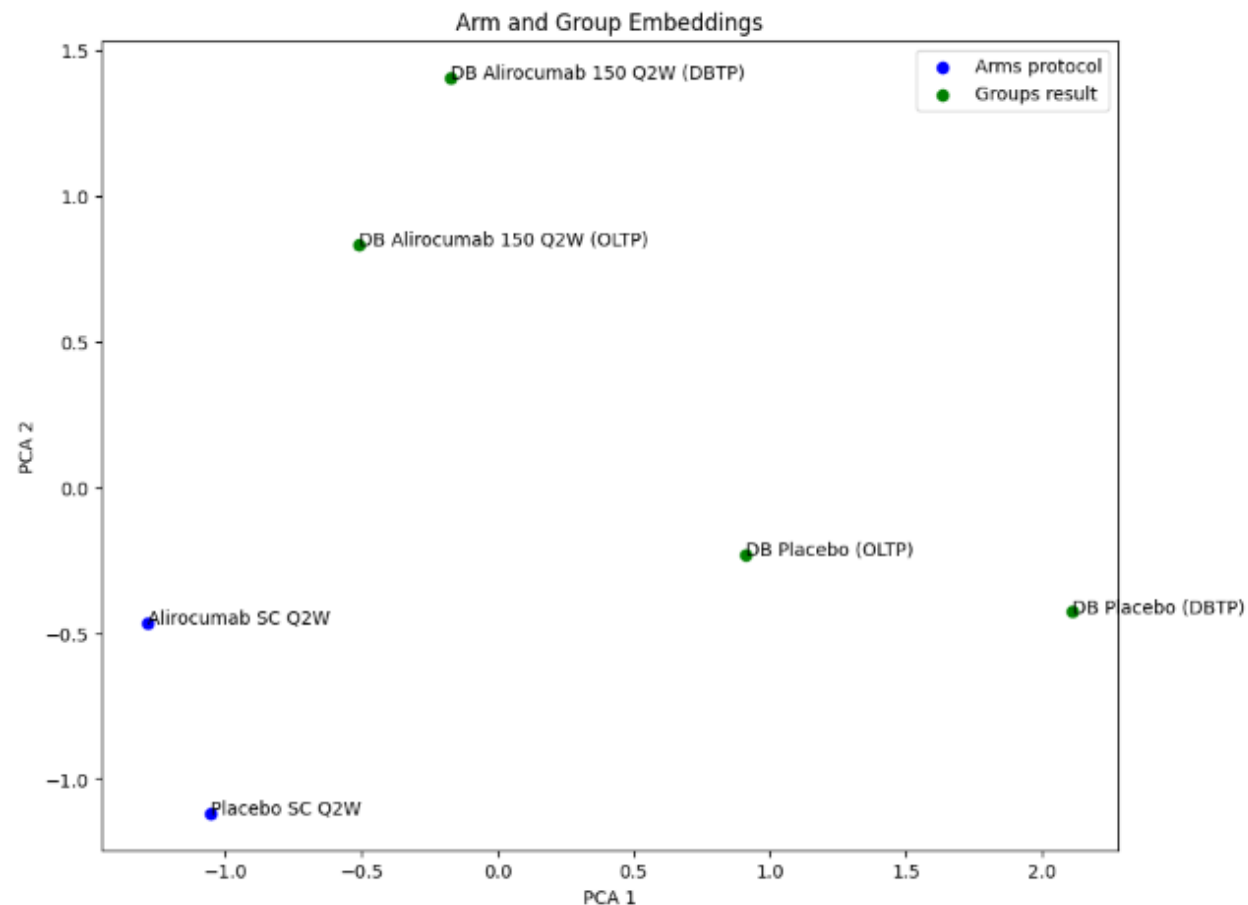
Input Sentence (group description)

DB Placebo (DBTP) Participants received matching placebo subcutaneously (SC) every 2 weeks (Q2W) from baseline (Day 1) through Week 10 during the double-blind treatment period.

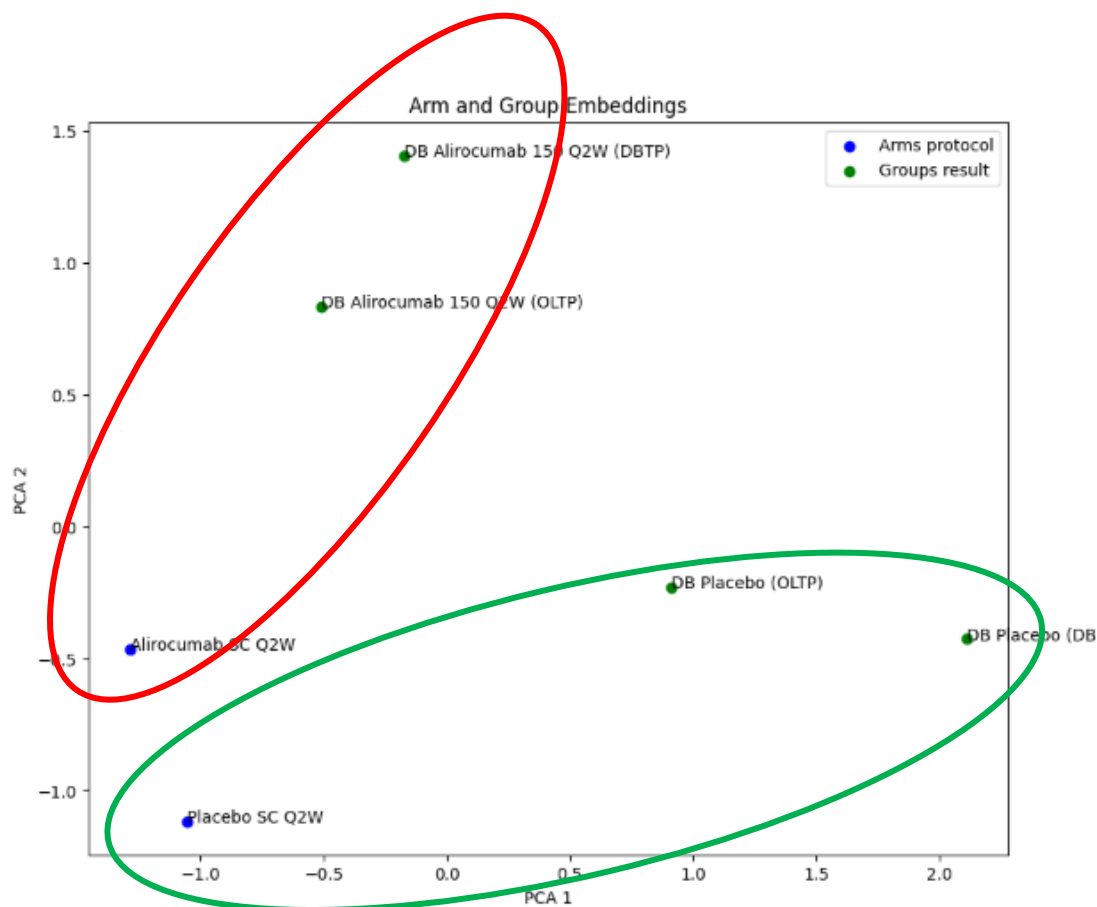
Biobert Model

Output Vector

[6.68930635e-02 5.47399791e-03
1.75069571e-01 2.32903928e-01
2.43534997e-01 -2.17751432e-02 -
2.46330842e-01 4.89819534e-02 -
1.37207925e-01 6.56889081e-02
2.15233654e-01 -2.05948368e-01
2.71767844e-02 6.01036511e-02
7.58204237e-02 7.48620406e-02 -
4.45633352e-01 6.22429848e-02]



Arm description and Adverse even in result Mapping with Biobert



[156]

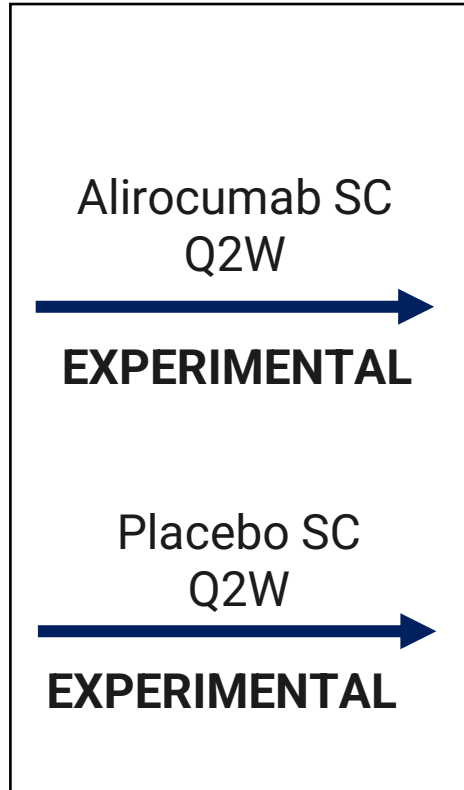
	Arm description	Type	Intervention Names	group	Result group description	Similarity	Best match
0	Placebo SC Q2W Matching placebo SC Q2W from baseline through week 10 during the double-blind treatment period/n/nStarting at week 12, and continuing through week 22, participants will receive open-label alirocumab SC Q2W Drug: Alirocumab Drug: Placebo	EXPERIMENTAL	[Drug: Alirocumab, Drug: Placebo]	EG000	DB Placebo (DBTP) Participants received matching placebo subcutaneously (SC) every 2 weeks (Q2W) from baseline (Day 1) through Week 10 during the double-blind treatment period.	0.946185	True
1	Alirocumab SC Q2W Alirocumab SC every 2 weeks (Q2W) from baseline (day 1) through week 10 during the double-blind treatment period/n/nStarting at week 12, and continuing through week 22, participants will receive open-label alirocumab SC Q2W Drug: Alirocumab	EXPERIMENTAL	[Drug: Alirocumab]	EG000	DB Placebo (DBTP) Participants received matching placebo subcutaneously (SC) every 2 weeks (Q2W) from baseline (Day 1) through Week 10 during the double-blind treatment period.	0.942058	False
2	Alirocumab SC Q2W Alirocumab SC every 2 weeks (Q2W) from baseline (day 1) through week 10 during the double-blind treatment period/n/nStarting at week 12, and continuing through week 22, participants will receive open-label alirocumab SC Q2W Drug: Alirocumab	EXPERIMENTAL	[Drug: Alirocumab]	EG001	DB Alirocumab 150 Q2W (DBTP) Participants in this arm received alirocumab 150 milligrams (mg) SC Q2W from baseline (Day 1) through Week 10 during the double-blind treatment period.	0.967398	True
3	Placebo SC Q2W Matching placebo SC Q2W from baseline through week 10 during the double-blind treatment period/n/nStarting at week 12, and continuing through week 22, participants will receive open-label alirocumab SC Q2W Drug: Alirocumab Drug: Placebo	EXPERIMENTAL	[Drug: Alirocumab, Drug: Placebo]	EG001	DB Alirocumab 150 Q2W (DBTP) Participants in this arm received alirocumab 150 milligrams (mg) SC Q2W from baseline (Day 1) through Week 10 during the double-blind treatment period.	0.963779	False
4	Placebo SC Q2W Matching placebo SC Q2W from baseline through week 10 during the double-blind treatment period/n/nStarting at week 12, and continuing through week 22, participants will receive open-label alirocumab SC Q2W Drug: Alirocumab Drug: Placebo	EXPERIMENTAL	[Drug: Alirocumab, Drug: Placebo]	EG002	DB Placebo (OLTP) Participants received matching placebo subcutaneously (SC) every 2 weeks (Q2W) from baseline (Day 1) through Week 10 during the double-blind treatment period. Starting at Week 12, and continuing through Week 22, all participants received open-label alirocumab SC Q2W	0.967669	True
5	Alirocumab SC Q2W Alirocumab SC every 2 weeks (Q2W) from baseline (day 1) through week 10 during the double-blind treatment period/n/nStarting at week 12, and continuing through week 22, participants will receive open-label alirocumab SC Q2W Drug: Alirocumab	EXPERIMENTAL	[Drug: Alirocumab]	EG002	DB Placebo (OLTP) Participants received matching placebo subcutaneously (SC) every 2 weeks (Q2W) from baseline (Day 1) through Week 10 during the double-blind treatment period. Starting at Week 12, and continuing through Week 22, all participants received open-label alirocumab SC Q2W	0.965228	False
6	Alirocumab SC Q2W Alirocumab SC every 2 weeks (Q2W) from baseline (day 1) through week 10 during the double-blind treatment period/n/nStarting at week 12, and continuing through week 22, participants will receive open-label alirocumab SC Q2W Drug: Alirocumab	EXPERIMENTAL	[Drug: Alirocumab]	EG003	DB Alirocumab 150 Q2W (OLTP) Participants in this arm received alirocumab 150 milligrams (mg) SC Q2W from baseline (Day 1) through Week 10 during the double-blind treatment period. Starting at Week 12, and continuing through Week 22, all participants received open-label alirocumab SC Q2W	0.980551	True
7	Placebo SC Q2W Matching placebo SC Q2W from baseline through week 10 during the double-blind treatment period/n/nStarting at week 12, and continuing through week 22, participants will receive open-label alirocumab SC Q2W Drug: Alirocumab Drug: Placebo	EXPERIMENTAL	[Drug: Alirocumab, Drug: Placebo]	EG003	DB Alirocumab 150 Q2W (OLTP) Participants in this arm received alirocumab 150 milligrams (mg) SC Q2W from baseline (Day 1) through Week 10 during the double-blind treatment period. Starting at Week 12, and continuing through Week 22, all participants received open-label alirocumab SC Q2W	0.972433	False

BioBERT embeddings applied to the arm description and group description

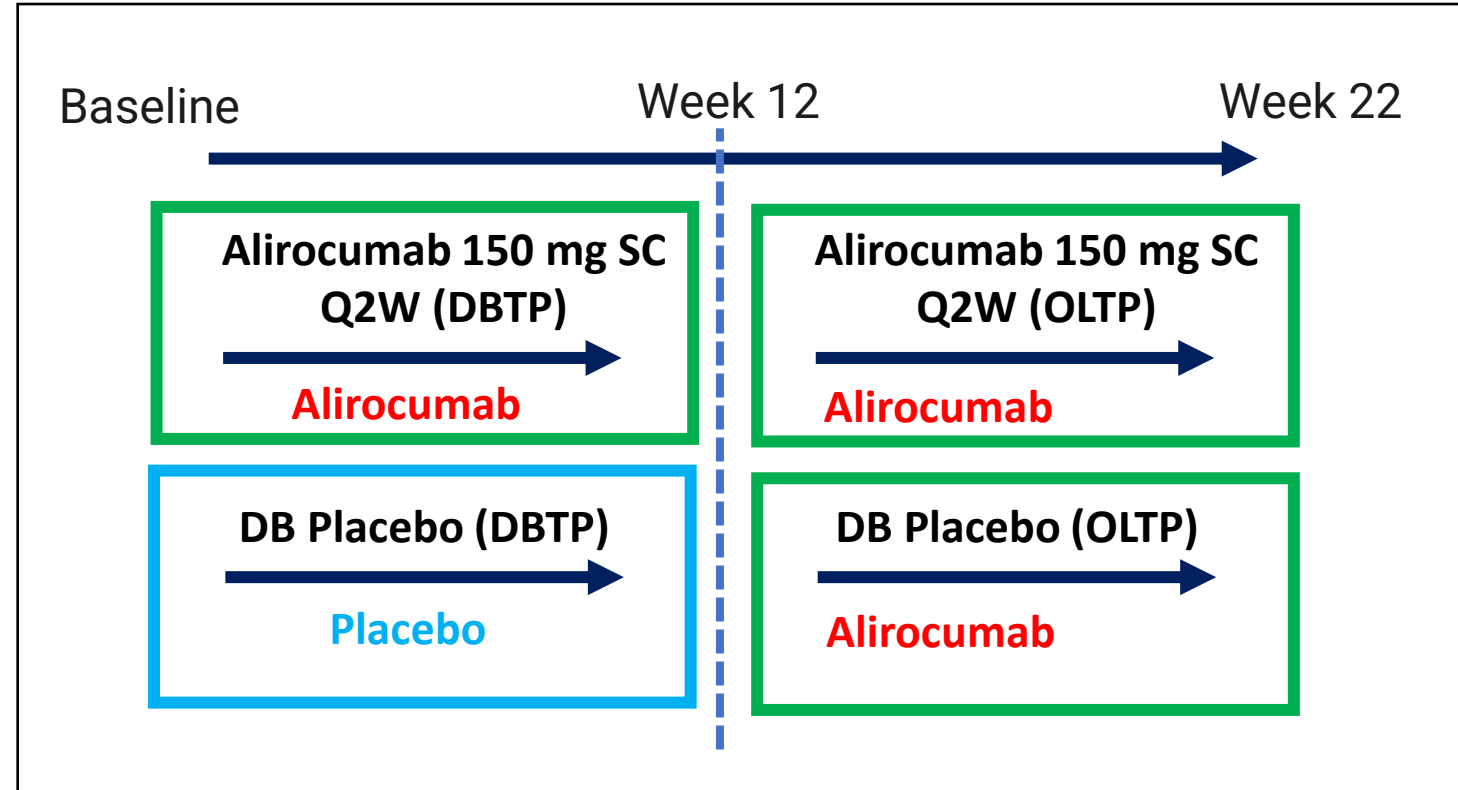
	Arm description	Type	Intervention Names	group	Result group description	Similarity	Best match
0	Placebo SC Q2W Matching placebo SC Q2W from baseline through week 10 during the double-blind treatment period Starting at week 12, and continuing through week 22, participants will receive open-label alirocumab SC Q2W Drug: Alirocumab Drug: Placebo	EXPERIMENTAL	[Drug: Alirocumab, Drug: Placebo]	EG000	DB Placebo (DBTP) Participants received matching placebo subcutaneously (SC) every 2 weeks (Q2W) from baseline (Day 1) through Week 10 during the double-blind treatment period.	0.946185	True
2	Alirocumab SC Q2W Alirocumab SC every 2 weeks (Q2W) from baseline (day 1) through week 10 during the double-blind treatment period Starting at week 12, and continuing through week 22, participants will receive open-label alirocumab SC Q2W Drug: Alirocumab	EXPERIMENTAL	[Drug: Alirocumab]	EG001	DB Alirocumab 150 Q2W (DBTP) Participants in this arm received alirocumab 150 milligrams (mg) SC Q2W from baseline (Day 1) through Week 10 during the double-blind treatment period.	0.967398	True
4	Placebo SC Q2W Matching placebo SC Q2W from baseline through week 10 during the double-blind treatment period Starting at week 12, and continuing through week 22, participants will receive open-label alirocumab SC Q2W Drug: Alirocumab Drug: Placebo	EXPERIMENTAL	[Drug: Alirocumab, Drug: Placebo]	EG002	DB Placebo (OLTP) Participants received matching placebo subcutaneously (SC) every 2 weeks (Q2W) from baseline (Day 1) through Week 10 during the double-blind treatment period. Starting at Week 12, and continuing through Week 22, all participants received open-label alirocumab SC Q2W	0.967669	True
6	Alirocumab SC Q2W Alirocumab SC every 2 weeks (Q2W) from baseline (day 1) through week 10 during the double-blind treatment period Starting at week 12, and continuing through week 22, participants will receive open-label alirocumab SC Q2W Drug: Alirocumab	EXPERIMENTAL	[Drug: Alirocumab]	EG003	DB Alirocumab 150 Q2W (OLTP) Participants in this arm received alirocumab 150 milligrams (mg) SC Q2W from baseline (Day 1) through Week 10 during the double-blind treatment period. Starting at Week 12, and continuing through Week 22, all participants received open-label alirocumab SC Q2W	0.980551	True

Example of mapping using BioBERT embeddings applied to the arm description and group description based on the higher cosine similarity
(example study NCT03156621).

Arm protocol



Group Result



DRUG FREE GROUP
GROUP with Alirocumab

Med7 open-source model and entity extraction

Input

« Participants received dupilumab 300 mg administered as SC injections q2w up to a maximum of 52 weeks »

Output

[('dupilumab', 'DRUG'), ('300 mg', 'STRENGTH'), ('SC', 'ROUTE'), ('injections', 'ROUTE'), ('q2w up', 'FREQUENCY'), ('52 weeks', 'DURATION')]

Participants received **dupilumab DRUG** **300 mg STRENGTH** administered as **SC ROUTE** **injections ROUTE** **q2w up FREQUENCY**
to a maximum of **52 weeks DURATION**

> [Artif Intell Med](#). 2021 Aug;118:102086. doi: 10.1016/j.artmed.2021.102086. Epub 2021 May 18.

Med7: A transferable clinical natural language processing model for electronic health records

Andrey Kormilitzin ¹, Nemanja Vaci ², Qiang Liu ³, Alejo Nevado-Holgado ³

Affiliations + expand

PMID: 34412834 DOI: [10.1016/j.artmed.2021.102086](#)

- **Drug:** Generic or brand name of the medication (adalimumab).
- **Dosage:** The total amount of a drug administered.
- **Strength:** The amount of drugs in a given dosage (200 mg)
- **Route:** The path by which the drug is taken into the body (oral, subcutaneous).
- **Frequency:** The dosage regimen at which the medication should be administered (once daily, every two weeks)
- **Duration:** The length of time that the drugs was prescribed for (for 16 weeks).
- **Form:** A particular configuration of the drugs intended for marketed use (tablet, injection)

Example of data extraction from group description text with med7 NER

	nctId	groupTitle	groupDescription	group_info_arm_type	DRUG	DOSAGE	STRENGTH	ROUTE	FREQUENCY	DURATION	FORM
0	NCT04115748	Filgotinib 200 mg (Main Study)	Filgotinib 200 mg tablet orally once daily + PTM filgotinib 100 mg tablet orally once daily + PTM adalimumab SC injection every two weeks for 16 weeks.	EXPERIMENTAL	['PTM filgotinib', 'adalimumab']	[]	['200 mg', '100 mg']	['orally', 'orally', 'SC']	['once daily', 'once daily', 'every two weeks']	['for 16 weeks']	['tablet', 'tablet', 'injection']
1	NCT04115748	Filgotinib 100 mg (Main Study)	Filgotinib 100 mg tablet orally once daily + PTM filgotinib 200 mg tablet orally once daily + PTM Adalimumab SC injection every two weeks for 16 weeks.	EXPERIMENTAL	['PTM filgotinib', 'Adalimumab']	[]	['100 mg', '200 mg']	['orally', 'orally', 'SC']	['once daily', 'once daily', 'every two weeks']	['for 16 weeks']	['tablet', 'tablet', 'injection']
2	NCT04115748	Adalimumab 40 mg (Main Study)	PTM filgotinib 200 mg tablet orally once daily + PTM filgotinib 100 mg tablet orally once daily + Adalimumab 40 mg SC injection every two weeks for 16 weeks.	EXPERIMENTAL	['PTM filgotinib', 'Adalimumab']	[]	['200 mg', '100 mg', '40 mg']	['orally', 'orally', 'SC']	['once daily', 'once daily', 'every two weeks']	['for 16 weeks']	['tablet', 'tablet', 'injection']
3	NCT04115748	Placebo (Main Study)	PTM filgotinib 200 mg tablet orally once daily + PTM filgotinib 100 mg tablet orally once daily + PTM adalimumab SC injection every two weeks for 16 weeks.	PLACEBO_COMPARATOR	['PTM filgotinib', 'adalimumab']	[]	['200 mg', '100 mg']	['orally', 'orally', 'SC']	['once daily', 'once daily', 'every two weeks']	['for 16 weeks']	['tablet', 'tablet', 'injection']
4	NCT04115748	Filgotinib 200 mg From Filgotinib 200 mg (LTE)	Filgotinib 200 mg tablet orally once daily + PTM filgotinib 100 mg tablet orally once daily for up to 34 weeks. Participants received filgotinib 200 mg in the Main Study.	EXPERIMENTAL	['PTM filgotinib', 'filgotinib']	[]	['200 mg', '100 mg', '200 mg']	['orally', 'orally']	['once daily', 'once daily']	[]	['tablet', 'tablet']

Example of data extraction from group description text with med7 NER model to obtain drug dosage, strength, route of administration, frequency, and duration of treatment

(example from NCT04115748 study).

Conclusion

Open-source databases like ClinicalTrials.gov and PubMed are valuable resources to monitor protocol practices and results:

- **Interest for Standardisation:** importance of data standardization across studies to ensure consistency and quality for data structure (arm/group), nomenclature (drug/disease)
- **Machine Learning:** Machine learning models can extract semantic meaning from unstructured data to improve analysis of complex protocols.
- **Enhanced Meta-Analysis:** Better standardization and open data adoption can lead to more systematic meta-analyses and valuable insights for future trials

Biopharma can use these API to get information about clinical trial for disease or competing drugs to prioritize R&D or marketing strategy.