

Disclaimer

The following report(s) provides findings from an FDA-initiated query using Sentinel. While Sentinel queries may be undertaken to assess potential medical product safety risks, they may also be initiated for various other reasons. Some examples include determining a rate or count of an identified health outcome of interest, examining medical product use, exploring the feasibility of future, more detailed analyses within Sentinel, and seeking to better understand Sentinel capabilities.

FDA wants to emphasize that the fact that FDA has initiated a query involving a medical product and is reporting findings related to that query does not mean that FDA is suggesting health care practitioners should change their prescribing practices for the medical product or that patients taking the medical product should stop using it. Patients who have questions about the use of an identified medical product should contact their health care practitioners.

The following report contains a description of the request, request specifications, and results from the modular program run(s).

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Overview for Request: cder_iqp_wp034

Request Description: In this report we aimed to characterize users of 51 new molecular entities (NMEs) that were approved by the FDA in 2021 in the TriNetX Live™ platform.

Data Source: We ran this query on January 19, 2024. This query contains data from 43 health care organizations (HCOs), provided through the TriNetX Live™ platform in their USA Network with No Shift from January 1, 2021 to the most recently available data, January 19, 2024.

TriNetX aggregates electronic health record (EHR) systems data from its partner HCOs to create queryable datasets. TriNetX datasets primarily comprise of clinical patient data such as demographics, diagnoses, procedures, labs, and medications. The USA Network with No Shift contains HCOs that do not date shift their data.

For more information on the TriNetX Live™ platform and the TriNetX data visit their website here: <https://trinetx.com/>

Study Design: In this retrospective cohort study, we identified counts of individuals with evidence of exposure to the 51 approved NMEs. We built 59 distinct cohorts using the Query Builder module in the TriNetX Live™ platform. We additionally described each cohort's demographic distribution using the Explore Cohort module.

Exposures of Interest: We examined 51 NMEs of interest. These included: aducanumab-avwa, amivantamab-vmjw, anifrolumab-fnia, asciminib, asparaginase erwinia chrysanthemi (recombinant)-rywn, atogepant, avacopan, avalglucosidase alfa-ngpt, belumosudil, belzutifan, cabotegravir, cabotegravir and rilpivirine (injectable only), casimersen, dasiglucagon, difelikefalin, dostarlimab-gxly, drospirenone and estetrol, efgartigimod alfa-fcab, evinacumab-dgnb, fexinidazole, finerenone, fosdenopterin, ibrexafungerp, inclisiran, infigratinib, loncastuximab tesirine-lpyl, lonapegsomatropin-tcgd, maralixibat, maribavir, melphalan flufenamide, mobocertinib, odevixibat, olanzapine and samidorphan, pafolacianine, pegcetacoplan, piflufolastat F-18, ponesimod, ropeginterferon alfa-2b-njft, serdexmethylphenidate and dexmethylphenidate, sotorasib, tepotinib, tezepelumab-ekko, tisotumab vedotin-tftv, tivozanib, tralokinumab-ldrm, trilaciclib, umbralisib, vericiguat, viloxazine, voclosporin, and vosoritide.

We used RxNorm medication terms and Healthcare Common Procedure Coding System (HCPCS) procedure codes in the Query Builder module. In order to be included in a cohort, we required evidence of a prescription, administration, or dispensing with the relevant NME of interest (with or without additional filters) between January 1, 2021 and January 19, 2024.

Sensitivity Analyses: For certain NME exposures which have non-specific RxNorm medication terms or fixed dose combination/co-packaged NMEs, we used filters for brand names or route of administration in the TriNetX platform to more accurately identify exposures. To this end, we included additional cohorts to compare patient counts with and without the filters. We included the following sensitivity tests:

- * Asparaginase erwinia chrysanthemi (recombinant)-rywn: with and without brand name Rylaze
- * Cabotegravir alone: overall, oral only, injectable only, and brand name Apretude or Vocabria. For the overall and oral only cohorts we additionally excluded patients with same-day exposures of rilpivirine.
- * Efgartigimod alfa-fcab: with and without brand name Vyvgart
- * Olanzapine and samidorphan: with and without brand name Lybalvi
- * Pegcetacoplan: with and without brand name Empaveli
- * Serdexmethylphenidate and dexmethylphenidate: with and without brand name Azstarys

Please see Appendix A for the list of RxNorm medication terms and HCPCS procedure codes, with information on filters used to define the exposures of interest in this request.

Overview for Request: cder_iqp_wp034

Cohort Eligibility Criteria: We created a separate cohort for each of the 51 NMEs with additional sensitivity cohorts as detailed in the "Exposures of Interest" section (total 59 cohorts). Patients of all ages were included in all the cohorts.

Please see Appendix B for the specifications of the cohort parameters for each of the 59 cohorts as included in the Query Builder.

Limitations: Algorithms used to define exposures, characteristics, and pregnancy, and mapping of source data to the data model are imperfect and susceptible to misclassification. Additionally, EHR data in the United States lacks longitudinality. The information before or after patients' healthcare encounters could be missing, especially if patient care was administered across different HCOs that may or might not participate in the TriNetX USA network. We are unable to determine if absence of evidence of a condition implies a true absence of a condition or if the condition was not observed in the data. Furthermore, not all HCOs provide brand name or route information for RxNorm terms or laboratory data. Therefore, data should be interpreted with these limitations in mind.

All counts provided through the TriNetX Live™ platform are rounded up to the nearest 10 to protect patient privacy. This rounding affects error, especially as sample sizes decrease. Error due to rounding can range from <0.09% when sample sizes are >10,000 to nearly 20% as sample sizes drop. Thus, all estimates should be interpreted as ranges, and small sample sizes should be interpreted with caution. Additionally, percentages are calculated based on these rounded numerators and denominators. Thus, due to rounding, the sum of each value in a category may not total to 100%.

The TriNetX Live™ platform uses RxNorm terms to identify medications, specifically the primary ingredient RxNorm terms.

- In case of fixed dose combinations/co-packaged medications (four NMEs in this query), the drugs are identified in the platform as the presence of primary ingredient RxNorm terms for all the individual medications on the same day (even if a multiple ingredient RxNorm term is made available by the National Library of Medicine), under the assumption that this refers only to the combined drugs and not two individual drugs prescribed concomitantly. We can have exposure misclassification if the assumption does not hold. To investigate this further, we have created sensitivity analyses cohorts, with and without the brand name/route of administration filter.
- Additionally, the RxNorm terms for certain NMEs in the query were non-specific i.e., referred to more than one drug in the market. E.g., the primary ingredient RxNorm term for Asparaginase erwinia chrysanthemi (recombinant)-rywn (Brand Rylaze, approved in 2021) is the same as for Asparaginase erwinia chrysanthemi (brand Erwinaze, approved in 2011). To investigate such instances further, we have created sensitivity analyses cohorts, with and without the brand name filter.

Notes: We ran this query on January 19, 2024. A re-run of this query for the same query period in the future may not yield the same results owing to the dynamic nature of the TriNetX Live™ network.

Please contact the Sentinel Operations Center (info@sentinelssystem.org) for questions and to provide comments/suggestions for future enhancements to this document. For more information on Sentinel's querying in the TriNetX platform, please refer to the Sentinel Website (<https://www.sentinelinitiative.org/methods-data-tools/methods/trinetx-rapid-querying>).

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Glossary of Terms for Analyses Using TriNetX Live™ Platform*

- Characteristic** - A medical fact (e.g., diagnosis, procedure, lab result) that occurred on or before the cohort-defining index event.
- Explore Cohort** - A description module on the TriNetX platform that presents a clinical profile of patients in a given cohort. Patient counts are rounded up to the nearest 10 before percentages are calculated, so the sum each of the values in one category may not total to 100%.
- Date Shifting** - A data obfuscation technique that some HCOs use to preserve patient privacy. Date shifting entails assigning each patient a random number of days (e.g., -365 to +365 days) and consistently adjusting each of their dates by that number of days, thus maintaining temporal relationships between records within a single patient.
- Filter** - A method of limiting terms included in queries to a specific subset of data. Filters include age at time of event, data source (electronic health record or natural language processing); brand name, route, and strength for medication terms; occurrence (first or most recent) for lab terms; and priority for diagnosis and procedure terms.
- Group** - A series of codes and terms defined with Boolean logic that are used to create a query cohort. For each group, users have the ability to specified time periods of interest, and the number of instances that the group must occur for cohort entry.
- Subgroup** - Within a group, additional subgroups can be specified to define temporal relationships between the terms in the subgroup (e.g., terms in subgroup B must occur within 5 days after terms in subgroup A). Users can require that these temporal constraints be applied to the 1) first, 2) last, or 3) any instance of each subgroup.
- Health Care Organization (HCO)** - Organizations that contribute electronic healthcare record data to the TriNetX data networks. HCOs include academic institutions and community health provider systems and a single HCO may contain one or more individual sites or facilities.
- Index** - The first date when a patient meets all of the cohort-defining criteria. In Analytics modules, the index can be defined as the date when a patient meets all of the cohort criteria, or only one specific group's criteria.
- Module** - A subsection of the TriNetX platform that performs a distinct functionality. Cohorts are created using the Query Builder module. Descriptive modules include Healthcare Organizations, Explore Cohorts, Rate of Arrival, Summary Statistics, and Analyze Criteria. Advanced analytic modules include Analyze Outcomes, Compare Outcomes, Compare Cohorts, Treatment Pathways, and Incidence and Prevalence.
- Network** - An aggregation of HCOs contributing data to the platform. Multiple networks are available for querying on the platform; the different networks represent subsets of HCOs organized by date-shifting practices or availability of downloadable datasets.
- Outcome** - A medical fact (e.g., diagnosis, procedure, lab result) that occurred on or after the cohort-defining index event.
- Query** - In the TriNetX platform, a query is a distinct cohort with a unique set of terms and logic. Query cohorts are created using the Query Builder platform module.
- Risk** - In Advanced Analytics modules, risk refers to the percentage of patients in each cohort with the specified outcome of interest.
- Priority** - An indication whether the code was the condition that the provider spent the most time evaluating or treating during a visit. Possible values include primary, secondary, or unknown.
- Term** - The codes used to specify patient cohort criteria in a query. Code options include diagnoses, procedures, medications, labs, demographics, genomics, and visits. Terms can be linked together using and/or Boolean logic. TriNetX also creates terms that group together multiple medical codes into single clinical concepts.
- Cannot Have Term** - A category of terms within a query group that patients must not have evidence of to be included in the cohort.
- Must Have Term** - A category of terms within a query group that patients must have evidence of to be included in the cohort.

Time Constraint - used to define time periods of interest for each group within a query. Time constraints can be defined relative to the date the query was run (e.g., any time before today), or defined based on specific dates (e.g., January 1, 2015 to September 30, 2020).

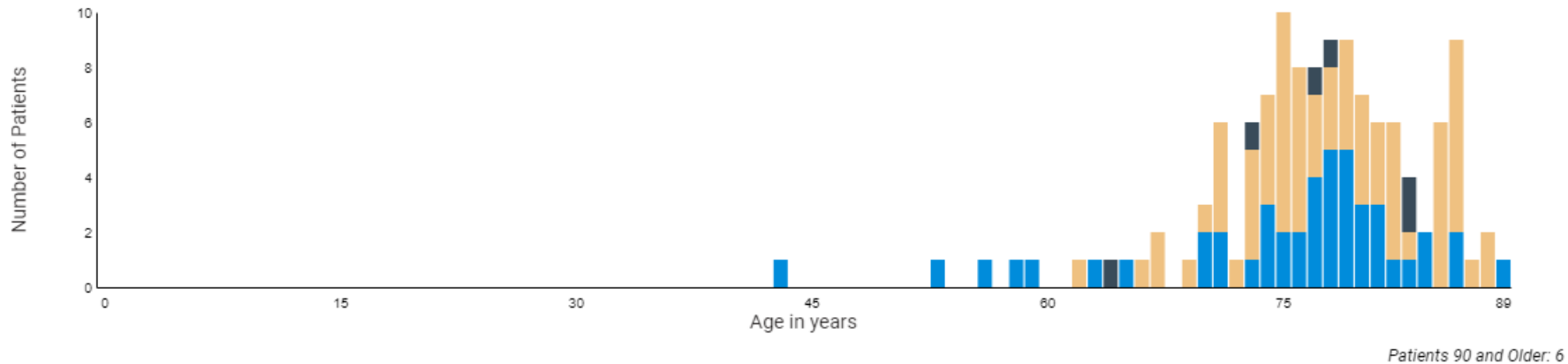
Treatment Pathway - In Advanced Analytics modules, the Treatment Pathways module returns the order in which patients received treatment and the prevalence of treatments, including combination of medications, following an index event.

TriNetX Codes - For commonly used laboratory terms, TriNetX aggregates Logical Observation Identifiers Names and Codes (LOINC) laboratory codes at a clinically significant level to new queryable TNX:LAB terms.

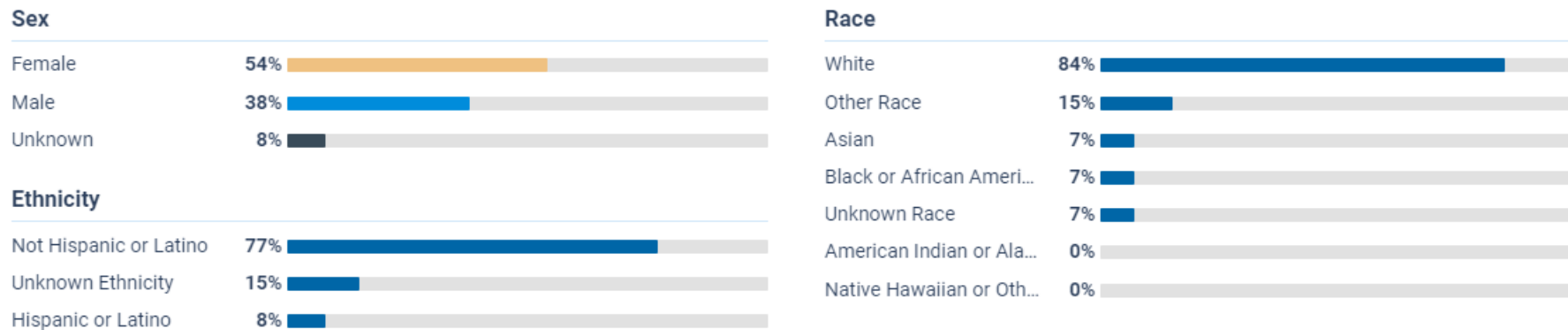
Visit - A type of term used to specify the type of medical encounter or facility where the encounter was recorded. Visit terms are derived by TriNetX from the source data. Visits are recorded separately from the codes or labs that occurred during the encounter; care settings are not attached to individual codes. Values for visit terms include: ambulatory, emergency, field, home health, inpatient encounter, inpatient acute, inpatient non-acute, laboratory, observation, pharmacy, pre-admission, short stay, virtual, and unknown.

*all terms may not be used in this report

Figure 1. Demographic Characteristics for Patients with Aducanumab-avwa Exposures, from January 1, 2021 through January 19, 2024

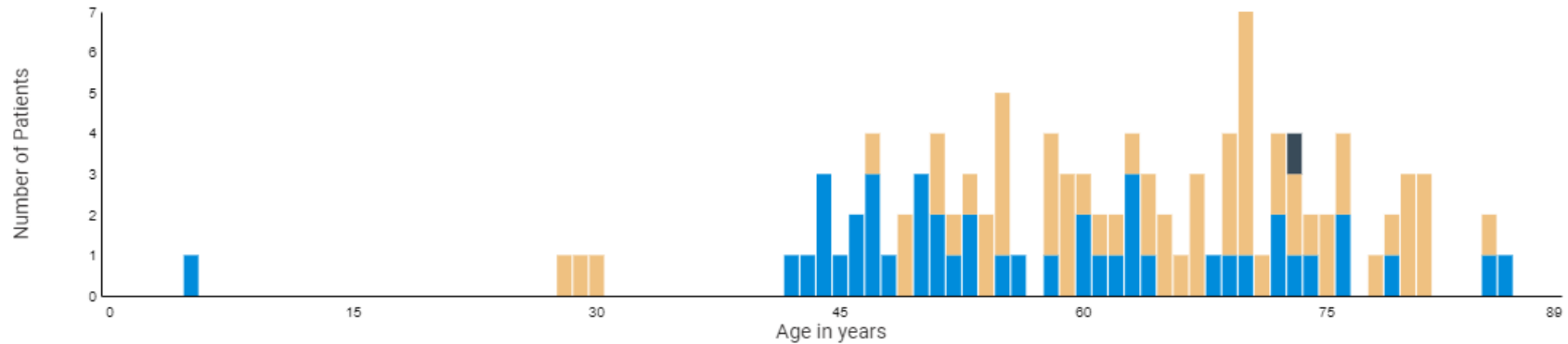


Total Patients	Minimum Age	Maximum Age	Mean Age	Standard Deviation
130	43	90	77	8



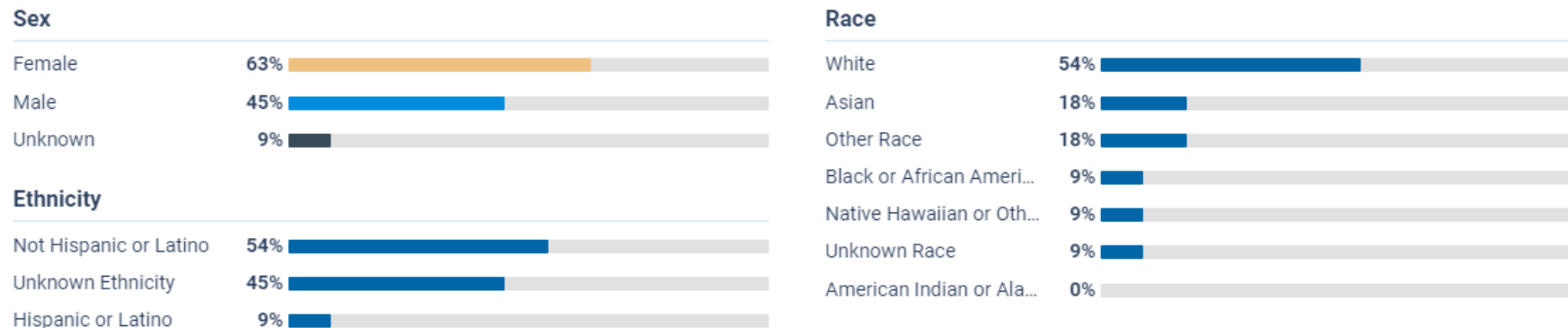
Generated by TriNetX

Figure 2. Demographic Characteristics for Patients with Amivantamab-vmjw Exposures, from January 1, 2021 through January 19, 2024



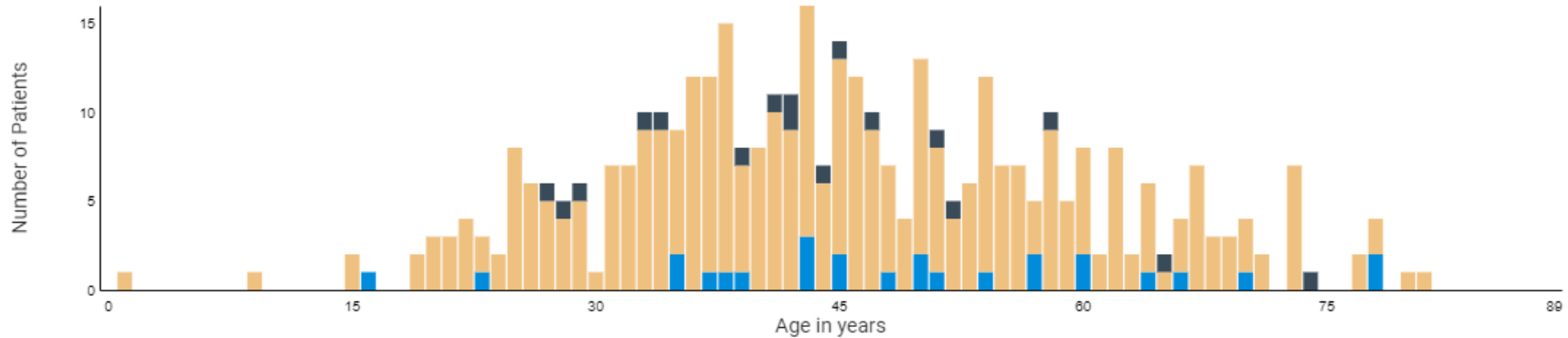
Patients 90 and Older: 3

Total Patients	Minimum Age	Maximum Age	Mean Age	Standard Deviation
110	5	90	62	14



Generated by TriNetX

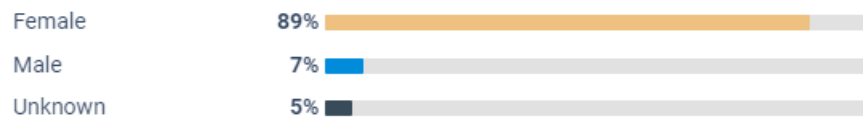
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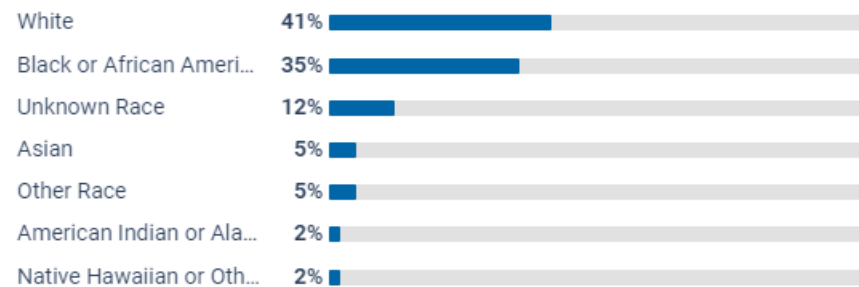
Patients 90 and Older: 0

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390	1	81	45	14

Sex



Race

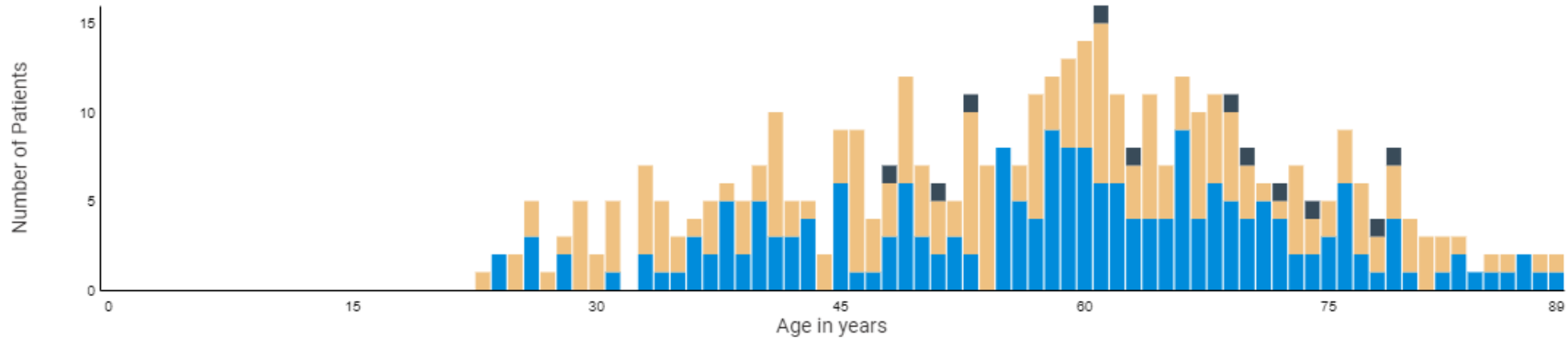


Ethnicity



Generated by TriNetX

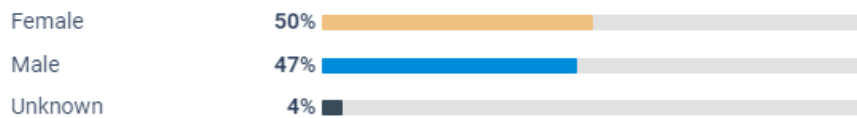
Figure 4. Demographic Characteristics for Patients with Asciminib Exposures, from January 1, 2021 through January 19, 2024



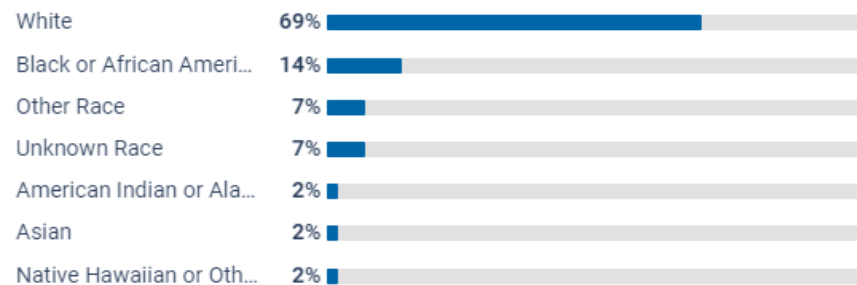
Patients 90 and Older: 3

Total Patients	Minimum Age	Maximum Age	Mean Age	Standard Deviation
420	23	90	57	15

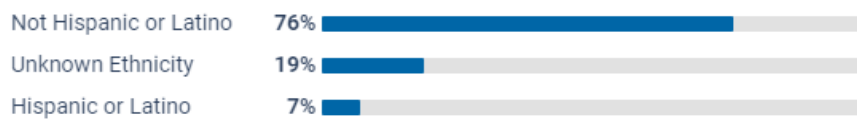
Sex



Race

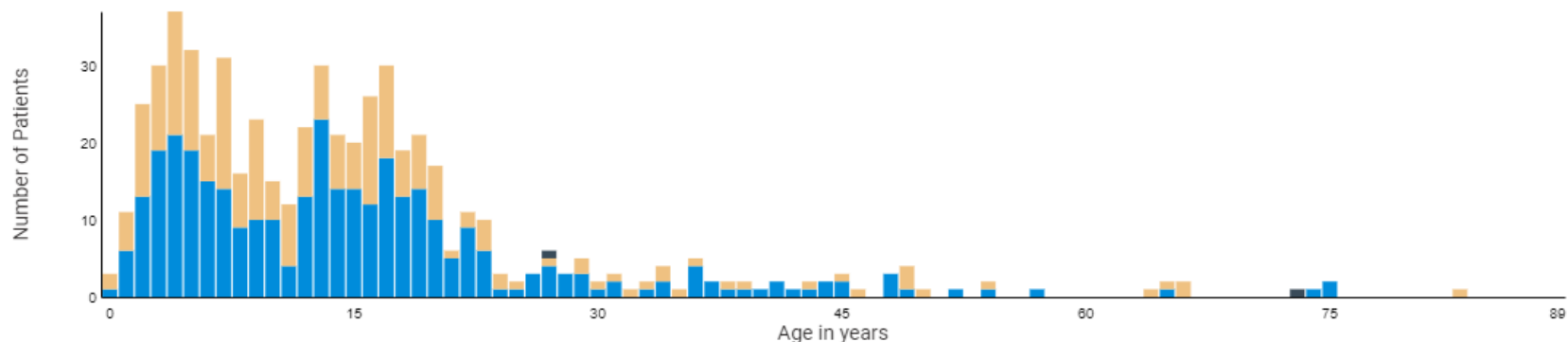


Ethnicity



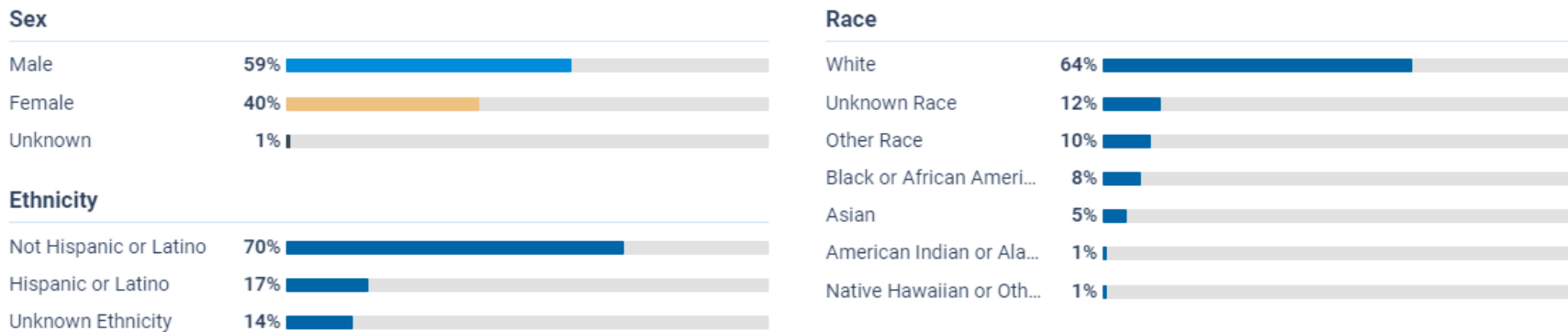
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Figure 5. Demographic Characteristics for All* Patients with Asparaginase Erwinia Chrysanthemi (Recombinant)-rywn Exposures, from January 1, 2021 through January 19, 2024



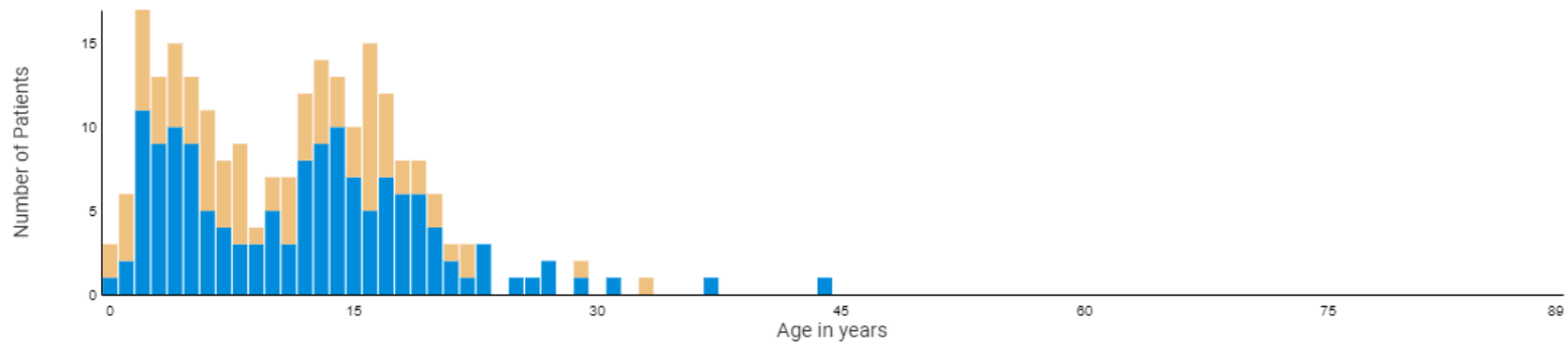
Patients 90 and Older: 1

Total Patients	Minimum Age	Maximum Age	Mean Age	Standard Deviation
570	0	90	15	13



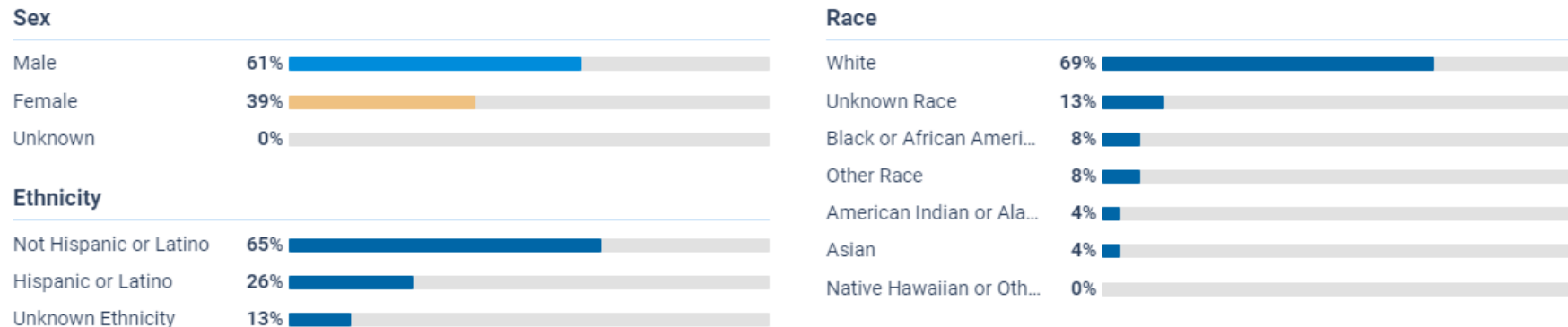
*No filters used

Figure 6. Demographic Characteristics for Patients with Asparaginase Erwinia Chrysanthemi (Recombinant)-rywn Exposures, Restricted to Brand Name Rylaze, from January 1, 2021 through January 19, 2024



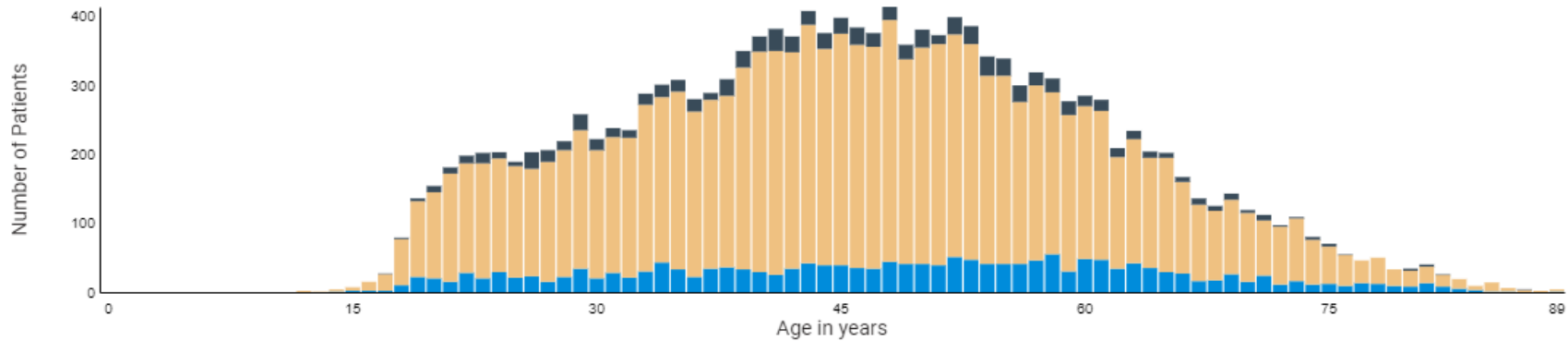
Patients 90 and Older: 0

Total Patients	Minimum Age	Maximum Age	Mean Age	Standard Deviation
230	0	44	11	7



Generated by TriNetX

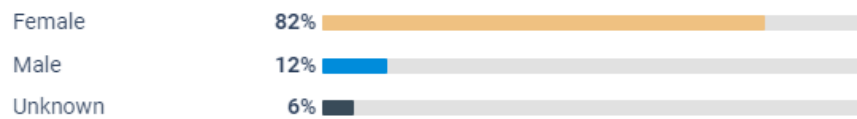
Figure 7. Demographic Characteristics for Patients with Atogepant Exposures, from January 1, 2021 through January 19, 2024



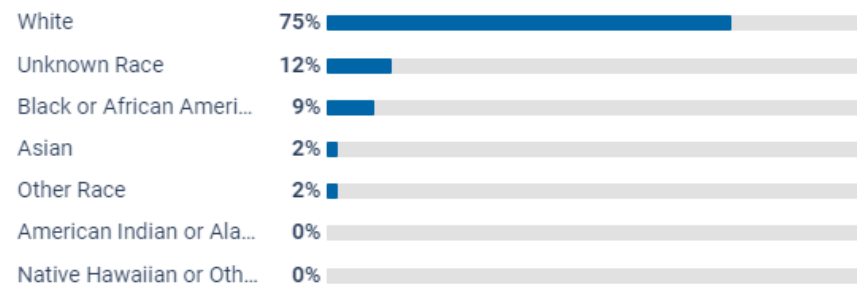
Patients 90 and Older: 8

Total Patients	Minimum Age	Maximum Age	Mean Age	Standard Deviation
15,290	12	90	46	15

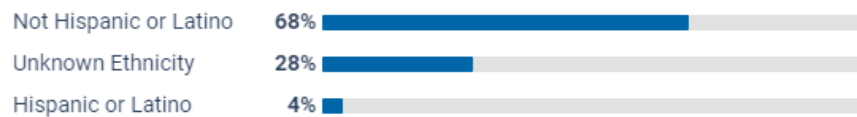
Sex



Race

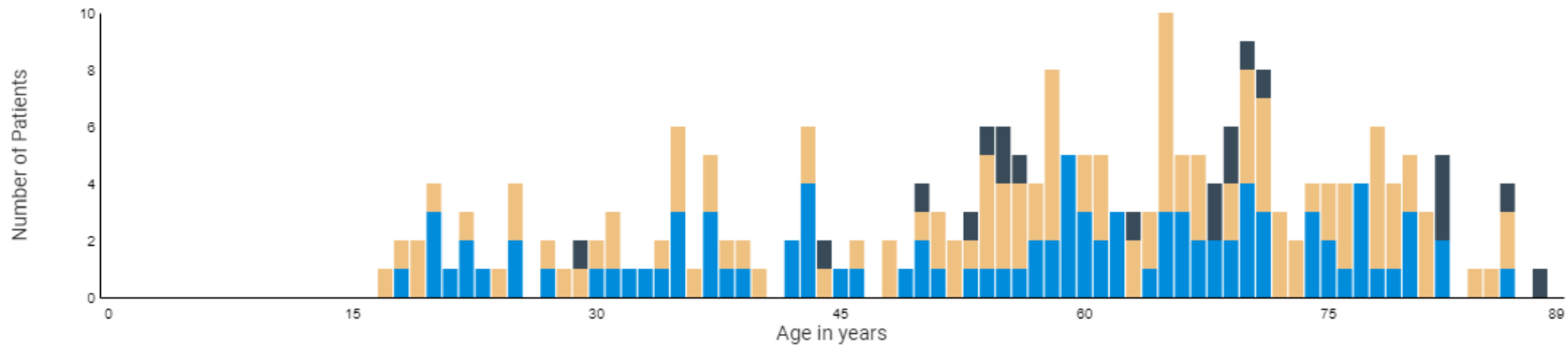


Ethnicity



Generated by TriNetX

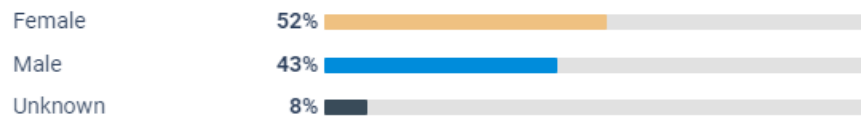
Figure 8. Demographic Characteristics for Patients with Avacopan Exposures, from January 1, 2021 through January 19, 2024



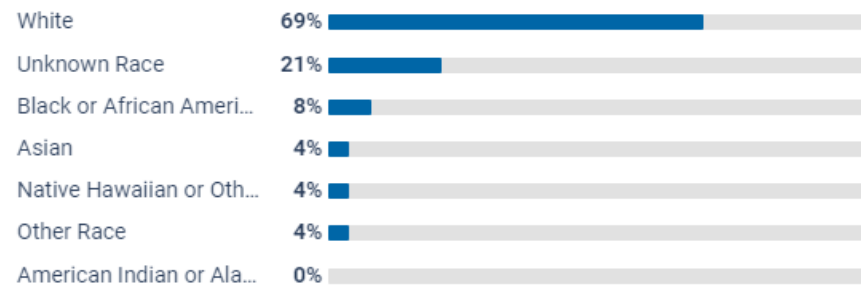
Patients 90 and Older: 1

Total Patients	Minimum Age	Maximum Age	Mean Age	Standard Deviation
230	17	90	57	18

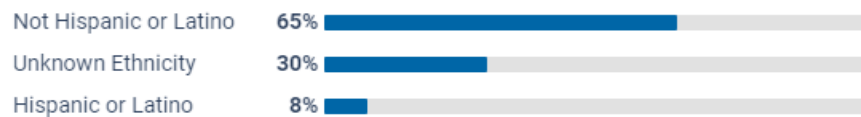
Sex



Race

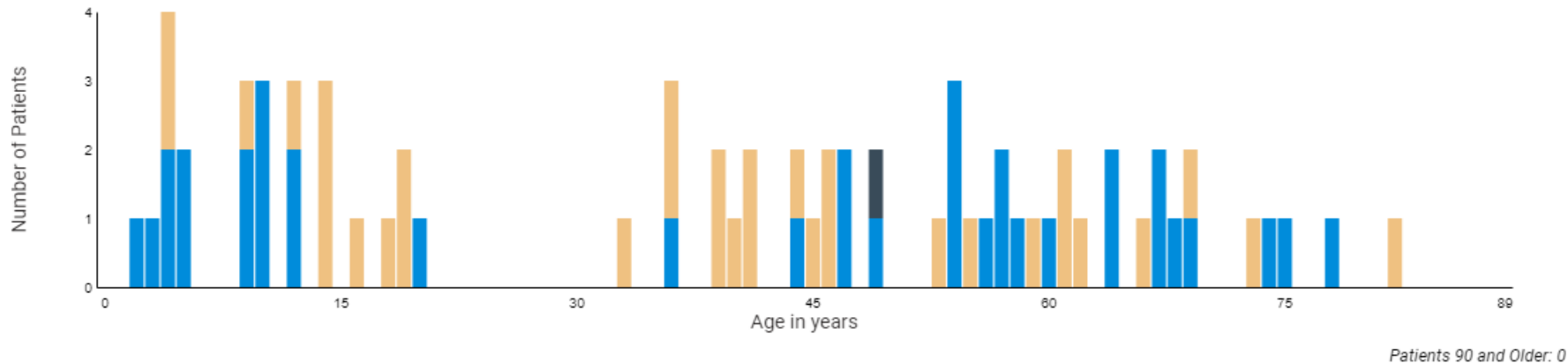


Ethnicity



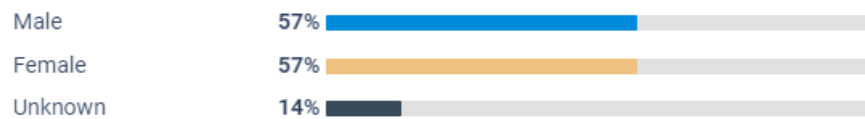
Generated by TriNetX

Figure 9. Demographic Characteristics for Patients with Avalglucosidase alfa-ngpt Exposures, from January 1, 2021 through January 19, 2024

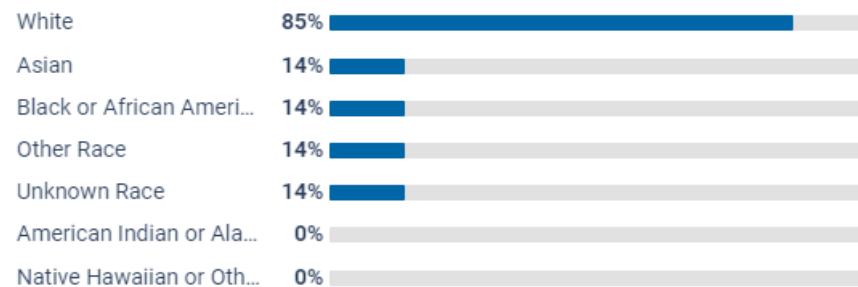


Total Patients	Minimum Age	Maximum Age	Mean Age	Standard Deviation
70	2	82	39	24

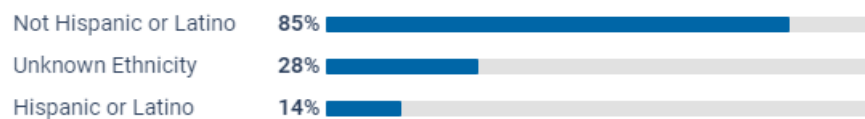
Sex



Race

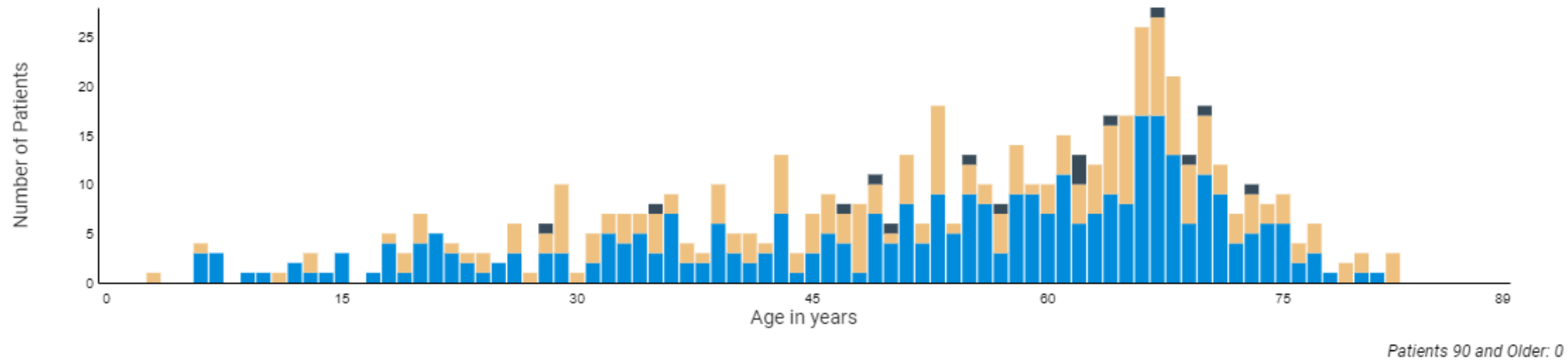


Ethnicity

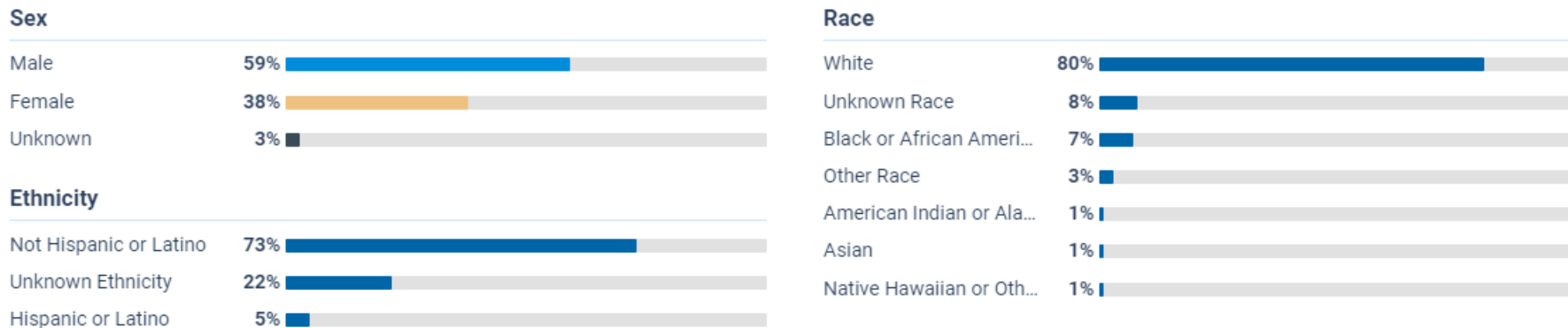


Generated by TriNetX

Figure 10. Demographic Characteristics for Patients with Belumosuil Exposures, from January 1, 2021 through January 19, 2024

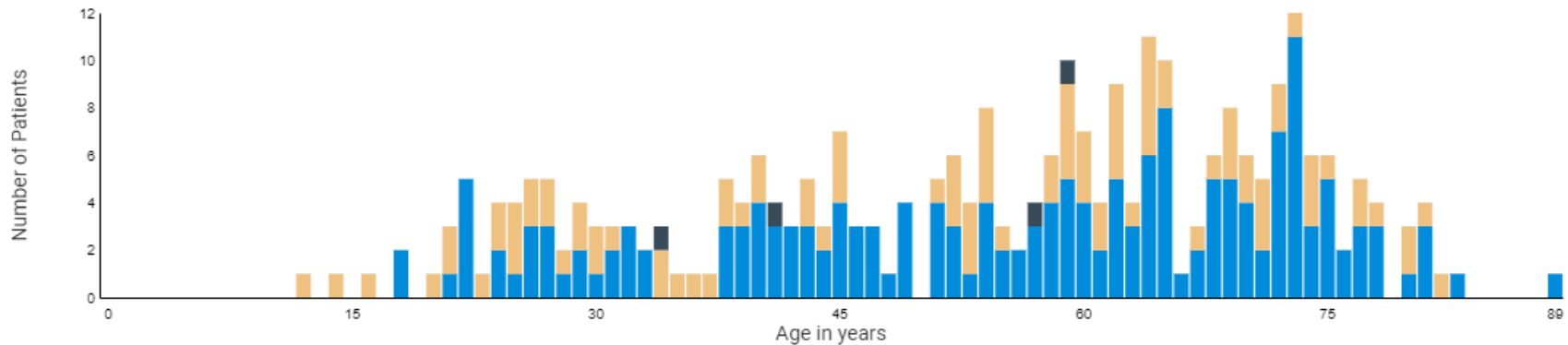


Total Patients	Minimum Age	Maximum Age	Mean Age	Standard Deviation
570	3	82	53	18



Generated by TriNetX

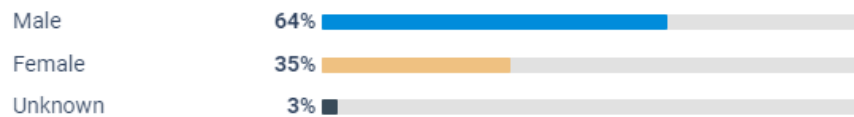
Figure 11. Demographic Characteristics for Patients with Belzutifan Exposures, from January 1, 2021 through January 19, 2024



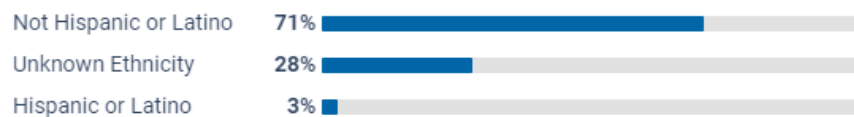
Patients 90 and Older: 0

Total Patients	Minimum Age	Maximum Age	Mean Age	Standard Deviation
280	12	89	54	18

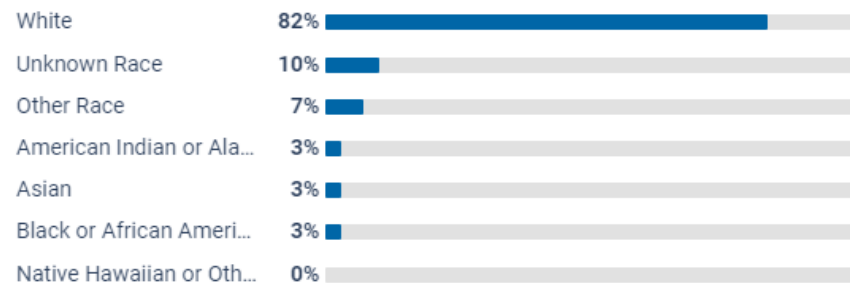
Sex



Ethnicity

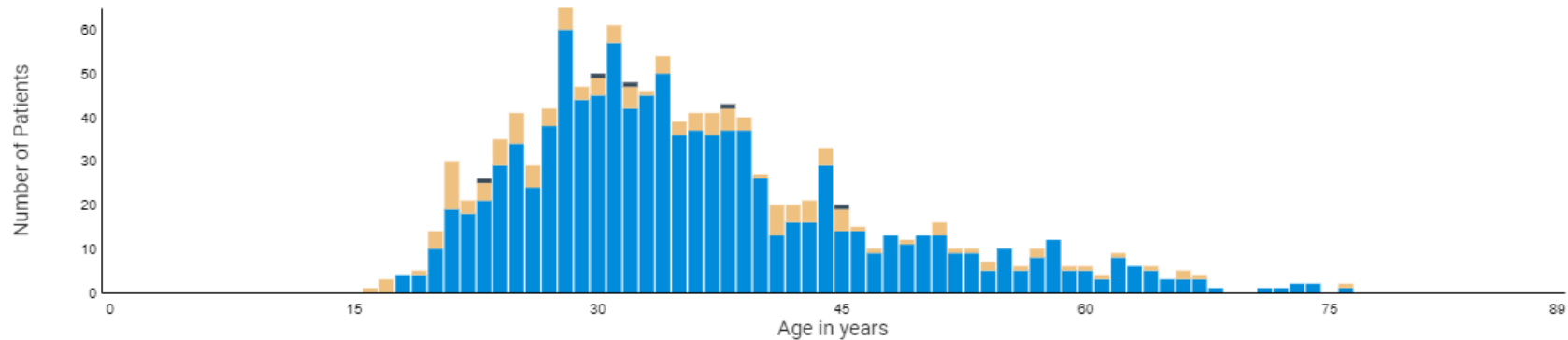


Race



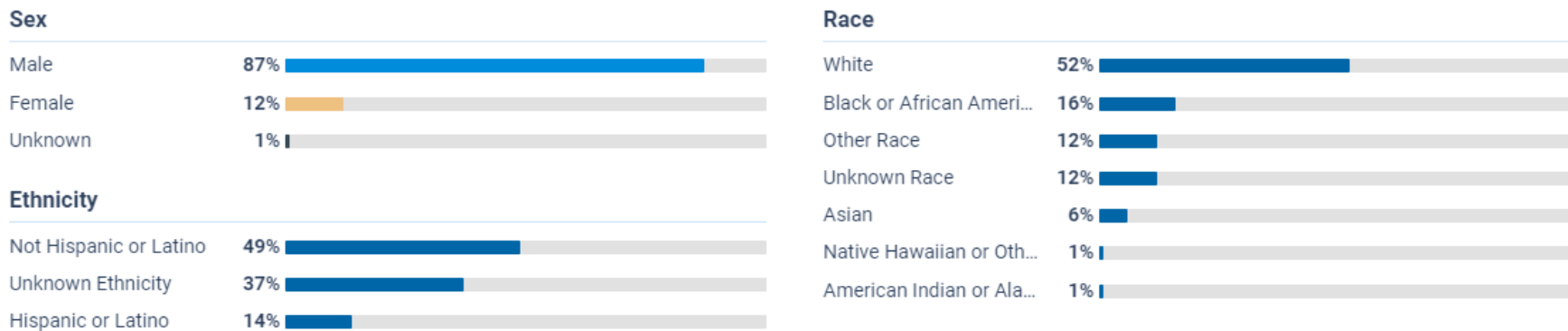
Generated by TriNetX

Figure 12. Demographic Characteristics for All* Patients with Cabotegravir Exposures, from January 1, 2021 through January 19, 2024



Patients 90 and Older: 1

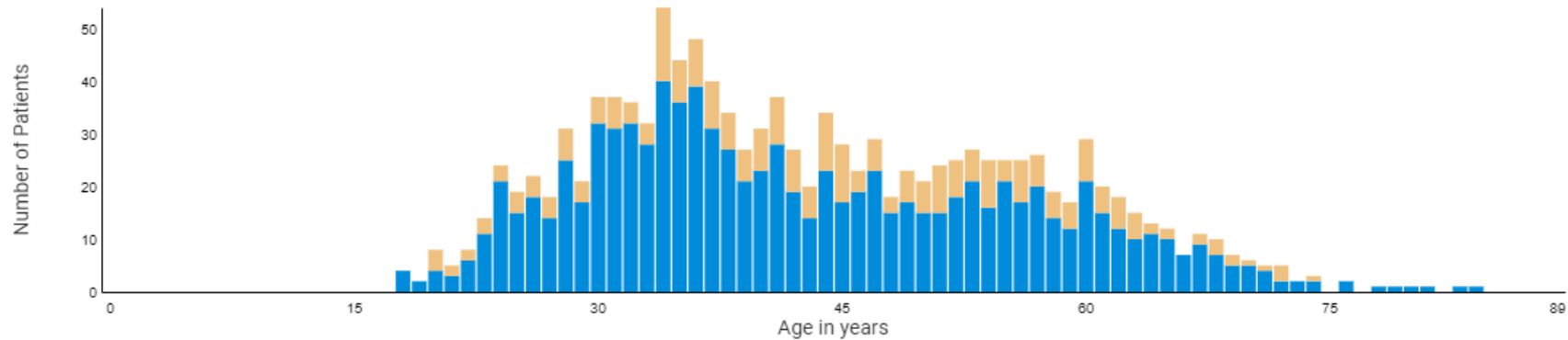
Total Patients	Minimum Age	Maximum Age	Mean Age	Standard Deviation
1,170	16	90	36	11



Generated by TriNetX

*All Patients with Cabotegravir Exposures Cannot Have Same Day Rilpivirine Exposure
 The exception added to avoid inclusion of cabotegravir-rilpivirine co-packaged medication

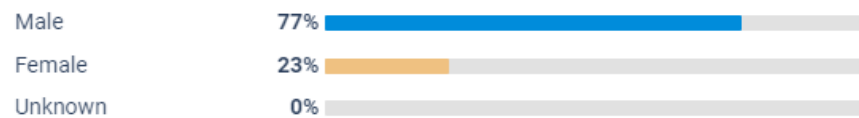
Figure 13. Demographic Characteristics for Patients with Cabotegravir Exposures, Restricted to Oral Exposures, from January 1, 2021 through January 19, 2024



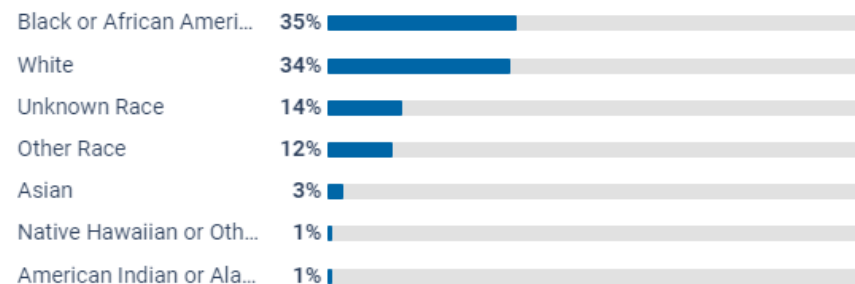
Patients 90 and Older: 0

Total Patients	Minimum Age	Maximum Age	Mean Age	Standard Deviation
1,240	18	84	43	13

Sex



Race

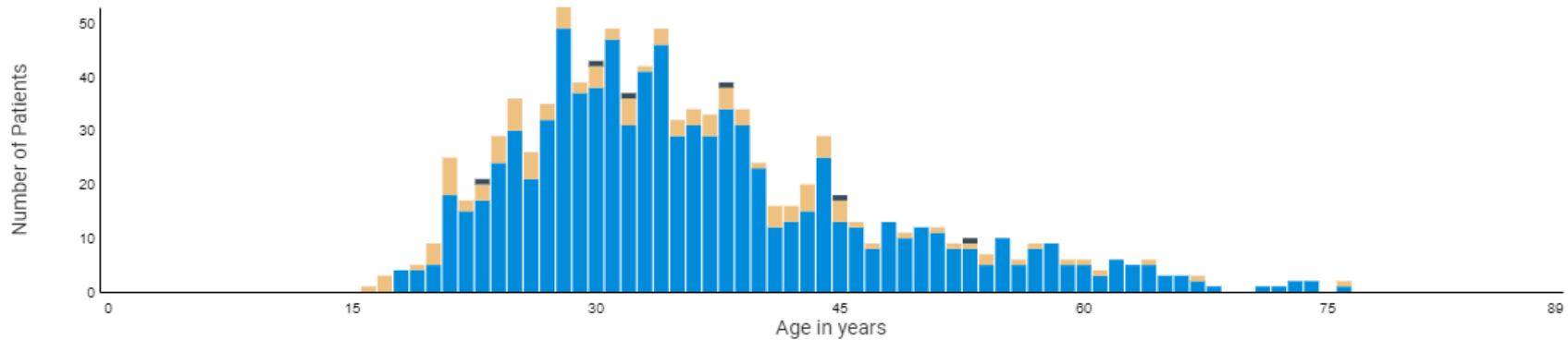


Ethnicity



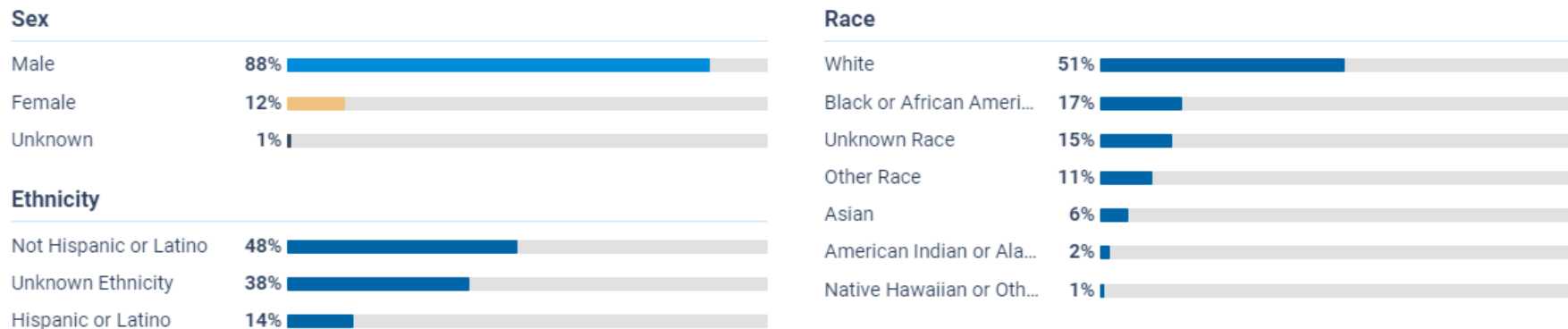
Generated by TriNetX

Figure 14. Demographic Characteristics for Patients with Cabotegravir Exposures*, Restricted to Injectable Exposures, from January 1, 2021 through January 19, 2024



Patients 90 and Older: 1

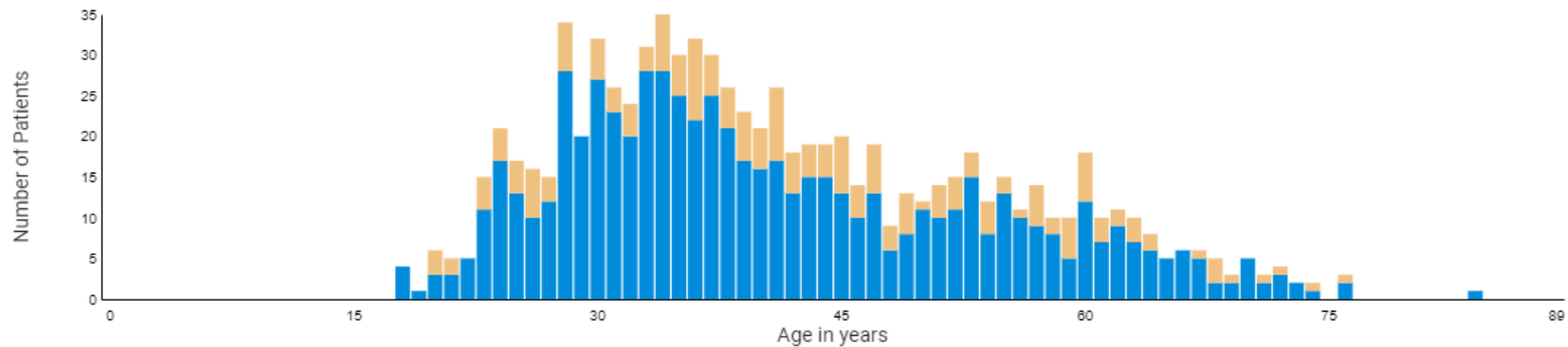
Total Patients	Minimum Age	Maximum Age	Mean Age	Standard Deviation
1,000	16	90	36	11



Generated by TriNetX

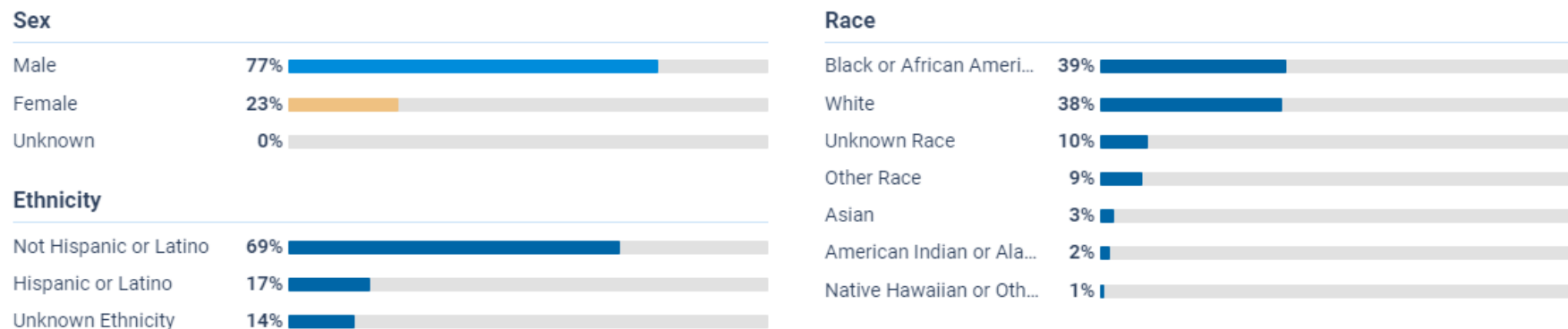
*All Patients with Injectable Cabotegravir Exposures Cannot Have Same Day Rilpivirine Exposure
The exception added to avoid inclusion of cabotegravir-rilpivirine co-packaged medication

Figure 15. Demographic Characteristics for Patients with Cabotegravir Exposures, Restricted to Brand Names Apretude or Vocabria, from January 1, 2021 through January 19, 2024



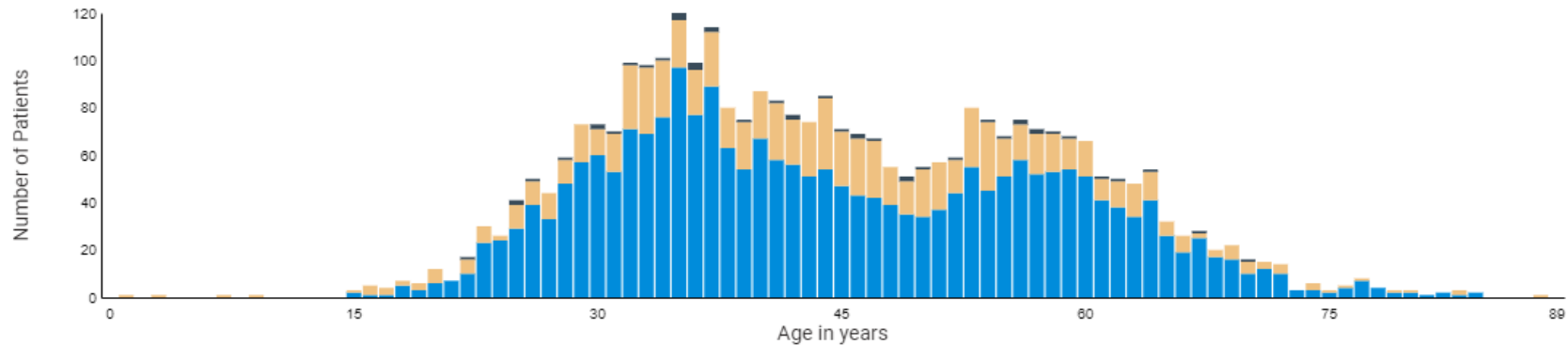
Patients 90 and Older: 1

Total Patients	Minimum Age	Maximum Age	Mean Age	Standard Deviation
860	18	90	41	13



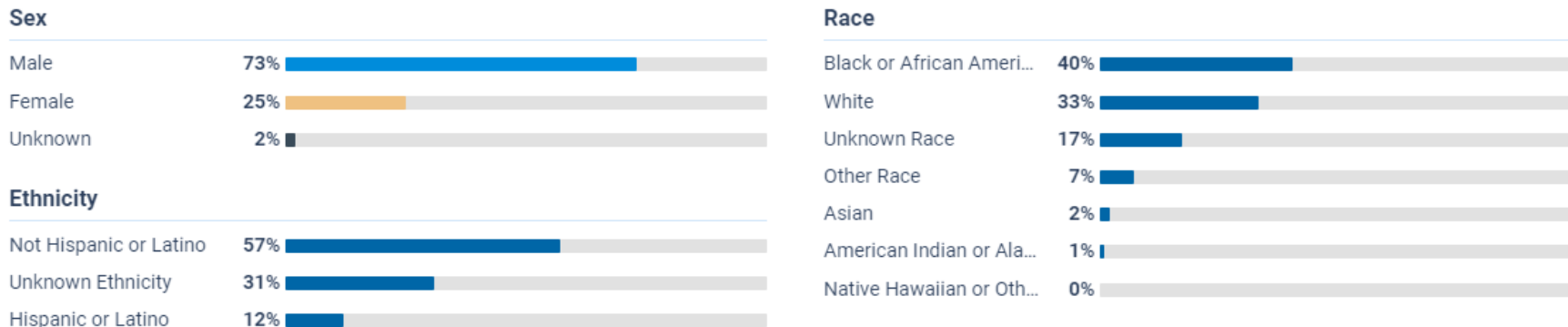
Generated by TriNetX

Figure 16. Demographic Characteristics for All Patients with Injectable Cabotegravir and Rilpivirine Exposures*, from January 1, 2021 through January 19, 2024



Patients 90 and Older: 0

Total Patients	Minimum Age	Maximum Age	Mean Age	Standard Deviation
3,200	1	88	45	13



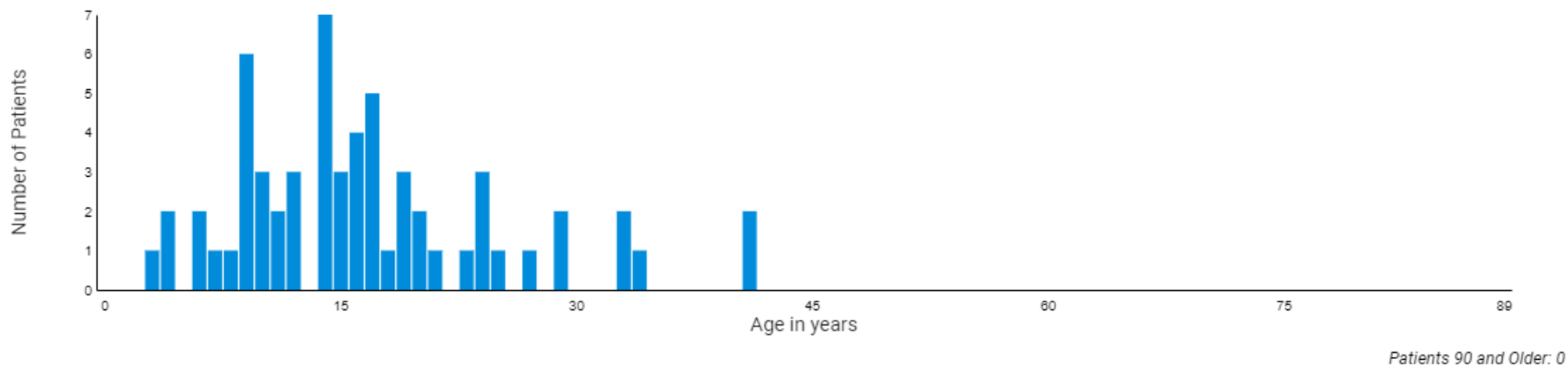
Generated by TriNetX

* The injectable cabotegravir and rilpivirine exposures occur on the same day.

Assumption is that the same day exposure refers to co-packaged cabotegravir and rilpivirine (brand name Cabenuva).

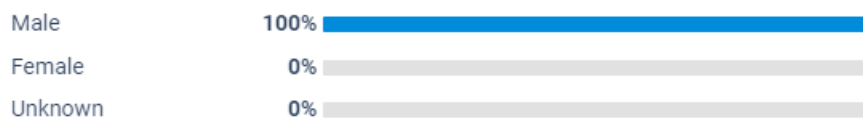
There is no sensitivity analyses cohort for this combination with a filter for brand name as Cabenuva is not available as a filter option on TriNetX.

Figure 17. Demographic Characteristics for Patients with Casimersen Exposures, from January 1, 2021 through January 19, 2024

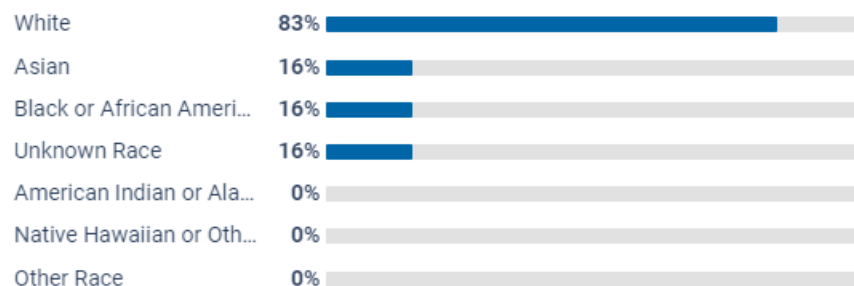


Total Patients	Minimum Age	Maximum Age	Mean Age	Standard Deviation
60	3	41	17	9

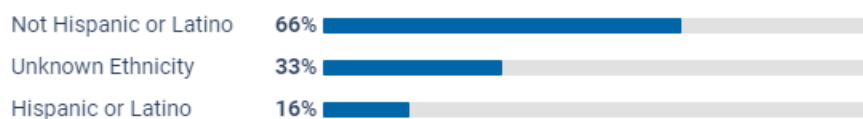
Sex



Race

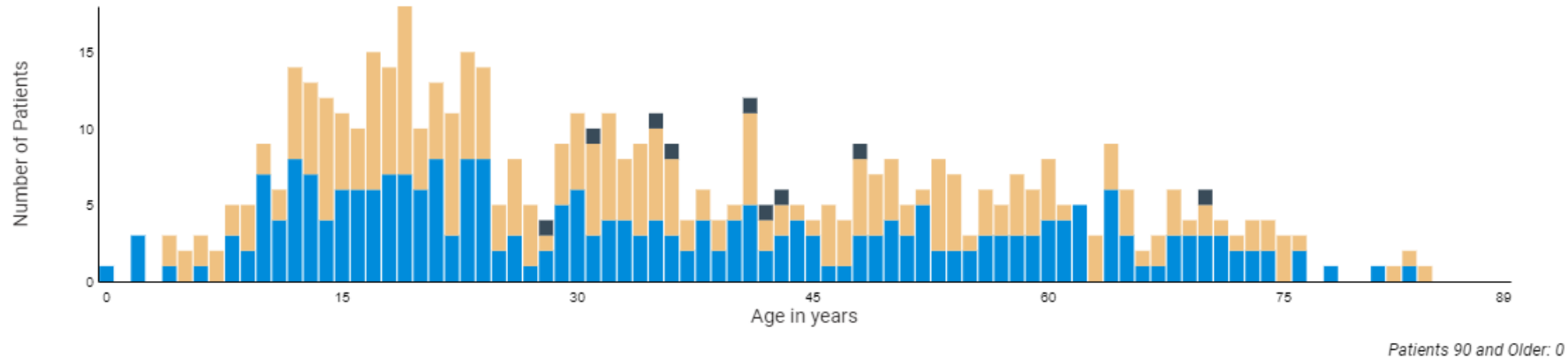


Ethnicity

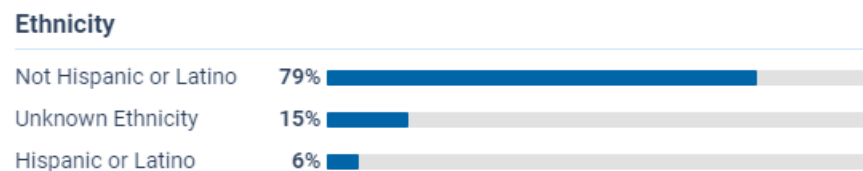
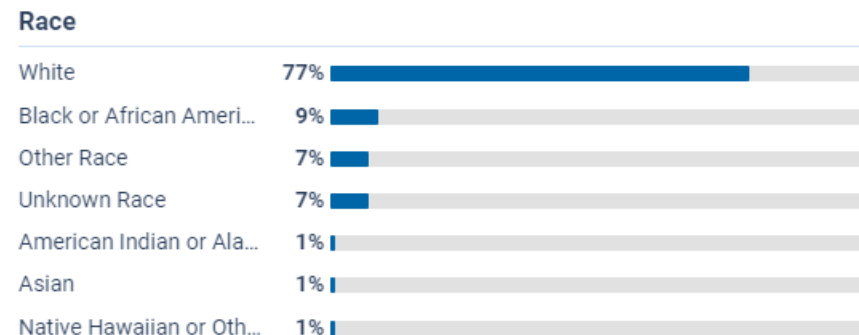
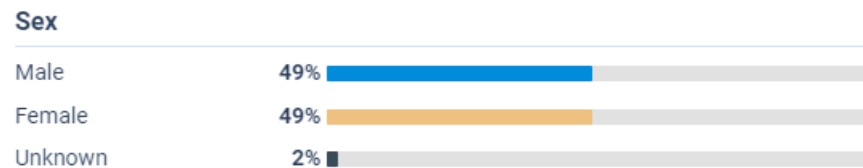


Generated by TriNetX

Figure 18. Demographic Characteristics for Patients with Dasiglucagon Exposures, from January 1, 2021 through January 19, 2024



Total Patients	Minimum Age	Maximum Age	Mean Age	Standard Deviation
530	0	84	35	20

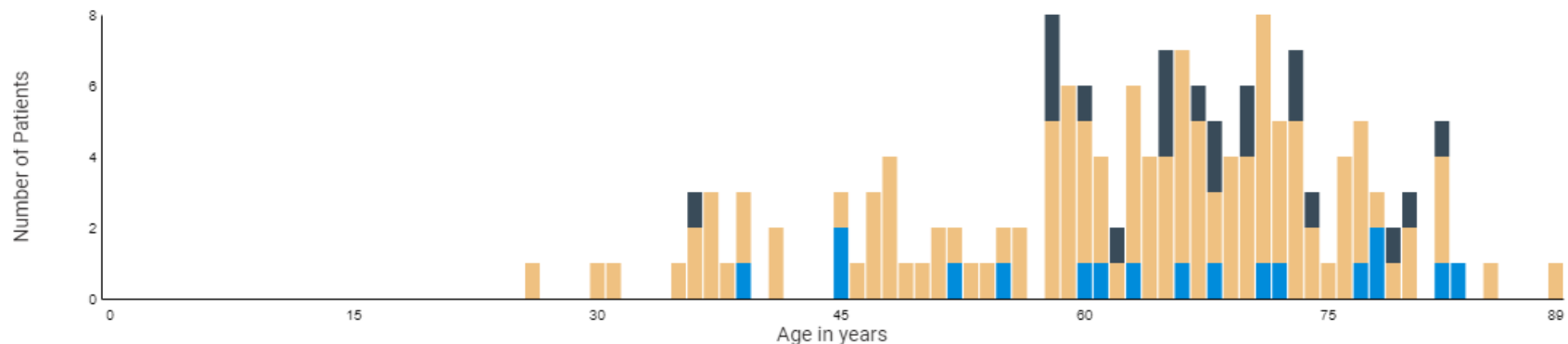


Generated by TriNetX

Figure 19. Demographic Characteristics for Patients with Difelikefalin Exposures, from January 1, 2021 through January 19, 2024

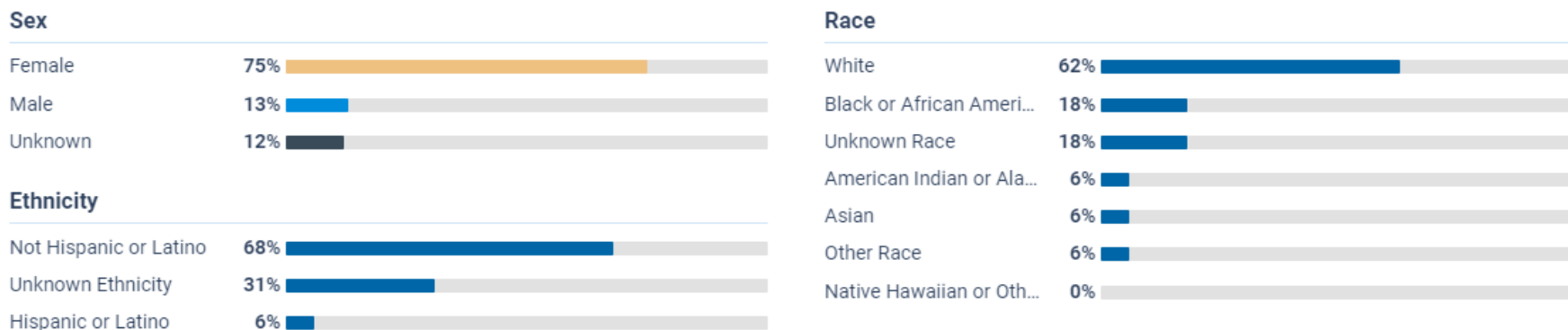
The cohort size is too small (10 or fewer patients) so detailed information cannot be produced by the TriNetX platform.

Figure 20. Demographic Characteristics for Patients with Dostarlimab-gxly Exposures, from January 1, 2021 through January 19, 2024



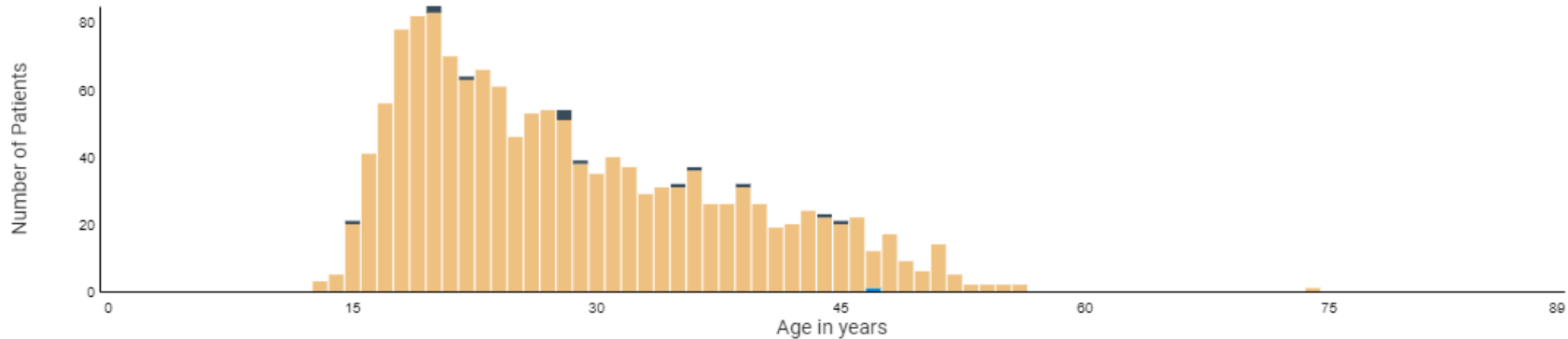
Patients 90 and Older: 1

Total Patients	Minimum Age	Maximum Age	Mean Age	Standard Deviation
160	26	90	63	13



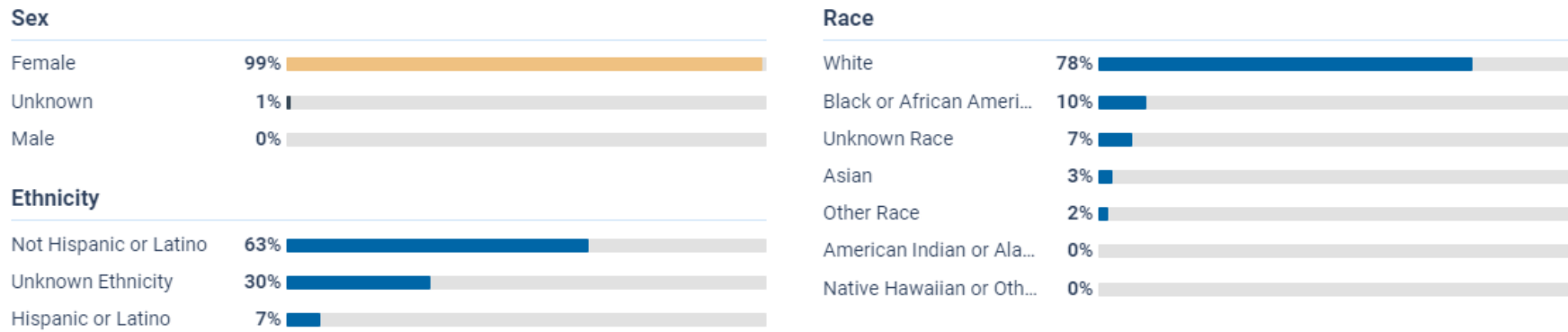
Generated by TriNetX

Figure 21. Demographic Characteristics for All Patients with Drospirenone and Estetrol Exposures*, from January 1, 2021 through January 19, 2024



Patients 90 and Older: 0

Total Patients	Minimum Age	Maximum Age	Mean Age	Standard Deviation
1,430	13	74	28	10



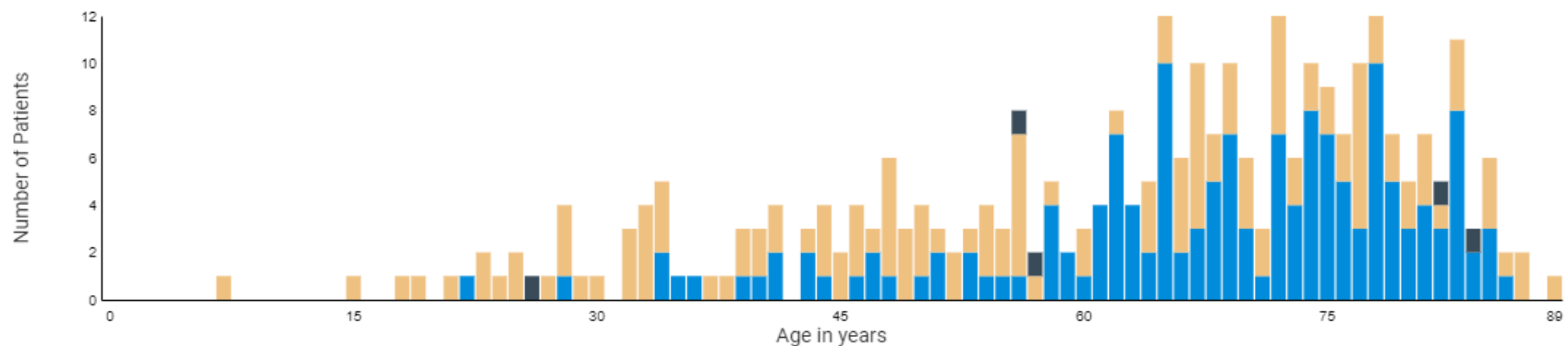
Generated by TriNetX

* The drospirenone and estetrol exposures occur on the same day.

Assumption is that the same day exposure refers to fixed dose combination of drospirenone and estetrol.

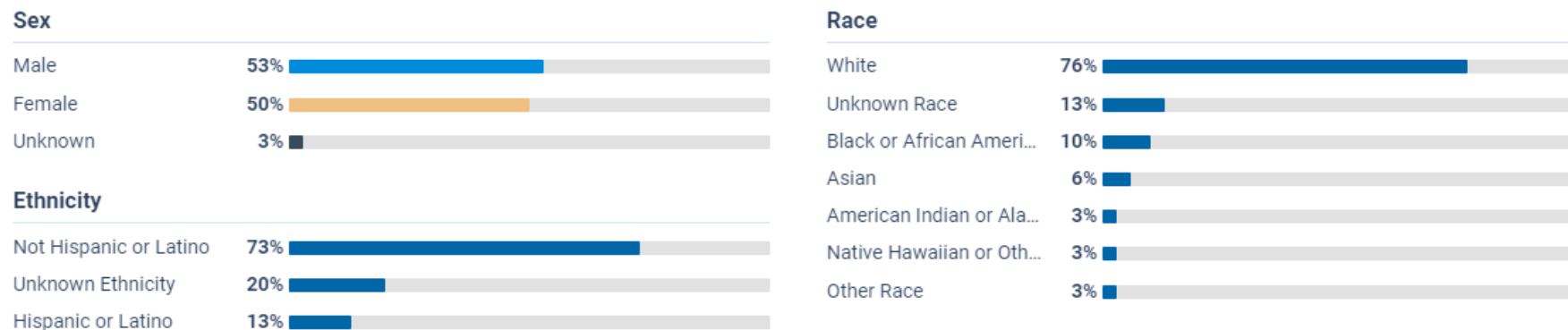
There is no sensitivity analyses cohort for this combination with a filter for brand name. The brand name NextStellis is not available as a filter option on TriNetX.

Figure 22. Demographic Characteristics for All Patients* with Efgartigimod alfa-fcab Exposures, from January 1, 2021 through January 19, 2024



Patients 90 and Older: 1

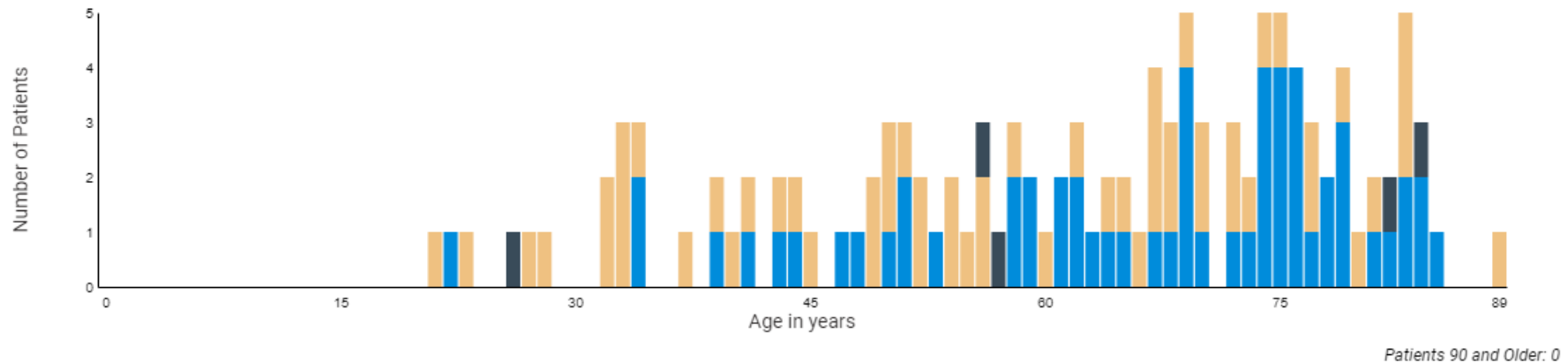
Total Patients	Minimum Age	Maximum Age	Mean Age	Standard Deviation
300	7	90	62	17



Generated by TriNetX

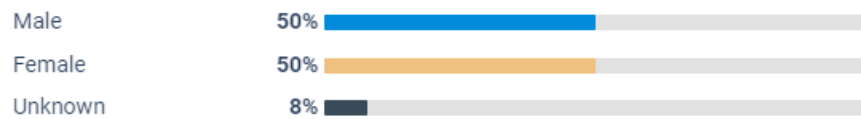
*No filters used

Figure 23. Demographic Characteristics for Patients with Efgartigimod alfa-fcab Exposures, Restricted to Brand Name Vyvgart, from January 1, 2021 through January 19, 2024

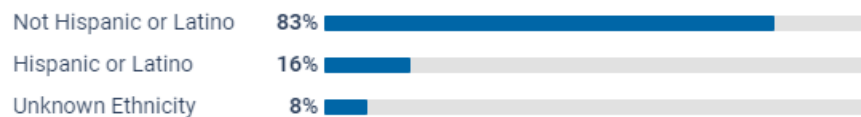


Total Patients	Minimum Age	Maximum Age	Mean Age	Standard Deviation
120	21	89	61	17

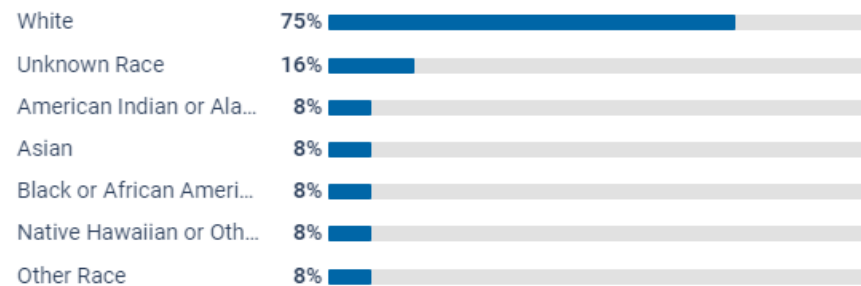
Sex



Ethnicity

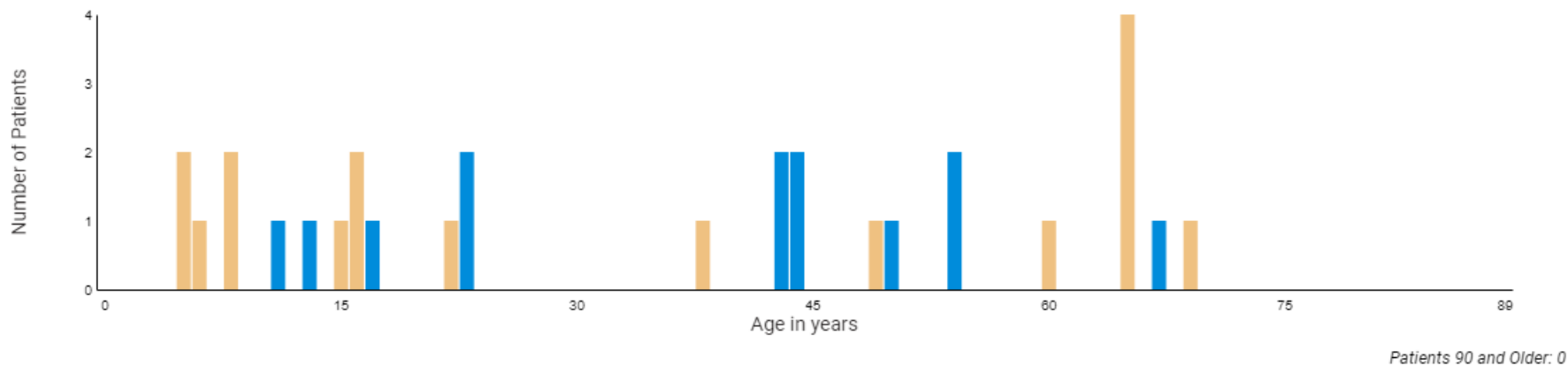


Race



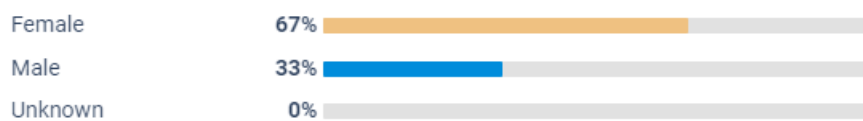
Generated by TriNetX

Figure 24. Demographic Characteristics for Patients with Evinacumab-dgnb Exposures, from January 1, 2021 through January 19, 2024

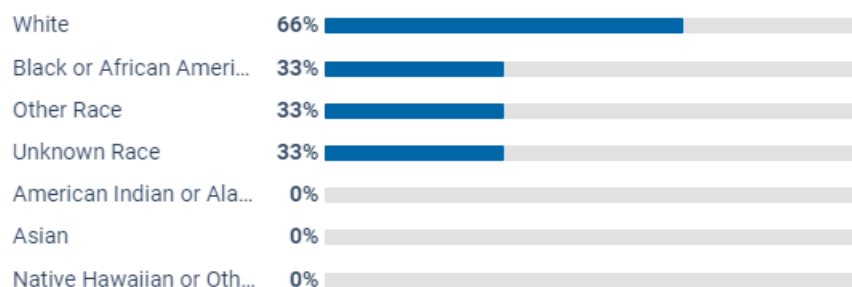


Total Patients	Minimum Age	Maximum Age	Mean Age	Standard Deviation
30	5	69	35	23

Sex



Race



Ethnicity

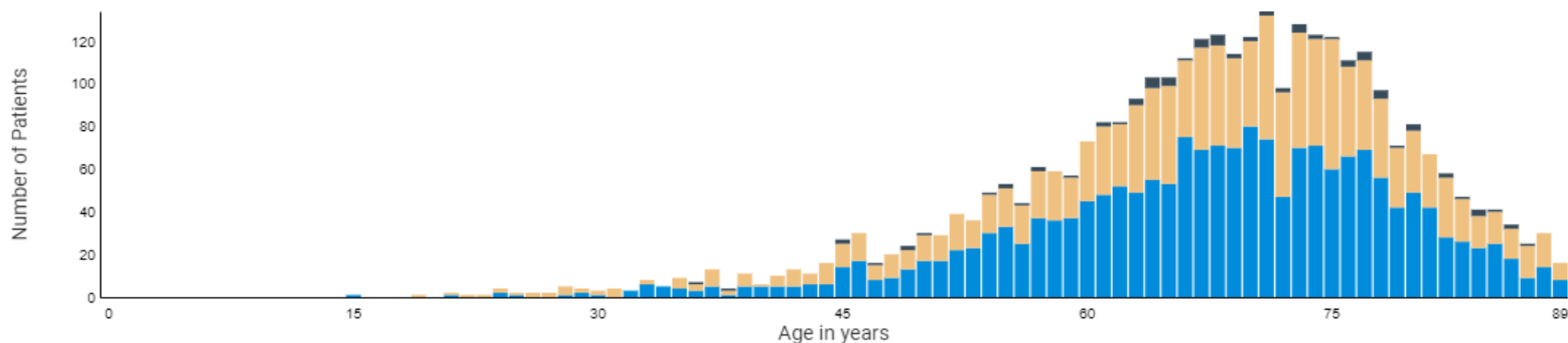


Generated by TriNetX

Figure 25. Demographic Characteristics for Patients with Fexinidazole Exposures, from January 1, 2021 through January 19, 2024

No patients were identified for this cohort.

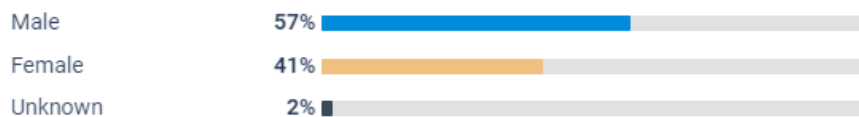
Figure 26. Demographic Characteristics for Patients with Finerenone Exposures, from January 1, 2021 through January 19, 2024



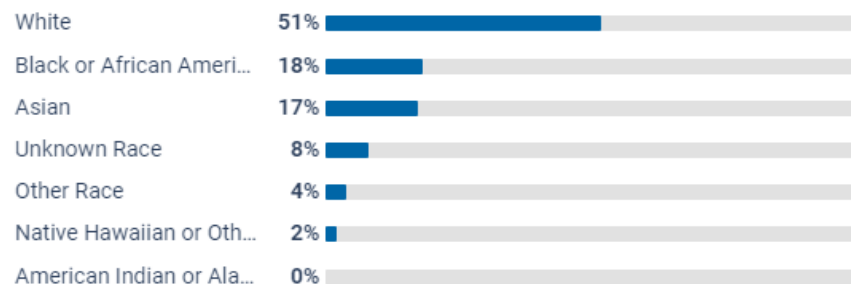
Patients 90 and Older: 41

Total Patients	Minimum Age	Maximum Age	Mean Age	Standard Deviation
3,330	15	90	68	12

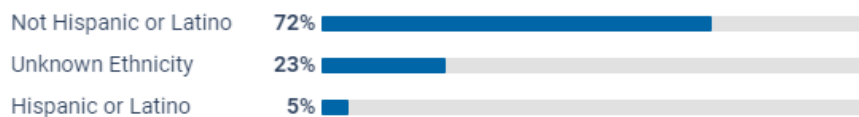
Sex



Race

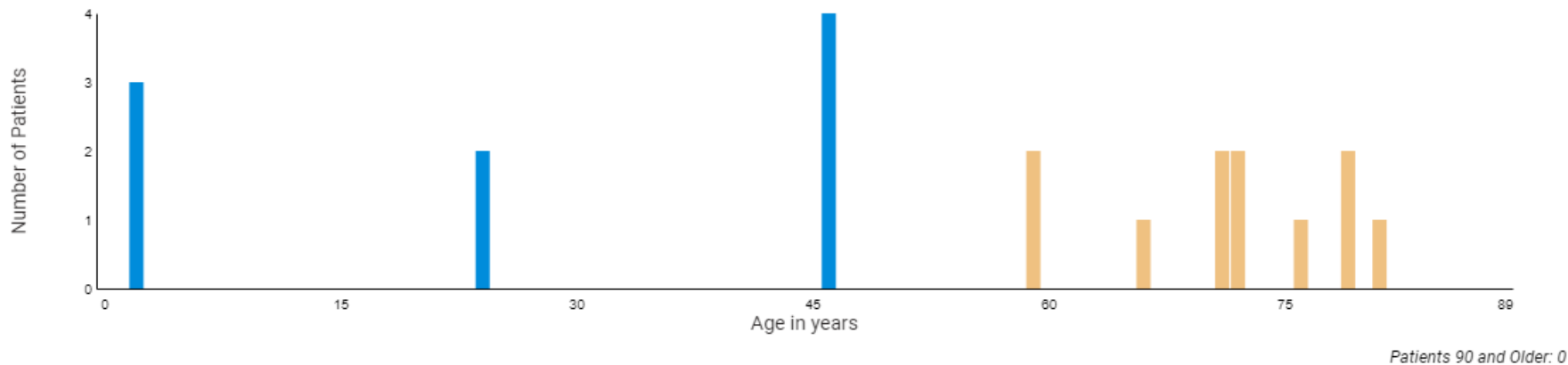


Ethnicity



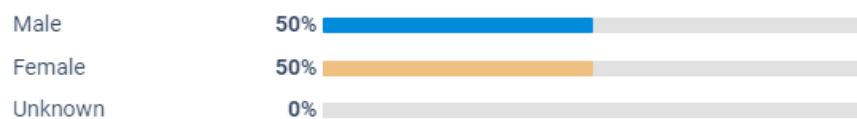
Generated by TriNetX

Figure 27. Demographic Characteristics for Patients with Fosdenopterin Exposures, from January 1, 2021 through January 19, 2024

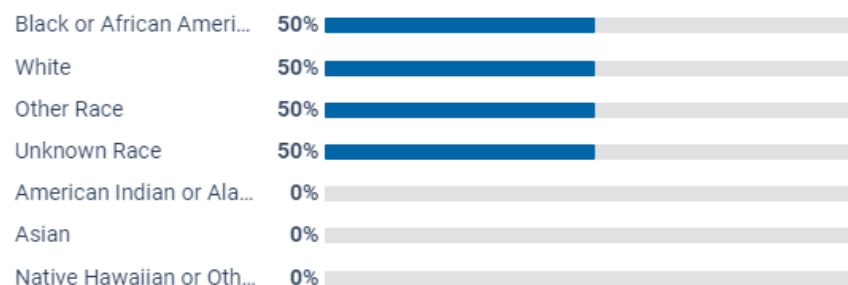


Total Patients	Minimum Age	Maximum Age	Mean Age	Standard Deviation
20	2	81	51	27

Sex



Race

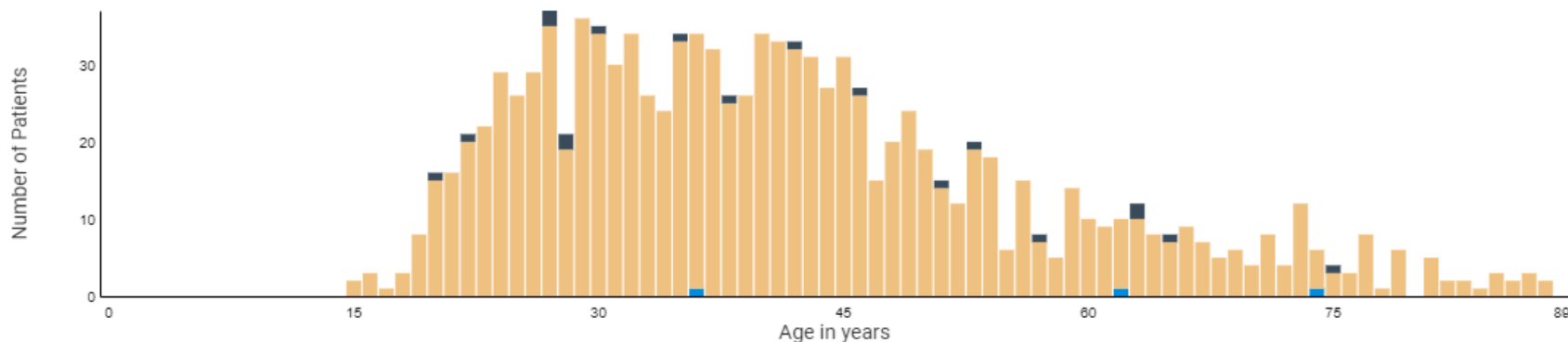


Ethnicity



Generated by TriNetX

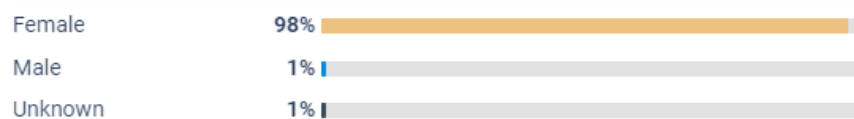
Figure 28. Demographic Characteristics for Patients with Ibrexafungerp Exposures, from January 1, 2021 through January 19, 2024



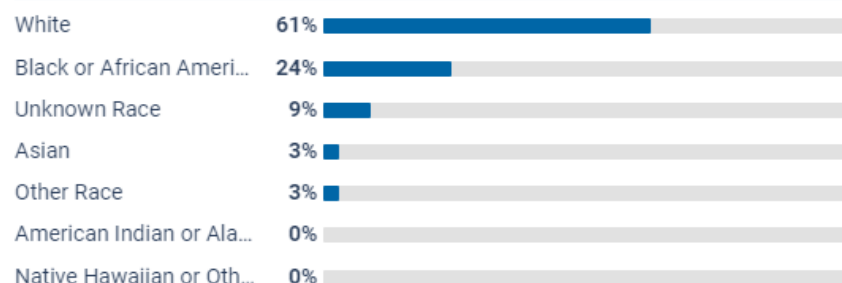
Patients 90 and Older: 2

Total Patients	Minimum Age	Maximum Age	Mean Age	Standard Deviation
1,140	15	90	42	15

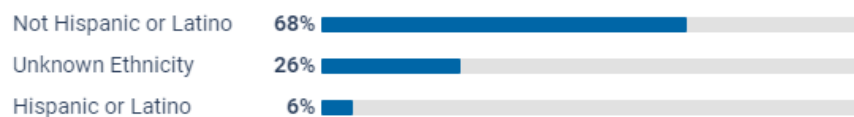
Sex



Race

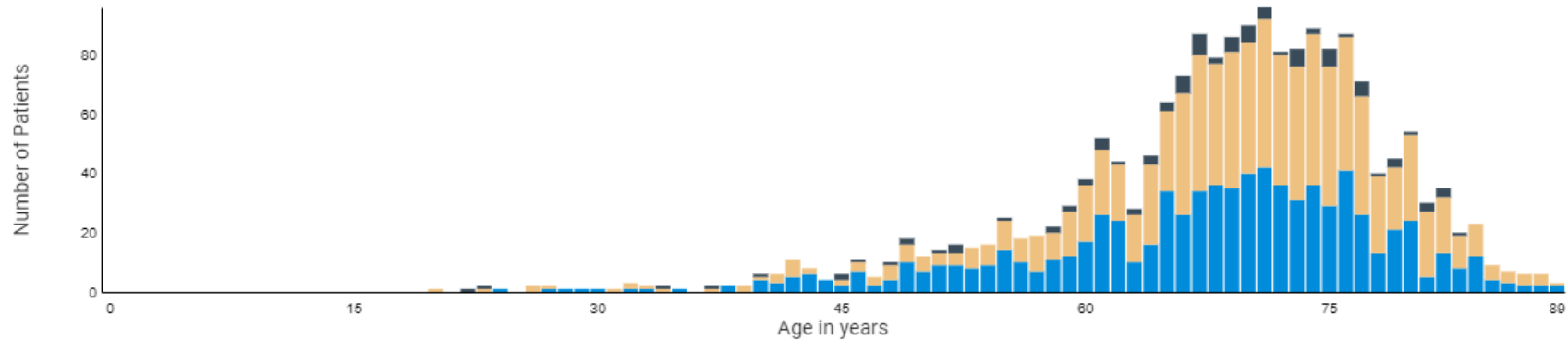


Ethnicity



Generated by TriNetX

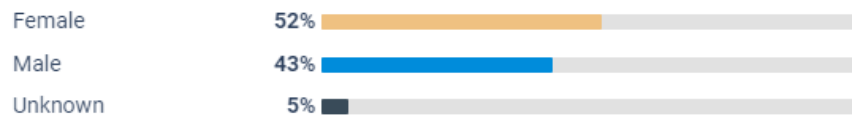
Figure 29. Demographic Characteristics for Patients with Inclisiran Exposures, from January 1, 2021 through January 19, 2024



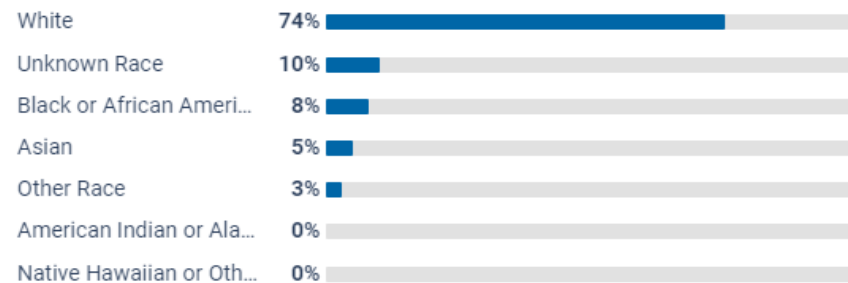
Patients 90 and Older: 9

Total Patients	Minimum Age	Maximum Age	Mean Age	Standard Deviation
1,860	20	90	68	10

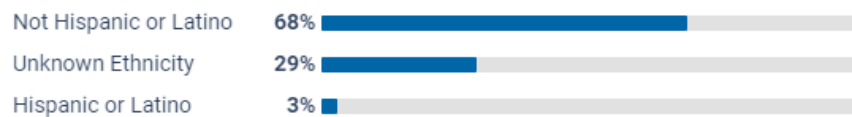
Sex



Race

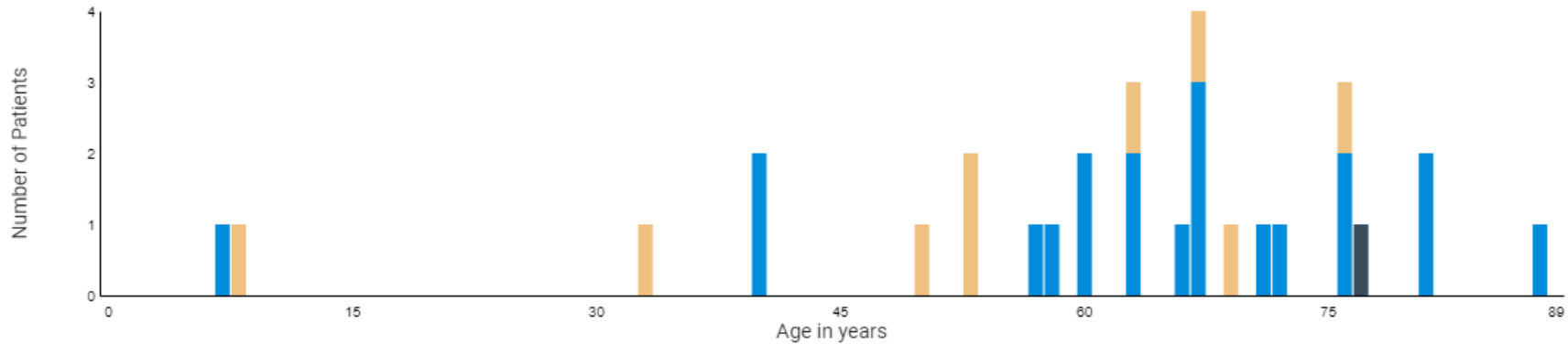


Ethnicity



Generated by TriNetX

Figure 30. Demographic Characteristics for Patients with Infigratinib Exposures, from January 1, 2021 through January 19, 2024



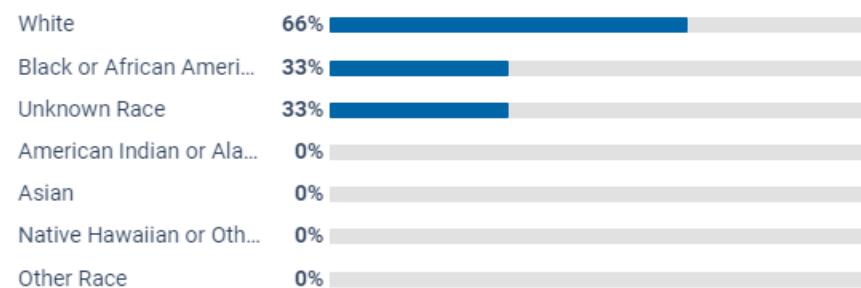
Patients 90 and Older: 0

Total Patients	Minimum Age	Maximum Age	Mean Age	Standard Deviation
30	7	88	60	19

Sex



Race

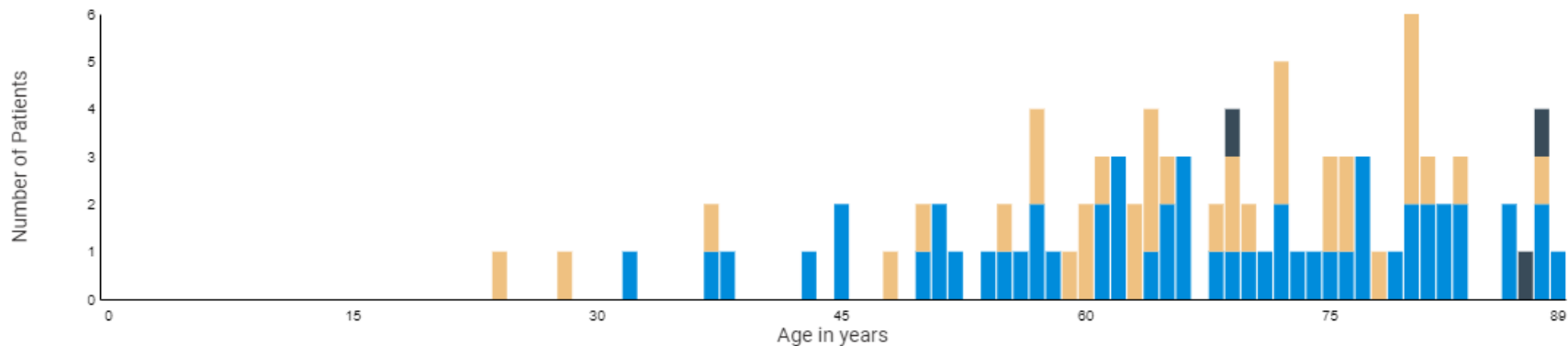


Ethnicity



Generated by TriNetX

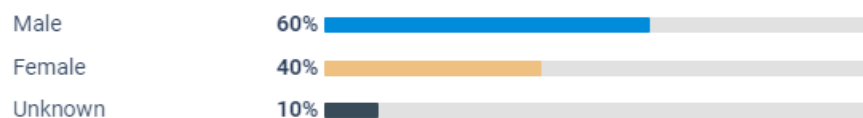
Figure 31. Demographic Characteristics for Patients with Loncastximab Tesirine-Ipyl Exposures, from January 1, 2021 through January 19, 2024



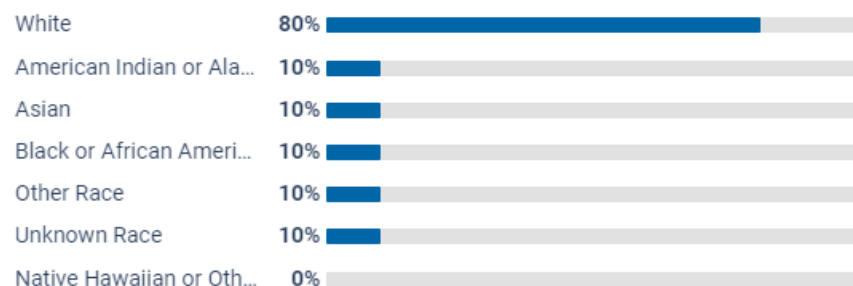
Patients 90 and Older: 6

Total Patients	Minimum Age	Maximum Age	Mean Age	Standard Deviation
100	24	90	68	15

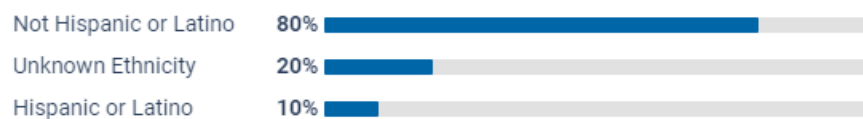
Sex



Race

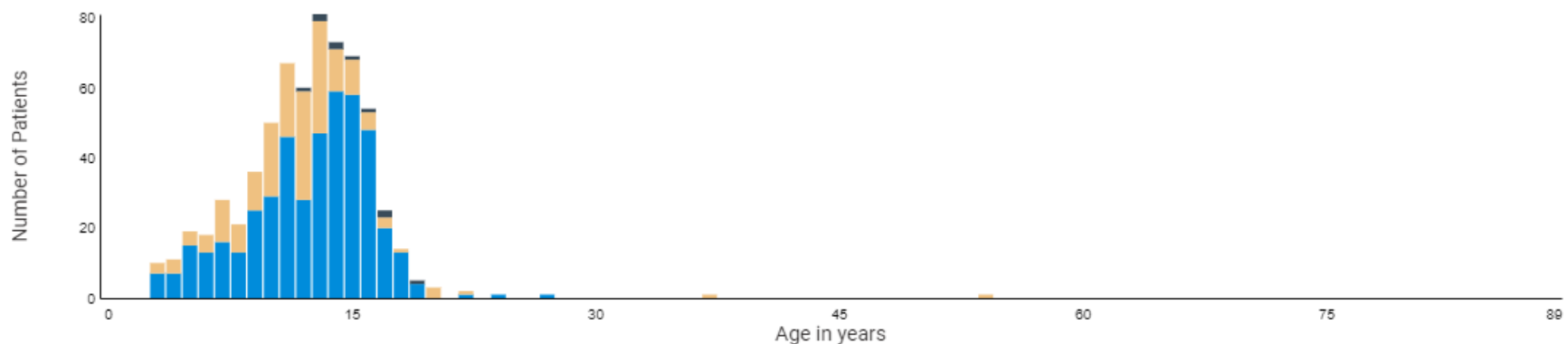


Ethnicity



Generated by TriNetX

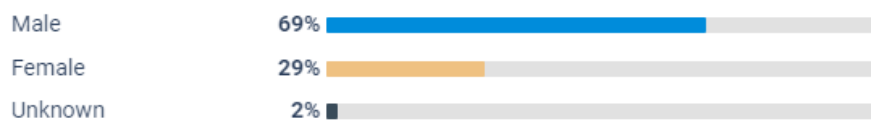
Figure 32. Demographic Characteristics for Patients with Lonapegsomatropin-tcgd Exposures, from January 1, 2021 through January 19, 2024



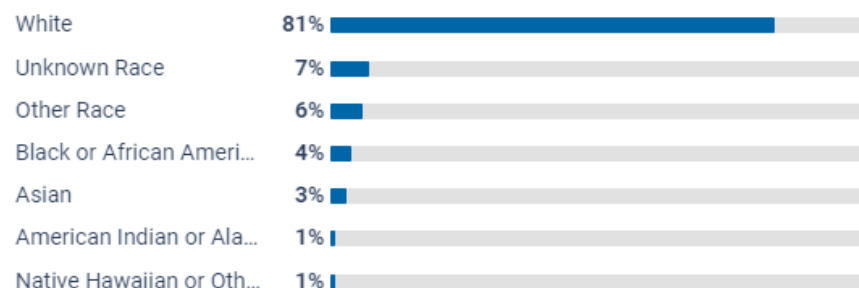
Patients 90 and Older: 0

Total Patients	Minimum Age	Maximum Age	Mean Age	Standard Deviation
650	3	54	12	4

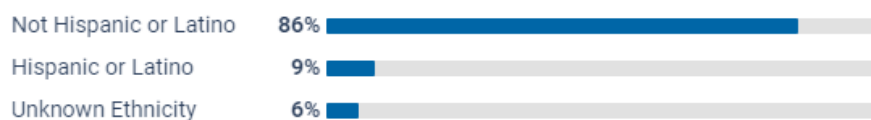
Sex



Race

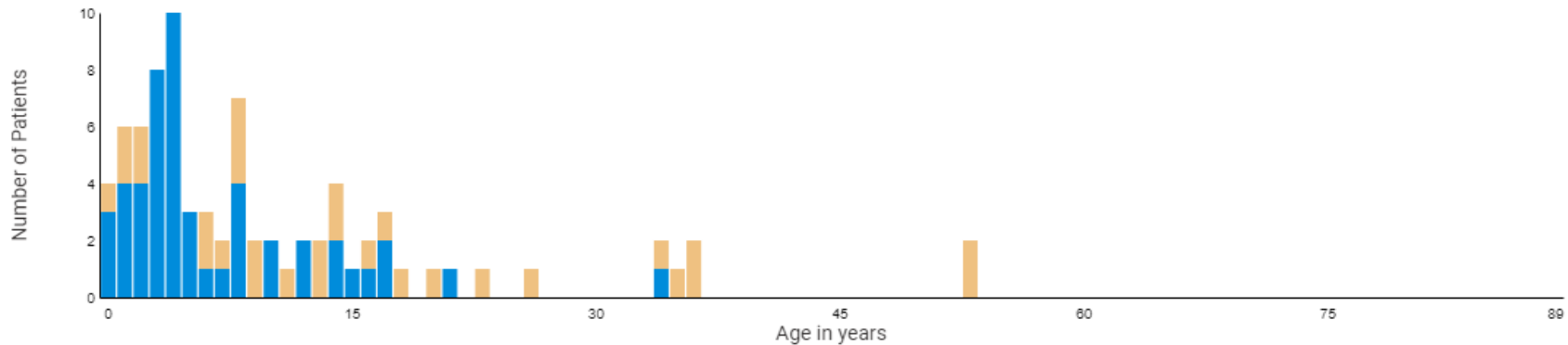


Ethnicity



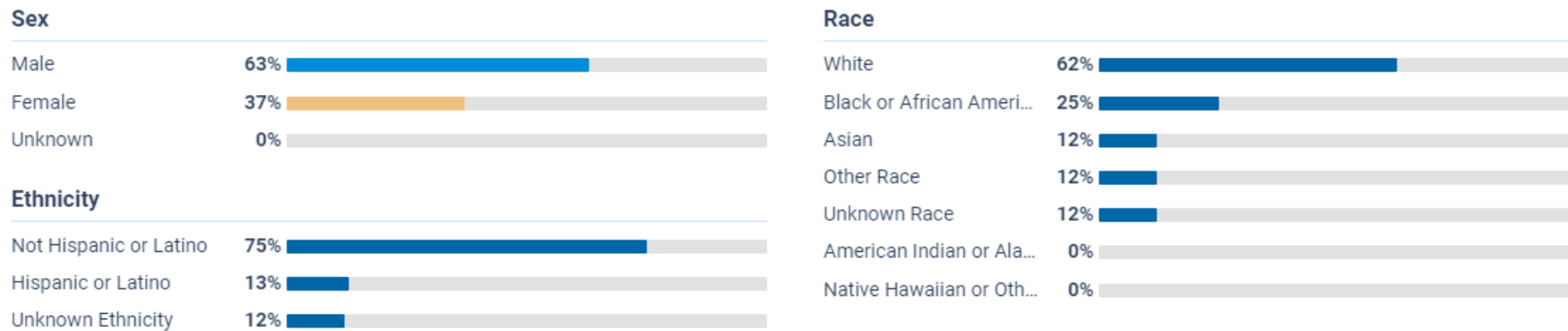
Generated by TriNetX

Figure 33. Demographic Characteristics for Patients with Maralixibat Exposures, from January 1, 2021 through January 19, 2024



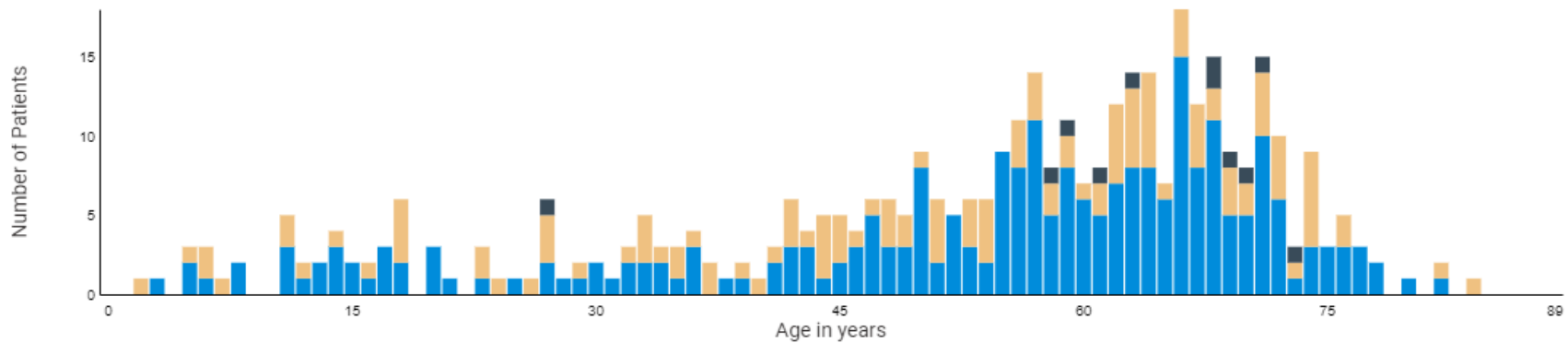
Patients 90 and Older: 0

Total Patients	Minimum Age	Maximum Age	Mean Age	Standard Deviation
80	0	53	10	11



Generated by TriNetX

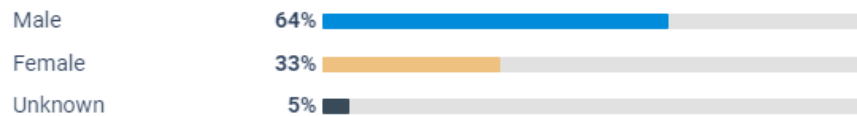
Figure 34. Demographic Characteristics for Patients with Maribavir Exposures, from January 1, 2021 through January 19, 2024



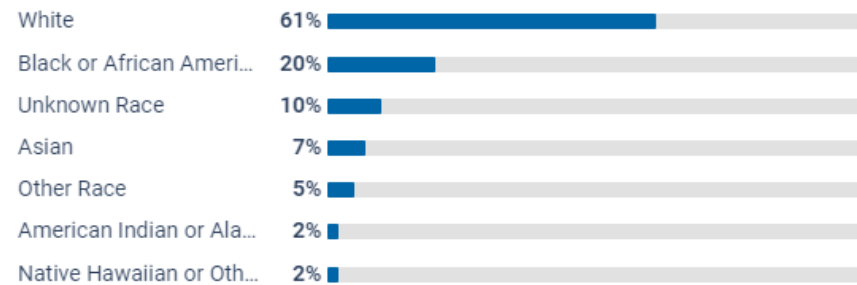
Patients 90 and Older: 0

Total Patients	Minimum Age	Maximum Age	Mean Age	Standard Deviation
390	2	84	53	19

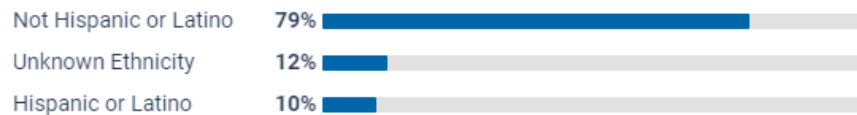
Sex



Race

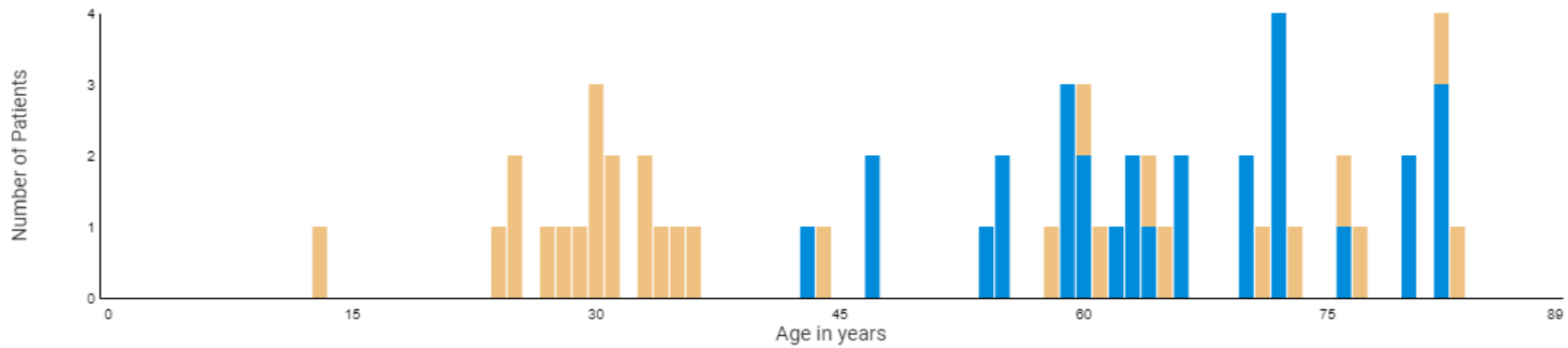


Ethnicity



Generated by TriNetX

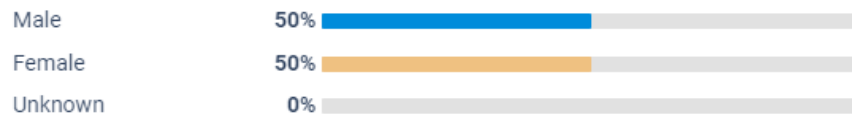
Figure 35. Demographic Characteristics for Patients with Melphalan Flufenamide Exposures, from January 1, 2021 through January 19, 2024



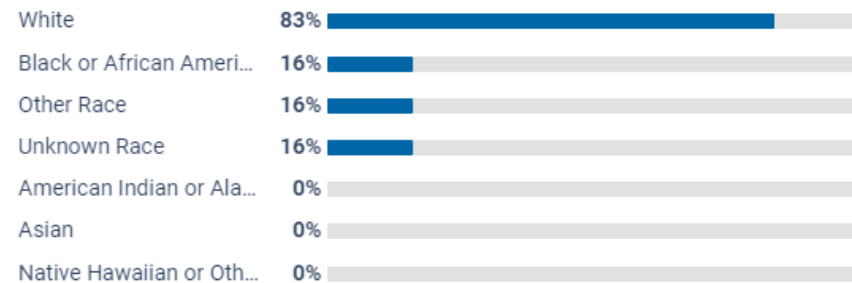
Patients 90 and Older: 2

Total Patients	Minimum Age	Maximum Age	Mean Age	Standard Deviation
60	13	90	56	20

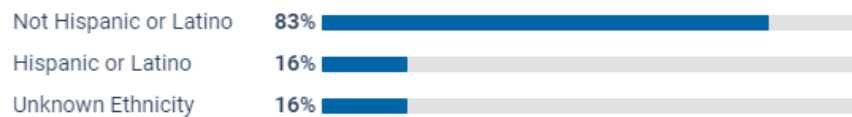
Sex



Race

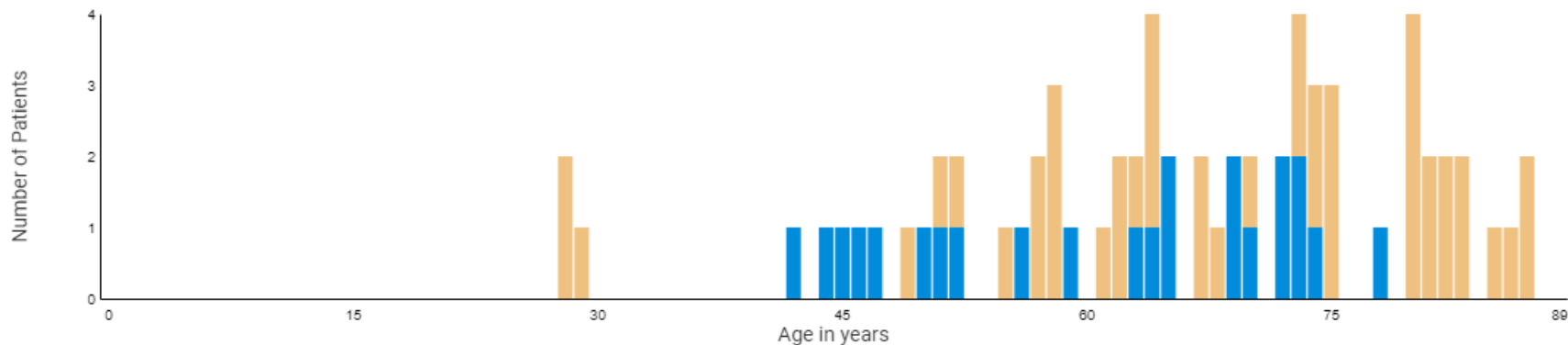


Ethnicity



Generated by TriNetX

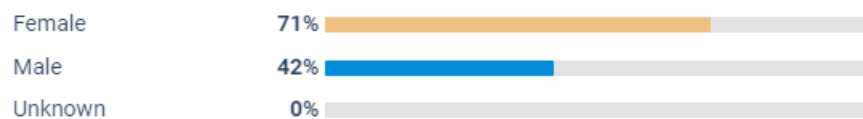
Figure 36. Demographic Characteristics for Patients with Mobocertinib Exposures, from January 1, 2021 through January 19, 2024



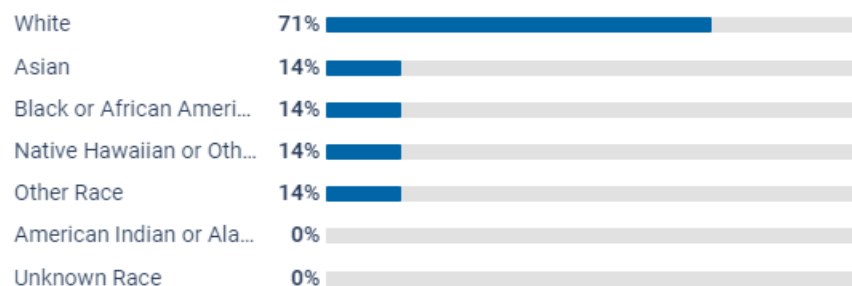
Patients 90 and Older: 3

Total Patients	Minimum Age	Maximum Age	Mean Age	Standard Deviation
70	28	90	66	15

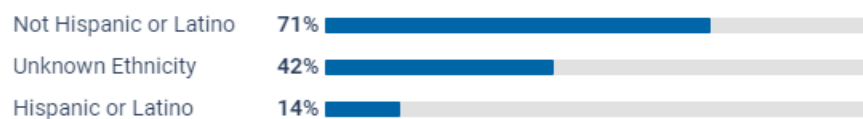
Sex



Race

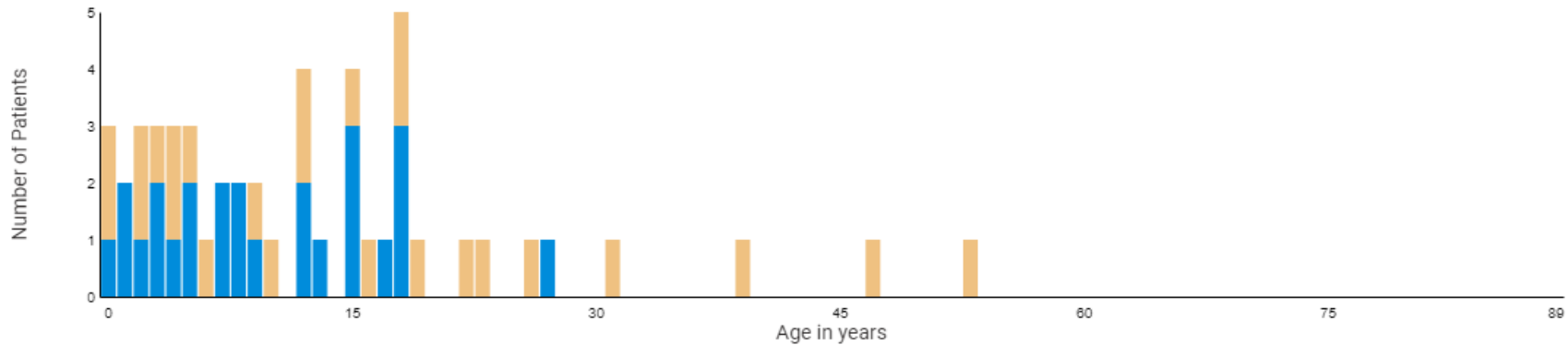


Ethnicity



Generated by TriNetX

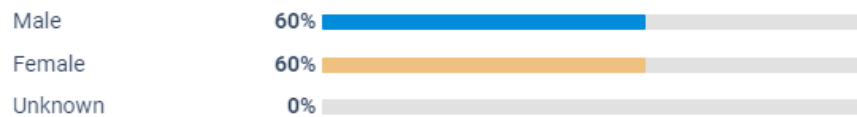
Figure 37. Demographic Characteristics for Patients with Odevixibat Exposures, from January 1, 2021 through January 19, 2024



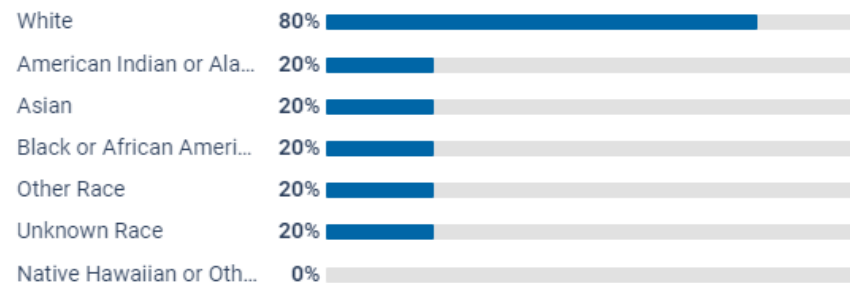
Patients 90 and Older: 0

Total Patients	Minimum Age	Maximum Age	Mean Age	Standard Deviation
50	0	53	13	12

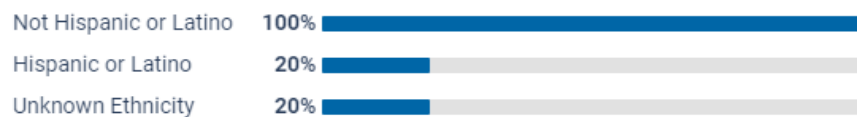
Sex



Race

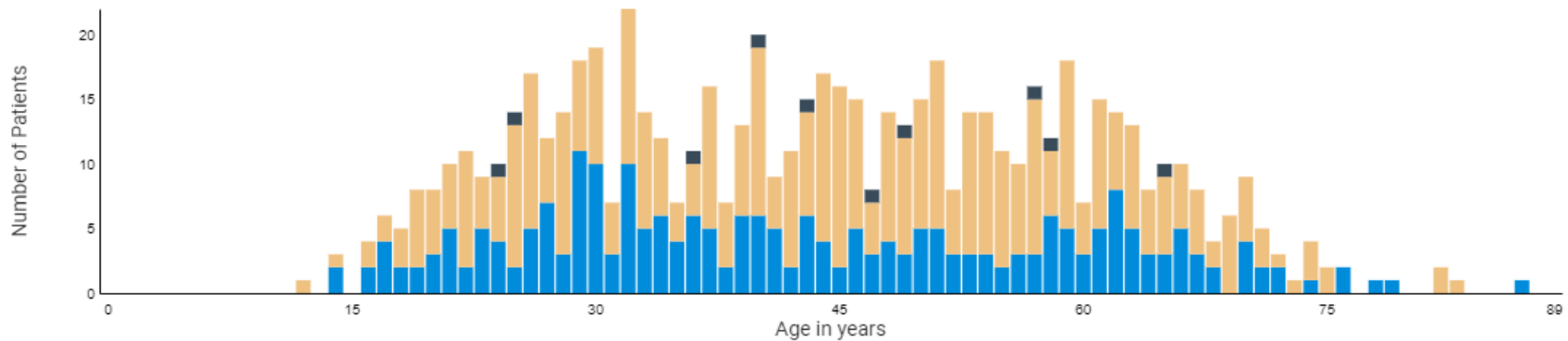


Ethnicity



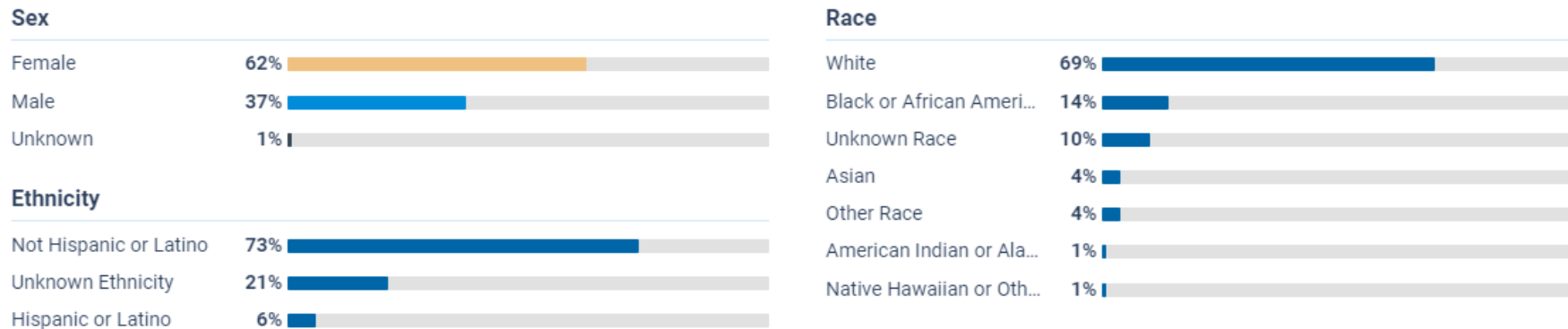
Generated by TriNetX

Figure 38. Demographic Characteristics for All Patients with Olanzapine and Samidorphan Exposures*, from January 1, 2021 through January 19, 2024



Patients 90 and Older: 1

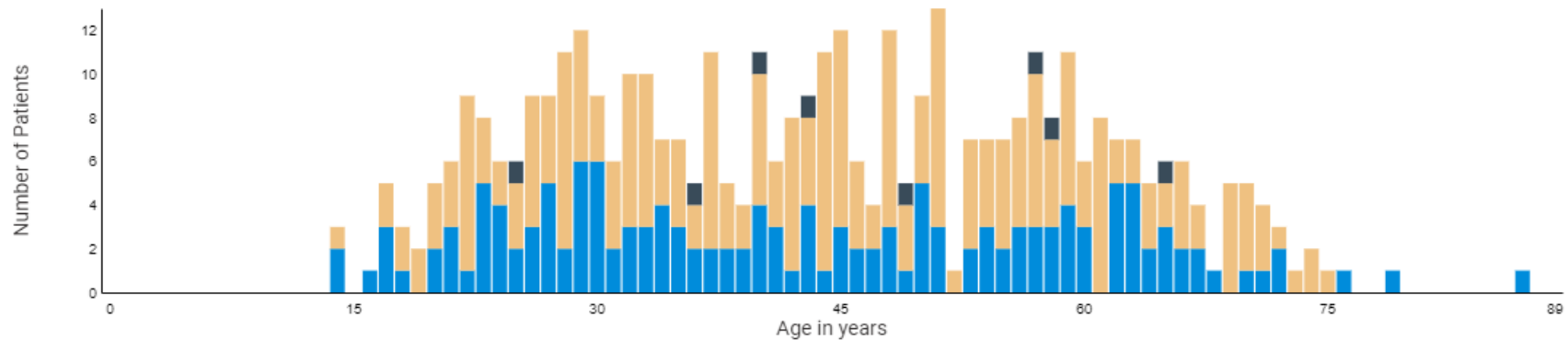
Total Patients	Minimum Age	Maximum Age	Mean Age	Standard Deviation
680	12	90	44	16



Generated by TriNetX

* The olanzapine and samidorphan exposures occur on the same day.
Assumption is that the same day exposure refers to fixed dose combination of olanzapine and samidorphan

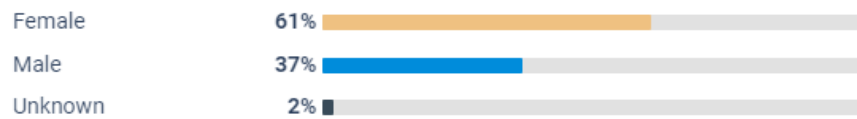
Figure 39. Demographic Characteristics for Patients with Olanzapine and Samidorphan Exposures, Restricted to Brand Name Lybalvi, from January 1, 2021 through January 19, 2024



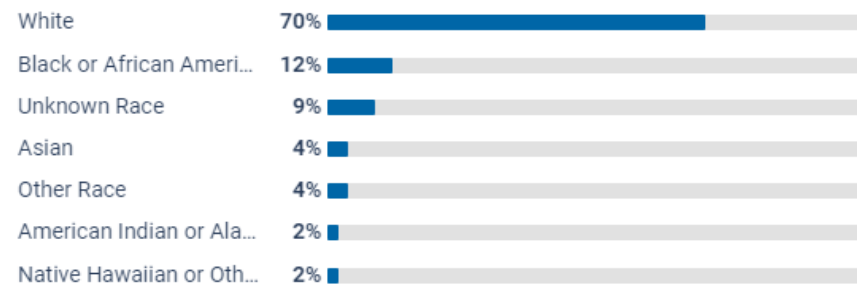
Patients 90 and Older: 1

Total Patients	Minimum Age	Maximum Age	Mean Age	Standard Deviation
410	14	90	44	16

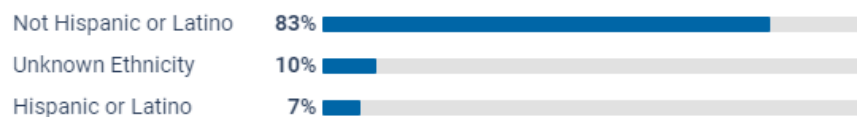
Sex



Race



Ethnicity

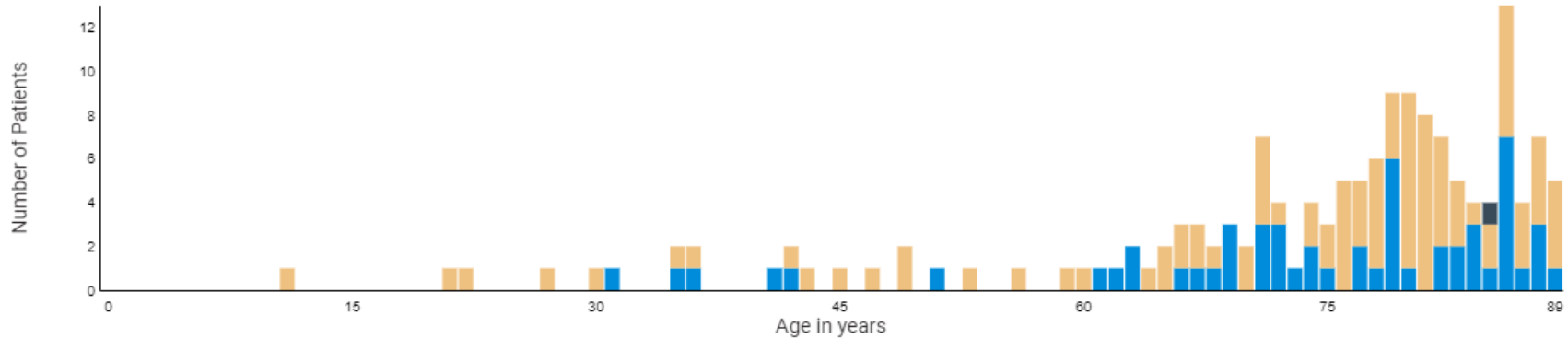


Generated by TriNetX

Figure 40. Demographic Characteristics for Patients with Pafolacianine Exposures, from January 1, 2021 through January 19, 2024

No patients were identified for this cohort.

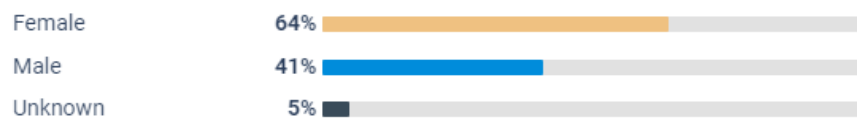
Figure 41. Demographic Characteristics for All Patients* with Pegcetacoplan Exposures, from January 1, 2021 through January 19, 2024



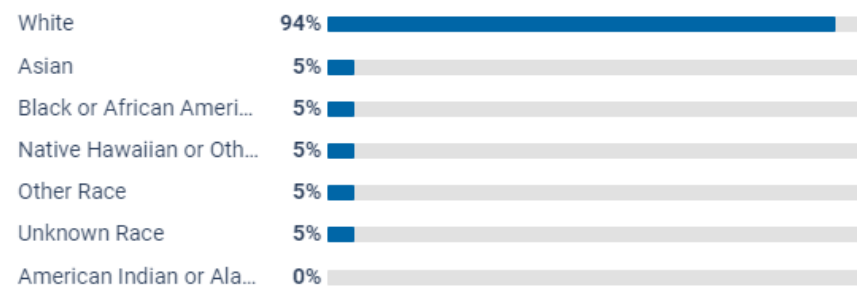
Patients 90 and Older: 17

Total Patients	Minimum Age	Maximum Age	Mean Age	Standard Deviation
170	11	90	74	16

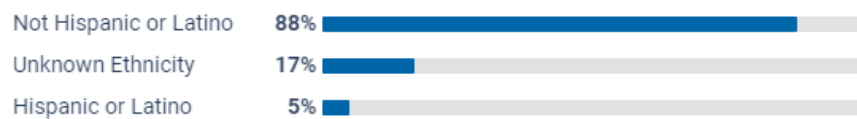
Sex



Race

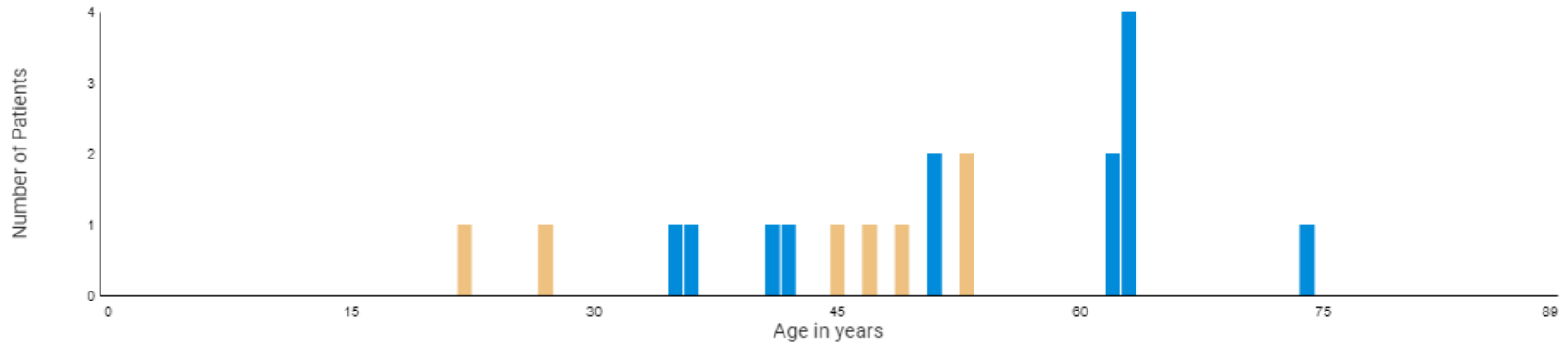


Ethnicity



*No filters used

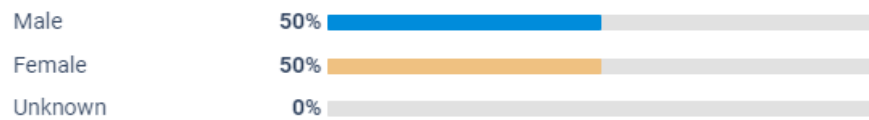
Figure 42. Demographic Characteristics for Patients with Pegcetacoplan Exposures, Restricted to Brand Name Empaveli, from January 1, 2021 through January 19, 2024



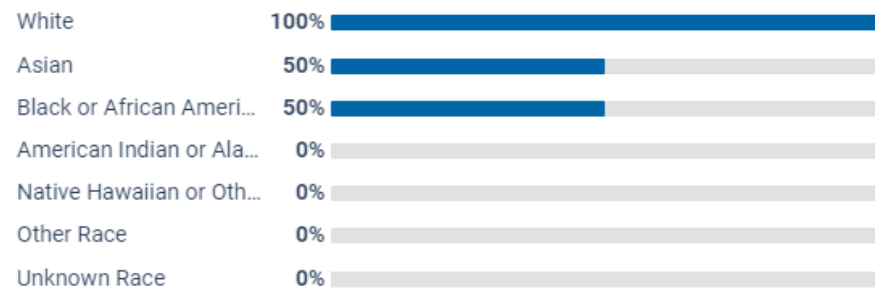
Patients 90 and Older: 0

Total Patients	Minimum Age	Maximum Age	Mean Age	Standard Deviation
20	22	74	50	14

Sex



Race

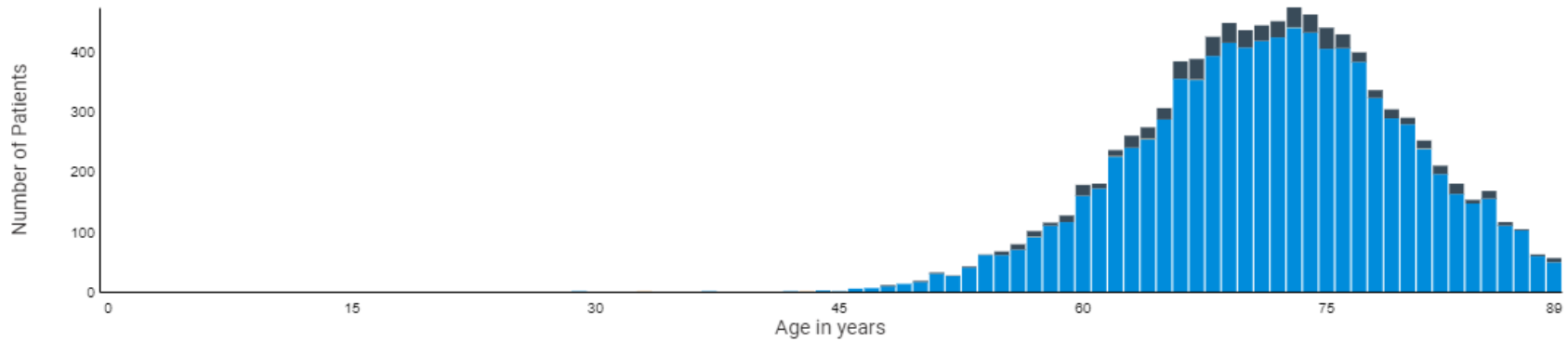


Ethnicity



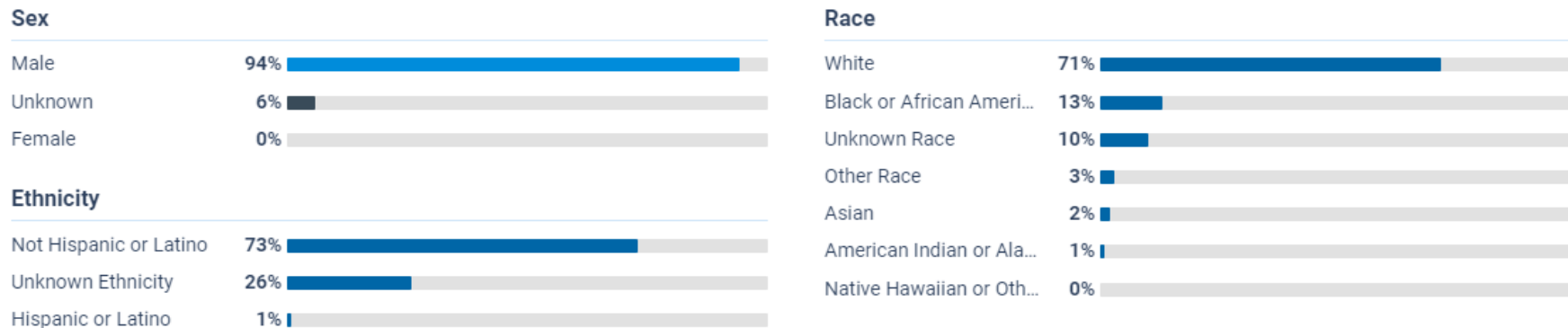
Generated by TriNetX

Figure 43. Demographic Characteristics for Patients with Piflufolastat F-18 Exposures, from January 1, 2021 through January 19, 2024



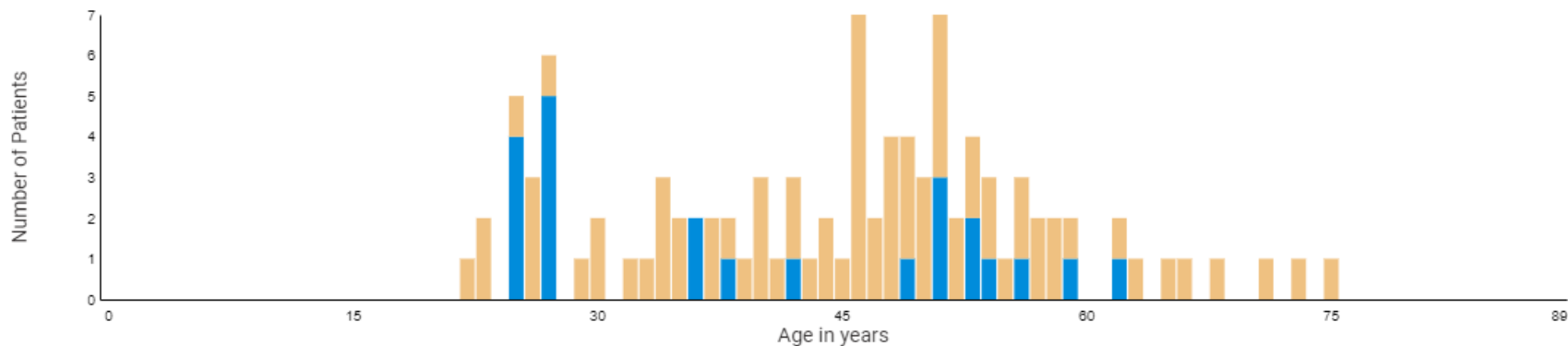
Patients 90 and Older: 162

Total Patients	Minimum Age	Maximum Age	Mean Age	Standard Deviation
9,720	29	90	72	8



Generated by TriNetX

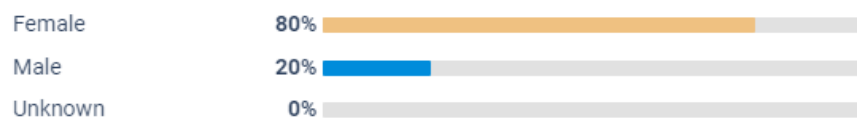
Figure 44. Demographic Characteristics for Patients with Ponesimod Exposures, from January 1, 2021 through January 19, 2024



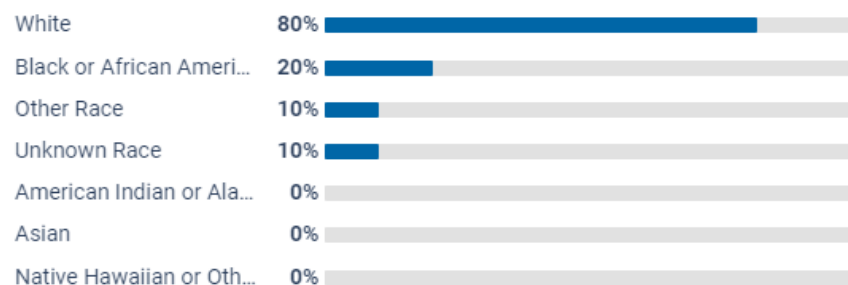
Patients 90 and Older: 0

Total Patients	Minimum Age	Maximum Age	Mean Age	Standard Deviation
100	22	75	44	13

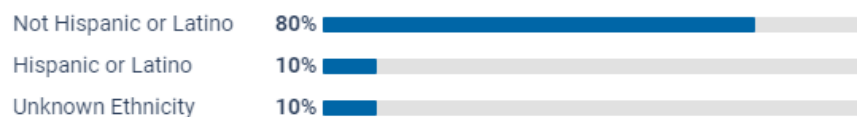
Sex



Race

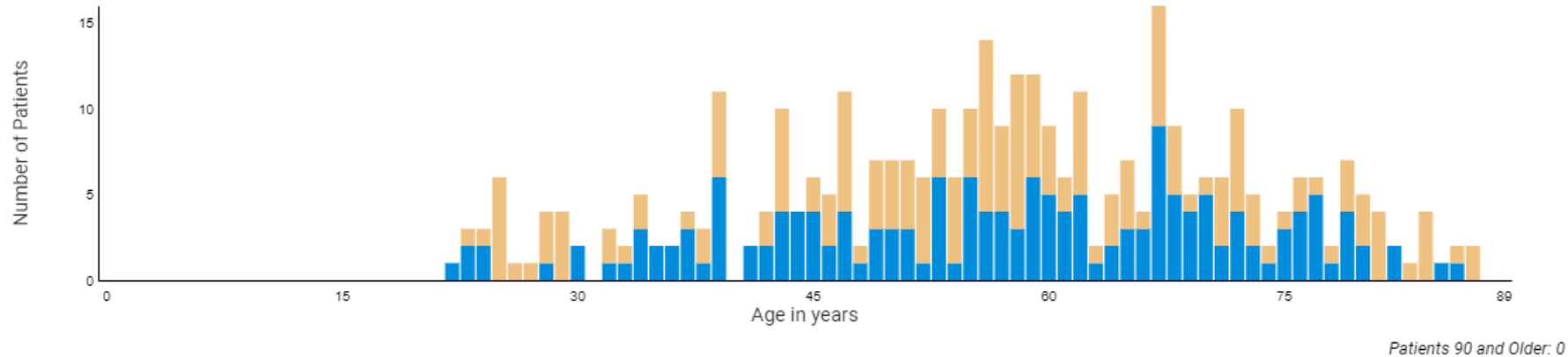


Ethnicity



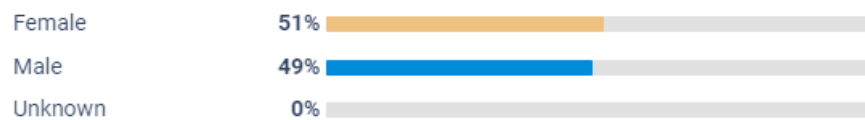
Generated by TriNetX

Figure 45. Demographic Characteristics for Patients with Ropeginterferon alfa-2b-njft Exposures, from January 1, 2021 through January 19, 2024

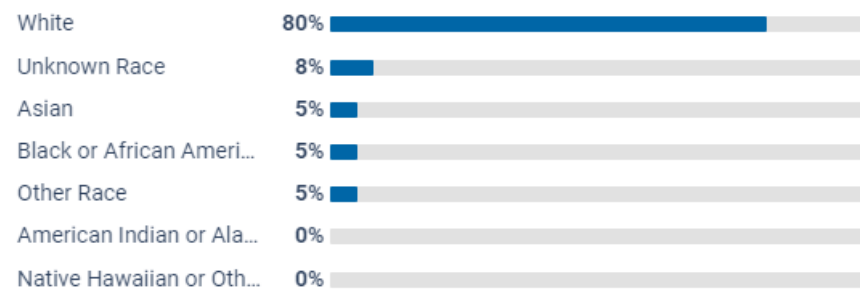


Total Patients	Minimum Age	Maximum Age	Mean Age	Standard Deviation
350	22	87	57	15

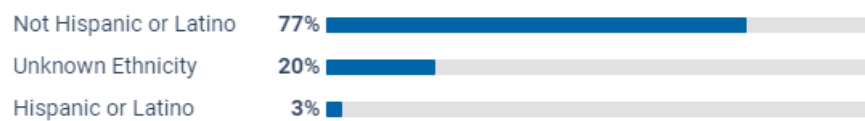
Sex



Race

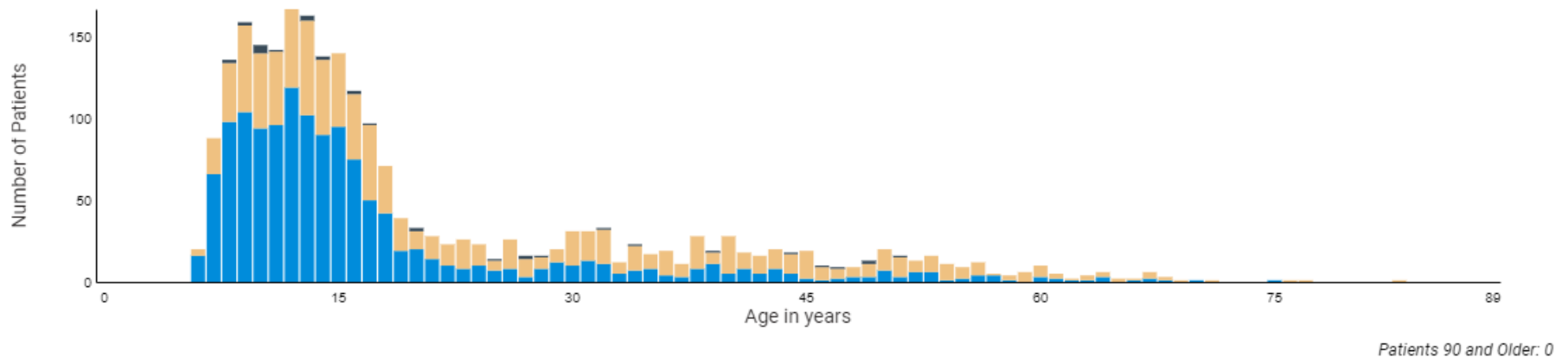


Ethnicity



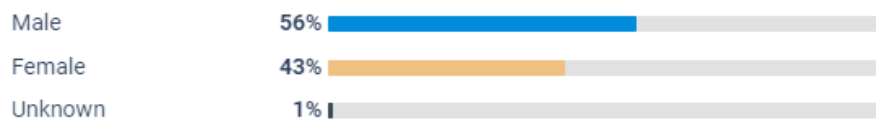
Generated by TriNetX

Figure 46. Demographic Characteristics for All Patients with Serdexmethylphenidate and Dexmethylphenidate Exposures*, from January 1, 2021 through January 19, 2024

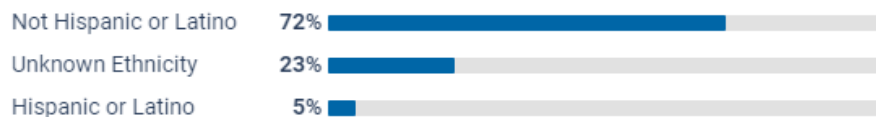


Total Patients	Minimum Age	Maximum Age	Mean Age	Standard Deviation
2,390	6	83	20	14

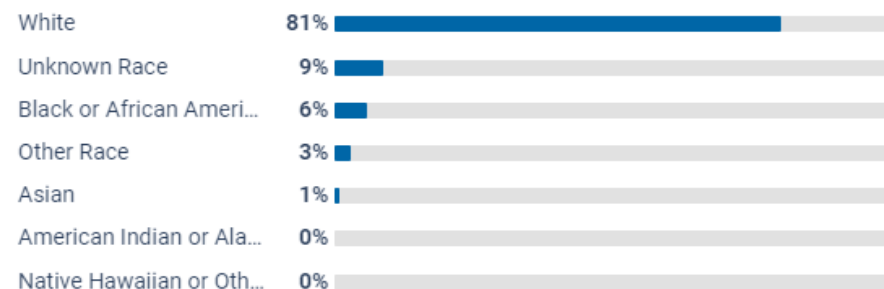
Sex



Ethnicity



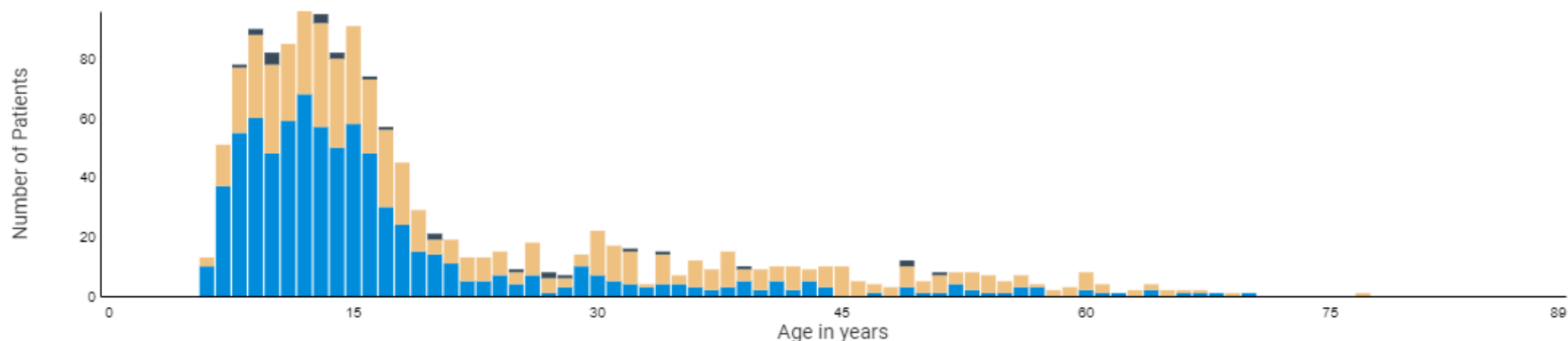
Race



* The serdexmethylphenidate and dexmethylphenidate exposures occur on the same day.

Assumption is that the same day exposure refers to fixed dose combination of serdexmethylphenidate and dexmethylphenidate

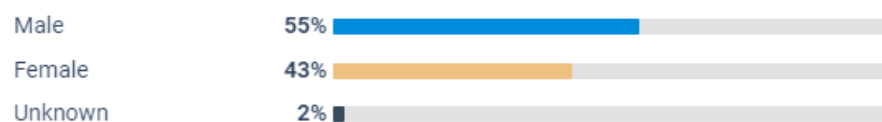
Figure 47. Demographic Characteristics for Patients with Serdexamethylphenidate and Dexmethylphenidate Exposures, Restricted to Brand Name Azstarys, from January 1, 2021 through January 19, 2024



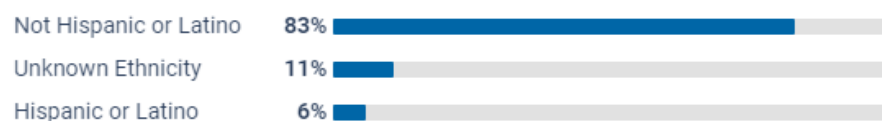
Patients 90 and Older: 0

Total Patients	Minimum Age	Maximum Age	Mean Age	Standard Deviation
1,400	6	77	20	14

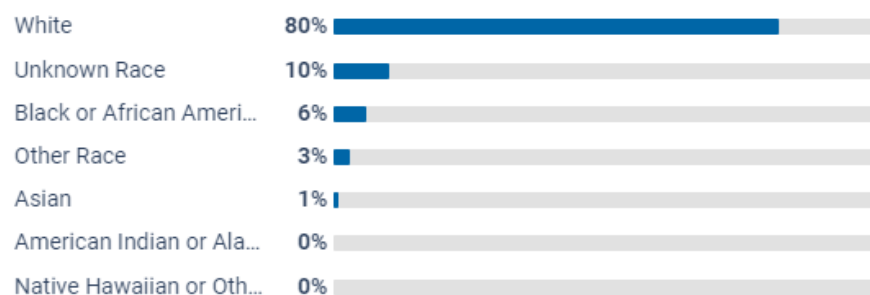
Sex



Ethnicity

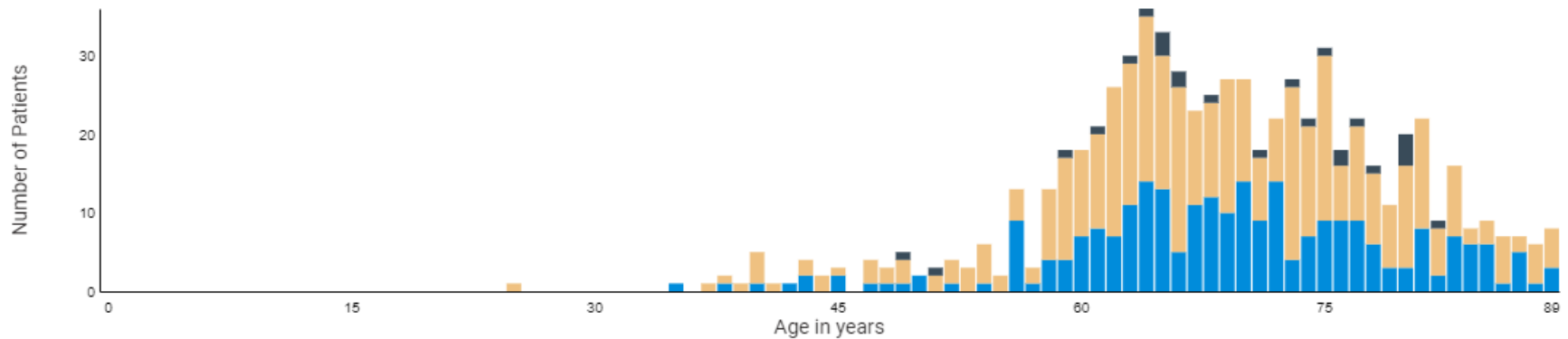


Race



Generated by TriNetX

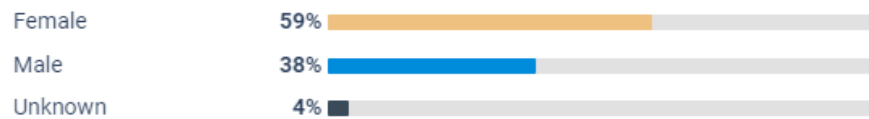
Figure 48. Demographic Characteristics for Patients with Sotorasib Exposures, from January 1, 2021 through January 19, 2024



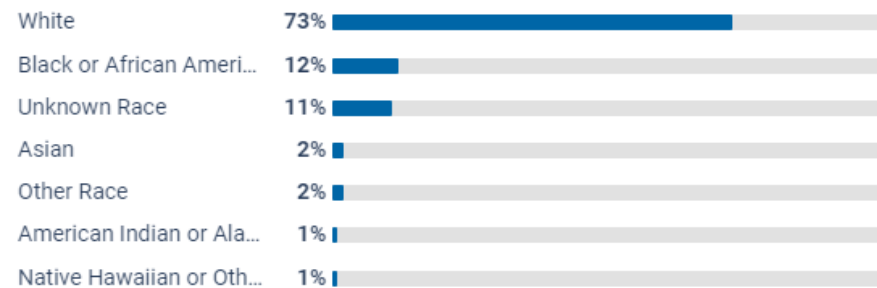
Patients 90 and Older: 16

Total Patients	Minimum Age	Maximum Age	Mean Age	Standard Deviation
710	25	90	69	11

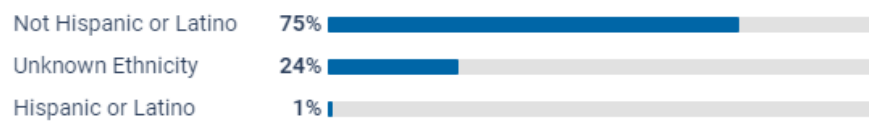
Sex



Race

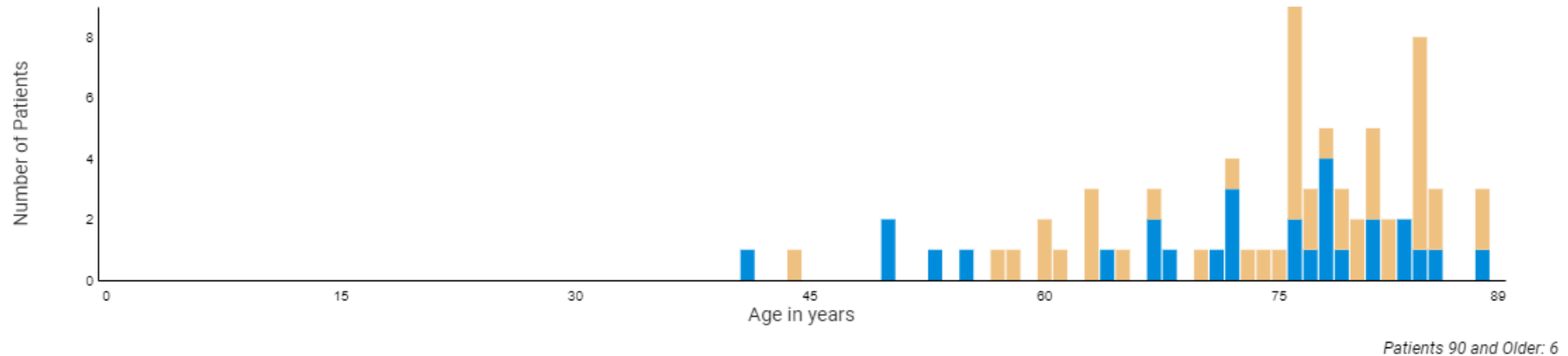


Ethnicity



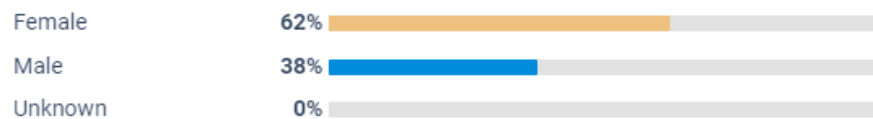
Generated by TriNetX

Figure 49. Demographic Characteristics for Patients with Tepotinib Exposures, from January 1, 2021 through January 19, 2024

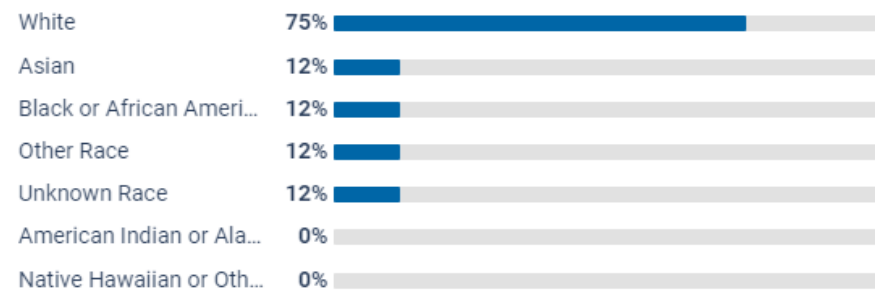


Total Patients	Minimum Age	Maximum Age	Mean Age	Standard Deviation
80	41	90	75	11

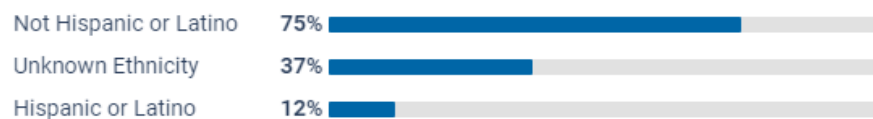
Sex



Race

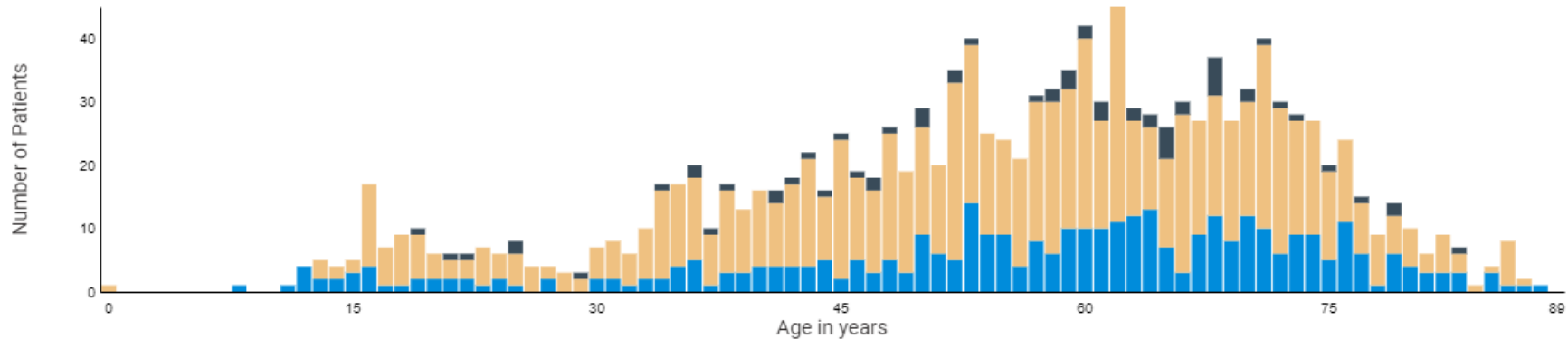


Ethnicity



Generated by TriNetX

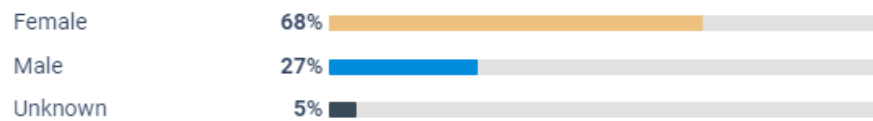
Figure 50. Demographic Characteristics for Patients with Tezepelumab-ekko Exposures, from January 1, 2021 through January 19, 2024



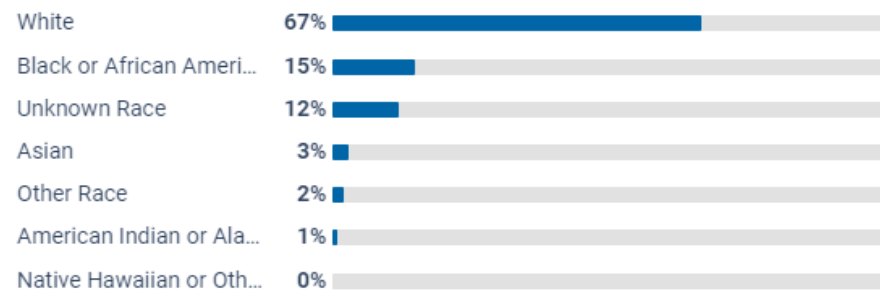
Patients 90 and Older: 3

Total Patients	Minimum Age	Maximum Age	Mean Age	Standard Deviation
1,340	0	90	55	17

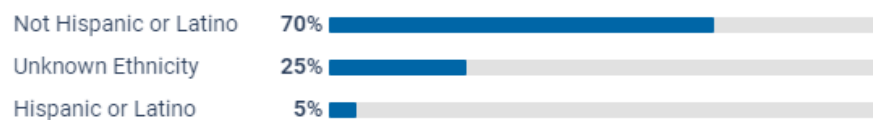
Sex



Race

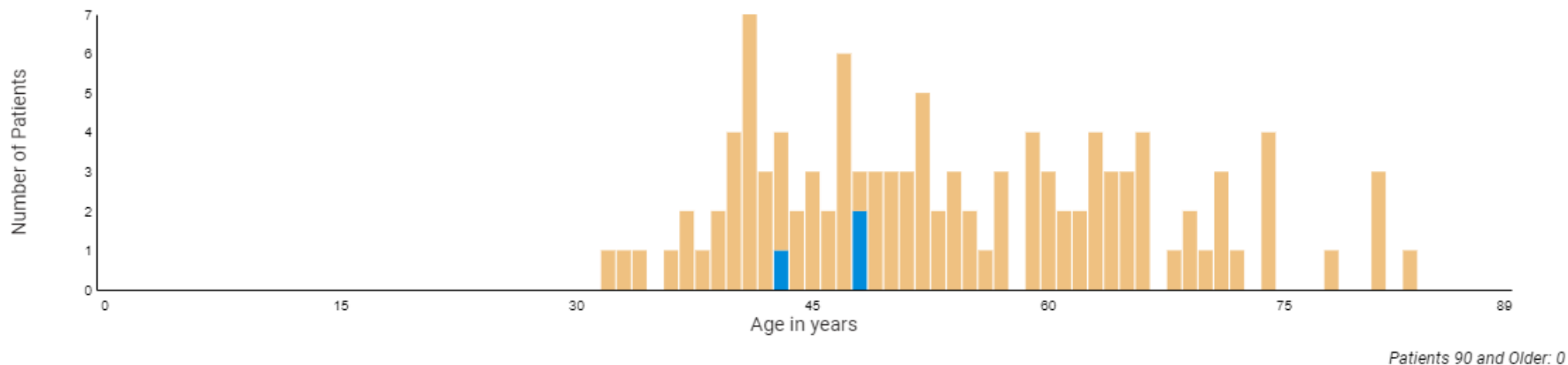


Ethnicity



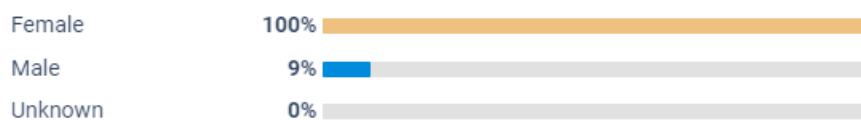
Generated by TriNetX

Figure 51. Demographic Characteristics for Patients with Tisotumab Vedotin-tftv Exposures, from January 1, 2021 through January 19, 2024

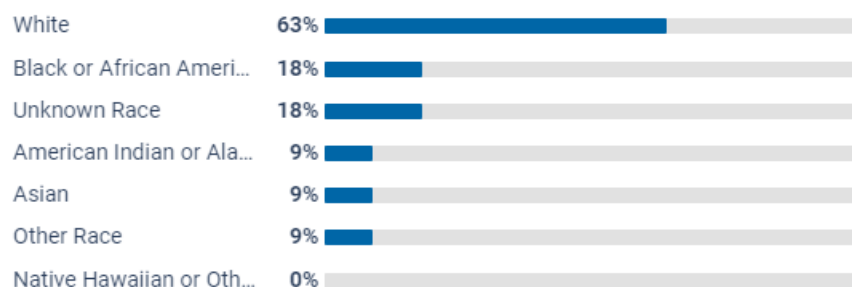


Total Patients	Minimum Age	Maximum Age	Mean Age	Standard Deviation
110	32	83	54	12

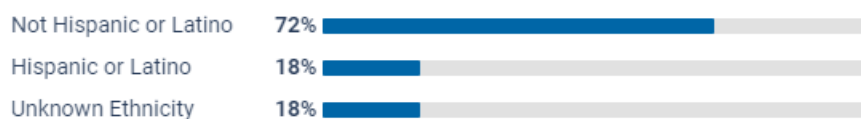
Sex



Race

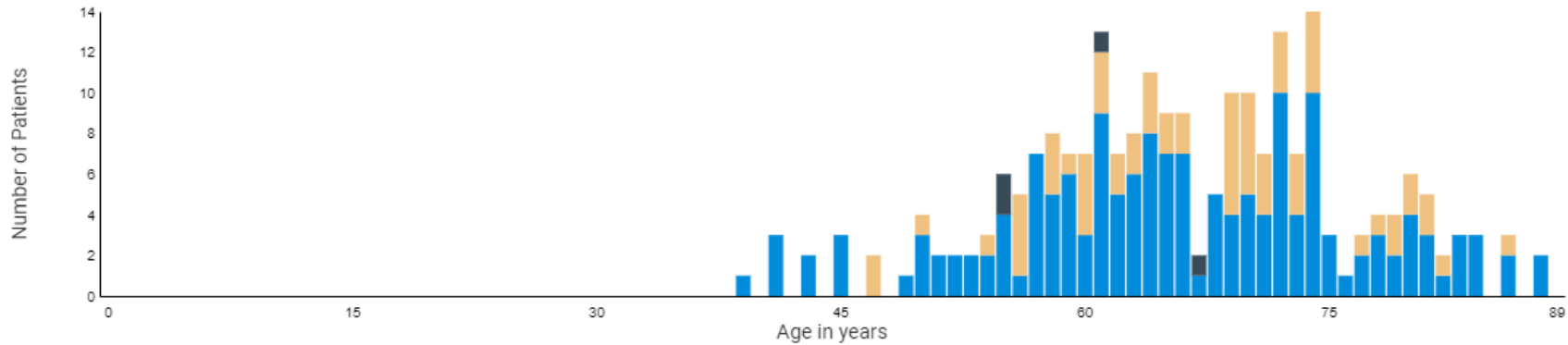


Ethnicity



Generated by TriNetX

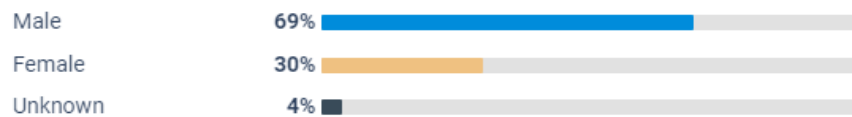
Figure 52. Demographic Characteristics for Patients with Tivozanib Exposures, from January 1, 2021 through January 19, 2024



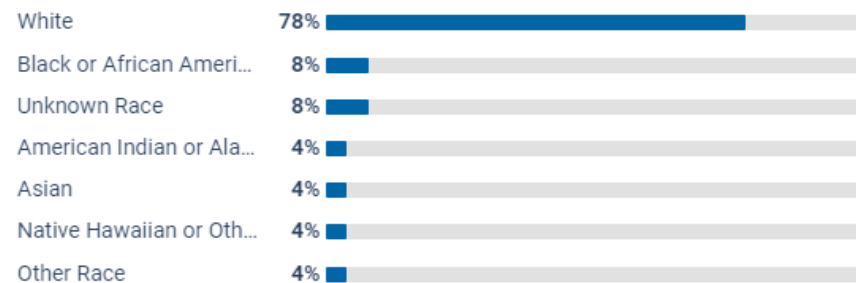
Patients 90 and Older: 1

Total Patients	Minimum Age	Maximum Age	Mean Age	Standard Deviation
230	39	90	66	10

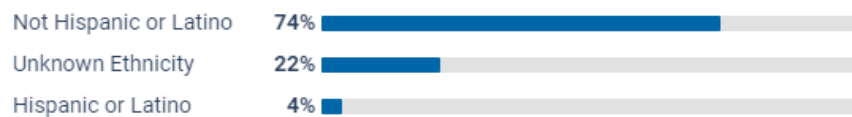
Sex



Race

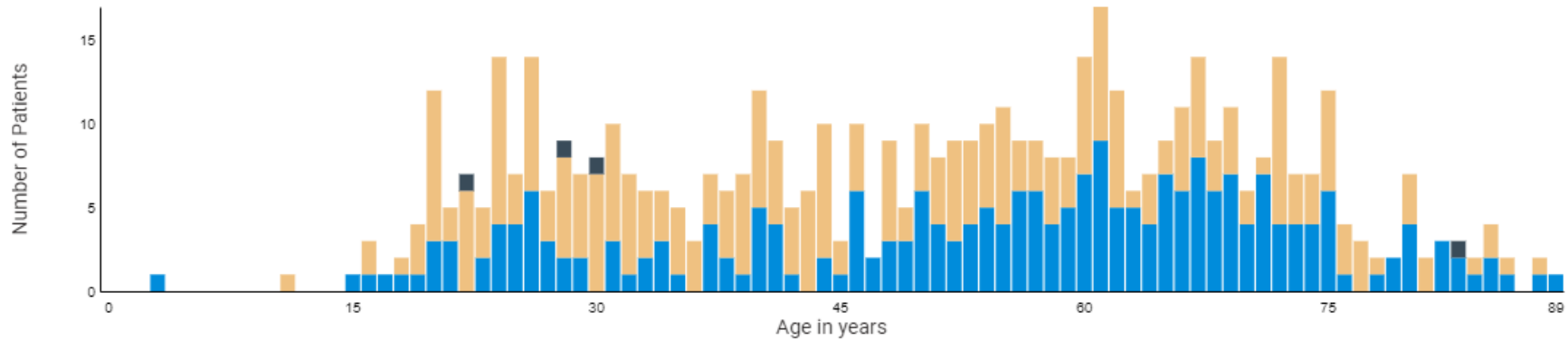


Ethnicity



Generated by TriNetX

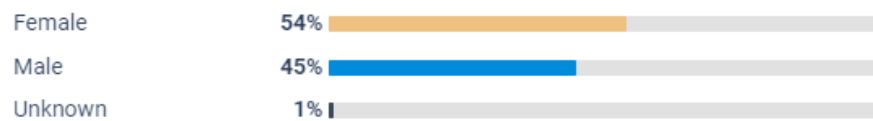
Figure 53. Demographic Characteristics for Patients with Tralokinumab-ldrm Exposures, from January 1, 2021 through January 19, 2024



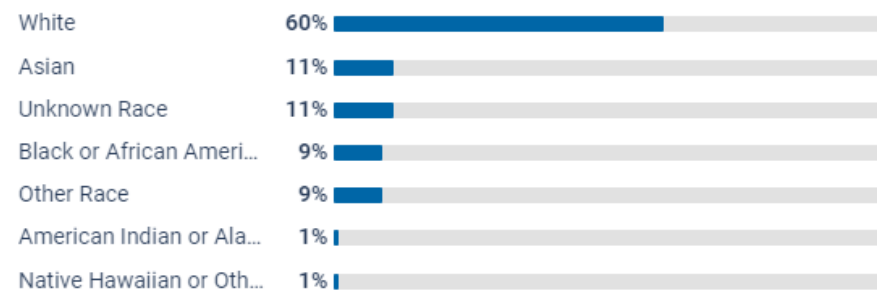
Patients 90 and Older: 3

Total Patients	Minimum Age	Maximum Age	Mean Age	Standard Deviation
530	3	90	51	19

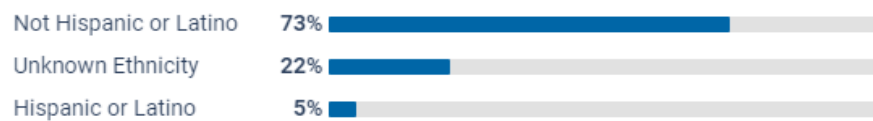
Sex



Race

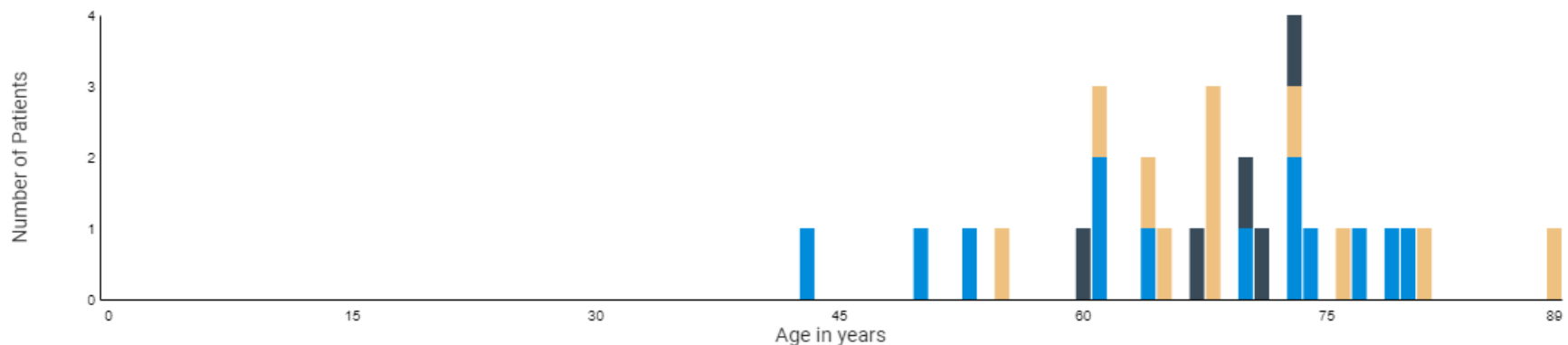


Ethnicity



Generated by TriNetX

Figure 54. Demographic Characteristics for Patients with Trilaciclib Exposures, from January 1, 2021 through January 19, 2024



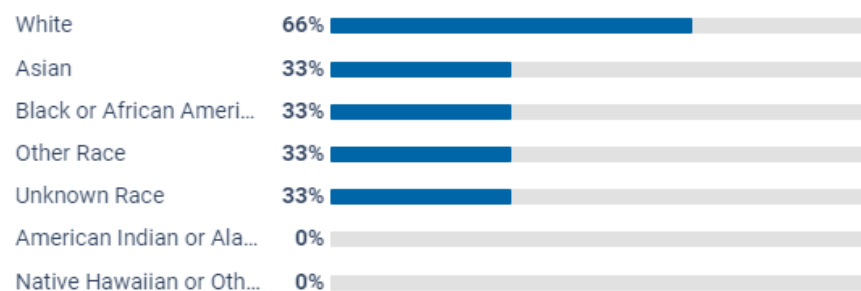
Patients 90 and Older: 1

Total Patients	Minimum Age	Maximum Age	Mean Age	Standard Deviation
30	43	90	69	11

Sex



Race

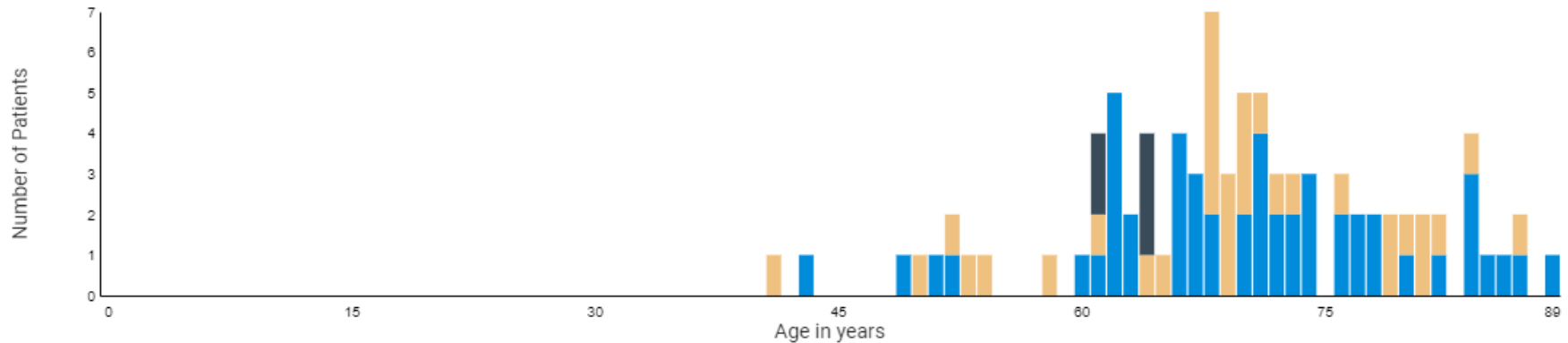


Ethnicity



Generated by TriNetX

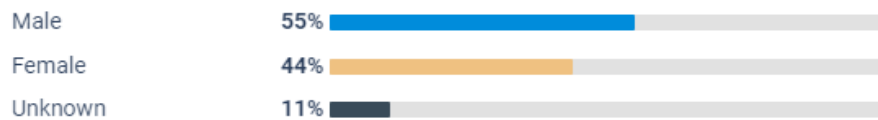
Figure 55. Demographic Characteristics for Patients with Umbralisib Exposures, from January 1, 2021 through January 19, 2024



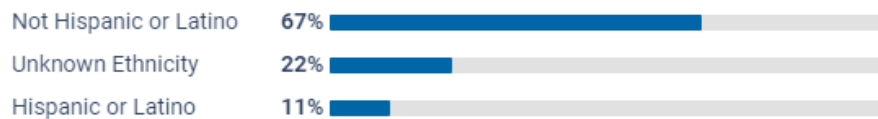
Patients 90 and Older: 3

Total Patients	Minimum Age	Maximum Age	Mean Age	Standard Deviation
90	41	90	70	11

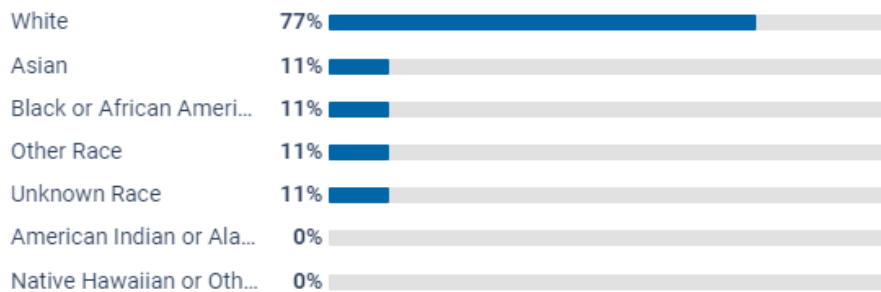
Sex



Ethnicity

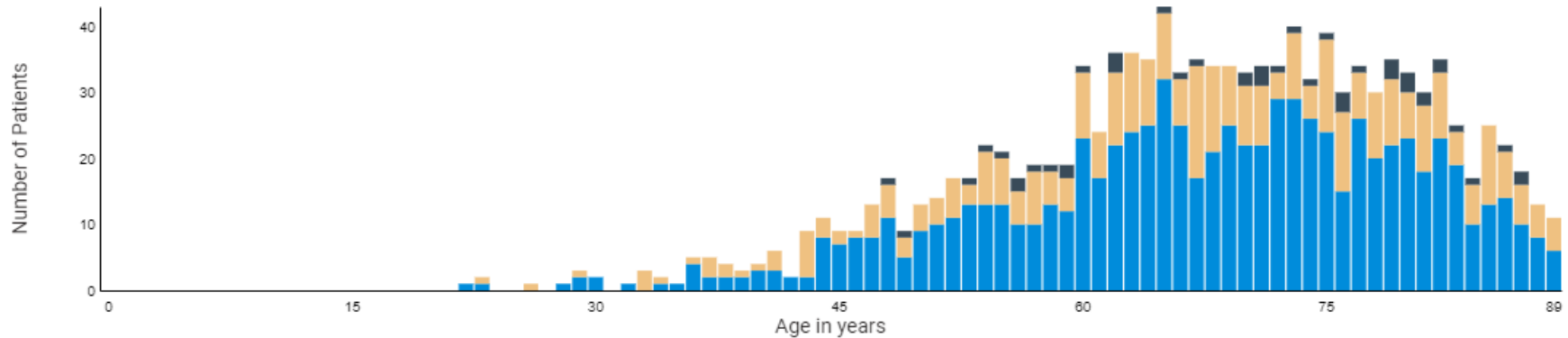


Race



Generated by TriNetX

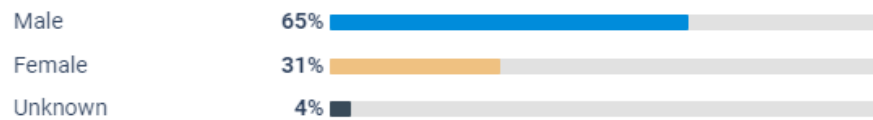
Figure 56. Demographic Characteristics for Patients with Vericiguat Exposures, from January 1, 2021 through January 19, 2024



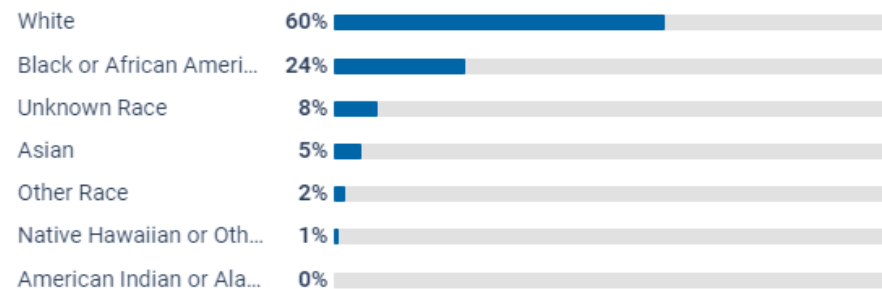
Patients 90 and Older: 45

Total Patients	Minimum Age	Maximum Age	Mean Age	Standard Deviation
1,260	22	90	68	13

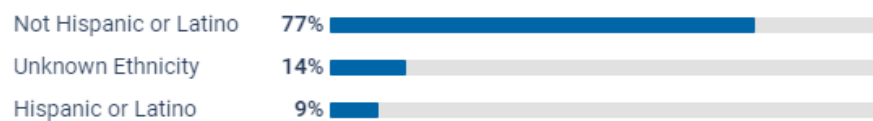
Sex



Race

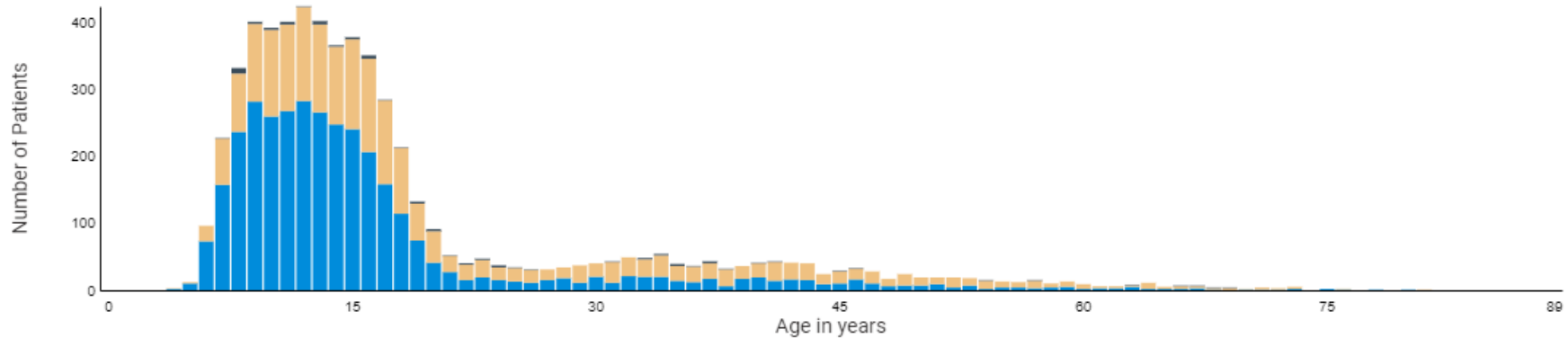


Ethnicity



Generated by TriNetX

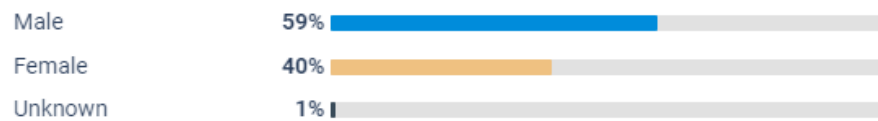
Figure 57. Demographic Characteristics for Patients with Viloxazine Exposures, from January 1, 2021 through January 19, 2024



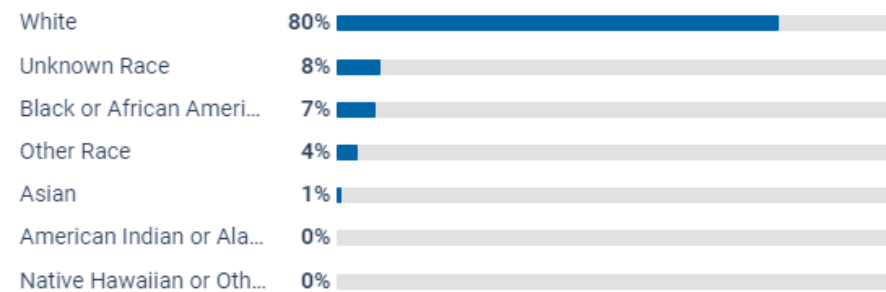
Patients 90 and Older: 0

Total Patients	Minimum Age	Maximum Age	Mean Age	Standard Deviation
5,820	4	81	18	13

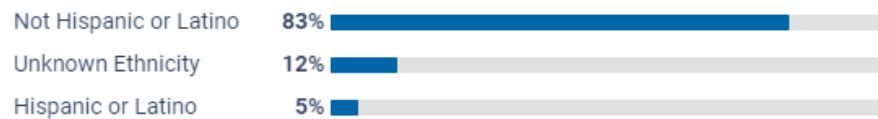
Sex



Race

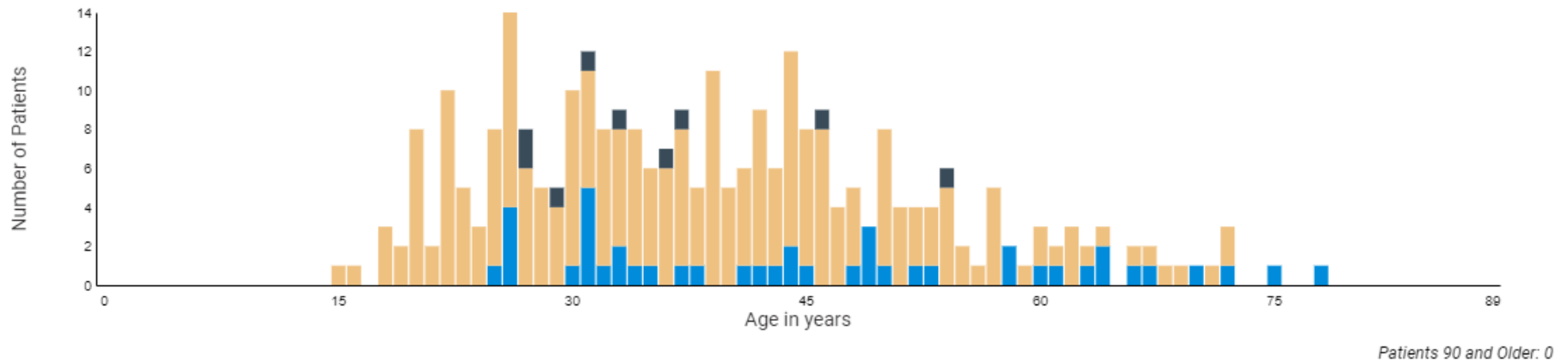


Ethnicity



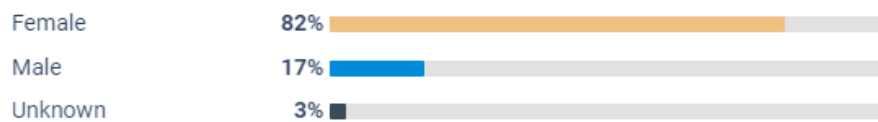
Generated by TriNetX

Figure 58. Demographic Characteristics for Patients with Voclosporin Exposures, from January 1, 2021 through January 19, 2024

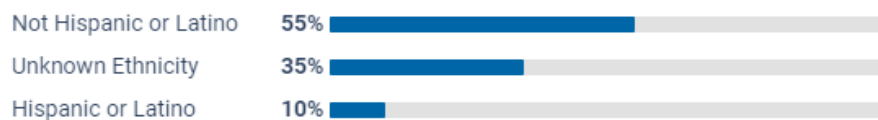


Total Patients	Minimum Age	Maximum Age	Mean Age	Standard Deviation
290	15	78	39	13

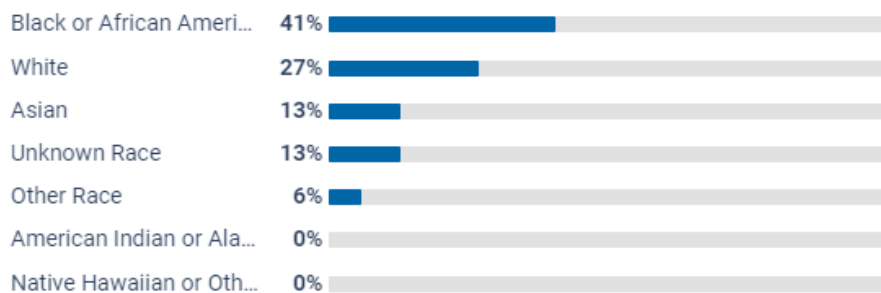
Sex



Ethnicity

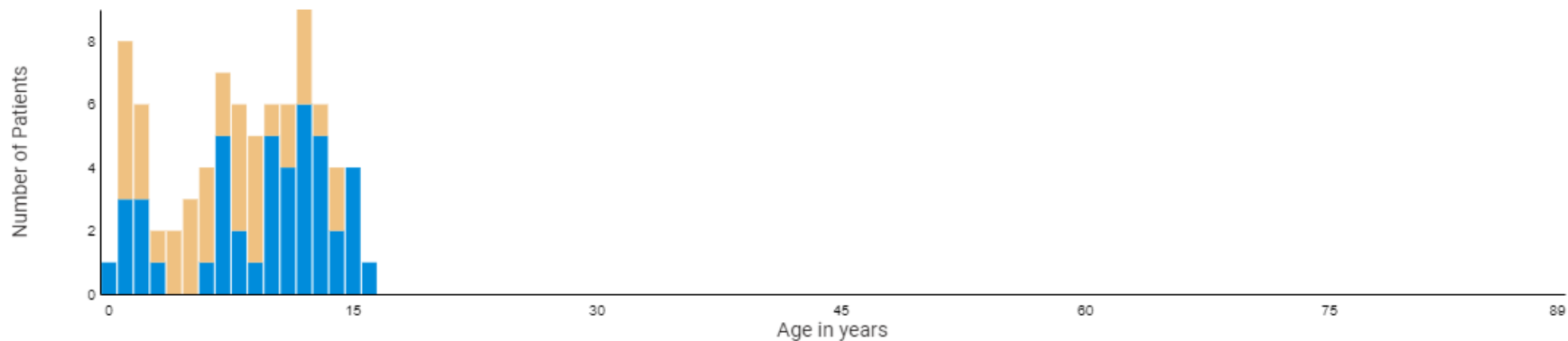


Race



Generated by TriNetX

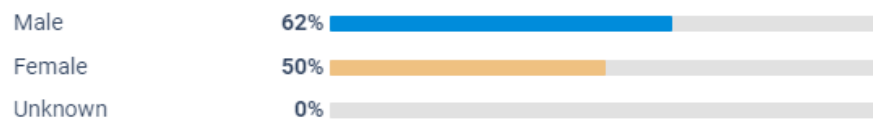
Figure 59. Demographic Characteristics for Patients with Vosoritide Exposures, from January 1, 2021 through January 19, 2024



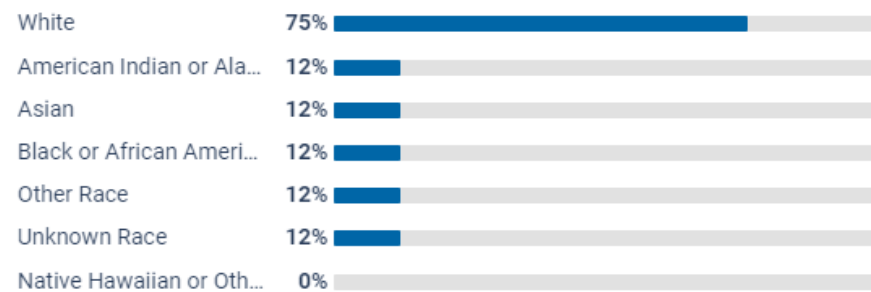
Patients 90 and Older: 0

Total Patients	Minimum Age	Maximum Age	Mean Age	Standard Deviation
80	0	16	8	4

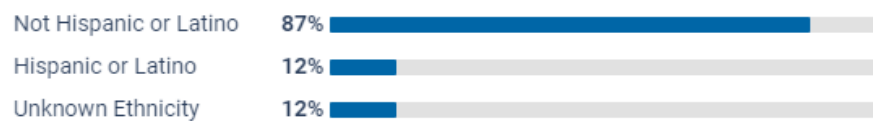
Sex



Race



Ethnicity



Generated by TriNetX

Appendix A. List of RxNorm Medication Terms and Healthcare Common Procedure Coding System (HCPCS) Procedure Codes Used to Define Exposures in this Request

Code	Code Type	Description	Filter
Aducanumab-avwa			
2557217		Aducanumab	
Amivantamab-vmjw			
2549199	RxNorm	Amivantamab	
C9083	HCPCS	Injection, amivantamab-vmjw, 10 mg	
J9061	HCPCS	Injection, amivantamab-vmjw, 2 mg	
Anifrolumab-fnia			
2565265	RxNorm	Anifrolumab	
C9086	HCPCS	Injection, anifrolumab-fnia, 1 mg	
J0491	HCPCS	Injection, anifrolumab-fnia, 1 mg	
Asciminib			
2584304	RxNorm	Asciminib	
Asparaginase erwinia chrysanthemi (recombinant)-rywn			
1156	RxNorm	Asparaginase	Brand: Rylaze
J9021	HCPCS	Injection, asparaginase, recombinant, (Rylaze), 0.1 mg	
Atogepant			
2571813	RxNorm	Atogepant	
Avacopan			
2572100	RxNorm	Avacopan	
Avalglucosidase alfa-ngpt			
2565814	RxNorm	Avalglucosidase alfa	
C9085	HCPCS	Injection, avalglucosidase alfa-ngpt, 4 mg	
J0219	HCPCS	Injection, avalglucosidase alfa-ngpt, 4 mg	
Belumosudil			
2564025	RxNorm	Belumosudil	
Belzutifan			
2567226	RxNorm	Belzutifan	
Cabotegravir (individually)			
2475077	RxNorm	Cabotegravir	Route: Oral, Injectable; Brand: Apretude, Vocabria
J0739	HCPCS	Injection, cabotegravir, 1 mg	
Cabotegravir and rilpivirine (co-packaged)			
2475077	RxNorm	Cabotegravir	Route: Injectable
1102270	RxNorm	Rilpivirine	Route: Injectable
C9077	HCPCS	Injection, cabotegravir and rilpivirine, 2 mg/3 mg	
J0741	HCPCS	Injection, cabotegravir and rilpivirine, 2 mg/3 mg	
Casimersen			
2480096	RxNorm	Casimersen	
C9075	HCPCS	Injection, casimersen, 10 mg	
J1426	HCPCS	Injection, casimersen, 10 mg	
Dasiglucagon			

Appendix A. List of RxNorm Medication Terms and Healthcare Common Procedure Coding System (HCPCS) Procedure Codes Used to Define Exposures in this Request

Code	Code Type	Description	Filter
2535233	RxNorm	Dasiglucagon	
Difelikefalin			
2569089	RxNorm	Difelikefalin	
Dostarlimab-gxly			
2539967	RxNorm	Dostarlimab	
C9082	HCPCS	Injection, dostarlimab-gxly, 100 mg	
J9272	HCPCS	Injection, dostarlimab-gxly, 10 mg	
Drospirenone and estetrol			
11636	RxNorm	Drospirenone	
2539031	RxNorm	Estetrol	
Efgartigimod alfa-fcab			
2587717	RxNorm	Efgartigimod alfa	Brand: Vyvgart
Evinacumab-dgnb			
2478335	RxNorm	Evinacumab	
C9079	HCPCS	Injection, evinacumab-dgnb, 5 mg	
J1305	HCPCS	Injection, evinacumab-dgnb, 5 mg	
Fexinidazole			
2564146	RxNorm	Fexinidazole	
Finerenone			
2562811	RxNorm	Finerenone	
Fosdenopterin			
2531288	RxNorm	Fosdenopterin	
Ibrexafungerp			
2560213	RxNorm	Ibrexafungerp	
Inclisiran			
2588243	RxNorm	Inclisiran	
OMOP5051438	RxNorm	Inclisiran	
Infigratinib			
2550729	RxNorm	Infigratinib	
Loncastuximab tesirine-lpyl			
2540964	RxNorm	Loncastuximab tesirine	
C9084	HCPCS	Injection, loncastuximab tesirine-lpyl, 0.1 mg	
Lonapegsomatropin-tcgd			
2569562	RxNorm	Lonapegsomatropin	
Maralixibat			
2571074	RxNorm	Maralixibat	
Maribavir			
2586068	RxNorm	Maribavir	
Melphalan flufenamide			
2531369	RxNorm	Melphalan flufenamide	
C9080	HCPCS	Injection, melphalan flufenamide HCl, 1 mg	
J9247	HCPCS	Injection, melphalan flufenamide, 1 mg	

Appendix A. List of RxNorm Medication Terms and Healthcare Common Procedure Coding System (HCPCS) Procedure Codes Used to Define Exposures in this Request

Code	Code Type	Description	Filter
Mobocertinib			
2570736	RxNorm	Mobocertinib	
Odevixibat			
2563966	RxNorm	Odevixibat	
Olanzapine and samidorphan			
61381	RxNorm	Olanzapine	Brand: Lybalvi
2559612	RxNorm	Samidorphan	Brand: Lybalvi
Pafolacianine			
2586857	RxNorm	Pafolacianine	
Pegcetacoplan			
2557372	RxNorm	Pegcetacoplan	Brand: Empaveli
Piflufolastat F-18			
2556617	RxNorm	Piflufolastat	
A9595	HCPCS	Piflufolastat F-18, diagnostic, 1 mCi	
Ponesimod			
2532300	RxNorm	Ponesimod	
Ropeginterferon alfa-2b-njft			
2587059	RxNorm	Ropeginterferon alfa-2b	
Serdexmethylphenidate and dexmethylphenidate			
2562176	RxNorm	Serdexmethylphenidate	Brand: Azstarys
352372	RxNorm	Dexmethylphenidate	Brand: Azstarys
Sotorasib			
2550714	RxNorm	Sotorasib	
Tepotinib			
2477103	RxNorm	Tepotinib	
Tezepelumab-ekko			
2587789	RxNorm	Tezepelumab	
J2356	HCPCS	Injection, tezepelumab-ekko, 1 mg	
Tisotumab vedotin-tftv			
2571095	RxNorm	Tisotumab	
OMOP5179229	RxNorm	Tisotumab vedotin	
Tivozanib			
2534233	RxNorm	Tivozanib	

Appendix A. List of RxNorm Medication Terms and Healthcare Common Procedure Coding System (HCPCS) Procedure Codes Used to Define Exposures in this Request

Code	Code Type	Description	Filter
Tralokinumab-ldrm			
2589225	RxNorm	Tralokinumab	
Trilaciclib			
2479690	RxNorm	Trilaciclib	
Umbralisib			
2478439	RxNorm	Umbralisib	
Vericiguat			
2475830	RxNorm	Vericiguat	
Viloxazine			
11196	RxNorm	Viloxazine	
Voclosporin			
2475166	RxNorm	Voclosporin	
Vosoritide			
2586354	RxNorm	Vosoritide	

Appendix B. Specifications Defining Query Builder Modules in this Request

Network:
USA No Shift network

Group 1:	Time Restrictions
Subgroup 1A	
<i>Must Have:</i>	
Aducanumab-avwa	January 1, 2021 - most recently available data
Cohort 2: Amivantamab-vmjw	
Group 1:	Time Restrictions
Subgroup 1A	
<i>Must Have:</i>	
Amivantamab-vmjw	January 1, 2021 - most recently available data
Cohort 3: Anifrolumab-fnia	
Group 1:	Time Restrictions
Subgroup 1A	
<i>Must Have:</i>	
Anifrolumab-fnia	January 1, 2021 - most recently available data
Cohort 4: Asciminib	
Group 1:	Time Restrictions
Subgroup 1A	
<i>Must Have:</i>	
Asciminib	January 1, 2021 - most recently available data
Cohort 5: Asparaginase erwinia chrysanthemi (recombinant)-rywn NO FILTER	
Group 1:	Time Restrictions
Subgroup 1A	
<i>Must Have:</i>	
Asparaginase erwinia chrysanthemi (recombinant)-rywn	January 1, 2021 - most recently available data

Appendix B. Specifications Defining Query Builder Modules in this Request

Cohort 6: Asparaginase erwinia chrysanthemi (recombinant)-rywn BRAND FILTER	
Group 1:	Time Restrictions
Subgroup 1A	
<i>Must Have:</i>	
Asparaginase erwinia chrysanthemi (recombinant)-rywn	January 1, 2021 - most recently available data
[FILTER]: Brand name = Rylaze	
Cohort 7: Atogepant	
Group 1:	Time Restrictions
Subgroup 1A	
<i>Must Have:</i>	
Atogepant	January 1, 2021 - most recently available data
Cohort 8: Avacopan	
Group 1:	Time Restrictions
Subgroup 1A	
<i>Must Have:</i>	
Avacopan	January 1, 2021 - most recently available data
Cohort 9: Avalglucosidase alfa-ngpt	
Group 1:	Time Restrictions
Subgroup 1A	
<i>Must Have:</i>	
Avalglucosidase alfa-ngpt	January 1, 2021 - most recently available data
Cohort 10: Belumosudil	
Group 1:	Time Restrictions
Subgroup 1A	
<i>Must Have:</i>	
Belumosudil	January 1, 2021 - most recently available data
Cohort 11: Belzutifan	
Group 1:	Time Restrictions
Subgroup 1A	
<i>Must Have:</i>	
Belzutifan	January 1, 2021 - most recently available data

Appendix B. Specifications Defining Query Builder Modules in this Request

Cohort 12: Cabotegravir OVERALL	
Group 1:	Time Restrictions
Subgroup 1A	
<i>Must Have:</i>	
Cabotegravir	January 1, 2021 - most recently available data
Subgroup 1B:	
<i>Cannot Have:</i>	
Rilpivirine	On the same day as subgroup 1A (cabotegravir)
Cohort 13: Cabotegravir ORAL	
Group 1:	Time Restrictions
Subgroup 1A	
<i>Must Have:</i>	
Cabotegravir	January 1, 2021 - most recently available data
<i>[FILTER]: Route = Oral</i>	
Cohort 14: Cabotegravir INJECTABLE	
Group 1:	Time Restrictions
Subgroup 1A	
<i>Must Have:</i>	
Cabotegravir	January 1, 2021 - most recently available data
<i>[FILTER]: Route = Injectable</i>	
Subgroup 1B:	
<i>Cannot Have:</i>	
Rilpivirine	On the same day as subgroup 1A (cabotegravir)
Cohort 15: Cabotegravir BRAND	
Group 1:	Time Restrictions
Subgroup 1A	
<i>Must Have:</i>	
Cabotegravir	January 1, 2021 - most recently available data
<i>[FILTER]: Brand = Apretude or Vocabria</i>	

Appendix B. Specifications Defining Query Builder Modules in this Request

Cohort 16: Cabotegravir and Rilpivirine INJECTABLE	
Group 1:	Time Restrictions
Subgroup 1A	
<i>Must Have:</i>	
Cabotegravir RxNorm	January 1, 2021 - most recently available data
[FILTER]: Route = Injectable	
Subgroup 1B:	
<i>Must Have:</i>	
Rilpivirine RxNorm	On the same day as subgroup 1A (cabotegravir)
[FILTER]: Route = Injectable	
OR	
Group 2:	Time Restrictions
Subgroup 2A	
<i>Must Have:</i>	
Cabotegravir and Rilpivirine HCPCS	January 1, 2021 - most recently available data
Cohort 17: Casimersen	
Group 1:	Time Restrictions
Subgroup 1A	
<i>Must Have:</i>	
Casimersen	January 1, 2021 - most recently available data
Cohort 18: Dasiglucagon	
Group 1:	Time Restrictions
Subgroup 1A	
<i>Must Have:</i>	
Dasiglucagon	January 1, 2021 - most recently available data
Cohort 19: Difelikefalin	
Group 1:	Time Restrictions
Subgroup 1A	
<i>Must Have:</i>	
Difelikefalin	January 1, 2021 - most recently available data

Appendix B. Specifications Defining Query Builder Modules in this Request

Cohort 20: Dostarlimab-gxly	
Group 1:	Time Restrictions
Subgroup 1A	
<i>Must Have:</i>	
Dostarlimab-gxly	January 1, 2021 - most recently available data
Cohort 21: Drospirenone and estetrol	
Group 1:	Time Restrictions
Subgroup 1A	
<i>Must Have:</i>	
Drospirenone	January 1, 2021 - most recently available data
Subgroup 1B:	
<i>Must Have:</i>	
Estetrol	On the same day as subgroup 1A (drospirenone)
Cohort 22: Efgartigimod alfa-fcab OVERALL	
Group 1:	Time Restrictions
Subgroup 1A	
<i>Must Have:</i>	
Efgartigimod alfa-fcab	January 1, 2021 - most recently available data
Cohort 23: Efgartigimod alfa-fcab BRAND	
Group 1:	Time Restrictions
Subgroup 1A	
<i>Must Have:</i>	
Efgartigimod alfa-fcab	January 1, 2021 - most recently available data
[FILTER]: Brand name = Vyvgart	
Cohort 24: Evinacumab-dgnb	
Group 1:	Time Restrictions
Subgroup 1A	
<i>Must Have:</i>	
Evinacumab-dgnb	January 1, 2021 - most recently available data
Cohort 25: Fexinidazole	
Group 1:	Time Restrictions
Subgroup 1A	
<i>Must Have:</i>	

Appendix B. Specifications Defining Query Builder Modules in this Request

Fexinidazole	January 1, 2021 - most recently available data
Cohort 26: Finerenone	
Group 1:	Time Restrictions
Subgroup 1A	
<i>Must Have:</i>	
Finerenone	January 1, 2021 - most recently available data
Cohort 27: Fosdenopterin	
Group 1:	Time Restrictions
Subgroup 1A	
<i>Must Have:</i>	
Fosdenopterin	January 1, 2021 - most recently available data
Cohort 28: Ibrexafungerp	
Group 1:	Time Restrictions
Subgroup 1A	
<i>Must Have:</i>	
Ibrexafungerp	January 1, 2021 - most recently available data
Cohort 29: Inclisiran	
Group 1:	Time Restrictions
Subgroup 1A	
<i>Must Have:</i>	
Inclisiran	January 1, 2021 - most recently available data
Cohort 30: Infigratinib	
Group 1:	Time Restrictions
Subgroup 1A	
<i>Must Have:</i>	
Infigratinib	January 1, 2021 - most recently available data
Cohort 31: Loncastuximab tesirine-lpyl	
Group 1:	Time Restrictions
Subgroup 1A	
<i>Must Have:</i>	
Loncastuximab tesirine-lpyl	January 1, 2021 - most recently available data

Appendix B. Specifications Defining Query Builder Modules in this Request

Cohort 32: Lonapegsomatropin-tcgd	
Group 1:	Time Restrictions
Subgroup 1A	
<i>Must Have:</i>	
Lonapegsomatropin-tcgd	January 1, 2021 - most recently available data
Cohort 33: Maralixibat	
Group 1:	Time Restrictions
Subgroup 1A	
<i>Must Have:</i>	
Maralixibat	January 1, 2021 - most recently available data
Cohort 34: Maribavir	
Group 1:	Time Restrictions
Subgroup 1A	
<i>Must Have:</i>	
Maribavir	January 1, 2021 - most recently available data
Cohort 35: Melphalan flufenamide	
Group 1:	Time Restrictions
Subgroup 1A	
<i>Must Have:</i>	
Melphalan flufenamide	January 1, 2021 - most recently available data
Cohort 36: Mobocertinib	
Group 1:	Time Restrictions
Subgroup 1A	
<i>Must Have:</i>	
Mobocertinib	January 1, 2021 - most recently available data
Cohort 37: Odevixibat	
Group 1:	Time Restrictions
Subgroup 1A	
<i>Must Have:</i>	
Odevixibat	January 1, 2021 - most recently available data

Appendix B. Specifications Defining Query Builder Modules in this Request

Cohort 38: Olanzapine and samidorphan OVERALL	
Group 1:	Time Restrictions
Subgroup 1A	
<i>Must Have:</i>	
Olanzapine	January 1, 2021 - most recently available data
Subgroup 1B:	
<i>Must Have:</i>	
Samidorphan	On the same day as subgroup 1A (olanzapine)
Cohort 39: Olanzapine and samidorphan BRAND	
Group 1:	Time Restrictions
Subgroup 1A	
<i>Must Have:</i>	
Olanzapine	January 1, 2021 - most recently available data
[FILTER]: Brand = Lybalvi	
Subgroup 1B:	
<i>Must Have:</i>	
Samidorphan	On the same day as subgroup 1A (olanzapine)
[FILTER]: Brand = Lybalvi	
Cohort 40: Pafolacianine	
Group 1:	Time Restrictions
Subgroup 1A	
<i>Must Have:</i>	
Pafolacianine	January 1, 2021 - most recently available data
Cohort 41: Pegcetacoplan OVERALL	
Group 1:	Time Restrictions
Subgroup 1A	
<i>Must Have:</i>	
Pegcetacoplan	January 1, 2021 - most recently available data
Cohort 42: Pegcetacoplan BRAND	
Group 1:	Time Restrictions
Subgroup 1A	
<i>Must Have:</i>	
Pegcetacoplan	January 1, 2021 - most recently available data
[FILTER]: Brand = Empaveli	

Appendix B. Specifications Defining Query Builder Modules in this Request

Cohort 43: Piflufolastat F-18	
Group 1:	Time Restrictions
Subgroup 1A	
<i>Must Have:</i>	
Piflufolastat F-18	January 1, 2021 - most recently available data
Cohort 44: Ponesimod	
Group 1:	Time Restrictions
Subgroup 1A	
<i>Must Have:</i>	
Ponesimod	January 1, 2021 - most recently available data
Cohort 45: Ropeginterferon alfa-2b-njft	
Group 1:	Time Restrictions
Subgroup 1A	
<i>Must Have:</i>	
Ropeginterferon alfa-2b-njft	January 1, 2021 - most recently available data
Cohort 46: Serdexmethylphenidate and dexamethylphenidate OVERALL	
Group 1:	Time Restrictions
Subgroup 1A	
<i>Must Have:</i>	
Serdexmethylphenidate	January 1, 2021 - most recently available data
Subgroup 1B:	
<i>Must Have:</i>	
Dexamethylphenidate	On the same day as subgroup 1A (serdexmethylphenidate)
Cohort 47: Serdexmethylphenidate and dexamethylphenidate BRAND	
Group 1:	Time Restrictions
Subgroup 1A	
<i>Must Have:</i>	
Serdexmethylphenidate	January 1, 2021 - most recently available data
[FILTER]: Brand = Azstarys	
Subgroup 1B:	
<i>Must Have:</i>	
Dexamethylphenidate	On the same day as subgroup 1A (serdexmethylphenidate)
[FILTER]: Brand = Azstarys	

Appendix B. Specifications Defining Query Builder Modules in this Request

Cohort 48: Sotorasib	
Group 1:	Time Restrictions
Subgroup 1A	
<i>Must Have:</i>	
Sotorasib	January 1, 2021 - most recently available data
Cohort 49: Tepotinib	
Group 1:	Time Restrictions
Subgroup 1A	
<i>Must Have:</i>	
Tepotinib	January 1, 2021 - most recently available data
Cohort 50: Tezepelumab-ekko	
Group 1:	Time Restrictions
Subgroup 1A	
<i>Must Have:</i>	
Tezepelumab-ekko	January 1, 2021 - most recently available data
Cohort 51: Tisotumab vedotin-tftv	
Group 1:	Time Restrictions
Subgroup 1A	
<i>Must Have:</i>	
Tisotumab vedotin-tftv	January 1, 2021 - most recently available data
Cohort 52: Tivozanib	
Group 1:	Time Restrictions
Subgroup 1A	
<i>Must Have:</i>	
Tivozanib	January 1, 2021 - most recently available data
Cohort 53: Tralokinumab-ldrm	
Group 1:	Time Restrictions
Subgroup 1A	
<i>Must Have:</i>	
Tralokinumab-ldrm	January 1, 2021 - most recently available data

Appendix B. Specifications Defining Query Builder Modules in this Request

Cohort 54: Trilaciclib	
Group 1:	Time Restrictions
Subgroup 1A	
<i>Must Have:</i>	
Trilaciclib	January 1, 2021 - most recently available data
Cohort 55: Umbralisib	
Group 1:	Time Restrictions
Subgroup 1A	
<i>Must Have:</i>	
Umbralisib	January 1, 2021 - most recently available data
Cohort 56: Vericiguat	
Group 1:	Time Restrictions
Subgroup 1A	
<i>Must Have:</i>	
Vericiguat	January 1, 2021 - most recently available data
Cohort 57: Viloxazine	
Group 1:	Time Restrictions
Subgroup 1A	
<i>Must Have:</i>	
Viloxazine	January 1, 2021 - most recently available data
Cohort 58: Voclosporin	
Group 1:	Time Restrictions
Subgroup 1A	
<i>Must Have:</i>	
Voclosporin	January 1, 2021 - most recently available data
Cohort 59: Vosoritide	
Group 1:	Time Restrictions
Subgroup 1A	
<i>Must Have:</i>	
Vosoritide	January 1, 2021 - most recently available data