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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 ID: 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.

<u>Data Source:</u> We ran this query on January 19, 2024. This query contains data from 50 health care organizations (HCOs), provided through the TriNetX Live™ platform in their USA Network with Minimal Shift from December 18, 2020 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 clinical patient data such as demographics, diagnoses, procedures, labs, and medications. The USA Network with Minimal Shift contains HCOs that date shift their data by 14 or fewer days (including 0). For more information on the TriNetX Live™ platform and the TriNetX data visit their website here: https://trinetx.com/.

<u>Study Design:</u> 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 December 18, 2020 and January 19, 2024.

<u>Sensitivity Analyses:</u> 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.

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Overview for Request: cder_iqp_wp034

<u>Cohort Eligibility Criteria:</u> 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.

<u>Limitations</u>: 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@sentinelsystem.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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Appendix B	Specifications Defining Query Builder Modules in this Request

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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 (eg, -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.

Fact - (Medical Fact) A unit of utilization that represents a medical observation on a patient (e.g., diagnosis, procedure, clinical observation).

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.

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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

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Figure 1. Demographic Characteristics for Patients with Aducanumab-avwa Exposures, from December 18, 2020 through January 19, 2024

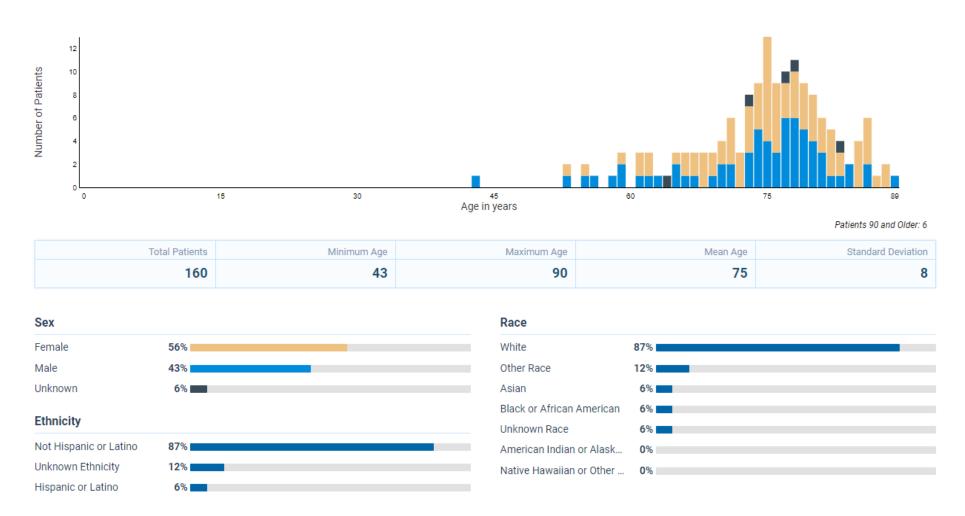




Figure 2. Demographic Characteristics for Patients with Amivantamab-vmjw Exposures, from December 18, 2020 through January 19, 2024

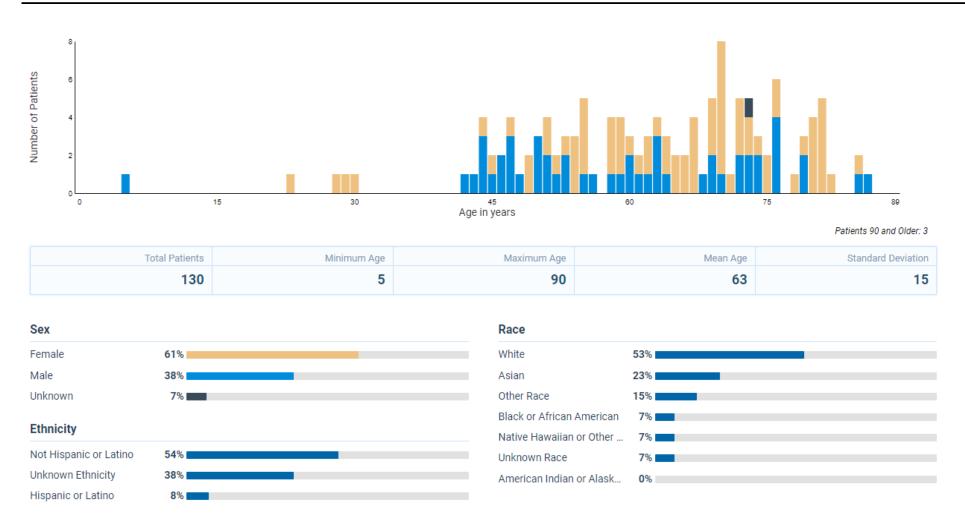
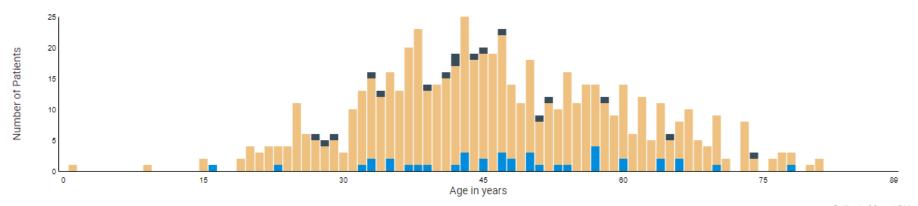


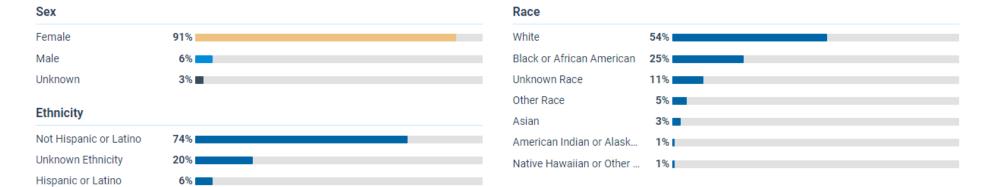


Figure 3. Demographic Characteristics for Patients with Anifrolumab-fnia Exposures, from December 18, 2020 through January 19, 2024



Patients 90 and Older: 0

Total Patients	Minimum Age	Maximum Age	Mean Age	Standard Deviation
620	1	81	46	13



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Figure 4. Demographic Characteristics for Patients with Asciminib Exposures, from December 18, 2020 through January 19, 2024

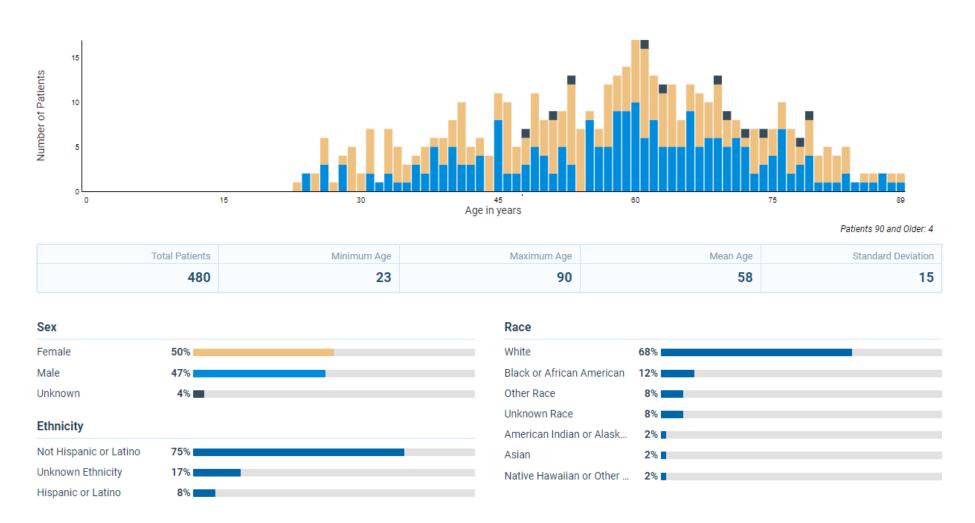
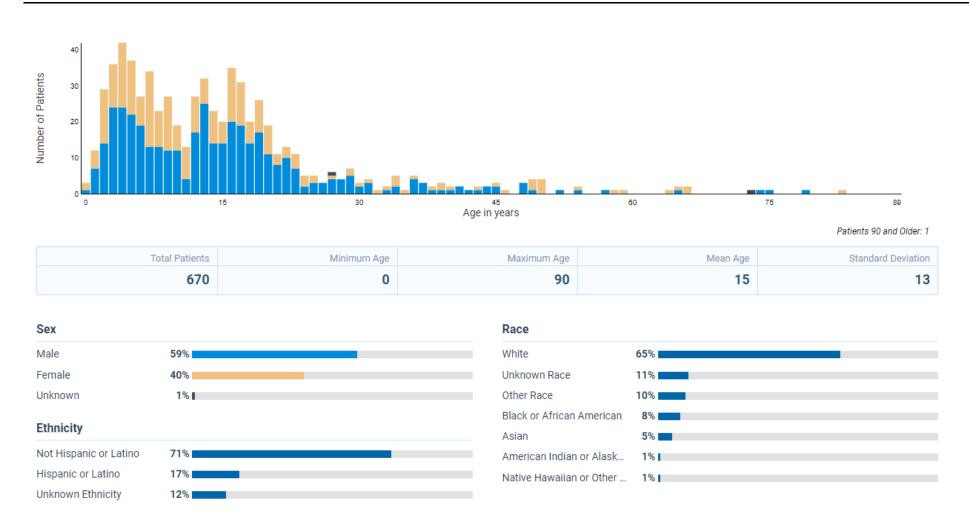




Figure 5. Demographic Characteristics for All Patients* with Asparaginase Erwinia Chrysanthemi (Recombinant)-rywn Exposures, from December 18, 2020 through January 19, 2024



*No filters used



Figure 6. Demographic Characteristics for Patients with Asparaginase Erwinia Chrysanthemi (Recombinant)-rywn Exposures, Restricted to Brand Name Rylaze, from December 18, 2020 through January 19, 2024

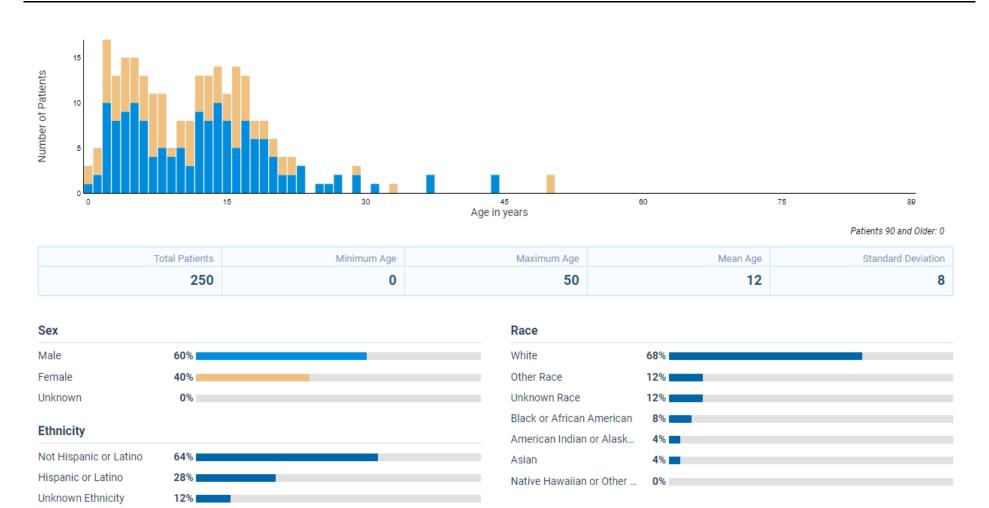




Figure 7. Demographic Characteristics for Patients with Atogepant Exposures, from December 18, 2020 through January 19, 2024

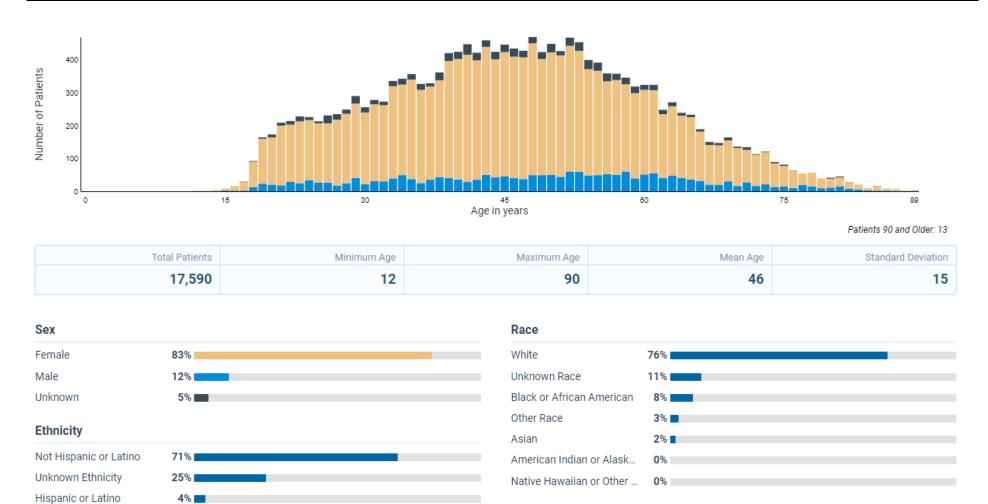




Figure 8. Demographic Characteristics for Patients with Avacopan Exposures, from December 18, 2020 through January 19, 2024

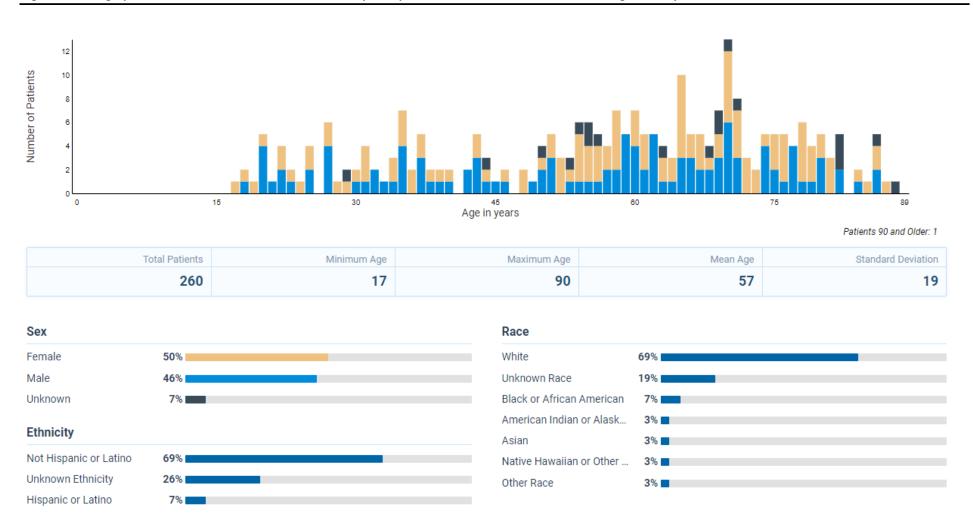




Figure 9. Demographic Characteristics for Patients with Avalglucosidase alfa-ngpt Exposures, from December 18, 2020 through January 19, 2024

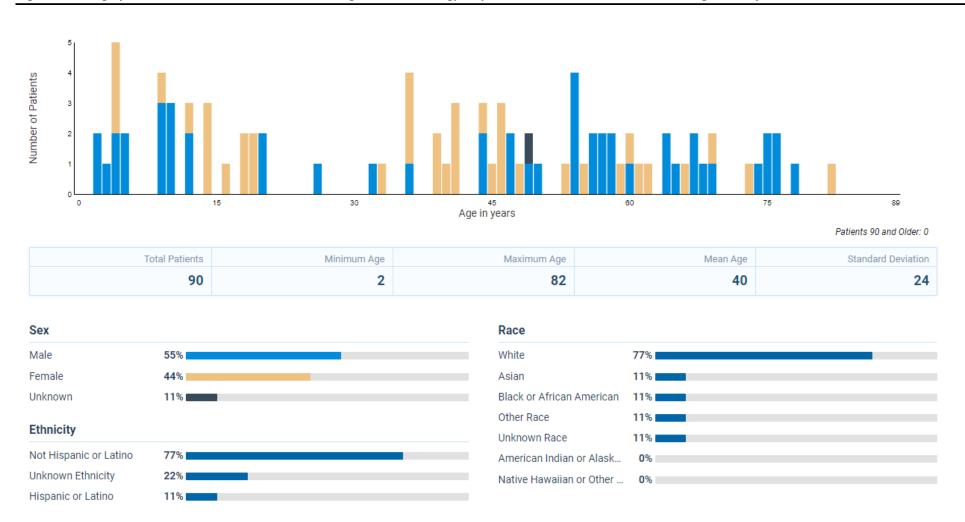




Figure 10. Demographic Characteristics for Patients with Belumosudil Exposures, from December 18, 2020 through January 19, 2024

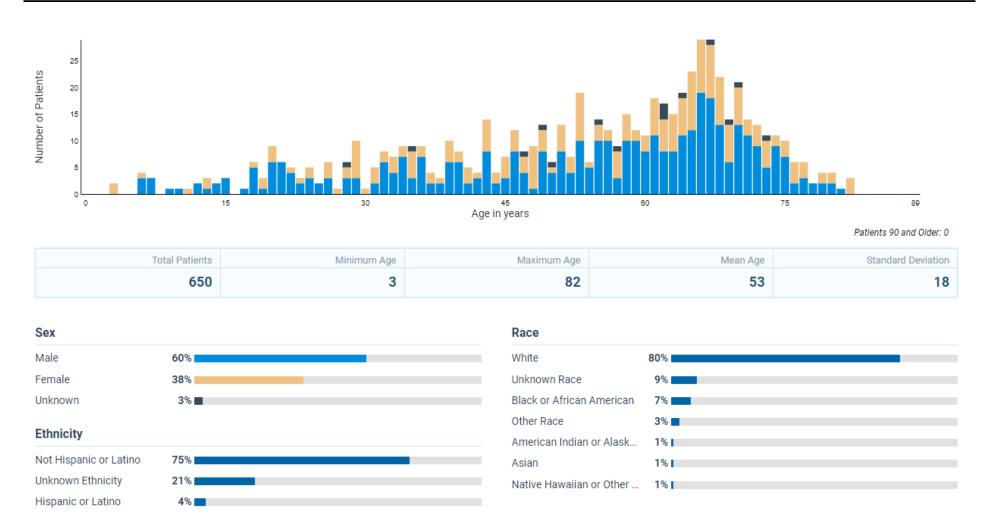




Figure 11. Demographic Characteristics for Patients with Belzutifan Exposures, from December 18, 2020 through January 19, 2024

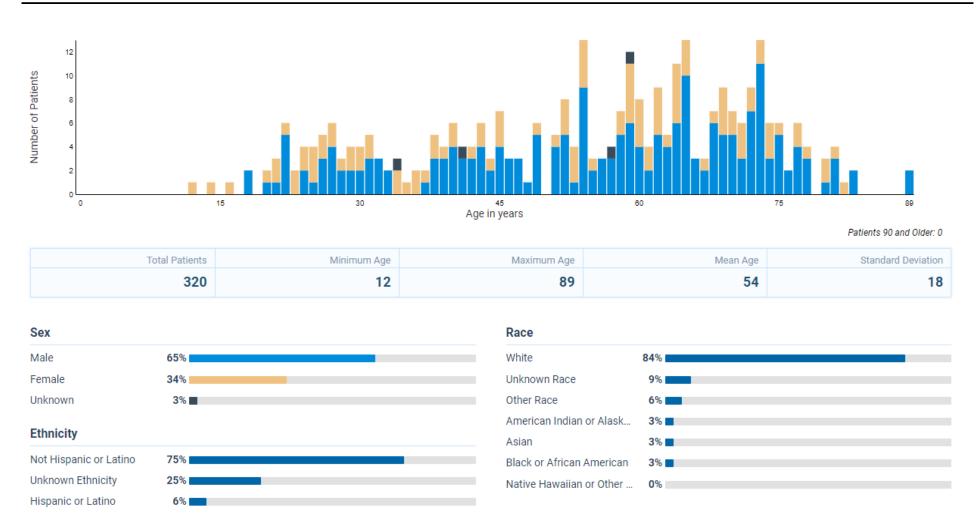
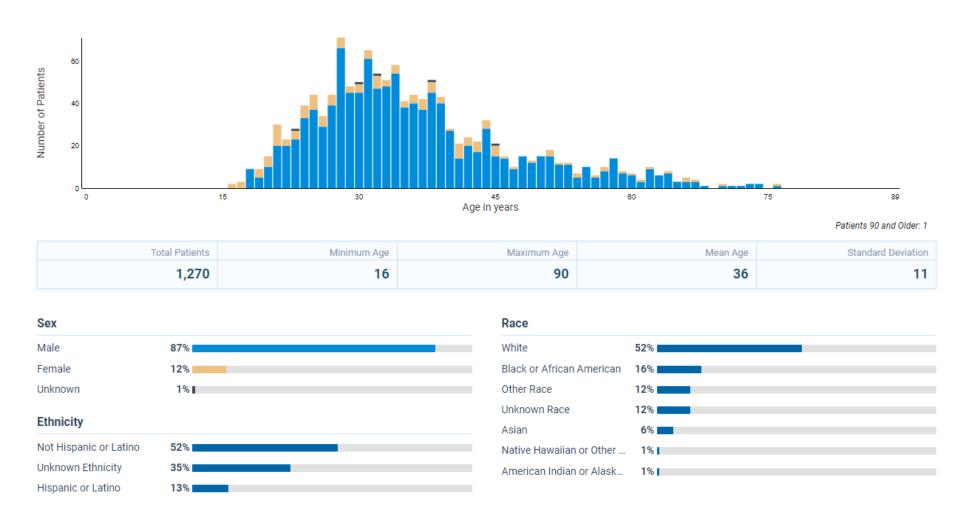




Figure 12. Demographic Characteristics for All* Patients with Cabotegravir Exposures, from December 18, 2020 through January 19, 2024



^{*}All Patients with Cabetogravir Exposures Cannot Have Same Day Rilpirivine Exposure

The exception added to avoid inclusion of cabetogravir-rilpirivine co-packaged medication



Figure 13. Demographic Characteristics for Patients with Cabotegravir Exposures, Restricted to Oral Exposures, from December 18, 2020 through January 19, 2024

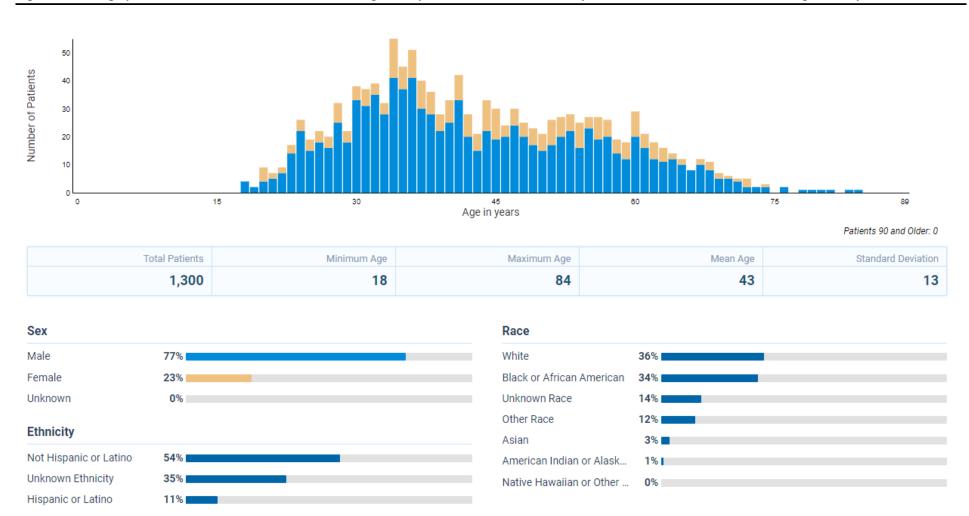
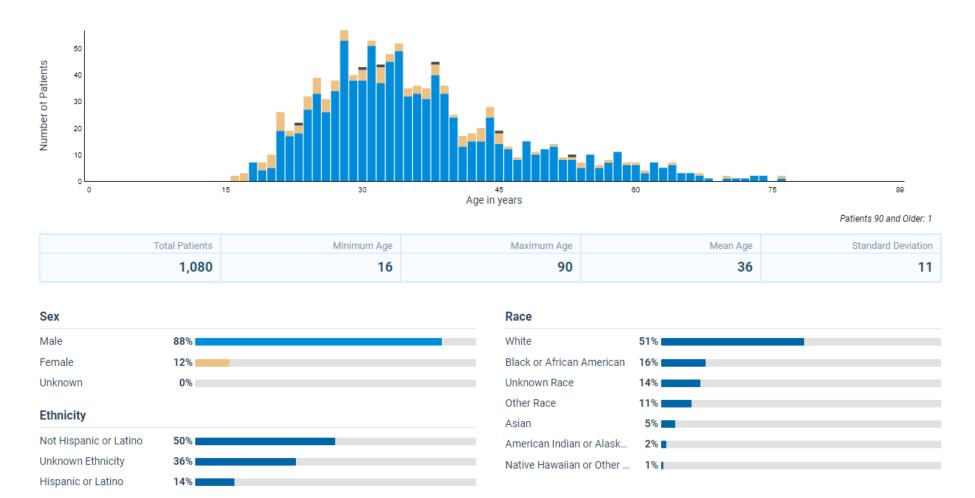




Figure 14. Demographic Characteristics for Patients with Cabotegravir Exposures*, Restricted to Injectable Exposures, from December 18, 2020 through January 19, 2024



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^{*}All Patients with Injectable Cabetogravir Exposures Cannot Have Same Day Rilpirivine Exposure
The exception added to avoid inclusion of cabetogravir-rilpirivine co-packaged medication



Figure 15. Demographic Characteristics for Patients with Cabotegravir Exposures, Restricted to Brand Names Apretude or Vocabria, from December 18, 2020 through January 19, 2024

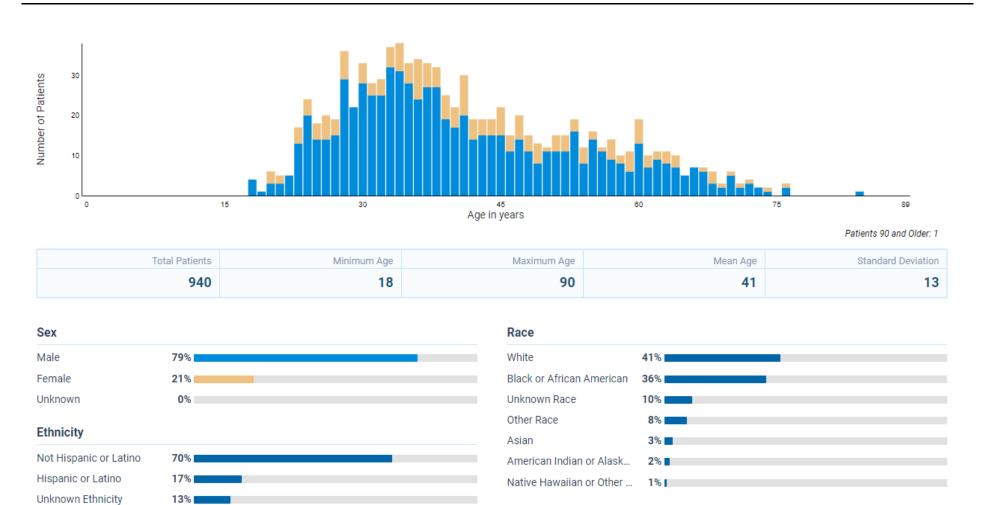




Figure 16. Demographic Characteristics for All Patients with Injectable Cabotegravir and Rilpivirine Exposures*, from December 18, 2020 through January 19, 2024



 $[\]hbox{* The injectable cabetogravir and rilpirivine exposures occur on the same day}.$

Assumption is that the same day exposure refers to co-packaged cabetogravir and rilpirivine (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.

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Figure 17. Demographic Characteristics for Patients with Casimersen Exposures, from December 18, 2020 through January 19, 2024

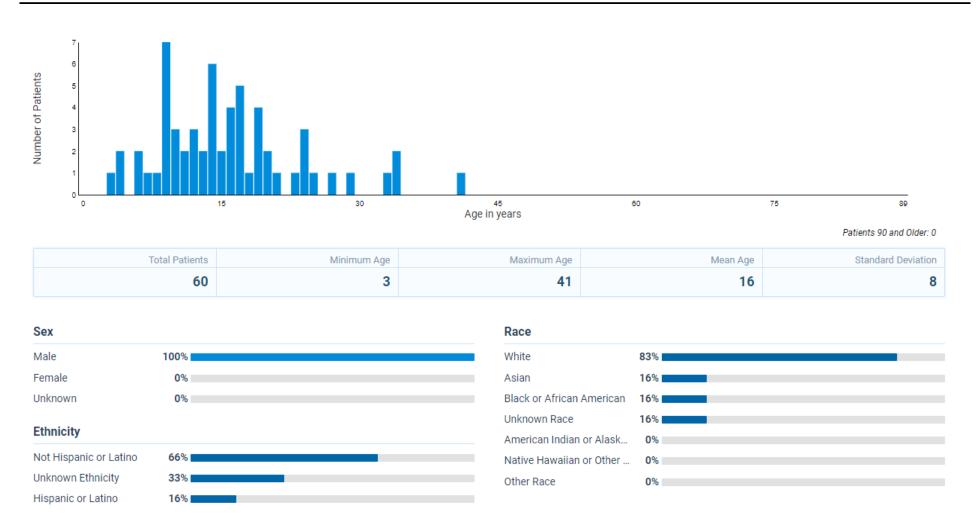
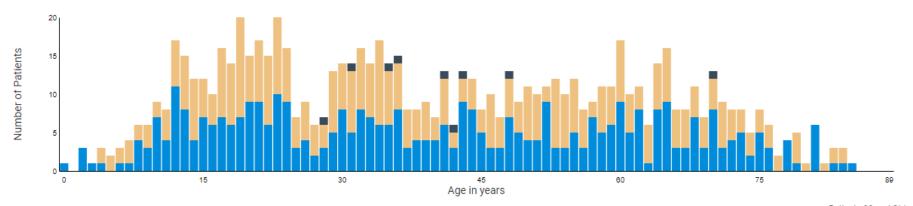




Figure 18. Demographic Characteristics for Patients with Dasiglucagon Exposures, from December 18, 2020 through January 19, 2024



Patients 90 and Older: 0

Total Patients	Minimum Age	Maximum Age	Mean Age	Standard Deviation
810	0	85	40	21

Sex		Race
Male	50%	White
Female	49%	Black or A
Unknown	1% ▮	Other Rac
Ethnicity		Unknown American
Not Hispanic or Latino	85%	Asian
Unknown Ethnicity	11%	Native Ha
Hispanic or Latino	4%	

Race	
White	81%
Black or African American	7%
Other Race	6%
Unknown Race	6%
American Indian or Alask	1%
Asian	1%
Native Hawaiian or Other	1%



Figure 19. Demographic Characteristics for Patients with Difelikefalin Exposures, from December 18, 2020 through January 19, 2024





Figure 20. Demographic Characteristics for Patients with Dostarlimab-gxly Exposures, from December 18, 2020 through January 19, 2024

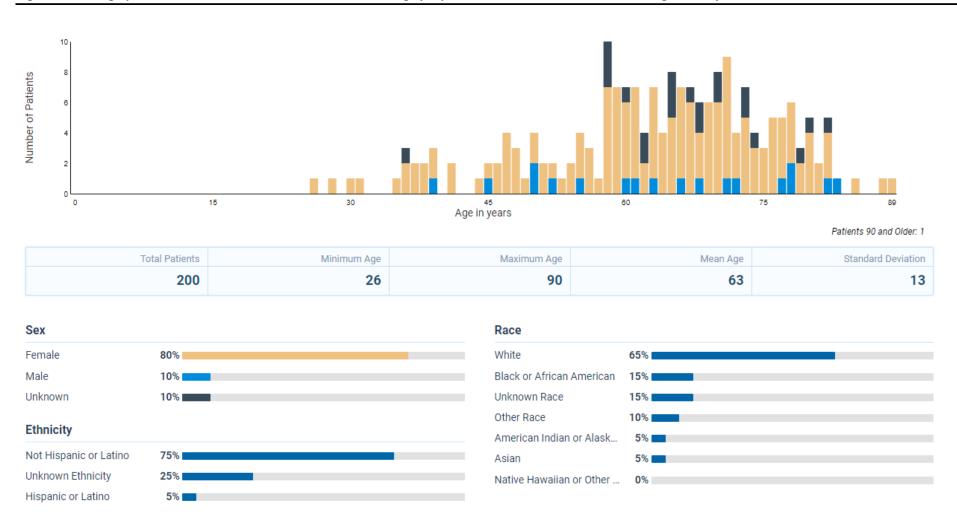
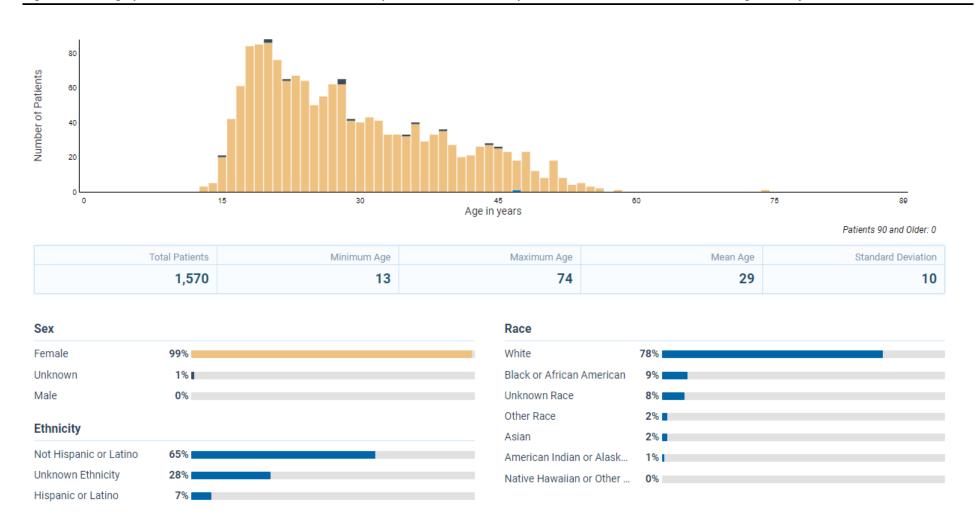




Figure 21. Demographic Characteristics for All Patients with Drospirenone and Estetrol Exposures*, from December 18, 2020 through January 19, 2024



^{*}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.

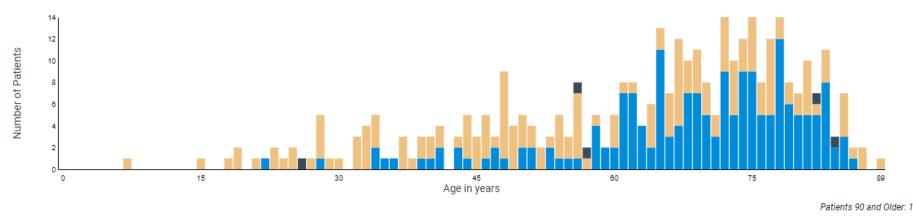
There is no sensitivity analyses cohort for this combination with a filter for brand name.

 ${\it The brand name Next Stell is is not available as a filter option on TriNet X.}$

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Figure 22. Demographic Characteristics for All Patients* with Efgartigimod alfa-fcab Exposures, from December 18, 2020 through January 19, 2024



Total Patients	Minimum Age	Maximum Age	Mean Age	Standard Deviation
360	7	90	63	17

Sex		Rad	e	
Male	52%	Whit	е	77%
Female	50%	Unk	nown Race	11%
Jnknown	2% ■	Blac	k or African Americar	n 8 %
en en		Asia	n	5%
Ethnicity		Ame	rican Indian or Alask.	2%
Not Hispanic or Latino	77%	Nati	ve Hawaiian or Other	2%
Unknown Ethnicity	16%	Othe	er Race	2%
Hispanic or Latino	11%			

^{*}No filters used



Figure 23. Demographic Characteristics for Patients with Efgartigimod alfa-fcab Exposures, Restricted to Brand Name Vyvgart, from December 18, 2020 through January 19, 2024

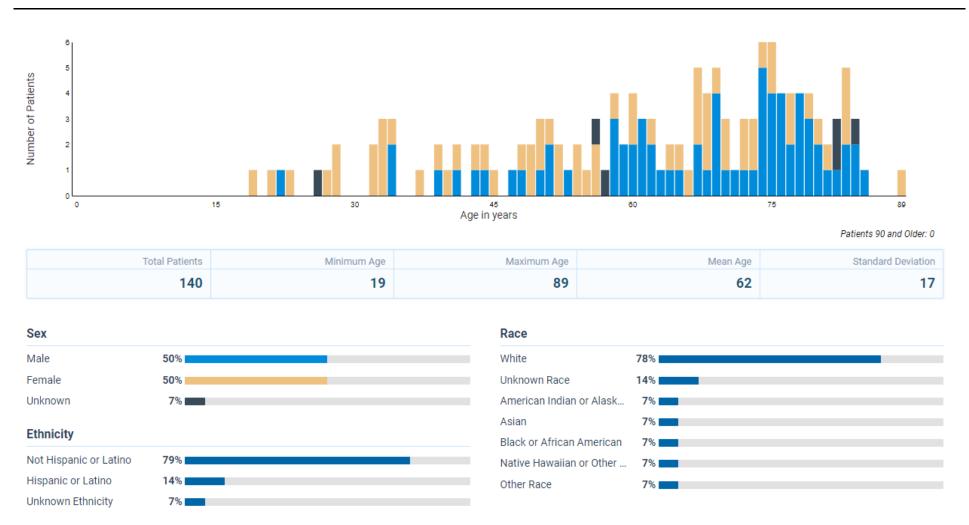




Figure 24. Demographic Characteristics for Patients with Evinacumab-dgnb Exposures, from December 18, 2020 through January 19, 2024



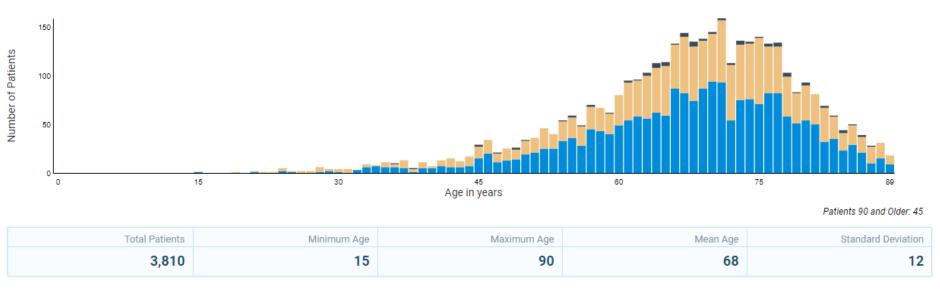


Figure 25. Demographic Characteristics for Patients with Fexinidazole Exposures, from December 18, 2020 through January 19, 2024

No patients were identified for this cohort.



Figure 26. Demographic Characteristics for Patients with Finerenone Exposures, from December 18, 2020 through January 19, 2024



		Race	
:	57%	White	54%
ale	41%	Black or African American	16%
own	2% ■	Asian	16%
icity		Unknown Race	8%
ty		Other Race	4%
oanic or Latino	74%	Native Hawaiian or Other	2%
vn Ethnicity	21%	American Indian or Alask	0%
or Latino	5%		



Figure 27. Demographic Characteristics for Patients with Fosdenopterin Exposures, from December 18, 2020 through January 19, 2024

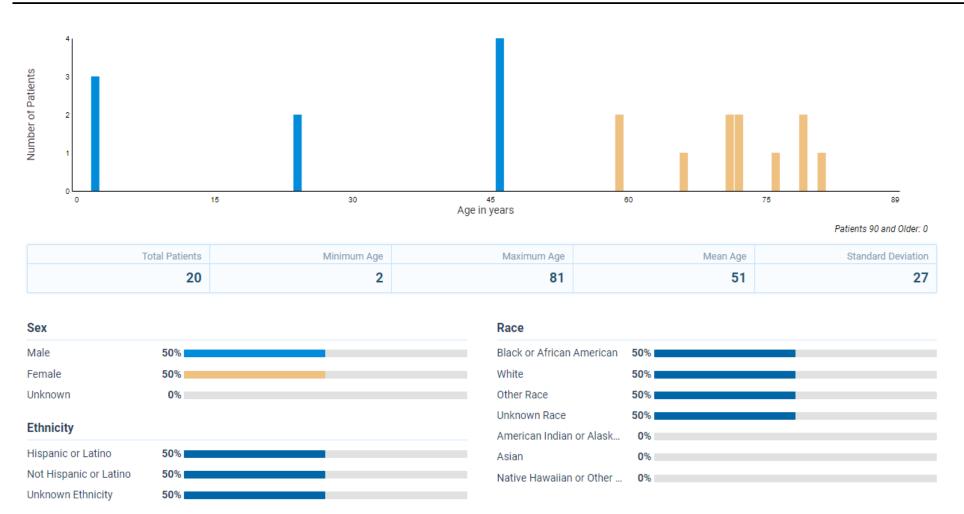




Figure 28. Demographic Characteristics for Patients with Ibrexafungerp Exposures, from December 18, 2020 through January 19, 2024

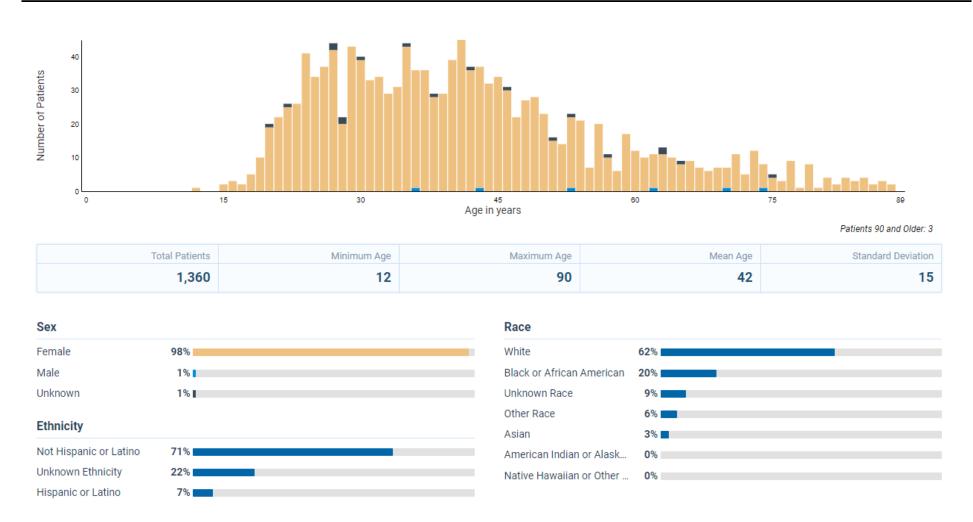




Figure 29. Demographic Characteristics for Patients with Inclisiran Exposures, from December 18, 2020 through January 19, 2024

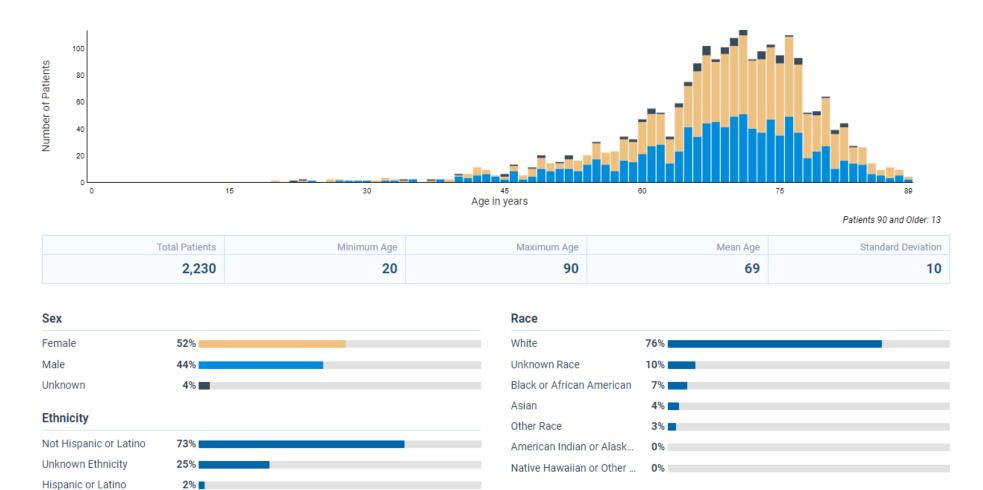




Figure 30. Demographic Characteristics for Patients with Infigratinib Exposures, from December 18, 2020 through January 19, 2024

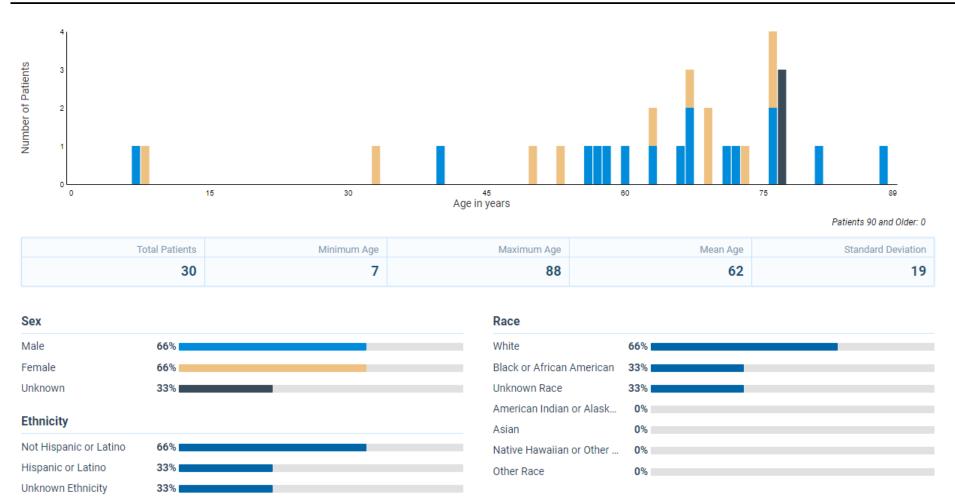




Figure 31. Demographic Characteristics for Patients with Loncastuximab Tesirine-lpyl Exposures, from December 18, 2020 through January 19, 2024

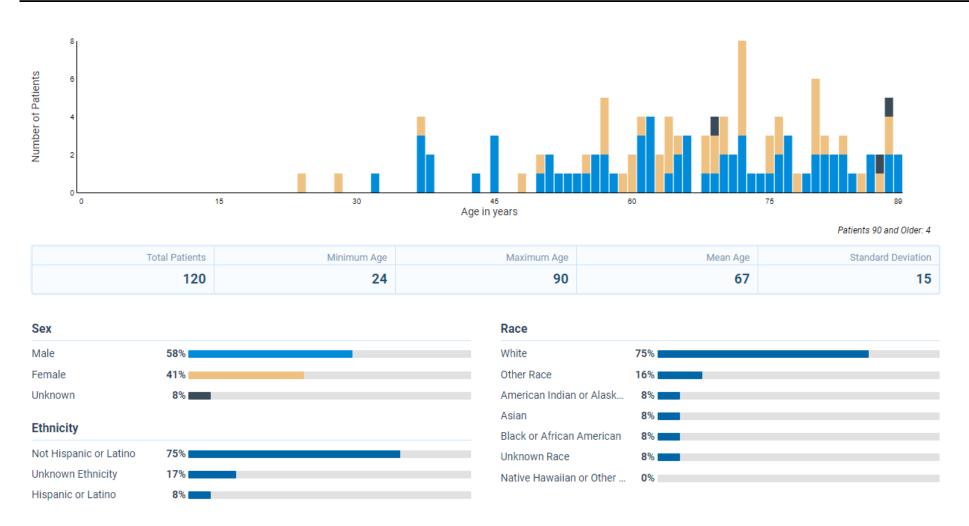




Figure 32. Demographic Characteristics for Patients with Lonapegsomatropin-tcgd Exposures, from December 18, 2020 through January 19, 2024

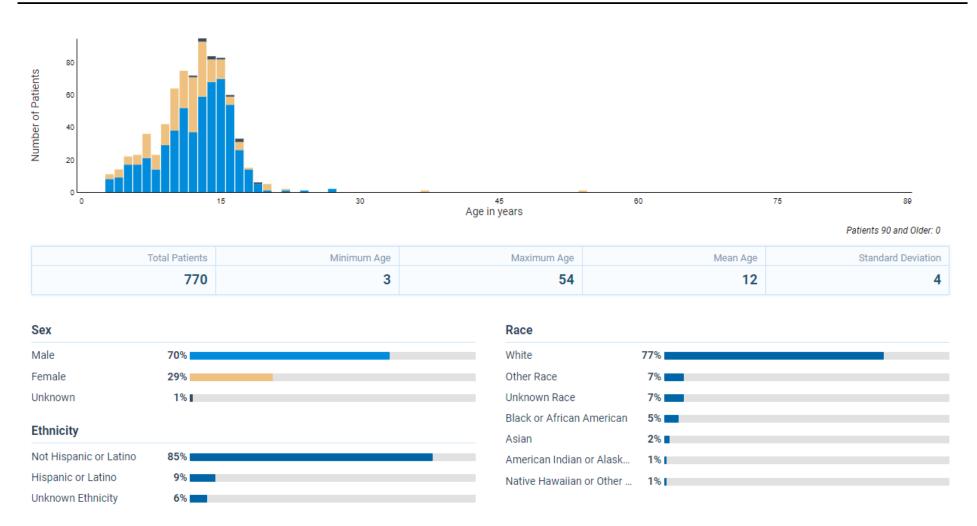
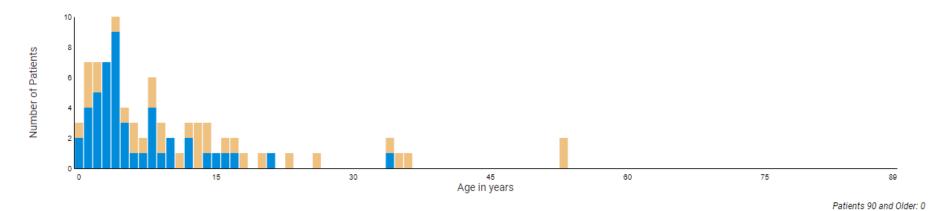




Figure 33. Demographic Characteristics for Patients with Maralixibat Exposures, from December 18, 2020 through January 19, 2024



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

Sex		Race	
Male	62%	White	62%
- emale	50%	Black or African American	25%
Inknown	0%	Other Race	25%
		Asian	12%
Ethnicity		Unknown Race	12%
lot Hispanic or Latino	87%	American Indian or Alask	0%
Hispanic or Latino	12%	Native Hawaiian or Other	0%
nknown Ethnicity	12%		



Figure 34. Demographic Characteristics for Patients with Maribavir Exposures, from December 18, 2020 through January 19, 2024

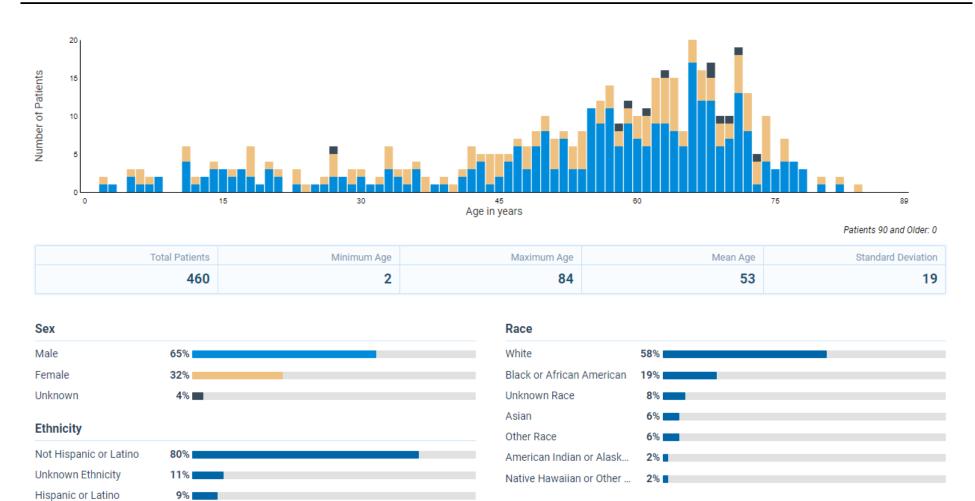


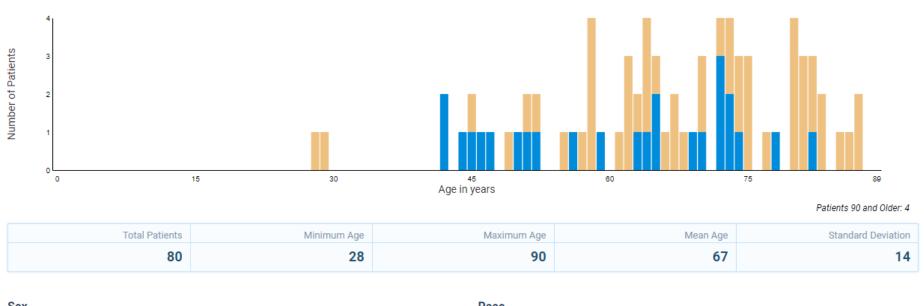


Figure 35. Demographic Characteristics for Patients with Melphalan Flufenamide Exposures, from December 18, 2020 through January 19, 2024





Figure 36. Demographic Characteristics for Patients with Mobocertinib Exposures, from December 18, 2020 through January 19, 2024



Sex		Race	
Female	62%	White	62%
Male	38%	Asian	25%
Unknown	0%	Black or African American	12%
En at the		Native Hawaiian or Other	12%
Ethnicity		Other Race	12%
Not Hispanic or Latino	62%	American Indian or Alask	0%
Unknown Ethnicity	37%	Unknown Race	0%
Hispanic or Latino	12%		

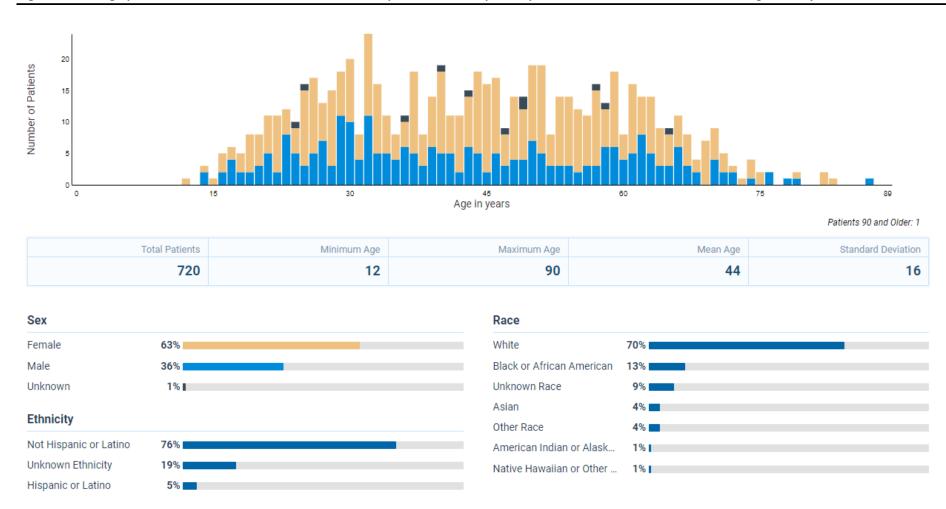


Figure 37. Demographic Characteristics for Patients with Odevixibat Exposures, from December 18, 2020 through January 19, 2024





Figure 38. Demographic Characteristics for All Patients with Olanzapine and Samidorphan Exposures*, from December 18, 2020 through January 19, 2024



^{*}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 December 18, 2020 through January 19, 2024

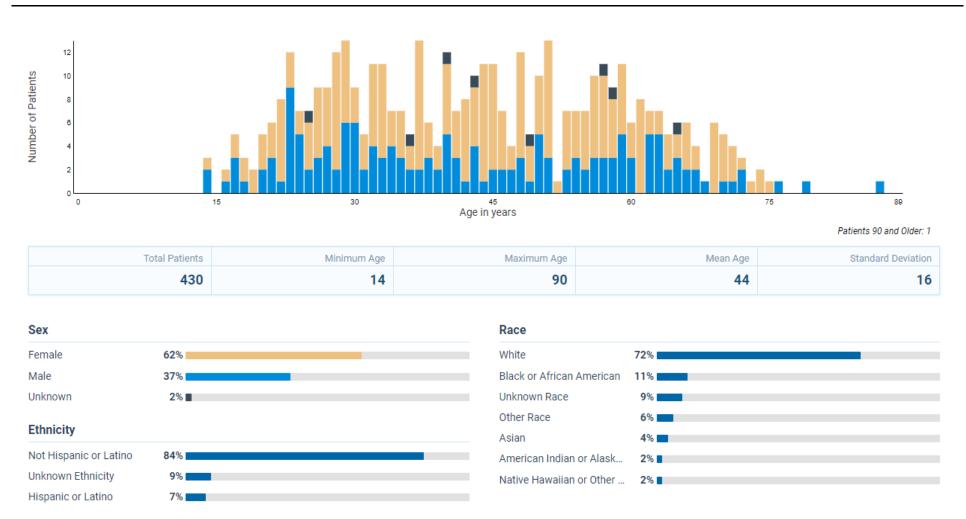


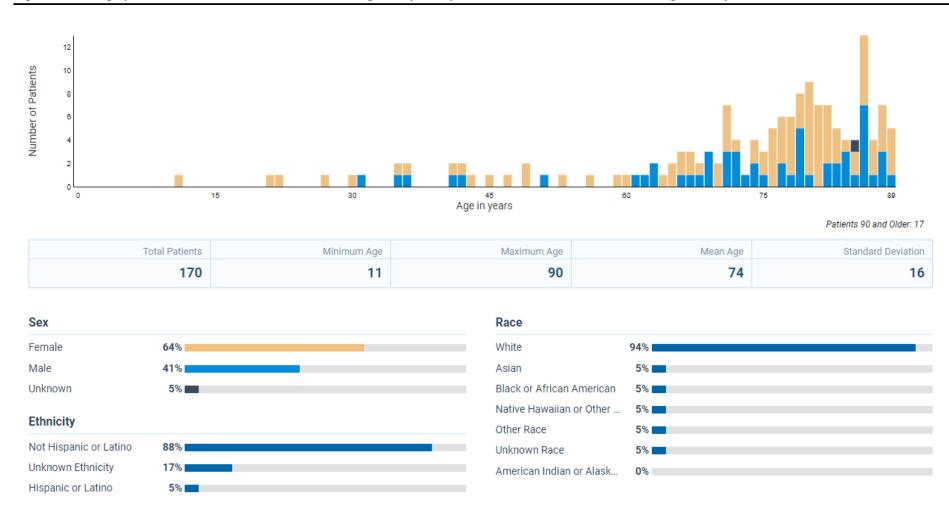


Figure 40. Demographic Characteristics for Patients with Pafolacianine Exposures, from December 18, 2020 through January 19, 2024

No patients were identified for this cohort.



Figure 41. Demographic Characteristics for All Patients* with Pegcetacoplan Exposures, from December 18, 2020 through January 19, 2024



^{*}No filters used



Figure 42. Demographic Characteristics for Patients with Pegcetacoplan Exposures, Restricted to Brand Name Empaveli, from December 18, 2020 through January 19, 2024





Figure 43. Demographic Characteristics for Patients with Piflufolastat F-18 Exposures, from December 18, 2020 through January 19, 2024

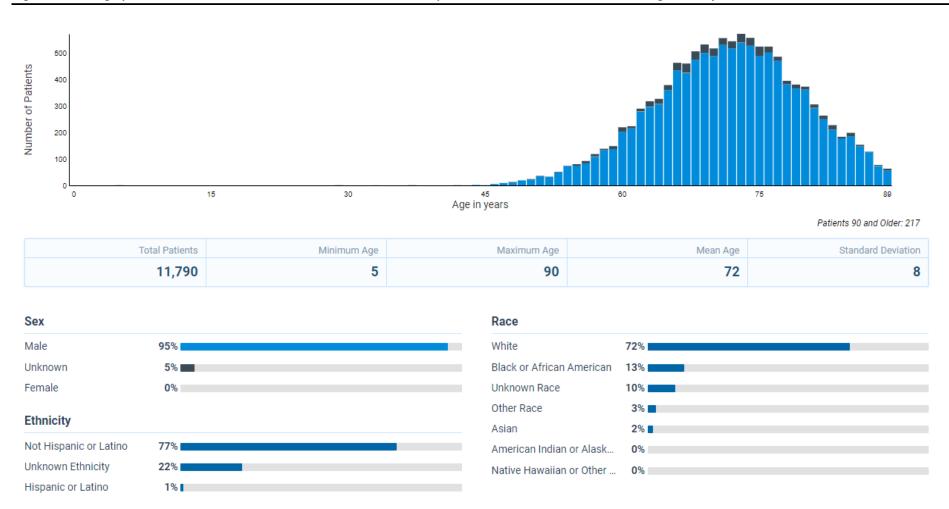
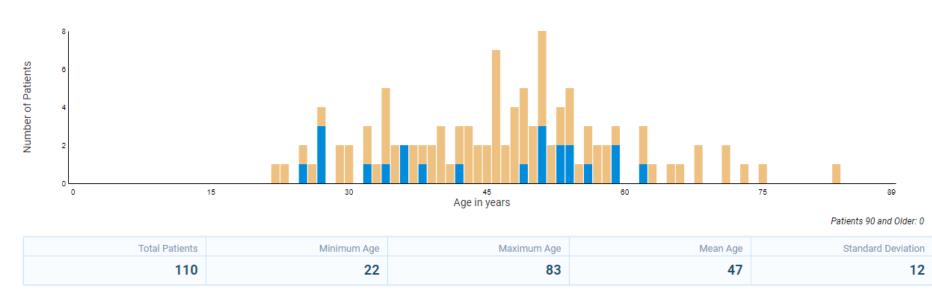




Figure 44. Demographic Characteristics for Patients with Ponesimod Exposures, from December 18, 2020 through January 19, 2024



Sex		Race	
Female	82%	White	72%
//ale	18%	Black or African American	18%
Unknown	0%	Other Race	9%
Pale of the c		Unknown Race	9%
Ethnicity		American Indian or Alask	0%
Not Hispanic or Latino	82%	Asian	0%
Hispanic or Latino	9%	Native Hawaiian or Other	0%
Jnknown Ethnicity	9%		



Figure 45. Demographic Characteristics for Patients with Ropeginterferon alfa-2b-njft Exposures, from December 18, 2020 through January 19, 2024

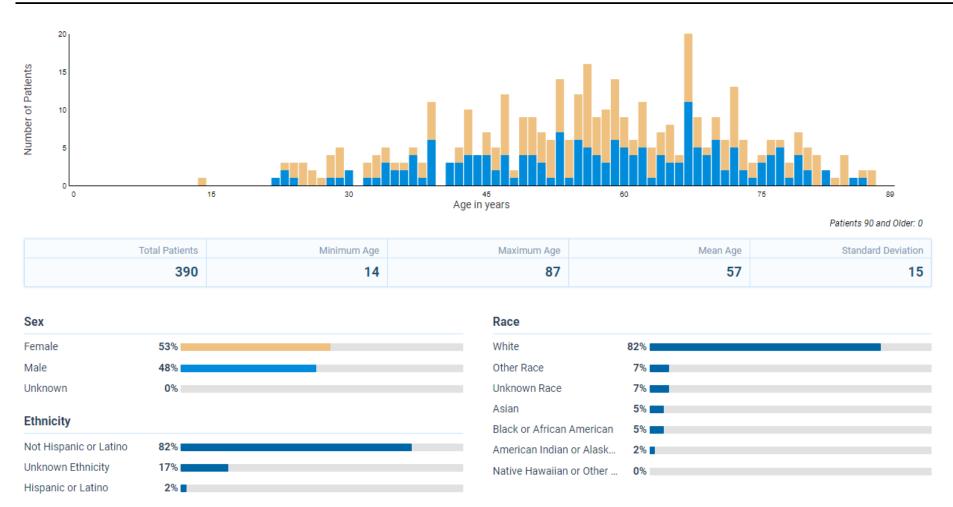
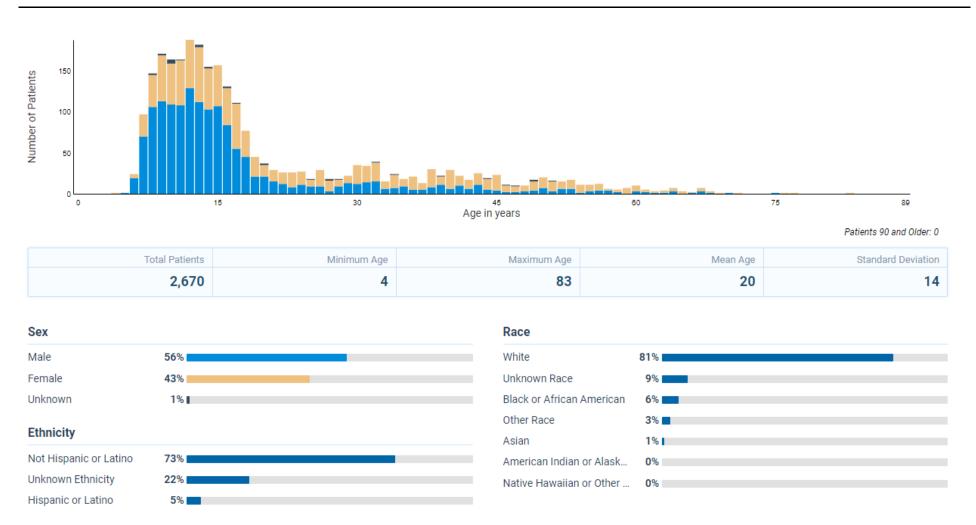




Figure 46. Demographic Characteristics for All Patients with Serdexmethylphenidate and Dexmethylphenidate Exposures*, from December 18, 2020 through January 19, 2024



^{*}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 Serdexmethylphenidate and Dexmethylphenidate Exposures, Restricted to Brand Name Azstarys, from December 18, 2020 through January 19, 2024

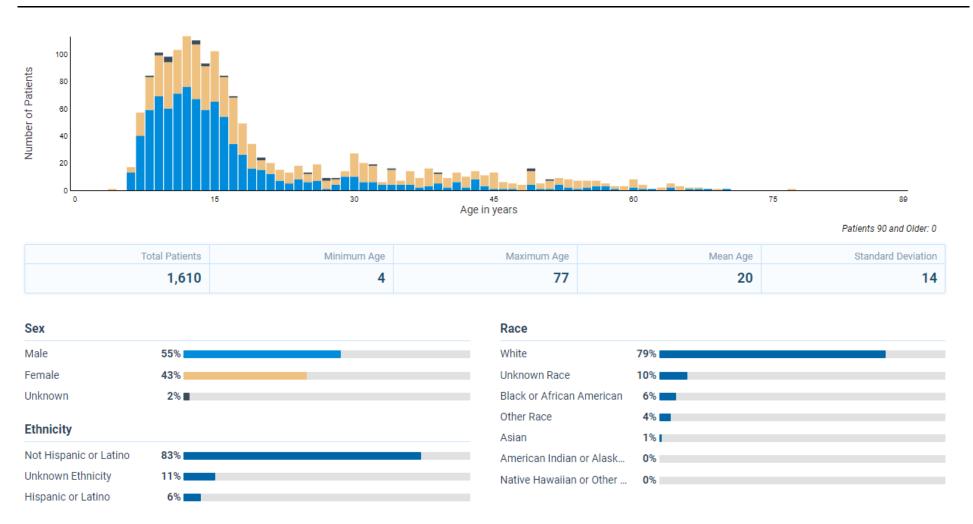
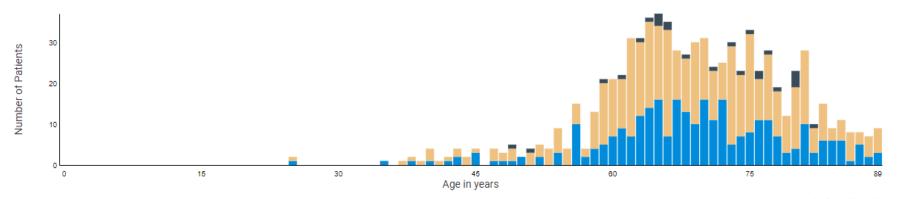




Figure 48. Demographic Characteristics for Patients with Sotorasib Exposures, from December 18, 2020 through January 19, 2024



Patients 90 and Older: 19

Total Patients	Minimum Age	Maximum Age	Mean Age	Standard Deviation
810	25	90	69	11

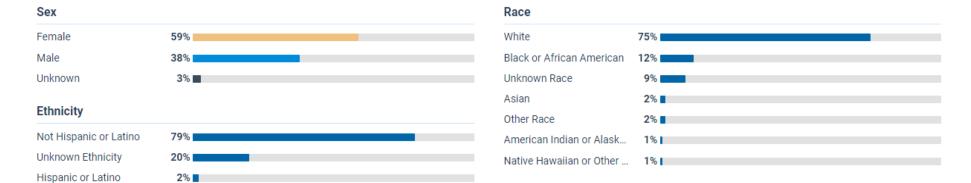




Figure 49. Demographic Characteristics for Patients with Tepotinib Exposures, from December 18, 2020 through January 19, 2024

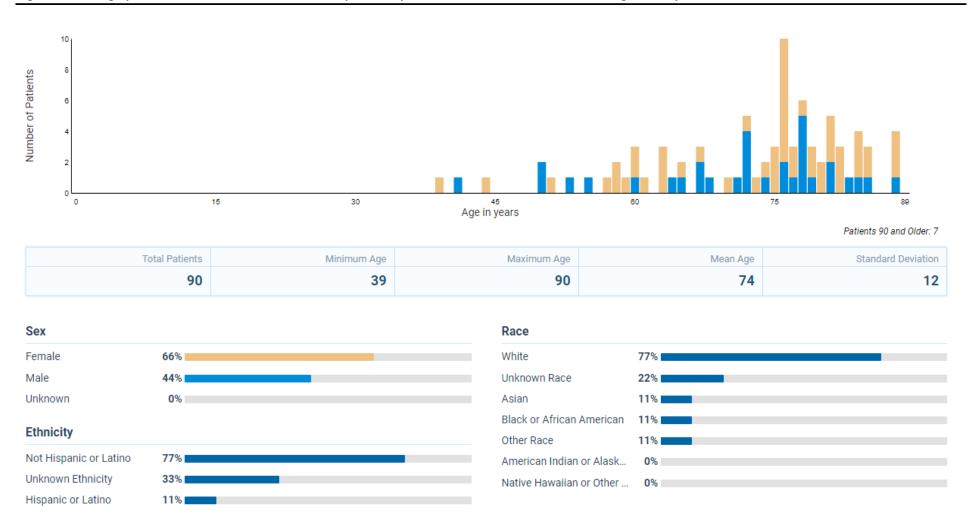
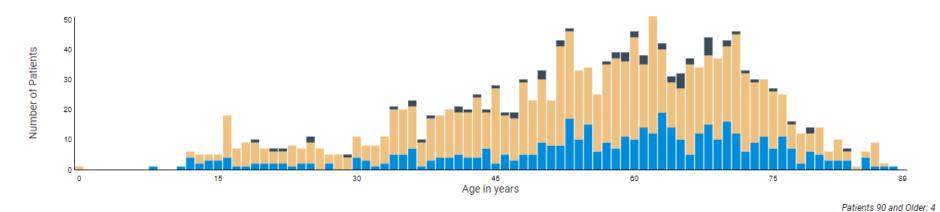




Figure 50. Demographic Characteristics for Patients with Tezepelumab-ekko Exposures, from December 18, 2020 through January 19, 2024



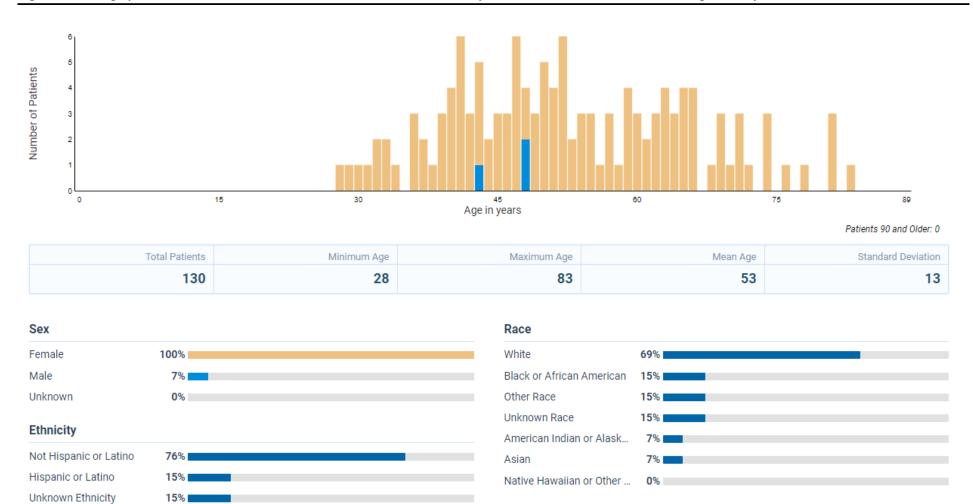
Total Patients Minimum Age Maximum Age Mean Age Standard Deviation
1,590 0 90 55 17

Sex		Race
Female	68%	White
Male	28%	Black or African Ame
Unknown	4%	Unknown Race
Ethnicity		Asian Other Race
Not Hispanic or Latino	74%	American Indian or A
Unknown Ethnicity	22%	Native Hawaiian or C
Hispanic or Latino	5%	

Race	
White	70%
Black or African American	14%
Unknown Race	11%
Asian	2 %
Other Race	2 %
American Indian or Alask	1%
Native Hawaiian or Other	0%



Figure 51. Demographic Characteristics for Patients with Tisotumab Vedotin-tftv Exposures, from December 18, 2020 through January 19, 2024



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15%



Figure 52. Demographic Characteristics for Patients with Tivozanib Exposures, from December 18, 2020 through January 19, 2024

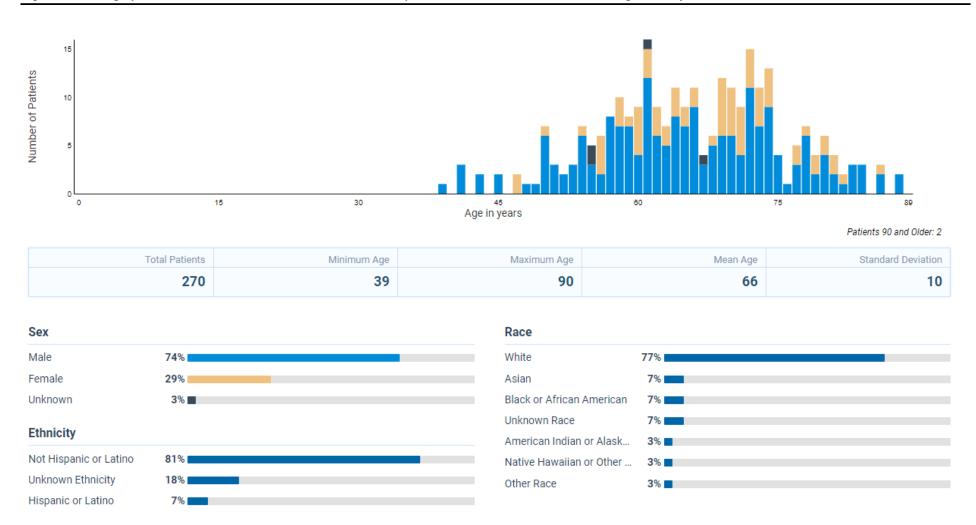
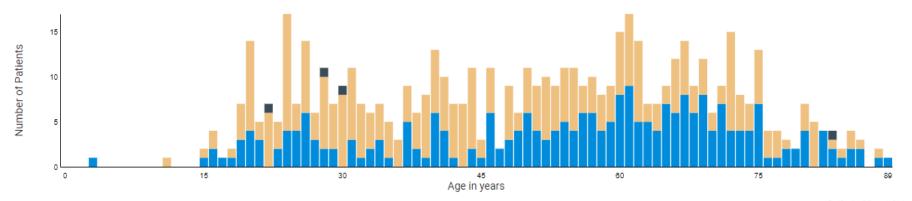




Figure 53. Demographic Characteristics for Patients with Tralokinumab-Idrm Exposures, from December 18, 2020 through January 19, 2024



Patients 90 and Older: 3

Total Patients	Minimum Age	Maximum Age	Mean Age	Standard Deviation
580	3	90	51	19

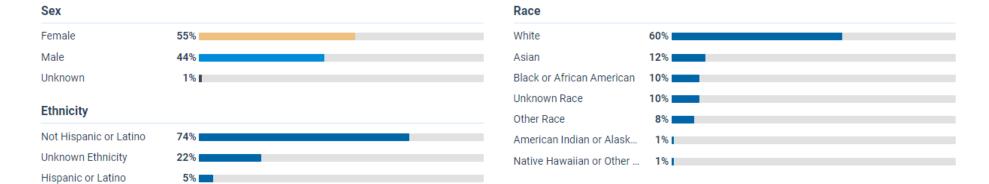




Figure 54. Demographic Characteristics for Patients with Trilaciclib Exposures, from December 18, 2020 through January 19, 2024

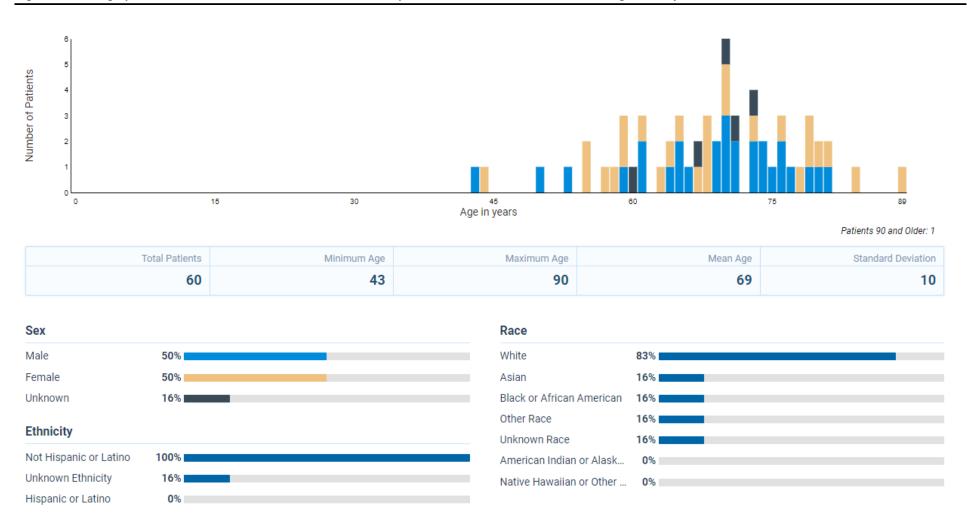




Figure 55. Demographic Characteristics for Patients with Umbralisib Exposures, from December 18, 2020 through January 19, 2024

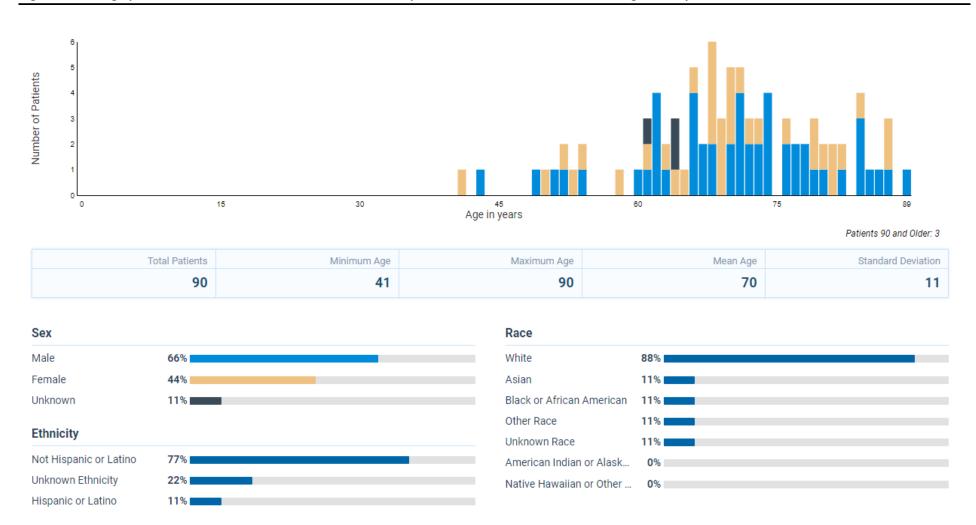
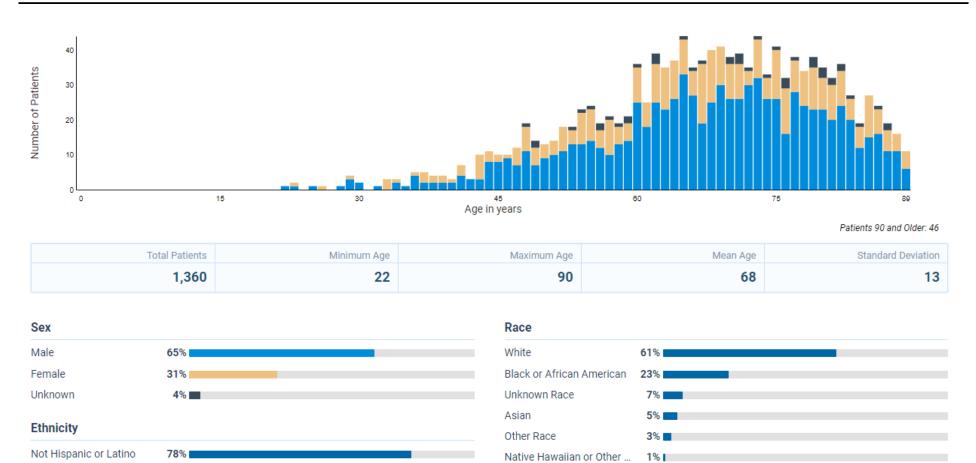




Figure 56. Demographic Characteristics for Patients with Vericiguat Exposures, from December 18, 2020 through January 19, 2024

Unknown Ethnicity

Hispanic or Latino



American Indian or Alask...



Figure 57. Demographic Characteristics for Patients with Viloxazine Exposures, from December 18, 2020 through January 19, 2024

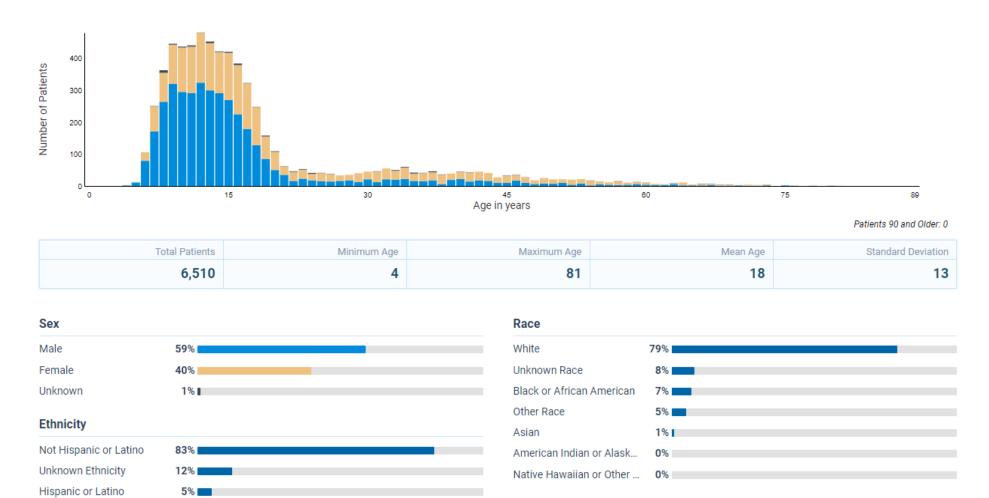
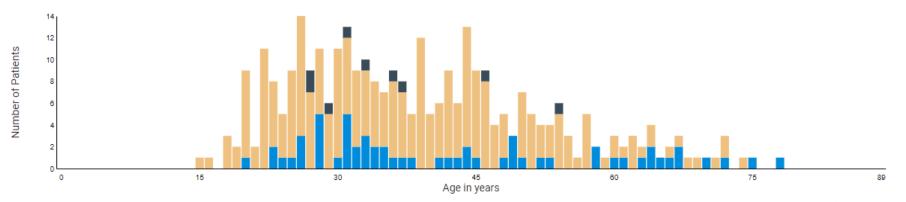




Figure 58. Demographic Characteristics for Patients with Voclosporin Exposures, from December 18, 2020 through January 19, 2024



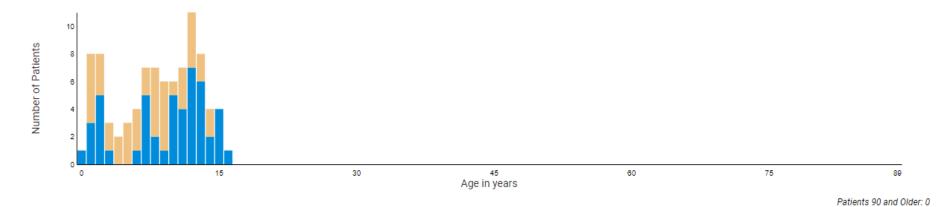
Patients 90 and Older: 0

Total Patients	Minimum Age	Maximum Age	Mean Age	Standard Deviation
320	15	78	39	13

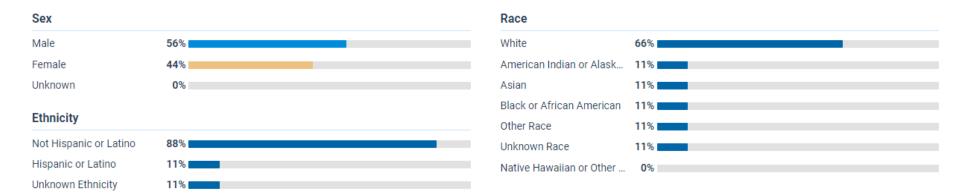
Sex Race 81% Female Black or African American 40% Male 18% White Unknown 3% Unknown Race Asian **Ethnicity** Other Race Not Hispanic or Latino American Indian or Alask... 3% Unknown Ethnicity Native Hawaiian or Other ... Hispanic or Latino 12%



Figure 59. Demographic Characteristics for Patients with Vosoritide Exposures, from December 18, 2020 through January 19, 2024



Total Patients	Minimum Age	Maximum Age	Mean Age	Standard Deviation
90	0	16	8	4



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Code	Code Type	Description	Filter
		Aducanumab-avwa	
2557217	RxNorm	Aducanumab	
J0172	HCPCS	Injection, aducanumab-avwa, 2 mg	
		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	

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Code	Code Type	Description	Filter
		Dasiglucagon	
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	

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Code	Code Type	Description	Filter	
J9247	HCPCS	Injection, melphalan flufenamide, 1 mg		
	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		

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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	

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Network:	
USA Minimal Shift network	

Cohort 1: Aducanumab-avwa			
Group 1:	Time Restrictions		
Subgroup 1A			
Must Have:			
Aducanumab-avwa	December 18, 2020 - most recently available data		
Cohort 2: Amivantamab-vmjw			
Group 1:	Time Restrictions		
Subgroup 1A			
Must Have:			
Amivantamab-vmjw	December 18, 2020 - most recently available data		
Cohort 3: Anifrolumab-fnia			
Group 1:	Time Restrictions		
Subgroup 1A			
Must Have:			
Anifrolumab-fnia	December 18, 2020 - most recently available data		
Cohort 4: Asciminib			
Group 1:	Time Restrictions		
Subgroup 1A			
Must Have:			
Asciminib	December 18, 2020 - most recently available data		
Cohort 5: Asparaginase erwinia chrysanthemi (recombinant)-rywn NO FILTER			
Group 1:	Time Restrictions		
Subgroup 1A			
Must Have:			
Asparaginase erwinia chrysanthemi (recombinant)-rywn	December 18, 2020 - most recently available data		



Cohort 6: Asparaginase erwinia chrysanthemi (recombinant)-rywn BRAND FILTER	R
Group 1:	Time Restrictions
Subgroup 1A	
Must Have:	
Asparaginase erwinia chrysanthemi (recombinant)-rywn	December 18, 2020 - most recently available data
[FILTER]: Brand name = Rylaze	
Cohort 7: Atogepant	
Group 1:	Time Restrictions
Subgroup 1A	
Must Have:	
Atogepant	December 18, 2020 - most recently available data
Cohort 8: Avacopan	
Group 1:	Time Restrictions
Subgroup 1A	
Must Have:	
Avacopan	December 18, 2020 - most recently available data
Cohort 9: Avalglucosidase alfa-ngpt	
Group 1:	Time Restrictions
Subgroup 1A	
Must Have:	
Avalglucosidase alfa-ngpt	December 18, 2020 - most recently available data
Cohort 10: Belumosudil	
Group 1:	Time Restrictions
Subgroup 1A Must Have:	
	December 19, 2020, most recently available data
Belumosudil Cohort 11: Belzutifan	December 18, 2020 - most recently available data
Group 1:	Time Restrictions
Subgroup 1A	Tillle Restrictions
Must Have:	
Belzutifan	December 19, 2020, most recently available data
Deizutiiaii	December 18, 2020 - most recently available data



Cohort 12: Cabotegravir OVERALL	
Group 1:	Time Restrictions
Subgroup 1A	
Must Have:	
Cabotegravir	December 18, 2020 - most recently available data
Subgroup 1B:	
Cannot Have:	
Rilpivirine	On the same day as subgroup 1A (cabotegravir)
Cohort 13: Cabotegravir ORAL	
Group 1:	Time Restrictions
Subgroup 1A	
Must Have:	
Cabotegravir	December 18, 2020 - most recently available data
[FILTER]: Route = Oral	
Cohort 14: Cabotegravir INJECTABLE	
Group 1:	Time Restrictions
Subgroup 1A	
Must Have:	
Cabotegravir	December 18, 2020 - most recently available data
[FILTER]: Route = Injectable	
Subgroup 1B:	
Cannot Have:	
Rilpivirine	On the same day as subgroup 1A (cabotegravir)
Cohort 15: Cabotegravir BRAND	
Group 1:	Time Restrictions
Subgroup 1A	
Must Have:	
Cabotegravir	December 18, 2020 - most recently available data
[FILTER]: Brand = Apretude or Vocabria	



Cohort 16: Cabotegravir and Rilpivirine INJECTABLE	
Group 1:	Time Restrictions
Subgroup 1A	
Must Have:	
Cabotegravir RxNorm	December 18, 2020 - most recently available data
[FILTER]: Route = Injectable	
Subgroup 1B:	
Must Have:	
Rilpivirine RxNorm	On the same day as subgroup 1A (cabotegravir)
[FILTER]: Route = Injectable	
OR	
Group 2:	Time Restrictions
Subgroup 2A	
Must Have:	
Cabotegravir and Rilpivirine HCPCS	December 18, 2020 - most recently available data
Cohort 17: Casimersen	
Group 1:	Time Restrictions
Subgroup 1A	
Must Have:	
Casimersen	December 18, 2020 - most recently available data
Cohort 18: Dasiglucagon	
Group 1:	Time Restrictions
Subgroup 1A	
Must Have:	
Dasiglucagon	December 18, 2020 - most recently available data
Cohort 19: Difelikefalin	
Group 1:	Time Restrictions
Subgroup 1A	
Must Have:	
Difelikefalin	December 18, 2020 - most recently available data



Cohort 20: Dostarlimab-gxly	
Group 1:	Time Restrictions
Subgroup 1A	
Must Have:	
Dostarlimab-gxly	December 18, 2020 - most recently available data
Cohort 21: Drospirenone and estetrol	
Group 1:	Time Restrictions
Subgroup 1A	
Must Have:	
Drospirenone	December 18, 2020 - most recently available data
Subgroup 1B:	
Must Have:	
Estetrol	On the same day as subgroup 1A (drospirenone)
Cohort 22: Efgartigimod alfa-fcab OVERALL	
Group 1:	Time Restrictions
Subgroup 1A	
Must Have:	
Efgartigimod alfa-fcab	December 18, 2020 - most recently available data
Cohort 23: Efgartigimod alfa-fcab BRAND	
Group 1:	Time Restrictions
Subgroup 1A	
Must Have:	
Efgartigimod alfa-fcab	December 18, 2020 - most recently available data
[FILTER]: Brand name = Vyvgart	
Cohort 24: Evinacumab-dgnb	
Group 1:	Time Restrictions
Subgroup 1A	
Must Have:	
Evinacumab-dgnb	December 18, 2020 - most recently available data
Cohort 25: Fexinidazole	
Group 1:	Time Restrictions
Subgroup 1A	
Must Have:	



Fexinidazole	December 18, 2020 - most recently available data
Cohort 26: Finerenone	
Group 1:	Time Restrictions
Subgroup 1A	
Must Have:	
Finerenone	December 18, 2020 - most recently available data
Cohort 27: Fosdenopterin	
Group 1:	Time Restrictions
Subgroup 1A	
Must Have:	
Fosdenopterin	December 18, 2020 - most recently available data
Cohort 28: Ibrexafungerp	
Group 1:	Time Restrictions
Subgroup 1A	
Must Have:	
Ibrexafungerp	December 18, 2020 - most recently available data
Cohort 29: Inclisiran	
Group 1:	Time Restrictions
Subgroup 1A	
Must Have:	
Inclisiran	December 18, 2020 - most recently available data
Cohort 30: Infigratinib	
Group 1:	Time Restrictions
Subgroup 1A	
Must Have:	
Infigratinib	December 18, 2020 - most recently available data
Cohort 31: Loncastuximab tesirine-lpyl	
Group 1:	Time Restrictions
Subgroup 1A	
Must Have:	
Loncastuximab tesirine-lpyl	December 18, 2020 - most recently available data



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Cohort 32: Lonapegsomatropin-		
	Group 1:	Time Restrictions
Subgroup 1A		
Must Have:		
Lonapegsomatropin-tcgd		December 18, 2020 - most recently available data
Cohort 33: Maralixibat		
	Group 1:	Time Restrictions
Subgroup 1A		
Must Have:		
Maralixibat		December 18, 2020 - most recently available data
Cohort 34: Maribavir		
	Group 1:	Time Restrictions
Subgroup 1A		
Must Have:		
Maribavir		December 18, 2020 - most recently available data
Cohort 35: Melphalan flufenam	ide	
	Group 1:	Time Restrictions
Subgroup 1A		
Must Have:		
Melphalan flufenamide		December 18, 2020 - most recently available data
Cohort 36: Mobocertinib		
	Group 1:	Time Restrictions
Subgroup 1A		
Must Have:		
Mobocertinib		December 18, 2020 - most recently available data
Cohort 37: Odevixibat		
	Group 1:	Time Restrictions
Subgroup 1A		
Must Have:		
Odevixibat		December 18, 2020 - most recently available data



Cohort 38: Olanzapine and samidorphan OVERALL	
Group 1:	Time Restrictions
Subgroup 1A	
Must Have:	
Olanzapine	December 18, 2020 - most recently available data
Subgroup 1B:	
Must Have:	
Samidorphan	On the same day as subgroup 1A (olanzapine)
Cohort 39: Olanzapine and samidorphan BRAND	
Group 1:	Time Restrictions
Subgroup 1A	
Must Have:	
Olanzapine	December 18, 2020 - most recently available data
[FILTER]: Brand = Lybalvi	
Subgroup 1B:	
Must Have:	
Samidorphan	On the same day as subgroup 1A (olanzapine)
[FILTER]: Brand = Lybalvi	
Cohort 40: Pafolacianine	
Group 1:	Time Restrictions
Subgroup 1A	
Must Have:	
Pafolacianine	December 18, 2020 - most recently available data
Cohort 41: Pegcetacoplan OVERALL	
Group 1:	Time Restrictions
Subgroup 1A	
Must Have:	
Pegcetacoplan	December 18, 2020 - most recently available data
Cohort 42: Pegcetacoplan BRAND	
Group 1:	Time Restrictions
Subgroup 1A	
Must Have:	
Pegcetacoplan	December 18, 2020 - most recently available data
[FILTER]: Brand = Empaveli	



Cohort 43: Piflufolastat F-18	
Group 1:	Time Restrictions
Subgroup 1A	
Must Have:	
Piflufolastat F-18	December 18, 2020 - most recently available data
Cohort 44: Ponesimod	
Group 1:	Time Restrictions
Subgroup 1A	
Must Have:	
Ponesimod	December 18, 2020 - most recently available data
Cohort 45: Ropeginterferon alfa-2b-njft	
Group 1:	Time Restrictions
Subgroup 1A	
Must Have:	
Ropeginterferon alfa-2b-njft	December 18, 2020 - most recently available data
Cohort 46: Serdexmethylphenidate and dexmethylphenidate OVERALL	
Group 1:	Time Restrictions
Subgroup 1A	
Must Have:	
Serdexmethylphenidate	December 18, 2020 - most recently available data
Subgroup 1B:	
Must Have:	
Dexmethylphenidate	On the same day as subgroup 1A (serdexmethylphenidate)
Cohort 47: Serdexmethylphenidate and dexmethylphenidate BRAND	
Group 1:	Time Restrictions
Subgroup 1A	
Must Have:	lo 1 40 2020 1 11 11 1 1
Serdexmethylphenidate	December 18, 2020 - most recently available data
[FILTER]: Brand = Azstarys	
Subgroup 1B: Must Have:	
Dexmethylphenidate	On the same day as subgroup 1A (cordovmethylphenidate)
	On the same day as subgroup 1A (serdexmethylphenidate)
[FILTER]: Brand = Azstarys	



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Cohort 54: Trilaciclib		
	Group 1:	Time Restrictions
Subgroup 1A		
Must Have:		
Trilaciclib		December 18, 2020 - most recently available data
Cohort 55: Umbralisib		
	Group 1:	Time Restrictions
Subgroup 1A		
Must Have:		
Umbralisib		December 18, 2020 - most recently available data
Cohort 56: Vericiguat		
	Group 1:	Time Restrictions
Subgroup 1A		
Must Have:		
Vericiguat		December 18, 2020 - most recently available data
Cohort 57: Viloxazine		
	Group 1:	Time Restrictions
Subgroup 1A		
Must Have:		
Viloxazine		December 18, 2020 - most recently available data
Cohort 58: Voclosporin		
	Group 1:	Time Restrictions
Subgroup 1A		
Must Have:		
Voclosporin		December 18, 2020 - most recently available data
Cohort 59: Vosoritide		
	Group 1:	Time Restrictions
Subgroup 1A		
Must Have:		
Vosoritide		December 18, 2020 - most recently available data