DEC 27, 2022

OPEN ACCESS

DOI:
dx.doi.org/10.17504/protocols.io.4r3l27my3g1y/v1

Protocol Citation: Shadera Slatter, Michelle Wang, Chia-Wei Lin, Jesse Sussell, Sarika Ogale, Debajyoti Datta, Atul Butte, Lyudmila Bazhenova, Vivek A Rudrapatna 2022. Methods for Clinical Chart Abstraction: Real-World ALK Inhibitor Treatment Patterns and Reasons for Discontinuation Study. **protocols.io** https://dx.doi.org/10.17504/protocols.io.4r3l27my3g1y/v1

Protocol status: Working
We use this protocol and it's working

Created: Sep 01, 2022

Last Modified: Dec 27, 2022

PROTOCOL integer ID: 69443

Keywords: Clinical chart abstraction, ALK Inhibitor, Treatment Patterns, Lung Cancer, Manual Data Abstraction

ATTACHMENTS

Methods for Clinical Chart Abstraction: Real-World ALK Inhibitor Treatment Patterns and Reasons for Discontinuation Study

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ABSTRACT

This protocol details the procedure of methods for Clinical Chart Abstraction: Real-World ALK Inhibitor Treatment Patterns and Reasons for Discontinuation Study performed at the University of California, San Francisco. The protocol defines each variable in detail ranging from demographics, disease characteristics, prior treatments, ALK inhibitor treatment, regimen adjustment and interruptions, ancillary treatments, treatment discontinuation, next treatment, serious adverse events, and other notable variables. These definitions can be used and applied when performing a manual chart abstraction looking at treatment patterns for a given medication(s). They can also be applied to more general manual chart abstractions seeking to characterize demographics and disease characteristics.

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GUIDELINES

Inclusion/exclusion:

1. ALK-positive advanced NSCLC.
2. Received ALK inhibitor (crizotinib, alectinib, ceritinib, brigatinib, lorlatinib) between January 2012 and November 2021 after advanced diagnosis date.
3. Age ≥ 18 years old.
4. Documentation for the start date (day/month/year or month/year) of the first ALK inhibitor treatment.

Records to review:

Both UCSF records and outside records were reviewed when accessible from the UCSF electronic health record database. This includes both electronic health record entered clinical notes (both in office and virtual appointments), telephone messages, online communication (via patient portal), imaging reports, pathology reports, clinical summaries, hospital admission/discharge records, as well as scanned clinical and administration documents.

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Demographics

1 **Date of Birth** – *Date*: Defined as the date of subject's birth.

2 **Sex** – *Binary*: Male/Female- Defined as the sex assigned at birth.

3 **Insurance** – *Nominal*: Defined as the insurance assigned to the subject in their electronic health record. If no insurance is recorded in the health record, subject's physical scanned insurance card is reviewed. If no scanned insurance card is found, other insurance related documents are sought out for review. If no insurance documents are found, variable is detailed as "unknown." If explicit mention of no insurance is found in the medical record, variable is detailed as "none." Variables are recorded as is exactly documented in the electronic medical record, with further consolidation during analysis.

4 **Copay** – *Continuous*: Defined as the financial copayment documented for their initial ALKi therapy. Copayment amount can be found in scanned insurance documents or in patient communication with hospital staff. "Copay" is entered into the search function of the electronic health record and all pertaining records are reviewed. If no copayment amount is found using the search function, scanned insurance/pharmacy documents are reviewed. If no copay amount is found, the variable is left blank.

5 **Smoking Status** – *Nominal*: Current; Former; Never; Unknown – Defined as the smoking status of the subject.

6 **ECOG Status** – *Ordinal*: 0; 1; 2; 3; 4 – Defined as the ECOG score closest to initiation of initial ALKi therapy, up to 3 months prior to initiation. The ECOG score documented closest to the initiation of ALKi therapy is used. If an ECOG score is provided on the day that the subject initiated ALKi therapy, that ECOG value is preferred. No ECOG values are recorded post initiation of ALKi therapy. "ECOG" is entered into the search function of the electronic health record and all pertaining documents are reviewed. If no score within the provided guidelines is found, both "performance status" and "ps" are also entered into the search function for review. If these search functions also do not reveal the desired result, records within the 3 months prior to ALKi initiation are manually reviewed, both in the electronic clinical record and in the scanned clinical documents. If no ECOG score is found the variable is left blank.

7 **ECOG Date** – *Date*: If ECOG status (variable 6) is completed, defined as the date of the clinical note/document associated with reported ECOG status. If no ECOG status is recorded the variable is left blank.

8 **ALKi Rendering Physician** – *Nominal*: Full professional name – Defined as the oncologist physician who provided care at the time of initiation of their initial ALKi. Clinical electronic records and scanned clinical documents are reviewed at the time of initiation of the initial ALKi to confirm the rendering provider. If the subject was seen outside of the institution for their initial ALKi care, and the records are unavailable for review, the variable is left blank.

9 **ALKi Rendering Physician NPI** – *Nominal*: If ALKi rendering physician (variable 8) is completed, defined as the NPI number associated with physician professional name reported on a verified online database. For subjects with care outside the United States at the time of their initial ALKi therapy, ALKi rendering physician (variable 8) is documented, however NPI variable is left blank. If no rendering physician is recorded, the variable is left blank.

Disease Characteristics

10 **Date of NSCLC Diagnosis** – *Date*: Defined as the date of biopsy confirmed diagnosis of NSCLC. If a full date (day, month, year) is not documented but the month and year are, then the 15th (mid-month) is recorded as a reference date. For example, if incomplete date is documented as March of 2012, variable is documented as 3/15/12.

11 **Stage of NSCLC** – *Ordinal*: I; IA; IB; II; IIA; IIB; III; IIIA; IIIB; IV; IVA; IVB - defined as the cancer stage at the time of initial NSCLC diagnosis.

12 **TNM Staging at the time of ALKi** – *Ordinal*: Defined as the full clinical cancer stage assigned at the time of initial ALKi initiation. If partial staging is documented, partial staging is recorded. If no TNM staging is found, the variable is left blank.

13 **ALK testing (non-variable):** Preferred data source = pathology/genetic report. If unavailable in the electronic health record, then clinical notes/documents are reviewed. If multiple tests are found, each test is assigned an associated row.

13.1 **Date of ALK tissue collection** – *Date*: Defined as the date in which the sample (tissue biopsy, fluid, blood) was collected and sent for ALK testing. If no report is available, and no documentation of tissue collection date is noted, variable is left blank.

13.2 **Date of ALK test reported** – *Date*: Defined as the report date on the pathology/genetic report. If no report is available, and no documentation of report date is noted, variable is left blank.

13.3 **Type of ALK test** – *Binary*: FISH/NGS - Defined as the type of testing performed on the sample to determine ALK genetic status. If no report is available, and no documentation of test type is noted, variable is left blank.

13.4 **Sample for ALK test** – *Nominal*: Biopsy; blood; fluid - Defined as the type of sample collected, that was used for ALK testing. If no report is available, and no documentation of tissue source is noted, variable is left blank.

13.5 **ALK fusion partner** – *Nominal*: Defined as the fusion partner noted during ALK testing. Most common

fusion partner is EML4. Not all tests report fusion partner. If FISH testing, fusion partner is generally not available. In such case, electronic health record search function is used for mention of fusion partner. If no mention of fusion partner in electronic health record, variable is left blank.

13.6 **ALK fusion variant** – *Nominal*: Defined as the variant of ALK mutation as noted by genetic testing. Most variants are associated with fusion partner EML4. Not all genetic tests indicate a fusion variant. Variable only documented if noted in report or clinical notes/documentation. If no mention of fusion variant in electronic health record, variable is left blank.

13.7 **Co-mutations** – *Nominal*: Defined as the co-mutations (those other than ALK mutations) identified during FISH/NGS testing. In the case of multiple mutations, mutations are separated with a semi-colon. If no co-mutations are noted in report, or no report available, variable is left blank.

14 **Metastasis characterization at baseline** – *Nominal*: Defined as the NSCLC metastases acquired by the subject at the time of initial ALKi initiation. If multiple metastases noted, variables are separated using a semicolon within the same row. If no metastases noted, variable is left blank.

15 **Metastasis characterization acquired during ALKi** – *Nominal*: Defined as the characterization of new metastases acquired (in new location within the body) while on initial ALKi therapy. If multiple acquired metastases noted, variables are separated using a semicolon within the same row. If no acquired metastases noted, variable is left blank.

16 **If brain - # of Mets** – *Discrete*: If metastasis characterization at baseline (variable 14) or metastasis characterization acquired during ALKi (variable 15) contains "brain," defined as the number of brain metastases at the time of diagnosis of brain metastatic disease. If no clear indication as to the number of metastases, the description from the imaging report is recorded. For example, "innumerable punctuate CNS lesions."

17 **Histology** – *Nominal*: Squamous cell carcinoma; Adenocarcinoma; Large cell carcinoma; Other - Defined as the histology documented at the time of NSCLC diagnosis.

18 **De novo status** – *Binary*: Yes/no – If yes, defined as NSCLC being the first occurrence of cancer. If no, defined as having a medical history of cancer outside of NSCLC.

Prior Treatments

19 **Prior treatment** – *Binary*: Yes/no – If yes, prior treatment for NSCLC is reported in electronic health record. If no, prior treatment for NSCLC is not reported. If no, variables 19.1-19.7 are left blank. If multiple prior treatments are documented, each prior treatment has its own associated row.

19.1 **Prior treatment drug** – *Nominal*: Defined as the drug or treatment provided to the subject prior to initial ALKi therapy. Includes chemotherapy, immunotherapy, targeted therapy, radiation, and surgery. Variables are recorded as is exactly documented in the electronic medical record, with further consolidation during

analysis. Prior treatments are listed only if they pertain to the direct treatment of NSCLC. Treatments for other co-morbidities are not listed.

19.2 **Prior treatment onset date** – *Date*: Defined as the date in which prior treatment was initiated. If a full date (day, month, year) is not documented but the month and year are, then the 15th (mid-month) is recorded as a reference date. For example, if incomplete date is documented as March of 2012, variable is documented as 3/15/12. If onset date is not found in the clinical record, the variable is left blank.

19.3 **Prior treatment end date** – *Date*: Defined as the date in which prior treatment was ended. If a full date (day, month, year) is not documented but the month and year are, then the 15th (mid-month) is recorded as a reference date. For example, if incomplete date is documented as March of 2012, variable is documented as 3/15/12. If end date is not found in the clinical record, the variable is left blank.

19.4 **Prior LOT** – *Ordinal*: Defined as the line of therapy in which the prior therapy was documented. If systemic therapy was given with radiation, both therapies are documented as the same line of therapy.

19.5 **Prior dose** – *Discrete*: Defined as the dose prescribed/used of the prior therapy. Pertains to chemotherapy, targeted therapy, immunotherapy, and radiation. Surgery is left blank. If no dose is documented in the electronic health record, the variable is left blank.

19.6 **Prior frequency** – *Ordinal*: Defined as the frequency prescribed/used of the prior therapy. Pertains to chemotherapy, targeted therapy, immunotherapy, and radiation. Surgery is left blank. If no frequency is documented in the electronic health record, the variable is left blank.

19.7 **If radiation – location of treatment** – *Nominal*: If prior treatment drug (variable 19.1) is within the category of radiation, defined as the location in which the targeted radiation was completed in the body. If radiation in the brain, the number of lesions targeted is documented. If whole brain radiation therapy, variable is left blank. If no locations are documented, the variable is left blank.

20 **Past clinical trial** – *Binary*: Yes/no – if yes, defined as participation in a clinical trial for the treatment of NSCLC prior to treatment of initial ALKi as documented in clinical notes. No is defined a no record of prior participation in a clinical trial.

ALK Inhibitor Treatment

21 **ALK treatment (non-variable):** All information pertains to the first ALKi used by the subject for treatment of NSCLC.

21.1 **ALKi Used** – *Nominal*: Crizotinib; Alectinib; Ceritinib; Brigatinib; Lorlatinib - Defined as the initial ALKi prescribed and taken by the subject for the treatment of NSCLC.

21.2 **Date of onset of ALKi treatment** – *Date*: Defined as the initiation date of the initial ALKi therapy. If a full date (day, month, year) is not documented but the month and year are, then the 15th (mid-month) is recorded as a reference date. For example, if incomplete date is documented as March of 2012, variable is documented as 3/15/12. If only the year is documented, the subject is excluded from the study.

21.3 **Date of end of ALKi treatment** – *Date*: Defined as the cessation date of the initial ALKi therapy. If a full date (day, month, year) is not documented but the month and year are, then the 15th (mid-month) is recorded as a reference date. For example, if incomplete date is documented as March of 2012, variable is documented as 3/15/12. If there is no record of the ALKi end date, but a date of initiation of next therapy is documented, then the day before the next therapy initiation date is recorded as the end date for the ALKi treatment. If the subject died while on ALKi treatment, then the death date is recorded as the end date of treatment. If there is no documentation of cessation of the ALKi treatment (either ongoing care or lost to follow up) "ongoing" is recorded and the "last date of observation" and "encounter type" variables are documented – see variable numbers 28-29 for further details.

21.4 **ALKi LOT** – *Ordinal*: Defined as the line of therapy of the initial ALK inhibitor in relation to any prior therapies used as treatment for NSCLC. If prior systemic therapy was used, LOT for ALKi would be defined as a subsequent use. If prior targeted radiation was used, ALKi is defined as concurrent LOT.

21.5 **ALKi dose** – *Discrete*: Defined as the originally prescribed dose at the onset of ALKi initiation.

21.6 **ALKi frequency** – *Ordinal*: Defined as the originally prescribed frequency at the onset of ALKi initiation.

Regimen Adjustment

22 **Dose Adjustment** – *Binary*: Yes/no - Defined as the clinical notation of a change in dosage and/or frequency of ALKi therapy from the currently prescribed dose and/or frequency. If no regimen adjustment is found, variables 22.1-22.4 are left blank. If multiple dose adjustments are found, each dose adjustment has its own associated row.

22.1 **Date of dose adjustment** – *Date*: Defined as the date the ALKi treatment dose and/or frequency was adjusted. If a full date (day, month, year) is not documented but the month and year are, then the 15th (mid-month) is recorded as a reference date. For example, if incomplete date is documented as March of 2012, variable is documented as 3/15/12. If there is a record of dose adjustment but no specific date or only the year is documented, then the variable is left blank.

22.2 **Original dose** – *Ordinal*: Defined as the currently prescribed dose and frequency of the ALKi prior to the dose adjustment.

22.3 **New dose** – *Ordinal*: Defined as the new prescribed dose and frequency of the ALKi. If there is a note of

dose adjustment but no specific value for the new dose and frequency, then the variable is left blank.

22.4 **Reason for dose adjustment** – *Nominal*: Defined as the clinically documented reason for dose adjustment. Variables are recorded as is exactly documented in the clinical record, with further consolidation during analysis. If there is a note of dose adjustment but no specific reason for the new dose and frequency, then the variable is left blank.

Regimen Interruption

23 **Regimen interruption** – *Binary*: Yes/no - Defined as the clinical notation of a pause in ALKi therapy. If no regimen interruption is found, variables 23.1-23.6 are left blank. If multiple regimen interruptions are found, each regimen interruption has its own associated row.

23.1 **Date of regimen interruption** – *Date*: Defined as the date the ALKi treatment was paused. If there is a note of regimen interruption but no specific date of initial pause or only the year is documented, then the variable is left blank.

23.2 **Date of regimen restart** – *Date*: Defined as the date the ALKi treatment was resumed. If there is a note of regimen interruption but no specific date of resuming or only the year is documented, then the variable is left blank.

23.3 **Reason for interruption** – *Nominal*: Evidence of disease progression; Adverse events/intolerance; Patient-reported inconvenience; Financial toxicity; Pregnancy; Death; Loss of follow-up / end of follow-up; Other; Unknown - Defined as the reason for regimen interruption as documented in the clinical record.

23.4 **If adverse events RI** – *Nominal*: If reason for interruption (variable 23.3) is documented as "Adverse events/intolerance," defined as the clinically documented adverse event that was the cause of the regimen interruption. Variables are recorded as is exactly documented in the clinical record, with further consolidation during analysis.

23.5 **If disease progression RI** – *Nominal*: If reason for interruption (variable 23.3) is documented as "Evidence of disease progression," defined as the type of imaging used to identify the disease progression that was the cause of the regimen interruption. Variables are recorded as is exactly documented in the clinical record, with further consolidation during analysis.

23.6 **If other interruption** – *Nominal*: If reason for interruption (variable 23.3) is documented as "Other," defined as the reason for regimen interruption, if no other categories accurately describe the situation as defined in the clinical record. Variables are recorded as is exactly documented in the clinical record, with further consolidation during analysis.

Ancillary Treatment

24 **Ancillary treatment** – *Binary*: Yes/no - defined as treatment provided to the subject concurrently with the initial ALKi for the treatment of NSCLC. If no, variables 24.1-24.6 are left blank. If multiple ancillary treatments are found, each ancillary treatment has its own associated row.

24.1 **Ancillary treatment drug** – *Nominal*: Defined as the name of the drug or treatment provided concurrently with the ALKi therapy. Can include chemotherapy, immunotherapy, targeted therapy, radiation therapy and surgery. Does not include medications to treat bone metastases. Variables are recorded as is exactly documented in the clinical record, with further consolidation during analysis.

24.2 **Ancillary treatment onset date** – *Date*: Defined as the date the ancillary treatment was initiated. If a full date (day, month, year) is not documented but the month and year are, then the 15th (mid-month) is recorded as a reference date. For example, if incomplete date is documented as March of 2012, variable is documented as 3/15/12.

24.3 **Ancillary treatment end date** – *Date*: Defined as the date the ancillary treatment was ended. If a full date (day, month, year) is not documented but the month and year are, then the 15th (mid-month) is recorded as a reference date. For example, if incomplete date is documented as March of 2012, variable is documented as 3/15/12. If the ancillary treatment does not have an end date (either ongoing care or lost to follow up) variable is left blank. If subject passed while on ancillary treatment, the end date is the death date.

24.4 **Ancillary dose** – *Discrete*: Defined as the originally prescribed dose at the initiation of ancillary therapy. Pertains to chemotherapy, immunotherapy, targeted therapy and radiation. Surgery is left blank. If no dose is documented, the variable is left blank.

24.5 **Ancillary frequency** – *Ordinal*: Defined as the originally prescribed frequency at the initiation of ancillary therapy. Pertains to chemotherapy, immunotherapy, targeted therapy and radiation. Surgery is left blank. If no frequency is documented, the variable is left blank.

24.6 **If radiation – location of treatment** – *Nominal*: If ancillary treatment drug (variable 24.1) is "Radiation," defined as the location in which the targeted radiation was completed in the body. If in the brain, the number of lesions targeted for radiation is documented. If whole brain radiation therapy, variable is left blank. If no locations are documented, the variable is left blank.

Treatment Discontinuation

25 **Treatment discontinuation** – *Binary*: Yes/no – Defined as a clinical documentation of ALKi treatment discontinuation. If no, variables 25.1-25.5 are left blank.

25.1 **Date of treatment discontinuation** – *Date*: (same as date of end of ALKi treatment (variable 21.3)). Defined as the cessation date of the initial ALKi therapy. If a full date (day, month, year) is not documented but the month and year are, then the 15th (mid-month) is recorded as a reference date. For example, if incomplete date is documented as March of 2012, variable is documented as 3/15/12. If there is no record of the ALKi end date, but a date of initiation of next therapy is documented, then the day before the next

therapy initiation date is recorded as the end date for the ALKi treatment. If the subject died while on ALKi treatment, then the death date is recorded as the end date of treatment.

25.2 **Reason for discontinuation** – *Nominal*: Evidence of disease progression; Adverse events/intolerance; Patient-reported inconvenience; Financial toxicity; Pregnancy; Death; Loss of follow-up / end of follow-up; Other; Unknown - Defined as the clinically documented reason for discontinuation.

25.3 **If adverse event TD** – *Nominal*: If reason for discontinuation (variable 25.2) is "Adverse events/intolerance," defined as the clinically documented adverse event that was the cause of the treatment discontinuation. Variables are recorded as is exactly documented in the clinical record, with further consolidation during analysis.

25.4 **If disease progression TD** – *Nominal*: If reason for discontinuation (variable 25.2) is "Evidence of disease progression," defined as the type of imaging used to identify the disease progression that was the cause of the treatment discontinuation. Variables are recorded as is exactly documented in the clinical record, with further consolidation during analysis.

25.5 **If other discontinuation** – *Nominal*: If reason for discontinuation (variable 25.2) is "Other," defined as the reason for treatment discontinuation, if no other categories accurately describe the situation as defined in the clinical record. Variables are recorded as is exactly documented in the clinical record, with further consolidation during analysis.

Next Treatment

26 **Next treatment** – *Binary*: Yes/no - Defined as the next treatment/drug used after discontinuation of the initial ALKi therapy for the treatment of NSCLC. If no next treatment occurred or was documented, variables 26.1 and 26b.2 are left blank.

26.1 **Next treatment drug** – *Nominal*: Defined as the name of the drug or treatment provided after the initial ALKi therapy. Can include chemotherapy, immunotherapy, targeted therapy, radiation therapy and surgery. Variables are recorded as is exactly documented in the clinical record, with further consolidation during analysis.

26.2 **Next treatment onset date** – *Date*: Defined as the date the next NSCLC treatment was initiated post ALKi treatment. If a full date (day, month, year) is not documented but the month and year are, then the 15th (mid-month) is recorded as a reference date. For example, if incomplete date is documented as March of 2012, variable is documented as 3/15/12. If no next treatment date is documented in the clinical record, the variable is left blank.

Serious Adverse Events

27 **Serious Adverse Events (non-variable):** Defined as any hospitalizations documented in the clinical record while on initial ALKi therapy. If no SAEs are noted in the clinical record, variables 27.1-27.3 are left blank. If multiple SAEs are found, each SAE has its own associated row.

27.1 **AE – primary diagnosis** – *Nominal*: Defined as the discharge diagnosis for any hospitalization events

while on ALKi therapy. If discharge diagnosis is not available, the reason for hospitalization as documented in the clinical record is recorded. Variables are recorded as is exactly documented in the clinical record, with further consolidation during analysis.

27.2 **Encounter** – *Nominal*: Defined as the type of the encounter for the SAE. In this case, only hospitalization defines the parameters of the SAE and therefore every result for this variable is hospitalization.

27.3 **Date** – *Date*: Defined as the admission date to the hospital for the associated SAE. If a full date (day, month, year) is not documented but the month and year are, then the 15th (mid-month) is recorded as a reference date. For example, if incomplete date is documented as March of 2012, variable is documented as 3/15/12.

Other

28 **Last date of observation** – *Date*: If date of end of ALKi treatment (variable 21.3) is "ongoing" variables 28 and 29 are completed. Defined as the date in which the most recent documentation in the clinical record confirmed ongoing treatment of the initial ALKi. The date documented determines whether subject is lost to follow up or censored due to ongoing treatment of the ALKi in real time.

29 **Encounter type** – *Nominal*: If date of end of ALKi treatment (variable 21.3) is "ongoing" variables 28 and 29 are completed. Defined as the type of encounter used to confirm ongoing treatment of the initial ALKi. Including but not limited to – appointment, community visit, discharge summary, office visit, patient message, progress note, telephone message and video visit. Variables are recorded as is exactly documented in the clinical record.

30 **Seen as consult** – *Binary*: Yes/no - Defined as receiving primary care of NSCLC outside of the UCSF system at the time of ALKi initiation. If no, the subject is receiving primary care of NSCLC within the UCSF system at the time of ALKi initiation.

31 **If deceased date** – *Date*: Defined as the date of death documented in the clinical record. Deceased date either recorded directly from the UCSF electronic health system overview, or from within the clinical documents.

Exclusion

32 **Exclude** – *Binary*: Yes/no - Defined based on the inclusion/exclusion criteria as detailed above. If no, variables 32.1-32.4 are left blank.

32.1 **Exclude reason** – *Nominal*: < 18 years old; ALK negative; ALK QNS; No ALK record; No ALKi start date; No ALKi taken; No NSCLC; and No UCSF record - Defined as the reason for exclusion from the study.

32.2 **If ALK negative – mutation** – *Nominal*: If exclude reason (variable 32.1) is “ALK negative,” defined as the most significant clinically documented mutation associated with NSCLC. If no significant mutation is found, variable is marked as none.

32.3 **If no NSCLC** – *Nominal*: If exclude reason (variable 32.1) is “no NSCLC,” defined as the diagnosis of other cancer as detailed in the clinical record. If no other cancer diagnosis is found, variable is marked as none.

32.4 **Excluded first ALKi given** – *Nominal*: If exclude (variable 32) is “yes,” defined as the clinically documented initial ALKi prescribed.