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A study to characterize access to specialty care received by American Indians/Alaska Natives (CATORI)

Submission date 11/10/2022	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol
Registration date 11/10/2022	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 08/04/2024	**Condition category** Other	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol

Background and study aims:
The main purpose of this study is to explore ways to improve access to specialty care and clinical research for participants who are American Indians (AI) or Alaska Natives (AN). The study findings may also help reduce the amount of time needed to diagnose participants, could help improve the patient experience and reduce the overall cost of healthcare to society.

Who can participate?
People who are over 18 years of age, self-identify as American Indian or Alaska Native and have any indication requiring referral to a specialist (neurologist, ophthalmologist, or oncologist).

What does the study involve?
Participants will have to be a part of this study for 12 months (1 year).
Participants will be seen by their primary care provider (PCP) and specialists as per the Standard of Care (SoC) frequency. The participants will be asked to complete surveys and questionnaires during the study: up to twice during the study: after a visit with a new doctor or healthcare provider and at Months 6 and 12. The study visits at Months 6 and 12 may not coincide with the participants visit to the PCP or specialist. Study-specific data including surveys/ questionnaires will be collected during primary care office visits, specialty care office visits, by phone or virtually. The surveys included in this study ask questions about trust in the healthcare system, financial burden, effects of medical conditions and barriers experienced when accessing the healthcare system.

What are the possible benefits and risks of participating?
Participants will not receive any health benefit from participating in this study, but the information learned in this study may help researchers and doctors learn more about medical conditions in general. Other patients with the medical conditions observed in this study may benefit from results of such research in the future.
Participants will receive monetary benefit on participating in this study.
There are no risks from participating in the study.

Where is the study run from?
Genentech (United States)

When is the study starting and how long is it expected to run for?
July 2022 to October 2024

Who is funding the study?
Genentech, Inc. (United States)

Who is the main contact?
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Contact information

Type(s)
Public

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT05624788

Protocol serial number
ML44072

Study information

Scientific Title
Study to characterize access to specialty care received by American Indians/Alaska Natives (CATORI)

Acronym
CATORI

Study objectives
The main aim of this study is to estimate the proportion of American Indians (AI)/ Alaska Natives (AN) participants who are seen by a specialist for advanced care of those referred following a primary care provider (PCP) referral to a specialist (referral completion) and to determine if this proportion is lower than that of the general population.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved, 28/09/2022, WCG IRB (1019 39th Ave., SE Suite 120 Puyallup, WA 98374, USA; +1 (0) 855 818 2289; clientservices@wcgirb.com), ref: 20225255

Study design
Prospective observational data collection study to define current care pathways for AI/AN participants.

Primary study design
Observational

Study type(s)
Other

Health condition(s) or problem(s) studied
Participants requiring referral to specialty care (neurology, ophthalmology, oncology)

Interventions
Participants who self-identify as American Indian or Alaska Native with any indication requiring referral to a specialist (neurologist, ophthalmologist, and oncologist) after a PCP standard of care visit will be observed to collect data, using several surveys (e.g., for trust in the healthcare system, financial toxicity, reasons for not being seen by a specialist) for 12 months. Data will be collected to determine whether a participant was seen by a specialist, was diagnosed with a specialized disease, participant characteristics potentially associated with being seen or not seen by a specialist, and the reasons/barriers why a participant was not seen by a specialist.

Intervention Type
Other

Primary outcome(s)
Percentage of AI/AN participants seen by a specialist for advanced care after PCP referral to a specialist assessed using data collected in electronic case report forms (eCRF) at Months 6 and 12

Key secondary outcome(s))
1. Percentage of participants seen by a specialist and treated for their disease assessed using data collected in eCRF at Months 6 and 12
2. Participant reported barriers to specialty referral completion assessed using data collected from surveys at Months 6 and 12

Completion date
14/10/2024

Eligibility

Key inclusion criteria

1. Aged 18 years or more
2. Ability to read English at 8th grade proficiency or have a household member willing to assist in translation to complete patient surveys
3. Self-identification as American Indian or Alaska Native
4. Referred to an oncologist, neurologist, or ophthalmologist for the first time
5. Personal landline or cell phone and/or access to internet
6. Willingness to complete all surveys in the study and participate for 12 months

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Currently under the care of a specialist (>3 months) to whom they are being referred to by the PCP (i.e., to be eligible, the specialty care physician should be new to the participant)
2. Currently or planned to receive care that requires in participant visits for the indication requiring referral from the PCP (e.g., radiotherapy, chemotherapy for cancer diagnosis) within 3 months of consent date

Date of first enrolment
14/10/2022

Date of final enrolment
31/03/2024

Locations

Countries of recruitment
United States of America

Study participating centre
TBD
United States of America
TBD

Sponsor information

Organisation
Genentech, Inc.

Funder(s)

Funder type
Industry

Funder Name
Genentech

Alternative Name(s)
Genentech, Inc., Genentech USA, Inc., Genentech USA

Funding Body Type
Government organisation

Funding Body Subtype
For-profit companies (industry)

Location
United States of America

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analyzed during the current study are not expected to be made available due to participant-level data not being a regulatory requirement and to protect patient privacy as this study is conducted in a small patient community.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Study website	Study website	11/11/2025	11/11/2025	No	Yes