ClinicalTrials.gov API - Displaying Clinical Study Data in RShiny

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PHUSE SDE 2024 UK

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End-to-End Biometrics

ClinicalTrials.gov

- Since February 2000, ClinicalTrials.gov has provided sponsor-provided information of over 450,000 clinical trials and observational studies

- Key summary information:
  - trial description
  - design details
  - eligibility criteria

Example Study Information

- Easy access to **public** study information

Study Overview

Brief Summary

The primary aim of this study is to determine if doxycycline (100 mg bid) will inhibit (by at least 40%) the increase in greatest transverse diameter of small abdominal aortic aneurysms (3.5-5.0 cm in men, 3.5-4.5 cm in women) over a 24-month period of observation in comparison to a placebo-treated control group.

Detailed Description

N-TA^3CT is a randomized, double-blind, placebo-controlled test of the hypothesis that doxycycline 100 mg bid, will reduce the rate of increase of maximum transverse diameter of small (3.5-5.0 cm among men and 3.5 to 4.5 cm among women) abdominal aortic aneurysms. The primary outcome is abdominal aortic aneurysm (AAA) maximum transverse diameter determined by CT scans at two-year follow-up with allowance for baseline (pre-randomization) diameter. Based on an anticipated growth rate of 2.5 mm per year in the placebo group and the current threshold at which surgical intervention will be offered to trial participants, (5.5 cm in men, 5.0 cm in women), the upper limit of AAA size for inclusion has been

+ Show more

Official Title

Non-Invasive Treatment of Abdominal Aortic Aneurysm Clinical Trial (N-TA^3CT)

Conditions

Aneurysm

Intervention / Treatment

- Drug: Doxycycline
- Drug: Placebo

Study Start (Actual)

2013-05

Primary Completion (Actual)

2019-07-23

Study Completion (Actual)

2019-07-23

Enrollment (Actual)

261

Study Type

Interventional

Phase

Phase 2

Design Details

Primary Purpose : Treatment
Allocation : Randomized
Interventional Model : Parallel Assignment
Masking : Double (Participant, Investigator)

Eligibility Criteria

Description

Inclusion Criteria:

- Patients 55 years of age or older, women post-surgical menopause or at least two years since last menses if natural menopause.
- CT scan documented infrarenal abdominal aortic aneurysm with maximum transverse diameter larger than 35 mm and no greater than 50 mm, in men, and larger than 35 mm and no greater than 45 mm in women.

Exclusion Criteria:

- Patients will be excluded from the study if they are unable to give their own informed consent to participate.
- have symptoms related to abdominal aortic aneurysm.
- have other intra-abdominal vascular pathology that may require repair within 24 months (e.g., renal artery stenosis, large iliac artery aneurysms, iliac occlusive disease, aneurysmal involvement of the renal artery).
- have had previous abdominal aortic aneurysm repair by open surgical or endovascular technique.

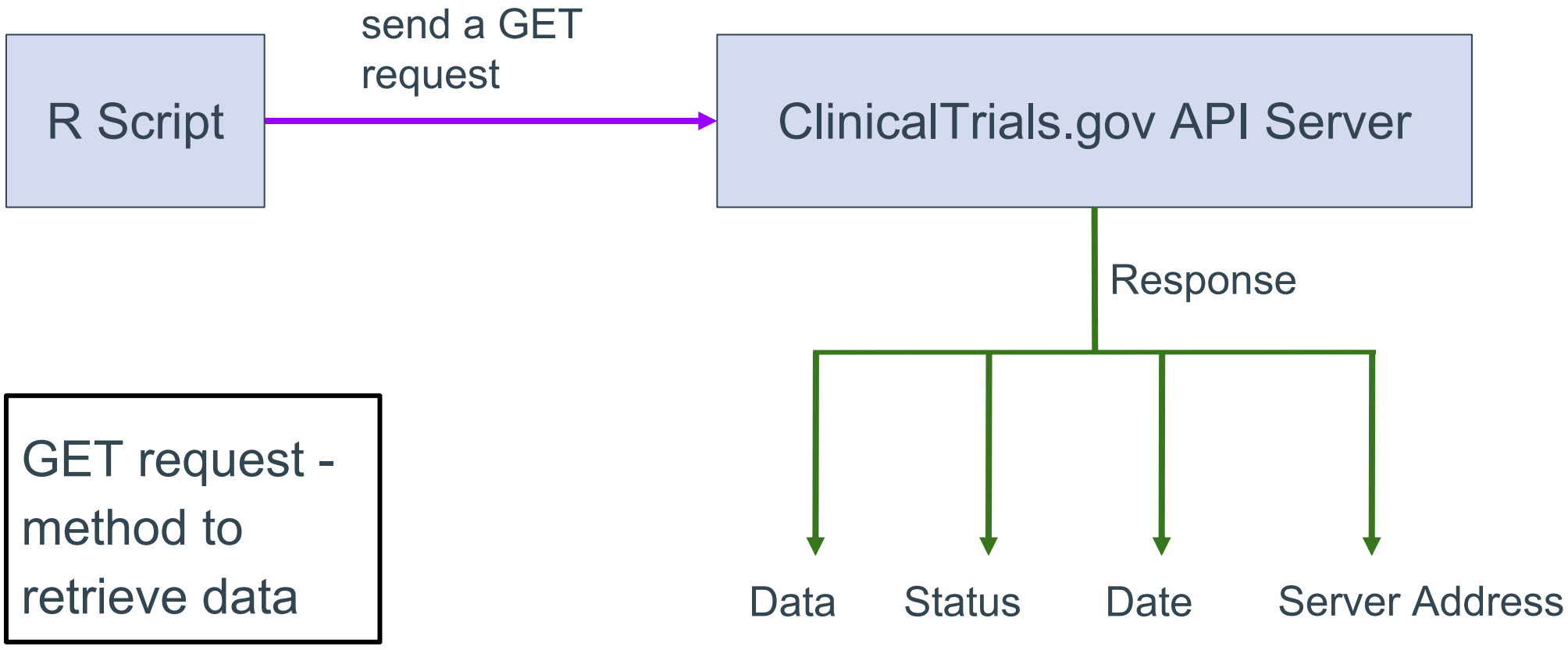
API (Application Programming Interface)

- Tools that allow software applications to share data

- Examples –
  - accessing weather data
  - paying with PayPal

- ClinicalTrials.gov API provides access to study information

Accessing Data



GET request - method to retrieve data

API URL

- Address of the server that the request is sent to
- Extract NCTID, condition, enrollment count of ‘aortic aneurysm’ studies -
  https://clinicaltrials.gov/api/v2/studies
  ?format=json
  &query.cond=aortic%20aneurysm
  &fields=NCTId%7CCondition%7CEnrollmentCount
  &sort=EnrollmentCount%3Adesc
  &pageSize=5

R Script to call API

```r
# load packages that contain functions that we use for API calling
library(dplyr)
library(httr)
library(jsonlite)
library(magrittr)
library(tidyr)

# send a GET request with API URL - retrieve data from the source
response <- httr::GET(
  "https://clinicaltrials.gov/api/v2/studies?format=json&query.cond
=aortic%20aneurysm&fields=NCTId%7CCondition%7CEnrollmentCount&sort
=EnrollmentCount%3Adesc&pageSize=5")

# view response - valid request returns 200
response

# convert response data to R object
response_list <- jsonlite::fromJSON(rawToChar(response$content))

# data is stored in a list - unnest data to expand list-columns
df <- as.data.frame(response_list$studies) %>%
  unnest(cols = `protocolSection`) %>%
  unnest(cols = `identificationModule`) %>%
  unnest(cols = `conditionsModule`) %>%
  unnest(cols = `designModule`) %>%
  unnest(cols = `enrollmentInfo`)

# clean the data by removing special characters
df[] <- lapply(df, function(x) gsub('c\\(', "", x))
df[] <- lapply(df, function(x) gsub('\\")', "", x))
df[] <- lapply(df, function(x) gsub('"', "", x))

colnames(df) <- c("NCTID", "Condition", "Enrollment Count")
```

Server address

```
> response
Response [https://clinicaltrials.gov/api/v2/studies?format=json&query.cond=aortic%20aneur
ysm&fields=NCTId%7CCondition%7CEnrollmentCount&sort=EnrollmentCount%3Adesc&pageSize=5]
  Date: 2024-04-11 12:35
  Status: 200
  Content-Type: application/json
  Size: 2.72 kB
{"studies":[
{"protocolSection":{"identificationModule":{"nctId":"NCT01864031"},"condition...
{"protocolSection":{"identificationModule":{"nctId":"NCT01804439"},"condition...
{"protocolSection":{"identificationModule":{"nctId":"NCT01704300"},"condition...
{"protocolSection":{"identificationModule":{"nctId":"NCT01947361"},"condition...
{"protocolSection":{"identificationModule":{"nctId":"NCT01937065"},"condition...
```

Status Code

Response Data (JSON format)

	NCTID	Condition	Enrollment Count
1	NCT01864031	Chronic Stable Angina, Unstable Angina, Coronary Heart Dis...	2240000
2	NCT01804439	Heart Diseases, Cardiovascular Diseases, Acute Myocardial I...	2240000
3	NCT01704300	Abdominal Aortic Aneurysm, Acute Myocardial Infarction, St...	2240000
4	NCT01947361	Abdominal Aortic Aneurysm, Coronary Heart Disease NOS, ...	1961286
5	NCT01937065	Abdominal Aortic Aneurysm, Coronary Heart Disease NOS, ...	1937360

Search ‘DATAQUEST R API Tutorial’

Displaying Data in RShiny

- Design a function to return specific query study data

```
study_search("aortic aneurysm")
```

	nctId	id	officialTitle	overallStatus	startDateStruct_date
1	NCT01937065	12 153R IP4	*NA*	UNKNOWN	2012-01
2	NCT03365050	0635	Data Linkage Between NHS AAA Screening Programme and ...	NOT YET RECRUITING	2021-12-01

- Design an interface where a user enters a condition
- Interface displays data

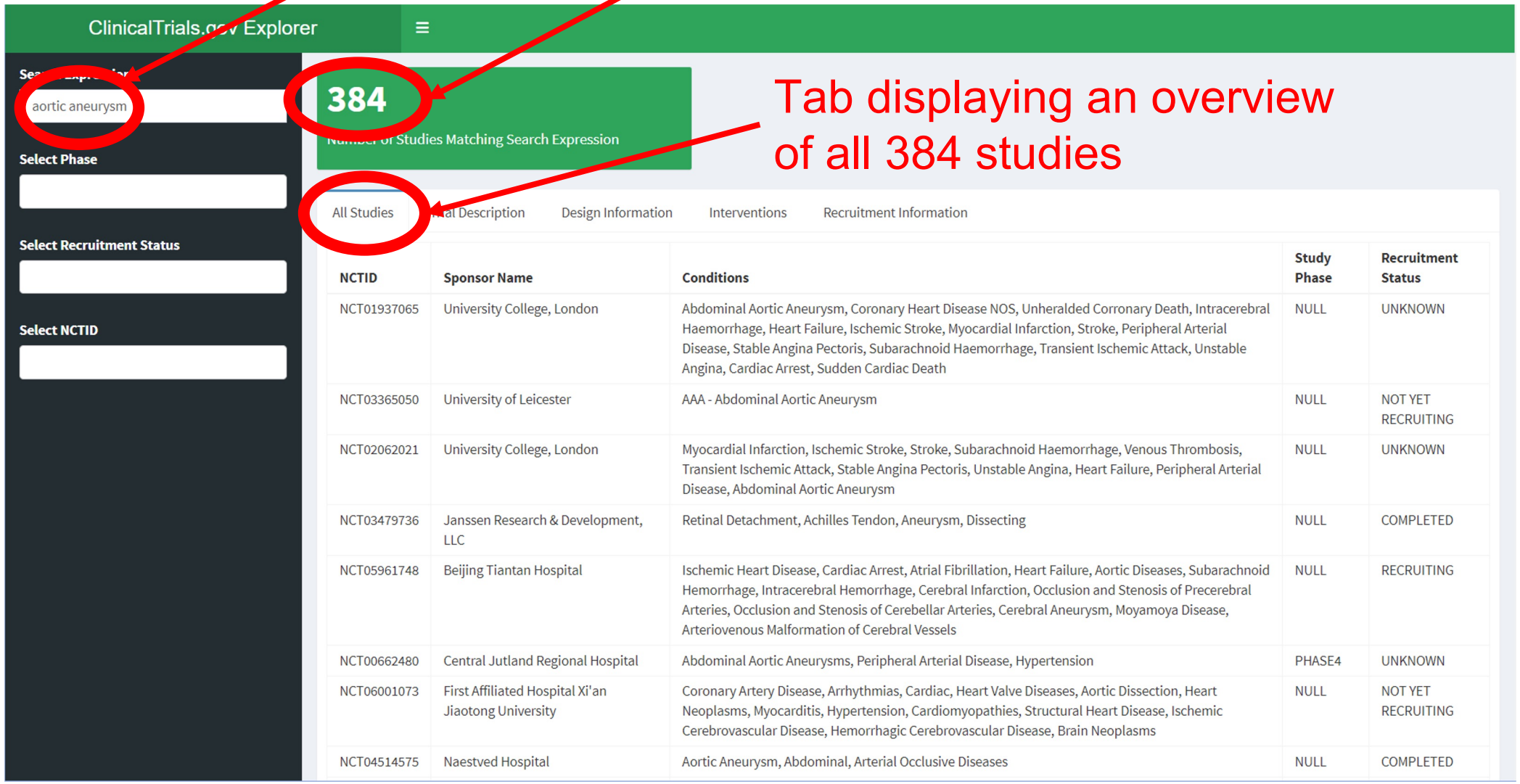
RShiny Demonstration

All ClinicalTrials.gov data is public. No confidential information is presented!

User search expression

Number of studies matching the search expression

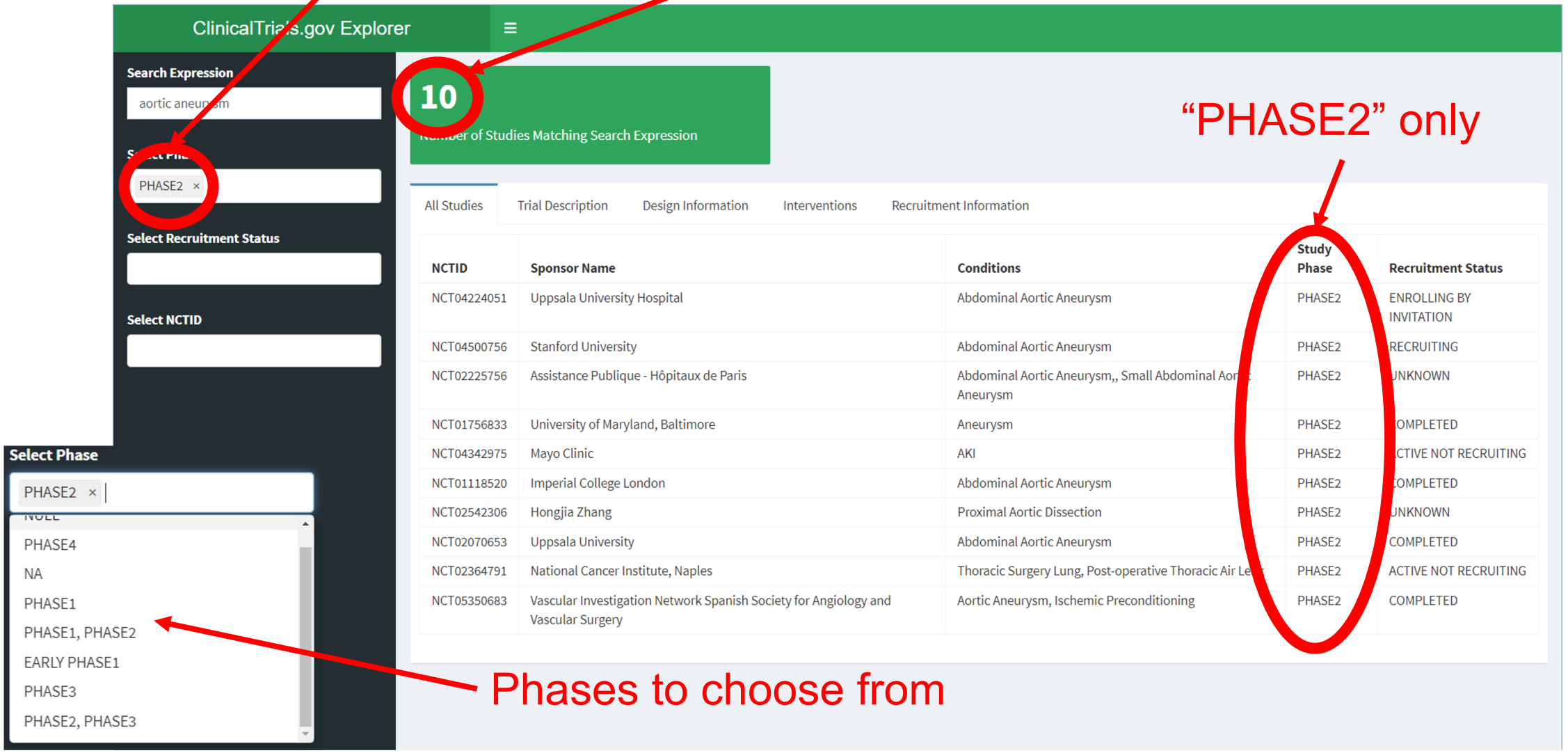
Tab displaying an overview of all 384 studies



NCTID	Sponsor Name	Conditions	Study Phase	Recruitment Status
NCT01937065	University College, London	Abdominal Aortic Aneurysm, Coronary Heart Disease NOS, Unheralded Corronary Death, Intracerebral Haemorrhage, Heart Failure, Ischemic Stroke, Myocardial Infarction, Stroke, Peripheral Arterial Disease, Stable Angina Pectoris, Subarachnoid Haemorrhage, Transient Ischemic Attack, Unstable Angina, Cardiac Arrest, Sudden Cardiac Death	NULL	UNKNOWN
NCT03365050	University of Leicester	AAA - Abdominal Aortic Aneurysm	NULL	NOT YET RECRUITING
NCT02062021	University College, London	Myocardial Infarction, Ischemic Stroke, Stroke, Subarachnoid Haemorrhage, Venous Thrombosis, Transient Ischemic Attack, Stable Angina Pectoris, Unstable Angina, Heart Failure, Peripheral Arterial Disease, Abdominal Aortic Aneurysm	NULL	UNKNOWN
NCT03479736	Janssen Research & Development, LLC	Retinal Detachment, Achilles Tendon, Aneurysm, Dissecting	NULL	COMPLETED
NCT05961748	Beijing Tiantan Hospital	Ischemic Heart Disease, Cardiac Arrest, Atrial Fibrillation, Heart Failure, Aortic Diseases, Subarachnoid Hemorrhage, Intracerebral Hemorrhage, Cerebral Infarction, Occlusion and Stenosis of Precerebral Arteries, Occlusion and Stenosis of Cerebellar Arteries, Cerebral Aneurysm, Moyamoya Disease, Arteriovenous Malformation of Cerebral Vessels	NULL	RECRUITING
NCT00662480	Central Jutland Regional Hospital	Abdominal Aortic Aneurysms, Peripheral Arterial Disease, Hypertension	PHASE4	UNKNOWN
NCT06001073	First Affiliated Hospital Xi'an Jiaotong University	Coronary Artery Disease, Arrhythmias, Cardiac, Heart Valve Diseases, Aortic Dissection, Heart Neoplasms, Myocarditis, Hypertension, Cardiomyopathies, Structural Heart Disease, Ischemic Cerebrovascular Disease, Hemorrhagic Cerebrovascular Disease, Brain Neoplasms	NULL	NOT YET RECRUITING
NCT04514575	Naestved Hospital	Aortic Aneurysm, Abdominal, Arterial Occlusive Diseases	NULL	COMPLETED

Filter by phase

Filtered Studies

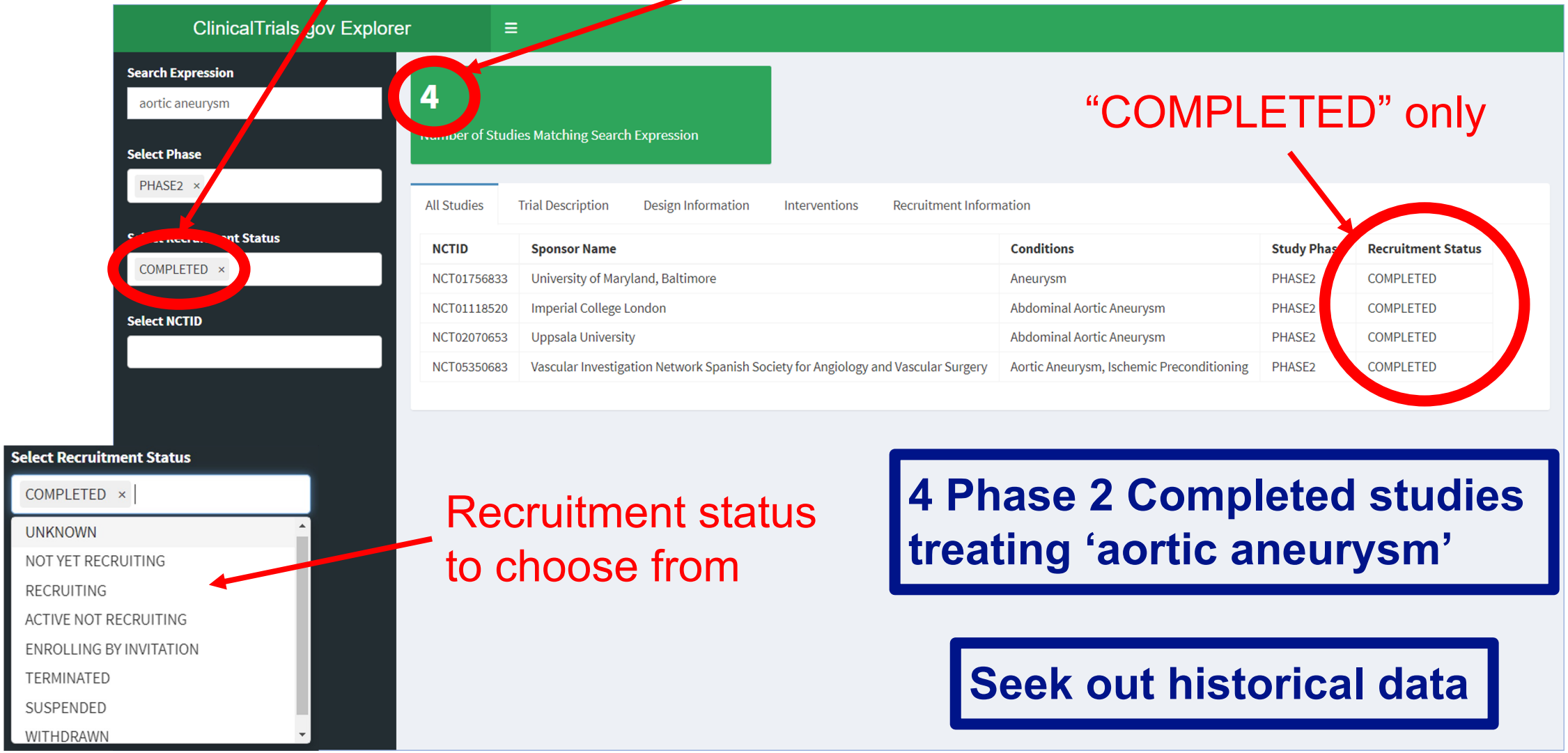


"PHASE2" only

Phases to choose from

Filter by recruitment status

Filtered Studies



"COMPLETED" only

Recruitment status to choose from

4 Phase 2 Completed studies treating 'aortic aneurysm'

Seek out historical data

Select NCTIDs to investigate

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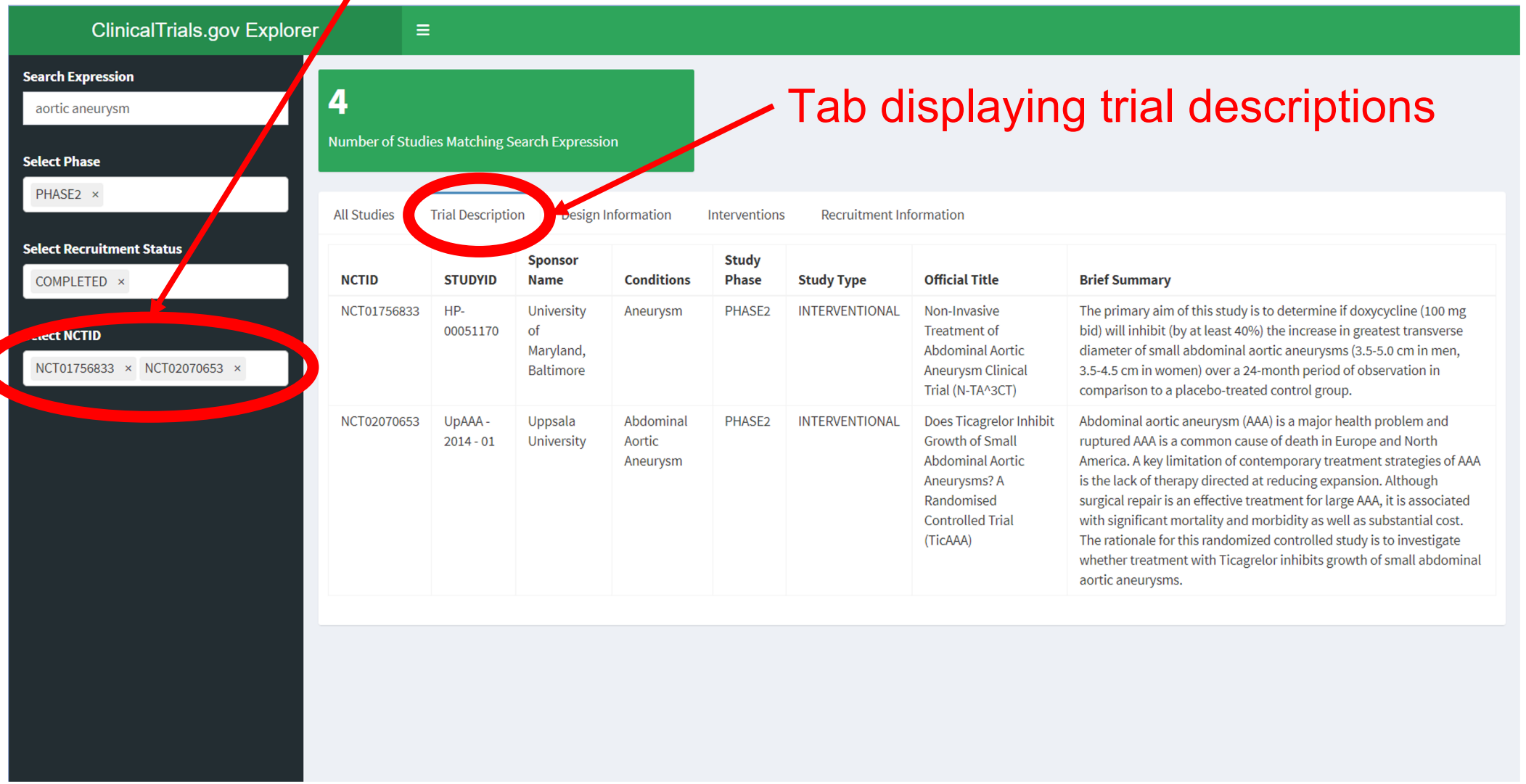
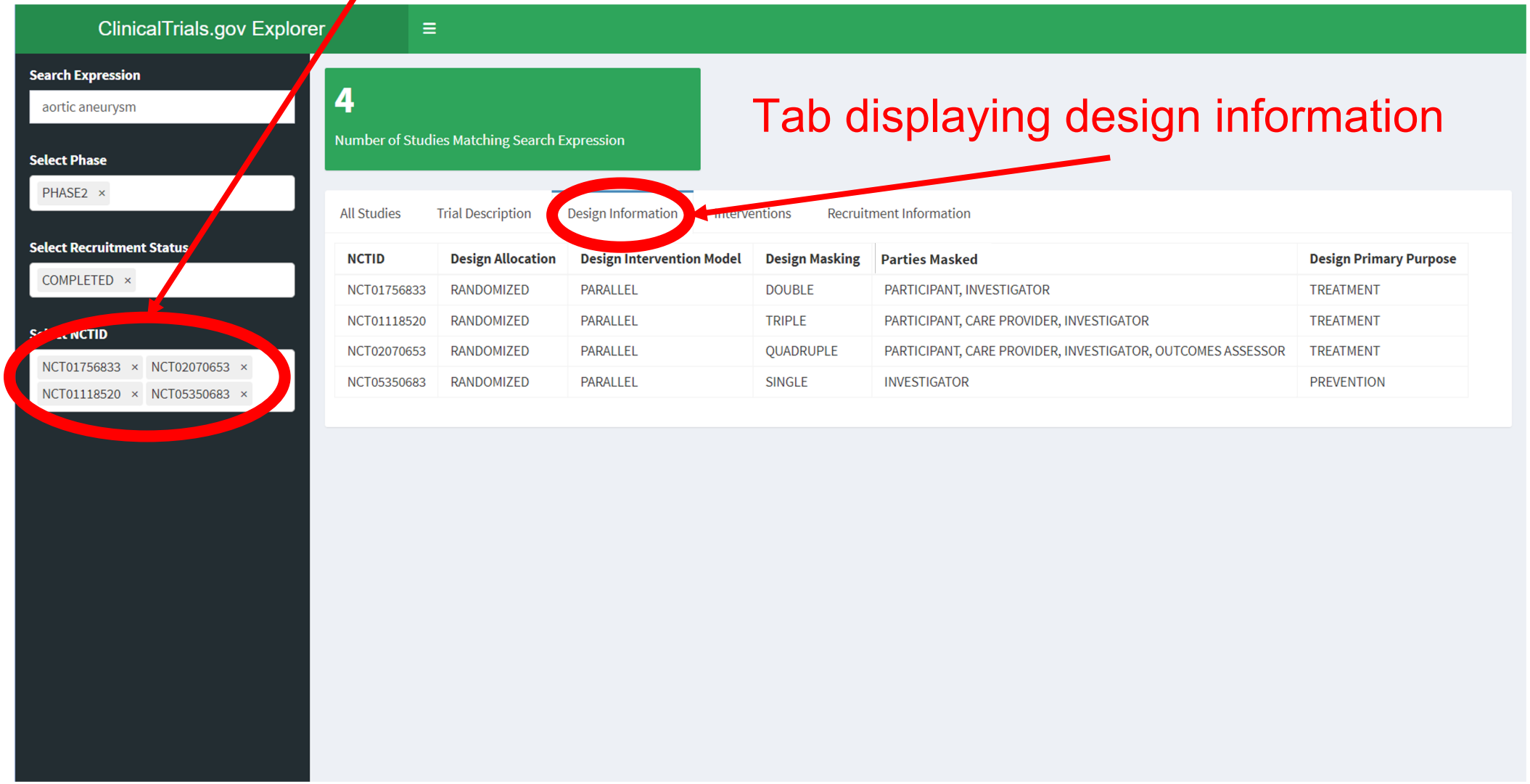
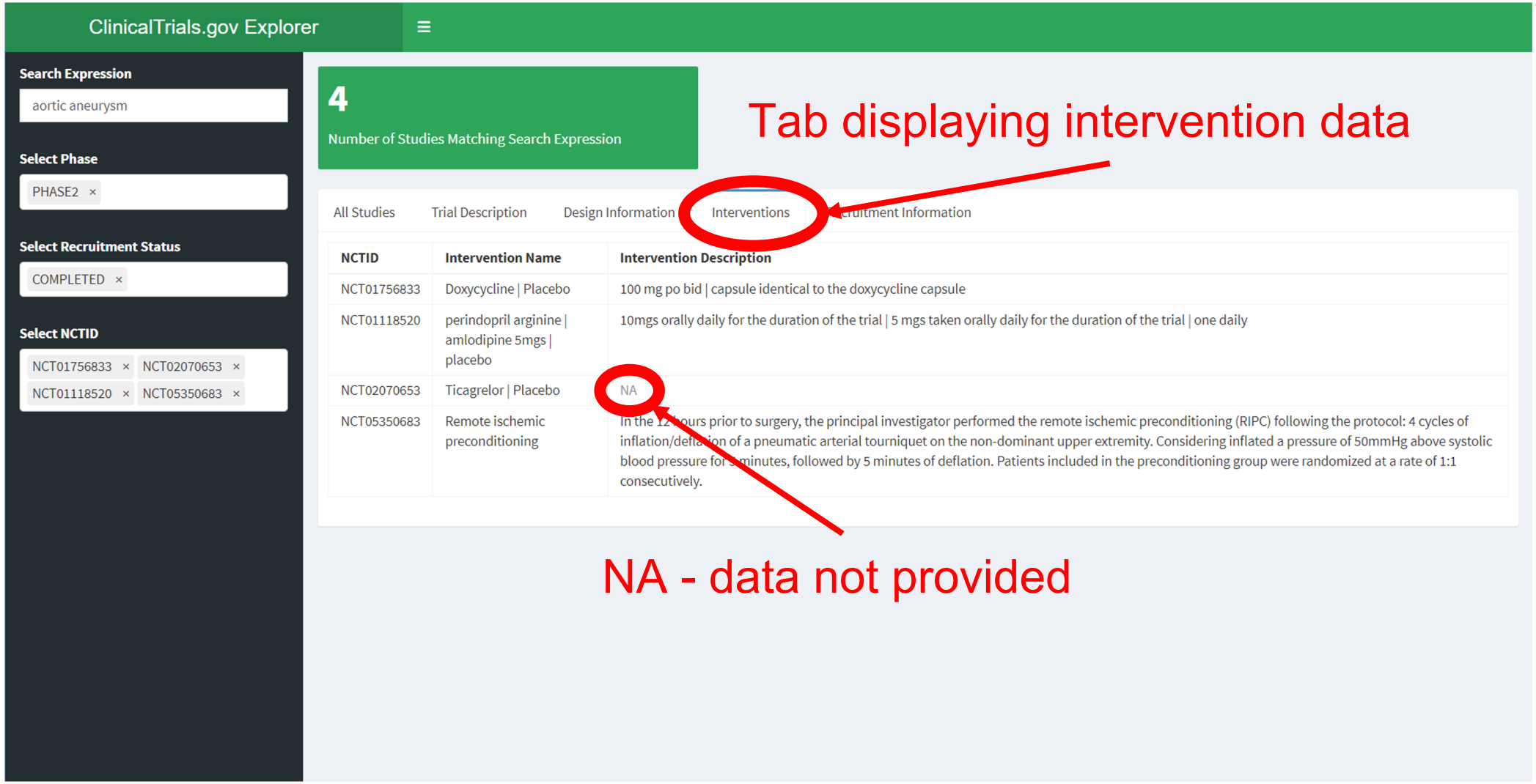


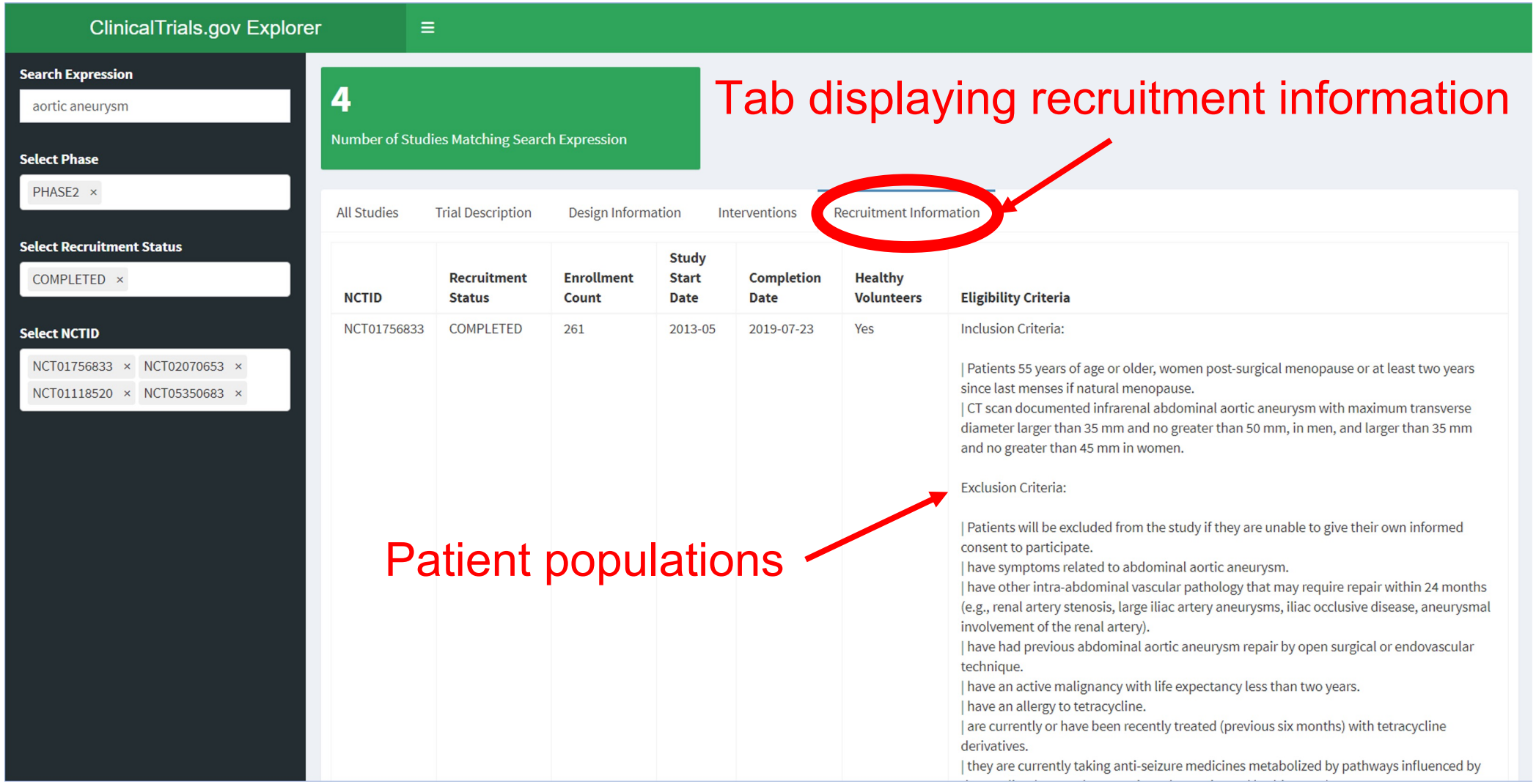
Tab displaying trial descriptions

Add or remove NCTIDs



NCTID	Design Allocation	Design Intervention Model	Design Masking	Parties Masked	Design Primary Purpose
NCT01756833	RANDOMIZED	PARALLEL	DOUBLE	PARTICIPANT, INVESTIGATOR	TREATMENT
NCT01118520	RANDOMIZED	PARALLEL	TRIPLE	PARTICIPANT, CARE PROVIDER, INVESTIGATOR	TREATMENT
NCT02070653	RANDOMIZED	PARALLEL	QUADRUPLE	PARTICIPANT, CARE PROVIDER, INVESTIGATOR, OUTCOMES ASSESSOR	TREATMENT
NCT05350683	RANDOMIZED	PARALLEL	SINGLE	INVESTIGATOR	PREVENTION


ClinicalTrials.gov Explorer
Search Expression
aortic aneurysm
Select Phase
PHASE2 ×
Select Recruitment Status
COMPLETED ×
Select NCTID
NCT01756833 × NCT02070653 × NCT01118520 × NCT05350683 ×
4
Number of Studies Matching Search Expression
Tab displaying intervention data
All Studies
Trial Description
Design Information
Interventions
NCTID
Intervention Name
Intervention Description
NCT01756833
Doxycycline | Placebo
100 mg po bid | capsule identical to the doxycycline capsule
NCT01118520
perindopril arginine | amlodipine 5mgs | placebo
10mgs orally daily for the duration of the trial | 5 mgs taken orally daily for the duration of the trial | one daily
NCT02070653
Ticagrelor | Placebo
NA
NCT05350683
Remote ischemic preconditioning
NA - data not provided


ClinicalTrials.gov Explorer
Search Expression
aortic aneurysm
Select Phase
PHASE2 ×
Select Recruitment Status
COMPLETED ×
Select NCTID
NCT01756833 × NCT02070653 ×
NCT01118520 × NCT05350683 ×
4
Number of Studies Matching Search Expression
Tab displaying recruitment information
All Studies
Trial Description
Design Information
Interventions
Recruitment Information
NCTID
Recruitment Status
Enrollment Count
Study Start Date
Completion Date
Healthy Volunteers
Eligibility Criteria
NCT01756833
COMPLETED
261
2013-05
2019-07-23
Yes
Inclusion Criteria:
| Patients 55 years of age or older, women post-surgical menopause or at least two years since last menses if natural menopause.
| CT scan documented infrarenal abdominal aortic aneurysm with maximum transverse diameter larger than 35 mm and no greater than 50 mm, in men, and larger than 35 mm and no greater than 45 mm in women.
Exclusion Criteria:
| Patients will be excluded from the study if they are unable to give their own informed consent to participate.
| have symptoms related to abdominal aortic aneurysm.
| have other intra-abdominal vascular pathology that may require repair within 24 months (e.g., renal artery stenosis, large iliac artery aneurysms, iliac occlusive disease, aneurysmal involvement of the renal artery).
| have had previous abdominal aortic aneurysm repair by open surgical or endovascular technique.
| have an active malignancy with life expectancy less than two years.
| have an allergy to tetracycline.
| are currently or have been recently treated (previous six months) with tetracycline derivatives.
| they are currently taking anti-seizure medicines metabolized by pathways influenced by
Patient populations

Future Developments

- Open-source
- Different search expressions?
  - sponsor + condition
  - filter by sponsor
  - advanced search
- Extract study results
  - participant flow
  - participant characteristics
  - adverse events

Arm/Group Title	Doxycycline	Placebo
Arm/Group Description	100 mg capsules, twice a day, for a period of two years. Doxycycline: 100 mg po bid	100 mg capsules, twice a day, for a period of two years. Placebo: capsule identical to the doxycycline capsule
Period Title: **Overall Study**		
Started	133	128
Completed	129	125
Not Completed	4	3
Reason Not Completed		
Withdrawal by Subject	4	3

Sex: Female, Male
Measure Type: Count of Participants | Unit of measure: Participants

Number Analyzed	129 participants	125 participants
Female	18 14.0%	17 13.6%
Male	111 86.0%	108 86.4%

Thank you for listening

Contact -

iolo.williams@veramed.co.uk