



## Pan Tumor Nivolumab Rollover Study

**CLINICALTRIALS.GOV IDENTIFIER**  
NCT03899155

**RECRUITMENT STATUS**  
RECRUITING

**FIRST POSTED**  
APRIL 2, 2019

**LAST UPDATE POSTED**  
NOVEMBER 24, 2021

### STUDY DESCRIPTION

#### Brief Summary

Main Objective of this study is to examine long-term safety of nivolumab in participants on treatment and in follow up.

**Condition or Disease:** Cancer

**Intervention/treatment:** Drug: Nivolumab

**Phase:** Phase 2

### DETAILED DESCRIPTION

N/A

### STUDY DESIGN

<b>Study Type:</b>	Interventional	<b>Actual Study Start Date:</b>	August 2019
<b>Estimated Enrollment :</b>	800 participants	<b>Estimated Primary Completion Date:</b>	August 2025
<b>Intervention Model :</b>	Parallel Assignment	<b>Estimated Study Completion Date:</b>	August 2025
<b>Masking:</b>	None (Open Label) ()		
<b>Primary Purpose:</b>	Treatment		
<b>Official Title:</b>	Pan-Tumor Study for Long Term Follow-up of Cancer Survivors Who Have Participated in Trials Investigating Nivolumab		

### ARMS AND INTERVENTIONS

Arm	Intervention/treatment
Experimental: Nivolumab Dose 1 Specified Dose on Specified Days	Drug: Nivolumab Solution for IV Injection
Experimental: Nivolumab Dose 2 Specified Dose on Specified Days	Drug: Nivolumab Solution for IV Injection

### OUTCOME MEASURES

Primary Outcome Measures:

1. Incidence of AEs leading to Discontinuation [ Time Frame: From Day 1 up to 100 Days after discontinuation of treatment ]
2. Incidence of drug related AEs [ Time Frame: From Day 1 up to 100 Days after discontinuation of treatment ]
3. Incidence of Adverse Events (AEs) [ Time Frame: From Day 1 up to 100 Days after discontinuation of treatment ]
4. Incidence of Serious Adverse Events (SAEs) [ Time Frame: From signature of Informed Consent up to 100 Days after discontinuation of treatment ]
5. Incidence of Select AEs [ Time Frame: From Day 1 up to 100 Days after discontinuation of treatment ]
6. Incidence of Immune-Mediated AEs [ Time Frame: From Day 1 up to 100 Days after discontinuation of treatment ]
7. Incidence of Death [ Time Frame: From signature of Informed Consent up to 100 Days after discontinuation of treatment ]

### ELIGIBILITY CRITERIA

**Ages Eligible for Study:** 18 Years and older (Adult, Older Adult)

**Sexes Eligible for Study:** All

**Accepts Healthy Volunteers:** No

**Criteria**

**Inclusion Criteria: -**

Signed Written Informed Consent Participants who have completed treatment with nivolumab, progressed on prior nivolumab treatment or discontinued nivolumab due to toxicity in the Parent Study are not eligible to receive nivolumab in this study. These participants may be enrolled for safety and survival follow-up only. Participant is eligible for nivolumab treatment as per the Parent Study, and/or Investigator assessed clinical benefit, or Participant is in or has completed the follow-up phase of the Parent Study i) Participant has completed or discontinued treatment, or ii) Participant has progressed on treatment, and/or iii) Participant is on subsequent therapy Exclusion Criteria: - Participant is not eligible for nivolumab treatment as per the Parent Study Participants not receiving clinical benefit as assessed by the Investigator (participant is still eligible for study if entering survival follow-up only) Any clinical adverse event (AE), laboratory abnormality, or intercurrent illness which, in the opinion of the Investigator, indicates that participation in the study is not in the best interest of the participant Participants in survival follow-up have no exclusion criteria.

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**CONTACTS AND LOCATIONS**

**Contacts**

Contact: Recruiting sites have contact information. Please contact the sites directly. If there is no contact information available, please email

[Clinical.Trials@bms.com](mailto:Clinical.Trials@bms.com)

Contact: First line of the email MUST contain NCT# and Site#

**Locations**

United States, California	Local Institution	San Francisco
United States, California	UCSF Medical Center - Helen Diller Family Comprehensive Cancer Center - Melanoma Center	San Francisco
United States, Connecticut	Local Institution	New Haven
United States, District of Columbia	Georgetown-Lombardi Comprehensive Cancer Center	Washington
United States, Florida	Local Institution	Orlando
United States, Florida	H. Lee Moffitt Cancer Center and Research Institute Hospital, Inc.	Tampa
United States, Georgia	Local Institution	Atlanta
United States, Illinois	The University of Chicago Medical Center	Chicago
United States, Illinois	Local Institution	Maywood
United States, Kansas	University of Kansas Cancer Center	Westwood
United States, Kansas	Cancer Center of Kansas	Wichita
United States, Kentucky	University of Louisville	Louisville
United States, Maryland	Johns Hopkins	Baltimore
United States, Massachusetts	Local Institution	Boston
United States, Massachusetts	Local Institution	Boston
United States, Massachusetts	Local Institution	Boston
United States, Michigan	Local Institution	Ann Arbor
United States, Minnesota	Allina Health	Minneapolis
United States, Missouri	Local Institution	Saint Louis
United States, Nebraska	GU Research Network/Urology Cancer Center	Omaha
United States, New Hampshire	Dartmouth-Hitchcock Medical Center	Lebanon
United States, New Mexico	Local Institution	Albuquerque
United States, New York	Roswell Park Cancer Institute	Buffalo
United States, New York	Local Institution	New York
United States, New York	Local Institution	New York
United States, New York	Local Institution	New York
United States, New York	Local Institution	New York
United States, North Carolina	Levine Cancer Center	Charlotte
United States, North Carolina	Duke University	Durham
United States, Ohio	Oncology Hematology Care	Cincinnati
United States, Ohio	Local Institution	Cleveland
United States, Ohio	The Ohio University	Columbus
United States, Pennsylvania	Lehigh Valley Hospital	Allentown

United States, Pennsylvania	St. Lukes University Health Network	Easton
United States, Pennsylvania	Local Institution	Philadelphia
United States, Pennsylvania	Local Institution	Philadelphia
United States, Pennsylvania	Hillman Cancer Center- U of Pitts Cancer Institute	Pittsburgh
United States, South Carolina	Charleston Oncology	Charleston
United States, South Carolina	Local Institution	Greenville
United States, Tennessee	Local Institution	Chattanooga
United States, Tennessee	Tennessee Oncology - Nashville	Nashville
United States, Texas	Local Institution	Dallas
United States, Utah	Local Institution	Salt Lake City
United States, Virginia	Local Institution	Charlottesville
United States, Wisconsin	Local Institution	Madison
United States, Wisconsin	UW Health - UW Carbone Cancer Center - Medical Oncology Clinic	Madison
Argentina, Buenos Aires	Centro Oncologico y de Investigacion Buenos Aires	Berazategui
Argentina, Buenos Aires	Instituto Fleming	Caba
Argentina, Tucuman	CAIPO Centro para la Atencion Integraldel Paciente Oncologico	San Miguel De Tucuman
Argentina	Local Institution	Buenos Aires
Argentina	Local Institution	Caba
Argentina	Local Institution	Cordoba
Australia, New South Wales	North Coast Area Health Service NCAHS - The North Coast Cancer Institute NCCI - Coffs Harbour Health	Coffs Harbour
Australia, New South Wales	Melanoma Institute Australia	North Sydney
Australia, New South Wales	Chris OBrien Lifehouse Hospital	Sydney
Australia, New South Wales	Calvary Mater Newcastle	Waratah
Australia, New South Wales	Westmead Hospital	Westmead
Australia, Queensland	Local Institution	Greenslopes
Australia, Queensland	Local Institution	South Brisbane
Australia, South Australia	Local Institution	Adelaide
Australia, South Australia	Lyell McEwin Hospital	Elizabeth Vale
Australia, Victoria	Cabrini Hospital Malvern	Malvern
Austria	Ordensklinikum Linz GmbH Elisabethinen	Linz
Austria	Allgemeine Krankenhaus Wien	Vienna
Austria	Klinikum Wels- Grieskirchen	Wels
Belgium	Universitair Ziekenhuis Gent	Gent
Belgium	UZ Brussel Campus Jette	Jette
Belgium	Cliniques Universitaires UCL de Mont-Godinne (CHU)	Yvoir
Brazil, RIO Grande DO SUL	Hospital de Caridade de Ijuí	Ijuí
Brazil, RIO Grande DO SUL	Irmandade da Santa Casa de Misericordia de Porto Alegre	Porto Alegre
Brazil, SAO Paulo	Local Institution	Porto Alegre
Canada, Alberta	Cross Cancer Institute	Edmonton
Canada, British Columbia	Local Institution	Vancouver
Canada, Nova Scotia	Local Institution	Halifax
Canada, Ontario	Durham Regional Cancer Ctr	Oshawa
Canada, Quebec	Local Institution	Montreal
Chile, Metropolitana	Local Institution	Santiago

Chile, Metropolitana	Local Institution	Santiago
Chile, Metropolitana	Bradford Hill Centro de Investigacion Clinica	Santiago
Chile, Valparaiso	Local Institution	VinadelMar
China, Anhui	Local Institution	Hefei
China, Beijing	Local Institution	Beijing
China, Guangdong	Local Institution	Guangzhou
China, Heilongjiang	Local Institution	Harbin Shi
China, Hunan	Local Institution	Changsha
China, Jilin	Local Institution	Changchun City
China, Shanghai	Local Institution	Shanghai
China, Shanghai	Local Institution	Shanghai
Czechia	Local Institution	Olomouc
Denmark	Local Institution	Odense C
Finland	Local Institution	Helsinki
France	Centre Hospitalier Universitaire de Bordeaux Hospital Saint Andre	Bordeaux
France	Centre Hospitalier Intercommunal de Creteil CHIC	Creteil
France	Centre Georges-Francois Leclerc	Dijon Cedex
France	Local Institution	Dijon Cedex
France	CHU Grenobles Alpes	Grenoble
France	Pole Biologie Pathologie Genetique - CHU de Lille	Lille Cedex
France	APHM - Hopital Nord	Marseille Cedex 20
France	APHM - Hopital de la Timone	Marseille
France	CHU Montpellier	Montpellier
France	Local Institution	Montpellier
France	Hopital europeen Georges Pompidou HEGP	Paris Cedex 15
France	Hospital Saint-Louis	Paris
France	Centre Hospitalier Lyon Sud	Pierre Benite Cedax
France	Local Institution	Rennes
France	Hopital Musse	Toulon
France	Local Institution	Toulouse Cedex
France	Institut Gustave Roussy	Villejuif
Germany	Universitaetsklinikum Aachen	Aachen
Germany	Local Institution	Gera
Germany	SRH Wald-Klinikum Gera GmbH	Gera
Germany	Local Institution	Goettingen
Germany	Universitaetsmedizin Gottingen	Gottingen
Germany	Local Institution	Hamburg
Germany	Local Institution	Heidelberg
Germany	Thoraxklinik	Heidelberg
Germany	Universitaetsklinikum Jena - Klinik und Poliklinik fuer Urologie	Jena
Germany	Local Institution	Kiel
Germany	Unv Schleswig-Holstein Campus Kiel	Kiel
Germany	Local Institution	Koeln
Germany	Katholisches Klinikum Mainz	Mainz
Germany	Local Institution	Mainz

Germany	Universitaetsklinikum Tuebingen	Tuebingen
Greece	Local Institution	Athens
Greece	Sotiria General Hospital of Chest Diseases	Athens
Greece	General Hospital of Athens Alexandra	Athens
Greece	Local Institution	Patras
Greece	Metropolitan Hospital	Piraeus
Greece	Interbalcan Medical Centre	Thessaloniki
Hungary	Local Institution	Budapest
Hungary	Orszagos Koranyi TBC es Pulmonologiai Intezet	Budapest
Hungary	DE Klinikai Kozpont	Debrecen
Ireland	Local Institution	Dublin
Ireland	Local Institution	Limerick
Israel	Local Institution	Haifa
Israel	Local Institution	Petach Tikva
Israel	Local Institution	Tel Hashomer
Italy	Istituto Tumori Giovanni Paolo II IRCCS Ospedale Oncologico Bari	Bari
Italy	Local Institution	Bergamo
Italy	Local Institution	Genova
Italy	Local Institution	Meldola
Italy	Local Institution	Milano
Italy	IRCCS Istituto Europeo di Oncologia	Milano
Italy	Local Institution	Milano
Italy	Fondazione IRCCS Istituto Nazionale Tumori	Milan
Italy	Istituto Nazionale dei Tumori	Napoli
Italy	Istituto Nazionale Tumori - Fondazione Pascale Italy	Napoli
Italy	Istituto Oncologico Veneto	Padova
Italy	AUSL Romagna	Ravenna
Italy	Istituto Nazionale dei Tumori Regina Elena	Roma
Italy	Azienda ospedaliero-universitaria Senese di Santa Maria alle Scotte	Siena
Japan, Aichi	Aichi Cancer Center Hospital	Nagoya
Japan, Aomori	Hirosaki University Hospital	Hirosaki
Japan, Hyogo	Kobe City Medical Center General Hospital	Kobe shi
Japan, Ibaraki	University of Tsukuba Hospital	Tsukuba
Japan, Ishikawa	Local Institution	Kanazawa-shi
Japan, Miyagi	Miyagi Cancer Center	Natori-shi
Japan, Niigata	Niigata Cancer Center Hospital	Chuo-ku Niigata-shi
Japan, Niigata	Niigata University Medical and Dental Hospital	Niigata-Shi
Japan, Osaka	Kindai University Hospital	Osakasayama
Japan, Osaka	Osaka Medical and Pharmaceutical University Hospital	Takatsuki shi
Japan, Tokyo	National Cancer Central Hospital	Chuo-ku
Japan, Tokyo	The Cancer Institute Hospital of JFCR	Koto-Ku
Japan, Tokyo	Keio University Hospital	Shinjuku
Japan	Local Institution	Fukuoka
Korea, Republic of	Local Institution	Seongnam-si
Korea, Republic of	Local Institution	Seoul

Korea, Republic of	Local Institution	Yeongtong-Gu, Suwon-Si
Mexico, Distrito Federal	Local Institution	Ciudad De Mexico
Mexico, Guanajuato	Local Institution	Leon
Mexico, Michoacan	Hospital Victoria Medical Center	Morelia
Netherlands	Local Institution	Rotterdam
Norway	Haukeland Universitetssjukehus	Bergen
Norway	Radiumhospitalet	Oslo
Peru, Lima	Centro de Investigacion Clinica Montesur	Santiago de Surco
Poland	Uniwersyteckie Centrum Kliniczne	Gdansk
Poland	Wojewodzkie Centrum Onkologii	Gdansk
Poland	Instytut MSF Sp zoo	Lodz
Poland	Ms Pneumed Janusz Milanowski Katarzyna Szmygin-Milanowska Sp. J.	Lublin
Poland	Centrum Medyczne Pratia Poznan	Poznan
Poland	Local Institution	Warsaw
Poland	Wojskowy Instytut Medyczny	Warsaw
Poland	Maria Sklodowska-Curie Memorial Cancer Center and Institute of Oncology	Warszawa
Portugal	Centro Hospitalar de Lisboa Norte EPE - HPV	Lisboa
Portugal	Instituto Portugues de Oncologia de Lisboa	Lisbon
Portugal	Local Institution	Porto
Romania	Institutul Oncologic Bucuresti IOB	Bucharest
Romania	Institutul Oncologic Prof. Dr. I. Chiricuta	Cluj Napoca
Romania	Local Institution	Cluj Napoca
Romania	Cardiomed SRL	Cluj-Napoca
Romania	Sf Nectarie Oncology Center	Craiova
Romania	SC Pelican Impex SRL	Oradea
Russian Federation	N.N. Blokhin National Medical Research Center of Oncology	Moscow
Russian Federation	N.N. Blokhin National Medical Research Center of Oncology	Moscow
Russian Federation	VitaMed LLC	Moscow
Spain	Hospital Teresa Herrera C.H.U.A.C.	A Coruna
Spain	Hospital General Universitario de Alicante	Alicante
Spain	Catalan Institute of Badalona Hospital Germans Trias i Pujol ICO	Badalona
Spain	Hospital Universitari Vall d Hebron	Barcelona
Spain	Hospital Clinic de Barcelona	Barcelona
Spain	Institut Catala dOncologia LHospitalet	Barcelona
Spain	Local Institution	Barcelona
Spain	Hospital Universitario de Burgos	Burgos
Spain	Local Institution	Granada
Spain	Centro Oncologico MD ANDERSON Internacional Espana	Madrid
Spain	Local Institution	Madrid
Spain	Local Institution	Madrid
Spain	Hospital Universitario Fundacion Jimenez Diaz	Madrid
Spain	Hospital 12 de Octubre	Madrid
Spain	Local Institution	Madrid
Spain	Hospital Universitario HM Sanchinarro	Madrid
Spain	Hospital Regional Universitario Carlos Haya	Malaga

Spain	Onkologikoa Of San Sebastian	San Sebastian
Spain	Local Institution	Santa Cruz de Tenerife
Spain	Hospital Universitario Virgen Macarena	Sevilla
Spain	Fundacio Investigao Hospital General Universitario de Valencia FiHgU	Valencia
Spain	Hospital Universitario y Politecnico de La Fe	Valencia
Sweden	Local Institution	Goteborg
Sweden	Local Institution	Malmoe
Sweden	Local Institution	Umea
Switzerland	Universitaetsspital Basel - Klinik fuer Onkologie	Basel
Switzerland	UniversitaetsSpital Zuerich - Dermatology	Zurich
Taiwan	Local Institution	Tainan
United Kingdom, Hampshire	Southampton General Hospital	Southampton
United Kingdom, Kent	Local Institution	Maidstone
United Kingdom	North Middlesex University Hospital	London
United Kingdom	Royal Marsden Hospital Sutton	London
United Kingdom	Royal Marsden Hospital	London
United Kingdom	The Christie Hospital	Manchester
United Kingdom	East & North Hertfordshire NHS Trust	Northwood

#### Sponsors and Collaborators

Bristol-Myers Squibb

#### Investigator

Study Director : Bristol-Myers Squibb Bristol-Myers Squibb

#### MORE INFORMATION

**Responsible Party :** Bristol-Myers Squibb  
**ClinicalTrials.gov Identifier :** NCT03899155  
**Other Study ID Numbers :** CA209-8TT, 2018-004362-34  
**First Posted :** April 2, 2019  
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**Studies a U.S. FDA-regulated Drug Product:** Yes  
**Studies a U.S. FDA-regulated Device Product:** No  
**Product Manufactured in and Exported from the U.S.:** Yes