ClinicalTrials.gov

ClinicalTrials.gov is a database of privately and publicly funded clinical studies conducted around the world.

A clinical study is a research study involving human volunteers that is intended to add to medical knowledge. There are two types of clinical studies: interventional studies, also called clinical trials, and observational studies. Both are included in this database, as are expanded access programs. A clinical trial is essentially a test of an intervention such as a new drug, diet, device or lifestyle change on a condition (disease or illness) to find out if it is safe and effective in people.

The description of the study is provided in full and in addition about 12% of the documents also present the results, in tabular form, of completed studies. Information about the study includes the condition, intervention, study design, phase, status, eligibility criteria, outcome measures, locations where the study is being conducted, sponsor, funding type, contact information, and more. Studies listed in the database are conducted in the USA and in 219 other countries.

The full-text of the study and specific indexing of the condition, intervention, outcome measures and several other study sections facilitate precise searching and accurate recall.

Use ClinicalTrials.gov to answer such questions as:

- What is the latest evidence for anti-PD-1 therapies in the treatment of cancer?
- Which studies can I use as a model for my own clinical trial?
- How effective is the Jamboxx device in treating patients with decreased respiratory function?
- Which companies are running phase 2 trials on treatments for myeloid leukemia?
- What are the adverse effects of nivolumab?

Date coverage 1980-present

Update frequency Daily (Monday to Friday)

Geographic coverage International

Document types Full text reports of clinical trials

Sources ClinicalTrials.gov allows the registration of clinical studies with human subjects that assess biomedical and/or health outcomes and that conform to any applicable human subject or ethics review regulations (or equivalent) and any applicable regulations of the national or regional health authority (or equivalent). See also https://clinicaltrials.gov/ct2/manage-recs/background

Publisher

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Bethesda, MD 20894

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ClinicalTrials.gov

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TI

A Phase III, Open-Label, Multicenter, Two Arm, Randomized Study to Investigate the Efficacy and Safety of Cobimetinib Plus Atezolizumab Versus Pembrolizumab in Patients With Previously Untreated Advanced BRAF V600 Wild-Type Melanoma: A Study of Cobimetinib Plus Atezolizumab Versus Pembrolizumab in Participants With Previously Untreated Advanced BRAFv600 Wild-Type Melanoma

PUB

ClinicalTrials.gov (Sep 1, 2017)

Highlighting: Off | Single | Multi

AB

Abstract (summary) Translate

This is a Phase III, multicenter, open-label, randomized study designed to evaluate the efficacy, safety, and pharmacokinetics of cobimetinib plus atezolizumab compared with pembrolizumab in treatment-naive participants with advanced BRAFV600 wild-type melanoma.
Recruitment status: Active, not recruiting

FT

Full Text Translate | Turn on search term navigation

Brief Summary

This is a Phase III, multicenter, open-label, randomized study designed to evaluate the efficacy, safety, and pharmacokinetics of cobimetinib plus atezolizumab compared with pembrolizumab in treatment-naive participants with advanced BRAFV600 wild-type melanoma.
Recruitment status: Active, not recruiting

Condition	Intervention/Treatment	Phase
Advanced BRAFV600 Wild-type Melanoma	Drug: Cobimetinib Drug: Atezolizumab Drug: Pembrolizumab	Phase 3

Study Design

Study Type	Interventional
Enrollment (Actual)	446 participants
Allocation	Randomized
Intervention Model	Parallel Assignment
Masking	None (Open Label)
Primary Purpose	Treatment
Study Start Date	December 11, 2017
Primary Completion Date	April 15, 2019
Study Completion Date	March 14, 2025

Arms and Interventions

Arm	Intervention/Treatment
Experimental: Cobimetinib and Atezolizumab Participants will receive 60 mg of cobimetinib orally from Days 1 to 21 along with 840 mg of atezolizumab by intravenous (IV) infusion on Days 1 and 15 of each 28-day cycle until investigator-determined disease progression, unacceptable toxicity, death, patient or physician decision to withdraw, or pregnancy, whichever occurs first. There will be no cobimetinib administration for 7 days (Days 22-28) in each cycle.	Drug: Cobimetinib Cobimetinib 60 mg tablets orally once daily on a 21 days on, 7 days off schedule. Drug: Atezolizumab Atezolizumab 840 mg as IV infusion once in every 2 weeks.
Active Comparator: Pembrolizumab Participants will receive 200 mg of pembrolizumab administered by IV infusion every 3 weeks (Q3W) until investigator-determined disease progression, unacceptable toxicity, death, patient or physician decision to withdraw, or pregnancy, whichever occurs first.	Drug: Pembrolizumab Pembrolizumab 200 mg as IV infusion once in every 3 weeks.

Outcome Measures

Primary Outcome Measure
Progression Free Survival (PFS) as Determined by the Independent Review Committee (IRC)
Time frame: Every 8 weeks (wks) from Day (D) 1 of Cycle (C) 1 through approximately 16 months
PFS is defined as the time from randomization to the first occurrence of disease progression, as determined by an

(. . .)

Arm/Group Title	Pembrolizumab	Cobimetinib and Atezolizumab
Arm/Group Description	Participants received 200 mg of intravenous (IV) pembrolizumab every 3 weeks (Q3W) until investigator-determined disease progression, unacceptable toxicity, death, patient or physician decision to withdraw, or pregnancy, whichever occurred first.	Participants received 60 mg of cobimetinib by mouth (PO) on a 21 days on, 7 days off schedule (dosing on Days 1-21, followed by no dosing on Days 22-28) plus 840 mg of atezolizumab by IV infusion of Days 1 and 15 of each 28-day cycle.
Period Title: Overall Study		
Started	224	222
Completed	0	0
Not Completed	224	222
Reason Not Completed		
Remain on Study	161	159
Death	41	45
Lost to Follow-up	3	3
Protocol Violation	3	0
Withdrawal by Subject	16	13
Symptomatic Deterioration	0	1
Other	0	1

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Indexing (details) Cite

SU, CON, INT	**Subject**	Condition: Advanced BRAFV600 Wild-type Melanoma, Melanoma Intervention: Cobimetinib, Atezolizumab, Pembrolizumab
TI	**Title**	A Phase III, Open-Label, Multicenter, Two Arm, Randomized Study to Investigate the Efficacy and Safety of Cobimetinib Plus Atezolizumab Versus Pembrolizumab in Patients With Previously Untreated Advanced BRAF V600 Wild-Type Melanoma
STIO	**Subtitle**	A Study of Cobimetinib Plus Atezolizumab Versus Pembrolizumab in Participants With Previously Untreated Advanced BRAFv600 Wild-Type Melanoma
SP	**Sponsor**	Hoffmann-La Roche
CTLOC	**Location**	University of Arizona Cancer Center, Tucson, Arizona, United States; City of Hope Comprehensive Cancer Center, Duarte, California, United States; USC Norris Cancer Center, Los Angeles, California, United States; USC Norris Cancer Center; USC Oncology Hematology Newport Beach, Newport Beach, California, United States; University of California at Irvine Medical Center; Department of Oncology, Orange, California, United States; ... *See full list of study locations in Full Text*
CTC	**Location country**	United States; Australia; Belgium; Brazil; France; Germany; Greece; Hungary; Italy; Korea, Republic of; Netherlands; Poland; Russian Federation; Spain; United Kingdom
CTSTAT	**Status**	Active, not recruiting
DTYPE	**Study type**	Interventional
CTPHS	**Phase**	Phase 3
STI	**Clinical trial ID**	NCT03273153 (ClinicalTrials.gov), CO39722, 2016-004387-18
PD, YR	**Publication date**	Sep 1, 2017
FTYPE	**Funder type**	INDUSTRY
RESULTS	**Results**	Yes
CTAGE	**Age**	Minimum age: 18 Years
GDR	**Gender**	All
HV	**Healthy volunteers**	No
NT	**Notes**	Has Study Protocol; Has Statistical Analysis Plan (SAP)
OM	**Outcome measure**	Progression Free Survival (PFS) as Determined by the Independent Review Committee (IRC); PFS as Determined by the Investigator; Objective Response as Determined by the Investigator; Objective Response as Determined by IRC; Disease Control Rate (DCR);... *See full list of outcome measures in Full Text*

CTSTART	**Study start**	December 11, 2017 (Actual)
CTCOM	**Primary completion**	April 15, 2019 (Actual)
CTFIRST	**Study first posted**	September 06, 2017 (Actual)
CTRES	**Results first posted**	May 11, 2020 (Actual)
CTLAST	**Last update posted**	September 28, 2020 (Estimate)
LA	**Language**	English
SL	**Language of abstract**	ENG
PUB	**Publication title**	ClinicalTrials.gov
PSTYPE	**Publication type**	Clinical Study
	URL	https://clinicaltrials.gov/ct2/show/NCT03273153
	Source attribution	ClinicalTrials.gov, © Publisher specific
AN	**Accession number**	NCT03273153
	Document URL	http://nightly-dialog.aa1.proquest.com/professional/docview/71435052?accountid=93293
FAV	**First available**	2020-09-28
UD	**Updates**	2020-09-28 2020-10-02 2020-10-04 2020-11-17 2020-11-17 2020-11-30 2020-11-30
	Database	ClinicalTrials.gov (1980 - current)

Search Fields

Field Name	Field Code	Example	Description and Notes
Abstract	AB	ab(melanoma and cobimetinib)	The abstract is the same as the Brief Summary at the beginning of the full text and allows a precise search of the study overview. The recruitment status is also included here. Use proximity and/or Boolean operators to narrow search results and double quotes for a precise phrase.
Abstract present	ABANY	“t cell lymphoma” AND abany(yes)	Add: *AND ABANY(YES)* to a query to limit retrieval to records with abstracts. Use double quotes to search for a precise phrase.
Accession number	AN	an(NCT03273153)	A unique document identification number assigned by the information provider.
Age	CTAGE	ctage(>17)	
All fields	ALL	all(cgm OR "continuous glucose monitoring")	Searches all fields except the full text. Use proximity and/or Boolean operators to narrow

Field Name	Field Code	Example	Description and Notes
			search results and double quotes for a precise phrase.
All fields + text	--	"continuous glucose monitoring"	Searches all fields including the full text. Use proximity and/or Boolean operators to narrow search results and double quotes for a precise phrase.
Clinical trial ID	STI	sti(nct01051856)	ClinicalTrials.gov assigns a unique identification code to each clinical study registered on ClinicalTrials.gov. Also called the NCT number, the format is "NCT" followed by an 8-digit number. Every item has an NCT number, and some items also have other identifiers from other trial study registries and National Institutes of Health grant numbers.
Collaborator	IR	ir(brigham)	An organization other than the sponsor that provides support for a clinical study. This support may include activities related to funding, design, implementation, data analysis, or reporting.
Condition	CON	con(melanoma) con("advanced brafv600")	The disease, disorder, syndrome, illness, or injury that is being studied. On ClinicalTrials.gov, conditions may also include other health-related issues, such as lifespan, quality of life, and health risks. Condition terms are MeSH terms assigned with an imperfect algorithm.
Document URL	URL		
Expanded access	XA	xa("intermediate size population")	Expanded access is a way for patients with serious diseases or conditions who cannot participate in a clinical trial to gain access to a medical product that has not been approved by the U.S. Food and Drug Administration (FDA). Also called compassionate use. This field shows the type of expanded access: - Individual Patients - Intermediate-size Population - Treatment IND/Protocol See Notes towards the end of this ProSheet and see also: FDA Expanded Access: Information for Patients.
First available	FAV	fav(202104018)	Indicates the first time a document was loaded on Dialog. It will not change regardless of how many times the record is subsequently reloaded, if the accession number remains the same.
From database[1]	FDB	medtronic AND fdb(clinicaltrials) medtronic AND fdb(1009959)	Useful in multifile searches to isolate records from a single file. FDB cannot be searched on its own;

[1] Click the "Field codes" hyperlink at the top right of the Advanced Search page. Click "Search syntax and field codes", then click on "FDB command" to get a list of database names and codes that can be searched with FDB.

Field Name	Field Code	Example	Description and Notes
			specify at least one search term then AND it with FDB.
Full text	FT, TX	tx(cobimetinib n/5 atezolizumab n/5 pembrolizumab)	This is the complete full text of the clinical trial. Use proximity and/or Boolean operators to narrow search results and double quotes for a precise phrase. Several sections of the full text are also searchable with their own field code, e.g. Location, Location Country, Status, Age, Gender, Outcome Measures and study dates, so very precise searching is possible in addition to the broader full text search.
Funder type	FTYPE	ftype(industry)	Describes the organization that provides funding or support for a clinical study. This support may include activities related to funding, design, implementation, data analysis, or reporting. Organizations listed as sponsors and collaborators for a study are considered the funders of the study. ClinicalTrials.gov refers to four types of funders: • U.S. National Institutes of Health • Other U.S. Federal agencies (for example, Food and Drug Administration, Centers for Disease Control and Prevention, or U.S. Department of Veterans Affairs) • Industry (for example: pharmaceutical and device companies) • All others (including individuals, universities, and community-based organizations)
Gender	GDR	gdr(all)	A type of eligibility criteria that indicates the sex of people who may participate in a clinical study (all, female, male).
Healthy volunteers	HV	hv(no)	A type of eligibility criteria that indicates whether people who do not have the condition/disease being studied can participate (yes, no)
Identifier (keyword)	IF	if("non-hodgkin lymphoma")	These are additional keywords provided by the responsible party, to add to the precise terms provided for Condition and Intervention. Keywords can be searched with SU as well as IF.
Intervention	INT	int(cobimetinib and pembrolizumab)	These are terms describing the process or action that is the focus of the clinical study. Interventions include drugs, medical devices, procedures, vaccines, and other products that are either investigational or already available. Interventions can also include noninvasive approaches, such as

Field Name	Field Code	Example	Description and Notes
			education, diet and exercise. Intervention terms are MeSH terms assigned with an imperfect algorithm.
Language	LA	la(english)	All documents in ClinicalTrials.gov are in English
Language of abstract	SL	sl(english)	All abstracts in ClinicalTrials.gov are in English
Last update posted	CTLAST	Ctlast(20190613)	The most recent date on which changes to a study record were made available on ClinicalTrials.gov.
Location	CTLOC	ctloc("university of arizona")	The locations of research facilities where the study is being conducted. The list of locations can be long so an abbreviated list is displayed in this field, but all locations are searchable with CTLOC. The full list is displayed in the full text.
Location country	CTC	ctc(france)	Countries in which research facilities for the study are located. A country is listed only once, even if there is more than one facility in the country. If a country is removed from the study, it will appear at the end of the list preceded by the word 'Removed:'.
Notes	NT	nt(sap)	The availability of study documents is noted here when appropriate. These include a study protocol, statistical analysis plan (SAP), and informed consent form (ICF).
Outcome measure	OM	om("progression free survival")	For clinical trials, a planned measurement described in the protocol that is used to determine the effect of an intervention/treatment on participants. For observational studies, a measurement or observation that is used to describe patterns of diseases or traits, or associations with exposures, risk factors, or treatment. Outcome measures include primary and secondary outcome measures. The primary one is the most important for evaluating the effect of an intervention or treatment. Most clinical studies have one primary outcome measure but some have more than one. Outcome measures can form a long list, so an abbreviated list is displayed here but all are searchable with OM. The full list of measures is displayed in the full text.

Field Name	Field Code	Example	Description and Notes
Phase	CTPHS	ctphs("phase 3")	The stage of a clinical trial studying a drug or biological product, based on definitions developed by the U.S. Food and Drug Administration (FDA). The phase is based on the study's objective, the number of participants and other characteristics. There are five phases: Early Phase 1 (formerly listed as Phase 0), Phase 1, Phase 2, Phase 3, and Phase 4. 'Not Applicable' is used to describe trials without FDA-defined phases, including trials of devices or behavioral interventions.
Primary completion date	CTCOM	ctcom(20190415) ctcom(201904) ctcom(>20181031)	The date on which the last participant in a clinical study was examined or received an intervention to collect final data for the primary outcome measure. Whether the clinical study ended according to the protocol or was terminated does not affect this date. For clinical studies with more than one primary outcome measure with different completion dates, this term refers to the date on which data collection is completed for all the primary outcome measures. The date may have "Actual" or "Estimate" displayed alongside. An estimated primary completion date is the date that the researchers think will be the primary completion date for the study.
Principal investigator	PIV	piv(houvenaghel)	The person who is responsible for the scientific and technical direction of the entire clinical study.
Publication date	PD	pd(20170901) yr(2017) pd(>201708)	This is the date on which the study sponsor or investigator first submitted the study record to ClinicalTrials.gov. There is typically a delay of a few days between the first submitted date and the record's availability on ClinicalTrials.gov (the first posted date).
Publication title	PUB	pub(clinicaltrials.gov)	This is the same for all documents – ClinicalTrials.gov
Publication year	YR	yr(2017) yr(2018-2020) yr(>2019)	This is the year of the publication date, i.e. when the study sponsor or investigator first submitted the study to ClinicalTrials.gov.
Publication type	PSTYPE	pstype(clinical study)	This is the same for all documents – Clinical Study.

Field Name	Field Code	Example	Description and Notes
References	REF	ref(venkatesh n/15 sepsis)	References may be provided and are related to the background and/or the results of the study. If the reference is to a document in Medline, the final eight digits are the accession number (PMID) of the document in Medline.
Results	RESULTS	results(yes)	About 12% of documents contain summary results in the full text, including participant flow, baseline characterisitics, outcome measure results and adverse events (including serious adverse events). Searching 'yes' in this field will identify studies with results.
Results first posted	CTRES	ctres(20200511) ctres(202005) ctres(2020) ctres(>20200331)	The date on which summary results information was first available on ClinicalTrials.gov.
Sponsor	SP	sp(hoffmann la roche)	The organization or person who initiates the study and who has authority and control over the study.
Status	CTSTAT	ctstat(active) ctstat("not yet recruiting") ctstat(terminated)	This indicates the current recruitment status or the expanded access status. See Notes towards the end of this ProSheet for further information on these status types.
Study first posted	CTFIRST	ctfirst(20170906) ctfirst(201709) ctfirst(2017) ctfirst(>20200606)	The date on which the study record was first available on ClinicalTrials.gov. There is typically a delay of a few days between the date the study sponsor or investigator submitted the study record (displayed in Publication Date) and the first posted date.
Study start	CTSTART	ctstart(20171211) ctstart(201712) ctstart(2017) ctstart(>20170528)	The date on which the first participant was enrolled in a clinical study. The date may be followed by 'actual' or 'estimated'. If 'estimated' it is the date that the researchers think will be the study start date.
Study type	DTYPE	dtype(interventional)	Describes the nature of a clinical study. Study types include - interventional (also called clinical trials) - observational (including patient registries) - expanded access
Subject	SU	su(melanoma) su(melanoma and cobimetinib)	The Subject field includes the terms from the Condition, Intervention and Identifier fields and allows a consistent cross-file search.
Subtitle	STIO	stio(cobimetinib and atezolizumab and pembrolizumab)	Many studies have a brief title in addition to the official title. It appears in the Subtitle field. Often the brief/subtitle is the same as or very similar to the official title.

Field Name	Field Code	Example	Description and Notes
Title	TI	ti(open label multicenter cobimetinib) ti(whi)	This is the official title of a protocol used to identify a clinical study. 'TI' searches all elements of the title – official title, brief title (subtitle) and title acronym (alternate title).
Title only	TIO	tio(cobimetinib)	TIO searches the official title only.
Alternate title	OTI	oti(whi)	The alternate title is usually an acronym or initials used to identify a clinical study (not all studies have one). For example the title acronym for the Women's Health Initiative is "WHI".
Updates	UD	ud(20181014)	The date(s) the record was loaded as a result of an update provided by the supplier.
URL	URL	url("https://clinicaltrials.gov/ct2/show/NCT03981913")	This is a link to the study on the NLM's ClinicalTrials.gov website.

Search Tools

Field codes are used to search document fields, as shown in the sample document. Field codes may be used in searches entered on the **Basic Search**, **Advanced Search**, and **Command Line** search pages. **Limit options**, **Look up lists**, and **"Narrow results by" filters** tools are available for searching. Some data can be searched using more than one tool.

Limit Options

Limit options are quick and easy ways of searching certain common concepts. Check boxes are available for:

Studies with expanded access, Studies with results, Studies accepting healthy volunteers, Child (0-17), Adult (18-64), Older adult (65+)

Short lists of choices are available for:

Study type, Study status, Phase, Country, Gender, Funder type, Study documents

Date limiters are available enabling you to select single dates or ranges for:

Publication date, Update date, Study start, Primary completion, Study first posted, Results first posted, Last study update posted

Look up Lists

You can browse the contents of certain fields by using Look up lists. These are particularly useful to validate spellings or the presence of specific data. Terms found in the course of browsing may be selected and automatically added to the Advanced Search form. Look up lists are available in the fields drop-down and in the search options for:

Condition, Intervention, Sponsor

“Narrow Results By” Filters

When results of a search are presented, the results display is accompanied by a list of “Narrow results by” options shown on the right-hand panel. Click on any of these options and you will see a ranked list showing the most frequently occurring terms in your results. Click on a term to apply it to (“narrow”) your search results. “Narrow results by” filters in Embase include

Study type, Status, Phase, Funder type, Subject, Condition, Intervention, Sponsor, Publication date

Notes

Expanded Access

Expanded Access is a way for patients with serious diseases or conditions who cannot participate in a clinical trial to gain access to a medical product that has not been approved by the U.S. Food and Drug Administration (FDA). It is also called compassionate use.

For more information, see FDA Expanded Access: Information for Patients.

Expanded access status is searchable in the Status (CTSTAT) field:

- **Available:** Expanded access is currently available for this investigational treatment, and patients who are not participants in the clinical study may be able to gain access to the drug, biologic, or medical device being studied.
- **No longer available:** Expanded access was available for this intervention previously but is not currently available and will not be available in the future.
- **Temporarily not available:** Expanded access is not currently available for this intervention but is expected to be available in the future.
- **Approved for marketing:** The intervention has been approved by the U.S. Food and Drug Administration for use by the public.

Expanded access type describes the category of expanded access under U.S. Food and Drug Administration (FDA) regulations. Expanded access type is searchable in the Expanded Access field:

- **Individual Patients**: Allows a single patient, with a serious disease or condition who cannot participate in a clinical trial, access to a drug or biological product that has not been approved by the FDA. This category also includes access in an emergency situation.
- **Intermediate-size Population**: Allows more than one patient (but generally fewer patients than through a Treatment IND/Protocol) access to a drug or biological product that has not been approved by the FDA. This type of expanded access is used when multiple patients with the same disease or condition seek access to a specific drug or biological product that has not been approved by the FDA.
- **Treatment IND/Protocol**: Allows a large, widespread population access to a drug or biological product that has not been approved by the FDA. This type of expanded access can only be provided if the product is already being developed for marketing for the same use as the expanded access use.

Recruitment status

- **Not yet recruiting**: The study has not started recruiting participants.
- **Recruiting**: The study is currently recruiting participants.
- **Enrolling by invitation**: The study is selecting its participants from a population, or group of people, decided on by the researchers in advance. These studies are not open to everyone who meets the eligibility criteria but only to people in that particular population, who are specifically invited to participate.
- **Active, not recruiting**: The study is ongoing, and participants are receiving an intervention or being examined, but potential participants are not currently being recruited or enrolled.
- **Suspended:** The study has stopped early but may start again.
- **Terminated**: The study has stopped early and will not start again. Participants are no longer being examined or treated.
- **Completed**: The study has ended normally, and participants are no longer being examined or treated (that is, the last participant's last visit has occurred).
- **Withdrawn**: The study stopped early, before enrolling its first participant.
- **Unknown**: A study on ClinicalTrials.gov whose last known status was recruiting; not yet recruiting; or active, not recruiting but that has passed its completion date, and the status has not been last verified within the past 2 years.

Document Formats

Document Format	Fields	Online	Export / Download
Brief view	Title and Publication date	✓	
Detailed view	Same as Brief view plus a 3-line KWIC window	✓	
KWIC (Keyword in Context)	Detailed view plus all occurrences of your search terms, highlighted within the fields where the terms occur	✓	✓
Preview (subscribers only)	Title, Publication title, Publication date, abbreviated Abstract, Subject terms	✓	
Preview (transactional)	Title, Publication date, abbreviated Abstract	✓	
Brief citation	Complete record minus Text, Abstract and Indexing	✓	✓
Full Text	Complete record	✓[2]	✓
Custom	Choose the fields you want		✓[3]

[2] In Online-view mode, Dialog gives access to two Document Formats only: *Brief citation*, and the 'most complete' format available. In ClinicalTrials.gov the most complete format is the full text.

[3] Custom export/download format is available in the following mediums only: HTML, PDF, RefWorks, RTF, Text only, XLS.

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Email: Customer@dialog.com
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