

FDA申請に必要なSEND-CT用語の検索

<https://datascience.cancer.gov/resources/cancer-vocabulary/cdisc-terminology>

FDA申請に必要なSEND-CT用語の検索

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SEND CT用語の検索

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CDISC Terminology

The [Clinical Data Interchange Standards Consortium](#) (CDISC) is an open, non-profit organization that develops and supports global data standards to improve the quality and interoperability of medical research and healthcare. CDISC standards are widely used for study planning and data collection, tabulation, analysis, and submissions to the U.S. Food and Drug Administration (FDA), Japanese Pharmaceuticals and Medical Devices Agency (PMDA), and other regulatory agencies internationally.

SEND CT用語は米国NCIのホームページからExcel/Word/Pdfなどでダウンロード可能です。
(注意：3か月に一度更新されます)

ALSO IN THIS SECTION

[FDA Terminology](#)[NCPDP Terminology](#)[Pediatric Terminology](#)

Standard for the Exchange of Nonclinical Data (SEND)

CDISC leads the [SEND](#) project, which guides the organization, structure, and format of standard nonclinical tabulation data sets for interchange between organizations such as sponsors and CROs and for submission to a regulatory authority such as the FDA. NCI EVS maintains and distributes SEND controlled terminology as part of NCIt.

- Download from the [CDISC SEND directory](#) on an NCI FTP site in [Excel](#), [text](#), [odm.xml](#), [pdf](#), [html](#) and [OWL/RDF](#) formats.
- Download changes from the previous release in [Excel](#) or [text](#) formats.

画面を下にスクロールするとSENDが出てきます。
(EXCELでダウンロードする場合にはEXCELを選択します)

CDISC: SEND Controlled Terminology

G6230 : Hyaline deposits or scarring within the renal glomeruli. (INHAND)

	A	B	C	D	E	F	
1	Code	Codelist Code	Codelist Extensible (Yes/No)	Codelist Name	CDISC Submission Value	CDISC Synonym(s)	CDISC
6217	C3744	C88025		Neoplasm Type	FIBROADENOMA, BENIGN	Breast Fibroadenoma; Fibroadenoma of Breast; Fibroadenoma of the Breast	A benign neoplasm originating from g component.
6218	C2868	C120531		Non-Neoplastic Finding Type	AMYLOID	Amyloidosis	An accumulation of amyloid protein.
6219	C132484	C120531		Non-Neoplastic Finding Type	ANGIECTASIS	Hemangiectasis	Dilatation of the blood vessels or end
6220	C120882	C120531		Non-Neoplastic Finding Type	FOCUS OF CELLULAR ALTERATION	Foci of Cellular Alteration; Focus/foci of Cellular Alteration	A localized proliferation of hepatocyte
6221	C34620	C120531		Non-Neoplastic Finding Type			
6222	C3046	C120531		Non-Neoplastic Finding Type			
6223	C120883	C120531		Non-Neoplastic Finding Type			
6224	C120884	C120531		Non-Neoplastic Finding Type			
6225	C120885	C120531		Non-Neoplastic Finding Type			
6226	C120886	C120531		Non-Neoplastic Finding Type	GERM CELL DEPLETION/GERM CELL DEGENERATION	Germ Cell Degeneration/Germ Cell Depletion	A finding that generally has features of degeneration.
6227	C26783	C120531		Non-Neoplastic Finding Type	GLIOSIS		Nonspecific reactive response of nerve and microglia rather than oligodendro
6228	C26784	C120531		Non-Neoplastic Finding Type	GLOMERULONEPHRITIS	Glomerular Nephritis	Inflammatory changes in the renal glomerular basement membrane, mesonephritic glomerulonephritis. Mononuclear inflammatory cell infiltration of glomerular capillary tufts and acellular crescent formation. Epithelial cells may also proliferate and form crescents.
6229	C120887	C120531		Non-Neoplastic Finding Type	GLOMERULOPATHY		Chronic degenerative changes in the glomerular capillary tufts and acellular crescent formation.
6230	C120888	C120531		Non-Neoplastic Finding Type	GLOMERULOSCLEROSIS	Glomerular Sclerosis	Hyaline deposits or scarring within the glomerular capillary tufts.

・ SEND DATAではSEND CT同義語に含まれる用語はSEND CT用語に変換しておく必要があります。
 ・ SEND CT用語にない用語はStudy Data Reviewer's Guide(SDRG)に記載する必要があります。

SEND CT用語の追加登録

NIH NATIONAL CANCER INSTITUTE

1-800-4-CANCER Live Chat Publications Dictionary

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New Term Requests

The [CDISC New Term Request](#) web page provides information on how to submit new terms and changes to existing terminology. This page helps members of the CDISC community submit new terms and changes to existing terminology.

CDISC Changes Files Provided

Each terminology data release includes a file that lists all terms in the release. Users who want to compare their own terminology analysis or mapping, for instance, with the NCI EVS to create such files. The software used for this purpose is available for download.

Updated: December 26, 2017

Term Suggestion

Quick Links

Contact Information:

Business Email: *

Name:

Business Phone Number:

Organization:

Privacy Notice: For term submission purposes we request business contact information only, not personal information. Your business email, and any other business contact information that you enter, will be stored in a publicly-accessible web site in support of CDISC term submission tracking. CDISC personnel may contact you.

Term Information:

Vocabulary:

Request Type:

Fill in the following fields as appropriate. For multiple term submissions, please click on and download [CDISC Controlled Terminology Multiple Term Request Spreadsheet](#) and add on your name and the end of the file name. Email this completed file to NciEvsCdiscHelp@mail.nih.gov. In addition, please fill out the New Term Request form indicating "File emailed separately" in Additional Information.