



C - C A T
Center for Cancer Genomics
and Advanced Therapeutics

Dear Members of Academic Institutions and Companies,
Information on C-CAT Data Utilization

Center for Cancer Genomics and Advanced Therapeutics (C-CAT) accumulates and stores data of tumor profiling tests/comprehensive genome profiling tests started as healthcare services provided by (national) health insurance in June 2019 and clinical information of corresponding patients upon individual consent. Anonymized data of patients who agreed to utilize their data (provide them to a third party) can be used for research/investigation of academic institutions and companies for the purpose of academic research and pharmaceutical development. Any result/intellectual property obtained from the use of the C-CAT data belongs to the user.

* Data will be available for utilization for international organizations at a later date.

About C-CAT

Center for Cancer Genomics and Advanced Therapeutics (C-CAT), National Cancer Center is an organization to accumulate, store and promote utilization of data of tumor profiling tests/comprehensive genome profiling tests performed as healthcare services provided by (national) health insurance at Hospitals for Cancer Genomic Medicine and clinical information. (URL: https://www.ncc.go.jp/jp/c_cat/)

About C-CAT Accumulated Data

The registration number has increased since tumor profiling tests/comprehensive genome profiling tests started as healthcare services provided by (national) health insurance in June 2019, and it exceeded 20,000 in August 2021. As of the end of Aug. 2021, 20,533 cases are registered. Over 99% of the patients agreed to utilize their data (provide them to a third party).

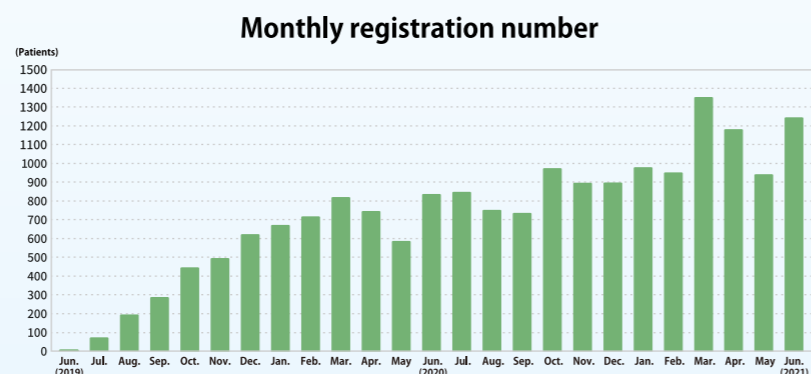
C-CAT cumulative registration number
As of the end of August, 2021

20,533

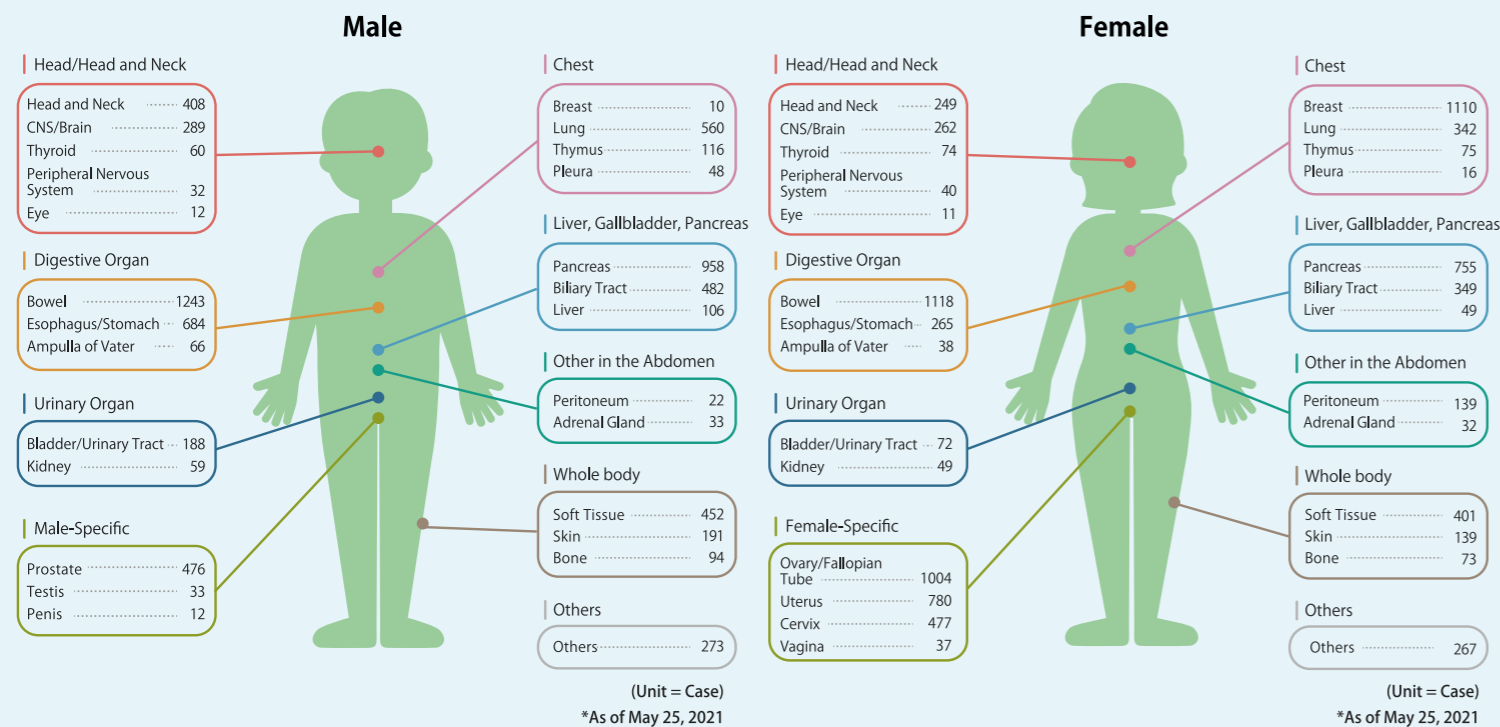
Consent rate for secondary utilization:

99.7%

(Consent rate aggregated as of May 25, 2021)



Cancer Type Breakdown



* The total number of cases in the cancer type breakdown of C-CAT registered data differs from the total C-CAT registration number and the monthly registration number due to the difference in the timing of data confirmation.

About Data Utilization Portal Site

"C-CAT data utilization portal site" is available as a portal site to utilize C-CAT accumulated data. Combination search of clinical information and gene mutation information is available, and the results can be browsed and downloaded.

C-CAT Accumulated Data

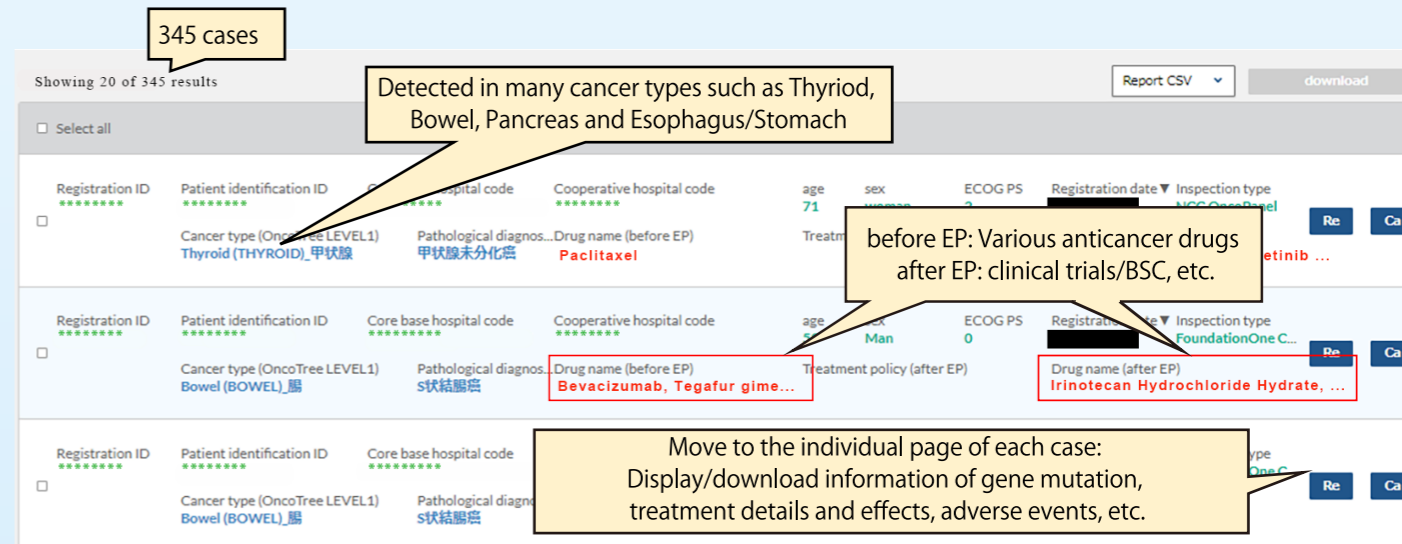
Clinical Information

Category	Item*
Basic information	(Hospital ID, registration ID), sex, age, cancer type, etc.
Sample information	Gene panel name, tumor cell content, specimen collection site, etc.
Patient background	Pathological diagnosis, smoking history, ECOG-PS, family history, etc.
Cancer type	Metastasis, CoDX test result, etc.
Pre-EP/Post-EP therapy	Drug name, start/end date of administration, best overall effect, adverse events, etc.
Outcome	Outcome, last follow-up date, date of death, cause of death

Mutation information: Gene mutations reported by tumor profiling test

To use the C-CAT data utilization portal site, the application for its use, the review of and approval from C-CAT Data Utilization Review Board, and the contract procedure are required. Please see "C-CAT data utilization portal site: contract process" for details. Available services include the search for information on all patients from which consent for secondary use is obtained and the use of information on gene mutation (including germline mutation) and clinical information (excluding ID's). Hospital ID and registration ID are available upon additional approval from C-CAT Data Utilization Review Board.

Example of a search for BRAF V600E mutation from all cancer types/nationwide



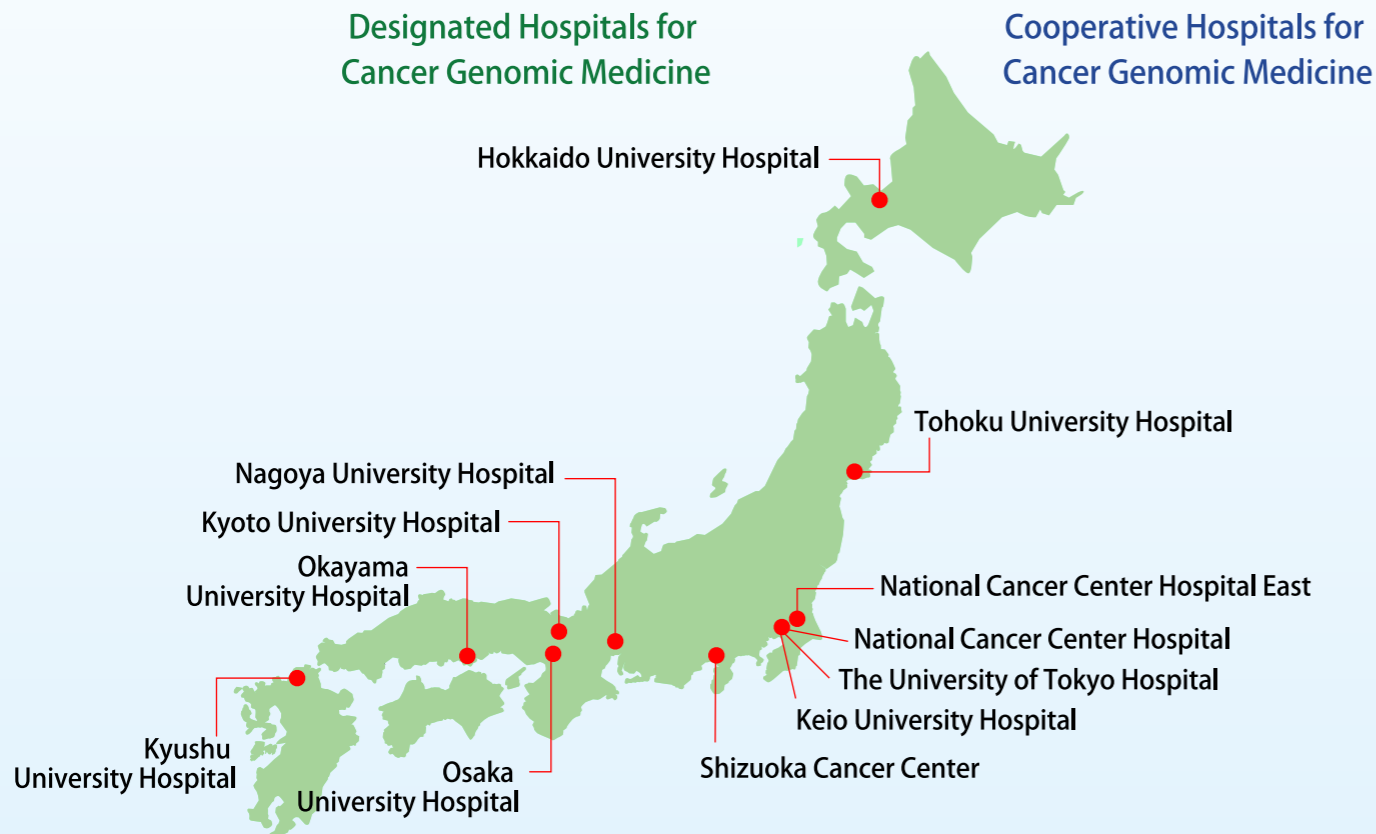
Hospital ID can be displayed
(upon approval from C-CAT Data Utilization Review Board)

An example of a search for a specific gene mutation (BRAF V600E mutation) is shown above. The corresponding 345 cases are displayed by case. Information on cancer type classification, pre/post-EP treatment, etc. are displayed. Detailed information can be browsed and downloaded at the individual page of each case.

Example of use of the C-CAT data utilization portal site

Data searched and obtained can be used for research/investigation of academic institutions and companies for the purpose of medical research and pharmaceutical development. Any result/intellectual property obtained from the use of the C-CAT data utilization portal site belongs to the user. An example of a search for specific gene mutation and cancer type is shown below. Hospital ID can be displayed if C-CAT Data Utilization Review Board accepts its need, such as when the feasibility of a clinical trial needs to be examined. We would be happy if the C-CAT data utilization portal site could help you consult with Hospitals for Cancer Genomic Medicine about clinical trials (C-CAT will not involve in consultations).

Designated Core Hospitals for Cancer Genomic Medicine (in red below)



C-CAT Data Utilization Review Board and Licensing Process

(Preparation before application)

“Registration number search function” is available for checking registered data prior to considering the use of the C-CAT data utilization portal site. The registration number search function provides combination search of clinical information and gene mutation results, as C-CAT data utilization portal site does, but it only displays the number of corresponding cases as the search result. The registration number search function can be used for free, but registration is required by entering your e-mail address, country/region and the classification of your affiliation. Please feel free to use the registration number search function banner on the “For Researchers (Utilization)” page of C-CAT official website.

In principle, the approval from the Institutional Review Board (IRB) of the affiliation, etc. is a prerequisite for application.

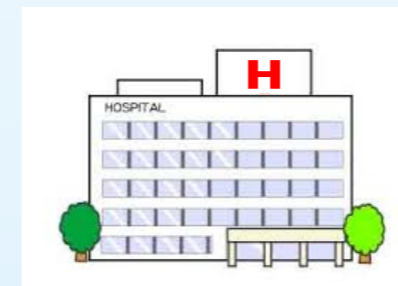
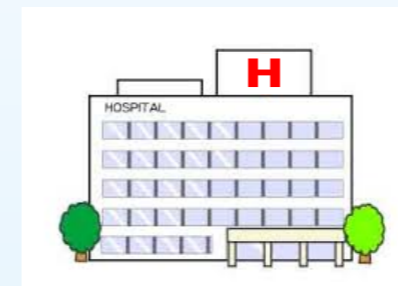
Example of use for planning clinical trials

Clinical Information

Category	Item*
Basic information	Hospital ID, sex, age, cancer type, etc.
Sample information	Gene panel name, tumor cell content, specimen collection site, etc.
Patient background	Pathological diagnosis, smoking history, ECOG-PS, family history, etc.
Cancer type	Metastasis, CoDX test result, etc.
Pre-EP/Post-EP therapy	Drug name, start/end date of administration, best overall effect, adverse events, etc.
Outcome	Outcome, last follow-up date, date of death, cause of death

Gene mutations reported by tumor profiling test

C-CAT data utilization portal site



Search by gene mutation and cancer type
→ Display/download the hospital ID/patient data



Anonymized data of mutation-positive cases at each hospital

→ Examine the feasibility of clinical trials based on information such as the number of patients

Contact Hospitals for Cancer Genomic Medicine (C-CAT will not involve in it)

About Fees

- The C-CAT data utilization portal site is available for browse/download after annual fee payment.
- Members of Hospitals for Cancer Genomic Medicine can browse/download from the C-CAT data utilization portal site for free. However, members of companies participating in collaborative researches need to pay the annual fee.
- For members of academia, we promote research by providing free browse of the C-CAT data utilization portal site to researches supported by AMED, Ministry of Health, Labor and Welfare/Ministry of Education, Culture, Sports, Science and Technology Grants-in-Aid for Scientific Research. However, members of companies participating in collaborative researches need to pay the annual fee.

C-CAT data utilization portal site: Contracting Process

User (company, research institution, etc.)

C-CAT

C-CAT Data Utilization Review Board



Approval



Secretariat

Research plan



Application form,
research plan, ethical review result

Licensing agreement for data use

Fee payment

Granting of the right to data use

Start using the C-CAT data
utilization portal site
Access from user's PC
Any result/intellectual property
belongs to the user

Application/Review

Contract/Provision

To apply for the use of the C-CAT data utilization portal site, please download "C-CAT Data Utilization Application Form" from the "For Researches (Utilization)" page of C-CAT official website, fill out the Form, and submit it to Section of Data Science Strategy, Center for Cancer Genomics and Advanced Therapeutics (C-CAT) (E-mail:

c-cat_use@ml.res.ncc.go.jp), with copies of the research plan submitted to the IRB and the result of ethical review. The use of C-CAT data is approved after reviewing the adequacy of the purpose of use, achievements of the applicant in conducting researches/investigations, and the management system at the affiliation such as information storage and destruction. The member list of C-CAT Data Utilization Review Board is available at the "For Researchers (Utilization)" page of C-CAT official website.

The access right to the C-CAT data utilization portal site is granted after the approval from C-CAT Data Utilization Review Board is obtained, "Licensing Agreement for C-CAT data" is concluded with C-CAT, and the fee is paid. The Agreement specifies that any result obtained from the use of the C-CAT data and any intellectual property based on the result belongs to the user, in addition to the obligations and prohibitions.

Please refer to the "For Researchers (Utilization)" page of C-CAT official website for details. Please see "About Fees" for the prices.

Once the access right to the C-CAT data utilization portal site is granted, users can access the portal site from their own declared PC. The access right is valid for a year, and the application for utilization extension and license renewal are required every year.

Contact for inquiries about utilization



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