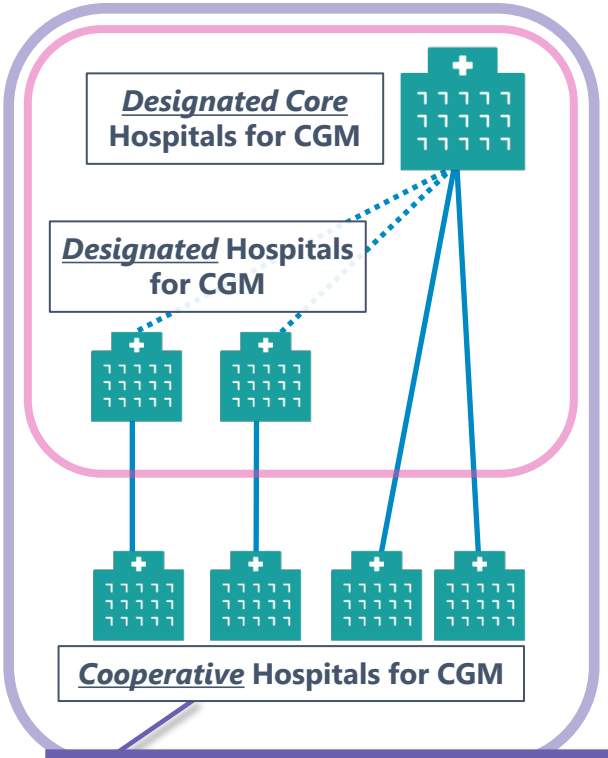
Cancer Genomic Medicine
（Core Hospitals, Panel Tests）

Hospitals for Cancer Genomic Medicine (CGM)



Designated Core and Designated Hospitals nominate* Cooperative Hospitals

	Patient Consultations (Tests)	Sample Preparations	Sequencing	Expert Panels	Report Preparation	Patient Explanations (Results)	Treatment	Advanced Treatment/Trials R&D	Specialist Training
Requirements									
Designated Core	Required		Outsource permitted	Required		Required		Required	
Designated									In collaboration with designated core and/or designated hospitals
Cooperative				Participates in meetings with designated core and/or designated hospitals					

**Nominations of Cooperative Hospitals at discretion of Designated Core and Designated Hospitals, upon confirmation that set requirements are met*

***Designated Core* Hospitals for CGM**	lead CGM by means of capacity building, clinical support, clinical research and development
***Designated* Hospitals for CGM**	provides treatment recommendations from gene panel test results in-house, clinical services at same level as core hospitals
***Cooperative* Hospitals for CGM**	gene panel tests provided in collaboration with (core) designated hospitals

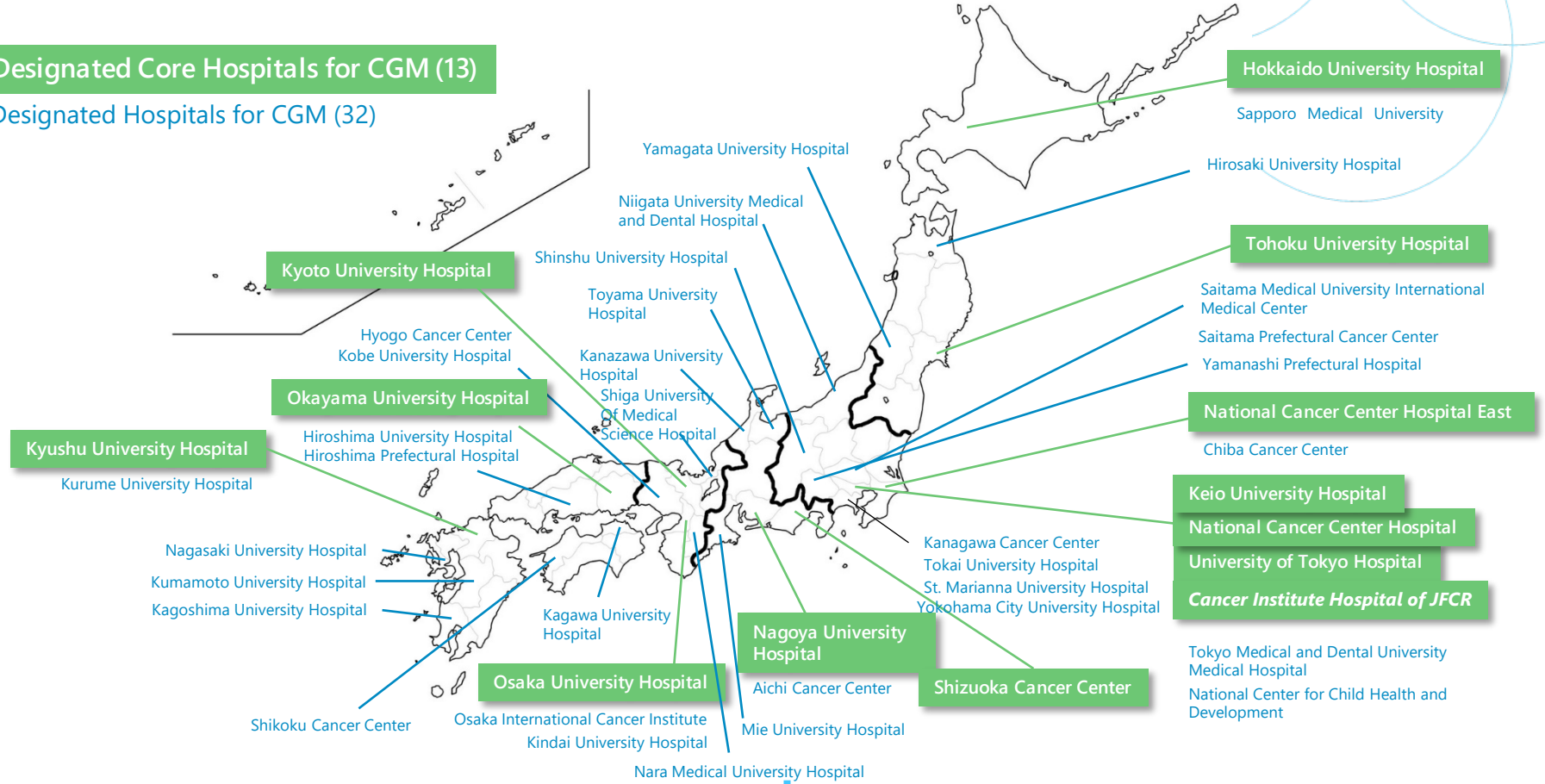
Excerpts, partially revised from submissions to the working group on designated CGM hospital requirements (21 Dec 2023)

Designated Core Hospital for Cancer Genomic Medicine- Requirements Review (Aug 2022)

Key points

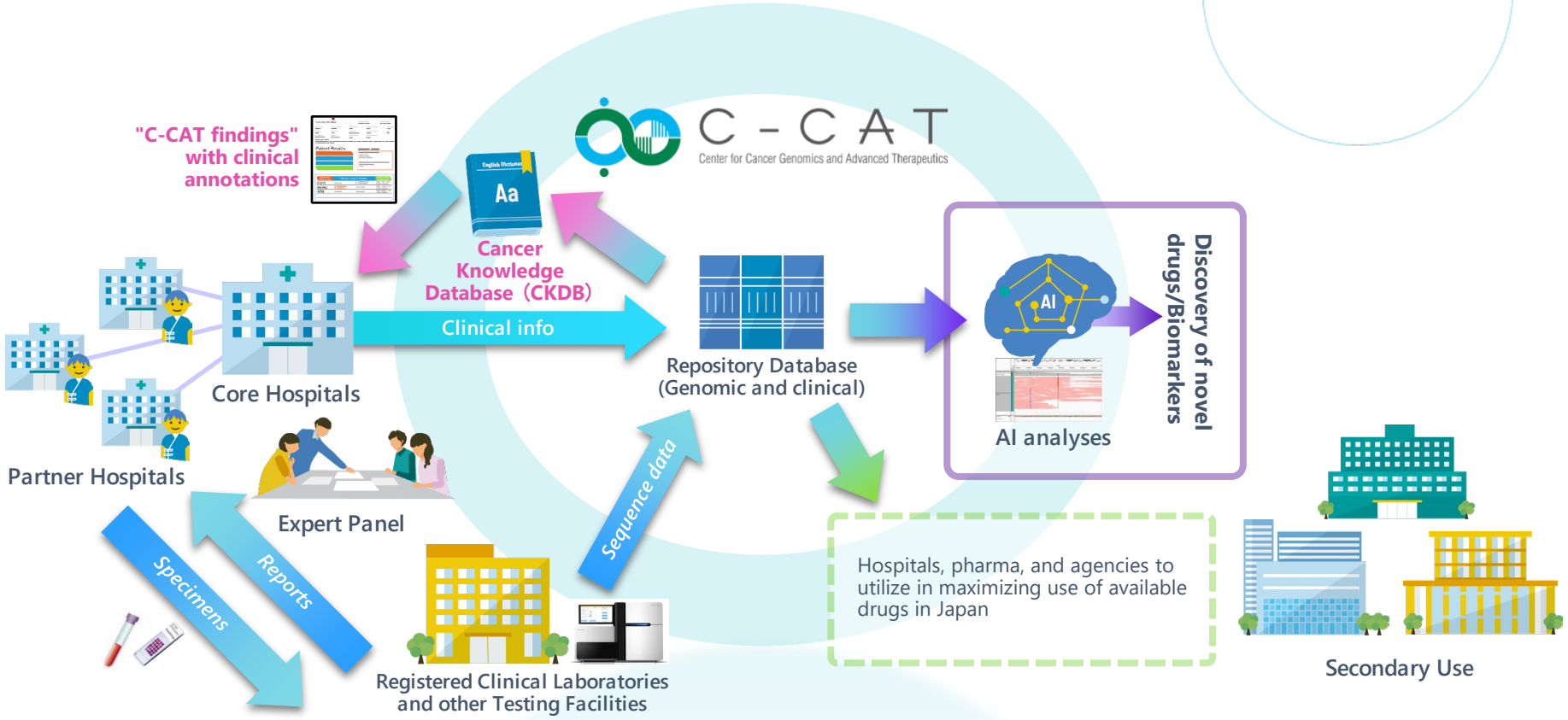
Care Provision Evaluation	• Cancer gene panel tests • Genetic counseling • Patients receiving personal/targeted treatment resulting from cancer gene panel tests • Clinical information registration to Center for Cancer Genomics and Advanced Therapeutics (C-CAT)
Deploying New Technology	• Add posts to accommodate liquid biopsy services • Transfer Expert Panel requirements revision authority to junior level • Cooperative Hospitals for Childhood Cancers type 1-A Eligible
Streamlining Designation Issues	• 10 Designated Core Hospitals for Cancer Genomic Medicine, 30 Designated Hospitals for Cancer Genomic Medicine with ambition and ability to be selected nationwide • Clarify role of Liaison Council of Cancer Genomic Medicine Institutions

Hospitals for Cancer Genomic Medicine (CGM)



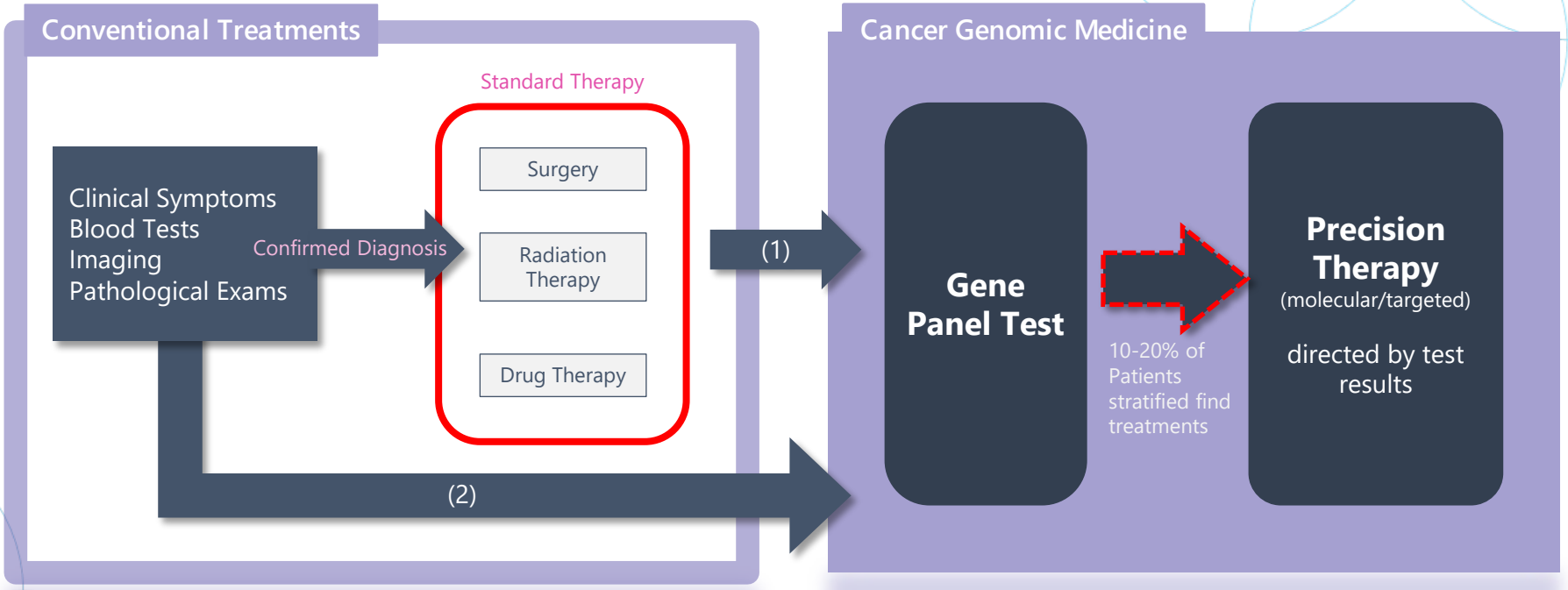
Oct 2024

Center for Cancer Genomics and Advanced Therapeutics (C-CAT, established at the National Cancer Center)



Excerpt from submissions to Cancer Genomic Medicine Promotion Consortium (8 Mar 2019)

Cancer Treatments using Gene Panel Tests



Patients who meet criteria (1) or (2), plus (3) may take gene panel tests*

(1) Solid tumor patients at late stages/with metastasis, who have completed standard therapy

(2) Solid tumor patients for whom there is no standard therapy available

(3) Judged a likely candidate for post-test chemotherapy by a physician, concluded from overall condition and organ function

** Gene panel test: analyzes hundreds of genetic mutations at once and may serve to select chemotherapies.*

Excerpts, partially revised from submissions to conference on the future direction of cancer care provision (12 Jun 2019)

Patient Access to new Treatments Owing to Cancer Gene Panel Tests

Analysis of 30,826cases

Cases with C-CAT reports returned
1 Jun 2019 – 30 Jun 2022
(n=33,933)

Excluded（n=3,107）

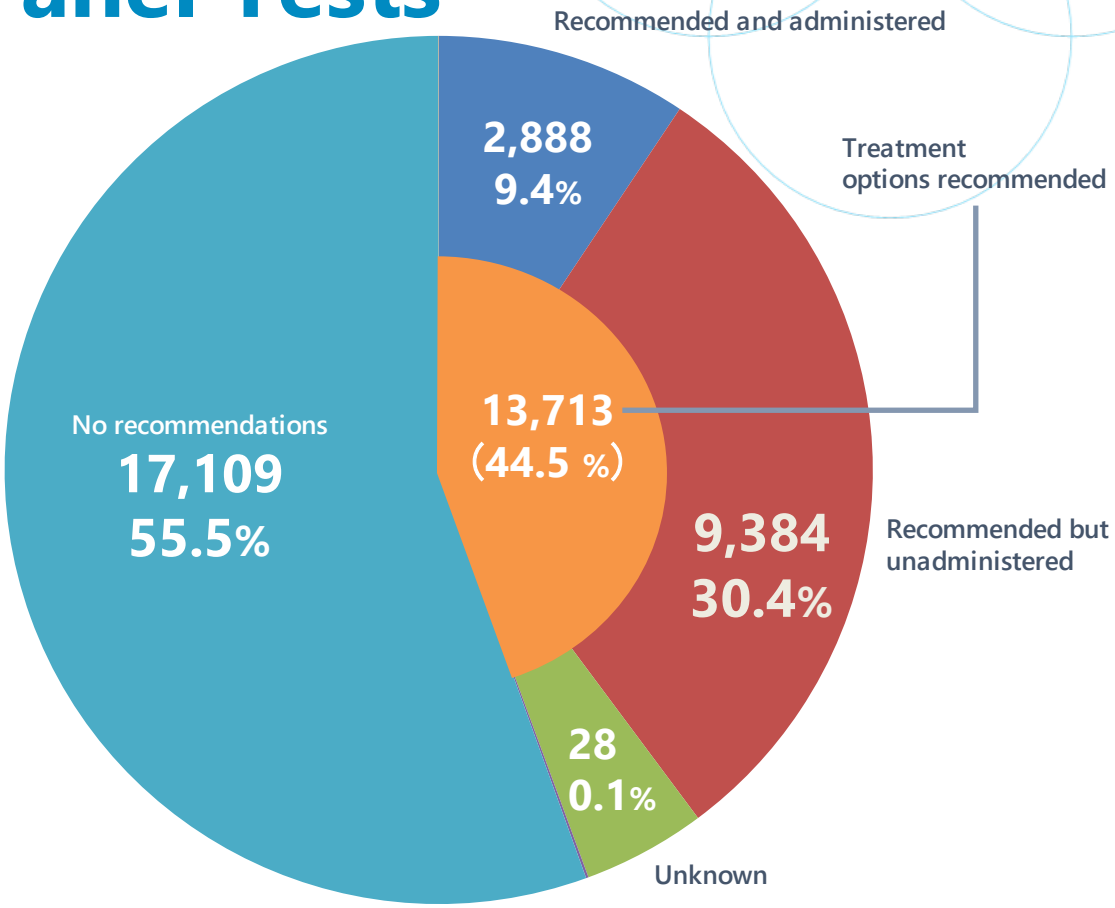
- Ver. 1.1.3 (n=1,292)
- Version unknown (n=1,814)
- V1.2.1 or later, version migration incomplete (n=1)

Cases included in analysis
Ver. 1.2.1 or later (n=30,826)

Excerpts from material submitted to Study Group on Designation of Designated Core Hospital for Cancer Genomic Medicine (13 Feb 2023)

Patient Access to new Treatments Owing to Cancer Gene Panel Tests

Expert Panel Results (n=30,826)



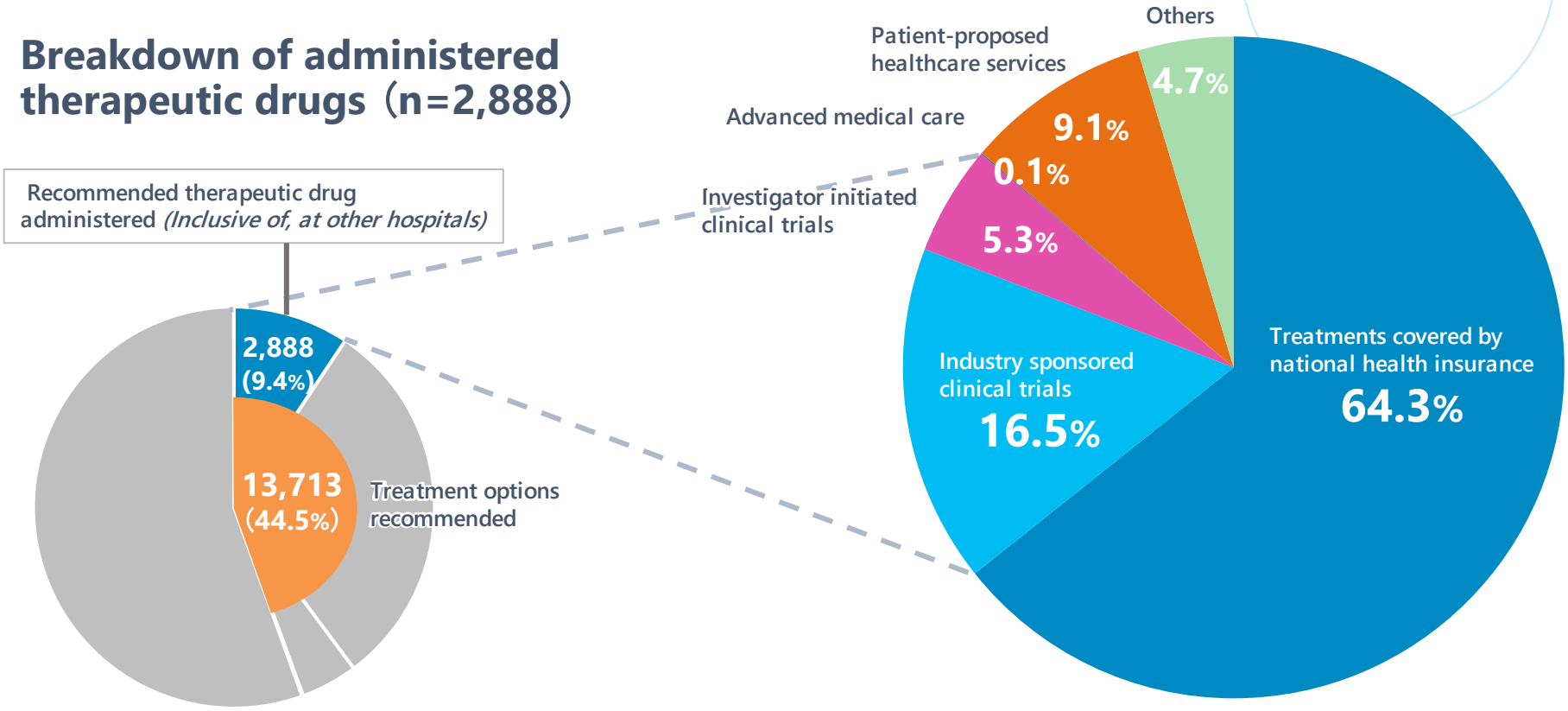
44.5% of cancer gene panel tests resulted in treatment recommendations

Of them, 9.4% had recommended drugs administered

Partially revised from documents submitted to the Study Group on specified of Designated Core Hospital for Cancer Genomic Medicine (13 Feb 2023)

Patient Access to new Treatments Owing to Cancer Gene Panel Tests

Breakdown of administered therapeutic drugs（n=2,888）



Partially revised from submissions to the Study Group on designations of Designated Core Hospital for Cancer Genomic Medicine (13 Feb 2023)

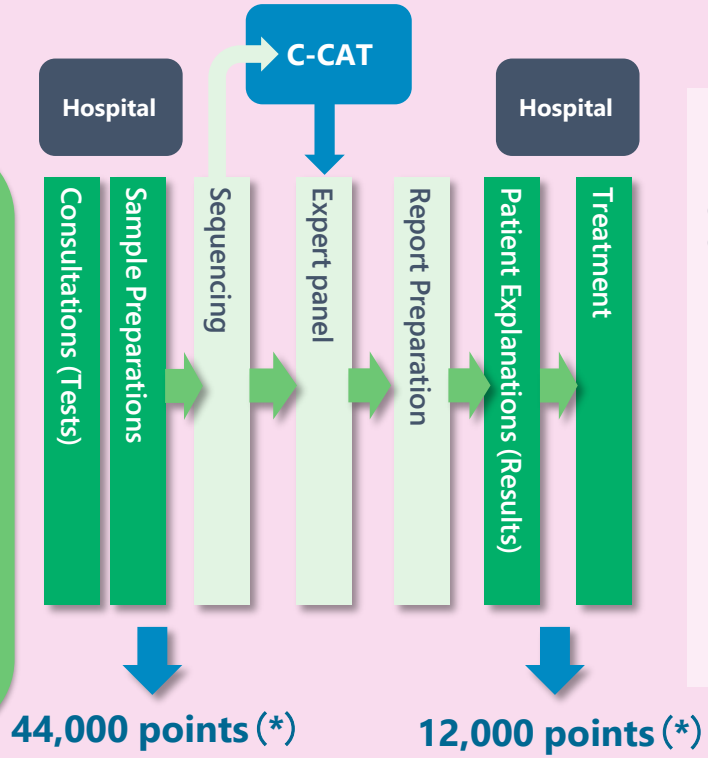
Cancer Gene Panel Tests

Eligibility

Patients (1) or (2) below whose primary physician sees a high likelihood of drug therapy indication resulting from the test

(1) Patients with solid tumors with no standard therapy

(2) Solid tumor patients who have/almost completed standard therapy



(*) Medical fee points (Revised Apr 2022)

<Rewards - Medical fee points >

○**Specimens submission**	44,000 points
○**Results explanation**	12,000 points
Total	**56,000 points**

<Requirements>

- Specimen submissions to Designated Core/ Designated/Cooperative Hospitals for Cancer Genomic Medicine
- Data submission to C-CAT
- Patient data returns
- Management ledger maintenance
- Quality and precision control
- Expert Panel
- Treatment strategy explained to patients

Insurance Covered Cancer Gene Panel Tests

Name	Developer	Samples	Regulatory approval	Insurance coverage	Features
NCC Onco Panel	Sysmex Corp	Tumor tissue whole blood	Dec 2018	Jun 2019	• Mutations in 124 cancer-related genes analyzed • Regulatory approval and insurance coverage as companion diagnostics
FoundationOne CDx	Chugai Pharmaceutical Co Ltd	Tumor tissue	Dec 2018	Jun 2019	• Mutations in 324 cancer-related genes analyzed • TMB scores/MSI determination tested • Regulatory approval and insurance coverage as companion diagnostics
FoundationOne Liquid CDx	Chugai Pharmaceutical Co Ltd	Whole blood (CtDNA)	Mar 2021	Aug 2021	• Mutations in 324 cancer-related genes analyzed • Regulatory approval and insurance coverage as companion diagnostics
Guardant360 CDx	Guardant Health Japan Corp	Whole blood (CtDNA)	Mar 2022	Jul 2023	• Mutations in 74 cancer-related genes analyzed • MSI determination tested • Regulatory approval and insurance coverage as companion diagnostics
GenMineTOP	Konica Minolta REALM	Tumor tissue whole blood	Jul 2022	Aug 2023	• Mutations of 737 cancer-related genes, 455 cancer-related fusion genes, exon skipping of 5 cancer-related genes, and gene expression levels of 27 cancer-related genes analyzed

as of Jan 2024

- CtDNA (Circulating tumor DNA): short fragmented DNA from tumor cells released in the blood
- Companion Diagnostics (CDx): A device that identifies patients with genetic mutations making them eligible to treatments approved in Japan
- TMB (Tumor Mutational Burden): The total number of mutations found in the DNA of tumors
- MSI (Microsatellite Instability): A change that occurs in certain cells (such as cancer cells) in which the number of repeated DNA bases in a microsatellite (a short, repeated sequence of DNA) is different from what it was when the microsatellite was inherited