

Annual review 2021



**Karolinska
Institutet**

KAROLINSKA
UNIVERSITY HOSPITAL

Karolinska Comprehensive Cancer Center

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Introduction



Welcome to the second edition of the Karolinska Comprehensive Cancer Center's annual review.

The annual review summarises the events of 2021 and aims to provide an insight into the activities taking place in the many different parts of Karolinska CCC.

It has been an intense and full year, and I would like to thank all of you who have made a fantastic contribution to making us all together Karolinska CCC.

During the year, the COVID-19 pandemic has continued to impact our daily lives, forcing us to take on new and even greater challenges to deliver world-class cancer care to, and with, our patients.

We have contributed to the effort to carry out 1,000 additional surgeries on top of the regular plan. We have found new creative solutions, developed our ways of working, delivered excellent research, and contributed to knowledge development in many areas.

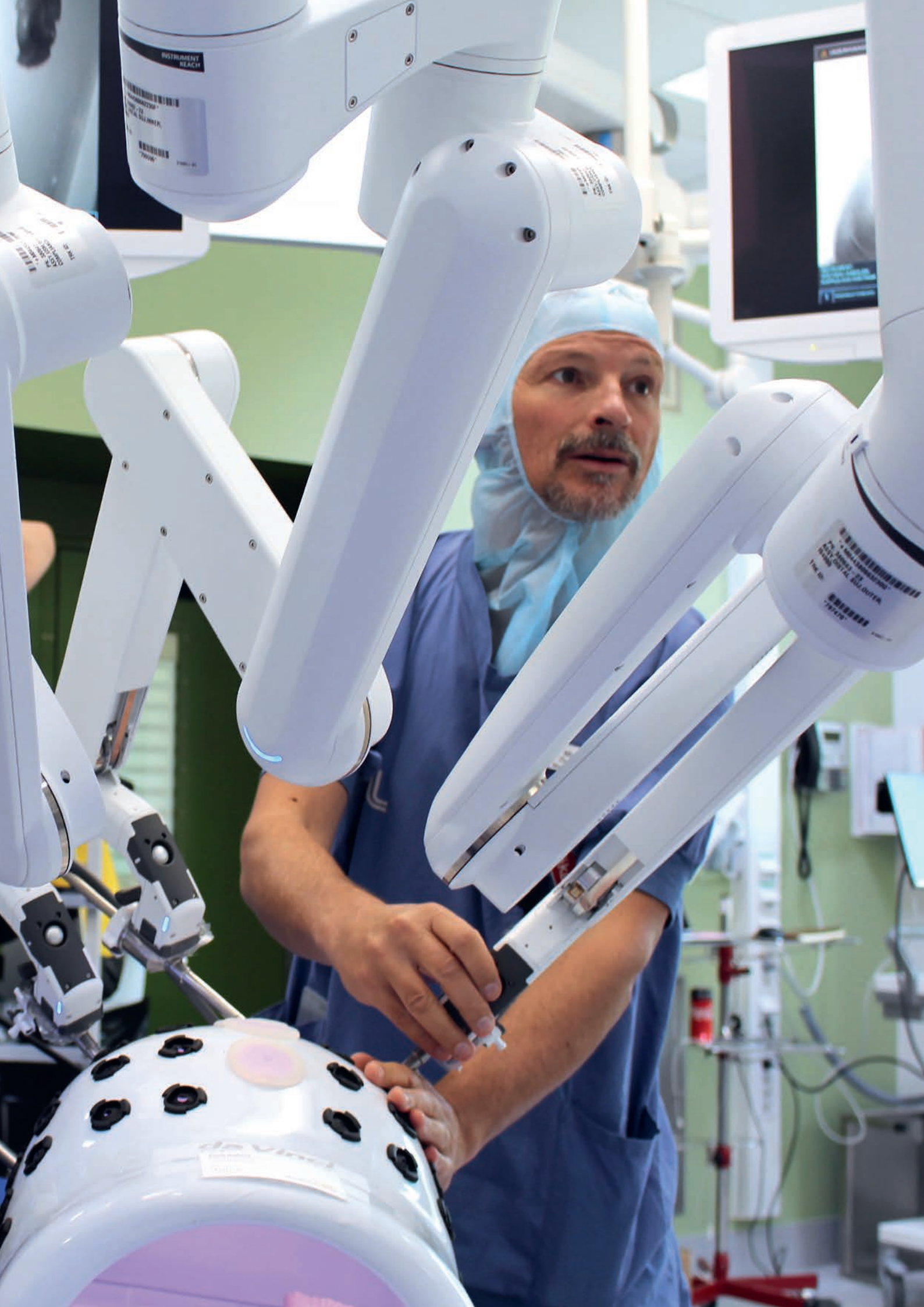
Quality is at the heart of all our efforts and the will to constantly improve is what drives us forward. The development of precision medicine has continued and a Precision Medicine Cancer Forum has been established to build consensus and identify the best ways forward. We have continued to develop and initiate new collaborations, both at home and around the world, which will provide even better conditions for the coming years.

I hope this will inspire you all!

Patrik Rossi
Managing Director Cancer Theme
Chairman Board of Directors Karolinska CCC

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Strategy, Vision and Mission

Our objectives

Karolinska University Hospital is Region Stockholm's university hospital with special responsibility for secondary and tertiary healthcare. The assignment also includes primary responsibility for the Stockholm Region's research and student education alongside the Karolinska Institute and other higher education institutions.

Our strategic focus is on high-quality care and maintaining accessibility and patient safety.

Our vision

We will cure and relieve tomorrow what no one can cure and relieve today.

We provide globally leading healthcare, education, and research to improve the quality of life and survival of patients in all aspects of healthcare.

Our Mission

We are the best at the most difficult. We take responsibility for our common resources.

Long-term objectives 2022–2025

- The patient is an active partner – patient empowerment
- Precision health – we will offer all patients an individualised care and treatment strategy
- We are at the forefront of breakthroughs
- Sustainable skills development
- Increase international collaborations
- We are an excellent Comprehensive Cancer Center



VISION

We will **cure and relieve tomorrow** what no-one can cure and relieve today



MISSION

We are **best at the most difficult**. We take **responsibility for our common resources**.

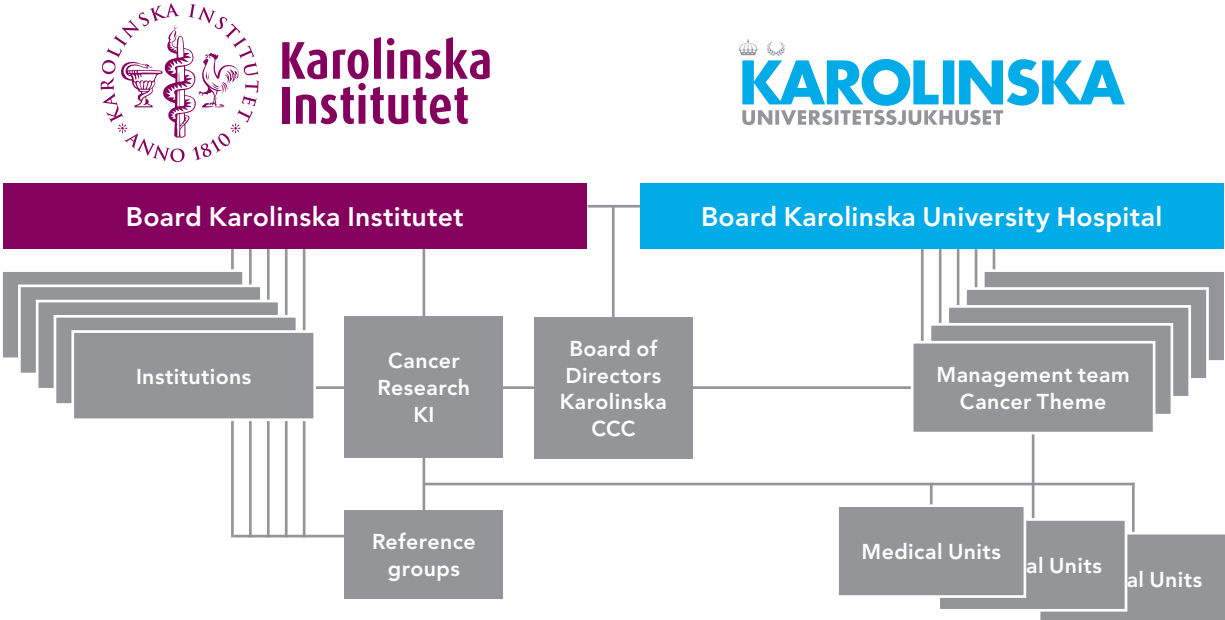
Organisation

The Karolinska Comprehensive Cancer Center (Karolinska CCC) brings together excellence within basic research, clinical research, and highly specialised cancer care. The centre is a joint initiative of Karolinska University Hospital and Karolinska Institutet. Karolinska CCC is Sweden’s first accredited Comprehensive Cancer Center according to the Organisation of European Cancer Institutes (OECI), a non-governmental, non-profit legal entity

established in 1979 to promote greater collaboration between European cancer centres and institutes. The accreditation entails that the organisations meet the high-quality standards set by the OECI for the area cancer care, research and education.

The OECI accreditation can be seen as both a seal of quality and a quality assurance programme, as it is followed up annually and is valid for five years.

Figure 1: Organogram Karolinska CCC.



Board of Directors (BoD)

In 2021, the BoD had the same set of members as in the previous year and met once a month. The focus has been on the development of Karolinska CCC, strategic collaboration with national and international organisations and networks within cancer research and cancer care.

A Memorandum of Understanding (MoU) has been signed with the National Institute of Oncology (NIO) in Hungary. NIO is the only accredited comprehensive cancer centre in Eastern Europe. The agreement with NIO covers everything from student exchanges and joint courses and conferences to research collaboration at various levels.

BoD has held three digital workshops with the Scientific Advisory Board (SAB) of Karolinska CCC. During these occasions, we have presented our organisations and focus areas such as Radiotherapy, Precision Medicine and collaboration with Paediatric Haematology/Oncology within Theme Children at Karolinska University Hospital. Based on the workshop with representatives from Radiotherapy, the SAB authored a report that formed the basis for the strategic plan developed by the Radiotherapy operations during the year. In March 2022, a two-day visit by the SAB is planned.



Patrik Rossi
Managing Director
Cancer Theme
Karolinska University Hospital
and Chair Board of Directors
Karolinska CCC.



Jonas Bergh
Professor in Oncology,
Director CRKI,
Karolinska Institutet.
Prefect Cancer Theme,
Karolinska University Hospital.



Anna Martling
Professor in Surgery,
Dean Karolinska Institutet
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Janne Lehtiö
Professor in Proteomics,
Karolinska Institutet.
Research Director, SciLifeLab.



Eva Jolly
Coordinating Officer,
Karolinska CCC.

Cancer Theme

Cancer Theme is one of the largest themes of Karolinska University Hospital. Cancer Theme investigates, treats, and cares for patients with some form of malignant tumour disease but also for non-cancer patient groups where relevant specialist knowledge is available within the theme, such as benign conditions in urology, endocrinology, hematology, and coagulation. Cancer Theme works actively with other parts of the healthcare system to take responsibility for the patient throughout the care process. By working with person-focused care, with collaboration between multi-professional and multidisciplinary teams, we strive to achieve results that make a difference for the patient.

Cancer Theme has spent the year of 2021 reviewing the specialist mission of oncology, the oncology operations, their roles and responsibilities. This has led to a clarification of the organisational affiliation of oncology with the following objectives:

- Countering organisational fragility, pooling recruitment efforts
- Creating stability in the development of oncology competence and competence on duty
- Strengthening the development of specialist areas

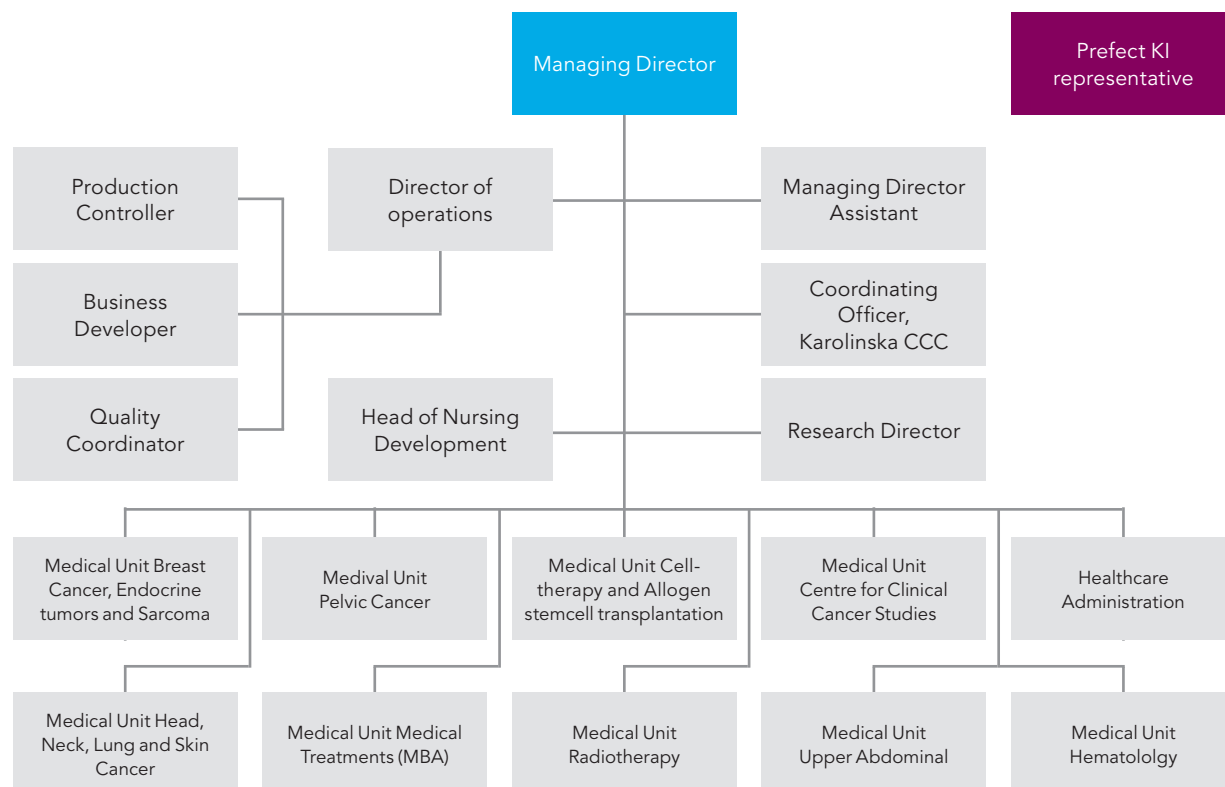
- Clarity of responsibility
- Shorter decision-making paths, e.g. by changing work methods
- Clarification of the accountability for the general mission of oncology

A decision was made to create sections for oncology and surgery in the medical units; Upper Abdominal, Pelvic cancers, Head, neck, lung and skin cancer and Breast cancer, endocrine tumors and sarcoma.

In 2021, it was also decided to reorganise the medical oncology treatment units (MBA) under one common medical unit, ME MBA. The background to the reorganisation is that organisationally fragmented MBA units were difficult to manage and caused various problems, such as different routines and work methods, unequal workloads for staff and unequal waiting times for patients.

The mission of the ME MBA is to increase access and create equal care for patients undergoing medical treatment within Cancer Theme. Pharmaceutical costs are a challenge and by having a clearer management structure towards external partners and an optimised use of pharmaceuticals, the aim is to reduce unnecessary costs for residual volumes and discarded medicine.

Figure 2: Organogram Tema Cancer.



Cancer Research KI (CRKI)

Cancer Research KI (CRKI) serves as an overarching umbrella organisation for cancer research at Karolinska Institutet, conducted by some 300 research groups at multiple campuses and departments. The overall goal is to generate new scientific discoveries that can be rapidly translated into clinical practice for the benefit of patients and society. Due to the pandemic, the organisation had to restrict its physical activities but through digital meetings, workshops and events we were able to reach out to both researchers at KI, international collaborators, and the general public and patient organisations during 2021.

In 2021 CRKI and Mayo Clinic Cancer Center arranged two digital symposia to further the collaboration between the institutes by bringing together the researchers in the breast cancer area and thereby also stimulating collaboration.

In April, we hosted “A Day of Cancer Research” for the first time, a live event where researchers

presented their research with the aim to introduce the public to the cutting-edge cancer research being conducted at KI. The focus was on new cancer treatments, fertility after cancer treatment, antioxidants and cancer, and rehabilitation. On 31 March and 11 November, joint workshops within the cancer area for patient organisations were held in collaboration with the Stockholm-Gotland Regional Cancer Centre with the aim to enable interaction and communication between different patient organisations, researchers and the general public. This is highly appreciated by patients, patient organisations and researchers alike as a tool for interaction and further education.

CRKI jointly arranged the 6th Annual Meeting of – Cancer Core Europe (CCE) with the organisation that was hosted by KI in 2021. The sessions focused on topics such as clinical trials and translational cancer research, Virtual data centre, Education & Training and talks on themes with interest for CCE current and future work.



Jonas Bergh, Professor and Director CRKI and Johanna Furuhjelm, Administrative Director CRKI.

National and international networks and partners

Care

- Landspítale University Hospital, Iceland for stem cell transplants and upper abdominal surgery and telemedicine support
- Tampere University Hospital, Finland for liver and pancreatic cancer
- Helse Vest RHF, Norway for radiotherapy and proton therapy at Skandion
- OECI
- Region Gotland
- Region Sörmland and Västmanland
- NRF Northern Healthcare Region Association (Västernorrland, Jämtland-Härjedalen, Västerbotten and Norrbotten)
- Dalarna Region
- Scandion for proton treatments

Education

- MD Anderson, cooperation agreement between Karolinska Institutet and MD Anderson
- Tampere University Hospital, Finland
- Landspítale University Hospital, Iceland
- Charité University Hospital, Germany
- Cancer Core Europe
- OECI
- Skandion
- ALF agreement KI
- Region Gotland
- Region Sörmland and Västmanland
- Dalarna Region

Research

- MD Anderson
- Cancer Core Europe
- OECI
- Tampere University Hospital, Finland
- Landspítale University Hospital, Iceland
- EUCCAT initiative of European University Hospital Alliance (EUHA)
- Skandion

Memorandum of Understanding with National Institute of Oncology in Hungary autumn 2021 in close collaboration with the Karolinska CCC

The agreement with NIO – a so-called memorandum of understanding (MoU) – applies to everything from student exchanges and joint courses and conferences to research collaboration at various levels. The parties undertake to comply with international principles and agreements on academic freedom.

Initiation of collaboration with King's College London within the cancer area

In the autumn of 2021, Cancer Research KI initiated a new collaboration in the cancer area with King's College of London (KCL) and under these premises, an MoU is being developed between KI and KCL.

Membership in Cancer Prevention Europe

Cancer Research KI is upholding the KI membership in Cancer Prevention Europe and has also taken the initiative through discussions at KI to develop the cancer prevention arena at KI. Executive Board member Martin Bergö and Professor Joakim Dillner actively participates in the meetings of CPE. KI was also well represented at the Cancer Prevention Europe 2021 digital Symposium on the 16th of April 2021, hosted by the International Agency for Research on Cancer (IARC/WHO).

Collaboration with industry and support in the area

One of the working pillars of the CRKI organisation is the collaboration with industry and in this arena, we aid in the process of establishing active and well-functioning collaboration together with the KI External Engagement Office and linking these functions to the right researchers in the cancer area. During 2021 we actively participated in several negotiations with industrial partners and also funded a mentorship programme for cancer researchers called Mentor4Research a service provided by the KI Innovation holding company.



Healthcare production and availability

We can look back on a dramatic 2021 in which we have adapted and adjusted our operations in an outstanding way. Karolinska CCC's collective effort is a major part of the hospital's success and what we have achieved during the year is incredibly impressive, delivering world-class cancer care and addressing the challenges posed by the pandemic while conducting research, education and continuing to initiate developmental work across the organisation.

We have included more than 2,000 patients in clinical studies, exceeding both 2019 and 2020, a positive trend that we will accelerate. Clinical

researchers, together with researchers at KI, have contributed to the COVID-19 research becoming leading in the country. We have managed to maintain good access to all forms of cancer treatment, and we have continued to improve the 5-year survival rate for cancer patients in the region.

Some patient groups, such as breast cancer, colorectal cancer and prostate cancer, are treated in several different hospitals in the region, while others are only treated at Karolinska CCC. The improved survival can be explained by several different factors, including improved diagnostics and treatment.

Figure 3: Relative 5-year survival, patients diagnosed (%) in the Stockholm-Gotland region.

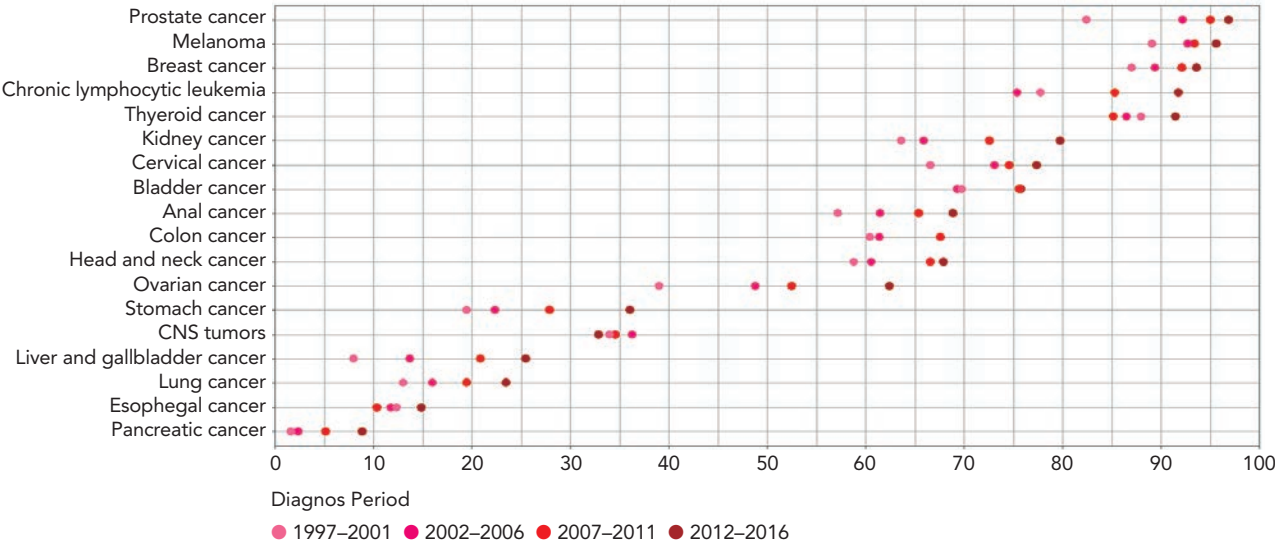
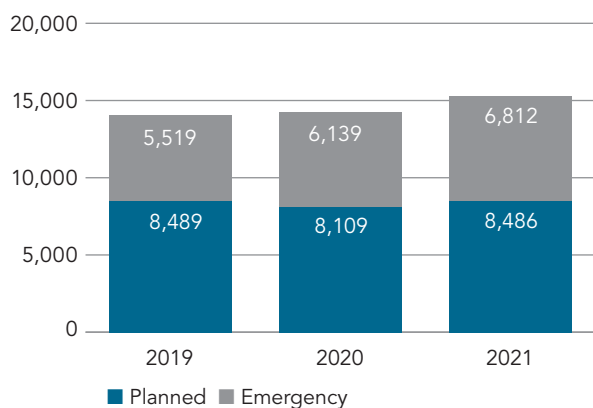
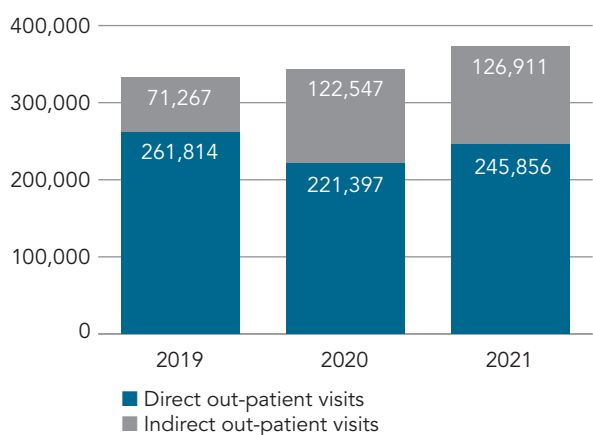


Figure 4: Number of planned and emergency admissions, 2019–2021.



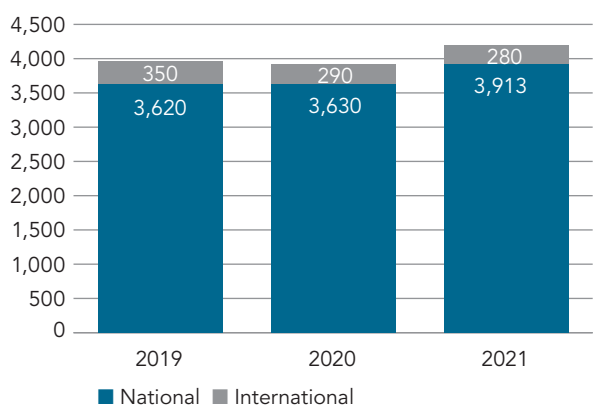
Admissions	2019	2020	2021
Number of admissions	14,008	14,248	15,298
Proportion emergency admissions	39%	43%	45%
Admissions with a covid diagnosis	0	548	235
Number of hospital beds	161,7	185,2	191,2

Figure 5: Number of direct and indirectly out-patient visits, 2019–2021.



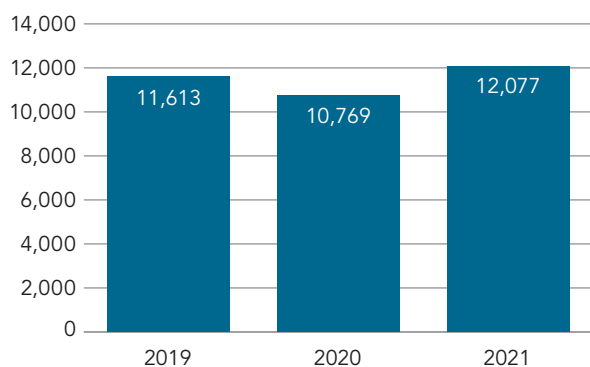
Out-patient visits	2019	2020	2021
Total number of visits	333,097	343,963	372,801
Direct visits	261,814	221,397	245,856
Indirect visits	71,267	122,547	126,911
Proportion indirect visits	21%	36%	34%
Number of unique patients	62,327	59,431	62,619
Number of new visits	19,763	16,709	18,252
Proportion of cancer patients	9,065	8,524	9,088

Figure 6: Number of national and international patients, 2019–2021.



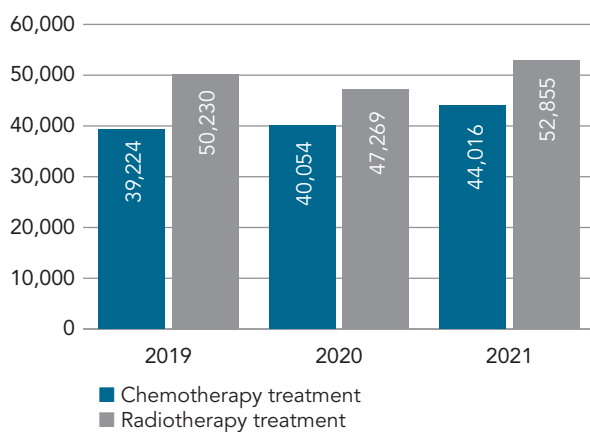
National and international patients	2019	2020	2021
Number of unique patients	3,970	3,920	4,193
International	350	290	280
National	3,620	3,630	3,913
Number of out-patients visits	11,776	11,840	13,182
Number of admissions	1,068	882	1,047
Multidisciplinary meetings	1,866	2,482	2,505
New visits	821	617	640

Figure 7: Number of surgical interventions, 2019–2021.



Surgery	2019	2020	2021
Surgical interventions	11,613	10,769	12,077
Day surgery	3,952	3,353	3,709
Robotic surgery	918	882	1,033

Figure 8: Number of treatments, 2019–2021.



Chemotherapy/ radiotherapy	2019	2020	2021
Chemotherapy treatment			
Number of unique patients	5,148	5,446	5,824
Number of treatments	39,224	40,054	44,016
Radiotherapy treatment			
Number of unique patients	3,346	3,380	3,774
Number of treatments	50,230	47,269	52,855
Proton therapy	1,730	1,788	2,324



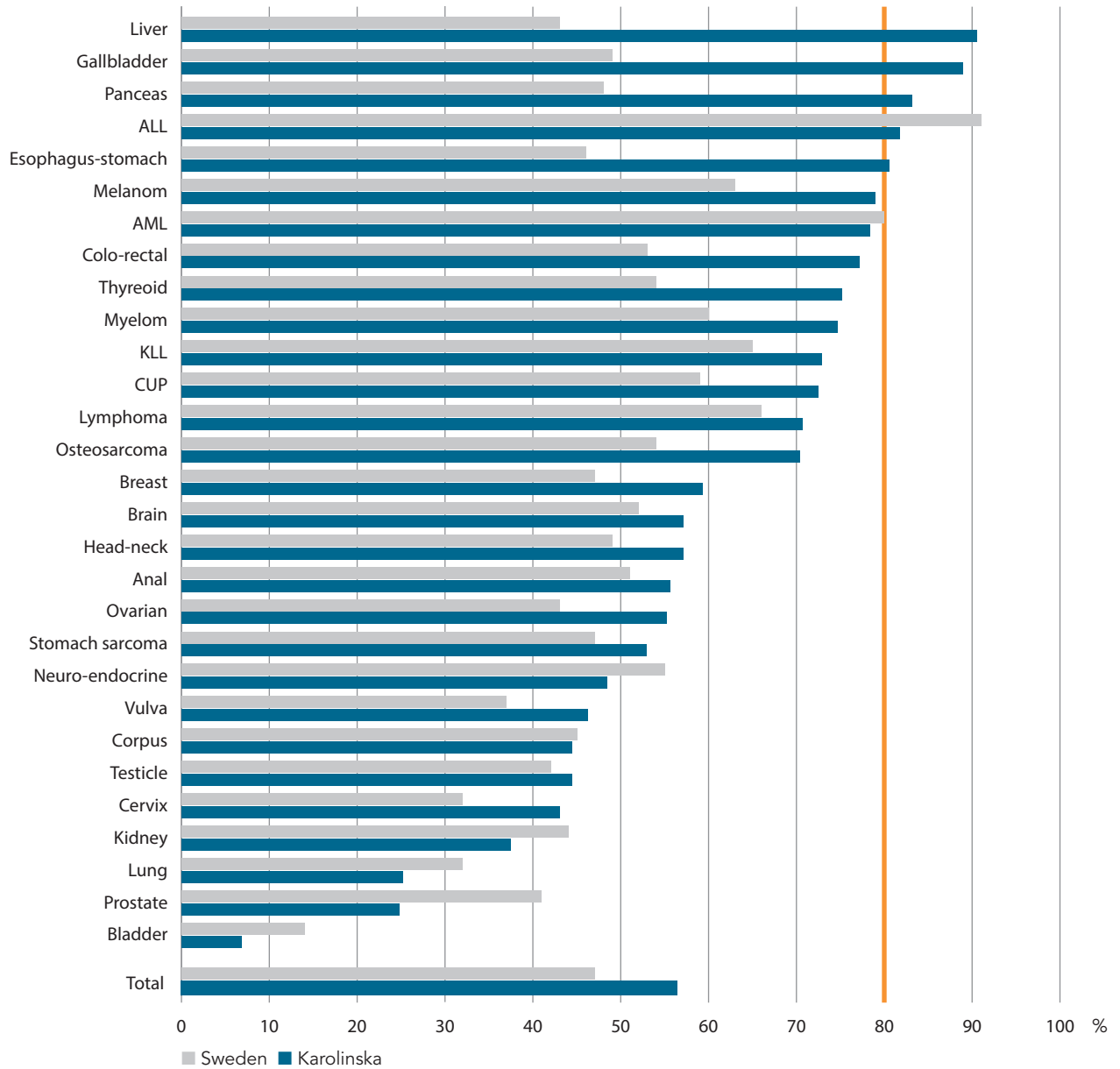
Standardised care pathways

Standardised care pathways (SVF) is a national approach to reduce waiting times for treatment

and increase equal care for patients with cancer.

The chart shows the proportion of patients who start treatment within the specified lead time.

Figure 9: Proportion of patients within specified lead time.



A positive development over time for all primary treatments, 2018–2021.

Figure 10: Proportion and numbers of patients starting surgical treatment within target, 2018–2021.

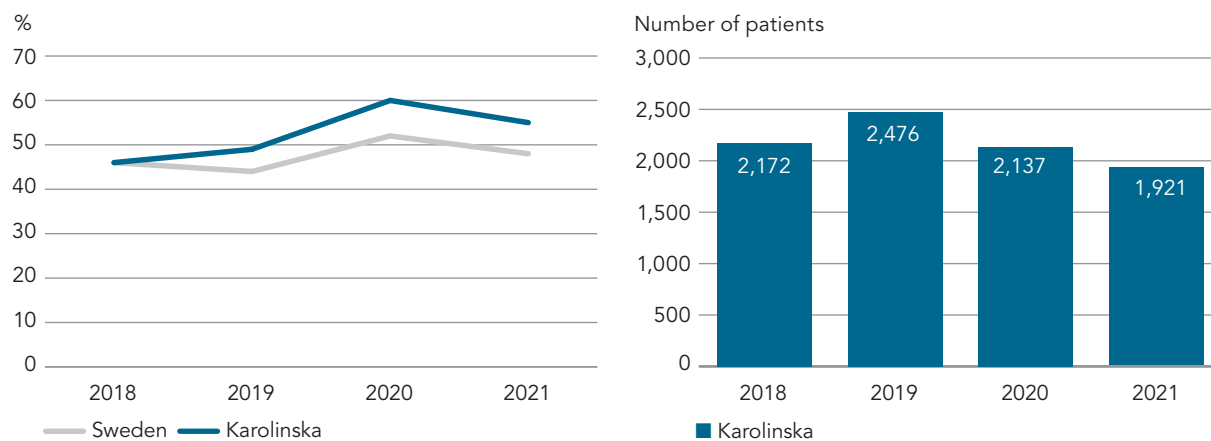


Figure 11: Proportion and numbers of patients starting radiotherapy within target, 2018–2021.

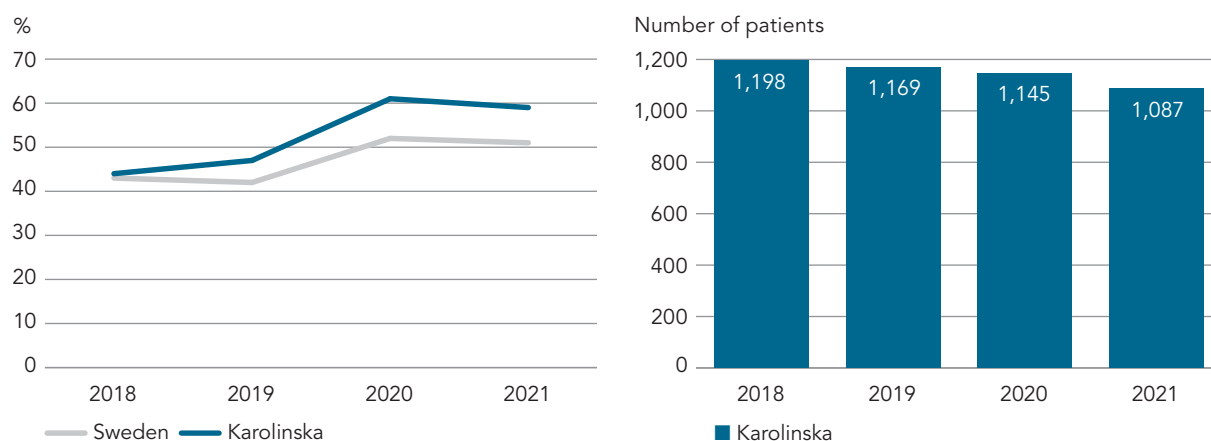
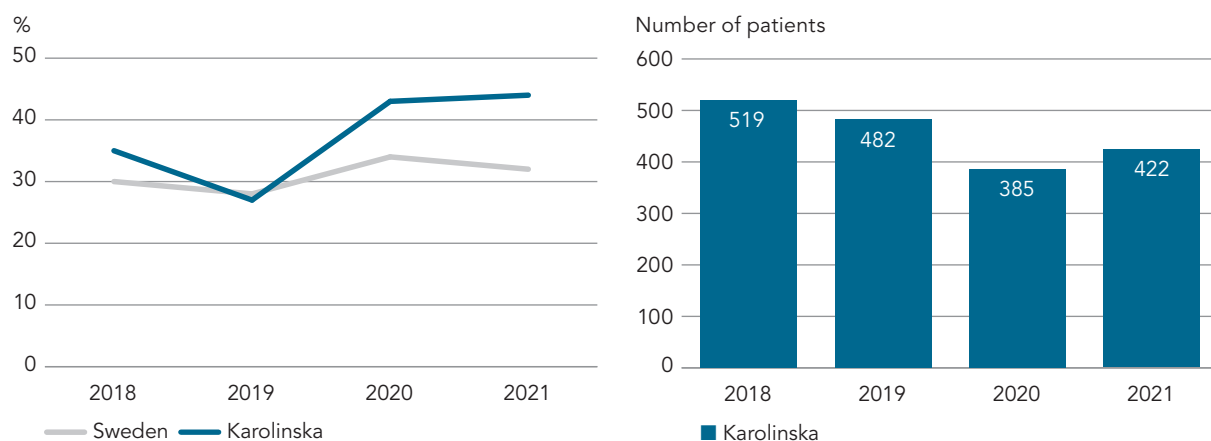
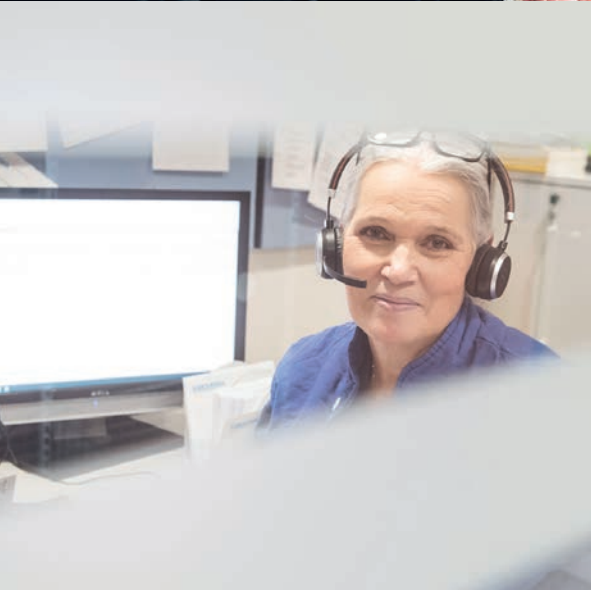


Figure 12: Proportion and numbers of patients starting radiotherapy within target, 2018–2021.







Employees

Karolinska CCC is leading the development in several areas, and many employees are making outstanding contributions. Here are some of the prizes awarded during the year:

- Anna Martling was named Cancer Researcher of the Year.
- Sahar Salehi has been awarded the 2021 Passionate Spirit Award in the Stockholm-Gotland Region by the Network Against Gynecological Cancers.
- Gabriella Bjerring, has received the award “Contact Nurse of the Year” at the RCC Day on 18 May 2021.
- In 2021, we have had 48 dissertations and the appointment of 12 associate professorships and 3 professorships.

Together, we have contributed to the Karolinska University Hospital being named the seventh best hospital in the world 2021 by Newsweek magazine.

Karolinska CCC offer skills and career development for all employees. Several options are available to stimulate development and research in healthcare. We share and gain knowledge from around the world. The aim is to integrate academic healthcare development into the whole operation. During the year, a Karolinska CCC careers page was developed on Karolinska.se, where all professional roles within the theme are described and highlighted.

Employee survey 2021 Cancer Theme

For two years, the operations have managed to maintain its performance levels in the employee survey despite a high workload due to the pandemic and is above average in all performance points compared to Karolinska University Hospital as a whole.



Figure 13: Compared to a year ago, Cancer Theme has a positive inflow of skills, 2020–2021.

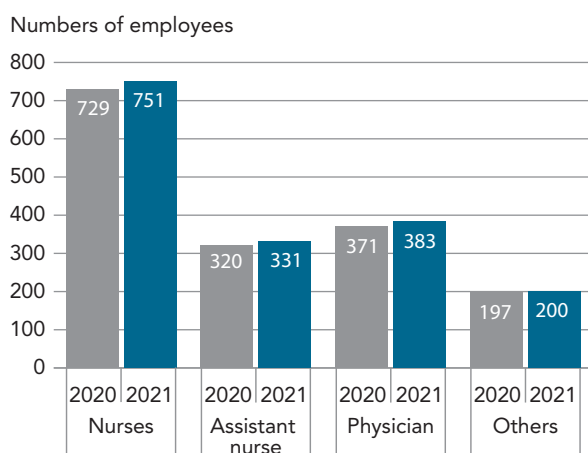
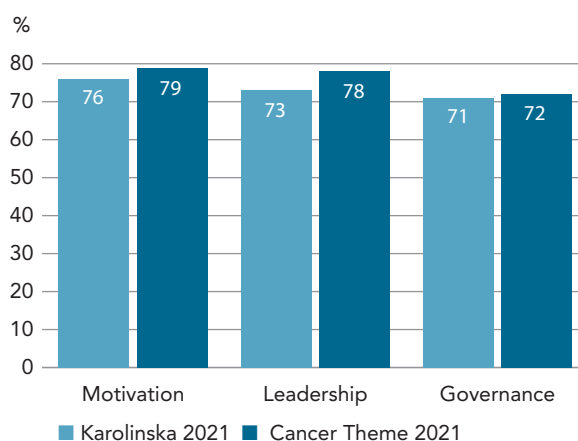


Figure 14: Result from the employee survey 2021.





Research and education

Education

Training in 2021 was affected by the ongoing pandemic, but were performed as planned with increased use of digital training formats and platforms.

Nursing

During the year, we have been able to offer clinical training to undergraduate students, assistant nurses, nurses, and specialist nursing students as planned.

We have continued to focus on tutor training, with several nurses completing the training during the year.

The introduction days for new employees have had around 250 participants in 2021.

In 2021, five Journal Clubs were conducted with varied issues:

- How are cancer patients who get COVID-19 actually doing?
- How does quitting smoking after a cancer diagnosis affect patients' quality of life?
- What are the digital solutions in cancer care that can improve patient care?
- What factors influence cancer patient's decisions to participate or not in clinical studies?
- What factors influence informing patients successfully about disease and treatment?

Medicine

During the year we have had high student activity in all our medical units. Supervision consists of both theoretical and bedside teaching, which takes place in both outpatient and inpatient settings.

For the oncology component, physicians participate in the student selected courses; The Art of Being a Good Doctor (T6), Multidisciplinary Cancer Care (T11), Advanced Care, Palliative Care and Oncology (T11). The Palliative Care course was awarded the Best Student Selected Course in medical programme in autumn 2021.

In addition, a number of the theme's surgical sections have been responsible for various elements of medical training such as elective surgery and other elements of undergraduate training. MOCC (Massive Open Online Courses)

has been developed to teach clinical examination techniques. An OSCE (Objective Structured Clinical Examination) station has been staffed with assessors.

Karolinska Clinical Cancer Talks

Karolinska Clinical Cancer Talks is a lecture series in cancer research and during the year several interesting and rewarding lectures have been given, both by our own researchers and by invited guest lecturers from abroad. A highlight was when in September we had the great honor and pleasure to welcome Professor Uğur Şahin from the University Medical Center in Mainz and CEO of BioNTech with the lecture "When a cancer vaccine tackled the pandemic".

Molecular Tumor Board

In September, the first Molecular Tumour Board (MTB) took place within the framework of Karolinska CCC. MTB is a forum for discussion of patient cases and learning about how molecular diagnostics can improve the care of patients in the future. A selection of themes:

- Results from the first 90 patients in the PSFF (pre-screening for Phase-I) ctDNA program.
- Molecular diagnostics in lung cancer.
- Molecular diagnostics in pancreatic cancer.
- "Molecular Health Solutions" tool.
- Germline mutations beyond BRCA.

MTB takes place every other Friday and is open for all employees.

Publication of the CRKI database on principal investigators at KI within the cancer field

CRKI has mapped cancer research at KI and created a database with information on principal investigators at the Institute. The database is aimed at researchers and others interested in gaining an overview of cancer research at KI, fostering new collaborations, learning more about specific cancer areas or exploring industrial interactions. The initiative is part of CRKI's ambition to act as a gateway for several market players interested in getting involved in cancer research at KI.

Figure 15: Tema cancer copublication organisations 2019–2021. 105 organisations have been included in addition to Karolinska Institutet (organisations with at least 20 publications). Connections between organisations need at least 12 publications to be shown.

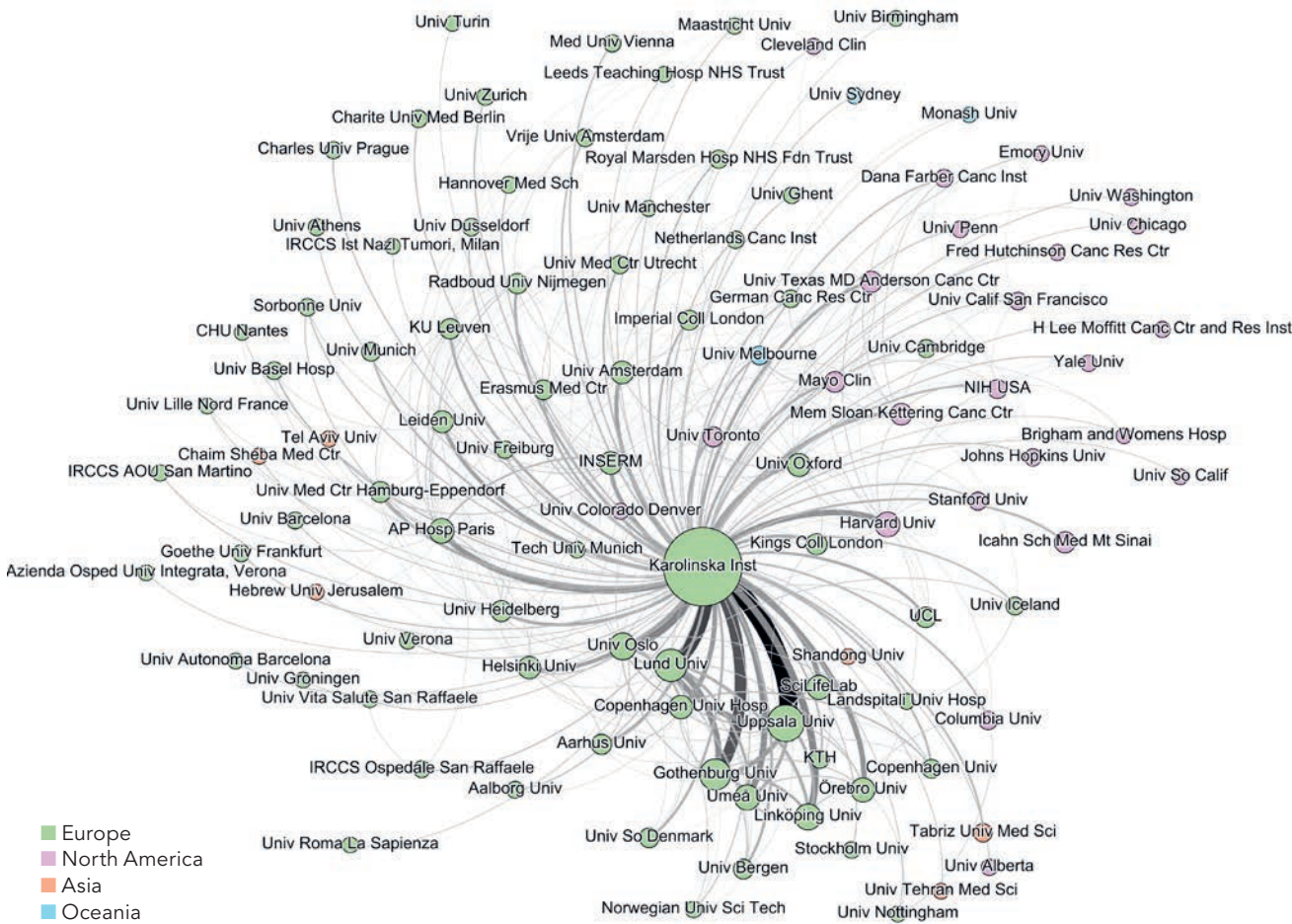
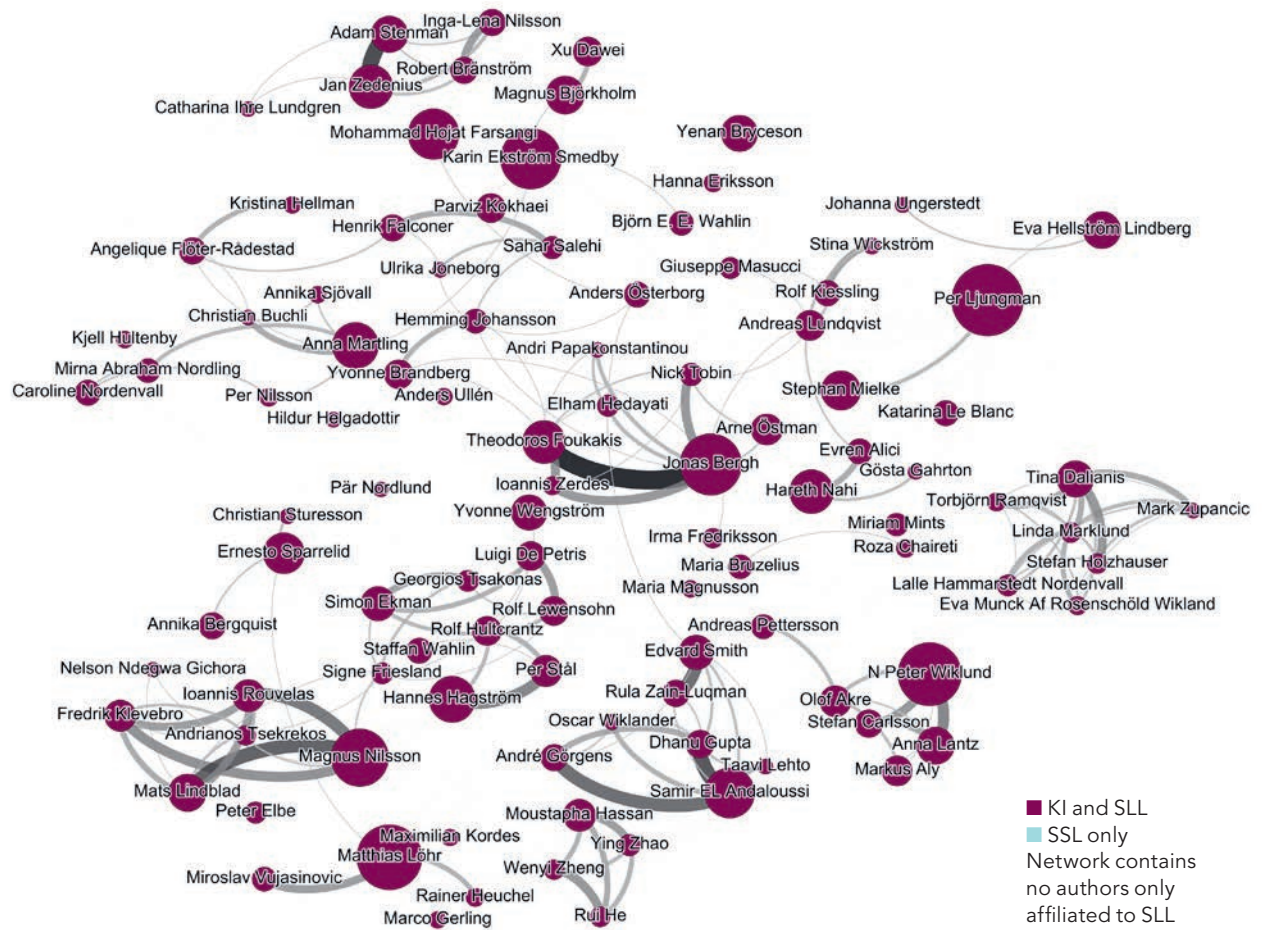
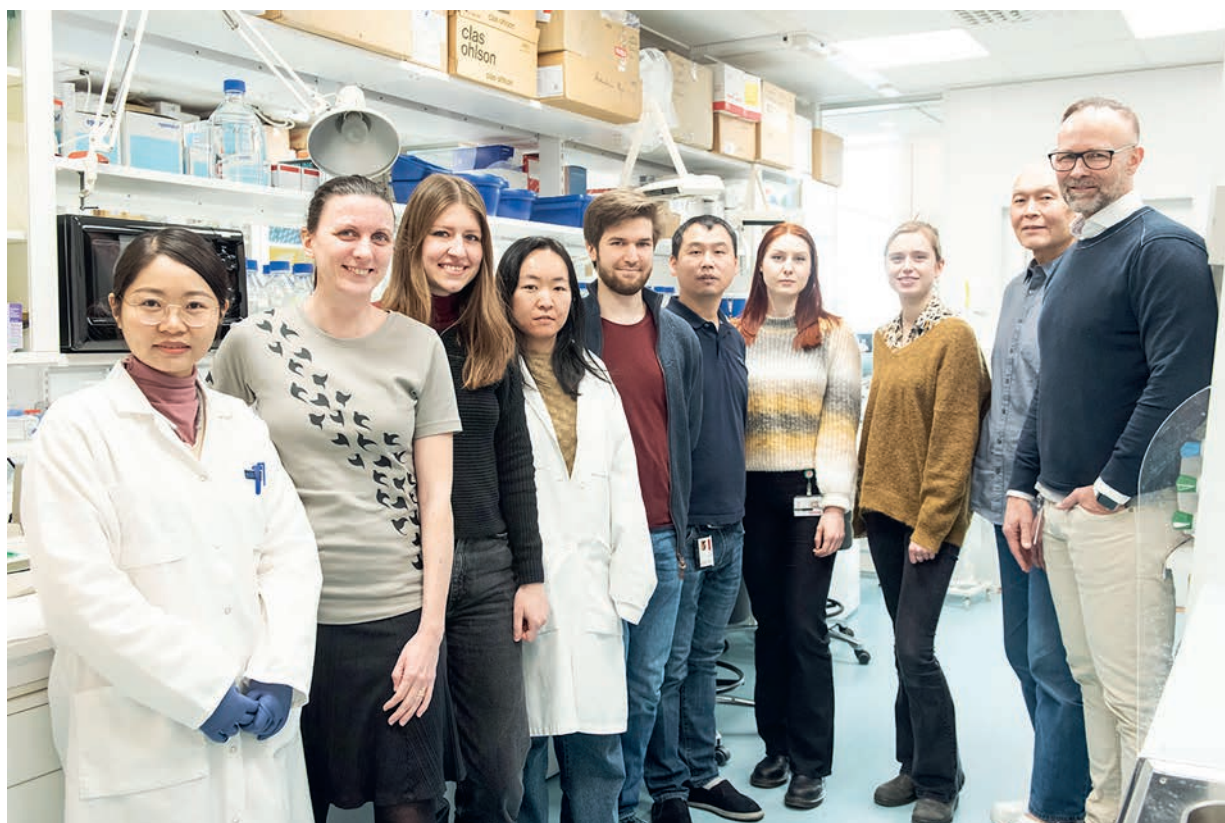


Figure 16: Tema cancer author network – at least 8 publications 2019–2021. 104 authors have been included (authors with at least 8 publications). Connections between authors need at least 1 publication to be shown.





Grants

The organisation awarded 14 research grants for collaborative and innovative projects in 2021. In total Cancer Research KI awarded funding close to 24 MSEK.

The Blue Sky Research Grant for Innovative Cancer Research is a one-year grant to support an innovative pilot project aimed at demonstrating proof of principle. 6 projects were granted funding in 2021.

Translational Seed funding grants for collaborative projects between a clinical and a preclinical researcher at KI. 6 projects were granted a two-year funding in 2021.

Joint call for applications within breast cancer research with **Mayo Clinic Cancer Center**, where two projects were awarded funding in 2021.

The Transition Grant is a funding initiative where CRKI awards funds to promising researchers with outstanding scientific merits, enabling them to consolidate their research. A transitional grant was awarded in 2021, providing two years of funding

Grant sources

During the year, we have received large and important research grants and we would like to thank our research funders for enabling continued research, development and innovation.

Our largest grant sources:

- EU
- Swedish Research Council (VR)
- Cancer Foundation
- Knut and Alice Wallenberg Foundation
- Childhood Cancer Foundation
- Radiumhemets forskningsfonder

Selected publications from the medical units

Cell-therapy and Allogeneic stem cell transplantation

Long-term clinical outcomes of tisagenlecleucel in patients with relapsed or refractory aggressive B-cell lymphomas (JULIET): a multicentre, open-label, single-arm, phase 2 study. *Schuster. S.J, et al. Lancet Oncol.* 2021 Oct;22(10):1403-1415.

Amelioration of systemic inflammation via the display of two different decoy protein receptors on extracellular vesicles. *Gupta. D, et al. Nat Biomed Eng.* 2021 Sep;5(9):1084-1098.

Safety and efficacy of the mRNA BNT162b2 vaccine against SARS-CoV-2 in five groups of immunocompromised patients and healthy controls in a prospective open-label clinical trial. COVAXID-collaborator group (shown separately). *Bergman. P*, Blennow. O*, Hansson. L*, Mielke. S*, Nowak. P*, et al. EBioMedicine.* 2021 Dec;74:103705. * Shared 1st authorship

Breast cancer, Endocrine tumors and Sarcoma

The value of cancer drugs: the regulatory perspective. *Pignatti. F, et al. Nature Reviews Clinical Oncology* Dec 6. 2021.

Trastuzumab for early-stage, HER2-positive breast cancer: a meta-analysis of 13 864 women in seven randomised trials. *Early Breast Cancer Trialists' Collaborative group (EBCTCG)*. Lancet Oncology* 8:1139-1150, 2021. *Jonas Bergh member of steering & writing committee chairing the EBCTCG.

Neoadjuvant Trastuzumab, Pertuzumab, and Docetaxel vs Trastuzumab Emtansine in Patients With ERBB2-Positive Breast Cancer: A Phase 2 Randomized Clinical Trial. *Hatschek. T, et al. JAMA Oncology* 7:1360-1367, 2021.

Pelvic cancer

The annual recurrence risk model for tailored surveillance strategy in patients with cervical cancer. *Cibula. D, et al. Eur J Cancer.* 2021 Oct 16;158:111-122.

Functional and Oncological Outcomes After Open Versus Robot-assisted Laparoscopic Radical Prostatectomy for Localised Prostate Cancer: 8-Year Follow-up. *Lantz. A, et al. Eur Urol.* 2021 Nov;80(5):650-660.

Increased risk of cancer in patients with primary sclerosing cholangitis. *Lundberg Båve. A, et al. Hepatol Int.* 2021 Oct;15(5):1174-1182. Centrum för Kliniska Cancerstudier

Support systems to guide clinical decision-making in precision oncology: The Cancer Core Europe Molecular Tumor Board Portal. *Tamborero. D, et al. Nat Med.* 2020 Jul;26(7):992-994.

Early alkaline phosphatase dynamics as biomarker of survival in metastatic castration-resistant prostate cancer patients treated with radium-223. *Van der Doelen. M.J, et al. Eur J Nucl Med Mol Imaging;* Published on-line March 8, 2021.,

Dabrafenib plus trametinib in patients with BRAFV600E-mutant low-grade and high-grade glioma (ROAR): a multicentre, open-label, single-arm, phase 2, basket trial. *Wen. P.Y, et al. Lancet Oncol.* 2022 Jan;23(1):53-64.

Hematology

T cells targeted to TdT kill leukemic lymphoblasts while sparing normal lymphocyte. *Ali. M, et al. Nat Biotechnol.* 2021 Dec 6. doi: 10.1038/s41587-021-01089

Risk of infections in patients with myeloproliferative neoplasms—a population-based cohort study of 8363 patients. *Landtblom. A, et al. Leukemia.* 2021 Feb;35(2):476-484.

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Head, Neck, Lung, and Skin cancer

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Survival and biomarker analyses from the OpACIN-neo and OpACIN neoadjuvant immunotherapy trials in stage III melanoma. *Rozeman. E.A, et al. Nat Med* 27, 256–263 (2021).

High-dose versus standard-dose twice-daily thoracic radiotherapy for patients with limited stage small-cell lung cancer: an open-label, randomised, phase 2 trial. *Grønberg. B.H, et al. Lancet Oncol.* 2021 Mar;22(3):321-331.

Radiotherapy

Re-irradiation for head and neck cancer: cumulative dose to organs at risk and late side effects. *Embring, A, et al. Cancers* 2021, 13, 3173.

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Upper abdominal

Extracellular vesicles are the primary source of blood-borne tumour-derived mutant KRAS DNA

early in pancreatic cancer. *Hagey, D.W, et al. J Extracell Vesicles*, 10: e12142.

IgG4-related diseases of the digestive tract. *Löhr, J.M, et al. Nature Reviews Gastroenterology & Hepatology* 2021.

Maternal obesity increases the risk and severity of NAFLD in offspring. *Hagström H, et al. J Hepatol.* 2021 Nov;75(5):1042-1048.

Clinical trials

68 new studies were launched during the year despite the impact of the pandemic on all aspects of the operation. The inclusion of patients in clinical studies has increased during the year and a total of 2,118 patients were included, which means that more than 23 per cent of new cancer patients are included in a clinical study.

Figure 17: Number of included patients, 2019–2021.

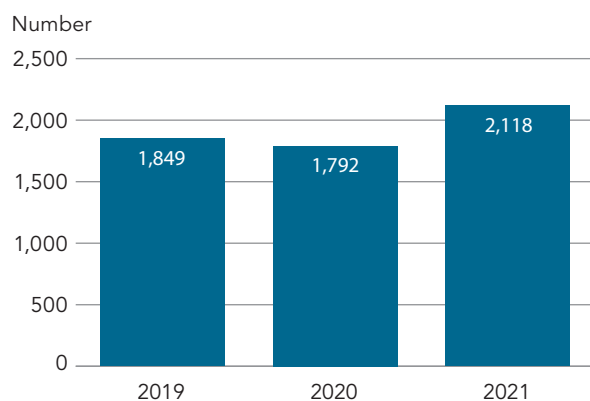


Figure 18: Proportion of new cancer patients included in clinical trials, 2019–2021.

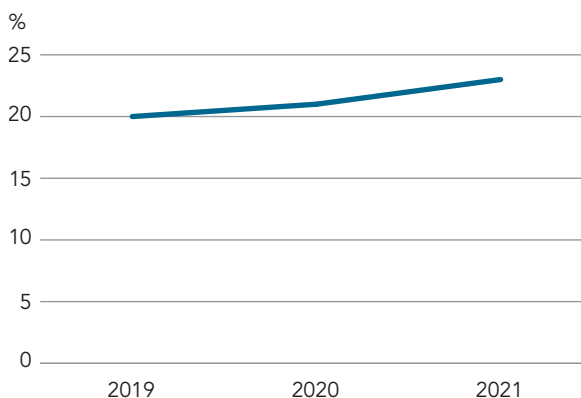


Table 1: Trials open for inclusion 31 December 2021.

	Cancer Theme	Breast cancer, endocrine tumors and sarcoma	Pelvic cancer	CAST	Phase 1-unit	Hematology	Head, neck, lung, skin cancer	Radiotherapy	Upper abdominal
Trials started in 2021 (2020: 40 st)	68	5	13	6	9	16	10	1	8
Ongoing trails 31 december 2021	383	48	81	16	27	96	61	3	51
Trials open for inclusion	153	11	32	7	21	32	19	3	28
Proportion of academic trials	59%	73%	62%	43%	19%	53%	68%	67%	86%



Development and innovation

Precision Medicine

Karolinska University Hospital, the Karolinska Institute and Region Stockholm are working together to increase the pace at which precision medicine, which, in short, means diagnostics, treatment and follow-up at the right time, tailored to the patient's individual needs, is introduced into clinical practice.

In 2021, the Precision Medicine Center Karolinska (PMCK) was established to promote seamless collaboration between academia and healthcare in diagnostics, treatment, development, and research. PMCK is part of a broader initiative, "Task Force for Accelerated Implementation of Precision Medicine", which is managed by the Dean of Karolinska Institutet North, Professor Anna Martling.

Karolinska CCC and SciLifeLab are working together to develop the field of precision medicine. Through interdisciplinary collaborations, for example in the national Data-Driven Life Science (DDLS) program, we are increasing the cutting-edge technology and expertise within the organisation.

Precision Medicine Forum Cancer (PM Forum Cancer)

Kristina Sonnevi, senior consultant in medical unit Hematology, manages the work within the PM Forum Cancer. Work has been done to map the patient groups where precision medicine is already being used and those groups that are in the process of introducing it into clinical practice.

The first year of the PM Forum Cancer has included work on

- Establishment of the current situation, objectives, and structure of the work
- Inventory and mapping and flows and projects
- Development of follow-up views
- Short and long-term projections of trends
- Analysis of conditions for implementation
- Environmental analysis and competence supply plan in cancer genomics
- Initiatives started on training for clinical staff

Reflex testing can improve diagnosis and treatment

The reflex testing project is a tangible example of how precision medicine can improve diagnosis and treatment for patients. It includes patients being investigated for colorectal cancer and involves an extended diagnostic procedure where a biopsy is sent for extensive gene sequencing that, in addition to other routine diagnostics, provides information on the optimal type of treatment.

"The fact that we can tailor treatment to each patient and also prevent other cancers will provide better survival rates and more gentle treatments," says Annika Sjövall, Associate Professor and senior consultant at medical unit Pelvic Cancer and manager of the Reflex Testing project.



Business development

Clinical Nurse Supervisor

During the year, clinical nurse supervisors have been employed in all inpatient departments. The clinical nurse supervisor is responsible for quality development and educational support for the less experienced nurses. The goal is to create good conditions for new nurses to stay in the profession through continuous education and a better learning environment for students. The aim is also to create a clinical career path and, through better teamwork, to develop quality of care.

Improved lead times

In medical unit Upper abdominal cancers, new approaches to standardised care pathways (SVF) have resulted in over 80 per cent of all patients receiving care on time (compared to around 50 per cent in 2019). This success is due to intensive multidisciplinary collaborations between surgeons, liaison nurses, oncologists, hepatologists, pathologists and radiologists. The contact nurses use SVF as a working tool and are responsible for ensuring that the patient is evaluated and treated within the specified time for each pathway. Already at referral assessment, an assessment is performed and documented which then follows the patient through the entire pathway; conference, out-patient and surgery/treatment planning. Identified factors that have delayed progression of SCP have been actively addressed, for example through dedicated times for PET/CT and endoscopic ultrasound.

One Number In

The aim of the “One Number In” project has been to increase accessibility for patients with post-treatment symptoms. A specialist nurse answers calls in the evenings and during weekends – a quality improvement compared to the past when patients called an inpatient department or went directly to accidents and emergencies. Around 700 patients have called for on duty counselling during the 4 months of the project, around 40 patients have needed to come to the hospital for a physical assessment and in some cases inpatient treatment.

Health Assessment

The aim of the health assessment is to assess rehabilitation needs in a structured way, so the right measures are put in place at the right time. The health assessment will facilitate work for the liaison nurse and the patient as the conversation can focus on relevant problems and assessment

of rehabilitation needs. The health assessment is also the basis for identifying self-care tools for the individual patient. Implementation of the health assessment has taken place in all departments during the year.



Fellowship for nurses

In the medical unit Upper Abdominal cancers, Advanced ERCP (Endoscopic Retrograde Cholangio-Pancreatography) examinations are performed. In 2021, a pilot project for nurse fellowships within ERCP was launched. There is great interest among nurses from the rest of the country to participate in the program. A strong focus is placed on individual planning of the Fellowship period and is based on the individual goals of the participants according to their experience, interests and needs. The participant will develop both theoretical knowledge of diseases that lead to ERCP and different types of interventions as well as the opportunity to participate in examinations. There is also a focus on product review and hygiene principles in the care setting. The aim is to promote national skills exchange and networking for nurses in ERCP.

Improved approaches to pain management

One of the areas identified as an area for improvement during the 2019 OECE accreditation was the measurement of the use of pain assessment instruments. That is, how many of the patients who report having pain were asked to rate their pain with a pain assessment instrument. To follow up on the documentation of pain assessment and treatment for patients at Karolinska CCC, a review medical records was conducted in the autumn, and a new review of medical records will be conducted in the spring of 2022.

Green Cross in out-patient clinics

The Green Cross is a visual method and a support in clinical work to identify risks and care injuries in real time and a tool for systematic improvement work. Within medical unit Radiotherapy, the Green Cross is used to improve problem areas and the aim is to improve the quality of care, patient safety and the work environment. Similar use is made at the endoscopy unit where the Green Cross is perceived to be a simple method of systematically evaluating work. The entire multi-professional team around the patient is involved and there is a system to ensure that procedures are followed, and patient safety measures are followed up. The aim is for all employees to be involved and to know which focus areas are relevant.

Palliative Organisation

A survey was conducted during the year on palliative care at Karolinska CCC to identify challenges and opportunities. A need for a palliative organisation/team was identified. One of the first activities was a workshop with the Intensive Care Unit, the Regional Cancer Centre and the Palliative Knowledge Centre. A specialist in palliative medicine has been hired within the operation and will be responsible for the work together with the specialist nurse in oncology.

Digital development

There are both demands and expectations on healthcare to provide patients with opportunities for digital solutions to facilitate care and treatment. Here are some examples of the initiatives Karolinska CCC has initiated during the year to increase patient participation digitally.

Comments and complaints

To make it easier for patients to leave comments, complaints or praise for their healthcare provider, a digital option to do so was introduced in summer 2021.

Self-sampling

For gynecological cancer a project has been launched to introduce self-sampling. Self-sampling entails that the patient receives instructions and documentation to book and carry out their own sampling. The new work process means less administrative work for healthcare professionals and more responsibilities for the patients in their treatment. The ambition is that the majority of operations within the theme will introduce self-sampling where possible.

Patient satisfaction

At Karolinska CCC, regular surveys of patients' experiences of the care and treatment they have received are conducted using hospital-wide questionnaires. These questionnaires are sent out digitally after each new visit or admission to inpatient care since autumn 2021.

The Alltid öppet-application

With Alltid öppet, it will be easier for patients to get in touch with the out-patient clinics via mobile phone and tablet. Via Alltid öppet, video visits with the healthcare team can be conducted, as well as the possibility to ask questions via the chat function, renew prescriptions or order copies of medical records. Several out-patient clinics have opened for this option, and implementation is planned for the remaining units in 2022.

Electronic appointment

15 minutes after the invitation to the appointment has been sent, it arrives to the patient who receives a text message inviting them to log in to the application to read their e-letter. The out-patient clinic in medical unit Hematology was the first to test this invitation method and the rest of Karolinska CCC's units are now following.

Digital symptom checking

Before medical oncology treatment, the nurse checks the patient's symptoms before the next treatment. This check is managed in different ways, but it is common for a nurse to call the patient two days before. During the autumn, a symptom check questionnaire has been developed. The patient answers the questions digitally and the nurse assesses the symptoms. An evaluation of the process is planned for spring 2022.

Initiatives from the Medical Units (ME) to improve care

Medical Unit Breast, Endocrine Tumors and Sarcoma (ME BES)

Over the past year the medical unit has worked intensively to optimise patient flows in both inpatient and outpatient care. This has meant that inpatient care has been divided into an oncological and a surgical component, while maintaining patient flow responsibility within each diagnosis group. In addition, the medical unit has focused on competence enhancement through internal training, conference activities and external training within nursing and medicine.

In 2021, the Breast Centre treated more than 600 new cases of breast cancer, about 28 per cent more cases than in 2020 and about the same number as in 2019. Patients diagnosed at Karolinska CCC during the period 2008–2021 had significantly better 10-year survival compared to the region and the rest of the country. For the second year in a row, “Breast lump day” was held; a day of open bookings for patients throughout the county with symptoms from the breasts.

The Endocrine tumors and sarcoma section has continued to streamline workflows and increased accessibility for referrals by introducing a day physician on call function that includes answering internal and external enquiries.

During the year, the Hereditary cancer section continued to develop the multidisciplinary conference on endocrine tumors and rare syndromes with increased cancer risks. Genetic counselling and program for checking for hereditary prostate cancer (male BRCA2 carriers) was initiated in October in collaboration with the Urological Cancer Section. The section is involved in the introduction of a fast track for direct/reflex screening of tumor tissue for gene analysis in colorectal cancer. Karolinska has been the coordinator of the MDT ERN-GENTURIS, the European Reference Network for Rare Genetic Tumour Risk Syndromes.



Medical Unit Pelvic Cancer

In the Gynecological cancer section, several important steps have been taken towards precision medicine for women with ovarian cancer. HRD (Homologous recombination deficiency) testing to detect specific mutations was widely introduced with the aim of offering more women treatment with so-called PARP inhibitors. This, together with a shortening of the time to chemotherapy

after surgery, means we can expect better survival rates for this until now incurable cancer.

During the year, a project was launched within the Urology and Oncological Urology sections to enable a regional multidisciplinary conference on urothelial cancer. The aim is that all patients with high-risk urothelial cancer should be discussed before curative as well as palliative treatment. The aim is to shorten lead times, ensure equal care and identify patients who could participate in studies.

The Colorectal cancer section has been working on a project to tailor oncological treatment. The prognosis of colorectal cancer may in some cases benefit from oncological treatment such as chemotherapy or immunotherapy before and/or after surgery to remove the tumor. However, oncological treatment may have side effects and not all tumors in patients are sensitive. In the Reflex Testing project, which started in 2021, tissue samples taken from the tumor for diagnosis in patients with colorectal cancer in Stockholm and Gotland are analysed for genetic information on sensitivity to chemotherapy and immunotherapy. The aim is to tailor oncology treatment for colorectal patients, thereby reducing both over- and under-treatment. It is hoped that this will also be reflected in improved prognoses. The testing also aims to identify patients with a hereditary predisposition to colorectal cancer, which may affect both treatment and follow-up programs for patients and their families.

Medical Unit Cell Therapies and Allogeneic Stem Cell Transplantation

The pandemic has also had a major impact on operations in 2021. The medical unit was very early to vaccinate both patients and staff to reduce the serious effects of COVID-19. We actively participated in the only prospective clinical study of a COVID-19 vaccine in severely immunocompromised patients published so far, together with several other medical units within and outside Karolinska CCC. The results of these activities were that very few patients fell ill in the latter part of the year and no deaths from COVID-19 were recorded.

CAR-T cell activity has increased significantly in 2021 with both the start of several clinical studies for new indications and a gradual increase in routine use of registered products. Collaboration within SWECARNET has deepened to give patients throughout Sweden access to this new treatment. We have also developed a technique to measure circulating CAR-T cells in order to better monitor the treatment.



A further innovative treatment has been administered in a clinical study in collaboration with the FAS1 unit, which involves T-cell receptor (TCR) modified cells that may offer additional treatment options for patients with solid tumors. Many of our patients suffer from complex and severe viral infections and we are therefore participating in a clinical study with multiviral-specific T-cells while developing the ability to produce our own T-cells against several different viruses.

Medical Unit Hematology

During the year, the Lymphoma section has introduced rotational nursing services for outpatient and inpatient nurses and introduced nursing rounds where nursing staff discuss and share knowledge about patients. Operations have made greater use of video calls as an

alternative to telephone contact or physical visits.

Several new clinical studies, such as bi-specific antibodies, have been launched in 2021, enabling new treatment options for severely ill patients.

The Bone marrow and Leukaemia section has continued to introduce precision medicine into everyday clinical practice over the past year, with treatment decisions linked to response within acute myeloid leukemia (AML) and to some extent myelodysplastic syndrome (MDS). Projects are also underway for the home administration of certain medicines.

The Myeloma section has focused on continuing to conduct a wide range of clinical studies with many new medicinal products in phase 1 and phase 2 for treatment-refractory patients. Work on the development of pain management for myeloma patients has continued successfully.

The Coagulation section has strengthened its collaboration with Accidents and Emergencies for patients with acquired haemophilia and a brand-new collaboration with geriatrics in Huddinge has been established for the aftercare process. For patients with antiphospholipid syndrome in need of inpatient care, a new collaboration agreement and care program has been developed in collaboration between Coagulation and Rheumatology.

A bleeding gene panel has been established in collaboration with the Special Coagulation Lab and Clinical Genetics to strengthen the diagnosis of platelet dysfunction and severe bleeding disorders of unclear genetic origin. It has also established guidelines for thrombosis/thrombosis prophylaxis in COVID-19 and a new national collaboration on the adverse reactions vaccine-induced immune thrombocytopenia and thrombosis (VITT) and thrombotic thrombocytopenic syndrome (TTS) from COVID-19 vaccine.

Medical Unit Head, Neck, Lung and Skin Cancer

To improve the emergency care of all Karolinska CCC patients, both medical and surgical problems, the Acute Assessment Unit (AAU) has extended its opening hours in the evenings and weekends so that patients not in need of Intensive Care Unit (ICU) resources can be assisted by skilled oncology trained staff. The AAU is now co-located with the ICU, which facilitates the joint management of all patients in need of emergency care.

Within the Lung Oncology Centre (LOC) has taken the initiative to start investigations according to a concept that exists in England, called RAPID, which means that patients should have completed all their investigations required for a therapeutic decision within 14 days. This work is being done in conjunction with MDK and will lead to significantly shorter SCP times and faster patient care. This pilot is now up and running after careful planning. We have also started nurse out-patient consultations for post-operative check-ups for operated lung cancer patients, which have been highly appreciated and lead times to follow-up has shortened.

To strengthen and release time from administration to nursing for liaison nurses, the unit's Booking Unit now books all doctors' appointments. Another new feature is that all contact nurses have their own new visit with the patient to draw up a My Care Plan.

Medical Unit Radiotherapy

During the year, the medical unit has worked on the following initiatives; installed and implemented a patient identification system based on facial recognition, standardised and to some extent automated dose plans for head and neck cancer patients based on "machine-learning", pre-radiation MRI in children to better define the radiation area, and they have introduced whole-body irradiation with VMAT (Volumetric Modulated Arc Therapy) which facilitates the treatment flow and quality assurance of the delivered radiation dose. In addition, radiotherapy has increased the number of patients enrolled in clinical studies during the year.

Medical Unit Upper Abdominal

Robotic assisted minimally invasive surgery has developed rapidly in 2021 and the purchase of another robotic system has provided even better opportunities to develop this treatment. For liver and pancreas surgery, the implementation of robotic assisted surgery has meant that a much higher proportion of operations can now be performed using minimally invasive techniques rather than open surgery.

Major steps have been taken during the year to further improve the assessment and treatment of early esophageal and gastric cancer. This strengthens our role as a national leader in this area as well.

During the year, close collaboration between several operations laid the foundations for offering the first patient with liver cancer treatment with selective internal radiotherapy, a form of treatment not previously provided at the hospital.

In December, the National Board of Health and Welfare commissioned the service to diagnose and follow patients with primary sclerosing cholangitis (PSC) within the framework of national highly specialised care (NHV). NHV entails that publicly funded care is provided at a maximum of five units in the country that meet the requirements of competence, availability and working in multidisciplinary teams. PSC is a chronic inflammation of the bile ducts with a risk of developing cancer. Through participation in the European Reference Network Rare Liver, training and development projects are conducted internationally and Karolinska is appointed as chair for this diagnostic area.

Patient involvement

During the year the “2.0 strategy for patient involvement” started with the aim to involve patients and their relatives in the development of care in Karolinska CCC. The strategy is based on involvement on different levels. At the strategic level the representatives from the Patient and Relatives Council (PNR) meets with the management team of Cancer Theme three times a year.

At the operational level, a patient representative is included in the medical units’ management team, which meet once a month.

For individual projects, such as the “Increased accessibility” project, there has been close cooperation between patient representatives and project managers. Patient representatives have been involved in the development of information material, provided input on the design of invitation letters and been part of the design of the work in the different components.

Cancer Research KI together with RCC Stockholm-Gotland organised a workshop about cancer for patient organisations within that area. During the day, participants were given an insight into cutting-edge cancer research, and on this occasion topics such as quality of life, complementary and integrative medicine and molecular diagnostics in cancer were discussed. The event provided an opportunity to discuss with the top researchers, health care professionals and policy makers within the cancer area.

The Gynecological cancer section has held quality seminars with patient representatives to identify indicators. A limited number of indicators, available in real time, were jointly developed. Goals have been achieved for most indicators, such as increased inclusion in clinical studies and improved results for all care pathways with shorter lead times from referral to treatment.





Quality report

Patient safety

All medical units (ME) have implemented a structured system for reporting, analysing, initiate improvement actions and evaluation regarding complications and deviations. A multi-professional group within each ME meets on a weekly basis. The responsibility of the multi-professional group is to structure the complications, analyse trends and follow up the improvement actions.

During the spring, 15 new event analysis managers were trained, and a network was established with the aim to discuss different aspects of the process and to offer support.

The hospital management together with Karolinska CCC has had their first patient safety dialogue where different risk areas were identified. This dialogue will be conducted annually.



Quality Report

Patient-focused care, follow-up of the experience of the received care

Patient satisfaction

The purpose of the survey is to obtain more information about the patient's experience of the care; how the patient experienced treatment from the staff, the patient's opportunity to be involved in decision making to the desired extent and that the information provided has been sufficient. In 2021, we changed the collection method, from having distributed questionnaires to the patient in connection with visits to sending out this questionnaire digitally. This work was initiated during the last quarter of 2021, which resulted in fewer responses.

Field	2019	2020	2021	Target
Professional approach	90%	91%	85%	90%
Participation	91%	92%	85%	90%
Information	94%	94%	92%	90%
Number of respondents	3,280	5,996	2,424	—

Nursing – Nutrition, pressure ulcers and falls

In January 2021, the collection method for indicators, nutrition, pressure ulcers and falls was changed. From having had a point prevalence measurement for selected cases so, this is now a continuous measurement. The information is retrieved directly from the medical records system and events from the documentation available. The report is digital and accessible to everyone.

Nutrition

The purpose of the follow-up is to ensure that a good care is ensured by identifying early on the patients at risk of developing malnutrition.

The major improvement that has taken place Field is the increase in prescribed measures to prevent malnutrition for patients at risk of this.

Field	2019	2020	2021	Target
Complete nutrition assessment	73%	74%	71%	80%
Percentage of patients with risk factors	47%	52%	52%	—
Percentage of at-risk patients with actions ordained	60%	65%	77%	90%
Number of respondents	567	598	8,952	—

Pressure ulcers

The follow-up is carried out to ensure that a good care is ensured by preventing and reducing the occurrence of pressure ulcers.

The results show that patients who were treated as inpatients were not risk assessed to the same extent as the previous year. The proportion of at-risk patients prescribed measures also increased in 2021.

Field	2019	2020	2021	Target
Percentage of patients at-risk assessed for pressure ulcers at enrollment	93%	96%	77%	80%
Percentage of patients with occurred pressure ulcers, category 2–4	5,50%	3,80%	—	3%
Percentage of at-risk patients with actions ordained	29%	50%	56%	60%
Number of respondents	188	180	8,952	—

Falls

The purpose of the follow-up is to ensure that a good care is ensured out by identifying early on the patients at risk of falling during the treatment period and taking measures to prevent falls.

The measurement shows that the number of risk assessments decreased, but that more patients with identified risks of falling have had preventive measures prescribed.

Field	2019	2020	2021	Target
Percentage of patients at risk assessed for fall at enrollment	89%	95%	78%	70%
Percentage of patients with a risk for falling with case prevention actions prescribed within 24h	79%	40%	56%	65%
Number of respondents	320	98*	8,952	—

* Few number of measurements due to the effect of the pandemic

Healthcare-related infections and hygiene routines

Care-related infection

The main purpose of the follow-ups is to establish a foundation for the improvement work carried out at each department within Karolinska CCC to reduce the proportion of patients affected by healthcare-related infections.

Outcomes for healthcare-related infections within Karolinska CCC are high and there are several causes, such as treatments causing compromised immune defenses, patients already susceptible to infection, as well as extensive surgical procedures.

Field	2019	2020	2021
Patients with care-related infection	21%	24%	20%
As a result of hospital treatment	20%	21%	19%
With antibiotic treatment for care-related infection	20%	23%	19%

Several medical units have identified working methods to improve performance:

- Early discontinuation of barriers compromising insertions and drains
- Conducting regular analyses of infections related to indwelling catheters
- Planning of training sessions for all staff
- Standardised discontinuation plans for e.g., urinary catheters, drains, indwelling catheters after specific surgical procedures

This work will continue in 2022 and Karolinska CCC will be a pilot for a project for data-driven information management and visualisation of healthcare-related infections.

Basic hygiene and clothing rules

This measurement is an observational study which all units should conduct each month. In 2021, we have observed some deterioration in all areas. Both general activities and activities specific to the operation will be developed to improve this result during the year.

Field	2019	2020	2021	Target
Disinfection before and after, gloves and protective clothing used correctly	68%	75%	74%	—
Suit, ring, nail, hair was used correct	88%	94%	93%	—
All 8 components correctly performed	63%	72%	70%	71%
Number of observations	1,392	2,049	1,777	—

Notifiable resistant bacteria

Measurement is carried out of the proportion of patients at increased risk of MRSA where complete MRSA cultures are taken at the time of admission according to applicable healthcare programme. One patient can have several risk factors. The follow-up is done through point prevalence measurement twice annually.

Field	2019	2020	2021	Target
Patients with proper handling according to care program	54%	66%	72%	90%
Number of observations	196	77*	150	—

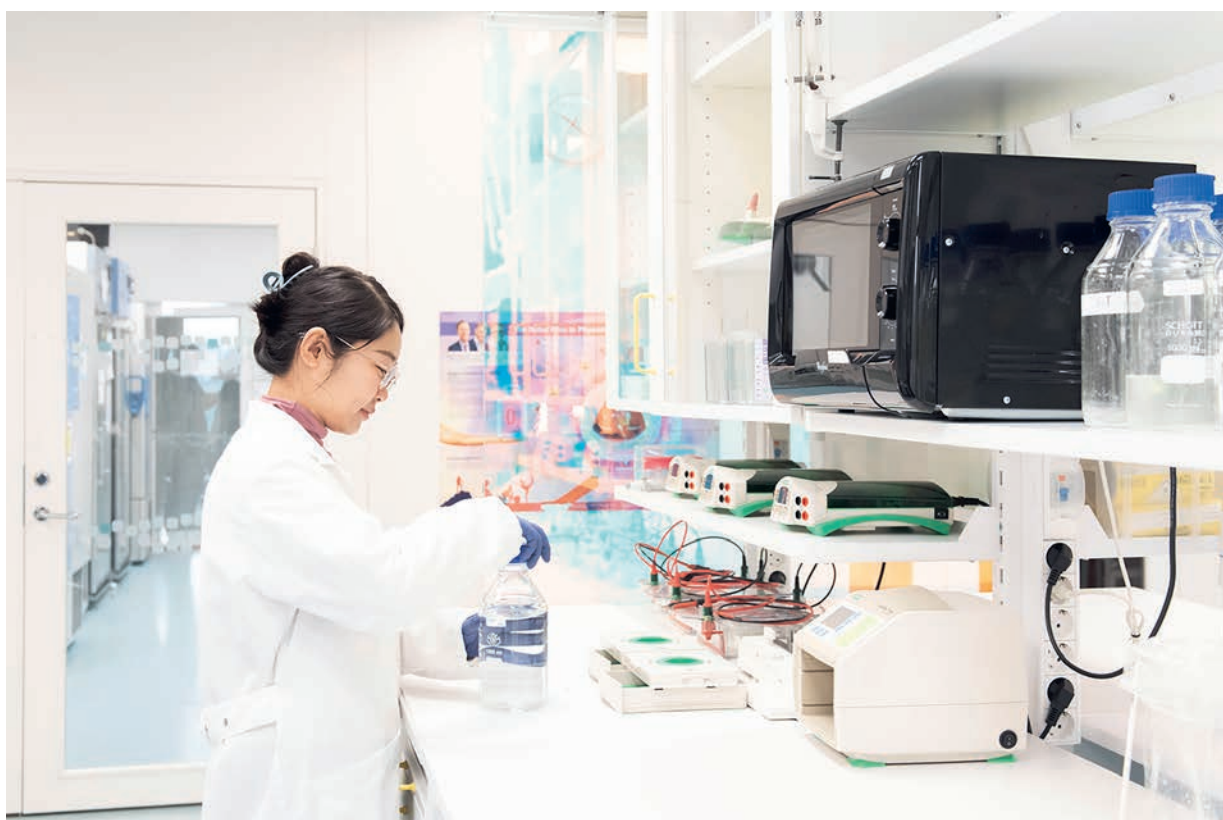
* Few number of measurements due to the effect of the pandemic

Environment

The environmental work in 2021 has been in line with the hospital's certification according to ISO 14001, which means recurring activities. We participated in e.g., the external environmental audit with most of our operations, where we received several suggestions for improvement from the auditors, but no deviations. As part of the continuous improvement process, all operations have for the first time had their annual environmental activities included in their respective business plans with monthly follow-up.

The vision is to have the environment integrated into all areas of operations. One area that has a positive impact on the environmental impact of operations is digitisation, both directly and indirectly. In particular, digitisation of care means a reduction in travel for both staff and patients and a reduced use of consumables.

Field	2019	2020	2021	Target
Environmental activities	100%	100%	100%	100%
Environmental functions	93%	90%	92%	90%
Environmental deviations	66 events	67 events	57 events	Increased number
Expired environmental anomalies	—	68%	78%	0%
Basic environmental education	64%	80%	83%	80%
Environmental training for managers	72%	86%	78%	80%
Medicines and the environment	76%	76%	76%	80%
Chemical inventory	69%	92%	100%	90%





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Karolinska Comprehensive Cancer Center