

2023 SWEDISH CANCER SOCIETY REPORT

Clinical Research – everyone's and no one's responsibility



**CANCER
FONDEN**

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Summary

Research is crucial to good cancer care and relies on health services taking up and using the results of research as soon as possible. This requires research to be carried out close to the patient, as a natural, integral part of the care.

We have examined how regional responsibility for clinical research is handled in the country's seven university healthcare regions. The review clearly shows that research is not given sufficient space in the organisation, governance and monitoring of healthcare. Clear and coherent processes for research, from regional management down to operational level, are missing or inadequate.

To meet the challenges of the future in cancer care, we need a knowledge-intensive cancer care system that constantly evolves. If research issues are not given greater prominence within the healthcare organisation, we risk missing out.

Greater political responsibility is now needed in the regions to give research the right conditions to become the integral part of healthcare that it needs to be. Research issues must be included in the management's work at the highest level and in the regions' competency maintenance work.

The Swedish Cancer Society wants every region to:

- Clarify where in the region the political responsibility for clinical research and development under the Health and Medical Services Act lies and is monitored
- Develop concrete plans for how clinical research will become part of everyday healthcare
- Set targets and indicators to measure clinical research
- Increase core funding for research and research support infrastructure.



Yesterday's research is today's standard treatments, and today's research is tomorrow's.

Administrator



New research advances needed

The number of people getting cancer has been increasing for years, and the increase seems likely to continue. In 2021, 68,810 people will be diagnosed with cancer.¹ From 2040, as many as 100,000 new cases of cancer are expected to be detected each year. As well as causing great suffering to all those affected, the cost of cancer to society is expected to more than double annually, from around SEK 35 billion today to over SEK 70 billion in 2040.

It is important for society as a whole to actively prevent and control as many cancers as possible. One key is research, and research has taken us a long way.

Statistics compiled by the Swedish Cancer Society show that research advances since 1970 have led to positive developments in cancer care. From three

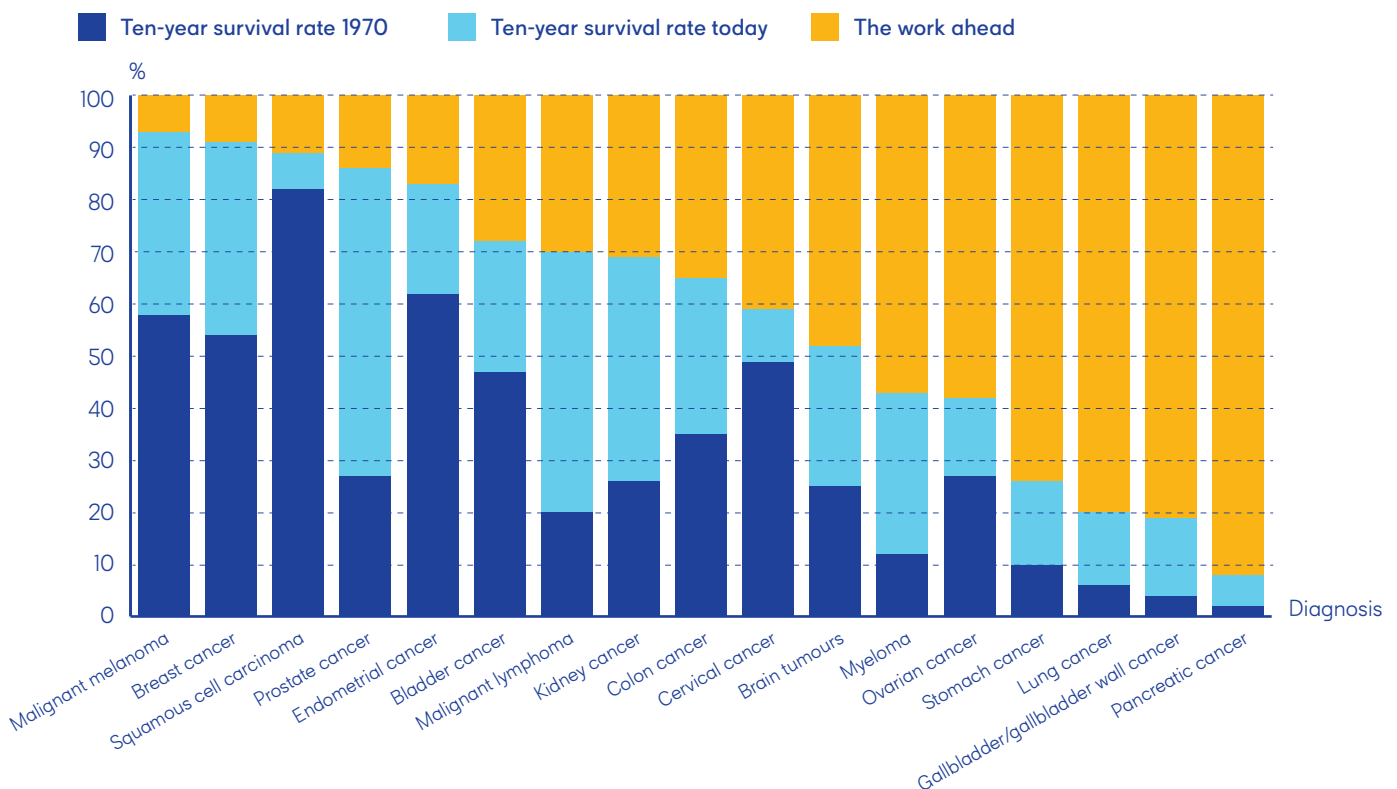
out of ten surviving cancer ten years after diagnosis, now around seven out of ten survive cancer. But the variation between cancers remains large. For some cancers, the survival rate is around 90%, while for others it can be as low as 10%.

Research is the basis of healthcare

Research in close collaboration with the health sector is crucial to the development of cancer care. It should go without saying that research is seen as a natural part of healthcare. Society as a whole needs to work towards the goal of defeating cancer and strengthening public health. However, policymakers have a particular responsibility to develop a broad but also effective research policy.

1. Official Statistics of Sweden, Health and Medical Care, National Board of Health and Welfare Art. no: 2022-12-8308

Figure 1. For several diagnoses we have come a long way, but for others it is more difficult to see progress in research, and it is clear that we still have a long way to go to beat cancer.



Central to good cancer care is that it builds on, adopts and uses the results of research as rapidly as possible. The implementation of new methods, treatments and approaches is a major challenge where there are large differences between regions.

It has long been recognised that the culture of a workplace plays a major role in how well the organisation is equipped to take on board the results of research advances and to conduct research itself. In the report on national knowledge support in healthcare², the government's investigator Sofia Wallström describes such a culture as "academic system thinking".

The inclusion of research issues in management, at the political level and in the organisations' competence provision work, is not only the key to improving the conditions for conducting clinical research. It is also a prerequisite for creating a workplace culture that is supportive of evidence and the introduction of new methods and approaches.

Clinical research is shrinking

The need for research to detect and diagnose difficult-to-treat cancers is great. Although clinical cancer research in Sweden is of high quality from many perspectives and has led to a clear improvement in survival rates for several cancers over the past 50 years, we cannot sit back. The need for continued research that can lead to new breakthroughs that change the outlook for those affected by cancer is crucial.

The decline in clinical research in Sweden is therefore a serious matter. Health professionals who also want to conduct research testify to both the lack of time for research and the low added value of research in today's healthcare organisation. At the same time, industry points to both challenges and reduced interest in clinical trials in

The concept of clinical research is based on research that requires healthcare structures and resources and that aims to solve a health problem or to identify factors that lead to improved health.

SOU 2009:43, Clinical research - A boost for healthcare

"An academic systems approach means that every encounter in healthcare is a potential source of patient-oriented research. The important thing is the culture and the feeling that everyone is part of an academic system. This feeling is important in order to create a working environment that is positive to evidence and to the introduction of new methods and new ways of working."

Knowledge-based and equal care - Requirements for a learning healthcare system, SOU 2017:48



Research is the basis for our work in healthcare. Without research, we are going backwards, and we will never progress and make things better.

Politician

Sweden. Since the early 2000s, the proportion of doctors trained as researchers has fallen by more than 15%.³ During the same period, the number of clinical trials started has fallen by 70%.⁴ Combining clinical service with research has been, and will be in the future, absolutely essential for the development of healthcare. In order to maintain a high quality of professional education and to meet the great need for competency maintenance in healthcare, more supervisors and teachers with high scientific competence in all professions are also required.

Joint appointments⁵, with the possibility of splitting time between clinical service and research, will enable a research-friendly care environment. Today, however, the situation is so serious that the application rate is low and only about 80% of the invitations are filled.⁶ The reasons for the low application rate and the failure to fill joint appointments require further analysis, but explanations emerging both in the Cancer Society's review and elsewhere are:

- that employees do not see that there are sufficiently clear career incentives for conducting research in the context of clinical service;
- that it is difficult to combine clinical service with research to the extent promised;
- that research time is often cancelled due to staffing problems in the workplace.⁷

Regulatory but shared responsibility for clinical research poses challenges

There is no doubt that research should be part of the core mission of healthcare. According to the Health Care Act, regions must participate in the financing, planning and

2. Kunskapsbaserad och jämlik vård - Förutsättningar för en lärande hälso- och sjukvård [Knowledge-based and equal care - Requirements for a learning healthcare system], Swedish Government Official Reports 2017:48

3. Forskningspolicy [Research policy], Swedish Medical Association 2020

4. Swedish Cancer Society 2020, Lumell, 2020, Kartläggning av den kliniska forskningsaktiviteten inom cancerområdet [Survey of clinical research activity in the field of cancer].

5. Regulated in Chapter 3, Section 8 of the Higher Education Act and Chapter 4, Section 2 of the Higher Education Ordinance

6. National Council for Health Care Competence Record no. 4.3-13549/2021-10

7. Forskande läkares villkor [Research physician conditions], Research survey from the Swedish Medical Association & SYLF 2022



implementation of clinical research work in the healthcare field. It is also specifically stated in the basic mission of primary care that it includes enabling participation in the implementation of research work.⁸ However, the responsibility is shared between the regions, as healthcare authorities, and the State, through universities and colleges, as the authority for education and research. These responsibilities are based on different legal provisions and therefore involve substantially different forms of governance, conditions and scope for action. Universities with medical and clinical research as part of their core business are dependent on healthcare structures and resources. For healthcare, research is a prerequisite for development and improved medical outcomes. This means that a very well-functioning collaboration between the parties is required – something that often involves organisational challenges and, not infrequently, conflicts of objectives. Only through clear common structures and consultations for the management and monitoring of research can the conditions for clinical research be improved.

University healthcare has a central role

The University Health Service has a specific mission to be a driving force in research. The responsibility is to be the engine of the system and to involve the entire health region in both research and implementation of new methods. In addition to the basic requirements set out in the Health and Medical Services Act (2017:30), the so-called ALF agreement between the State and certain regions on the training of doctors, clinical research and the development of healthcare extends this responsibility. The ALF agreement includes nationally agreed minimum levels that set out what university healthcare should

achieve. One of the minimum requirements is to collaborate with other healthcare units within their own and other regions when planning and conducting clinical research studies. Today, however, we know that primary care, for example, has a very limited role in clinical cancer research⁹ and that there are large regional differences in the overall number of cancer patients enrolled in research studies.¹⁰

Several parts of the healthcare chain therefore need to be involved in clinical research, and inequalities in participation in clinical trials need to be evened out. This is particularly important as we move towards more advanced care being delivered closer to the patient and in different parts of the healthcare organisation than has traditionally been the case. This includes, for example, the development of new intermediate forms of care and specialised rehabilitation in the home, to reduce the need for inpatient care.¹¹ These fundamental changes in the organisation of care place particular demands on a scientific approach where research, monitoring and development are constantly present to ensure that changes and reorganisations can be implemented without compromising patient safety.

8. Health and Medical Services Act (2017:30)

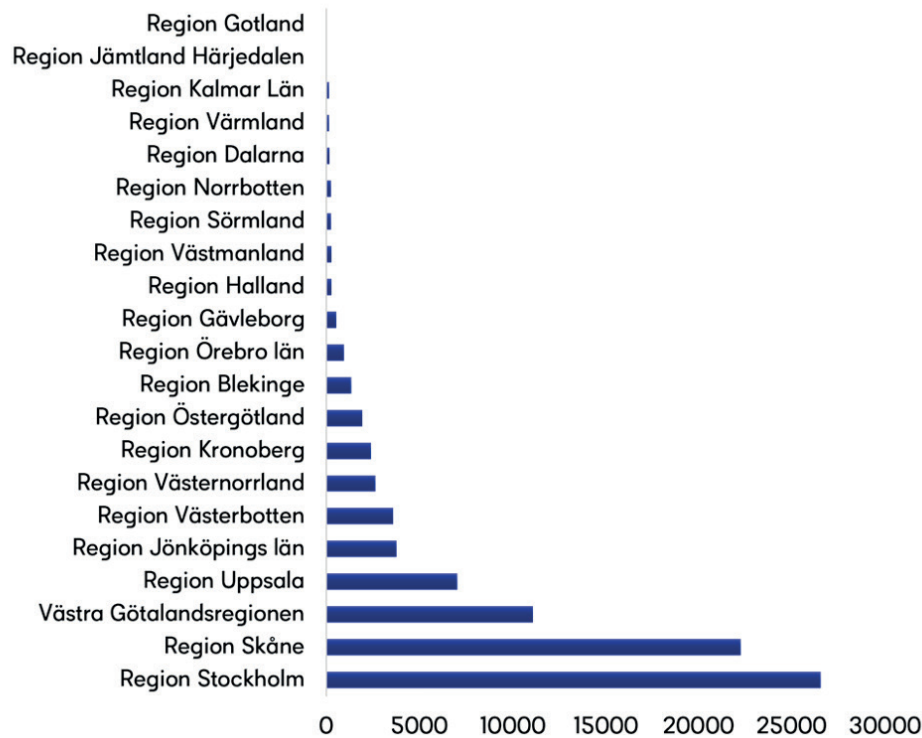
9. Primärvården har en begränsad roll i den kliniska cancerforskningen [Primary care has a limited role in clinical cancer research], Swedish Cancer Society 2020, Lumell, 2020, Survey of clinical research activity in the field of cancer

10. Swedish Cancer Society 2020, Lumell, 2020, Kartläggning av den kliniska forskningsaktiviteten inom cancerområdet [Survey of clinical research activity in the field of cancer]

11. Uppföljning av omställningen till en mer nära vård 2020 [Follow-up of the transition to a closer care 2020], National Board of Health and Welfare 2021

Large differences in the number of cancer patients participating in studies.

Number of patients in registered ongoing studies (August 2020).



Number of patients in registered ongoing studies per 1,000 new cancer cases annually (August 2020).

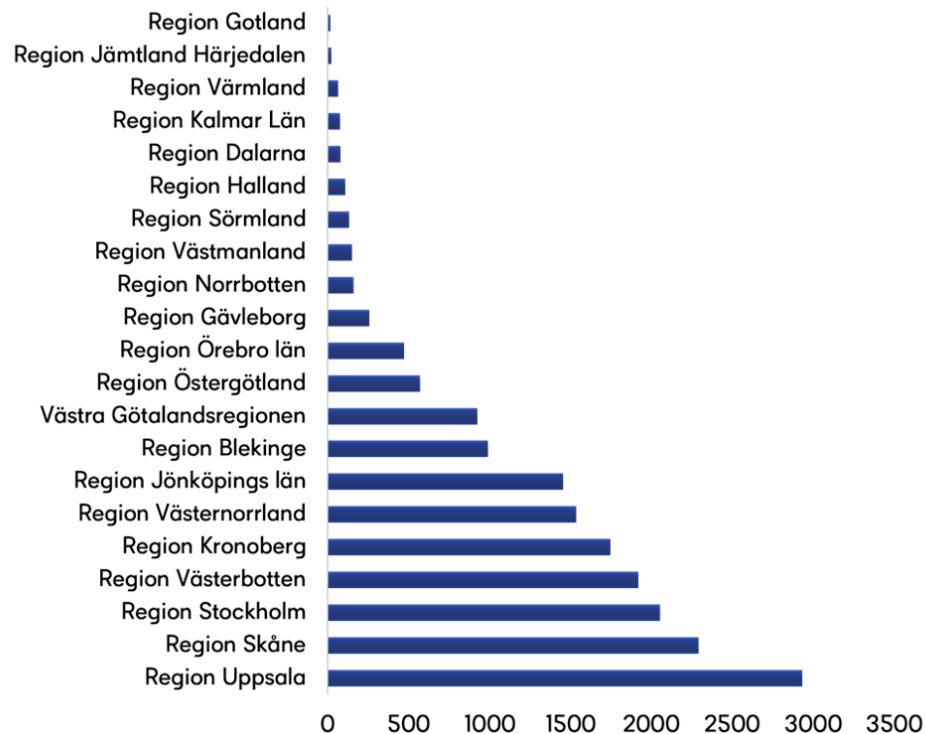


Figure 2 There are very large differences between regions in the number of cancer patients enrolled in studies – even when cancer incidence in the regions is taken into account. (Source: Cancer trials in Sweden – RCC 2020; National Board of Health and Welfare 2017; ClinicalTrials.gov 2020; SCB 2019)

Note: The number of new cancer cases refers to age: 0-85+ for all tumours; Studies vary in size and some studies with large numbers of patients have a large impact; In studies conducted in several regions in parallel, the number of patients participating has been allocated between regions based on population size; Some studies do not report the number of patients and are therefore excluded from analysis; The number of new cancer cases is based on 2017 statistics, and population size is based on 2019 statistics



More accredited cancer centres needed

The difficulties in giving research sufficient space within healthcare and in achieving a well-functioning collaboration between universities and healthcare are neither new nor unique to Sweden.

In 1979, the Organisation of European Cancer Institutes (OECI) was founded to promote collaboration between European healthcare providers and research institutes in the field of cancer. Since 2008, the OECI has offered an accreditation programme to assist European cancer centres in implementing quality systems for cancer care. Today, there are 68 European cancer centres, 19 of which are accredited as Comprehensive Cancer Centres, CCCs. Being an accredited CCC means that the centre meets quality standards in terms of care, prevention, diagnosis, treatment, nursing, rehabilitation, and research, teaching and training. The overall goal is to create a holistic approach to team-based care, where multiple actors work together and where care and treatment, research, innovation, teaching and education are integrated in cancer care.

There are currently three accredited CCCs in Sweden. Karolinska University Hospital and Karolinska Institutet were the first in Sweden to be accredited as CCCs in spring 2020. In the spring of 2022, Skåne University Hospital and Sahlgrenska University

Hospital also received accreditation according to the requirements of the OECI.

Accrediting university hospitals does not solve all the challenges facing both healthcare and research in one fell swoop. However, it is a step towards bringing Swedish cancer research and care even closer together.

The Organisation of European Cancer Institutes (OECI) was founded in 1979 with the mission to:

- Reduce cancer morbidity and mortality and support cancer patients
- Link the expertise and competence of European cancer institutes in care and research
- Strengthen cancer centres and promote communication and collaboration among them.

The Comprehensive Cancer Centre accreditation programme was launched in 2008 with the aim of:

- Giving all cancer patients in Europe equal access to high quality cancer care
- Reducing fragmentation
- Assisting European Cancer Centres in implementing quality systems for cancer care through standards/indicators and peer review/audit.

Need for further government action to strengthen clinical research

The importance of clinical research is highlighted in several national policy documents, declarations of intent and agreements. In December 2019, Sweden's life science strategy was launched and a life science office was set up with the aim of making Sweden a leader in the field. Integrating research and innovation into healthcare is one of the main objectives of the national strategy. However, there is currently a lack of concrete action to achieve the objectives in the priority areas.¹²

In connection with the launch of the life science strategy, a position paper¹³ was also presented by the Swedish Association of Local and Regional Authorities (SKR), which describes in general terms how SKR believes that the regions can contribute to meeting the strategy's objectives. Strengthened collaboration among regions, the State and industry is described as necessary to create the conditions for effective clinical research. It is also established that clinical research should be included in business planning and monitoring and be an integral part of the healthcare mission for all healthcare providers, public and private.

The government's 2020 research policy bill, which describes the research policy direction for 2021-2024, proposes strengthening clinical research in sever-

al ways. Among other things, it promises increased investment in research infrastructure, funding for research that contributes to the development of precision medicine, and investments in graduate schools to improve the quality of healthcare education.¹⁴

However, the Swedish Cancer Society believes that further national action is needed. The government needs to take concrete steps to achieve the objectives of the life science strategy. In the forthcoming research policy proposal, the conditions for clinical research should be specifically highlighted. Long-term investments in commonly accessible research support infrastructure and national coordination and availability of health and medical care data are key elements where the government has a major responsibility. The government also needs to provide support for planning and mapping out how staffing levels in the healthcare sector need to be dimensioned, to avoid the risk of research being held back due to staff shortages.

12. Nationell strategi för life science [Sweden's national life sciences strategy] - Regeringen.se

13. Society, patients and healthcare need clinical research. Position paper on clinical research for the best possible care - not only today but also tomorrow, Swedish Association of Local Authorities and Regions, 2020

14. Government Bill 2020/21:60, Forskning, frihet, framtid - kunskap och innovation för Sverige [Research, freedom, future - knowledge and innovation for Sweden]

The Swedish Cancer Society's review of political accountability for clinical research

Based on current legislation, the current research policy bill, position papers and agreed strategies, clinical research appears to be a priority at national level. Despite this, we find ourselves in a situation with reduced clinical research activity and constant reports that research is taking a back seat in healthcare planning and organisation.

In this report, the Swedish Cancer Society therefore focuses on improving understanding of how the national intentions for clinical research are translated at the regional level and what obstacles need to be overcome to improve the conditions for clinical research in cancer care. The review is limited to the seven university health regions, as they have a specific mandate to drive research. However, the results of the review are also interesting for other regions.

The audit shows that research issues are not sufficiently pursued actively through regional policy and that the coherent process for research that should

exist is lacking in various ways. As a result, research is not given sufficient opportunities to be a natural part of healthcare.

It has consistently been noted that clinical research needs a more solid foundation on which to rest. This requires a clear line from policy to administration and on to hospital management, operational level and individual clinical researchers and back. This is what the 2023 Swedish Cancer Society Report on research is all about.

The review highlights two issues:

- How can clinical research be integrated in a long-term and continuous way into a healthcare environment under pressure without the risk of being pushed aside due to lack of time and resources?
- How should responsibility for clinical research be structured and distributed so that it is seen as a core task in the same way as healthcare production?



PHOTO: SCANDINAV

Scope of the review

The Swedish Cancer Society has examined how the seven university healthcare regions in Sweden assign research tasks to their operations and how they follow up on them. The aim of the review was to examine how to create the best possible conditions in Sweden for clinical cancer research.

A key starting point for the Cancer Society's review has been to approach clinical research by seeing it as part of a coherent process – from political accountability through to everyday healthcare and back again (see Figure 1).

The overall focus of the review has been the status of research questions and whether they follow a clear chain from policy to practice. The Cancer Society has organised the review into two parts. The first part follows how research is described in the university health regions' key healthcare policy documents, with a particular focus on research addressed in budgets, operational plans, research policies and strategies, and annual reports and research financial statements. The second part includes in-depth interviews with key individuals at different levels, based on the steps in the process chain shown in Figure 4.¹⁵

An important starting point for the Cancer Society's review is that, according to the Health and Medical Care Act, regions must participate in the financing, planning and implementation of clinical research work as well as systematic and quality-oriented monitoring of the activities.

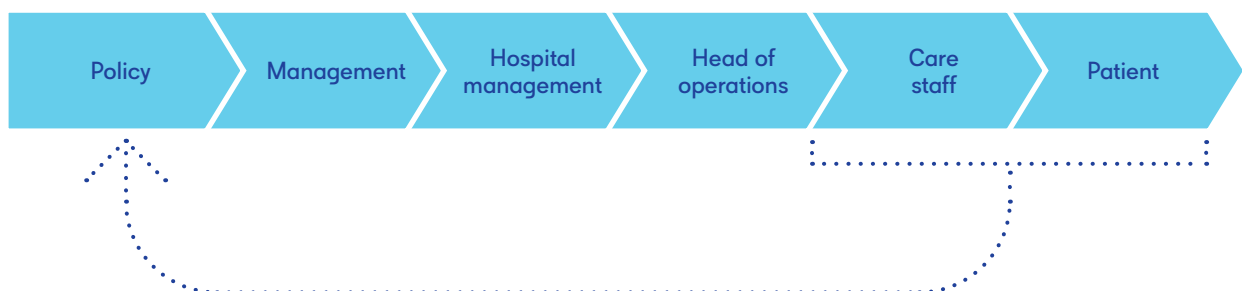
It has become clear that many challenges related to health research are common to the seven regions. This chapter presents the overall picture, while the

Three themes in particular have emerged from the review, and these are that there is:

- **Will and high ambitions** for clinical research in the university health regions. At the same time, there is often a lack of political governance and shared political responsibility, which means that the research process is not as coherent as it needs to be to optimise the conditions for research throughout the organisation and activities of the healthcare system.
- **Varying ways of measuring and monitoring research.** Targets and indicators vary between university health regions and create different conditions and difficulties for the activities. Research issues are perceived as complex, and when healthcare production is more political and day-to-day, clinical research can fall by the wayside.
- **Research is crowded out.** Closely linked to the lack of health professionals, management and governance as well as support structures. Combined with the pressures of everyday healthcare, this means that research risks being pushed aside in favour of healthcare production.

15. The overall review approach is described in more detail in Annex 1.

Figure 4. Clinical research as a coherent process.



breakdowns for each region examined are provided in Annex 2.

Will and high ambitions

“It may be that we need to be clearer that research is a politically important issue.”
– Politician

The Swedish Cancer Society’s review shows that there are major regional differences in the way research missions are assigned and followed up in the seven university healthcare regions. Nevertheless, they all have one thing in common: there is a will and high ambitions to achieve good results and be a leader in research both nationally and internationally.

For example, Region Västerbotten’s goal is to be a leader in research, innovation and digitalisation, and Region Uppsala’s is to be internationally recognised in research and innovation. Another example is the Stockholm Region, whose goal is to conduct world-leading research and become one of the world’s five leading life science regions in research for better health.

When it comes to where the research questions are placed at the overall policy level, there are wide variations. For example, the Örebro region has a special committee for research and development, while in the Stockholm region the regional board is responsible for research in healthcare.

Political responsibility is often shared between regional boards and health boards or the equivalent. Region Västra Götaland has seemingly divided research responsibilities among its regional board, healthcare board and the politically appointed board of Sahlgrenska University Hospital. Region Skåne also has a politically appointed board for its university hospital, combined with the fact that the regional board has overall responsibility for research issues and the health board has more concrete and direct responsibility. The situation is similar on the administrative side, where health administrations and regional management offices may have shared responsibilities.

As a result, based on organisational maps and governance documents, it is often unclear where the main responsibility for research lies and how responsibility is divided among politicians, administrators and hospital management. In some interviews, this was explicitly raised as a problem. The quotes below are telling examples.

“Responsibility is unclear in our organisation. The research is in the hands of the regional government, but we are not the ones with the money and the activities.”
– Politician

“Everyone’s responsibility becomes no one’s responsibility. This applies to both education and research, which are in the same situation.”
– Politician

The conclusion from the interviews is also that it varies to what extent research issues are seen as part of a coherent process in the regions.

For example, an official in the administrative management of Region Örebro describes it as a relatively new university healthcare region that is a bit of an “underdog” and that research issues are therefore very important for the region. This is clearly linked to the importance of the clinical research process and its perceived coherence from the political mandate to the implementation at hospital level – and back again:

“We have a political structure that broadens research. The fluffy goals boil down to missions and indicators. We follow up to check that we are doing what we need to and that we are on the right track.”
– Administrator

Region Östergötland sees it differently:

“We have had a working committee under the regional board. We have worked on policy issues, strategy documents and so on, but the fact is that research is becoming a bit of an island with just a few people in charge. I miss the clear loop all the way around.”
– Politician

Others say that it works reasonably coherently overall, although there is room for improvement.

“I see that we could do more. We could work for more clinical research, make conditions better so researchers want to do research. But in terms of coherence, I find that it is.”
– Politician

“We set our goals and they should flow down through the organisation. We have a relatively coherent process for research.”
– Politician

The view of the research process from the political level to the hospital level and the implementation in everyday life may also differ depending on where you are in the health and medical care organisation. One tendency is that politicians and management still think it works relatively well, but that it becomes more complex and unclear what the research mission actually is at the hospital level, as the quotes reveal.



“There are never clear mandates from politics. It’s more business-driven. It’s easy for research funding to go to preclinical studies. Our university expects clearer signals from the region.”

– Administrator

Some of the ambiguities around process issues also relate to the fact that it can be difficult for policy makers to know how much they can and should direct research. The notion that research should be protected as free creates a level of uncertainty about the role of politics and how much and what politics can and should control. Another track in the interviews is linked to the Health and Medical Care Act and that it can be perceived as vague.

“Maybe they should tighten up the Health and Medical Care Act. It says that the regions should contribute to research, but perhaps it should say ‘conduct’ instead? It gives a government body a greater opportunity to make demands and follow up.”

– Administrator

Everyone interviewed by the Swedish Cancer Society made it clear, however, that ambitions are high and that there is a very strong desire to give clinical research the best possible conditions. The type of reasoning expressed in the quote below shows that it is linked to a lack of processes and clarity surrounding accountability.

“Ambition is high. However, I think the processes could be a bit clearer. Who has functional responsibility and who has line responsibility, and how do you reconcile that?”

– Administrator

The Swedish Cancer Society’s overall assessment is that there are gaps and weaknesses in the coherence of clinical research from policy to implementation at the hospital level. There are many reasons for this, including the complexity of research issues, the fact that research should be free and that governance and management are not as developed as desired, in addition to the fact that it can be difficult to see a clear political role.

Varying ways of measuring and monitoring research

“We have poor indicators to measure research. How should we follow it? Sometimes you come up with a very general indicator that doesn’t really say anything.”

– Politician

Policy objectives and indicators are crucial for monitoring the research mission. This part of the review shows clearly that impact targets and indicators differ widely among regions.

In the Stockholm, Örebro and Uppsala regions, targets and indicators are clear and include the number of new academically initiated clinical studies, the number of ongoing clinical studies and that clinical research and innovation takes into account the knowledge, experience and willingness of residents, relatives and patients to participate in clinical research and views them as co-creators. In other cases, the objectives are more general, and it has also been difficult to find specific indicators. This is the case, for example, for Västra Götaland Region and Region Västerbotten,

where there are indicators at the overall level, although they are not specifically focused on research but rather on innovation and digitisation.

In most cases, there is follow-up in the regions' annual reports, in half-yearly and annual reports or in the form of research financial statements. At the same time, the nature of the follow-up varies. While some are specific, as in the Örebro and Stockholm regions, others are more general. This is very much related to whether or not targets and indicators are clear. Those with clearer objectives and indicators can seemingly do more concrete follow-up.

The regions themselves have also identified gaps in the governance and management of their key policy documents. An example of this is Region Skåne, which writes that "it needs to be ensured that there are management structures for research and innovation at group level, as well as at administrative and operational level". Another example is Region Östergötland, which argues that "there is a need to clarify responsibilities and processes for monitoring the region's research and development policy".

At the same time, it has been difficult to get a picture from the policy documents alone of what is being monitored and how it is being used, and whether it means anything in terms of changes in objectives and indicators. The same applies to how healthcare staff and managers perceive the monitoring and whether they consider the indicators set to be relevant.

The interviews have provided important in-depth information, to gain more knowledge about what is measured in terms of research objectives and indicators, to what extent they are monitored and in what way. In some cases, it has become clear that more detailed follow-up is being carried out in a variety of ways, but particularly at hospital level. This may include the existence of various forms of forums or networks for research and development, both at the highest hospital management level and sometimes also at operational and clinical level, the demand for follow-up, and the measurement by regions and hospitals of such things as the number of PhD students and lecturers, the number of PhDs and research merits, published research articles and research time spent.

However, the Swedish Cancer Society's overall impression is that there is a lack of metrics to paint a good picture of what is being monitored in the seven university health regions and why the regions have chosen these particular metrics. There are several illustrative and illuminating quotes in this regard. A selection of them is presented below.

"Impact targets and indicators are relevant but not comprehensive. They are very general. The objectives of research are many: research is seen as a way to maintain staff competency or to implement knowledge. Everyone sees their share. So you have to look at what the research is aiming at, and that is that the patient receives the right care and the best adapted treatment. But we don't measure that."

- Administrator

"The region makes its reports, which all look so incredibly nice, but in practice it's pretty thin. Conducting research in today's clinical landscape is not easy. It sometimes look a little too good in the report."

- Care staff

"The level of detail of the feedback is different in different instances. It is not asked in detail how many people we have included in studies, for example. The soft issues are not reported."

- Head of Operations

There is a wide range of perspectives on how clinical research is and is not monitored. At the same time, the coherence of the process varies in terms of follow-up. In some regions there is a clear gap between hospital and policy level, while in other regions there is a gap between administration and policy, but also hospitals. The quote below gives an example of the former:

"We report back quite well to the hospital management because we demand as much. We have management charts for the activities, and we also have special initiatives. Questions are asked about what happened and there is a clear dialogue."

- Head of Operations

The vast majority of those interviewed by the Cancer Society also specifically mentioned the ALF evaluations as important from a follow-up perspective. What is meant here are the evaluations, by the National Board of Health and Welfare and the Swedish Research Council, of university healthcare and clinical research quality that everyone participated in over the course of 2022 and which are carried out in the university healthcare regions every four years.¹⁶ The ALF evaluations are seen as very important.

The Swedish Cancer Society sees follow-up as a key element in ensuring that clinical research is given the best possible conditions. Therefore, a major focus during the interviews was on process and follow-up

16. The university hospital regions are also known as ALF regions. This means that they have specific agreements with the state on medical education and research (abbreviated as ALF) with the aim of promoting "the development of healthcare and cooperation in clinical research and medical education". The latest evaluation was due to start in 2021 but was delayed due to the Covid pandemic and was carried out in 2022. The results of the ALF evaluation are to be reported by the Swedish Research Council and the National Board of Health and Welfare to the Government by 31 March 2023 and 31 May 2023, respectively.

issues. An in-depth question posed to all of them therefore concerned similarities and differences between how research work is assigned and how healthcare production is commissioned.

The commissioning of healthcare production is seen as much more concrete than in the case of research.

“We have monthly monitoring on availability, how long patients wait in the emergency room, and we have financial monitoring, but we don’t have research figures that we follow.”

- Head of Operations

“I guess you could say that healthcare production is more concrete compared to a research mission. We have a certain degree of freedom, and there is no formal follow-up from the region, but we report everything in our annual report.”

- Hospital manager

“Healthcare production is more politically influenced. There are more ideas. Small providers, large providers, private and non-private. That’s not the case with research.”

- Administrator

In some interviews it was mentioned that research cannot or should not be “commissioned” in the same way as healthcare, as healthcare and research are different processes. What is meant above all is that research should be free from political interference.

“Politicians should demand that research is done, and create the conditions for it to be done. Period. Not what! Politicians must have faith in the research community and that we will research what needs to be researched.”

- Care staff

“It’s one thing to control production processes. The basis for research is that it is free, and researchers must decide for themselves what is relevant. That research is free – that is a successful model. In short, research cannot be managed in the same way as healthcare processes.”

- Hospital manager

However, the Swedish Cancer Society does not perceive that the interviewees see a contradiction between a coherent research process that better supports the conditions and implementation of clinical research on the one hand and independent research on the other. One is not deemed to exclude the other.

The interviews reveal what could be monitored to better inform clinical research, its challenges and potential for improvement.

“One important thing that clinics could report and brag about to each other is ‘this many nurses are working on

clinical trials, this many patients are included in clinical trials’. But where such a thing should come from, I don’t know. We measure and record a lot of things for healthcare but we have few managers who understand how to produce those publication lists. And that’s just one way to measure. The percentage of patients entering studies would be something... if it became as important as other metrics.”

- Care staff

“The number of clinical trials is a good measure. We like that indicator. It helps us get people to register. We believe that the database as a working tool can sharpen the quality of delivery.”

- Hospital manager

“The care managers in the organisation would need to have a clear mission and also be evaluated on research and education in a different way.”

- Care staff

Several interviewees link the demand for clearer metrics to the very fact that research is not monitored and measured in the same clear way as healthcare production. The vast majority see this as a shortcoming that makes it difficult to establish how the conditions for research could be developed and structurally improved. As one politician notes:

“I think we talk a little too little about research and development and a little too much about healthcare production. It’s rare to read in the papers that we don’t do enough research. It’s about waiting times in the emergency room and the availability of care. This means that research and preventive health work are not perceived as urgent.”

- Politician

The Swedish Cancer Society’s assessment is therefore that politicians seem to have difficulty knowing how to monitor and control research. There is no doubt that research should be free, but at the same time, managers and health professionals, in particular, are looking for a framework that can support the implementation of research in practice. Better functioning processes around clinical research, and sometimes even more political leadership, are called for.

There is a strong commitment to research among all those interviewed by the Cancer Society, and a lot of development work is underway. The research base could be strengthened with better conditions, where research has a given and self-evident status as a core mission in healthcare, so that care, research and education are integrated in a good and sustainable way. The difficulty of making this work is another key theme that is addressed further in the next section.

Research is crowded out

“The conditions are a bit too bad and it’s all about staff shortages and human resources. Financially and in terms of resources, we have created relatively good conditions, but we need more space in the system.”
– Politician

In addition to what we have focused on so far in both the document review and interviews, which is the coherent process around the research issues, there is a very clear theme that almost all interviewees brought up as a bottleneck for research implementation. What you might call the “stark reality” of healthcare. In part, this is an effect of the timing of the review, which was conducted when Sweden was just coming out of the long and resource-intensive Covid-19 pandemic. At the same time, it is not possible to say that this is the only explanation. The healthcare system is pressed for resources, which means that there is a shortage of health workers, and this is a main reason why research is pushed aside, according to the interviewees.

There are several telling quotes that highlight this as a very big challenge, and below is a selection of these.

“The challenge on the floor is to free up time for research. With tough production requirements, it’s hard to uphold research.”
– Care staff

“We measure how much research time you have. You don’t use up the time and funds you have been given because you don’t have the time. Everyday life comes first.”
– Politician

Difficulties in taking time off for research also seem to apply when there is a decision at hospital management level that time should be taken off.

In short, there are conflicts of goals and interests at the intersection of research and healthcare production that need to be resolved. Many of the interviewees point to the importance of the supply of skills, especially nurses, and that research must be constantly and actively “pushed”:

“One challenge is to get the health sector to see the research as theirs.”
– Administrator

The issue of responsibility also seems to be central here. It is clear that there is a broad consensus that research is being squeezed out – from the policy level to the operational level. It is often described as there being “no room in the system for research”. Knowing that this is the case, what can be done at regional level, and whose responsibility is it? **And perhaps more**

importantly, how can we change the view of research being seen as air in the system to being an integral part of healthcare?

“If we don’t create an organisation to have time for research, research will not be done. Then there is only healthcare production. There used to be a culture of working extra on your research in your spare time. That culture no longer exists.”
– Administrator

“I would like to get away from the idea of dedicated enthusiasts and see better structural conditions introduced for research to function in the long term and on an ongoing basis.”
– Head of Operations

It is clear that those we interviewed are pushing and doing their best to make time for research, and many stress that they are doing their very best with the conditions that exist. However, the Cancer Society’s assessment is that more is needed if Sweden is to seriously break the trend of a declining number of clinical trials. Greater political ownership is needed to enable the important integration of clinical research and healthcare delivery.

Conclusions of the review

Lack of clarity in who has overall regional responsibility for research as a whole and the lack of a consistent process – from the political level down to the operational level – leads to a lack of clarity in both governance and monitoring of research. This, in turn, is an important explanation for the downgrading of clinical research at the operational level, particularly when health services are under pressure.

The Cancer Society’s review clearly shows that there are shortcomings in the way research assignments are given, but above all in the monitoring of research in the regions’ various healthcare activities.

There is great potential to improve clinical research and give it a greater and more prominent place in healthcare. It is very much a question of developing structurally sound conditions for research in everyday healthcare. This places greater demands on governance and political leadership. It also places greater demands on the provision of skills, managers and leaders who are committed to and interested in clinical research and see the major benefits that clinical research has for good and equal health – not least in the longer term.

The Swedish Cancer Society’s proposals for strengthening clinical research

Free research must be protected. It is not the research ideas that need more political control, but it is now necessary for politicians to take full responsibility for

providing the necessary conditions for research in the form of resources and supporting infrastructures and to ensure that research is brought closer to patients and integrated into healthcare development.

*“Our core business is research, education and healthcare. You have to keep reminding people of that.”
- Administrator*

The Swedish Cancer Society believes that concrete action is needed to address the gaps that separate healthcare from research. Clinical research needs to become an integral part of regular healthcare activities. The Cancer Society’s review shows that greater regional political responsibility is needed to make this a reality.

In order to meet the requirements that already exist today in the Health Care Act regarding research and quality development, clearer governance of the

research mission within the regions is needed. Clinical research needs to be more part of a coherent process, with a focus on political accountability to administrative and hospital management and to everyday healthcare. In order to create continuity, it is important to feed results and insights back in both directions. Similarly, it is important that the seven university health regions start with their specific challenges and gaps. The review also highlights the need for sharper national monitoring of both the regions’ responsibility for research, as set out in the Health and Medical Care Act, and the shared responsibility between universities and regions.

Only through clearer governance and a higher priority for research in the organisation of healthcare at regional level can we achieve effective and broad clinical research that will enable us to find solutions for the healthcare of the future.



How to improve conditions

All interviews conducted in the context of this Cancer Society report concluded with the question: **What would you say are the three most important measures to improve the conditions for research in your region?**

The responses were very consistent across the seven university health regions. According to the interviewees, the main issues are:

1. Healthcare must see research as part of its core mission
2. The importance of avoiding repression
3. Reduce the administrative burden on the clinical researcher.
4. Sustainable and stable funding is essential.
5. Setting targets that can be followed up in a concrete way.

All regions in Sweden need to see research as the core mission it is, and research needs to be demanded and controlled to the same extent as the rest of the health-care system. In regions with a commissioning model, care and research commissioning needs to be better synchronised to improve the coordinated management of healthcare as a single system including research.

For clinical research to work, there needs to be a well thought-out organisation and working method throughout the healthcare system that allows the majority of professionals time to conduct research. Several interviewees highlighted the shortage of nurses as a major problem. A key measure, therefore, is to ensure that the supply of skills across the health service works – from filling new posts to training more staff and retaining nurses in the care sector.

Regions need to develop work on research support functions. These include facilitating access to and management of data for clinical researchers, expanding administrative and legal support, and improving IT

systems. The support functions, infrastructure and co-operation that already exist in the regions also need to be disseminated and used. In addition, the exchange of knowledge among regions needs to be improved.

In addition to government research funding for university healthcare, stable regional funding is needed that goes beyond project funding. This includes increased funding to create more research posts.

A recurring and telling quote from the review has been “What is not measured is not done”. This touches on what many highlight: the lack of clear objectives and indicators to do concrete follow-up.

Some also highlight the need for support in the form of strengthened legislation.

The Swedish Cancer Society wants every region to:

- Clarify where in the region the responsibility for clinical research, quality and development under the Health and Medical Care Act lies and is monitored
- Develop concrete action plans that clearly describe how clinical research will be integrated into daily healthcare operations – with a particular focus on management structures and operational governance
- Set targets and indicators to monitor clinical research. One measure highlighted by several in the Swedish Cancer Society’s review is the number of patients included in clinical trials and the number of research nurses and doctors
- Increases core funding for research and research support infrastructure. A first intermediate target should be to allocate at least 1% of total health expenditure to research
- Creating common structures for the management and monitoring of research together with universities and colleges.

At the national level, the Swedish Cancer Society wants:

- Uniform indicators of research activity will be developed to monitor the participation of healthcare activities in clinical research. Indicators should be developed in collaboration with representatives of researchers, regions, patients and other health professionals
 - An authority, preferably the National Board of Health and Welfare, should be commissioned to monitor and evaluate the integration of clinical research in healthcare on an annual basis, using the nationally uniform indicators as a basis
 - Reimbursement models for research production linked to the follow-up should also be created
- A registry should be developed to provide a comprehensive national record of ongoing and planned clinical trials
- The government must take concrete steps to achieve the clinical research objectives of the life science strategy
- Measures to promote clinical research should be specifically highlighted in the forthcoming research policy proposal
 - Long-term investments in commonly accessible research support infrastructure and national coordination and availability of health and medical care data are key elements where the government has a major responsibility.
- The government is increasing support for planning and mapping out how staffing levels in the healthcare sector need to be dimensioned in order to avoid research being repressed due to staff shortages
- All university hospitals should initiate a process to accredit cancer care and research and achieve Cancer Centre (CC) or Comprehensive Cancer Centre (CCC) status according to the OECI standard.

The Swedish Cancer Society's work to strengthen clinical research

The Swedish Cancer Society has allocated SEK 900 million to Swedish cancer research in 2022, with over 15% of the funds going directly to clinical research. More than 230 research projects will be supported, enabling them to continue working towards the goal of beating cancer.

The Swedish Cancer Society is thus one of the largest funders of Swedish cancer research. In comparison, the basic funding of research in the health sector in 2018 was estimated at 0.5% of the regions' total healthcare costs. If the regions were instead to allocate the equivalent of 1% of healthcare costs to research, this would be an increase of SEK 1.4 billion.¹⁸

At the same time, in addition to the need for research to be closely linked to the healthcare system to achieve the best possible health outcomes, university-affiliated researchers depend on access to healthcare structures and results to make their contribution. Close collaboration between universities and healthcare providers in the management, planning and monitoring of clinical research is therefore a prerequisite for the resources invested in cancer research to benefit society.

As a research funder, we at the Swedish Cancer Society have good opportunities to contribute to increased collaboration. In 2021 and 2022, we made a special investment in radiotherapy research where cooperation between universities and healthcare is a prerequisite for the allocation of funds.

In 2023, the Cancer Society will also focus on clinical treatment research where collaboration between universities and healthcare is of utmost

importance. We also see an increased need for funding for services, particularly in the area of health research. That's why we have taken a special initiative in this area in 2022 and 2023. Enabling more professionals to conduct research is central to effective and broad-based research, something to which we attach great importance and where we see a high level of demand.

In recent years, the Swedish Cancer Society has increased its support for clinical research, for example through the special invitations mentioned above, but also by providing more clinical researchers with grants to cover their salaries. However, as the review clearly shows, in order for us as research funders to do even more to support clinical research, the organisational conditions for clinical researchers must be clearly improved. In this way, the funds invested can have the greatest possible impact. As several researchers testify in the review, we as a research funder have also seen how several clinical researchers have difficulty spending their research grants because they simply do not get enough time for research from their employer.

We at the Swedish Cancer Society are convinced that when researchers, healthcare professionals and patients meet, interact and contribute different input, great things can be achieved together. Now is the time for those in power, both at regional and national level, to seriously tackle the research issue and give cancer research the conditions it needs to achieve our common goal of defeating cancer faster!

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Government Bill 2020/21:60, Forskning, frihet, framtid – kunskap och innovation för Sverige [Research, freedom, future – knowledge and innovation for Sweden]

Annex 1

Review implementation

In the autumn of 2022, the Swedish Cancer Society reviewed how the seven regions with university hospitals in Sweden approach and follow up on research. The regions included in the review are:

- Skåne, incl. Skåne University Hospital
- Stockholm, incl. Karolinska University Hospital
- Uppsala, incl. Uppsala University Hospital
- Västerbotten, incl. Norrland University Hospital
- Västra Götaland, incl. Sahlgrenska University Hospital
- Örebro, incl. Örebro University Hospital
- Östergötland, incl. Linköping University Hospital

The aim of the review was to examine how clinical research can be given the best possible conditions by reviewing the regional processes for clinical research, from policy to health professionals. The review is based on two elements.

Document review

The audit began with a reading of the regions' main policy documents, with a focus on the wording on research, research objectives and indicators, and monitoring.

The main governance documents were requested from the university health regions' registrars and were:

- Regional budget 2022, including the budget of the Health Board

- The Regional Board's business plan 2022
- Health Care Board business plan 2022
- The region's research strategy/policy
- Hospital agreements (if any) with the region's university hospitals
- Business plan for the region's university hospital 2022
- Political organisation chart
- Organisational chart of the health administration
- The latest interim and annual reports from the Regional Council, the Health Board and the university hospitals of the region
- Research financial statements

The documents reviewed by the Cancer Society are therefore similar for all seven university health regions.

In-depth interviews

Based on the overall picture of the document review, the Cancer Society then conducted a total of 20 interviews with various key people in the seven university regions. The selection of individuals for interviews was based partly on collecting a wide range of politicians, administrative and hospital managers, heads of operations and healthcare staff, and partly on obtaining more interviews in the regions where the policy documents were more unclear and difficult to assess. The interviews conducted by the Swedish Cancer Society are distributed as shown in the table below.

Region	Policy	Administrator	Hospital management	Head of operations	Care staff
Skåne			X	X	X
Stockholm		X	X		X
Uppsala	X	X			
Västerbotten	X		X	X	
Västra Götaland	X	X	X	X	
Örebro			X	X	
Östergötland	X	X		X	

NOTE: In Region Örebro and Region Västerbotten there is no hospital director. Instead, the hospital is managed by the Director of Health and Medical Services.

For managers and healthcare professionals, the Cancer Society has focused on cancer services and clinical researchers in the field of cancer. For policy, administrative and hospital managers, the focus of the interviews has been the research process in general. The questions that the interviews focused on were whether research is seen as part of a coherent process, research objectives and indicators, monitoring of research in practice, how people view their own responsibility and role in the region's research, differences and similarities in how research assignments are given and how healthcare production is commissioned, and whether the practical conditions for the implementation of clinical research are perceived as good or not. All interviewees were also asked about the three most important measures to improve the conditions for research in the region.

Processing and thematisation

Both the document review and the interviews have been analysed and processed to identify patterns and similarities, as well as differences between the university health regions in terms of clinical research.

In the analysis work, the three themes identified in the chapter "The Swedish Cancer Society's review of the political responsibility for clinical research" have emerged as the central focus of the review's findings, although there are also some differences among the regions.

The regional results have also been processed and are presented separately in Annex 2.

The Swedish Cancer Society's vision is to beat cancer. By funding cutting-edge research, spreading the word about cancer and influencing decision-makers on key issues, we help to ensure that fewer people are affected and more people survive cancer.

The Swedish Cancer Society is an independent, non-profit, non-subsidised organisation. Our work depends entirely on bequests and donations from individuals and companies.

We are one of the largest funders of Swedish cancer research. Since 1951, we have awarded more than SEK 13 billion to the top research projects in Sweden. The cancer survival rate has more than doubled over the same period.

Today, thanks to advances in research, two out of three people who get cancer survive. We've come a long way, but we're not there yet.

#togetheragainstcancer



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