ACTION PLAN

THE STOCKHOLM REGION'S LIFE SCIENCE STRATEGY

Clinical Trials in Region Stockholm

Region Stockholm

Introduction

In 2018, the Regional Council in Stockholm decided to develop a new regional life sciences strategy as part of a broad cross-party collaboration. The aim was to work with the industry and other actors systematically and in a structured way to identify opportunities and obstacles to the life science sector's continued growth and development.

The new Life Sciences Strategy was adopted in spring 2021 (RS 2019-0751). The strategy has ambitious objectives, aiming to make Stockholm one of the world's leading life sciences regions.

The strategy has identified five strategic development areas:

1. World-leading access to structured health and care process data.
2. Health and social care systems available for interaction with research and innovation and collaboration with business.
3. Precision medicine gives patients and residents access to high-resolution diagnostics and personalised prevention and treatment.
4. Interdisciplinary collaboration creates solutions to complex challenges.
5. Life science companies research, develop and grow in the Stockholm region.

Alongside this, work began on developing a new strategy for research, education and development for Region Stockholm. The new Research, Education and Development (RED) Strategy was adopted in September 2021 (RS 2019-0750). The RED Strategy covers all of Region Stockholm's areas of responsibility and must be applied by all organisations funded by Region Stockholm. The strategic direction of the RED Strategy comprises ten points:

1. Region Stockholm will make structured health data available in a coordinated, secure, ethical and consistent manner.
2. Clinical research across the healthcare system.
3. Education and training across the healthcare system.
4. University healthcare and knowledge management will work together to turn research outcomes into day-to-day clinical practice.
5. An enquiring culture, expertise, research time and infrastructure at Region Stockholm will create the conditions for medical breakthroughs.
6. The leadership culture at Region Stockholm fosters excellent learning at all levels.
7. Region Stockholm will stimulate industry-initiated clinical research for the benefit of residents, patients and relatives.
8. Region Stockholm will stimulate research and development in the public transport system.
9. Region Stockholm will contribute to sustainable urban development.
10. Region Stockholm will actively promote interdisciplinary and integrated research.

Implementation

In order to realise the Life Sciences Strategy, several actors need to implement measures within their own organisation and in collaboration with others. Healthcare providers and life science companies thus have a key role to play in this endeavour. The strategy is therefore complemented by structured work, organised and monitored via joint working groups and *action plans*.

The working groups appointed to produce the action plans will set goals, subsidiary goals and indicators for the work, identify specific measures in different areas where action is required, and allocate responsibility for each action. The Director of Research and Innovation will report annually to the Regional Director on work completed under the action plan.

A working group responsible for an action plan is not part of the line organisation as such, but is the collaborative arena in which concrete coordination and work towards shared goals takes place. The working group therefore has no decision-making function. Members of the working group represent their own organisations and act as the interface between them and the work of the action plan. In this role, members of the working group are expected to gain endorsement for the action plan in their own organisation. One important task is to identify the extent to which joint work is consistent with, or deviates from the mission and goals of each party. If the working group identifies conflicts of interest, these should be raised both within the working group and within the respective line organisation. The success of the work within the action plan is based on all participating actors taking responsibility for their role, and on a willingness to cooperate that leads to continuous improvement.

The content of the action plans is established in an iterative process that includes the following steps:

1. Identify activities already in place in the Stockholm region and nationally that target the identified goals.
2. Identify the gaps and needs that are not being addressed.
3. Initiate activities to address these needs.
4. Communicate actions and goals.
5. Follow up each goal and evaluate the activities.
6. Align strategic objectives with activities.

Work on the individual action plans must also take account of the goals and subsidiary goals set out in Region Stockholm's other strategies. These are:

- Research, Education and Development Strategy for Region Stockholm (RS 2019-0750)
- Life Sciences Strategy for the Stockholm Region (RS 2019–0751)
- Innovation Strategy for Region Stockholm (RS 2019-0672)
- Regional Development Plan for Stockholm, RUFS 2050 (LS 2015-0084)
- Business and Growth Strategy for the Stockholm Region (RS 2020-0780)
- Sustainability Strategy for Region Stockholm (RS 2020-0779)
- IT and Digitalisation Strategy 2020–2023 (RS 2019-0669)

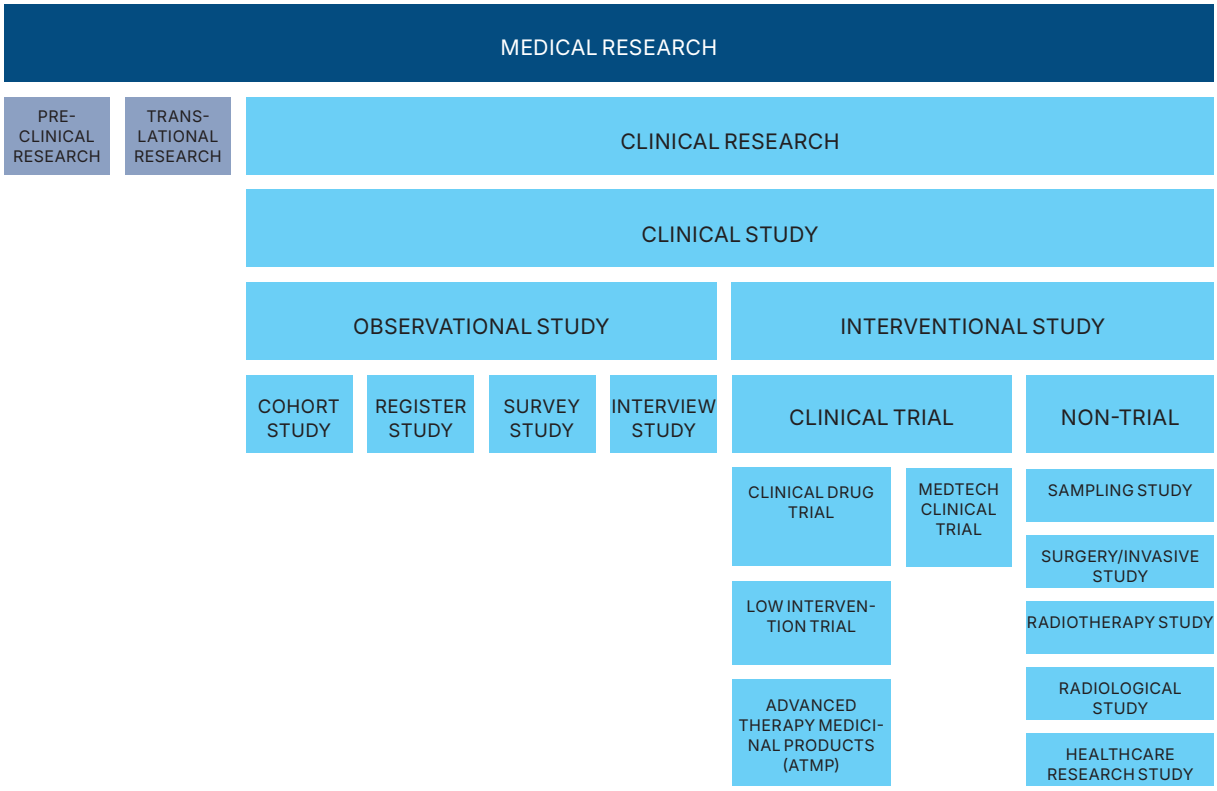
Action plan: Clinical Trials

This action plan describes the work under the theme of *Industry-initiated Clinical Trials*. The area of *clinical research* is clearly identified in both the Life Sciences and RED strategies.

Clinical research is mainly conducted as clinical trials, which is research that requires access to healthcare resources. Clinical studies, in turn, include both observational and interventional studies, where *clinical trials* are interventional studies involving pharmaceuticals or medical technologies.

Clinical trials are divided into two groups depending on how they are initiated and funded; *Academic Clinical Trials* and *Industry-initiated Clinical Trials* (figure 1).

The operational scheme illustrates how clinical trials relate to other clinical research. Clinical trials are a subset of clinical studies, which are themselves a subset of medical research. The size of each box does not correspond to the proportion of research represented by each category.



Source: Handbok för forskare/prövare vid uppstart av klinisk studie (Handbook for researchers/investigators when starting a clinical trial), Karolinska University Hospital, 2023.

Since this action plan describes the work under the theme of *Industry-initiated Clinical Trials*, it responds to the following sections of the Life Sciences and RED strategies:

From the Life Sciences Strategy:
To further develop healthcare, both private and public healthcare providers need to participate in clinical research. Region Stockholm is collaborating with KI, KTH and Stockholm University, the business community and the healthcare sector to ensure that clinical research is an integral part of this development.

From the RED Strategy:
Industry-initiated clinical research benefits society by improving the quality of care, patient safety and employee skills development, and via increased productivity, job creation and cost savings for pharmaceuticals and medical technologies. Region Stockholm will develop clear channels of contact for business collaboration, transparent rules and a culture that supports collaboration between healthcare and the business community, in accordance with current regulations. Region Stockholm must have clear channels of contact and be able to offer test environments for the research and development of new products or services.

The primary target groups for this action plan are Region Stockholm and healthcare providers operating in the region. Other target groups include, but are not limited to, patient and family representatives, pharmaceutical and medical technology trade associations and companies in the life sciences sector.

The action plan has been prepared by a working group at Region Stockholm's Regional Management Office through the Research and Innovation Department. The project manager of the working group has reported to the Director of Research and Innovation, who leads and coordinates the work on all action plans linked to the region's Life Sciences Strategy and RED Strategy. The working group has been supported by a broad reference group consisting of representatives from

- Capio St Göran
- Danderyd Hospital
- Karolinska University Hospital
- KI Biobank (KIBB)
- Clinical Studies Sweden – Stockholm Gotland Forum
- The Swedish Association of the Pharmaceutical Industry (Lif)
- Norrtälje Hospital Tiohundra
- St. Erik Eye Hospital
- Stockholm Health Care Services (SLSO)
- Stockholm Medical Biobank (SMB)
- Stockholms sjukhem
- Sweden Bio
- Swedish Medtech
- Södersjukhuset
- Södertälje Hospital

The reference group has contributed important and constructive reflections and input regarding the inventory of needs carried out, as well as the focus of the measures proposed by the working group. In parallel with the reference group's contribution, in-depth meetings and interviews were conducted with actors at various levels to gather knowledge, ensure that the working group has understood and compiled this correctly, and to test ideas.

Region Stockholm's Programme Office for Life Sciences is responsible for following up the action plan and ensuring that its goals and subsidiary goals are realised. The working group initiates the activities and actions required to achieve the goals, and ensures that the action plan is continuously developed and regularly updated.

Background and challenges

The national life sciences strategy identifies *more industry-initiated clinical drug trials in Swedish healthcare* as a strategic goal. The strategy recognises that new knowledge in the form of health-promoting methods, products and treatments is best developed and evaluated where patients and users are, and with their expertise and involvement in the development process[1].

Furthermore, the strategy states that the number of clinical drug trials has declined since the year 2000, and that the sector's actors feel conditions for conducting clinical research have deteriorated in recent years, as time and resources have become increasingly scarce in the health sector, combined with longer lead times caused in part by the interpretation and application of the GDPR.

In March 2023, Sweden's Ministry of Climate and Enterprise presented several proposals aimed at improving conditions for clinical trials in order to promote a stronger life sciences sector[2]. The premise underlying the proposals is that current conditions for clinical trials play a crucial role in ensuring the development of health care and that patients have early access to new treatments. The proposals are grouped into specific actions in five areas covering vision, partnerships and collaboration, funding and infrastructure, training and promotion, and monitoring and learning.

In order to secure Region Stockholm's position as the natural choice for conducting clinical trials, healthcare providers in Region Stockholm must create the conditions to collaborate, plan for and provide opportunities for all relevant patients to participate in clinical trials. In particular, the measures identified in the action plan will promote the ability of healthcare providers to accept and deliver services in *industry-initiated clinical trials*.

[1] A national life sciences strategy, Ministry of Enterprise and Innovation, 2019.

[2] Förslag på åtgärder för att skapa bättre förutsättningar för kliniska prövningar (Proposals for actions to improve conditions for clinical trials), Ds 2023:8, Ministry of Climate and Enterprise, 2023.

Goals, subsidiary goals and actions

Goal 1:

Region Stockholm is recognised for its trial-friendly climate, its clear vision and its competitive processes.

Goal 2:

Healthcare providers in Region Stockholm are managed, organised and resourced to conduct clinical trials in a scalable manner.

Goal 3:

Healthcare providers in therapeutic networks[3] have access to appropriate administrative support for planning and monitoring clinical trials.

Goal 4:

Region Stockholm has a sustainable supply of expertise for conducting clinical trials.

Each goal has subsidiary goals and details the actions that need to be implemented in order to achieve the goals. Several actions involve the implementation of pilot projects to test and evaluate individual practices and processes on a small scale before broader implementation is considered. Experience from the pilot projects will define resource needs in terms of scale, but also the type of resources that are justified to achieve the goals.

Goal 1:

Region Stockholm is recognised for its trial-friendly climate, its clear vision and its internationally competitive processes.

Subsidiary goals

1. There is a dynamic and strategic therapeutic area approach to the work of Region Stockholm based on an analysis of pharmaceuticals and medical technologies in the pipeline, in relation to the needs identified by healthcare providers, researchers and patients.
2. There is an agreed regional vision based on the strategic direction.
3. Region Stockholm collects and publishes descriptive statistics on clinical trials that contribute to in-depth knowledge about involvement in, and implementation of clinical trials.
4. Information about clinical trials that are recruiting research subjects is publicly available.
5. Region Stockholm's work is characterised by collaboration and a partnership around clinical trials.

Actions

Actions need to be focused in order to achieve the desired effects. This is done on the basis of an agreed strategic direction. The strategic direction is developed by analysing companies' ongoing research and product development linked to disease and therapeutic areas in clinical trials. This is then matched against the needs of healthcare providers and recipients, with the aim of identifying priority therapeutic areas. It is for the medical profession to assess whether a request to conduct a clinical trial can or has the potential to meet the medical needs of the intended patient population. This process also includes identifying the necessary conditions for establishing a partnership between the relevant actors. A generic approach and process for identifying a strategic direction is being tested and evaluated in a pilot. The focus on prioritised therapeutic areas creates a framework

[3] In this context, a therapeutic network refers to a multi-provider network that, for a diagnosis/indication/patient population, collaborates on the planning, implementation and follow-up of clinical trials.

in which measures can be tested and evaluated, and then implemented and disseminated.

Specifying the vision is a prerequisite for monitoring goal fulfilment and effects over time, with the support of indicators corresponding to *the number of clinical trials started* and *the proportion of research subjects included*. The vision and indicators must be in line with Region Stockholm's ambition for Stockholm to become one of the world's leading life sciences regions (RS 2019-0751).

Making descriptive statistics available requires the development of effective and sustainable methods for collecting data on participation in trials on an ongoing basis where they are conducted, i.e. at individual healthcare providers. The data collected could also be used to publicise which clinical trials are recruiting research subjects. The collection of statistics must not result in an unreasonable use of resources by the healthcare provider, and the data reported must be reliable and of good quality.

The data that is collected, collated and reported is important and fulfils several key functions, including:

- visibility and appeal
- monitoring the achievement of goals
- comparisons and evaluation of measures
- ability to respond to downward trends

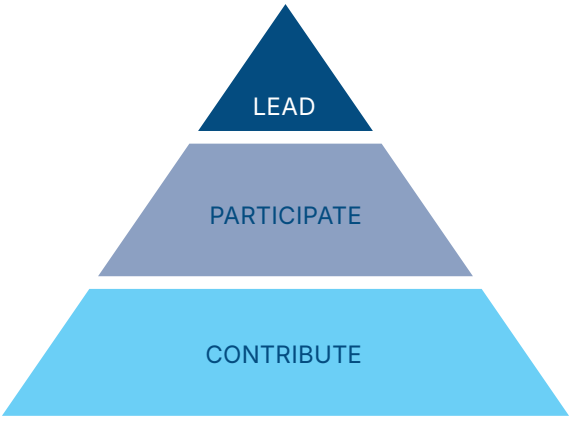
Capacity to establish partnerships at both regional and national level will be a crucial factor in Region Stockholm being an attractive and competitive clinical trial organiser. Regional, multi-provider therapeutic networks are a key part of the partnership. Generic processes for including therapeutic networks in the partnership will be tested and evaluated in a pilot project. There are established forms of regular dialogue with residents and patients as part of the partnership.

Goal 2:

Healthcare providers in Region Stockholm are managed, organised and resourced to conduct clinical trials in a scalable manner.

Subsidiary goals

1. There is an established model for therapeutic networks, including tier structuring across care providers, which is built around knowledge management.
2. Aggregated statistics and indicators are used continuously for target-based management of healthcare providers in Region Stockholm.
3. Healthcare providers that are part of therapeutic networks have public, transparent research price lists and sign agreements that ensure at least full cost coverage for conducting clinical trials.
4. Digital tools and shared approaches contribute to more efficient implementation of clinical trials. Information on clinical trials recruiting research subjects is available to Region Stockholm residents.
5. The feasibility process is accessible, predictable and coordinated between healthcare providers in Region Stockholm.



A healthcare provider may lead, participate in and/or contribute to clinical trials. Most healthcare providers need to contribute to and participate in clinical trials, while a few lead them. The role and responsibilities of the healthcare provider may vary between clinical trials.

Actions

Region Stockholm has a mix of healthcare providers, all of which, whether private or commissioned by the region, fulfil important functions for the implementation of clinical trials. The degree of involvement will vary between healthcare providers and different clinical trials, resulting in a tiered structure (figure 2). The role and responsibilities of the healthcare provider in therapeutic networks should be highlighted in agreed principles for the therapeutic network. This should be done through dialogue between the network's constituent healthcare providers and with relevant aspects of knowledge management, such as the relevant regional programme area. The therapeutic network model and process for establishing networks based on the strategic direction are identified and evaluated in the form of pilot projects.

To strengthen the implementation capability of therapeutic networks to conduct clinical trials, the feasibility of introducing a new career path for clinical trialists will be explored. A clinical trialist is a GCP-trained[4] doctor who is funded as part of their job to be the principal investigator and to respond to requests to conduct clinical trials (feasibility).

Descriptive statistics, both qualitative and quantitative, of clinical trials, including outcomes against individual indicators, are relevant for adequate target-based management, regionally but also locally at each healthcare provider. Therapeutic networks have an important role in co-creating and gaining endorsement for what are deemed to be reasonable target levels for the specific therapeutic area. It is important that the data collected can be broken down and aggre-

[4] GCP (Good Clinical Practice) is an international regulatory framework that, together with other legislation, regulates how clinical trials should be planned, conducted and reported in accordance with the authorisation issued by the Medical Products Agency.

gated at care provider and organisation level. Individual and aggregated target levels thus need to be endorsed by the respective management of the healthcare provider concerned.

In order to streamline and quality assure that clinical trials are conducted cost-effectively, the various healthcare providers in the therapeutic networks must establish and publish price lists for the hourly rates (i.e. the healthcare system's cost price) that are linked to the various types of treatment and follow-up appointments (research visits) in the trials. Public price lists increase the transparency and predictability of the system for both healthcare providers and responsible companies.

Digitalisation in healthcare offers opportunities to carry out trial-related steps where the patient is located. New, digital and decentralised approaches will be considered, evaluated and developed to enable more residents of Region Stockholm to participate in clinical trials. Region Stockholm, its healthcare providers and therapeutic networks will therefore closely follow and contribute to the development of decentralised clinical trials where relevant.

In order for residents of Region Stockholm to be informed about clinical trials that are relevant to them, digital tools for this purpose should be evaluated and developed, for example through a tool in existing platforms.

Goal 3:

Healthcare providers in therapeutic networks have access to appropriate administrative support for planning and monitoring clinical trials.

Subsidiary goals

1. There is administrative, digital support for resource planning in the healthcare organisation in connection with the planning and start-up of clinical trials, as well as for individual appointment planning for the research subject in the context of the trial in question.
2. The healthcare provider has access to centralised, qualified advice to conclude, negotiate and set up agreements with the trial's authorised sponsor.
3. The care provider has access to qualified expertise support for monitoring agreements and finances during and after the completed trial.

Actions

In order to streamline administrative work around a clinical trial, improve predictability and gain an overview of implementation capacity, robust systems are needed to enable planning, and to secure and gain an overview of the resources needed over time to conduct a trial in accordance with the trial protocol. In this context, resources refer to both expertise in connection with examination and treatment visits, and the availability of relevant equipment for examinations to be carried out in the context of the trial. Information on the individual planning of the subject's examination and treatment visits also results in an individual care and treatment plan for the subject's participation in the trial.

Under the auspices of healthcare providers and in some cases on behalf of the region, Region Stockholm has a limited number of administrative support functions for entering into an agreement to conduct a clinical trial. Based on the strategic direction, objectives and indicators for the region, the capacity and availability of established support functions need to be streamlined and strengthened in parallel with the establishment and availability of complementary support. The starting point is to strengthen and make available what works.

To ensure that the healthcare provider's participation in clinical trials is consistent with the agreed budget, the healthcare provider needs support with follow-up. The support function needs to be located at each healthcare provider, which means it will be particularly important to establish networks for the exchange of knowledge and experience, especially in matters relating to contract law and the handling of personal data.

Goal 4:

Region Stockholm has a sustainable supply of expertise for conducting clinical trials.

Subsidiary goals

1. Organisations participating in therapeutic networks have access to, and undergo ongoing GCP training and other appropriate training for relevant staff and managers.
2. Therapeutic networks systematically involve junior staff as co-investigators to ensure uninterrupted access to qualified investigators.
3. Therapeutic networks continuously share experiences.

Actions

Current, regularly updated GCP knowledge is essential for the ability and qualification to conduct industry-initiated clinical trials. To be able to compete globally, organisations that are part of therapeutic networks need to be able to demonstrate early in the feasibility process that the staff and managers involved are adequately trained and qualified. Generic models will be developed and disseminated based on the processes that are currently in place with various healthcare providers, to ensure the continual supply of qualified research staff.

Models and methods to strengthen therapeutic networks via a wider exchange of experience on processes and practices will be developed through pilot projects.

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