AGREEMENT ON CLINICAL TRIALS OF PHARMACEUTICALS AND MEDICAL TECHNOLOGY

FOR PUBLICLY FUNDED HEALTHCARE, THE PHARMACEUTICAL INDUSTRY, THE MEDICAL TECHNOLOGY INDUSTRY, THE BIOTECHNOLOGY INDUSTRY AND THE LABORATORY TECHNOLOGY INDUSTRY

Sveriges Kommuner och Regioner (SKR – the Swedish Association of Local Authorities and Regions), Läkemedelsindustriföreningen (Lif – the Swedish Association of the Pharmaceutical Industry), Swedish Medtech (the Association for Medical Technology in Sweden), SwedenBio (the Swedish Life Science Industry Organization) and Swedish Labtech (the sector organization for diagnostics, laboratory equipment, analysis and biotechnology companies in Sweden) have agreed the conditions for collaboration on clinical trials of medicines and medical technology (referred to below as "clinical trials"). This is the first time that this agreement has covered SKR and all four industry associations in the life sciences.

The aim of the agreement is to simplify the formal management of contractual collaboration on clinical trials, in the context of current legislation, by providing guidance on the ethical, legal, and financial considerations that need to be considered by both responsible authorities and companies to ensure positive collaboration around clinical trials. Clear conditions for the relevant parties to the agreement will simplify the undertaking of clinical trials.

The parties agree that compliance with this agreement is a shared responsibility. The parties undertake to disseminate information about the agreement to their respective members and to recommend, and work actively to ensure, that relevant members put it into practice.

The parties agree to jointly monitor the rules of the agreement through the partnership group for clinical trials that they are setting up.

This agreement applies from 1 July 2020 until further notice and replaces the previous agreement on conducting clinical trials between SKR (previously SKL) and Lif.

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1. Collaboration on industry-initiated clinical trials

An essential factor in the life sciences strategy objective for more industry-initiated clinical trials

In Sweden there has long been valuable collaboration between academia, healthcare, and industry. This collaboration will help to develop healthcare, dental care, and social care with the aim of providing patients with treatment and care that are effective, evidence-based, and safe.

The life sciences are a knowledge-intensive sector that is very important for Sweden, as the Government's strategic investment in the life sciences field demonstrates. The effective development of new treatments, methods and products requires close, trusting collaboration between the actors. There is considerable potential for improved collaboration, which the partners are keen to support through this renewed agreement on clinical trials. In addition to the parties to the previous agreement – SKR and the pharmaceutical industry – this agreement also involves the medical technology, biotechnology, and laboratory technology industries.

Clinical trials represent research that is closely linked to actual healthcare practice and are essential for the development of new pharmaceuticals, diagnostics and medical technology products that contribute to the continuous development of healthcare and improved treatment outcomes.

The agreement complements the legislation and ethical guidelines that underpin the conducting of clinical trials. It highlights the guidelines that the parties have agreed should be observed by both the health care sector and industry when conducting clinical trials.

Clinical trials generate values that go beyond the contracted work on documenting new products. Collaboration through clinical trials provides expertise and experience for both the healthcare sector and industry that lead to innovations that benefit patients. The parties agree that these values are of benefit to Sweden as a whole and that a broader-based collaboration should be encouraged as intended by the life sciences strategy.

There is considerable global competition. By distinguishing ourselves with our responsible approach and a positive climate for collaboration, Sweden can continue to be an attractive country in which to locate industry-initiated and industry-sponsored clinical trials. The parties recognize that there is a need for us to work together more to develop the conditions and incentives needed to encourage clinical trials in Sweden. They therefore seek to develop the consultative body brought into being by the previous agreement into a partnership group for clinical trials, which will work actively to facilitate an increase in the trials being conducted in Sweden.

Clarity, transparency, and monitoring develop trust. Through the clinical trials partnership group, the parties will seek to monitor on an ongoing basis how the agreement is being complied with, how the conditions for conducting clinical trials are being developed and how each party is addressing the obstacles and challenges that currently need to be overcome if Sweden is to become a frontrunner in the field, continuing to host high-quality, responsible clinical trials.

2. General assumptions

Healthcare is in a constant state of change, at the same time as the demand for safer and more effective diagnostics and treatments is increasing. Care is moving closer to where the patients are, which means that it will increasingly be provided as primary care, in the home or remotely. Healthcare is also undergoing rapid digitalization. New ways of dealing with and treating patients are being developed.

Pharmaceuticals and medical, bio and laboratory technologies are also increasingly being integrated, for example, through the development of new diagnostic methods, software and apps that can support medical treatment. New types of treatment – for example precision medicine, which is more specialized, personalized and focuses on small groups of patients – require new types of clinical trials. New legislation at the European and national levels mean new requirements are being placed on both authorities and industry. New knowledge, increased collaboration and the sharing of experience will enable the new needs to be met.

Together with the experiences from the previous agreement, these changes in external circumstances, the work of Kliniska Studier Sverige (Clinical Studies Sweden) and the regional research nodes and the recognized need to simplify the conducting of clinical trials in Sweden form the starting point for the revision of the earlier agreement.

In the Government's life sciences strategy, collaborative structures have been identified as one of eight priority areas for development. Through this agreement, the parties will be helping to enhance national collaboration on clinical trials.

This is the first time that this agreement has covered SKR and all four industry associations in the life sciences.

3. Purpose and objectives

Through this agreement, the parties wish to encourage a shared responsibility to fulfil the main objective of clinical trials – to develop new knowledge, new treatment methods and/or new products and services that benefit patients.

The aim is to develop a consistent approach. Operating within the framework of existing legislation, the agreement will simplify the formal management of contractual collaboration on clinical trials. The agreement will provide guidance on the ethical, legal and financial considerations that need to be taken into account by both responsible healthcare authorities and the industry to ensure positive collaboration around clinical trials. The agreement will also help to clarify how the *Överenskommelse om samverkansregler* (Agreement on collaboration regulations)[1] is to be applied in clinical trials.

The aim is to work towards more clinical trials in Sweden in line with the Government's life sciences strategy. The parties seek, therefore, to:

- create clarity for the relevant parties to the agreement and thus simplify the planning, contracting and conducting of clinical trials
- create transparency for the general public, patients and the healthcare sector
- develop forms of collaboration to meet the challenges that need to be addressed

4. Scope of the agreement

In order for new pharmaceuticals, diagnostics and medical technology to be developed, there must be opportunities within healthcare to conduct clinical trials. Clinical trials can be initiated by companies (industry-initiated) or by the healthcare sector (researcher-initiated). Researcher-initiated trials can be sponsored by industry and/or funded through research funds. This agreement covers clinical trials. However, the principles it contains should also be applied to non-interventional (observational) studies.

All staff and managers in the healthcare sector and in the industry, and the consultants engaged by

[1] Agreement on Collaboration Regulations

companies, are covered by this agreement.

Irrespective of whether or not companies belong to a trade body, the healthcare sector will apply what has been agreed to all companies in the pharmaceutical, medical technology, biotechnology and laboratory technology sectors.

Irrespective of whether or not healthcare is publicly or privately funded, members of the Swedish Association of the Pharmaceutical Industry, Swedish Medtech, SwedenBIO and Swedish Labtech, and any consultants they engage, will apply what has been agreed when clinical trials are conducted in Sweden.

5. For clinical trials, the following applies

Under the terms of this agreement, clinical trials will conform with the fundamental principles in the Agreement on Collaboration Regulations [2] and will be undertaken with respect for the parties' obligations and use of the parties' expertise and experience.

In addition to what is covered by this agreement and current legislation, staff and managers in the healthcare sector and the industry must comply with the rules on travel, hospitality and secondary occupations in the Agreement on Collaboration Regulations and other policies and work codes/codes of conduct that individual employers have put in place in their own organizations.

Assessment of enquiries about clinical trials from industry or the healthcare sector must be objective and impartial, and the enquiry must be dealt with promptly.

5.1. Public access and confidentiality

Most regional council documents are to be considered public records under the Swedish Public Access to Information and Secrecy Act and may be disclosed if they are not deemed confidential.

Under the Act, data that is necessary to enable the responsible authority to make a decision on providing resources for a clinical trial and for monitoring and checking the trial while it is being conducted is deemed confidential. The parties to the agreement agree that this data can be shared internally within the region to enable the clinical trial to be conducted. A confidentiality assessment must always be undertaken in relation to external parties.

5.2. Contracts

A contract governing implementation and remuneration will be drawn up between the company and the responsible healthcare authority before each clinical trial. Contracts cannot be made solely between companies and healthcare employees. The conducting of clinical trials and associated contracts is subject to Swedish law and Swedish regulatory control.

Contracts must comply with the Declaration of Helsinki in respect of the patient's treatment after the clinical trial has ended.

The contractual parties have joint responsibility for regularly checking that the clinical trial is proceeding according to contract.

If a clinical trial is discontinued, significantly changed, or ended, the other party/ies to the contract must be notified immediately, and details must be recorded in a supplementary contract if necessary.

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[2] SwedenBIO has not subscribed to the Collaboration Regulations and is not covered by the Agreement on Collaboration Regulations.

5.3. Financial remuneration

The financial remuneration relating to the agreed contract must be used to cover any additional expenses incurred by the responsible healthcare authority for conducting the clinical trial. The remuneration must correspond to the costs of the services and utilities provided by the organization concerned and must be based on the cost price. The self-cost principle includes salaries, interest, and depreciation/amortization. In addition to remuneration for the contracted service, there may be additional charges in relation to assuring the running of the clinical trial, contracting and overheads. All expenses must be accounted for in a transparent manner.

The financial remuneration must be utilized in accordance with the Agreement on Collaboration Regulations.

Companies may reimburse researchers for expenses related to their involvement in the clinical trial. Payments must be made by the responsible healthcare authority or a third party.

5.4. Insurance

For researcher-initiated clinical trials, it is the care provider's responsibility to ensure the trial is covered by insurance in accordance with the Swedish Patient Injury Act.

For industry-initiated clinical pharmaceutical trials, the pharmaceutical company is responsible for ensuring that the clinical trial is covered by Swedish Pharmaceutical Insurance or has equivalent insurance cover.

For industry-initiated clinical trials of medical and laboratory technology products, the company is responsible for ensuring that the necessary insurance cover is in place.

5.5. Resources

In order to conduct clinical trials effectively, it is very important that both the responsible healthcare authority and the company ensure that the necessary resources and skills can be provided throughout the procedure and that the other party is notified of any changes.

5.6. Transparency

Pharmaceutical companies are required to report details of both ongoing clinical trials and the results of completed clinical trials to a publicly accessible database.

Medical technology companies should report details of both ongoing clinical trials and the results of completed clinical trials to a publicly accessible database. For clinical trials conducted with the permission of the Swedish Medical Products Agency, the final report must be available on request.

For researcher-initiated clinical trials, the responsible healthcare authority is required to report details of both ongoing clinical trials and the results of completed clinical trials to a publicly accessible database.

The responsible healthcare authority and company are responsible for maintaining an overview of ongoing and completed clinical trials within their own organizations.

Either contractual party must inform the other party of the results of any clinical trial that affects the activity of the other party.

6. Partnership group for clinical trials

The previous agreement has incorporated a consultative body whose purpose has been to enable the parties to continuously monitor the agreement and to work up proposals for revision as needed. The parties agree to develop this consultative body into a national partnership group that will involve direct dialogue between the parties acting as representatives of the healthcare sector and industry,

with the aim of improving the prospects for clinical trials in Sweden. The partnership group will be able to handle both strategic and more operational issues and run joint projects. The group will also be responsible for compliance with and development of the agreement. Organizational and working arrangements for the partnership group will be developed by the parties jointly.

The parties seek to jointly encourage all actors to contribute putting the practical framework in place to enable the healthcare sector and patients take part in clinical trials. The parties have initially identified the need for continued action to simplify contracting procedures and to ensure that contracted clinical trials are monitored as they proceed. Through the partnership group, and together with other national initiatives, the parties also seek to support the work of developing a framework for national statistics and incentives to conduct clinical trials and to improve coordination and conditions in relation to enquiries about studies.

The agreement will be supplemented with a more detailed guide that will support the healthcare sector and the industry with contracting and in the conducting of clinical trials.