Agreement on collaboration between Genomic Medicine Sweden and life science industry representatives

For Genomic Medicine Sweden, the pharmaceutical industry, the medical device industry, the biotechnology industry, and the laboratory technology industry

Date: 2022-09-20

Preparation: The agreement has been developed jointly by Genomic Medicine Sweden, Läkemedelsindustriföreningen, Swedish LabTech, Sweden Bio and Swedish Medtech.

Summary

Genomic Medicine Sweden (GMS) and the Swedish trade industry associations, the Research-Based Pharmaceutical Industry (Lif), Swedish Medtech, SwedenBio and Swedish Labtech (hereinafter referred to as the Parties), have agreed on a framework for collaboration related to the activities of GMS.

The Agreement aims to facilitate collaboration between companies and GMS and to clarify the conditions for collaboration between the Parties and the members of the Parties, by providing, together with other agreements for collaboration with the health care sector[1,2,3], guidance on legal considerations, creating conditions for collaboration for the mutual benefit of the Parties and ensuring the development of collaboration between the Parties in a spirit of trust.

The Parties undertake to disseminate knowledge of the Agreement to their respective members and to recommend and actively promote its implementation by the members concerned. The Parties agree to jointly monitor the framework of the Agreement once a year.

Collaboration contributing to the development of precision medicine

Collaboration between Genomic Medicine Sweden (GMS) and the life science industry is important to enable the development and implementation of precision medicine in Sweden in accordance with the government's goals in the national life science strategy[4]. Joint development is valuable to the Parties from various perspectives such as basic research and increased knowledge of disease mechanisms, development of new diagnostics and treatments, and development of new products and services based on molecular genetic diagnostics.

Aims and objectives

The purpose of the Agreement is to facilitate collaboration and clarify the conditions for collaboration between the Parties and the Parties' members by providing guidance, together with other agreements for collaboration with the health care sector[1,2,3], on legal considerations, and to create conditions for collaboration of mutual benefits to the Parties and to enable the development of collaboration between the Parties in a spirit of trust.

The Parties wish to jointly contribute to the development of precision medicine for the benefit of patients by collaboratively developing, testing, and evaluating, for example, diagnostics, analyses, and treatments, as well as actively participating in other collaborative activities that advance the field and contribute to the development and implementation of precision medicine. The aim is to work together to strengthen national foundations for precision medicine by developing knowledge and expertise that will benefit patients in the form of individual-based and accurate diagnostics and treatments.

The trade industry associations

The four trade industry associations bring together companies in the life science sector that operate in or target the Swedish market. The industry associations have the ambition to strengthen Swedish life science in collaboration with healthcare providers, politicians, civil servants, and patient representatives.

GMS

GMS is a national initiative, in the form of a collaborative project, with the vision to strengthen and develop Swedish healthcare and enable research in precision medicine. The aim is to give patients

across Sweden equal access to accurate diagnostics and thus contributing to improved possibilities for implementation of a more personalized care, treatment and prevention.

GMS consists of 14 partners consisting of regions with university hospitals and universities with faculties of medicine:

- Partner regions: Region Västra Götaland, Region Skåne, Region Stockholm, Region Uppsala, Region Västerbotten, Region Örebro län and Region Östergötland.

- Partner universities: University of Gothenburg, Karolinska Institutet, Linköping University, Lund University, Umeå University, Uppsala University and Örebro University.

The relationship between the parties constituting GMS is governed by a main agreement. The activities of GMS cover the diagnostic and therapeutic areas of rare diseases, solid tumors, hematology, pediatric cancer, microbiology/infectious diseases, pharmacogenomics, and complex diseases. In addition, GMS activities cover the areas of ethics and legal aspects, health economics, informatics and data sharing, education, communication, and industry collaboration.

Forms of collaboration

Collaboration between the Parties shall be based on a jointly identified topic and be of mutual benefit to the Parties.

Collaboration shall be conducted in accordance with the applicable legislation and in such a way that the Parties maintain an independent position in relation to each other. The starting point is that all collaborations should be documented, open to scrutiny and add value by bringing benefits to the Parties. Examples of forms of collaboration covered by the agreement are:

- Knowledge sharing - e.g., meetings, seminars, workshops, conferences, symposia, networking events, webinars, panel discussions, roundtable discussions.

- Joint innovation- and development projects - refers for example to activities aimed at developing technologies, analytical platforms, or tools, such as algorithms; an innovation or development project may result in intellectual property rights.

- Joint pilot projects - refers to scalable innovation and development projects carried out related to a defined part of the GMS activities, e.g., a diagnostic area, or in a regional context.

- Joint research projects - refers to the implementation of ethically approved research projects in which two or more partners collaborate on a jointly defined hypothesis. Where collaborative research involves clinical trials and non-interventional studies, the agreement on clinical trials between the Swedish Association of Local Authorities and Regions (SKR) and the Swedish trade industry associations[3] must be considered. Research results must be published in open-access scientific journals.

Financial compensation

The Agreement does not involve any financial commitment between the Parties. Specific collaborative activities may involve financial commitments which shall be regulated in separate agreements. The Parties acknowledge that the universities and regions constituting the GMS are public entities whose purchases are regulated under the Public Procurement Act.

Collaboration implies an independent approach between the Parties and must not entail the risk of taking or giving a bribe. Examples and guidance can be found in the "Specification of Collaboration Situations"[5].

Agreement

Collaboration must be documented and, where necessary, regulated in agreements. Joint innovation-, development- and research projects may be governed by separate collaboration agreements.

Signing

This agreement has been signed by all parties

References

1. Agreement on clinical trials of pharmaceuticals and medical technology
2. Agreement on Collaboration Regulations
3. Överenskommelse om samverkan mellan SKR och industrins företrädare avseende kvalitetsregister (in Swedish)
4. Sweden's national life science strategy
5. Specification of Collaboration Situations