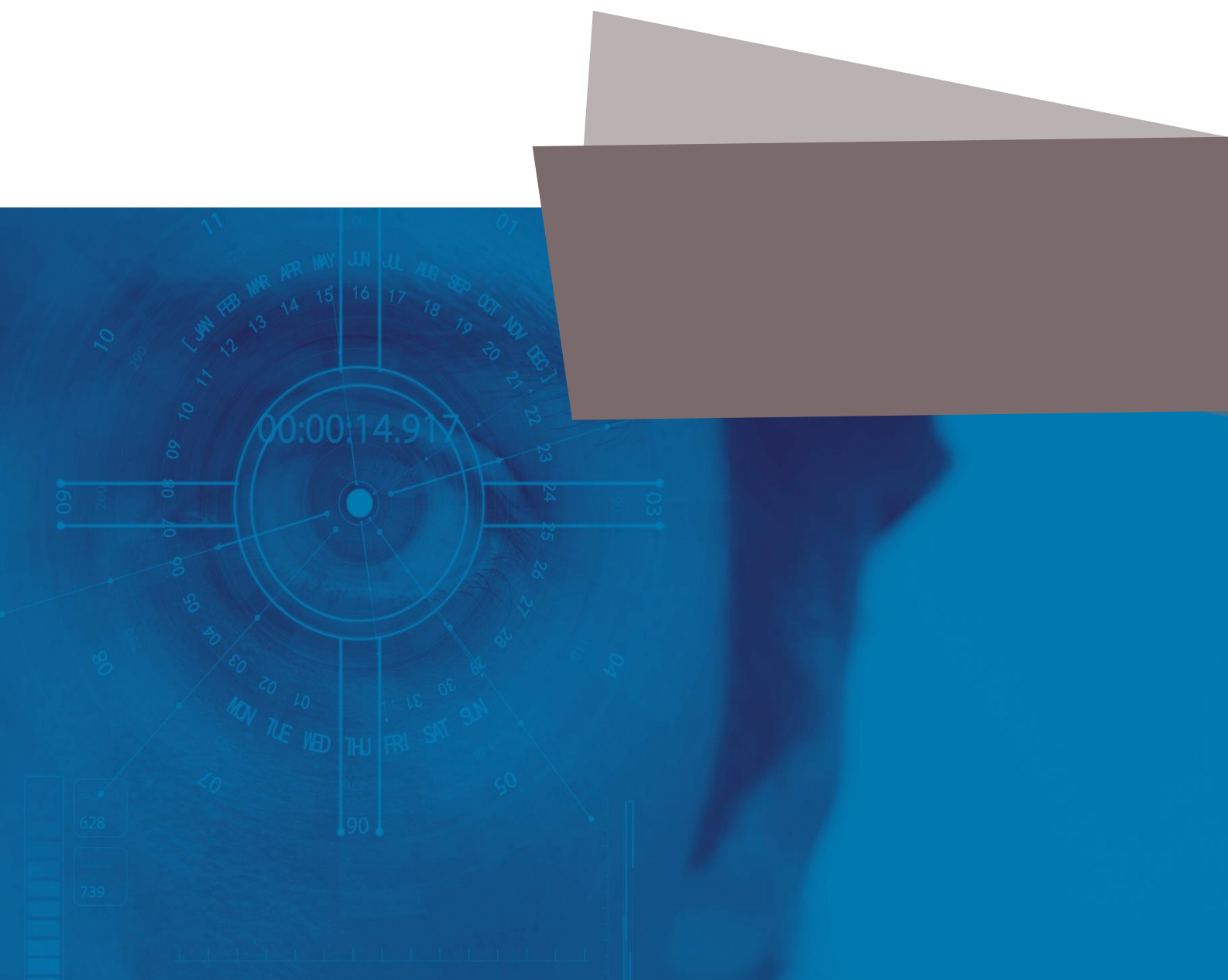




CAIDX TOOL #5

GUIDING PRINCIPLES FOR PUBLIC-PRIVATE COOPERATION

For clinicians and companies in the early stages of a cooperation project



Background

The Guiding Principles for Public-Private Cooperation is intended to support clinicians/researchers who are interested in learning more about important aspects to consider when writing a cooperation agreement with an external party, e.g. a private company.

The tool gives an overview of main topics that needs to be regulated in such a contract. It includes aspects to consider allowing a future procurement of the solution that has been co-developed.

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The need of a good contract

The most important barrier to public-private cooperation is the lack of or bad contracts. It is of great importance to write a contract with extreme clarity. Contracts should not be drafted in a way that they can become a problem in a procurement process later. Among other things, the contract needs to specify what is being bought, what is being delivered, and what is the final goal/result of the project. It is important, already at an early stage, to discuss the parties' main objectives. For a researcher, this could include the right to publish results. In AI projects, it is also important to reach an agreement regarding Intellectual Property Rights (IPR), such as data rights and copyright. If an agreement can't be reached regarding the parties' main objectives, there is no point in continuing the discussions with the company.

If a cooperation project is successful, it might be followed by a procurement. It is of utmost importance that the hospital plans and conducts the tendering process in a manner that does not disqualify the commercial partner from submitting tenders. It is of equal importance that the commercial partner's contractual advantage (if any), as a consequence of doing the cooperation project, is eliminated.

Rights

Before starting a cooperation with a private company, it is crucial to define who brings what to the table and who will own what when the project is finalized. All matters concerning IPR need to be specified in a contract. Such IPR can include patents, copyright, trade secrets, knowhow, and more. More specifically, how the project will deal with IPR created jointly during the project (foreground knowledge) and IPR created singlehandedly parallel with or before the project (background knowledge) needs to be covered.

Background knowledge

The standard way of dealing with background knowledge is that each party will keep their own IPR, i.e., the knowledge that they had coming into the cooperation project. For a cooperation project to be as fruitful as possible, it is crucial that the parties can use the other parties' background knowledge to the extent necessary for completing the project. It should also be specified that all parties should ensure that third parties, such as employees and consultants, will provide all relevant IPR available to the other parties free of charge.

Foreground knowledge

There are different alternatives to how a cooperation project will deal with foreground knowledge. There are two main ways to deal with this in contracts. Either through 1) "complete openness", or 2) "Partial openness". In alternative 1, the project will make all generated foreground knowledge available to the public on a current basis. This means that all parties accept that they cannot protect the rights of the project's foreground knowledge. In alternative 2, the project will work with complete openness about the project's results, except for foreground knowledge from the project that may be protected and the rights to do so should belong to the commercial partner. If alternative 2 is chosen, then it should be included in the contract that the public partner must be granted a free non-exclusive license to use the commercial partner's foreground knowledge if it is necessary to perform the cooperation project. Alternative 1 is often preferred from the perspective of a future procurement. However, it might be difficult to convince the companies to agree on this alternative as it presents a significant risk for them.

Fair practices

Transparency

The cooperation project must be well planned before it starts. All parties must have all the necessary information about the cooperation, and the parties must reach a mutual agreement through a signed contract. It should also be clear for outsiders what the project is about, each partner's contributions to the project (of course without jeopardizing the IPR of the company), and whether there is a potential conflict of interest.

Equal treatment

A cooperation project must be carried out in a way that makes sure that there is no favorizing in choosing a specific commercial partner for a cooperation project. The choice of commercial partner needs to be objective, and the criteria must have been decided before the process of choosing a partner begins. The goals of the cooperation need to be specified in great detail by the medical center. It is important to significantly narrow down the selection criteria to ensure that the right commercial partner is chosen. The solution that best fits the criteria will be the one selected for the cooperation project.

Sharing of results

The results of the cooperation project are to be shared, as initially defined in the cooperation agreement. In order to prepare for a future procurement, it is necessary to share enough information from the project to create a fair playing field for the companies. It is favorable if the results from the tests of the solution in a clinical environment can be published in a scientific journal; the right to do so needs to be regulated in the contract. Scientific publication is of course interesting for the company from a publicity perspective, but it is also a way to show that the cooperation project is beneficial also for the researchers.

Contributions to a cooperation project

From a cooperation perspective, the harder it is for external partners to get access to resources such as data, researcher hours, provision of facilities, potential transfer of background knowledge, etc., the more detailed this needs to be regulated in the cooperation agreement. (See "Equal treatment" above).

One thing that can become an issue at a later stage, when it comes to procurement of a co-developed solution, is the access to resources. If a company has been granted access to e.g., data, this has sometimes been seen by the procurement department as an “unfair advantage”, i.e., illegal state aid. This then led to the exclusion of that commercial partner from the future procurement process. There are two ways to deal with this situation; either by opening the access to data for companies under equal terms, or by specifying in a cooperation contract that even though the company is allowed access to data, this is part of a mutual beneficial cooperation project. The contract then needs to specify clearly what each partner contributes to the project, and also what each partner gets out of the cooperation project. If it is clearly stated in a contract that both parties contribute and gain equally from the cooperation, then it is no longer the case that the company has got an unfair advantage. Even without a financial transaction, it is still a transfer of value between the partners.

Example

The company contributes with IPR and expertise, and the researchers contribute with data access, research, and clinical knowledge. The company gets to keep their (now improved) IPR which has become more valuable through the validation in a clinical setting in the cooperation project. The hospital gets “right to free use” of the knowledge that has been created and the right to publish the results from the testing. Some Regions might want to include a market-based royalty in the contract.

From project to procurement

If the cooperation project has been conducted in a manner where foreground knowledge has been dealt with in “complete openness” and that the generated foreground knowledge has been regularly published (see alternative 1 above, in the section on “Foreground knowledge”), then this transparency ensures equal treatment of all companies. There is no unfair advantage, since all generated foreground knowledge is readily available to all companies that are interested in taking part in the procurement process.

If the cooperation project has been conducted in “partial openness”, then the hospital should be entitled to make the necessary foreground and background knowledge available to all potential tenderers to level the playing field. It is important to continuously collect and document the knowledge that is generated within the project. Projects in “partial openness” require that the hospital imposes an obligation on the potential tenderers to keep the knowledge confidential and only use it for writing their tender. Furthermore, the company should be obliged to grant a license to their foreground knowledge (on market conditions) as necessary for the tenderers. Otherwise, any procurement is meaningless as the company in the cooperation project will be the only possible tenderer.

The commercial partner in the cooperation project may not in any way seek to affect the wording of a tender specification or otherwise seek to impact the planning of a tender procedure, such as trying to influence selections of methods, materials, or standards.

For a concrete example of how to draft a collaboration agreement for public private cooperation, please read the [national standardized collaboration agreement from Denmark](#) (available in English).

CAIDX

– CLINICAL AI-BASED DIAGNOSTICS

About the project

The project CAIDX establishes cooperation between artificial intelligence (AI) providers and healthcare institutions to help healthcare professionals integrate AI, and thus improve diagnostics and treatment.

Implementation: January 2023 - December 2025

Project partners

- Innovationsklinikken (Aalborg Universitetshospital) (Lead partner)
- Wroclaw Technology Park
- BioCon Valley
- Tartu Biotechnology Park
- Lower Silesian Centre of Oncology, Pulmonology and Hematology
- Region Skåne
- Innovation Skåne
- Rostock University Medical Centre
- AUH Innovation, Aarhus Universitetshospital
- Danish Life Science Cluster
- The wellbeing services county of Southwest Finland
- Business Turku

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