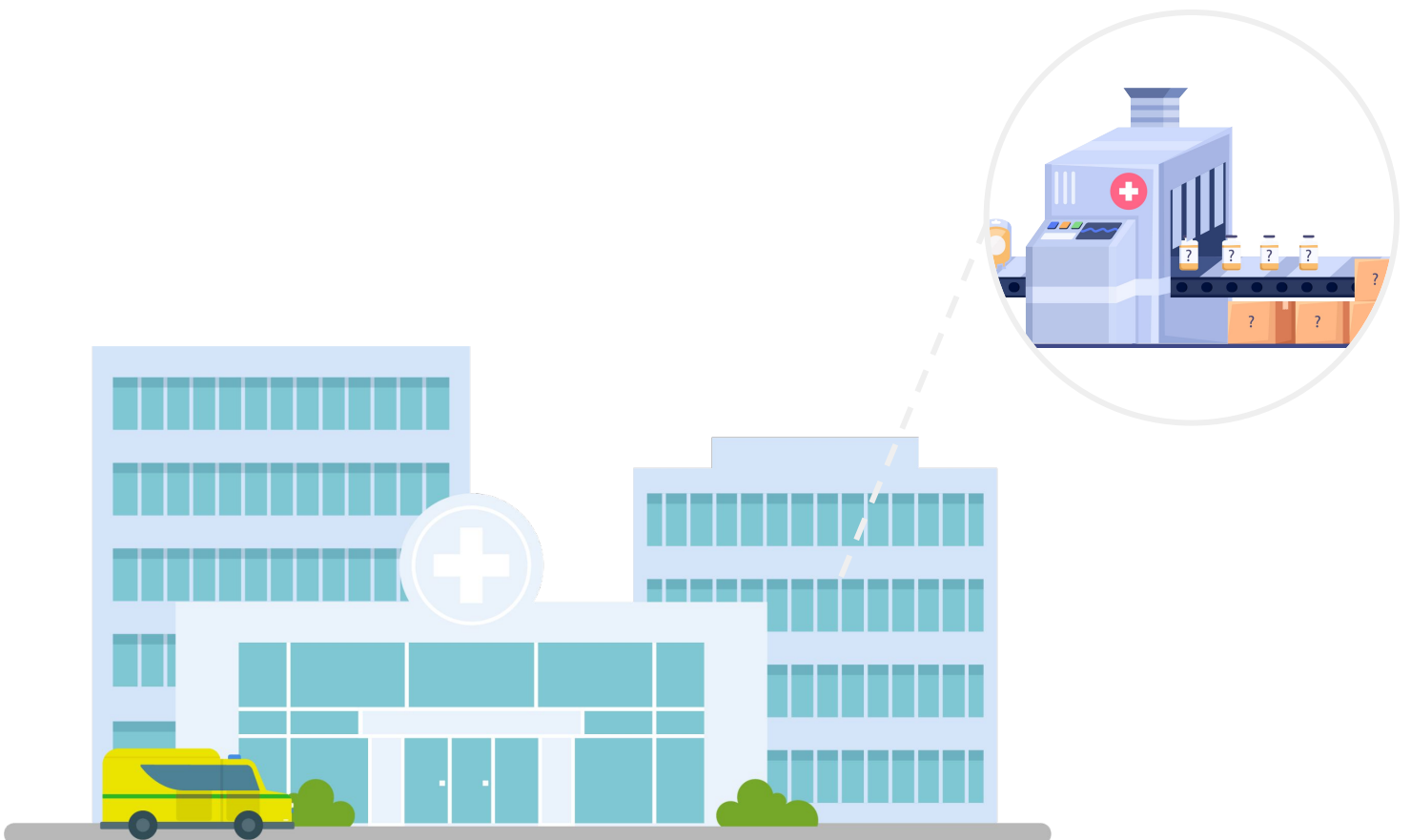


Invitation to dialogue conference by Helse Bergen August 23rd 2022



Helse Bergen invites to a dialogue conference with market stakeholders who wish to participate in the development of a system for drying blood plasma for use in the treatment of patients with life-threatening bleeding

Helse Bergen has up to 13,5 million NOK to develop an innovative solution to produce dried blood plasma for use in treatment of patients that suffers life-threatening bleeding.

We need to establish a more predictable and effective access to this vital product, which is crucial in many acute situations. In dialogue with the market we wish to collect input from the industry on potential solutions and interest around cooperation for the innovation - either with suppliers or through cooperation with several suppliers. The goal with this dialogue conference is to clarify whether potential suppliers understands our needs, and sees potential opportunities for solutions and eventual challenges in our project.

We will, through our dialogue conference, collect input from the industry to establish a basis for a future competition with description of needs, goals and functional requirements.

TARGET AUDIENCE: Potential suppliers of innovative solutions that can help solve challenges related to production of dried blood plasma. This includes developers of technology for blood plasma, manufacturers of packaging, developers of IT-solutions and designers.

BACKGROUND: National and international guidelines recommend early blood transfusion to patients with large bleedings. Early transfusion of blood plasma can help save lives.

As a result of long distances of transportation, challenging weather conditions with risk of closed airports and roads, Norway is in a special challenging position to secure access to health care for patients with life-threatening bleedings. To be able to follow medical recommendations, it is necessary to ensure access to lifesaving blood product at all levels of health care, including prehospital care.

In Norway blood plasma is stored frozen. Blood plasma, which is used in treatment of patients in Norway today, is imported and stored in the Blood Banks. The process of thawing blood plasma can take up to 45 minutes, dependent of which type of plasma thawer is used, and it has a limited due date after thawing. This makes it difficult to have reliable access to blood plasma outside hospitals.



Helse Bergen HF Haukeland University Hospital is Norway's second largest University Hospital, which employs around 13.500 people with a goal to give the best treatment possible to our patients.

We had around one million patient meetings in 2021. Haukeland University Hospital collaborate closely with the University of Bergen to secure a high-skilled and interdisciplinary research environment within medicine and health in the region, and infrastructure that enables research on a high international level.

Department of Immunology and Transfusion medicine (The Blood Bank in Bergen), is Norways second largest Blood Bank. It performs around 18.500 blood collections each year from around 10.000 blood donors.

CHALLENGE AND description of needs

To ensure fast and equal access to blood plasma for all bleeding patients, regardless of where in the country you live and the level of health care you receive treatment from, we need a product that can be used immediately and stored at room temperatures. By this it can be available early in the treatment chain. This can be achieved by using dried blood plasma. Dried plasma is an existing product on the market, but with significant limitations on the supply side.

Today, all dried blood plasma is imported from a large centralized production facility outside the Nordic region. The product is distributed nationally, regionally and locally to civil and military health service, ambulance helicopters and oil-related rescue services.

At intensive care units and in emergency rooms in Helse Bergen and other hospitals in Norway, dried blood plasma is deployed for use in situations where there is no time to wait for frozen blood plasma from the Blood Banks to be thawed. The main challenge with today's system is the high international demand for dried blood plasma. This has resulted in delivery problems of this product. Being dependent of import of such an important product for patient care makes us vulnerable. It poses risk of reduced ability to handle increased demand (major incidents such as terrorist attacks, natural disasters and war) or reduced access (such as pandemics). Norway has a sufficient number of blood donors to be self-sufficient in blood plasma, and the Blood Banks have the

infrastructure needed to carry out this work. In-house production of dried blood plasma is not challenging or resource-intensive in terms of time or personnel, but the technology required to produce dried blood plasma is lacking.

OBJECTIVE: To ensure access to and to become self-sufficient of dried blood plasma, Helse Bergen wants to establish technology for production of dried blood plasma in a blood bank.

The goal is to cover the demand and preparedness of dried blood plasma at all hospitals, in the municipal health service, ambulance service, military operations and rescue services.

The goal is achieved through, collaboration with commercial partners, developing a technological platform for local production of dried blood plasma that is tailor-made for Norwegian conditions and the Blood Bank-service.

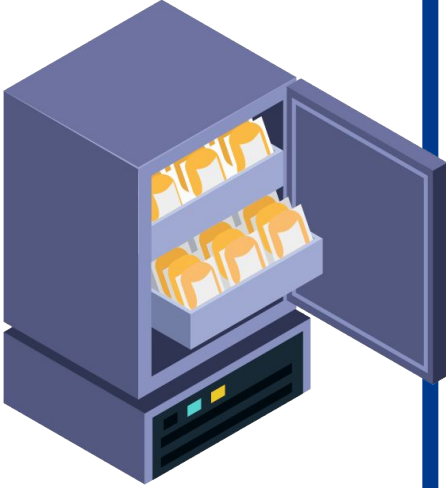


THE JOURNEY OF THE BLOOD

from blood donation to transfusion



Plasma is dried. Disposable equipment is used for production and storage of blood plasma

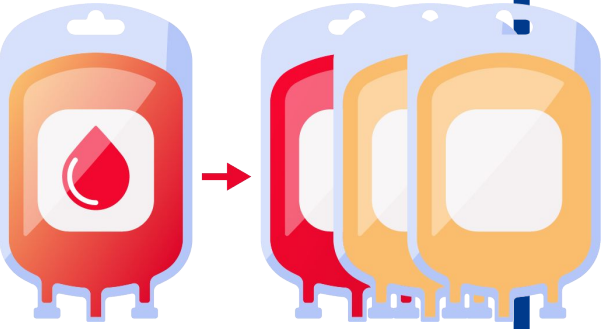


Preparation of product immediately before transfusion



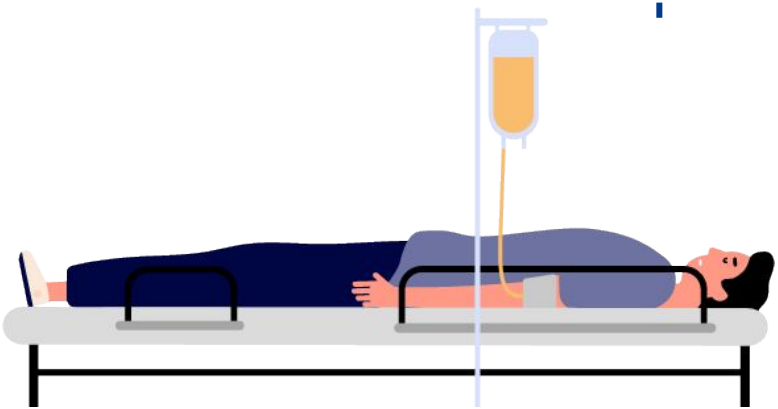
Transfusion and documentation

Blood donor gives blood at the Blood Bank



Blood is separated and blood plasma is temporarily stored in refrigerator or freezer

Dried blood plasma is stored at room temperature or in a refrigerator



SUMMARY NEEDS

From the Blood Bank

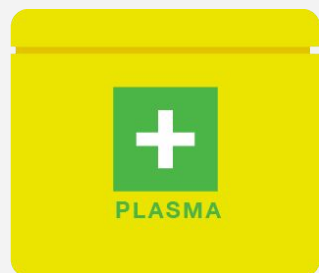
LOCAL PRODUCTION

The Blood Bank needs local production of dried blood plasma, because there is unstable access to the product today, as it is a high-demand product internationally, with limited availability.



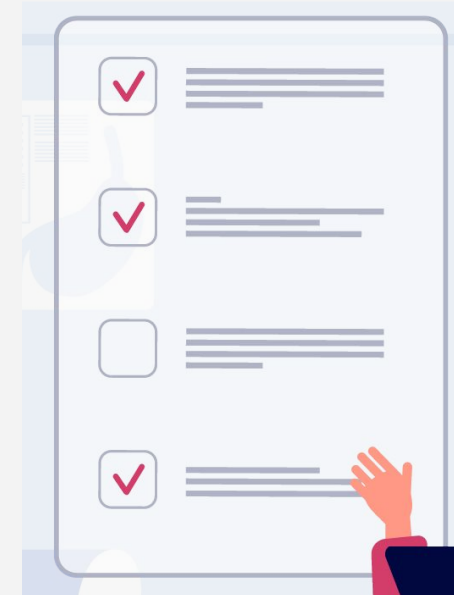
TECHNOLOGY

The Blood Bank needs technology that enables production of dried blood plasma at their premises. The technology should be scalable, so that production can be quickly increased when needed.



HUMANE USE

The final product of dried blood plasma must be approved for treatment of patients.

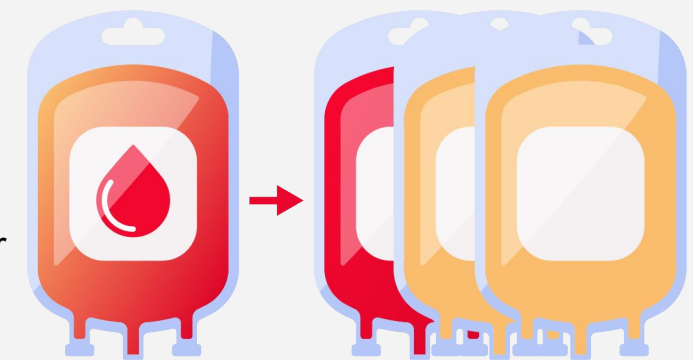


DOCUMENTATION AND REPORTING

The product must be clearly marked so there is no uncertainty about its use. This will also make it easier to document and report the transfusion. There are special requirements for traceability of blood products.

DISPOSABLE EQUIPMENT

The Blood Bank needs functional material and disposable equipment which can withstand harsh conditions. The packaging and disposable equipment must meet requirements for sterile closed systems, and can not contain substances that can cause allergic or toxic reactions.



SUMMARY NEEDS

From end users



SIMPLE

Many first aiders experience that they are “one hand short” in emergency situations. They need it to be quick and easy to start treatment. They depend on a safe and user-friendly product, where they do not need to worry about making mistakes, so they can start treatment quickly.

EMERGENCY PREPAREDNESS AT SEVERAL LOCATIONS

In Norway, we have many remote municipalities and towns, and Norwegian weather and geography can make it challenging to reach the patient both by ground and air ambulance in time. If one have dried blood plasma in readiness outside the hospitals, it can contribute to increase patient safety in situations where you otherwise do not reach them in time.



BREAKABLE SAFETY

Paramedics on missions may find themselves in situations where they have to move in difficult terrain. Therefore it is important that packaging and product are breakage-proof, so that the soldier can move freely without being afraid of damaging the equipment or deteriorating the quality.

EFFICIENT PREPARATION

When a person has life-threatening bleeding, it is essential to start transfusion as soon as possible. Survival can in such cases depend on minutes, and then it is critical that mixing of dried blood plasma does not take longer than necessary.



BRIEFLY ABOUT Innovation Partnership

Innovation Partnership is a form of competition introduced in Norway in 2017. This will make it easier for public and business sectors to collaborate on developing new technology and new solutions, where companies compete to create the best solutions. Innovation Norway wants to contribute so that the public sector can order and buy innovative solutions.

Innovation-partnership is a procurement procedure regulated in Part III of Public Procurement Regulations where the purpose is to develop new solutions to a specific need by facilitating product and service development, in a collaborative process between the Client and the Supplier. The Client announces the competition in the market and the procedure has the following characteristics in relation to other procedures in the regulations:

- The procedure shall only be used for procurement of goods and

services which as of today are not on the market.

- Innovation partnerships are entered through negotiation.
- Partnerships can be entered with one or more suppliers.
- The development work must be structured in phases with one or more sub-goals.
- After each phase the Client can, based on the sub-goals, terminate the innovation partnership
- The Client will, during the development process, pay remuneration to suppliers who

participate in the partnership.

- The innovation process is based on an unresolved need and will end in purchase and implementation of completely new products and solutions. The procurement procedure therefore combines the development phase and the subsequent purchase in one and the same call.

The purpose of the dialogue conference is to get ideas and input from the market on how the client can have the unresolved need covered through innovative solutions. This will enable the client to better prepare a tender basis. At the same time, suppliers and companies will receive information about the client's needs, so that they are better prepared to develop

new and better solutions. The market dialogue is published openly on www.Doffin.no as an indicative announcement, and consists of a dialogue conference with subsequent one-on-one meetings. All interested parties have the opportunity to sign up for the conference and / or one-on-one meetings. Participation in dialogue conferences and / or one-on-one meetings is not a prerequisite for being able to participate in an upcoming tender competition.

Helse Bergens goal for the project is a functional and robust solution. For suppliers who cannot deliver a complete solution, we encourage you to make contact with players who can make the delivery complete.



AGENDA DIALOGUE CONFERENCE

August 23rd, 2022

TIME: 12.00 - 15.30

PLACE: Eitri Medical Incubator

ADDRESS: Haukelandsbakken 31, 5009 Bergen

REGISTRATION DEADLINE: 19th of August 2022

Welcome and opening

Expectations from Helse Bergen

The Bloodbanks needs for dried blood plasma

Blood preparedness

BREAK

Our everyday life as a user of dried blood plasma

Brainstorming

Summary brainstorming

Summary and the next steps

For more information, see: <https://helse-bergen.no/blodplasma>

DICTIONARY

| | |
|----------------------------------|--|
| BLOOD PLASMA | The liquid part of our blood. Used for substitution of volume in bleeding patients. Contains coagulation factors and fibrinogen which are important for stopping bleeding. |
| DRIED BLOOD PLASMA | Blood plasma where the water is removed (dehydrated). Plasma powder is dissolved in sterile water just before use and used for the same indications as fresh frozen plasma. Dried plasma can be prepared for transfusion within a few minutes. It is stored at room temperature or in a refrigerator and the shelf life is long, at least for up to 15 months. |
| BLOOD TRANSFUSION | Blood transfusion is given to patients who are bleeding or lacking blood components such as red blood cells, platelets or blood plasma. |
| LIFE-THREATENING BLEEDING | Bleeding that is so severe that patients go into bleeding shock. The causes of severe bleeding can be many, such as accidents or injuries, extensive surgery, medical conditions or childbirth. |

WHAT HAPPENS AFTER the dialogue conference

During 2022-2023, a competition will be held to enter into one or more innovation partnerships, which aim to develop technology for drying blood plasma. See estimated timeline below for a more detailed plan.

Helse Bergen aims to announce an invitation to register interest in participating in the competition for innovation partnerships in the autumn of 2022.

REGISTRATION

For more information and registration:

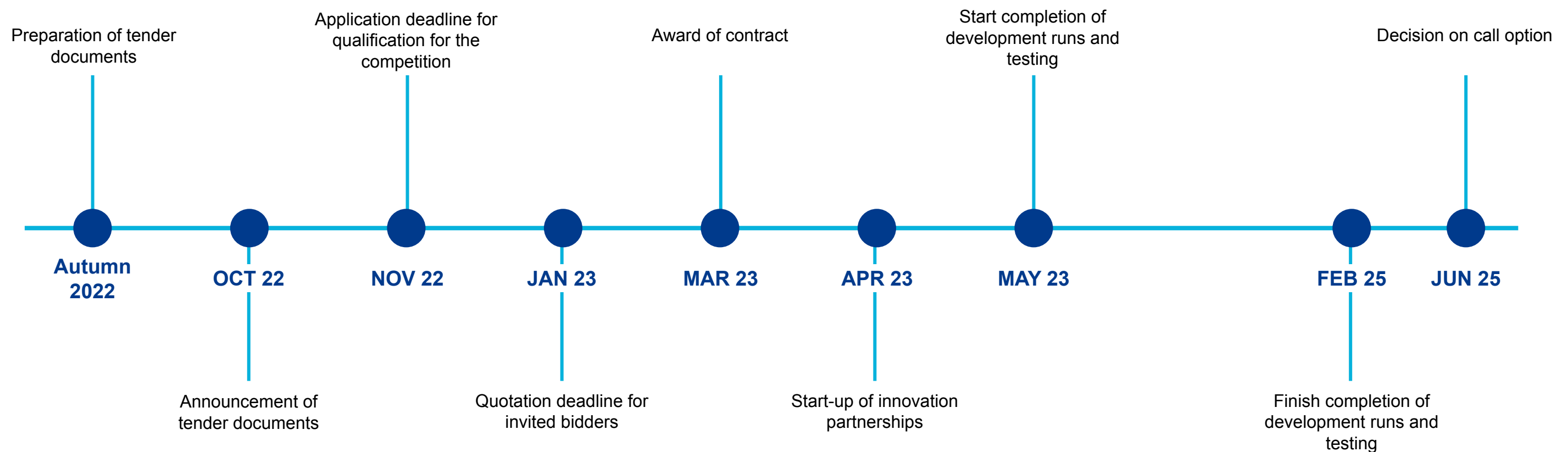
<https://helse-bergen.no/blodplasma>

To get directly to the registration form,:

<https://forms.gle/tYgHxNa9LJxcZAuf9>



ESTIMATED TIMELINE



Read more at our website:

<https://helse-bergen.no/blodplasma>

Sign up here:

<https://forms.gle/tYgHxNa9LJxcZAuf9>



**Innovative
anskaffelser**