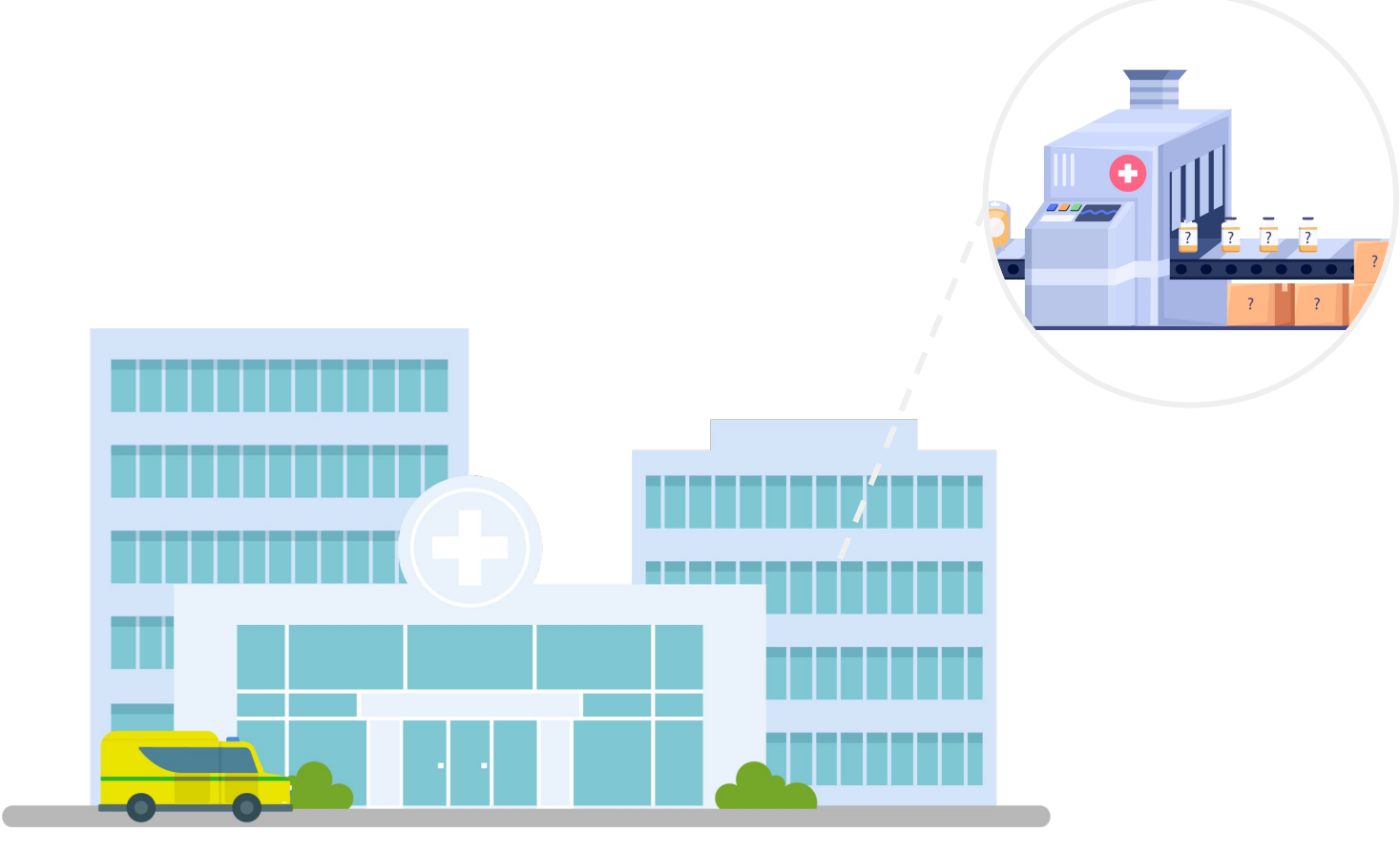
HELSE BERGEN
Haukeland University Hospital

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 will present our needs for establishing a more predictable and effective access to this vital product, which is crucial in many acute situations. In the continuation 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: 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 equal access to health care for patients with life-threatening bleedings. To be able to fulfill medical recommendations planning access to lifesaving blood product in all steps of the treatment chain, including situations outside hospitals.

In Norway blood plasma is stored frozen and has a limited due date after defrosting. Blood plasma, which is used in treatment of patients in Norway today, is imported and stored in Bloodbanks. The process of defrosting blood plasma can take up to 45 minutes, dependent of which type of plasmatine is used, and has a limited due date after defrosting. This process 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 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 (Bloodbank in Bergen), is Norways second largest Bloodbank. It performs around 18.500 blood draws each year from around 10.000 blood givers.

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, one must have a product that can be used immediately and stored at normal surrounding temperatures so it can be available early in the treatment chain. This challenge can be solved by using dried blood plasma. This is an existing product on the market, but with significant limitations on the supply side.

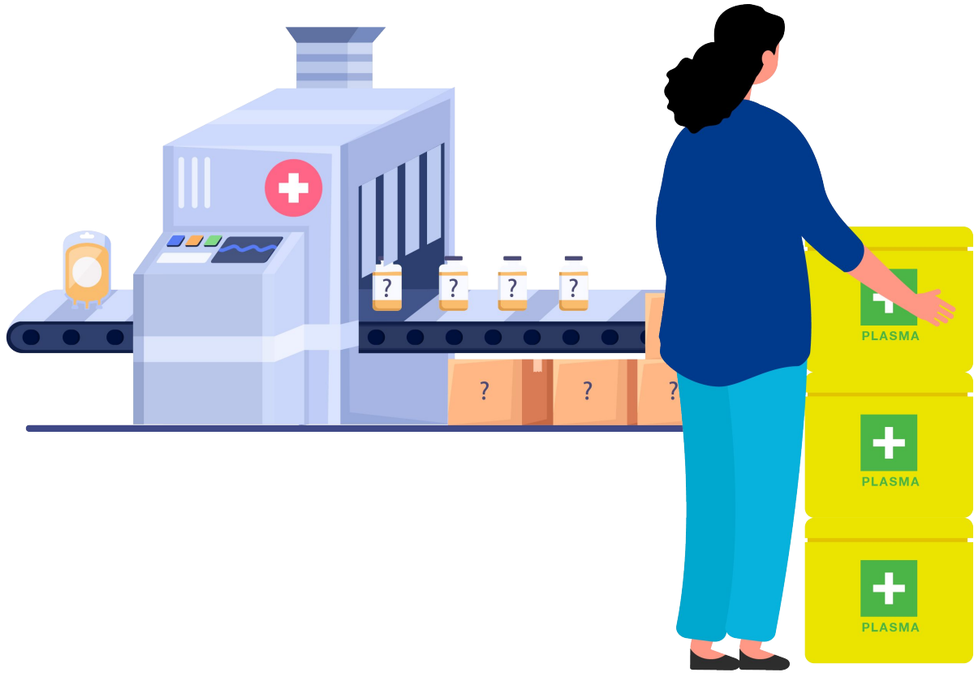
Today, all dried blood plasma is imported from a large centralized production facility outside the Nordic region. The product is nationally, regionally and locally distributed to civil and military health service, ambulance helicopters and oil-related rescue services.

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 blod plasma from Bloodbanks to defrost. The main challenge with today's system is a high international demand for dried blood plasma. This has resulted in several episodes of delivery problems of this product. Being dependent of import of such an important product for patient care makes us vulnerable. It poses a risk to have lack of preparedness 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 area-wise 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.

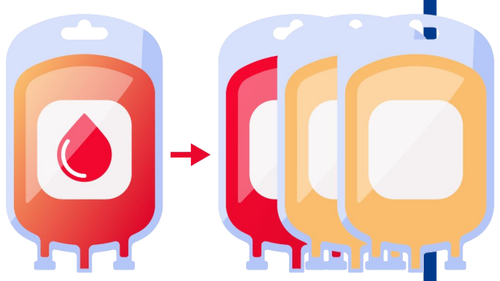
The goal is achieved through, collaboration with commercial partners, developing a technological platform for local production of dried blood plasma that is tailor-made for Norwegian conditions and the Bloodbank-service.



THE JOURNEY OF THE BLOOD

from blood donation to transfusion

Blood donor gives blood at the Bloodbank



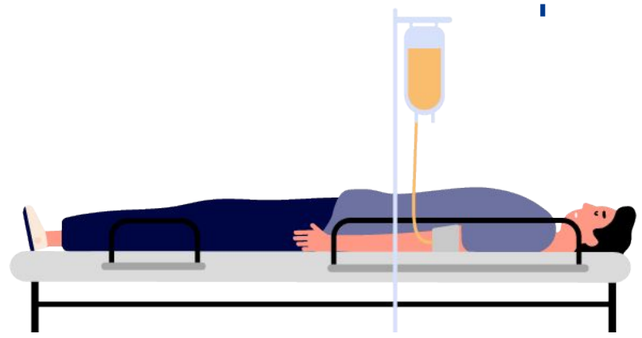
Blood is separated and blood plasma is temporarily stored in refrigerator or freezer

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

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

Preparation of product next to the patient

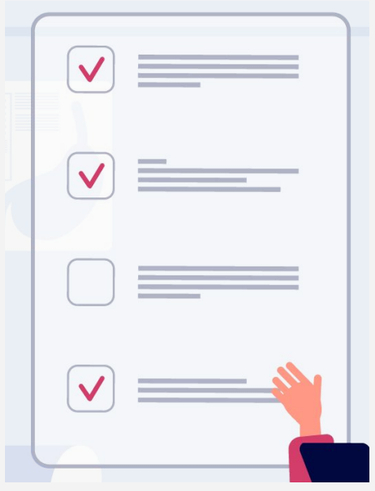
Transfusion and documentation



SUMMARY NEEDS
From Bloodbank

LOCAL PRODUCTION

The Bloodbank 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.

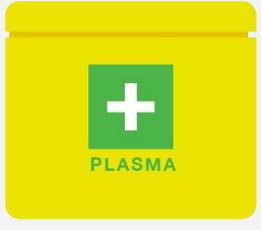


DOCUMENTATION AND REPORTING

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.

TECHNOLOGY

The Bloodbank needs technology that enables production of dried blood plasma at the blood banks premises. The technology should be scalable, so that production can be quickly increased when needed.

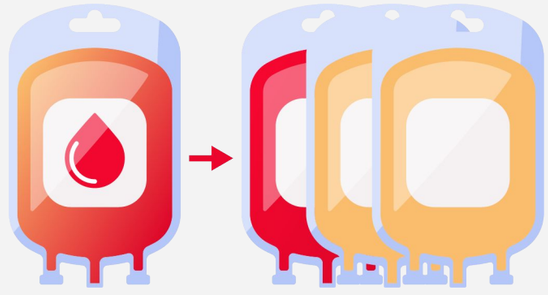


HUMANE USE

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

DISPOSABLE EQUIPMENT

The Bloodbank 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 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 terrain 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 MIXING

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 that was introduced 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 no one has seen before.

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 can Client, 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 cover the unresolved need through innovative solutions. This will enable the client to better prepare a tender basis. At the same time, suppliers and companies receive information about the client's needs, so that they are better prepared to deliver offers, and possibly 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

Subject: 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 fluid part of our blood. 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 frozen blood plasma. The blood plasma can be prepared for transfusion within a few minutes. Dried blood plasma is stored at room temperature or in a refrigerator and the shelf life is long, at least for up to 15 months (FFP).
BLOOD TRANSFUSION	Blood transfusion. 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 cause 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

HELSE BERGEN
Haukeland universitetssjukehus

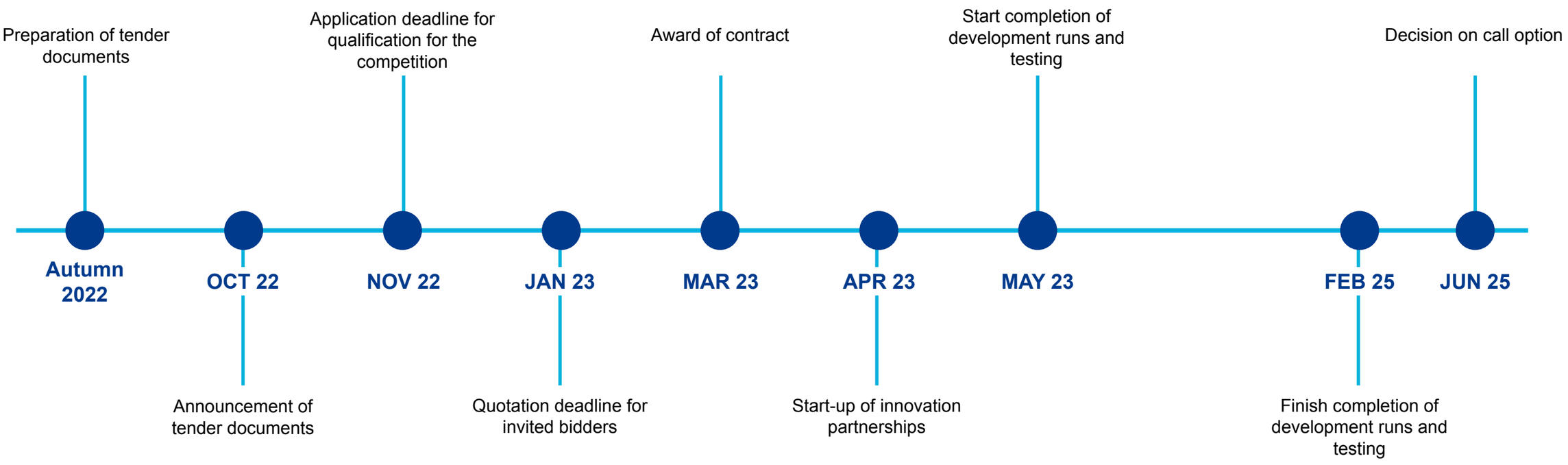
SYKEHUSINNKJØP

Blodbanken
Haukeland universitetssjukehus

Innovasjon Norge

Innovative anskaffelser

ESTIMATED TIMELINE



Read more at our website:

https://helse-bergen.no/blodplasma

Sign up here:

https://forms.gle/tYgHxNa9LJxcZAuf9

HELSE BERGEN
Haukeland universitetssjukehus

SYKEHUSINNKJØP

Blodbanken
Haukeland universitetssjukehus

Innovasjon Norge

Innovative anskaffelser