Minutes from the Dialogue Conference
Helse Bergen Dried Plasma Innovation Partnership Project

Tuesday 23.8.2022 at 12:00-15:30
Eitri

Appendix 1: PowerPoint presentation used at the conference
Appendix 2: Summary of the group work

Agenda:

Welcome and opening words: Clinic director and steering group leader Gunnar Mellgren
The challenges and description of needs: Project manager Torunn Apelseth
What is an Innovation Partnership and what does it entail: Stig Bang-Andersen
Blood preparedness: Geir Strandenes
Break with refreshments
Our everyday life as a user of dried blood plasma: Christopher Bjerkvig
Group work: PwC
Summary from group work: PwC
Process and the way forward: Hilde Christin Eiken
Finishing words: Project manager Torunn Apelseth
Tour of the blood bank (voluntary): Project managerTorunn Apelseth

Welcome and opening words: Clinic director and steering group leader Gunnar Mellgren

The clinic director and steering group leader welcomed the participants to the dialogue conference on dried blood plasma. The participants were briefed on the background to the project. In Norway, long transport distances and weather-related challenges put us in a special position when it comes to ensuring equal access to blood transfusion. Dried blood plasma is a wished-for product and in short supply in the world. Early transfusion of blood plasma saves lives for patients with major bleeding.

The clinic director and steering group leader informed that Helse Bergen has received 15 million NOK for the project, and that the suppliers will be allocated 13.5 million NOK for the development. This gives us the opportunity to perform an innovation process together and to provide sustainable solutions. The dialogue conference will ensure that the market can provide input to Helse Bergen, which will further be used in the preparation of competition documents.

The challenges and description of needs: Project manager Torunn Apelseth

The project manager presented the challenge situation and the descriptions of needs from Helse Bergen, which is also available at www.helse-bergen.no/blodplasma. The project manager clarified that the need and the challenge are not unique to the Nordic region, but are international need. A product adapted to this need will have a large market potential. Furthermore, it was informed that with which method the drying process is to be done is completely open. The same applies to solutions for packaging and mixing/preparing of the dried blood plasma.

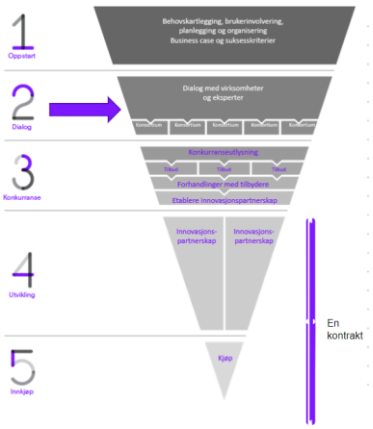
What is an Innovation Partnership and what does it entail: Stig Bang-Andersen

The innovation adviser from the Norwegian Supplier Development Program (Leverandørutviklingsprogrammet, further referred to as LUP), presented the opportunities available to suppliers and what it means to enter into an innovation partnership.

Helse Bergen has mapped the challenge situation and the needs with support from service designers and users, and now wants to get input for the competitive basis.

LUP clarified that Helse Bergen wants new solutions and they want to collaborate. Suppliers can collaborate with other suppliers on solutions that they do not have themselves or lack further down the value chain.

The purpose of the dialogue conference is for suppliers to have the opportunity to provide input early in the process.



Furthermore, it was clarified that the suppliers compete for the development process itself, but there is no competition for the final product. This is a process. LUP referred to phase 2 in the area and where the dialogue conference provides further input.

LUP informed that what is said during the dialogue conference is shared with everyone, but the one-to-one meetings are not shared further. Helse Bergen ensures equal treatment and that business secrets are safeguarded.

Questions that come after the dialogue conference will also be shared with everyone. A non-disclosure agreement can be drawn up if this is desired. Written input and information from one-to-one meetings are not shared with everyone.

LUP referred to the webinar on innovation partnerships for those who want more information.

Blood preparedness: Geir Strandenes

The blood preparedness plan from 1965 was presented. It was referred to that during the Second World War over 10 million units of dried plasma were produced.
It is important to have a scalable system.

Reference was made to several regulations and legislation that apply to the provision of blood and blood products. Plasma alone is not the whole solution, but it is the "bridge to blood".

Norway should be self-sufficient throughout the entire value chain - this also applies to equipment and disposable equipment.

Our everyday life as a user of dried blood plasma: Christopher Bjerkvig

The participants were presented with the air ambulance service and where in the country they have access to dried blood plasma. Furthermore, it was presented that plasma can have several uses, for example for burn victims, patients with severe infection or who are in septic shock.

It was demonstrated in front of the participants how to mix the components from dried blood plasma until it is ready for use on patients.

Summary: PwC

Group work was carried out in three groups. There was a review of the tasks and a joint presentation from the groups. During the summary, it was specified the importance of a good collaboration agreement and that it is followed up on time. It is important to conduct meetings with follow-up on action points to maintain continuity during the development process.

Group 3:
The group summarized that the biggest challenge will be the regulations and the legal part. It is important to connect with the professional environment. The market needs to better understand this with patents and where the challenges are. Help from the users are important.
The group said that they had received many good answers in the meeting, and that it will be important to understand how blood plasma is made today.

Helse Bergen commented that the legal and regulatory framework will be clarified in collaboration with relevant external resources such as DFØ, the Directorate of Health and the Norwegian Medicines Agency.

Group 4:
The group summarized that the understanding of the product with good descriptions of needs was a very good and clear. The group wants more information about the framework and regulatory guidance, as this appears unclear to the market. The group also lacks information about the time line. Questions was asked to Helse Bergen if this must be produced in Norway and how this should be scaled?

The group also provides input that during the competition process and the preparation of competition documents there must be clear guidelines, but at the same time, that there is openness and room for creativity in the way the competitive basis is prepared.
Group 4 also pointed out that there was a lack of an overview of the rules.
What can become a challenge in the implementation is understanding of roles and responsibilities, time, access to those who are in charge of the need today, scope creep, and teams that lack expertise in packaging.
It was made clear from LUP that we, through market dialogue, can facilitate formation of consortiums, but Helse Bergen will not be able to match suppliers. LUP gave the advice that matchmaking can be done within the clusters and this must be done without Helse Bergen.

Group 5:
The group pointed out that the presentations were good and clear with good examples of the need.

It was given input from the group that it is important to know the size of the area intended used for the technology, how much space can be expected to fit this instrument, and how large a facility we must plan for.
Questions were asked to whether the ownership rests with Helse Bergen or whether ownership is shared.

Further input to the project: This must be interdisciplinary, IT, logistics, technology, medicine, there must be transparency between the suppliers throughout the process.
Knowledge of the current process of how blood is stored today.
The process of documentation. Existing IT systems use may be difficult to integrate into the production line.
It is a big challenge to have a sterile production and it comes with a fairly significant price tag, need to know requirements.
Questions about what happens to funding if the money runs out.
The group also asked whether there will be enough blood that can be used during development and to make the product itself.

Process and the way forward: Hilde Christin Eiken

Helse Bergen gave thanks for good input during the dialogue conference and explained the next steps.

Sykehusinnkjøp (Norwegian Hospital Procurement) went through the process for an innovative procurement and informed that the process is quite similar to competition with negotiation, but with some important differences, including

- Competition cannot be awarded without negotiation
- Requirements for the supplier's qualifications in research and/or development
- Development and purchase in the same contract
- Payment of innovation funds during the development phase

Helse Bergen can enter into a contract with one or more suppliers. This is assessed when the offers are received.

Helse Bergen will now work its way up to the competition phase.

It was clarified that the competition does not want to exclude smaller or new suppliers who have good ideas, by finding a suitable list for the qualification requirements that also takes entrepreneurial companies into account.
A payment plan will be created through the phases set for the development course of 1.5 years. The market can provide input on what is the most appropriate payout plan ahead of the competition.

It was pointed out that the project can be contacted via Helse Bergen's website or via Doffin.

Finishing words: Project manager Torunn Apelseth
The project manager thanked the market for participation and good input.
Suppliers were welcomed to one-on-one meetings

QUESTIONS AND ANSWERS:

Question: Is Helse Bergen looking for a supplier who will develop the technology?
Answer from the project manager: Yes. We want to have this technology developed so that we can buy it and produce dried blood plasma at our Blood Bank. Helse Bergen will be active participants in the development and testing of technology and the dried blood plasma.

Question: What is an appropriate production volume?
Answer from the project owner: Today, Helse Bergen disposes of units of 200 ml. It may be appropriate to have a larger volume on the units since this product is used to treat patients with bleeding who need a lot of blood products. Approximately 5,000 units of plasma are transfused per year at Helse Bergen, which corresponds to a volume of approximately 1,000 litres. As of today, we use somewhere between 10-20 liters a week. It is desirable that Helse Bergen can produce and distribute somewhere between 10-20 liters a week. But it depends on which market solution we end up with in the end. If we are to produce for several institutions, there may potentially be a need for more.

Question: Can other solutions be used that are easier than the current solution?
Answer: The easiest would be a product that looked like an ice pack, or similar. At the scene of an accident, you have little time and few hands. It is a wish from the end users at the air ambulance that the solution is simple to prepare before transfusion and that it takes little time. It takes approximately 9-15 minutes to prepare the current dried blood plasma for use. Air ambulances have an average time of 9 minutes at the scene of the accident - i.e. from the time they land until they are in the air again. Often they start mixing dried blood plasma on the way to the scene of injury to be ready by the time they arrive. But the reality does not always agree with what is described from the emergency central, and they do not know whether they need the product until they have seen the patient.

Question: Is there a system for tracking dried plasma?
Answer: It is a regulatory requirement that we must be able to trace all blood products from the blood donor to the patient. This also applies to the dried blood plasma that we will produce with the technology we want to develop.

Question: Can a bag of blood plasma contain plasma from several blood donors?
Answer: There is a limit to how many donors can be in the same mixture for the product to be defined as a blood product. But it can be beneficial to mix from some. We do not have this as an requirement.

Questions: Do the users have other requirements in relation to features or something they miss?
Answer: Basically, the product is too cumbersome as it is today. It takes too long to dissolve and the packaging could be smaller. The volume per unit is too small for the patient population in the air ambulance.
Follow-up question: Is there a number for how much blood a patient normally receives?
Answer: With caution, it is estimated that the sickest patients receive around 8-9 units of whole blood - this corresponds to 4 liters of blood products in 24 hours. But if you start treatment with blood products early, you usually need less blood.

Question: Is it allowed to add something to the bottle to make it dissolve faster?
Answer: It may be possible, but this might lead to a classification as a drug. If so, the threshold for getting it approved becomes significantly higher. This can be explored during the development process.