LIFE10 ENV/SE/037

Final Report
Covering the project activities from 01/09/2011 to 30/06/2017

Reporting Date
31/10/2017

LIFE+ PROJECT NAME or Acronym
PVCfreeBloodBag

Project Data

Project location	Sweden, Finland, Denmark, Poland, Italy
Project start date:	01/09/2011
Project end date:	30/06/2017 **Extension date:** n/a
Total Project duration	70 months
Total budget	€ 2,204,464
Total eligible budget	€ 2,204,464
EU contribution:	€ 1,091,040
(%) of total costs	49.49
(%) of eligible costs	49.49

Beneficiary Data

Name Beneficiary	Jegrelius Institute for Applied Green Chemistry/ Region Jämtland Härjedalen
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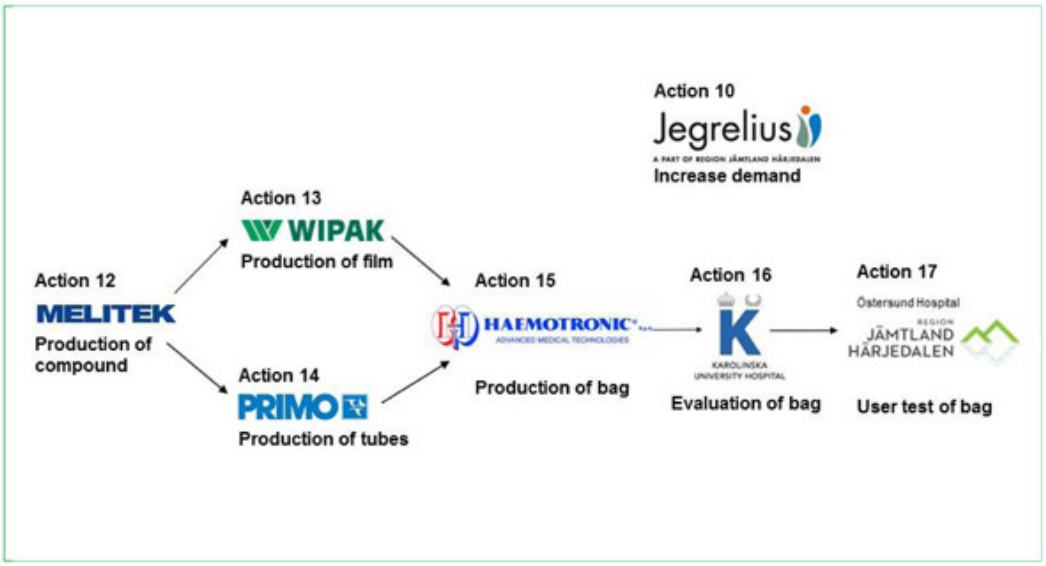
1. List of contents

2. Executive Summary

The first project objective, as stated in the Grant Agreement, is to demonstrate that public healthcare organisations and private plastic manufacturers can cooperate in removing barriers to a PVC-free blood bag.
The second objective is a fall-back alternative in case the bags becomes too expensive for general use. The bags will then be proposed for vulnerable patient groups as premature babies and people with chronic diseases. The third objective is to offer a material that can be used to replace PVC in other medical applications. A fourth objective is to offer the new material for food industry applications.

The project has demonstrated that is possible to produce a PVC-free set of four bags, with the ability to store red blood cells. The bags have fulfilled our requirement specifications[1], including gap analysis for CE marking which was made by the notified body ItalCert[2]. We have together with organisations, such as the NGO Health Care Without Harm, UNDP, Life-SUBSPORT, Life-Edesia, Life-ChildProtect, increased awareness and demand for a safer blood bag.
Further improvements and evaluations are necessary before market introduction, but the increased awareness and demand will facilitate the next step for suppliers who want to be at the forefront. We have removed the barriers to introducing PVC-free blood bags on the market. The economic analysis[3] performed suggests that, with co-ordinated and motivated set of buyers, the prototype developed in the project is economically viable and attractive to those companies participating in the project. Furthermore, *if* a clear demand is demonstrated, the global healthcare companies that dominate the PVC blood bag market could similarly produce a non-PVC blood bag at a price almost identical to that of today's PVC bags.

Four companies representing the links in the supply chain have produced the new bag and Karolinska University Hospital has evaluated the bags ability to store red blood cells. Region Jämtland Härjedalen was responsible for the user tests, for increasing demand and is the Coordinating beneficiary.



[1] Appendix 1 in Prestudy ISBN 978-91-977681-2-2, Listed as publication at www.pvcfreebloodbag.eu
[2] Annex 7.2.9
[3] Economic feasibility study Annex 7.2.10

Melitek in Denmark produced the compound for both film and tubings. The compound is sent to Wipak in Finland and to Primo Profile in Poland. Wipak produced the film and Primo Profile in Poland produced the tubings.
Both Wipak and Primo then sent the material to Haemotronic in Italy. Haemotronic produced different prototypes of a blood bag. In order to do the in-vitro tests a set of three bags was needed, as well as a filter and needle. A PVC-free filter and a needle have been provided by an external source. The set of bags was re-designed for the user tests to include a fourth bag.

The evaluation by Karolinska University Hospital was an in-vitro study in which two different storage solutions were used. The evaluation showed promising result and is published in the International Journal of Transfusion Medicine, Vox Sanguinius. In the user tests, for which Region Jämtland Härjedalen was responsible, we simulated the handling of the bags using water that was colored green, making it easier to detect any leakage. Four hospitals in Sweden performed tests: Östersund, Trollhättan, Jönköping and Uppsala.
As well as the storage tests and the user tests, a pre-audit for CE marking, life cycle assessments and an economic feasibility study have been performed.

The two life cycle assessments were procured and performed by external consultants.
The first[4] LCA in 2012 highlighted the benefits of a fictive polyolefin bag compared to a bag made of PVC and DEHP. This led to a new scientific opinion "On the safety of medical devices containing DEHP (di (2-ethylhexyl) phthalate) plasticized PVC on groups possibly at risk" requested by The Scientific Committee on Emerging and Newly Identified Health Risks. Hans Gulliksson from Karolinska was as a member of the expert committee.

The second life cycle assessment was based on data from the beneficiaries, which mean as close as possible a real product. In order to compare the new bags with the existing bags - regarding impact on the environment and health, an external company, Miljögiraff, made a LCA. We selected PVC/DEHP based bags for comparison, since they are the most common bags on the market.

This LCA is published on the project website[5] along with a critical review of the LCA.
It shows that it is possible to decrease the toxicity risks for human health by changing for a PVC-free alterative, without the increase of other risks to environment or human health
Also, there are potentials for improvements to lower the global warming impact. Since the use of fossil resources dominates in both cases, it is recommended that effort should be taken increase the fossil free share and to use recycled material if possible. Also, alternative to incineration could be considered.

Blood bags are medical devices, which means that they are subject to special legislation, the EU Directive for Medical devices. To verify the quality of the bags we commissioned a notified body for a CE marking pre-audit. Action 15.
Alice Ravizza, who represented Haemotronic, created a technical file for the notified body Italcert which performed the pre-audit. A technical file bases on data from all beneficiaries.
The pre-audit gave us a gap analysis for CE marking, showing the status of the product and what remains to be done: scaling up production and validating the sterilization cycle for commercial lots. Annex 7.2.9

[4] Link to LCA report 1, 2012
[5] Link to LCA report 2, 2017

To facilitate market introduction of the new bag an increased demand is necessary. This has been achieved through cooperation and dissemination of information within European healthcare. We have worked with healthcare, other projects, decision-makers, and organisations to increase awareness and demand. Meetings, seminars, webinars, a YouTube clip, hand-outs and newsletters have been used to communicate and all this information is easily accessible via the project's website.

The cooperation with Health Care Without Harm along with result from the pre-study has led to an evident example of an increased demand. In plenary session 22 October 2013 the European Parliament voted favourably for the European Commission's proposal on Medical devices that stipulates a ban of hazardous chemicals in medical devices.

In April 2017 the European Commission announced that there will be new rules on medical devices to enhance safety and modernise public health.

"The new Regulations on medical and in-vitro diagnostic medical devices proposed by the Commission in 2012 will help to ensure that all medical devices - from heart valves to sticking plasters to artificial hips – are safe and perform well. To address this, the new rules will improve market surveillance and traceability as well as make sure that all medical and in vitro diagnostic devices are designed to reflect the latest scientific and technological state-of-the art. The rules will also provide more transparency and legal certainty for producers, manufacturers and importers and help to strengthen international competitiveness and innovation in this strategic sector. "

The implementation of the new rules will influence the market introduction of a new blood bag and thus it is very important how they will be formulated.

Problems encountered in the project have merely been caused by changes in organisation and of administrative art. However, since the actions regarding production and evaluation are highly interdependent, the organisation and administration obstacles caused delays effecting the production and evaluation of the prototype bag.

The project's objectives have been intact during the project time, but the project have been prolonged twice to fulfil them, 15 months prolongation in total.

Production and evaluation of five prototypes were planned for, but a shortcut was taken by evaluating fewer prototypes than planned for. Further improvements of the bags quality and further evaluations of the blood bag was needed to secure high enough standard.

The project has demonstrated that it is possible to produce a completely PVC-free set of four bags.
We also have

- a promising in vitro study[6] of the bags ability to store red blood cells
- revealed by user tests that improvements still are required, but the potential problems identified in the pre-study were solved.
- a life cycle assessment, indicating that PVC-free is better than PVC, regarding impact on health, and that there are ways to lower the impact on environment
- a gap analysis for CE-marking that shows what is left to do.[7]

[6] Read more in section 5.1.5 and Annex 7.2.8
[7] Read more in section 5.5.4 and Annex 7.2.9

- increased awareness and demand; The project has together with HCWH among others, worked for a stronger legislation regarding medical devices. The projects objectives are being shared by many; with interest from for example EBA and UNEP.
- an Economic Feasibility Study that evaluates the economic viability of bringing a PVC-free blood bag to market. The study assess the investments required and the manufacturing costs.

What is left before market introduction? A more thorough description is found in section 5.2.9 and the After-Life Communication plan Annex 7.3.28, but in short we need

- Quality improvements of the bag
- Evaluation of new storage solutions
- Further evaluations of the bags properties and ability to store red blood cell
- Scale up of production
- Validation for sterilisation cycle for commercial lots
- CE-marking

And the implementation of the new directive could also facilitate market introduction by steering towards plastics without plasticizers.

We need a higher demand. Without the buyers a market introduction would be very slow. One way is to strengthen legislation as mentioned above. Another way is to collaborate and stand behind the same requirements specifications.

Since it is a life-saving product and a complex product, the quality of the bag is essential. We know that further improvements are needed and thus we need the supply side.

We have investigated different opportunities to speed up market introduction. The two main pathways are either from the demand side or the supply side, but we suggest that supply and demand work together. That is what made this project work.

One dream scenario involves

- Healthcare providers for raising demand
- Karolinska University Hospital for evaluation
- A supplier of new storage solutions/ additive solutions
- Haemotronic for technology transfer and scale up
- A committed blood bag producing company
- A stronger regulation (Read more in section 5.2.7)
- An independent criteria document that organisations with different national regulations could stand behind.

Deliveries	Action	Delivered
Project website	2	21/10/2011
Notice Boards	3	18/11/2011
A plan for the implementation phase		
Monitoring protocol	5	27/03/2012
Initial Report	1	21/03/2012
LCA of PVC blood bag	6	23/03/2012
Presentation of the LCA	7	08/02/2012
Inception Report	1	30/03/2012
Progress Report 1	1	01/02/2013

Mid-term Report	1	30/09/2014	
Monitoring of blood transfusion operations Oct 2015			Annex 7.2.5
Economic feasibility study	17	16/10/2017	Annex 7.2.10
Technical report	20	01/10/2016	
Publication of the technical report	20	01/01/2017	Annex 7.2.8
LCA of the new PVC-free bag	21	01/03/2017	Annex 7.2.3
Final Layman's report	19	30/05/2017	Annex 7.3.2
After-LIFE communication plan		30/09/2017	Annex 7.3.28
Audit result	9	30/10/2017	Annex 8.22
Final report with payment request	23	31/10/2017	

MILESTONES OF THE PROJECT (Revised Part C after Amendment 2)

Name of the Milestone	Code of the associated action	Deadline	Achieved
Project start	1	01/09/2011	01/09/2011
First seminar	7	01/03/2012	08/02/2012
Production of the first PVC-free prototype	12-15	01/07/2012	01/03/2014*
First Evaluation of a prototype performed	16	31/12/2015	31/12/2015**
A non-PVC blood bag tested and approved according to the Requirements Specification	15,16,17	30/03/2016	30/03/2016** 27/03/2017
Final Workshops	22	01/05/2017	30/05/2017

*A bag was produced before March 2014, but design improvements to fulfill requirements for the evaluation was needed. **The evaluation of the bag started with testing the properties, but the first storage study was finalised the 31/12/2015 and the second was finalised 30/03/2016. The user tests were performed later and the confirmation by the pre-audit of CE marking was ready in the end of March 2017.

3. Introduction

The healthcare sector uses large quantities of plastic consumables that may contain hazardous substances and cause considerable amount of waste. There are many examples[8] were healthcare is succeeding in phasing out hazardous substances, but currently no acceptable PVC-free blood bag for red blood cells is available on the market. Today's bag is made of PVC (polyvinylchloride) and consists of up to 40 percent plasticizer. The most commonly used plasticiser in blood bags is the phthalate DEHP, di(2-ethylhexyl)phthalate, which is classified as a reproductive disruptor and is also forbidden in toys. The risks of DEHP are emphasized in the directive for medical devices.

The challenges of introducing a new blood bag to the market, found in the pre-study, are both technical and economic as well as a lack of clear demand. The blood bag is an important life-saving product and also a complex product.

The core actions in this project is therefore to increase demand by cooperation with European healthcare dissemination knowledge and awareness, and to produce a blood bag in four steps followed by evaluation and user tests.

The compound is produced by Melitek and delivered to Wipak and Primo to produce film respectively tubings. Film and tubings are then shipped to Haemotronic for production of prototype bags. The bags are evaluated with blood storage studies by Karolinska University Hospital. Region Jämtland Härjedalen has been responsible for user tests simulating real handling of the bags as centrifugation, sealing of tubes and so on.

At the end of the project we have fulfilled the first objective and thus we have a PVC-free prototype set of bags that fulfils requirement specification[9] , including gap analysis for CE-marking. An economic feasibility study and an estimate of environmental impact of the new blood bag is also available. The outcome of the project shall convince blood bag producers of the importance and profitable of clinical testing, thus taking the bag out on to the market.

The second objective is a fall-back alternative in case the bags becomes too expensive for general use. The bags will then be proposed for vulnerable patient groups as premature babies and people with chronic diseases. This is assessed in the economic feasibility study. Additional project objective 3 is to open up for the use of the new material in other medical applications and this is estimated to be very feasible and is considered in the after-life communication plan.[10] The fourth objective is to offer the new material for food industry applications. This will not be prioritized in the After-Life activities, since focus will be a partnership within healthcare and that polypropylene is already in common use within food industry.[11]

Expected long term benefits are minimised patient exposure to potentially hazardous substances, a better working environment for both manufacturers and hospital employees,

[8] The Substitution list from *The national substitution group on chemicals in articles* in Sweden.
[9] Appendix 1 in Prestudy ISBN 978-91-977681-2-2, Listed as publication at www.pvcfreebloodbag.eu
[10] Annex 7.3.28
[11] Read more in section 5.2.9

health improvements, spin-off effects on other products, means less overall exposure, less impact on the environment from a life-cycle perspective, reduced costs in healthcare due to a healthier population and less costs for handling waste and need to clean smoke from waste combustion that is less contribution to climate change.

The implementation of the new medical device regulation will be very important for the market introduction of new medical devices. A stronger legislation indicating a ban of endocrine disrupting chemicals and potentially hazardous substances will enhance the introduction of better alternatives. A strong legislation is a part of an increased demand and would promote PVC free blood bags *unless* there are exceptions for certain medical devices. The new bag neither include EDC's nor CMR's, and thus would be the safest alternative considering harmful substances.

The project demonstrates a method in how to substitute harmful substance while enhancing competitiveness and innovation and therefore serve as a basis for development in REACH regulation as defined in the aim and scope of REACH regulation.

Using a material without harmful substances is also an advantage regarding circular economy. When recycling material it is important not to recycle the harmful substances. The "cleaner" the material, the higher the potential to recycle successfully.

The regulations for chemicals in recycled materials as well as in primary products are important. The two different regulations is a key challenge for the circular economy according to Echa's newly appointed head Mr Hansen. [12] Current EU legislation does not apply the same level of scrutiny to recycled materials as that on virgin material.

The economic feasibility study[13] points out that, despite a number of outstanding technical challenges, with co-ordinated and motivated set of buyers, the prototype developed in the project is economically viable and attractive to those companies participating in the project. Furthermore, if a clear demand is demonstrated, the global healthcare companies that dominate the PVC blood bag market could similarly produce a non-PVC blood bag at a price almost identical to that of today's PVC bags.

The use of a completely new supply chain is also in line with what is recommended on an EU-level: In a report commissioned by Echa in 2015 – carried out by the Lowell Centre for Sustainable Production – it is recommended that the agency create or expand mechanisms for greater supply chain collaboration and engagement. ECHA now plans to set up a supply chain network to promote substitution, a European multi-stakeholder network that focuses on promoting the substitution of hazardous chemicals.
The agency will invite the European Commission, member state authorities, businesses, NGOs and academic institutions to join the network.

[12] The information is from ChemicalWatch newsletter 12 Oct 2017
[13] Annex 7.2.10

4. Administrative part

4.1 Description of the management system

As Coordinating Beneficiary Region Jämtland Härjedalen is responsible for administration, monitoring the progress of the project as well as reporting to the commission.
The project manager together with communication officer, financial officer and support from IT and administration, take care of management and dissemination of information, including documentation, networking and contact with public bodies and NGO's.

Documents regarding procurement, agreements, grants and similar are archived in the public archive and other documents at the servers for Region Jämtland Härjedalen. The project website www.pvcfreebloodbag.eu has been used as a project platform for all documents, except working documents, budget and confidential reports from beneficiaries to CB. Instructions on how to report costs and time are on the website as well as minutes[14] from meetings.

Monitoring of the project, Action 5, is facilitated by a Monitoring protocol placed on the web site and in the output table, provided by the commission. The updated action plan in the end of each PMG protocol is also useful for monitoring the project progress. The project has worked according to plan and budget and deviations have been acted on. A monitoring visit by EC was made 4 April 2014. Three different monitors have followed the project; Diderick Velthoen visited CB in May 2012 and the second monitor, Pekka Hänninen visited Östersund in August 2012, November 2013 and in April 2014. The third monitor, Inta Dũce, visited CB in September 2015, 2016 and 2017.

The project management group (PMG) consists of representatives from all beneficiaries and has meetings four times a year. At the end of each protocol an up to date action list is available. The minutes from the PMG meetings are placed on the project's website after two weeks of correction possibilities. A total of 33 meetings have been held. Due to problems with the on-line meetings, regular telephone meetings have been held from meeting number 8 and onward.
The Partnership Agreement was signed on 15 May 2012 and the shares were distributed according to the partnership agreement. The partnership agreement was revised in the beginning of 2014 and is valid from 01 January 2013.

Description of changes due to Amendments to Grant Agreement
Three amendments to the Grant Agreement have been approved.
The first amendment was a necessary change of beneficiary. An additional beneficiary, Primo Profile, took over responsibility of making the tubings, Action 14, from Totax. The production line from Totax in Denmark was moved to Poland after Totax closed their facility. The amendment was approved the 6th of December 2013.

The second amendment included a request for a one year prolongation, a change of organisation, technical changes and changes in budget. The amendment was formally approved the 18th of November 2015.

[14] Link to were the minutes are found.

The third amendements was applied for in order to fulfil the projects objectives about CE-marking. A three months prolongation was approved the 13th of February 2017 and arrived at CB 23rd of February 2017.

There are 23 actions in the project. The seven actions highlighted in green are the projects core actions.

Nr	Action
1	Project management
2	Web site and media work
3	Notice boards and dissemination of project information
4	Project meetings for the Project Management Group
5	Monitoring the project's progress
6	Organisation of first seminar Action 7
7	First seminar – Kick- off in Copenhagen
8	Networking with other projects
9	Audit
10	Increase demand
11	Production of brochures, reports, posters, invitations etc
12	Production of compounds for film and tubes used in blood bags
13	Production of film for the blood bags
14	Production of tubes to be used in blood bags
15	Production of a PVC-free blood bag
16	Evaluation and monitoring of blood bags by Karolinska
17	User test including economic feasibility study of PVC-free blood bag
18	After-LIFE Communication plan
19	Final layman's report
20	Technical publication based on the evaluation results of blood bags
21	Organisation of concluding workshops action 22
22	Concluding workshops
23	Final project report

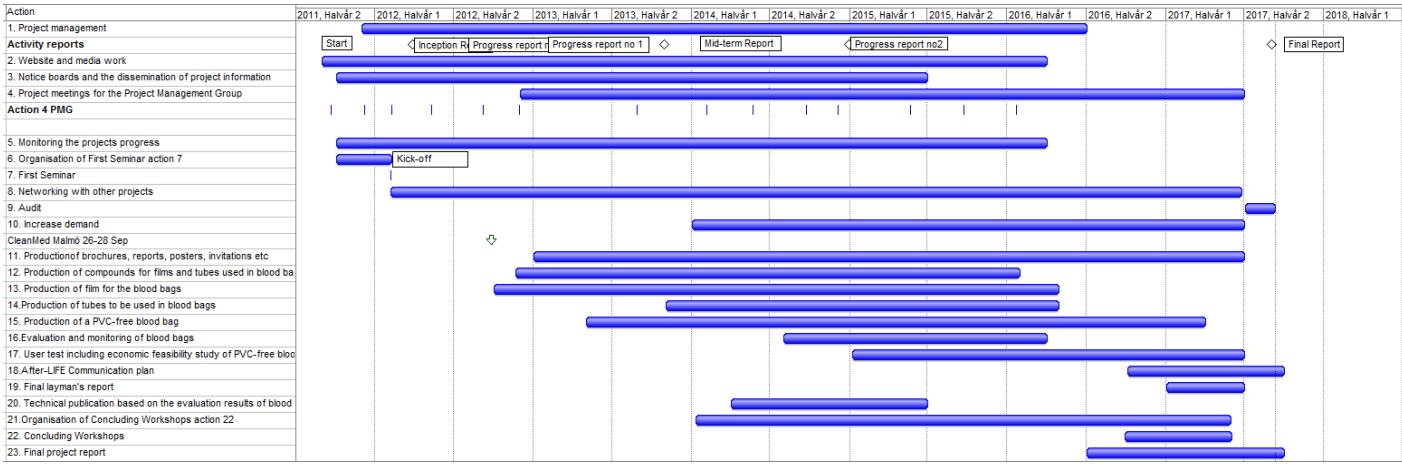
The project manager has visited all beneficiaries to learn more about their business and activities in the project. PM looked at the production facilities including monitoring, quality control and waste management. PM also visited Beneficiary 2 and 6 a second time.

The mid-term report was delivered 30/09/2014 and the mid-term payment was released the 10th of March 2015. Our financial officer forwarded all shares of the payment to the beneficiaries in April after clearance with the financial department.

Following the monitors visit and the EC's approval of the second amendment there have been remarks and questions from the EC regarding project management including financial issues. Feed back to these issues were presented in the Mid-Term report

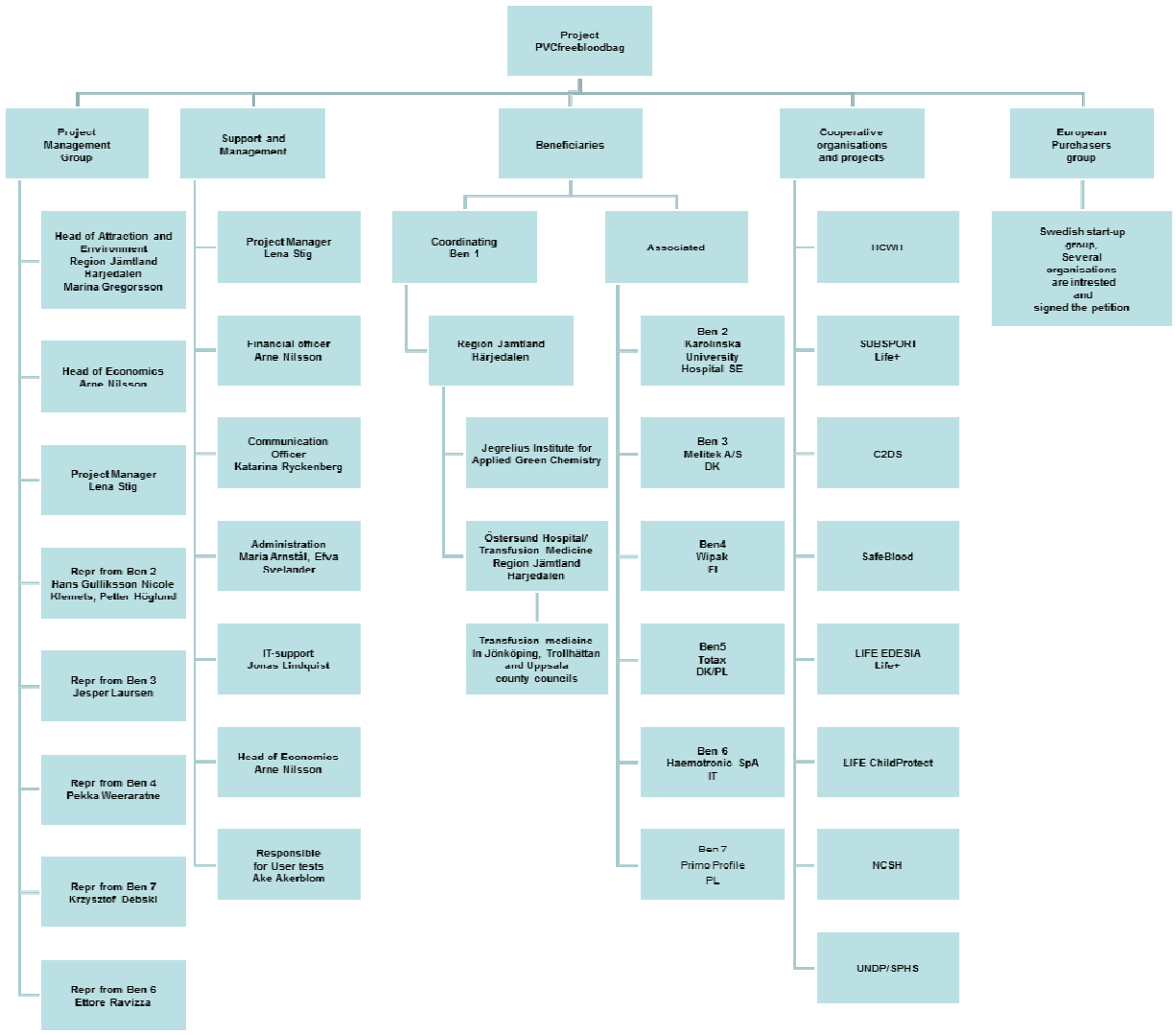
An additional deliverable named "LCA of a PVC-free blood bag" was procured with the same procedure as the former LCA and based on the real materials used in this project. The purpose was to strengthen the environmental arguments for the new bag and thus facilitate market introduction. CB also procured external assistance for a critical review of the LCA, for writing the economic feasibility study, for technical support of the final webinar, and for the audit of the project. Annex 7.1.3-7.1.12

The below Gant scheme is also available as Annex 7.1.2



The number of progress reports have been reduced in number by instruction from the EC. The first progress report was not requested so after communication with both monitor and EC it was not delivered.

The project organisation



Organogram of project organisation

The 1 January 2015 the Regional Council of Jämtland merged together with Jämtland County Council into Region Jämtland Härjedalen. The management team did not change, but the organisation number was changed.

The management team consists of

Project Manager	Lena Stig
Controller	Arne Nilsson
Financial Officer	Maria Arnstål
Administrator	Efva Svelander
Communication Officer	Katarina Ryckenberg
IT Support	Jonas Lindquist

Responsible for User Test Åke Åkerblom, Östersund Hospital

The PMG consists of

Head of Welfare, Climate and Competence: Marina Gregorsson

Controller	Arne Nilsson
Project Manager	Lena Stig
Communication Officer	Katarina Ryckenberg

Hans Gulliksson, Petter Höglund, Linda Nilsson represents Beneficiary 2, Karolinska
Jesper Laursen represents Beneficiary 3, Melitek
Pekka Weeraratne represents Beneficiary 4, Wipak
Krzysztof Debski and Daniel Jaworski represents Beneficiary 7, Primo
Ettore Ravizza and Alice Ravizza represents Beneficiary 6, Haemotronic

Cooperation organisations

HCWH Health Care Without Harm Europe
LIFE08 ENV/D/027 Life-SubsPort with Swedish representation from ChemSec.
LIFE12 ENV/IT/0633 Life-EDESIA
LIFE12 ENV/NL/0833 Life-ChildProtect
NSCH - Nordic Center of Sustainable Healthcare
EBA-European Blood Alliance
Safe Blood, project also working with Melitek and Haemotronic
C2DS, Comité pour le Développement Durable en Santé
Swedish National Substitutions Group on Chemicals in Articles
UNDP, United Nations Development Programme
Nordic Ecolabelling, Swan

4.2 Evaluation of the management system

When Jegrelius Institute for Applied Green Chemistry applied for Life+ they belonged to Jämtland county council the project application was based on the existing organisation. During organisational changes the Institute was moved to Regional council of Jämtland. Unfortunately, the administration and economic support was scarce the first 6 months due to insufficient resources. From March 2012 an economist has been engaged in the project, which fulfilled resources required in the project.

During 2012 the regional council of Jämtland changed their economic system and routines, which meant switching back to a more well-known system also used by the county council of Jämtland. New routines for invoices, payment procedures have also been changed recently. When the former monitor Diderick Velthoen visited CB on 24 May 2012 the whole system was shown regarding traceability and reliability.

In the second half of 2012 Pekka Hänninen became the project monitor. Mr Hänninen visited CB on three occasions and been of great support regarding administrative details in the project. We have been very satisfied with all three monitors.

The problems encounter by the project manager in managing the project have been regarding getting time sheets on monthly bases and also having to apply and put energy on getting a full-time employment as needed to manage the project properly.

Inta Dũce met PM, financial officer Linda Andersson and head of economics Arne Nilsson in 2015. At that moment the financial officer was about to leave her employment at CB and the responsibility for the financial issues was taken over by the Head of Economics. Maria Arnstål was introduced to the project and has transferred all data from existing excel sheets into the new template from September 2015. This change of excel sheets in the middle of the project caused extra work for the financial officer.

The lead times for getting information both from associated beneficiaries and from the commission have sometimes been long. For example, the answer regarding the amendment for Primo Profile, as an additional beneficiary, took several months leading to a late revision of the partnership agreement. The request for the second amendment was sent to EC the 1th of June 2015 and was formally approved the 18th of November 2015.

Monitoring of the projects progress according to plan and budget have been followed by a monitoring protocol and by regular Project Management Group meetings. In parallel with the monitoring protocol the EC's Output indicator table is used

The chain of event causing the delay like domino bricks were several.

- There have been changes of personnel at Karolinska giving more work for new personnel and CB organising the Kick-off and changes of personnel at Totax giving further delays of the Partnership agreements.
- Wipak put their investments on hold waiting for the Partnership Agreement to be signed and thus film production did not start in time.
- In parallel the material specification took longer than expected, but they are important to get the optimal compound quality from the beginning.
- The earthquake in Italy at the end of May 2012 caused a lot of material damage for Beneficiary 6/Haemotronic in addition to the loss of four lives.
- The series of changes for production of tubings that started with a change in personnel followed by moving of the production from Denmark to Poland and finally the complete close down of Totax as a company. Primo Profile applied for an amendment replacing Totax completely from 2013 which was approved.
- The delivery of compound from Melitek to Wipak was delayed since the first production trial had to be run outside the company and thus a confidentiality agreement had to be signed before compound could be delivered.

- Some technical issues regarding production of the blood bag have been solved, but delayed the start of the evaluation.
- The second user tests were delayed and as a consequence the technical file followed by the pre-audit of the CE-marking.

Due to the delays the project requested amendment changing the Mid-term report from 30/10/2013 to 30/04/2014 which was approved by the EC in April 2013.

The 4th of April 2014 the EC's technical desk officer Stefan Welin and financial desk officer Tommy Sejersen visited CB in Östersund, together with monitor Pekka Hänninen and represents from Haemotronic and Karolinska. The project was presented and both financial, communication and technical issues was discussed.

The MidTerm report was delivered later than planned, 30/05/2014, after advice from the monitoring visit. This report was not approved with reference to that the reported expenses was below the 150% threshold. The project need to consume 150% of the first pre-financing payment in order to get the next payment.

Action 4: Project meetings for the Project Management group
A few changes have been made in the composition of the PMG group.
The unit leadership in Region Jämtland Härjedalen is no longer shared. Marina Gregorsson is sole manager of former unit for Attraction and Environment, now named Welfare, Climate and Competence. The financial officer at CB was changed 2015, when Maria Arnstål replaced Linda Andersson.
New members have also joined from the other beneficiaries, and attendance depend on what is on the agenda. Daniel Jaworski from Primo, Alice Ravizza from Haemotronic, Jouni Vikman from Wipak and Nicole Klements and Petter Höglund from Karolinska. Jouni Wipak left Wipak in 2016 and Nicole Klements was replaced by Linda Nilsson during her maternity leave.
We strive to have at least one representative form each beneficiary at the meetings and Beatrice Aspevall Diedrich and Maria Matl from Transfusion Medicine in Karolinska follow the project by the minutes.

There have been 33 meetings so far and all minutes include an updated action plan.[15]

Action 5: Monitoring the project's progress
The monitoring protocol is being updated regularly with activities.
Website visitors are monitored with Google Analytics. One exception was during the transfer to new web format in March 2015.
The number of website visitors increases when news are launched at the web site. For example, at the Kick off in the beginning of 2012, in connection with Clean Med September 2012, visits to Brussels March 2013 and EBA November 2015, around the webinar 2015, the release of the short movie and the report January 2016. Also when press releases are made the visitor numbers go remarkable high.

There are a number of articles on the internet referring to the project.
The Output Indicator table, providing statistics, is attached as Annex 7.4

[15] The meeting's minutes on the website under Documents/Minutes.

Action 6: Organisation of First seminar and Action 7: First seminar was completed in 2012 and the outcome is reported in section 5.2.4 and 5.2.5.
Action 21: Organisation of Final seminar and Action 22: First seminar was completed in 2017 and the outcome is reported in section 5.2.11and 5.2.12.

Action 9: Audit
Due to lack of resources in form of available personnel, the auditor unit at Region Härjedalen could not perform the audit as intended. The procurement unit also was scarce of resources. PM then prepared the request for offer together with the internal auditor and the controller.

In the grant agreement we planned the audit process to be shared by all beneficiaries. CB being responsible for the overall audit as well as t for the two public beneficiaries specifically. The private beneficiaries 3-7 were supposed to assign an external auditor each, and send the audit reports to CB. The estimated audit costs for the private beneficiaries were 14 155 Euro. Later after discussion with the monitor we became aware of that this was not a procedure we could follow.
In the requested offer we estimated the amount to be 80 to 200 000 SEK taken into account what was in budget for benificary 3-7.
Our internal audit unit sent the request for offer to three firms and got two offers. The request for offer and the agreement is attached as 7.1.11-12

The first version of the Audit report was rejected due some inconsistencies. This was the main reason for us to ask for one more month before delivery of this final report.
The Audit report is found as Annex 8.22

Action 23: Final report
The writing of the report started in 2016 and Hans Gulliksson from Karolinska wrote his part before March 2016.
We intended to write the report within the frame of the project, but prior to the last amendment we realised that this was not feasible.

5. Technical part

5.1. Technical progress

The core actions in the project consist of the production of the bag divided in four steps followed by the evaluation of the bag. To increase demand, Action 10, is also a core action, but a part of dissemination of information as well. Therefore Action 10 is dealt with in section 5.2.
Action 1, 4, 5 and 9 is described in section 4.1 and 4.2
Action 2, 3, 6, 7, 8, 10, 11, 18,19, 21 and 22 is described in section 5.2.
All actions are described in Part C in the Grant Agreement.

The supply chain starts with Melitek/Action 12, continues with Wipak/Action 13, Primo/ Action 14 and Haemotronic/Action 15.

5.1.1 Action 12 Production of compound

The action is completed and expected result is achieved. The responsibel beneficariy for this action is Melitek in Denmark.
A non-PVC compound suitable for production of blood bag according to ISO 3826-1:2003 has been produced. A price estimate for the compound in industrial scale has been calculated and is used in the economic feasability study[16].
Environmental data have been collected and used in the life cycle assessment of the new bag compared with existing PVC/DEHP bag. Melitek also provided data for the Technical file prepared by Haemotronic. The technical file required for the pre-audit for CE-marking.

In order to produce compound, assessment of raw material, planning and preparing trial and production-scale compound manufacturing was needed. The compound was produced on a production-scale machine requiring purging with sufficient run-up times.

The material specifications were completed on 01/06/2012. Both the required specifications and transfusion units' requests were evaluated to make them properly. Mechanical properties have been tested in the laboratory.

Compound has been delivered to Wipak in Finland and to Totax/Primo in Poland. The first batch of compound was delivered to Wipak on 20/11/2012. The delay was caused by the extra time spent for the thourough material specification and that a confidentially agreement had to be signed before compound could be delivered to Wipak. This becauseWipaks first production trial had to be run outside Wipak's facilities.

The waste residues from the production of compound are very low. Residues are reused in the production of new compound compositions and material of too low a quality is sent to a municipal plant for incineration, producing energy. There is no waste disposal into landfills.

[16] Annex 7.2.11

PM visited Melitek's production facilities and was showed how monitoring, quality control and other tests were performed. Since their customers are in the medical field, the quality is of outmost importance. Melitek is also a driver of innovation and are cooperating with demanding customers and in innovative projects. These engagements make flexibility and small-scale tests necessary.

Melitek has delivered compound to both Wipak and Primo. The selection of the optimal compound composition has been made throughout the project. Jesper Laursen played an important role in the improvement process since he has a good overview and knowledge of the whole supply chain.
The latest improvement on both tubings and film is based on changes in of the compound quality. Melitek made an effort to find good quality compound with lowest price possible. A raw material that give the best value for money. A lower price will of course facilitate market introduction later as long as the high quality is maintained. A technical data sheet, a collection of environmental data and a cost estimation was made after the final compound was selected.

5.1.2 Action 13 Production of film for blood bags

The action is completed, and the expected result achieved. The responsible beneficiary for this action is Wipak in Finland.

A reproducible film with mechanical and barrier properties suitable for a blood bag have been produced. A cost estimate for the industrial scale product was made for the Economic feasibility report and a collection of environmental data for the life cycle assessment. Wipak also provided Haemotronic with data for the Technical file.
Data sheets for film properties have been compiled. External testing of film was not made.

Production activities are

- Reception, storage and testing of raw material
- Purging of production machine with the raw material before compounding
- Extrusion for reaching stable production process conditions

The first trials of production was successful. Film was shipped to Haemotronic 16/01/2013.
The production start was delayed due to both a delayed partnership agreement and the delayed delivery of compound. Since the first trial of film production had to be run outside Wipak, a confidentiality agreement was signed before the shipment of compound. There were two parallel productions to consider at Wipak, one external and one internal, and these two needed to be synchronized.

Wipak has produced film in regular production line, meaning clean room facilities in September 2013 and film has been delivered to Haemotronic. PM also received welded trial bags in May 2013.
Technical modifications of the film have been done during the production trial.

During PM's visit to the production site in Nastola March 2014 she was shown the premises meaning the production of film, monitoring room for the clean room facilities, the laboratory and handling of waste.

Wipak uses LEAN to create an effectiveness, traceable production and a safe working place. Each film batch is provided with a barcode. This means that waste material also is sorted according to bar codes. The bare code corresponds to the material composition. Later PM had the opportunity to meet product manager Kari Aaltonen, who is responsible for a long-term waste project aiming at increasing raw material recycling.
From 1996 Wipak has increased their raw material recycling from 3.7% to 52,1%. Waste disposal into landfill was low from the beginning. Incineration of waste producing energy at a municipality plant has decreased due to increased raw material recycling. The recycling is both for internal and external purposes. Internally they make plastic cores/pipes for roles. Some waste is regranulated and sold. Waste material with controlled content is sold both to Europe and China. The strategy is to continue to increase the raw material recycling.

Wipak produces both products for the food packaging industry and the medical industry and is not using any PVC. The company has a PVC-free policy.

Wipak has produced six runs of film. The six runs all together were needed to trim the films to meet the final product requirements. The fifth run was used in the bags for the in-vitro tests. The properties were satisfying, but a minor adjustment of compound quality was made in the sixth run to improve production of the bag. The sixth run with material was for the validation of the bags in action 15 in a bigger scale and also for the user tests in action 17. It was produced in September 2015 and was shipped to Haemotronic. Wipak was also planning for one more improvement in case the improved bags for the user tests are not satisfying enough.

A purchase of a film producing prototype was planned for in the budget, but the purchase became unnecessary. The film properties were good enough for the in-vitro tests and the user tests to take place. If there have been time to evaluate one more set of bags this purchase would have been made for further changes of the film's properties.

5.1.3 Action 14 Production of tubes to be used in blood bags

The action is completed and the expected result achieved. The responsible beneficariy for this action is Primo in Poland.
The production activities are reception and storage of raw material, pre-production activities as planning, preparing and purging, extrusion for reaching stable production process conditions and QC measure and control of dimensions to fulfil regulatory requirements, external testing of tubing for fulfilling regulations, cost estimation for production and collection of environmental data.

Reproducible non-PVC tubings that fulfill regulatory requirements have been produced. A price estimate for the tubings at an industrial scale and environmental data of the production have been delivered for the economic feasability study[17], the life cycle assement[18] and the technical file for the external pre-audit of CE-marking.

[17] Annex 7.2.11
[18] Annex 7.2.3

The tubes are beeing produced by an extrusion process giving controlled quality and dimensions. The tubings are made by compound from Melitek and shipped to Haemotronic for use in production of the prototype bag.

From January 2013 the responsibility for tube production lies on Primo Profile in Poland since Totax Plastics A/S no longer exist as a company. Totax Plastics A/S was owned by Primo Denmark since 2010. These changes are a part of the projects delays and started after the Kick-off in February 2012, when there was a change of personnel at Totax Plastics A/S. The representative in the PMG, left the company, and Krzysztof Debski replaced him as a member of the PMG. This change delayed the partnership agreement and, as a consequence, investments in action 13/ Film production were put on hold.

The production facilities have been up and running in Poland since 2012, when the production was moved from Denmark to Poland, but the close down of Totax consumed time of Primo Profile. Totax Plastics A/S existed as a company under 2012 belonging to Primo Poland instead of Primo Denmark. From 2013 Totax Plastics A/S no longer exist.

PM visited the production plant in Zory, Poland in November 2012 to go through the changes and get confirmation of their commitment. Krzystof Debski and Primo Profile was committed to take over the responsibility. The project applied for an amendment of an additional beneficiary in June 2013. The amendment to the grant agreement was approved 6 December 2013.

Krzystof Debski visited CB in Östersund in 8 January 2014, where he met PM and the financial officer Linda Andersson, to go through time sheets and to sign the revised partnership agreement.

Primo has received compound from Melitek and technical specifications from Haemotronic. The technical specifications differ somewhat from plan and a new tool for the production of the tubings was made. After additional design discussions of the bag in April and June 2014 further changes of the tubings were also made.
First delivery of tubes to Hamotronic for production of bags was made in September 2014.

The new tool was produced in order to produce tubings according to the design requests from Haemotronic and Karolinska. The technical requirements on the properties of the tubings were higher than estimated in beginning and more consumables were needed. New technical specifications in the production of tubes also requires more consumables.

The mentioned new properties of the tubings need to be controlled on-line during production. The original simpler process did not require this quality control. The additional costs for this new quality control have been paid for by the beneficiary.

When PM visited the production site in Zory, Poland the production was shown. Primo is driven by Customer demand, and PVC is still a major compound in their production. Primo are however interested in more sustainability projects and by achieving Totax they are shifting towards a bigger share in Medical products. The potential to shift more products for PVC free products is important and may be a spin-off of the project.

The tubings are working and are sufficient for the set of bags for the in-vitro evaluation. However, the tubings are a bit stiffer than estimated to be. Before the user tests, the compound quality was changed for the following production run of the tubings. There was no change in the inner surface that are in contact with blood and solutions. These tubings was produced in March and sent to Haemotronic for the production in action 15, in April 2016.

5.1.4 Action 15 Production of a PVC-free blood bag

The action is completed, and the expected result is achieved. The responsible beneficiary for this action is Haemotronic in Italy.
Prototype polyolefin bags suitable for preparation and storage of blood components that could be recommended for further testing of CE-criteria have been manufactured.
The description of action 15 was updated after amendment 2 to include more activities related to production of a set of four bags including filter and needle. It was made clear that a set of three bags including a needle and filter was necessary to perform the in-vitro studies in Action 16.

Blood bags for storage tests, user tests and pre-audit for CE marking have been produced.
A price estimate for the set of bags in industrial scale has been calculated and is used in the economic feasibility study[19].
Environmental data was collected and used in the life cycle assessment[20] of the new bag compared with existing PVC/DEHP bag.
Before production of the bag took place, product and quality requirements were defined.
The best methods for welding and general manufacturing were set.
The prototype bag was produced of the film from Wipak and tubing from Primo.
Prototype bags were sent to Karolinska for evaluation. The bag was also tested for CE-criteria. Methods used in production are according to ISO standards for cytotoxicity, irritation, sensibility and acute system toxicity as testing for impermeability to microorganisms and physical testing. Iso standard compliance is demonstrated in the Technical File, Annex 6, that was sent to the notified body ItalCert.
Materials used in production are also listed in the Technical file, Annex 5.

Packaging was selected according to specifications for impermeability to microorganisms and to compliance to iso standards on physical properties[21], but testing for impermeability to microorganisms and physical properties of packaging was not performed as it part of the packaging validation, design transfer and out of scope of the project.

The earthquake in northern Italy at the end of May 2012 caused a lot of material damage for Beneficiary 6/Haemotronic, in addition to the loss of four lives. One of the production sites was destroyed and equipment and materials have been moved from Mirandola to Carbonara. Production was moved from Mirandola to Carbonara and up at full speed after a few months. However, there was a further delay due to the fact that Haemotronic had to fulfil delayed obligations to customers.

[19] Annex 7.2.10
[20] Annex 7.2.3
[21] In the Technical file, Annex 5, sent to Italcert

Monitor Pekka Hänninen paid Haemotronic a visit in 2013, monitoring their time and cost reports.

The first delivery of film was good enough for first production trials, but the quality of the film was not good enough for bags intended for evaluation. Haemotronic made preliminary weldings of the film received from Wipak in the beginning of 2013. Machinability and physical properties were first priority. Chemical and physical properties were verified and good enough for a bag to be evaluated by Karolinska. Haemotronic received several batches and last batch had required properties for a prototype bag. The design of the prototype bag with two different dimensions of the tubings has been set. The first bag was produced in March 2014 and bags for evaluation will be delivered to Karolinska. Alice Ravizza visited Karolinska University Hospital to verify the design of the bag. The design discussions were held at Karolinska 12-14 May 2014. The physical properties of a complete set of bags was checked first time at Karolinska the 20-21st of January 2015. This set of three bags was a totally PVC-free set, and were tested with water at Karolinska.
The set is made up from material from the whole supply chain; action 12, 13, 14 and 15, including filter and needle from an external source. After some improvements the second trial with the set of bags was performed at Karolinska 8th of June 2015.

The scope of the production was changed, and different options were investigated in parallel in May, June and July. There has been a dialogue with Haemotronic, Karolinska and Primo to find the best solution.

Waste management primarily means internal reuse for suitable applications. When there is no internal use, the material is re-grained and sold for external use.

The scope of production of a PVC-free blood has been changed, since a set of bags, included filter and needle was necessary for the in-vitro evaluation in action 16.
The activities in the original application was based on the production of one bag. Later it became obvious that a set of bags including filter and a donor needle was needed to evaluate the blood bag. The set also needed to be sterile. The need for design and production adjustments have increased. Several items and services necessary for producing the full set was outsourced by Beneficiary 6. The corresponding activities caused by the change in scope are described in the updated part C[22].

The whole action has been updated as part of the amendment no 2 and is describing the actual situation. A more detailed description of action 15 is found in the revised Part C that is on the web site.

Sets of bags for the in-vitro evaluation in action 16 was delivered 31/08/2015 to Karolinska. The set of bags was proven sufficient enough for the evaluation for the in-vitro tests. However, before scaling up production for the user tests, improvements were made. There were different technical scenarios to choose from.
PM met Alice Ravizza the 29th of September 2015 in Stockholm and discussed some of the possible solutions regarding bag properties and how to best verify that the bag fulfil the criteria for CE-marking.

[22] Link to revised Part C

Haemotronic confirms that the project is able to fulfil the essential requirements that are listed in annex I of Medical Device Directive 2007/47. Haemotronic has a good design history file and could draft a full technical file.
Annex I in the directive is the list of essential requirements for safety which is mandatory for all medical devices. Haemotronic have given proof of compliance.
Annex II is a kind of certificate. Companies can choose amongst different kinds of certificates and Annex 2 is the most complete certificate, because it includes the company quality management system. Haemotronic products are all certified according to Annex II and the files of this PVCfreeBloodBag project also comply with annex II.

In the budget Haemotronic has budget posts for external assistance for validation according to ISO-standards and production consultant and this was suitable to use for a pre-audit.

Regarding CE-labelling we have interpreted the Common Provision art 25-27 as the cost for the CE-mark in itself is not an eligible cost in similarity to eco-labelling.

However, since one of the objectives is to demonstrate that it is possible to produce a blood bag that fulfils CE-labelling, an assessment from a third part is required for credibility. A pre-audit from a Notified Body. A pre-audit on annex 1 requirements of Medical Device Directive 2007/47 and on quality management system requirements according to annex 2.
A pre-audit does not end up with a CE-mark in itself, just a gap analysis for CE.

Quality improvements was as explained needed before scale up, user tests and validation according to methods described in action 15 in part C.
The plan was to produce 3 lots of 45 bag sets for each hospital performing the user tests. In order to improve the bag quality, a change in the tooling was made. The design of bag and surfaces in contact with blood, storage solution and blood components will be the same, i.e. the in-vitro evaluation remains valid.

Blood bags are medical devices which means that they are subject to special legislation, the EU Directive for Medical devices. To verify the quality of the bags we commissioned a notified body for a CE marking pre-audit.
Alice Ravizza, who represented Haemotronic, created a technical file for the notified body Italcert which performed the pre-audit.
The pre-audit gave us a gap analysis for CE marking, showing the status of the product and what remains to be done: scaling up production and validating the sterilization cycle for commercial lots.
The blood bags is a class IIb Medical device and 100% PVC-free.

The product is designed to comply to the expected Medical Device Regulation, which latest released draft (22 February 2017) limits the use of some substances including phthalates (reference Annex I, 10.4.1)

The medical device is designed by beneficiary 6 Haemotronic according to their ISO 13485 quality management system and a Technical File has been compiled for a pre-audit.

The device is not ready for CE marking as some Essential Requirements are not completely met. More details are found in the Annex 7.2.10 Pre-audit report.

1. Essential Requirement 4 and 5 regarding shelf life evaluation: the device may undergo shelf life and transportation testing only after the sterilization cycle is validated
2. Essential Requirement 6 regarding clinical data evaluation: the device was tested for the capacity of preservation of red cells and met regulatory requirements for up to 28 days. This time length is shorter than the state of the art; different preservation solutions may improve storage time. Moreover, there are currently no data on plasma preservation.
3. Essential Requirement 8.3 and 8.4 regarding sterilization: the device is compatible with Steam and Gamma sterilization, in appropriate containers. The sterilization cycles are not yet validated. The validation of such cycles requires the manufacturing of at least 3 commercial lots, which is currently out of the project scope.

At the webinar the 30th of May Alice Ravizza presented the regulatory status of the blood bags. More dissemination of information is described in section 5.2.

5.1.5 Action 16 Evaluation and monitoring of blood bags

The action is completed and the expected result is achieved. The responsible benificary of this action is Karolinska University Hospital in Sweden.
Prototype polyolefin bags suitable for preparation and storage of blood components that could be recommended for further testing of CE-criteria were manufactured in Action 15. The result would be compiled for the technical report.

A new medical laboratory scientist was recruited in January 2015 and the evaluation started with trial tests at Karolinska in January 2015. The verifying of the physical properties of the bag set was first performed with water. Alice Ravizza, representing Haemotronic, participated in the tests together with Hans Gulliksson and personnel from the laboratory.

In September 2015 the working group was strengthen by physician and professor Petter Höglund, who together with Hans Gulliksson, was responsible for the evaluation of the blood bags, together with his research team. PM met Petter Höglund the 29th of September in Karolinska and introduced him to the project.

All beneficiaries updated their plans to meet the requirements from Karolinska to start the in-vitro studies in September 2015. The in-vitro study started in October by blood donation at a blood donor center in Stockholm, followed by sampling and analysis at Huddinge site of Karolinska. A second blood donation occasion was made in November and two more donation occasions in January 2016.

In a first evaluation, blood bags filled with water were tested to secure the durability of the blood bags, especially during centrifugation as evidenced by the absence of leakage from blood bags.
In a second step, a red blood cell (RBC) preparation and storage study was performed to make sure that RBCs could be stored in the new blood bags meeting established clinical and quality criteria. This trial focused on the storage of RBCs, since increased disintegration of RBCs (hemolysis) was expected in the absence of the stabilizing effects

associated with leakage of plasticizer from the walls of the present blood bags manufactured of polyvinyl chloride (PVC). Since present standard RBC additive solutions were not expected to be successful, new additive solutions in an R&D phase should be needed.
Method work and promising tests were performed. However, tests using the actual prototypes were delayed as a consequence of problems associated with actions 12-15.

Since a new R&D RBC additive solution was needed, an agreement with an external company[23] regarding supply of a specific RBC additive solution (designation E-Sol 5, code FX1066B) was signed. CB helped out by providing legal assistance concerning the agreement between Karolinska and the Fenwal Company. PM wanted to secure that the agreement was in compliance with Common Provision, Grant agreement, Partnership Agreement and Public Procurement Act.

The first test of durability of the polyolefin blood bags filled with water was performed in January 2015 (12 units). Four defective units were found associated with either a crack in a luer connector or in side weldings or bag surface.
The manufacturing process was reviewed and improved and in May 2015, new blood bags were filled with water and tested (18 units). The previous problems with luer connectors had been attended to and side weldings of the blood bags were improved. However, the new polyolefin bags were found to be more vulnerable to centrifugation. The bags had to be more carefully stabilized in the centrifuge cups than present standard PVC blood bags.

When the in vitro RBC storage studies were to be started in the autumn 2015, the previously mentioned Fenwal Company had been purchased by a different company and the RBC additive solution intended to be used was no longer available. In this situation, the design of the study had to be revised. A different R&D RBC additive solution (designated PAGGG-M) was generously supplied by Sanquin, the national blood organisation in the Netherlands. The composition of PAGGG-M was based on the same functional principals as E-Sol 5. In addition and in parallel, a commercially available RBC additive solution was tested (designated PAGGS-M). This solution had been shown to be successful in a previous study using blood bags manuctured of a different plastic (PVC/DINCH).
The in vitro studies were performed in 4 steps. Totally 20 units of whole blood were collected from normal voluntary blood donors after obtaining their written consent. In the first two steps 5 plus 5 units were collected and RBCs were stored in PAGGS-M . Studies started October 21 and November 09, 2015, respectively. In the next two steps, studies started January 21 and 26, 2016, respectively (5 plus 5 units) using PAGGG-M as additive solution. The RBC units were stored for 42 days at 2-6 ºC. Sampling was performed once a week and a number of standard in vitro varibles were measured reflecting metabolism and disintegration of RBCs during storage. The results of the studies are summarized in section 5.1.7. (Action 20).

Blood from blood donations (whole blood) is separated into different blood components before being used for blood transfusion, generally into red blood cells (RBCs), platelets, and plasma. The plasticizer in the present standard blood bags is a phthalate (DEHP) that converts the major plastic component (PVC) to a soft plastic material suitable for

[23] Fenwal Europe, Mont-Saint-Guibert, Belgium

manufacturing of blood bags. This plasticizer leaks into the blood components stored in such a blood bag. Quite unexpectedly, it was found that DEHP is integrated into the outer layer of RBCs, thereby stabilizing the cells and decreasing the disintegration of RBCs during storage, i.e. the hemolysis. In the absence of plasticizer in the new test polyolefin blood bag material, it could be expected that the stability of RBCs might be a problem. For this reason, the evaluation of the new blood bag started with laboratory (in vitro) RBC storage studies. RBCs were stored in specific additive solutions that contain different components necessary for RBC metabolism and function during storage for up to 6 weeks. Two different RBC storage solutions were included in the tests, one commercially available (designation PAGGS-M) and one from the R&D stage that generously was supplied by Sanquin, the national blood organisation in the Netherlands (designation PAGGG-M). A number of standard RBC in vitro parameters were included in the tests, reflecting RBC metabolism and stability of cells during storage. Samples were drawn once a week for the tests.
As expected, the results suggested that hemolysis would be the limiting factor. Regarding PAGGS-M, hemolysis levels were acceptable only for 2 weeks of storage. Those were not acceptable results since present standard methods allow for 6 weeks of storage of RBCs. On the other hand, with PAGGG-M, hemolysis levels were acceptable for 4 weeks of storage. Those are encouraging results, although efforts to reduce hemolysis would be recommended. All other parameters for storage in PAGGG-M were acceptable and similar to the standards of today. The result of the in vitro RBC storage study has been published in a scientific peer reviewed journal in transfusion medicine, viz. Vox Sanguinis (2017) 112, 33-39. Annex 7.2.8

The end-of-life of the evaluated bags will be standard incineration with heat recovery. The bags are sent to "Vattenfall Värme Uppsala" in containers, according to hospital routines.

Petter Höglund, Hans Gulliksson and Stephan Meinke from Karolinska presented results as part of action 22, Concluding workshops. Stephan Meinke also presented result from the in-vitro study the 12th of May in Stockholm. The audience was from Transfusion medicine in Sweden.

5.1.6 Action 17 User test including economic feasibility study

The action is completed, and the expected result is achieved. The responsible beneficiary is Region Jämtland Härjedalen.
The expected outcome is a thorough evaluation of the bags performance presented as part of the final report. An economic feasibility study based on cost estimates from action 12-15 is expected.

The user tests mean simulating all handling of blood bag imitating reality. Handling blood bags involves filling, centrifugation, sealing of tubings et cetera.

Åke Åkerblom from Östersund Hospital in Region Jämtland Härjedalen was participating in the testing of the bags with water at Karolinska 8 June 2015. This in order to set up a test protocol for the user tests
He has also been interacting with Alice Ravizza to secure that the user tests verify the criteria's for CE-labelling. 02/02/2015

We sent out questions to health care organizations in Sweden, regarding the user tests, to find out if the interest to participate was still there. We aimed at five hospitals involvement in the user tests and ended up with four.
During the in-vitro evaluation in action 16, representatives from Karolinska and Haemotronic assessed that the quality of the bag sets was insufficient for user test. Thus the user tests was delayed.

Besides improved sets of bags clamps/clamp tools and plastic sealer was required for all hospitals performing the user tests. The clamp tools could be borrowed from hospitals and the sealer was bought after a technical survey with the help from Haemotronic.

The user tests in Östersund was recorded and used for a demonstration movie to those performing the tests. Åke Åkerblom presented the result from the first user tests at the seminar in Östersund the 27th of September 2016. His presentation was recorded and is on the website [24]
The short version of user test demonstration is on the web[25] and has been used in presentations.
The second round of user tests was performed in Trollhättan, Jönköping, Östersund and Uppsala. The test protocols were sent to Haemotronic along with pictures and used in the Technical File provided for the pre-audit for CE-marking.
The check list for the hospitals to use is in Annex 7.2.6 and the compilation of the result is in Annex 7.2.7

The centrifugation of the bags is the most critical step. This was seen in the first trials with water performed at Karolinska. The weldings was reinforced prior to the user tests.

The economic feasibility study is reported as a separate delivery Annex 7.2.7
External expertise was assigned Annex 7.1.4-5

The economic feasibility study is based on calculations and data from the beneficiaries. The conclusions from the study are the following: Blood bags represent a niche product for PVC with small volumes relative to other uses. The supply chain is dominated by a small number of specialised producers, generally wielding significant market power. These companies have integrated global operations and have invested significant sums of money in their current production capabilities leading to path dependency. Furthermore, the economics from a manufacturer perspective have shown a general decline in recent years with greater investment now going towards automated devices.
There is also a non-harmonised regulatory environment, making the investment in a replacement bag more costly and difficult to justify for manufacturers. Overcoming these barriers requires legislation and/or concerted pressure from buyers at a level whereby the market size is clear and attractive. This means demonstrating a clear European/Global demand, although Sweden could act as a lead/reference customer.
On a positive note, research has shown that buyer led initiatives have been successful in bringing forward PVC alternatives for nearly all other medical devices. Furthermore, the cost of these products is on par with PVC versions in most cases. On the downside, the lack of success with bringing forward an alternative to red blood cells seems to have most to do with the role of DEHP in stabilising red blood cells combined with the overall

[24] Link to presentation
[25] The link to the short version of the user tests

performance and low cost of PVC. This is real technical challenge to be overcome by manufacturers in addition to the general economic, legislative and institutional barriers. Recent efforts have revolved around finding alternative softeners to DEHP which offer these preservative qualities, while still retaining PVC as the polymer. Eastman Chemicals and BASF both now offer alternatives to DEHP, thereby providing a clear alternative without altering other aspects of their PVC manufacturing value chain.
The economic analysis performed as part of the current project demonstrates that it is economically feasible to manufacture the prototype polyolefin blood bag at a price very close to today's PVC blood bags. Furthermore, the time to market and the breakeven period for the upfront investment are both relatively short.
The primary economic risk to those companies involved in the current project, aside from the technical risks of manufacturing a new product, is that they fail to generate adequate demand due to the higher cost at low production volumes. To overcome this risk one option is to loss lead, whereby the manufacturer initially sells at a loss in order to stimulate demand, thereby bringing down the production costs through economies of scale. Another alternative, is to differentiate the new bag based on its health benefits and initially target the high-risk patient segments. Engagement with those responsible for procuring blood bags will help to determine whether they are prepared to pay a higher price per bag for a small volume, on health and environmental grounds, and therefore a small annual increase in cost.
A further risk stems from the current incumbents. Although they are currently pursuing a strategy of replacing DEHP with alternative softeners, they may themselves develop and market a non-PVC bag if a clear market is seen to exist, or alternatively reduce the price of their existing PVC products to protect market share. The companies involved in the existing project should seek to mitigate this risk by negotiating longer term contracts with buyers in order to lock in demand prior to making any upfront investments.
From the buyer perspective, this feasibility study has demonstrated that it is possible to procure a substitute bag at a competitive market price, particularly where upfront, longer term commitments are made. Although Karolinska alone is not large enough to stimulate the market, a group of 10-20 similar hospitals across Europe could be enough to kick-start the market. A technology procurement project co-ordinated across a group of like-minded hospitals would seem to be a feasible procurement strategy.
In summary, despite a number of outstanding technical challenges, the economic analysis performed in this study suggests that, with co-ordinated and motivated set of buyers, the prototype developed in the project is economically viable and attractive to those companies participating in the project. Furthermore, if a clear demand is demonstrated, the global healthcare companies that dominate the PVC blood bag market could similarly produce a non-PVC blood bag at a price almost identical to that of today's PVC bags.

5.1.7 Action 20 Technical publication based on the evaluation results of blood bags

The action is completed, and the responsible beneficiary was Karolinska University Hospital.

The result of the in vitro red blood cell (RBC) storage study has been published in a scientific peer reviewed journal in transfusion medicine, viz. Vox Sanguinis (2017) 112, 33-39. The technical design of the studies is described in section 5.1.5. (Action 16) above.

Two different RBC additive solutions were tested, viz. PAGGS-M and PAGGG-M. A number of standard RBC in vitro parameters were included, viz. intracellular concentrations of adenosine tri-phosphate (ATP) and 2,3-di-phospho-glycerate (2,3-DPG), extracellular pH, extracellular concentrations of glucose, lactate and potassium, and hemolysis. Two parameters were of specific interest, viz. ATP and hemolysis. ATP has been shown to correlate with in vivo survival of RBCs after transfusion and the concentration of ATP should exceed certain levels of content in RBCs. Hemolysis is not allowed to exceed a certain level according to general medical regulations within the European Union.

RBCs of today can normally be stored for 6 weeks. Regarding PAGGS-M, ATP levels were acceptable for 5 weeks and hemolysis levels only for 2 weeks of storage. Those were not very encouraging results. On the other hand, with PAGGG-M, ATP levels were acceptable for at least 6 weeks and hemolysis levels for 4 weeks of storage. Those are quite good results, although efforts to reduce hemolysis would be recommended. For further details, please see the publication in Vox Sanguinis. It should be emphasized that this is a first preliminary study of RBC storage in a new type of blood bags without plasticizer. Further development and studies will be necessary. Future possible steps are outlined in section 5.2.9 and 5.4.

5.2 Dissemination actions

5.2.1 Objectives

The objective is to stimulate and verify the interest in replacing blood bags of PVC with PVC-free blood bags. Since an increased demand for the new bag is essential for the outcome, dissemination of information is of outmost importance.
Dissemination of project information is made through action 2, 3, 6, 7 ,8 , 10 ,11 and 18-23. The best overview of all dissemination activities is found in the Output Indicator table. Annex 7.4

5.2.2 Action 2 Website and media work

CB, Region Jämtland Härjedalen, is the responsible beneficiary, but all beneficiaries have been engaged in the media work.
More than 50 000 visits on the web site were expected and this has been tracked using Google analytics. Articles in newspapers or magazines was expected as well as press releases in each of the beneficiaries' countries. The target audience group is in the medical sector, particular in transfusion medicine and within the plastic industry.

The project's web site www.pvcfreebloodbag.eu is used for communication and documentation. Press releases[26], reports, news, information and minutes are examples of

[26] Link to where the press releases are found

what are found on the web site. The petition, as it is a way of showing the demand, is easy accessible. A link to EU's Life+ web site is on the top of the start page.
The project logotype includes the web address. Links to all beneficiaries are found on the start page of the website in form of their own logotype. All beneficiaries have information about the project on their own web sites.

At project start the software Joomla was chosen for the website in order to get support from Regional council of Jämtland. The website was hacked several times from the autumn 2012 and for security reasons the website was transformed to WordPress and placed in a web hotel.

A webinar was held together with HCWH 22 Oct 2015, using a WebEx platform. HCWH Europe organised the webinar together with us. The title of the webinar was How to bring safer blood bags to healthcare[27]. Annex 7.3.14
Both the demand and supply side were represented by voices from healthcare and industry and the presenters were Gustav Eriksson, Head of Environment at Karolinska University Hospital, Jesper Laursen, Business Director and co-owner of MELITEK, and Lena Stigh, Project Manager, PVCfreeBloodBag, Jegrelius Institute for Applied Green Chemistry. The moderator host was Grazia Cioci, Deputy Director, HCWH Europe.

A short video about the project has been launched.[28] The video is targeting healthcare organisations with the purpose to increase demand. The video-clip was launched in January 2016 and disseminated on LinkedIn and by all beneficiaries. HCWH has promoted the video and the petition in both their newsletter and in separate mails to their members. You will find the video named PVCfreeBloodBag on YouTube. Annex 7.3.11

The project was contacted by the Dutch TV-program RADAR about participating in a TV-show about EDC's in healthcare. PM briefed a journalist about the project and sent the short video for them to use. The Dutch consumer affairs TV show 'Radar' was sent the 8th of February 2016. The show 'Radar' featured a piece drawing attention to the problem of EDCs found in food packaging and in medical devices such as medical tubing, gloves, and blood bags. Head of Environment Gustav Eriksson, from Karolinska University Hospital in Sweden, spoke about the PVC-Free Blood Bag Project.[29]

In January 2016 the Project started a Twitter account.

Press release 1: 27 July 2011
The first press release announced the approval of the project.

Press release 2: 6 Feb 2012
The second press release presented the project prior to the first seminar, Action 7.

Press release 3: May 2012
The press release presenting the LCA performed by Raul Carlson and commissioned by our project aroused attention from the plastics industry. The European Council of Vinyl

[27] Link to webinar recording and presentations
[28] https://www.youtube.com/watch?v=ckGj1yKaZzw&feature=youtu.be
[29] A link to the TV show. In Dutch with interviews in English

Manufacturers sent out a press release about the LCA on 23 July 2012 and we have added the link on LinkedIn to it.
A link to their press release is also presented on our website, together with a statement from the project.[30] We agreed on that the study and the results only was a complement to the SCHENIR report (Scientific Committee on Emerging and Newly Identified Health Risks), and that the study is in line with project objectives.

Our statement about the vinyl manufacturers' press release was
"The Life Cycle Assessment commissioned by our project compared a PVC/DEHP blood bag to a fictive polyethylene bag. This LCA does not contradicts the mentioned SCENIHR report from 2008, especially since the SCENIHR report is not considering alternatives to PVC but are focusing on the safety of medical devices containing DEHP-plasticizied PVC. The safety is also of enormous concern to PVCfreeBloodBag, as well as the quality of both bag and blood components. The blood bag is complex and an important life-saving product. We consider the LCA as a complement to earlier studies and since DEHP is already classified as a reproductive toxic (67/548/EEC, 28th ATP, Annex 1) and the Medical device directive (2007/47/EC) emphasises the risks the result did not come as a surprise. "

The author Raul Carlsson has been available to answer regarding the content and quality of the LCA.

The Scientific Committee on Emerging and Newly Identified Health Risks of the European Union requested a revised scientific opinion on the safety of medical devices containing DEHP (di (2-ethylhexyl) phthalate) plasticized PVC. Hans Gulliksson from Karolinska University Hospital/Beneficiary 2 was invited and elected as an external expert. The work of the committee resulted in a publication, "Scientic Committee on Emerging and Newly-Identified Health Risks (SCE-NIHR): Opinion on the safety of medical devices containing DEHP-plasticized PVC or other plasticizers on neonates and other groups possibly at risk."[31]

Press release 4: 5 November 2014
A press release launched prior to project manager's visit to Haemotronic that was combined with Health Care Without Harm's Annual General Meeting. A PR to promote the meeting and the project.

Press release 5: 22 October 2015
A press release to announce that the in-vitro studies started. This was a very important action. We have been eager to start the evaluation of the bag. We brought a photographer to the blood donation center in Stockholm to catch the moment.
The PR resulted, amongst other, in an announcement by HCWH Europe and Life+ Communication team.

Press release 6: 23 September 2016 (Annex 7.3.29)
This press release in Swedish, was to announce the final seminar in Östersund.

[30] A link to our comments about the LCA
[31] European Union 2015; ISSN:1831-4783:ISBN:978-92-79-35606-3

Press release 7 and 8: 18 October 2016 (Annex 7.3.30)
An announcement to promote the final seminar in Copenhagen and the project result.

Media activities by Benificiary 3, Melitek
PM and Jesper Laursen from Melitek was interviewed by the editor of Medical Plastics News for an article focusing on DEHP in medical devices. The magazine is audited and the print circulation covers 6,000 medical plastic device manufacturers in Europe and 15,000 digital subscribers around the world. [32]

Media activities by Melitek have resulted in a part of a publication from the Danish eco-council about the substitution of hazardous substances.[33] Melitek is also presented as as a good example of creating innovative growth, in an article including their work for PVC free blood bags. It was published in national Danish morning newspapers on 23 October 2012 and the article was also published in English in connection with a conference in Copenhagen.

Melitek has been interviewed on national Danish TV.

In Denmark, a film has been produced for education at nursing schools. Both blood bags and the hazardous PVC/DEHP are topics covered in the film.
Jesper Laursen was also was a speaker in the webinar 22 October 2015 mentioned above.
The 9th of November 2016 HCWH Europe hosted a webinar about The new Medical Devices Regulation – An engine for EDC substitution? It is available on their website[34].
The title of Jesper Laursens talk was *Substitution of hazardous chemicals in medical devices*

Media activities by Beneficiary 2, Karolinska
Karolinska has promoted both the first seminar and the final seminars.
They have also called for hospitals to join the user tests in action 17.
Karolinska have been contributing with lecturers at webinars and conferences
They have used their website platform to communicate collaboration.[35]

Media actives by Beneficiary 4, Wipak
Wipak have presented the project in a Newsletter. See next chapter on Action 3.

Media actives by Beneficiary 7, Primo
The 16th of April 2015 Primo published an article about the project.[36]

News published on the website are listed in chronological order below. There is a search option at the website, were one may select News per month and year. A list of over the more than 80 news is attached as Annex 7.3.34.

[32] A link to the article
[33] Read more here
[34] A link to webinar 9 November 2016
[35] A link to Karolinska website
[36] Link to Primo's article on their website

5.2.3 Action 3 Notice boards and dissemination of project information

Expected are at least 15 notice boards and attendance at four conferences as a speaker or with a poster. Dissemination of project information is also made through action 2, 6,7,8,10,11 and 18-23.
The best overview of all activities is found in the Output Indicator Table. Annex 7.4

The notice boards describe the project and are disseminated to public bodies, institutions, organisation and at conferences.
Communication channels have been seminars, conferences, press releases, mail, telephone, LinkedIn and the website. We target the Red Cross, European Blood Alliance, NHS and other healthcare organisations in Europe.
Additional dissemination material have been produced. See section 5.2.8

All beneficiaries have project information on their website.

Beneficiary 2/Karolinska: Link
Beneficiary 3/Melitek[37]: Link
Beneficiary 4/Wipak[38]: Link
Beneficiary 5/Haemotronic: Link
Beneficiary 7/Primo[39]: Link

Five Newsletters have been launched and disseminated to target groups. They are also on the website.

Newsletter 1, 2013
The first newsletter was targeting healthcare with a survey of estimation of the number of blood bags and number of transfusions made in Europe attached. This willalso made to give more input to the mapping of European healthcare and those organisations that buy blood bags.

Newsletter 2, 2013
The second newsletter announced the first trial of the film and promoted the CleanMed conference in Oxford. It also included the news about PM speaking at the Life-EDESIA kick-off.

Newletter 3, 2015
The third newsletter was launched 28/05/2015. It was about the first trials of the new bags and promoted the webinar and the film among other things.

Newletter 4, 2016
The fourth newsletter was launched 04/04/2016. Annex 7.3.17
Among the news was the report about a survey to gather information about blood transfusions regarding statistics, procurement and environmental requirement in Europe. It also promoted the YouTube-clip and the final seminars.

[37] http://www.melitek.com/MELITEK---Specialist-in-medical-technologies/PVCfreebloodbags
[38] http://www.winnovations.wipak.com/project/non-pvc-bloodbags

[39] http://www.primo.com/news/latest-news?Action=1&NewsId=120&M=NewsV2&PID=45190

Newsletter 5, 2017
The fifth newsletter was launched 05/01/2017. Annex 7.3.18
Among the news was the publication of the in-vitro study and

Activities year by year
2012
PM attended a regional innovation conference in Sundsvall 2012 with a project banner and hand-outs, along with a power point presentation. In October 2012 PM represented PVCfreeBloodbag at the Swedish Chemical Agency's annual conference in Stockholm, Forum for a non-toxic environment.

Hans Gulliksson, Karolinska and PM presented the project at two lectures at the regional Transfusion Medicine days in Örebro, Sweden, 13-14 March 2012.

PM has been contacted by the French organisation C2DS, Comité pour le Développement Durable en Santé, in order to work together on information about why PVC should be phased out from healthcare. HCWH have also been in contact with the project manager for more information about blood bags as a medical device.

CleanMed Europe 2012 was a success. The project made a lot of new and important contacts, had new signings of the petition and the project was picked as one of the best examples and presented in plenum. The workshop was well attended and resulted in discussions and networking with similar European projects – both public and within the industry aiming at phasing out PVC/DEHP. Presentations from all speakers at the workshop are on the website.
PM and CO also participated in the HCWH board meeting that discussed the planning of the next CleanMed Europe.
The project had an abstract accepted for the Swedish Medical National Conference 2012 in the Transfusion Medicine section. A new Prezi presentation was made for a 15-minute presentation, but unfortunately PM had to cancel due to illness.

2013
In CleanMed Europe 2013 we attended with a poster about the benefits of a new blood bag. In October 2013 PM was invited to speak at a conference about Procurement with environmental and social demands. PM spoke about how to achieve a new non-toxic product exemplified with a blood bag.

Hans Gulliksson attended an international expert meeting in transfusion medicine (BEST Collaborative) in Denver, CO, USA in October 2013 and made a presentation on the PVC/DEHP situation in Europe. The reception of the presentation may be characterized as expectant. The industry primarily seems focus on PVC plastic with a different plasticizer (DINCH).

2014
When discussing the new personnel succeeding Inger Johed at Karolinska, we decided to focus on communication skills in order to strengthen action 3, 10 and 21. It will be an advantage communicating with healthcare when belonging to healthcare yourself. The new person was appointed in August 2014.

PM participated in the HCWH annual general meeting and attended a workshop about sustainable healthcare in Bologna 6-7th of November 2014. At the meeting PM presented project progress and suggested a CleanMed lecture from the project focusing on demand and supply. Next CleanMed Europe was planned to take place in September or October 2015. However, the conference was later cancelled due to lack of financial resources. Instead of that lecture the project decided to arrange a webinar together with HCWH.

2015

PM was invited to present the project at the opening seminar for Nordic Center for Sustainable Healthcare 28/05/2015. The presentation was about how to get a new safe blood bag into healthcare. Nicole Klemets held a presentation about Karolinska University Hospital's vision of a sustainable healthcare. The interest was great and both presentations received good response with several questions.

PM has been contacted by the French organisation C2DS, Comité pour le Développement Durable en Santé, more than once since they share our objectives. Before the Annual member meeting held in Bologna PM was asked to be part of a video clip intended to be used in a presentation held by C2DS with the industry in France as target group.

The 29th of September 2015, both PM and Nicole Klemets from Karolinska attended a meeting summoned by the National Agency for Public Procurement in Stockholm. PM presented the project and the progress.

The 22nd of October 2015, we sent a webinar[40] organised together with HCWH Europe. A webinar about how and why to bring a new, safer blood bag to healthcare. Both the demand and supply side were represented by voices from healthcare and industry and the presenters were Gustav Eriksson, Head of Environment at Karolinska University Hospital, Jesper Laursen, Business Director and co-owner of MELITEK, and Lena Stigh, Project Manager, PVCfreeBloodBag, Jegrelius Institute for Applied Green Chemistry. The moderator host was Grazia Cioci, Deputy Director, HCWH Europe.

Handouts were sent to Mid Sweden European Office in Brussels.

Alice Ravizza was supposed to be speaking at a conference in Berlin the 2-3rd of December 2015. Unfortunately she became ill.

2016

The 12–13 May 2016 Lena Stigh and Stephan Meinke represented the project as invited speakers when Karolinska University Hospital arranged a specialized seminar in Transfusion medicine.

5.2.4 Action 6 Organisation of First seminar

Expected result was 150 people participating in a lunch to lunch seminar in a central town in Europe. Cooperation and help from HCWH was expected especially regarding invitations to healthcare organizations.

[40] A link to the webinar in 2015.

Copenhagen was chosen, and a survey of suitable conference facilities was made.[41] Karolinska is responsible for action 6 and action 7, but due to changes in personnel at Karolinska the work was shared with Coordinating beneficiary.
After date and place were set, Karolinska procured facilities, food and refreshments. CB made a registration set-up at the web site and send out invitations. Agreements with external lecturers and moderator was arranged. The final programme was set and hand-outs for the seminar was produced.

5.2.5 Action 7 First seminar

The objective was to create a higher awareness of the situation in transfusion medicine and that the first seminar would be the start of an increased demand in European healthcare.
The lunch to lunch seminar[42] was held at the National museum of Copenhagen the 8 Feb 2012. Moderator was former Head of Environment at Stockholm county council Anna Linusson.
Each beneficiary held a presentation the first day to give a background of and presentation of the project. The second day invited speakers from HCWH and Department of Pediatrics and Neonatology in Westfriesgasthuis, spoke about the risks and effects of using PVC in the healthcare sector. A procured life cycle assessment was presented by Raul Carlson from eco2win.

The presentations from all speakers are provided at the website.

There were over 50 participants at the seminar and among them representatives from the plastic industry indicating interest of our project. During the time around the seminar the number of visits on the web site increased.

Lessons learned
We did not reach the targeting group of people from the health care sector, despite a large number of invitations. Among the reasons are late invitations from HCWH and from ourselves. In public organisations plans for conferences often have to be taken 6 month in advance.

5.2.6 Action 8 Networking with other projects

Expected result is an exchange of information and cooperation with four identified Life+ projects. As mentioned before activities in 3, 8 and 10 tend to get entangled and not easy to separate.

2012
CleanMed[43] in Malmö 2012 made new opportunities for networking with other projects. PM and CO attended the Life +SUBSPORT workshop about their developed substitution portal.

[41] Request for offer and agreement in Annex 7.1.x
[42] A link to documents and presentations
[43] A conference for sustainable healthcare. Link to more information.

The Life + project CLIRE LIFE09/ENV/SE0347 attended the CleanMed conference, but their presentation was at the same time as our seminar. PM has contacted the project along with one more Life+ project but has not yet got a response.
The project MediSafeLIFE 05/ENV7UK/0131 that we intended to work with, turned out to be unsuccessful and has ended.

Hans Gulliksson has been to US for a meeting, were the members of the European expert group on PVC /DEHP, made a presentation of the situation in Europe. The status on the other side of the Atlantic are that there is no strategy regarding these chemical problems yet. The industry tries to change to other plasticisers, Canada avoid them as much as possible.

LIFE-EDESIA
PM was invited as a speaker to the Kick-off in October 2013 for a Life+ project with shared objectives to phase out harmful chemicals. The project is called LIFE-EDESIA, LIFE+12 ENV/IT/000633

At the meeting the 14th of October PM spoke about the challenges in getting a PVC-free blood bag. LIFE-EDESIA is an ambitious project aiming at facilitating substitution of Endocrine Disrupting Chemicals as phthalates, bisphenol and parabens. There were several other speakers and stakeholders at the meeting. According to Professor Federica Chiellini from University of Pisa the new plasticizer DINCH, replacing DEHP, is similar in structure to DEHP and thus might have similar properties as DEHP. The available risk assessment is made by the same company that manufacture the substance, BASF.

PVCfreeBloodBag and PM have been part of the panel following the project.
The project manager of Life+ EDESIA Stefano Lorenzetti was invited as speaker to our final seminar in Östersund the 26-27 of September, Action 22. You will find a recording of Stefano Lorenzetti's presentation at the website along with his presentation[44].

Health Care Without Harm are running a project about Endocrine Disrupting Chemicals in Medical Devices and PM has supported HCWH with arguments and information in order to strengthen legislation to ban EDC and CMR in medical devices. The 22nd of October the EP voted favourably for the EC proposal to ban hazardous chemicals (EDC and CMR) in Medical Devices.
The project has, together with HCWH Europe, among others, pushed for stronger legislation on medical devices. In March 2013, project manager Lena Stig visited the European Parliament for a lunch debate arranged by HCWH on how to move towards a non-toxic European healthcare. She also participated in a policy strategy meeting on how to phase out EDCs in medical devices. A subsequent process, in which the PVCfreeBloodBag project participated, resulted in a proposal and, in plenary session 22 of October 2013, the European Parliament (EP) voted in favour of the European Commission's proposal on Medical Devices that among other issues, stipulates a ban on hazardous chemicals in medical devices.
In April 2015, the EC announced that new rules to enhance patient safety and modernize public health are on the way. The implementation of the new rules will be important for the introduction of new bags.

[44] Link to Stefano Lorenzetti's presentation

At the HCWH annual general meeting in Bologna 6th and 7th of November 2014 PM had the opportunity to meet PM from LIFE+ project ChildProtect LIFE12 ENV/NL/0833.

Life-ChildProtect
The project is working on substitution of endocrine disruptive chemicals, EDC's and thus share our projects overall objectives. They have four different target groups; policy makers, producers, parents and professional.
We have shared information. A guide on how to avoid EDC's in everyday products is available for printing and we also have a link to their project on our web site.[45]
The project manager of Life+ ChildProtect was invited as a speaker to our final seminar in Östersund the 26-27th of September, Action 22. You will find a recording of Chantal van den Bossche's presentation at the website along with her presentation.[46]

Swetox
PM attended a seminar arranged by Swetox 28/01/2015. Swetox is a collaboration between eleven Swedish universities with a chemical safe world as a vision. They are running a EU-project called EDC-MixRisk that will develop risk assessments about endocrine disrupting chemicals. One outcome from the seminar was that PM sent information to both Life-EDESIA and Swetox to facilitate contact since both of them are working with risk assessments of EDC's.

In 19th of June 2017 PM attended a workshop[47] that Swetox arranged together with ReproUnion about EDC's.

The project has increased awareness and demand in partnership with projects and organisations related to healthcare or the phasing out of harmful chemicals.

Life Subsport: www.subsport.eu
HCWH – Health Care Without Harm: https://noharm-europe.org
NCSH – Nordic Center for Sustainable Healthcare: www.sustainablehealthcare.se
EBA – European Blood Alliance: www.europeanbloodalliance.eu
UNDP – United Nations Development Programme: www.undp.org
C2DS – Comité pour le développement durable en santé: www.c2ds.eu
Life EDESIA: www.iss.it/life/index.php?lang=2
Life ChildProtect: http://childprotectfromchemicals.eu/
The National Substitution Group on chemicals in articles

5.2.7 Action 10 Increase demand

Expected result is that, during the projects life span, 20 networking organisations and 50 new organisations will sign the petition. The objective is to remove barriers for market introduction of PVC free blood bags and this is made by verify customer demand for the new bags. The target groups are healthcare organisations and opinion leaders as politicians that may influence decisions.

[45] http://childprotectfromchemicals.eu/
[46] Link to Chantal van den Bossche's presentation
[47] A link to the Programme

Expected is also to compile more statistics about the number of blood bags purchased in Europe and the number of blood transfusions that are performed annually.
The support from the majority of Swedish healthcare organisation with their signed Letter of intent is the starting point as well as support from Health Care Without Harm.

The mapping of European organisations and surveys to obtain more statistics is wanted. In order to increase demand we want to map European healthcare and those organisations that buy blood bags. PM has sent out request to organisations linked to the European Blood Alliance for contacts and information.
A bachelor's student in environmental engineering, Amitis Moazedian, has helped us with this mapping and started a survey of how many blood bags are bought annually and how many blood transfusions are performed in Europe. We were initially targeting the Red Cross, European Blood Alliance and the NHS. A working document with countries, organisations and contact information was gathered and updated. Her work was later taken up upon by Erik Stenholm.

Mapping of European organisations and surveys to obtain more statistics was performed by Erik Stenholm, employed by Karolinska during the summer of 2015. The report was launched 28 January 2016 on the website[48]. The publication is a separate deliverable in the project. The survey was based on a questionnaire sent to Norway, Denmark, France, England, Finland, Italy, Poland, Spain and Germany. The survey shows differences in both operational structure and awareness about environmental issues among the nine European countries.

2012
The project was responsible for one session at the CleanMed conference in Malmö 2012. The title of the session was "B3 PVC Replacement Strategies in Healthcare"
Responsible person was the Communication Officer Katarina Ryckenberg.
The five lectures which also are on our website[49] were

- Vendula Krcmarova, Arnika Association, Czech Republic, "Mapping the Options to Eliminate PVC in Czech Hospitals to Reduce Patient Exposure to Harmful Phthalates"

- Lena Stigh, Jegrelius Institute for Applied Green Chemistry, Sweden, "PVC free Blood Bag Wanted"

- Dirk de Man, University Hospital of Antwerp**,** "Experiences with rubber flooring as an alternative use of PVC"

- Peter Skals, Coloplast A/S, Denmark, "Phasing out PVC and Phthalates from a Producer Point of View"

- Eva Dalenstam & Linda Linderholm, Swedish National Substitution Group on Chemicals in Goods, Sweden, "The Substitutionlist -Guiding You on a Non-toxic Healthcare"

[48] Link to report. Annex 7.2.5
[49] A link to more information

More than 50 persons attended the session and there were a lot of reflections and questions. All presentations are available as pdfs on the web site.
The CleanMed conference gave contacts with United Nations Development Programme, WHO, Ecological Physicians Society/German Affilitae of ISDE, along with some others.

2013
The project attended CleanMed 2013 in Oxford with a poster titled “Would you buy a PVC free blood bag?”

PM was, in March 2013, invited to the European Parliament in Brussels. She participated in a lunch debate on how to move towards a non-toxic European healthcare. The event titled: "Towards Non-toxic Healthcare: Alternatives to Phthalates in Medical Devices" was organised by Health Care Without Harm (HCWH) Europe and hosted by French MEP Corinne Lepage.
In addition, she also participated in a policy strategy meeting on phasing out EDCs in medical devices.
The dialogue with HCWH about the arguments for a stronger legislation on medical device continued after the meeting. The 22nd of October the European Parliament voted favorable for the EC’s proposal on Medical Devices that among other issues stipulates a ban on hazardous chemicals in medical devices.[50]

2014
PM visited the Finnish Red Cross in March 2014 and presented the project.

The project continued to focus on cooperation with European Blood Alliance. If the board of EBA support the project, it will facilitate support national support. The meeting at the Finnish Red Cross that are a member in European Blood Alliance confirmed the importance. We aim at co-arrangement of one of the final seminars.

The LCA, the dissemination of information and the cooperation with other organisations as HCWH, C2DS have increased the awareness of EDC’s in medical devices and in blood bags in particular. In the article *Should DEHP be eliminated in blood bags*?[51], Sweden with the PVCfreebloodbag-project is mentioned as the only country among those represented in International forum that has an active program for replacing DEHP from blood bags. This by a non-PVC bag.
In the same report there is also concern raised for DEHP-exposure to sensitive patient groups, such as neonates.

2015
The SCENIHR Opinon on *The safety of medical devices containing DEHP-plasticized PVC or other plasticizers on neonates and other groups possibly at risk,* adopted 25 June 2015 also raise concern about sensitive patient groups. The abstract ends with “There is a strong need to develop and collect data on exposure of alternative materials in the actual conditions of use, to refine knowledge on their toxicological profile and to develop other alternative materials with a favourable profile both for efficiency and safety”

This is all in line with what the project is working for. To demonstrate that this is possible.

[50] Link to News on website
[51] Vox Sanguinis (2014) 106-176-195

PM has contacted EBA in earlier to present the project, but it was not until the summer of 2015 she was first contacted by EBA.

The project manager was invited to European Blood Alliance by EBA's procurement officer. PM presented the project to the technical committee in Birmingham the 16th of October 2015.[52] Marco Goldoni from Haemotronic joined her at the meeting. The presentation was followed by questions and discussions. The opinions varied in the group whether they could support the initiative or not. The project being a demonstration project made some of their initial proposal not feasible.

PM had a follow-up conversation afterwards with the procurement officer, who said she would send minutes and a statement about their opinion about the project. EBA are concerned about the sensitive patient groups as highlighted in the expert group opinion earlier.

The procurement officer was also interested in the possibility initiating a procurement project with Karolinska University Hospital as the project owner. That could be one way of facilitating the market introduction of a PVC-free blood bag and part of an After-Life activity.

More general requests from different areas in the world for PVC-free blood bags have been received by the project manager. For example, for the Asian market, Turkey and Iran.

2017

Project manager Lena Stig was one of the speakers at the Nordic Conference on Sustainable Healthcare the 15th of February in Stockholm. Among the other speakers were Anja Leetz from HCWH, Rachel Billod-Mulalic from C2DS and several members of NCSH. They are all from cooperating organisations, sharing the same objective to phase out harmful chemicals from healthcare.
PM presented project result under the heading "Projects that push the envelope"

B:4 Projects that push the envelope
Constant incremental improvements are not always enough – sometimes a paradigm shift is necessary. The session highlights projects in the Nordic region that represent real progress: a new hospital, a strategy for comprehensive energy-efficient renovations of existing building stock, and much more to inspire new thinking.
Gustav Eriksson, environment director, New Karolinska Solna University Hospital
Kristina De Geer, environmental strategist, EU LIFE+ project Climate Friendly Health and Care, CLIRE
Lena Stigh, project manager, PVCfreeBloodBag
Hulda Steingrimsdottir, Environmental Coordinator Landspitali /The National University Hospital of Iceland

[52] Link to News on website

We have also been approached by Nordic Ecolabelling that have criteria document for Disposable bags, tubes and accessories for healthcare.[53]
They are considering revising their criteria document to include blood bags. We have supplied them with complying information.

5.2.8 Action 11 Production of brochures, reports, posters, invitations etc

High quality posters, brochures, invitations, programmes and reports are expected.
Material is produced by the project members but graphic design, proofreading are made by subcontractors.
Hand-outs, poster, plain note books with Life+ and project logotypes have been prepared for different events. Project presentations have been prepared and they are tailored depending on the audience and time limits.
Material have been updated exchanging Totax for Primo on web site, hand-out and one poster.
All publications are on the website along with other documents.
Material is attached as annexes 7.3.1 to 7.3.18 The virtual material is only attached as links.

All productions are provided with Life logotype and project logotype.
Project presentations have been prepared and they are tailored depending on the audience and time limits of the presentation.

The webinar production was a joint work together with HCWH. Gustav Eriksson, Head of Environment at Karolinska, Jesper Laursen from Melitek and PM from CB prepared one power point presentation each. Aidan Long from HCWH arranged the set-up and invitation link for the webinar and Grazia Cioci from HCWH was the host. Questions could be asked via a chat to Katarina Ryckenberg.

The short movie started with PM writing the script and discussing the scope with Stockholm County Council, Nicole Klements at Karolinska. We decided to record the movie in SLL's hospital in Solna
Charlotta Brask from Stockholm County Council took part in the movie representing demand and Jonas Lindquist handled the camera the 5th of May 2015. The actual cutting of the video was postponed since Jonas unexpectedly had to take over new duties during the autumn as when our IT-manager passed away.
We solved the situation by employing Färgteve filmproduktion. We also employed Lisa Cockette from Anything English regarding proof reading of the script and as speakers' voice in the movie. The movie was placed at Region Jämtland Härjedalens' YouTube channel and launched 19 January 2016. These costs are covered by budget for external assistance for action 2, 3 and 11.

During the start of the in-vitro evaluation and blood donation in Stockholm a photographer was employed to take pictures. The intention was to use the pictures in coming media activities and publications such as the Final layman's report in action 19. The report by Erik Stenholm has been provided with one of the pictures and with an ISBN-number. The report was made ready for print before launched. Annex 7.2.5

[53] Nordic Ecolabelling of **Disposable bags, tubes and accessories for health care.** Version 1.6 • 13 December 2007 – 31 March 2019

Print costs are in budget for 19, 23 and action 11 referring to action 3, 8, 10 and 22.

5.2.9 Action 18 After-LIFE Communication plan (Annex 7.3.28)

As action 18, an After-Life Communication plan, has been written with the objective to disseminate project experiences about removing the barrier to introduction of the new blood bag. The project group have discussed several scenarios during the last year and also asked organisations and audience at webinars and seminars. The pre-audit for CE-marking, the life cycle assessment and the economic feasibility study also been given valuable input on how to proceed to stimulate market introduction of a new blood bag.

In short we need

- Quality improvements of the bag
- Evaluation of new storage solutions
- Further evaluations of the bags properties and ability to store red blood cell
- Scale up of production
- Validation for sterilisation cycle for commercial lots
- CE-marking

The evaluation of the bags, Action 16, resulted in a clear picture of what is left to do regarding the bag.

First, it should be emphasized that further tests and validations will be required before the new polyolefin bags can be considered suitable for routine use. The plastic in the present blood bags, DEHP-plasticized PVC is quite inexpensive; suggesting that introduction of the new bags may be associated with increased costs. For this reason, future regulations of presence of hormone disturbing substances in medical plastics within the European Community may have a great influence on the introduction of PVC-free blood bags. On the other hand, concern has been expressed on the effects of large amounts of such substances on the safety of medical devices containing DEHP-plasticized PVC or other plasticizers on neonates and other groups possibly at risk (European Union 2015; ISSN:1831-4783: ISBN: 978-92-79-35606-3).
A possible initial approach might be to introduce the new blood bags for transfusion of patients within those specific risk groups and then gradually increase the use of the new blood bags to additional groups of patients.

The physical properties of the new polyolefin plastic are significantly different from those of the present PVC-DEHP. The polyolefin bags were found to be more vulnerable, especially to centrifugation. Specially designed plastic inserts for the centrifuge cups may improve the stability of the blood bags during centrifugation, which is a necessary step for the preparation of blood components.

The blood bags consist of a system of individual bags interconnected with plastic tubing. Those tubing need to either be sealed to close tubing before disconnection or be sterile connected to other tubing. Specific sealing equipment is available today.
The sealing conditions are somewhat different; implicating that new sealing equipment for closing blood bag tubing will be needed. On the other hand, the present sterile connecting devices may be possible to use. However, the use of sterile connecting device processes in this context needs to be validated.

Plasma should also be tested regarding the stability of coagulation and activation pathway variables and platelets regarding biochemical, functional and haematological parameters during storage.

Only two different RBC additive solutions were tested. Additional new RBC additive solutions may be of interest for similar tests. The RBC additive solution PAGGG-M gave encouraging results except for its reduced capability to prevent hemolysis. There will be room for further development of this solution or other RBC additive solutions to address the hemolysis problems**.** Other additive solutions could improve the quality of red blood cells stored in the new blood bags. That is to prolong the storage time

The dream scenario that was presented at the final webinar consists of partnership involving Karolinska University Hospital for evaluation, a supplier of new storage solutions/ additive solutions, Haemotronic for technology transfer and scale up and a committed blood bag producing company.

A stronger regulation and an independent criteria document that organisations with different national regulations could stand behind would also facilitate market introduction. A blood bag with the Nordic Swan EU-label would be one way to make it easy for the buyers.
PM has been invited to speak at a Medical device conference[54] in November and HCWH has arranged a workshop[55] with the title "Can the Medical Devices regulation act as an engine for substitution?" PM will be represented at the workshop.

Several of the beneficiaries have been networking during the projects last month. Networking and dissemination of information to initiate after Life activities.
Petter Höglund from Karolinska University Hospital attended ISBT Congress in Copenhagen 19-21th of June.
Alice Ravizza representing Haemotronic attended MedTech Summit in Amsterdam 19-23rd of June
PM attended Swetox & Reprounion workshop on EDC's in Copenhagen the 19th of June
Jesper Laursen from Melitek attended AMI Medical Tubing Conference the 6-7th of June in Cologne, Germany

We also have started up with telephone meetings and several of the beneficiaries are committed for the next step, taking the blood bags out on to the market. Karolinska University Hospital has applied for funding for preparing the next step towards market introduction. The life cycle assessment will together with the economic feasibility study and the pre-audit for CE-marking act as a basis for the product and it's potential.

The second project objective was a fall-back alternative in case the bags becomes too expensive for general use. According to the economic feasibility study this seems not to be the case unless the market volumes are too small. The third objective to offer a material that can be used to replace PVC in other medical applications seems very valid and different suggestions have come up in discussions. The fourth objective, however, to offer the new material for food industry applications will not be prioritized in the future. The

[54] Link to the conference site
[55] Link to the invitation

material polypropylene is already in common use in food industry. One of the beneficiaries, Wipak, is already producing PVC-free packaging material for the food industry.

5.2.10 Action 19 Final layman's report

The Final layman's report was published and launched the 30th of May. Due to delay with the pre-audit for CE-marking, we did not manage to have the Layman report ready in time for the concluding seminars in Action 22, as expected.
The English version of the Layman report was proof read by an external expert. All drafts versions with pictures and text was then sent for graphical design. The layman's report has been translated into beneficiaries' languages as well as into German, French and Spanish. Some of the translations have been made by the beneficiaries, but some was translated by a company on framework agreement at CB. Annex 7.3.2-10.
The Layman reports will be distributed from the projects website, and from all beneficiaries' sites, as well as by some cooperating organisations.

The Layman report could be used for several different purposes; to show a good example on how to drive innovation, on how to phase out harmful chemicals and how to cooperate between industry and public sector.

5.2.11 Action 21 Organisations of Concluding Workshops action 22

As learned from the First seminar it is important to set the dates early to get high attendance. The planning started in October 2014 and one activity was a webinar survey. A survey to investigate what kind of virtual presentations and seminars are most suitable for us to use in the final workshops. Our IT-support Jonas Lindquist has together with Nicole Klemets at Karolinska and the communication officer looked into different tools. Arranging the webinar together with HCWH, described in 5.2.2, was part of this action as a practical way of testing the webinar format.

The procurement and the performance of the second life cycle assessment was also placed in this action. The result will be presented in the final seminar in Östersund and Copenhagen. Action 22. The report in itself is a delivery. Annex 7.2.3
In addition to the LCA we assigned a third part to assess a critical review of the LCA. Annex 7.2.4

A life cycle assessment is an international standardised method used to investigate the environmental impact of a product from a life cycle perspective. Two different products were assessed: a conventional set of blood bags made of PVC and DEHP and the projects PVC-free set of bags mainly made of polypropylene. The scope was from extraction of raw materials, production, installation, use and service to the waste proposal.

The impact assessment showed that there were no major difference of global warming potential, fossil depletion, and agricultural land occupation of the two sets.
Regarding potential water scarcity and human toxicity, the Impacts of PVC/DEHP based set was substantially higher compared to the PVC-free set.

We decided early on that one of the final workshops would be in Östersund in September in adjacent to the UNESCO conference 2015. Unfortunately, this did not work, since the UNESCO conference made it hard to book seminar facilities and hotels. The date was set to a 27-28 September 2016. A lunch to lunch seminar.

A second workshop to reach a big audience with European healthcare was planned in adjacent to CleanMed 2016. The organiser HCWH, set the date to 19-21 October 2016.

In order to target the field of Transfusion Medicine, presentations of the in-vitro evaluation at two international conferences was suggested. There were two different options available.
- An expert meeting of BEST (Biomedical Excellence for Safer Transfusion) in October
- International Society of Blood Transfusion (ISBT) conference in September

Hans Gulliksson wrote an abstract for the expert meeting in Orlando and the abstract was accepted. Since the Orlando meeting required the result to be presented first at their conference, we decided not to present result at the ISBT conference that Petter Höglund went to.

A seminar or oral presentation at Medica/Compamed in November 2015 was planned. This is a conference with high attendance from the industry. We settled for letting the four companies in the supply chain present the project at their monters.

When the date for the seminar in Östersund was set, we distributed the date in Newsletter as well as on the web site. We planned to record the seminar in Östersund.

Professionals was invited along with project partners and representatives of public authorities on EU level and national level connected to Health and Consumers Directorate respectively Medical products agency, National Board of Health and Welfare and similar authorities. Focus on the workshops was discussed in PMG meetings.

The programme for the two seminars in Östersund and Copenhagen was decided, and speakers were invited. The project managers of Life-EDESIA and Life ChildProtect was invited to Östersund.
The programme (Annex 7.3.23) of the lunch to lunch seminar is the following in short:

Welcome – Moderator Anna Longueville, researcher and lecturer at the Ecotechnology Department at Mid Sweden University
The importance of new innovations and projects like the PVCfreeBloodBag – Björn Eriksson, Head of Region Jämtland Härjedalen
The project – a brief introduction and presentation of beneficiaries – Lena Stig, PM
Searching for plasticizers' alternatives by animal-free screening in the LIFE-EDESIA project – Stefano Lorenzetti, Istituto Superiore di Sanità (ISS) – Rome, Life-EDESIA project manager
In-vitro study of red blood cells stored in the new blood bags with a toxicological background from a transfusion medicine perspective – Hans Gulliksson PhD, Associate Professor Clinical Immunology/Transfusion Medicine Karolinska University Hospital
User tests of the PVC-free blood bags – Åke Åkerblom, Chemist and Axel Robertsson, Medical Laboratory Scientist, Östersund Hospital 16.10–16.20
Summary/Discussion

Mingle dinner at the museum – "Young blood, a bloody history" – Petter Höglund Professor, Karolinska University Hospital Wednesday 28th of September 08.45–09.00
Start day two – Moderator Anna Longueville
ChildProtect: How to create awareness among consumers on EDCs, Endocrine Disrupting Chemicals – Chantal Van den Bossche, Coordinator Public Relations & Press WECF International & the Netherlands (Utrecht)
Life Cycle Assessment of the PVC-free bag – Josefin Sjons, Environmental Scientist, Miljögiraff
The Future – Gustav Eriksson, Head of Environmental department at Karolinska University Hospital
Summary/Discussion/Future – Moderator Anna Longueville

The title of the seminar at CleanMed Copenhagen 20 October 2016 13.30-15 was
B5 | Innovation for sustainable healthcare products: Outcomes of the European PVC-free blood bag project
The short programme is
Welcome – Moderator Katarina Ryckenberg, CO
The project – a brief introduction and presentation of beneficiaries – Lena Stig, PM
In-vitro study of red blood cells stored in the new blood bags – Stephan Meinke PhD,
Life Cycle Assessment of the PVC free bag – Marcus Wendin, Environmental engineer and LCA expert, Miljögiraff AB
Next step - CE-labelling and market introduction – Alice Ravizza,
Concluding remarks and future scenarios – Lena Stig, PM
Question and Discussion

Since some of the results was not in place during the final seminars we arranged a webinar in May 2017. An external company was assigned in order to manage the technical part since the support and web platform within Region Jämtland Härjedalen. Annex 7.1.9 -10

5.2.12 Action 22 Concluding workshops

In action 22 we intended to hold four workshops and we also looked into the possibilities to attend the workshops virtually. We aimed for the concluding workshops to be in adjacent to meeting or conferences held by healthcare for example together with European Blood Alliance. The objective was to disseminate awareness and increase demand for a PVC-free blood bag for different target groups.
Project result and how to further introduce the new blood bag into the global market were presented.

The activities in this action were

- Lunch to lunch seminar in Östersund 28-29 September 2016
- Seminar and plenary presentation at CleanMed in Copenhagen 20 Oct 2016
- Presentation of the in-vitro studies at an International expert meeting in Transfusion medicine in Orlando 18-25 October.
- Dissemination of information and display of the new prototype bag at a fair in Düsseldorf 14-17 November 2016
- Poster presentation at Italian conference 6-8 April 2017
- Poster presentation at WHO Global Forum on Medical Device 10 May 2017
- Final webinar to summarise the result 30 May 2017

All presentations from the seminar in Östersund were recorded and are available at the website.[56]
It was a lunch to lunch seminar attended but several different organisations and the discussions were fruitful.

At the CleanMed Conference there was besides the seminar a presentation at Plenum with Petter Höglund representing demand and Jesper Laursen representing supply.

Hans Gulliksson attended the international expert meeting in transfusion medicine (BEST Collaborative) in Orlando, FL, USA in October 2016, this time to present the results of the in vitro RBC study. There was an interest from Sanquin, the national blood organisation in the Netherlands to test the polyolefin bags in connection with their ongoing studies to further develop new RBC additive solutions. The industry still seems to give priority to PVC plastic with a different plasticizer (DINCH).

Alice Ravizza presented a poster regarding "Human factors engineering and user-friendly design in the PVCfreebloodBag project." At an Italian conference 6-8th of April. Annex 7.3.19

Alice Ravizza and PM also took the opportunity to apply for and present a poster at WHO Global Forum on Medical Devices the 10th of May in Geneva. Several Contacts were made, for example with PATH, a catalyst for global health.

The Final webinar was sent the 30th of May at 13-14 CET.
The title of the webinar was *One step closer to a safe blood bag.*

Have we overcome the challenges?
How far away is a market introduction?
What comes after LIFE?

The speakers were
Petter Höglund, Professor, Karolinska University Hospital, Sweden
Alice Ravizza, The project's regulatory coordinator, Haemotronic, Italy
Lena Stig, Project Manager, Region Jämtland Härjedalen, Sweden
Moderator: Lisa Cockette, Anything English
Jesper Laursen, Pekka Weeraratne and Krzysztof Debski were available for questions together with the speakers above.

Lesson learned

28-29 September Östersund
The seminar was very successful although the number of participants were modest. As well as very professional and interesting lectures, the whole venue with locally produced food, historical surroundings and cultural evening events were much appreciated. Credibility to the LIFE project. The seminar were remembered and referenced to in several different networks and meetings around Europe.

[56] Link to presentation material from final webinars

We failed in reaching enough persons in the target groups of health care and decision makers. Over all during the whole project period these groups have been the most difficult to reach. It seems like they need more academic published results in their own channels and are less open for development and research outside their own sector. For the decision makers group generally, the publicity factor is of importance.

20 October Copenhagen

The seminar was held within the CleanMed Europe conference 19-21 October. The project hosted one the parallel seminars plus also had two speakers on stage in plenary. The parallel seminar was the best visited at conference. The project has worked consistently with the CleanMed audience for many years and it gave result. This time also outside the European sphere. It is positive to have many specialized speakers from the different parts of the project. To actually display the success of collaboration and working together from different fields and specialities.
The speakers in plenary also made a huge success as we stepped out of the box with traditional lectures and instead had one medical professor and one business director on stage in a dialog representing demand and supply.

18-25 October Orlando

In Orlando, 18-25 October adjacent to BEST Biomedical Excellence for Safer Transfusions/ISBT International Society of Blood Transfusions annual meeting Hans Gulliksson presented the result from the in vitro tests performed at Karolinska University Hospital. This seminar gave very good response in target groups we had not reached before. And this is a very important target group.
It was due to the many years of previous work with networking and sharing results, but of most importance has the work, contacts and the network of Hans Gulliksson been.
A determing factor was the publication of an article in Vox Sanguinis, which gave the project the chance to be present at the conference. Another factor for the good result is Karolinska University Hospital - that the study was performed there and that the publications authors were employed there.

14- 17 November Düsseldorf

This workshop was arranged and performed by the beneficiary companies which all attended the Compamed/Medica in Düsseldorf 14-17 November with over 5,000 exhibitors. It is hard to examine the results of this workshop. A lot of people within in contact with the industry were potentially reached. Maybe the event was too big. But the project think it was very good to show the good results and outcome from a very fruitful collaboration both between different companies from different countries and between the industry and European healthcare. The insight, knowledge and results from the project over the years has not only affected healthcare organisations but also the plastic industry.

WHO Global Forum on Medical Device

It would have been a very good opportunity to speak at this event. A poster was good, but in order to reach more potential partners for increasing demand or for production of bags in the future the plenary is the best place to be. The attendance resulted in several global contacts.

May 30 Final webinar

This was again a very good mix of speakers with different specialities and from different fields. It was a very good opportunity to make a resume of nearly all the achievement in

the project since it was only one month from the end of the project and also to open the doors for a after LIFE discussion.
We tried new technology which made it possible to, in an environmentally friendly way, reach participants from all over the world – which we did. But lack of technical equipment and technical support resulted in a lack of time to promote the webinar. Unfortunately the were a couple of webinars and conferences at the same time attracting the same target audience – but this will probably be common in the future as the number of interesting events increases with the digital development.

5.2.13 Action 23 Final report with payment request

The report has been written by the project manager, the communication officer and the financial officer with input from all beneficiaries.
The After Life Communication plan is attached as 7.3.28

5.3 Evaluation of Project Implemention

The first two (Project start and First seminar) of the six milestones in the project was achieved in time. The third milestone, Production of the first PVC-free prototype, was not be achieved in time. This is mostly explained by administrative reasons and organisation changes. See the table below. The deadlines for milestones 4-6 were revised after amendment number two.

MILESTONES OF THE PROJECT (Revised Part C after Amendment 2)

Name of the Milestone	Code of the associated action	Deadline	Achieved
Project start	1	01/09/2011	01/09/2011
First seminar	7	01/03/2012	08/02/2012
Production of the first PVC-free prototype	12-15	01/07/2012	01/03/2014*
First Evaluation of a prototype performed	16	31/12/2015	31/12/2015**
A non-PVC blood bag tested and approved according to the Requirements Specification	15,16,17	30/03/2016	30/03/2016** 27/03/2017
Final Workshops	22	01/05/2017	30/05/2017

*A bag was produced before March 2014, but design improvements to fulfill requirements for the evaluation was needed.
**The evaluation of the bag started with testing the properties, but the first storage study was finalised the 31/12/2015 and the second was finalised 30/03/2016. The user tests were performed later and the confirmation by the pre-audit of CE marking was ready in the end of March 2017.

The estimated milestone "A non-PVC blood bag tested and approved according to the Requirements Specifications" was expected to be achieved by 01/07/2014.
Production and evaluation of five prototypes were planned for, but a shortcut to gain time was possible. Setting the material specifications of the compound took longer than expected, but a thorough work for a high quality initially have increase than chances for sufficient quality bag earlier than estimated.

The chain of events causing the delay like domino bricks were several.

- There have been changes of personnel at Karolinska giving more work for new personnel and CB organising the Kick-off and changes of personnel at Totax giving further delays of the Partnership agreements.
- Wipak put their investments on hold waiting for the Partnership Agreement to be signed and thus film production did not start in time.
- In parallel the material specification took longer than expected, but they are important to get the optimal compound quality from the beginning.
- The earthquake in Italy at the end of May 2012 caused a lot of material damage for Beneficiary 6/Haemotronic in addition to the loss of four lives.
- The series of changes for production of tubings that started with a change in personnel followed by moving of the production from Denmark to Poland and finally the complete close down of Totax as a company. Primo Profile applied for an amendment replacing Totax completely from 2013 which was approved.
- The delivery of compound from Melitek to Wipak was delayed since the first production trial had to be run outside the company and thus a confidentiality agreement had to be signed before compound could be delivered.

Due to the delays the project requested amendment changing the Mid-term report from 30/10/2013 to 30/04/2014 which was approved by the EC in April 2013. The Mid-term report 30/05/2014 was not approved since we did not reach the threshold of 150% at consumption of the first pre-payment. Some of the reported cost items was considered ineligible or questionable without further justifications. The Mid-term report was delivered 30/09/2014

The progress report no 2 was delivered 28/02/2016 and included was a list with response to issues from the EC.

To the action list discussed at the PMG meetings one extra column has been added to see whether the activity was foreseen in revised proposal and plans or not. It is available in Annex 7.1.13. Most of the activities are presented more thoroughly in the section 5.1 and 5.2

In Part C[57], in the Grant agreement, revised in May 2015 each activity is described along with expected result. In the table below, we compare each action to the expected result.

[57] The link to Part C

Action	Expected result	Result and lesson learned
1 Project management	Project management will ensure the smooth running of the project and that necessary action is taken early if something goes wrong. The output will include agreements with sub-contractors with skills from substitution and the biopolymer industry, graphic design, proofreading and translation. A part-time project communicator will be recruited as a temporary employee. Life + Requirements and project goals fulfilled. Satisfied Commission as well as satisfied project members.	It has been very important to have a financial officer dedicated to the project. This is extra important in our public organisation, when PM is not allowed access to the administrative and financial system. The plan was to assign one before the start of the project. Unfortunately, the first financial officer at CB was employed half a year into project start. The second financial officer did a really good work but have not always been able to prioritize the project before other tasks. PM has performed tasks not intended for her. One major problem has been receiving timesheets and verification of costs from some of AB regularly. The commitment from all beneficiaries have been high.
2	The project website will be continuously updated. It will receive at least 50,000 visits during the project's lifetime. The companies' websites will be created within 6 months of the project's initiation. They will be updated at least twice before the termination of the project. There shall be at least three press releases in each of Sweden, Italy, Finland and Denmark, which will result in articles in newspapers. The total number of press releases is expected to exceed fifteen. Articles in magazines and other professional media will be an important mode of dissemination. They will target the medical sector, in particular blood treatment, environmentalists, plastics manufacturers, if possible focussing on food packaging specialists and public procurement experts.	The teamwork before the launch of the website was successful. We did not reach the number of visits that we estimated. Despite using google analytic from the beginning to track and count the visitors we have not been able to count for the whole period of the project. The first website was hijacked and therefore we needed to set up and secure a new website. All beneficiaries have been involved in media activities and most of them have improved their own websites during the project time. The number of press releases from CB have been 8 and then there have been press releases from the beneficiaries and 5 newsletters.
3	At least 15 notice boards. Attendance at three conferences.	The result has been more than been fulfilled. The project has attended three CleanMed conferences, WHO Global Forum on Medical devices and some more.

4	Good control of the project and continuous contact between the partners will be maintained through efficient, climate-saving meetings.	33 PMG meetings have been held. Only one of them have been in real life. Each beneficiary has reported progress and the protocol has been placed on the website two weeks after.
5	The project will work according to the project's plan and budget. Deviations will be identified at an early stage and subsequently acted on.	The monitoring protocol has not been updated every third months as expected, but the protocols from action 4 with a cumulating action list in the end of each protocol has been a good way for monitoring the progress.
6	150 people participating in the seminar	One new activity was added to this action and it was made with approval after a dialogue with monitor and EC. We procured an LCA consultant for performing and LCA and presenting it at the event.
7	The seminar will have 150 participants from a majority of EU countries. There will be representation from healthcare organisations, plastics manufacturers, public procurement experts and environmental NGOs. A European blood bag purchasers group will be constituted. It will act as a reference group to the project, in particular concerning the increase demand Action and the After LIFE+ dissemination activities. An additional dozen organisations will sign the petition for PVC-free blood bags within a month after the seminar. The project newsletter will get another 50 subscribers. There will be 10 extra subscribers to news from the CLIRE project.	The number of attendance was not as high as expected. We expected to get more help marketing the event from cooperation partner and we did not reach the target group. The quality of the event and the speakers' presentations were good.
8	Information, presentations or posters at each other's project events or websites. Attendance to provide information at one event per project and reciprocal attendance at our first seminar. A short and a long-term follow-up of the effectiveness of information about how to limit climate change according to the CLIRE project.	We have shared information and attended workshops and events with several Life+ projects and other organisations. We have had contact with CLIRE, but have not worked together with climate change. We have been focusing on increasing awareness and substitution of harmful chemicals.
9	Approved audit of the project.	We planned for an audit were the internal auditor would be responsible for the audit

		and that the other beneficiaries would send approved certificates to the auditor. It was not until the third monitor pointed out that this was not possible that we changed the plan. One external audit firm was procured since the internal auditor was not able to audit as planned.
10	During the project, 20 networking European organisations and 50 new organisations will sign the petition.	When we monitored the structure of transfusion medicine organisations, it became obvious that the way to reach our target groups were different than we thought. Member organisations of EBA expressed an interest to sign, but wanted the head of the organisation to go first. New organisations have signed the petition, but not as many as we wanted. The best way to increase awareness have been working with HCWH for a stronger regulation regarding medical devices. The project has been pointed out as in the forefront regarding safer blood bags which made EBA contact the project.
11	High quality production of 2 posters, 3 brochures, 4 invitations, 4 programmes and 2 reports	A number of high quality products have been delivered. However due to the last delay some reports have not been transformed to a printed format and printed.
12	Non-PVC compounds which are suitable for the production of blood bags, as per the requirements in ISO 3826-1:2003, and the compounds being reproducible at defined production parameters. An estimate of the price needed to pay for compounds that are produced on an industrial scale. Environmental data about this step.	Expected result fulfilled. To set the material specification was made very thoroughly and took longer than expected. Melitek has been a good advocate for PVC- free medical devices in general. Detailed information in section 5.1.1
13	Non-PVC film which is suitable for the production of blood bags and the film being reproducible at defined production parameters An estimate of the price necessary to pay for films that are produced on an industrial scale. A set of environmental data about the production of film.	Expected result fulfilled. Detailed information in section 5.1.2
14	Non-PVC tubing which is suitable for the production of blood bags	Expected result fulfilled. The change of beneficiary and the

	and which is reproducible at defined production parameters becoming possible and which meets regulatory requirements. An estimate of the price needed to pay for tubing that is produced at an industrial scale. A set of environmental data from production of tubings	following transfer of the production from Denmark to Poland was not foreseen and caused a delay in to different ways. Both a delay of the partnership agreement and later on a delay of tube production. Detailed information in section 5.1.3
15	Blood bags that fulfil criteria for internal use as subassemblies for set manufacturing and CE marking. An estimate of the price necessary to pay for blood bags that are produced at an industrial scale. Environmental data about the production of PVC- free bags	The scope of this action was changed in amendment into a larger and more detailed version. The first step of CE-mark was performed by an external firm and resulted in a gap analysis of what remains before a CE-marked product. Detailed information in section 5.1.4
16	One or two prototypes are recommended for further testing.	One prototype was evaluated with two different storage solutions. This prototype was recommended with improvements a more storage solutions. Detailed information in section 5.1.5
17	A thorough evaluation of the blood bags' performance with a positive outcome	The evaluation was made by user tests and an economic feasibility study. The outcome was positive, but there are still improvements to do. Detailed information in section 5.1.6
18	A plan shall be included in the final project report, action 23. The plan shall be implemented because of the benefits it offers the involved stakeholders, including project beneficiaries.	The basis for the plan and the method is different from the intended method. The beneficiaries have themselves discussed on the basis of the result in the project how to proceed with the next step. There are several actions available for promoting a market introduction of a new bag. Read more in section 5.2.9
19	A short and easily accessible report in both paper and electronic format at the end of the project.	A 10-page Layman report was launched in the end of the project, thus not in printed form. Read more in section 5.2.10
20	Publication in a scientific journal.	The in-vitro study was published in the scientific journal Vox Sanguinum
21	50 people registered for each workshop. Four workshops are needed in order to limit the number of participants to allow an interactive exchange about how to introduce PVC-free blood bags in European countries. Target groups are blood bag suppliers and healthcare organisations, as well as	The dissemination of the project result have been as part of five other conferences/ meetings with different target groups; Copenhagen; European healthcare Orlando; International Transfusion medicine Düsseldorf: Industry and healthcare Italy: National healthcare Geneva: Medical device, regulation,

	environmentalists and the people involved in public procurement. One of the workshops will be held in Sweden and the other three in strategic places in Europe in order to achieve good dissemination, while limiting the average travelling distance and thus the carbon footprint. The workshops will be one-day meetings incl. an evening social activity. Every beneficiary will be involved in the concluding workshops. Four key persons in four selected European countries will be asked to come to each workshop. They will be asked to present a strategy for how to facilitate the introduction of PVC-free blood bags in their country. These workshops will be organised as "green", climate-friendly events regarding transportation, facilities, food and materials. Exhibitors regarding other examples of phasing out PVC in health care will be invited, as well as other parties that are interested in this demonstration of a public procurement effort.	International Two events were hosted completely by the project: Östersund lunch to lunch Webinar 30 May The lunch to lunch event was recorded and thus reach a bigger audience. The same outcome is for webinar.
22	Four European international workshops attended by selected healthcare providers and European countries, as well as interested parties among plastics manufacturers and in public procurement. Reports on lessons learned from these workshops. 50 new organisations shall sign the petition for PVC-free blood bags. There will be an input to the follow-up of the CLIRE information at the first seminar.	The dissemination of the project result have been as part of five other conferences and meetings with different target groups. A lunch to lunch seminar. Lesson learned is that scanning of different opportunities is very important. To get organisations signing the petion has been more difficult than expected.
23	Approved report both in pdf and in print	In the original budget we had the final report within the time frame of the project. Most of the costs for writing it is now not eligible and the report will not be printed.

5.4 Analysis of long-term benefits

5.4.1 Environmental benefits

Since the volume of single use plastics and multiple use plastic in healthcare is very high, it is important to design new products, with non-toxic recycling, in mind. In circular economy material without hazardous substances should be avoided. It is an advantage to use a plastic such as polypropylene that do not need a plasticiser instead of using PVC.

This is also important to consider if one in the future wants to reduce the climate impact by using recycled material. Today fossil resources dominate the production of both PVC and PP. In 2017 the European Commission asked for consultation in regulating substances of concern in recycled material.[58]

A successful phase out of PVC blood bags would approximately reduce the amount of DEHP globally with approximately 2000 tonnes. Both PVC and DEHP is on Stockholm County Councils phase out list. DEHP is listed as a substance of very high concern in REACH[59]. PVC in itself may have impact on the environment in both production phase and waste. This includes release of heavy metals and phthalates and release of dioxines and climate gases during combustion.

The life cycle assessment compared the new bag's impact on the environment with the existing bag. The biggest difference between the two bags is due to whether the plasticiser, DEHP, is used or not. The LCA also indicates that there are ways to reduce environmental impact. Annex 7.2.3

The previous LCA[60] showed that since there is no need to clean smoke from waste combustion less contribution to climate change will be less.

Less impact on the environment from a life-cycle perspective,
Also, when looking into the aspects of recycling of materials it is an advantage to use a compound as free from hazardous substances as possible.

The volume of single use plastics and multiple use plastic in healthcare is very high. Designing new products, with easy and non-toxic recycling, in mind, would have on impact on circular economy.

The decision to have different regulations for chemicals in recycled materials than for chemicals in primary products is a key challenge for the circular economy, according to Echa's newly appointed head Bjorn Hansen.
A smooth transition to a circular economy involves "finding the balance" between materials that have a value and need to be recycled, and the hazardous substances in them that should be eliminated, Hansen said.
Echa has a dual role to play, he added, by "supporting the understanding of the hazardous properties of chemicals and also the uses of materials" across the supply chain "in order to enable the development of products and chemicals for a circular economy".

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[58] http://ec.europa.eu/smart-regulation/roadmaps/docs/plan_2016_116_cpw_en.pdf
[59] Registration, Evaluation, Authorisation and restriction of Chemicals
[60] Link to LCA 2012Link to LCA 2012

5.4.2 Expected long-term benefits

Besides the environmental benefits, the minimised patient exposure of potentially hazardous substances is regarded as the most important aspect in healthcare.
The youngest patients are the most vulnerable ones and there are other sensitive patient groups as those with chronical illness. We are all exposed to endocrine disrupters from multiple sources, but healthcare should not be one of these.
If we get rid of EDC's, in the long run we will have healthier populations and long-term healthcare costs.

In 2015 an updated scientific opinion[61] stated that exposure to DEHP may significantly exceed the tolerable daily intake (TDI) in some specific groups, including adult patients undergoing haemodialysis and.premature neonates in intensive care units (NICU)
Premature neonates in NICU and infants subjected to ECMO represent a high-risk population to DEHP exposure. The report is going through the current knowledge about plasticizers and also that the aggregate exposure from plasticisers from consumer products should be taken into account.

"Content of the opinion:
Use of PVC medical devices may lead to a higher exposure to DEHP compared to everyday sources affecting the general population. Examples of medical procedures with a potential for high exposure to DEHP are multiple procedures in preterm neonates, haemodialysis, heart transplantation or coronary artery bypass graft surgery, massive blood transfusion of red blood cells and plasma or peritoneal dialysis. The Opinion also focuses on these sorts of clinical procedures that result in high DEHP exposure.
Based on the available scientific evidence, SCENIHR considers that:
Adult patients undergoing haemodialysis have the highest exposure, due to the chronic nature of the treatment.
Children are potentially at higher risk, particularly neonates and infants due to their low body weight are particularly prone to high level of exposure on a body weight basis.
• There is evidence suggesting that DEHP causes the most severe reproductive toxicity in animal studies, when compared to other alternative plasticizers. There is therefore a strong need to develop and collect data on exposure of alternative materials in the actual conditions of use in order to refine the knowledge on their toxicological profile. The possibility of replacing DEHP with these products could then be considered, taking account the efficacy of the treatment as well as the toxicological profile and leaching properties of the alternative materials"
Also when considering circular economy material without harmful chemicals would be an advantage and the costs for handling waste would go down.

It would also lead to better working environment for both manufacturers and hospital employees.

Spin-off effects on other products such as tubings or treatments using disposable plastics means less overall exposure. This will be looked into in after life activities. We have discussed what kind of medical devices and treatments that are suitable.

[61] The safety of medical devices containing DEHPplasticized PVC or other plasticizers on neonates and other groups possibly at risk (2015 update) ISBN: 978-92-79-35606-3

When going for objectives number two and three in the next step, that is to

5.4.3 Replicability, demonstration, transferability

The project has demonstrated how to drive innovations towards non-toxic healthcare.
The pre-study identified potential problems regarding welding, the connection between tube and bag, and the choice of sterility method. These problems have been solved, but the user tests revealed that improvements are still necessary.

The success of the project depends on both cooperation and knowledge.

The four beneficiaries in the supply chain have been committed to produce a high-quality product and the evaluations and additional assessments have verified the quality and performance of the bag. A technical file based on data from all beneficiaries has been compiled by Alice Ravizza, who is the projects regulatory coordinator, before the pre-audit for CE-marking. The pre-audit confirmed the gap analysis performed by Alice Ravizza and pointed out was is left to do before market introduction.

Prior to the CE marking, it should be emphasized that further tests and validations will be required before the new polyolefin bags can be considered suitable for routine use. The plastic in the present blood bags, DEHP-plasticized PVC is quite inexpensive; suggesting that introduction of the new bags may be associated with increased costs. For this reason, future regulations of presence of hormone disturbing substances in medical plastics within the European Community may have a great influence on the introduction of PVC-free blood bags. On the other hand, concern has been expressed on the effects of large amounts of such substances on the safety of medical devices containing DEHP-plasticized PVC or other plasticizers on neonates and other groups possibly at risk (European Union 2015; ISSN:1831-4783: ISBN: 978-92-79-35606-3).
A possible initial approach might be to introduce the new blood bags for transfusion of patients within those specific risk groups and then gradually increase the use of the new blood bags to additional groups of patients.

We have looked into different partnership cooperation's and also possible future financial solutions. Karolinska University Hospital and some of the companies representing the supply chain are very interested to take the next step. Karolinska have

5.4.4 Best practice lesson

The survey about blood transfusion operations and procurement in Europe (Annex 7.2.5) indicates that Sweden is in the forefront demanding safer products for healthcare.

The project has been involved in strategy and policy work at EU-level towards non-toxic healthcare. The meetings and arguments from the project have resulted in a proposal that lead to new rules regarding medical devices. A stronger legislation indicating a future ban of endocrine disrupting chemicals and potentially hazardous substances will enhance the introduction of better alternatives. A strong legislation is a part of an increased demand.

Since the blood bag is considering as a complex and difficult product to introduce to the market, the method where demand and supply work together, in the project could facilitate for simpler products.

5.4.5 Innovation and demonstration value

The projects main objectives is to lower the barriers to market introduction of one of the more challenging products. The blood bag is a complex and life-saving product.
It should be able to store red blood cells and besides fulfilling quality requirements on blood components high material properties are required. For example, the bags should withstand centrifugation and differences in temperature.
Another challenge are the costs. What if the new product become very high?
The market analysis in the pre-study pointed out that a new product would not be profitable for the producers with investments and long lead times.
A lack of clear demand has also been a barrier to market introduction.
We have, with collaboration with

Using a new supply chain and working together with the demand side has been working well and could have a catalytic effect in continues work.

The economic feasibility study points out that there is no acceptable alternative to replace PVC/DEHP on the market.

An increased awareness of the benefits with safer products now raised the demand and that is an important factor

The spin-off effect to other product groups in healthcare is major. If the quality and properties is verified it would be easy to transfer it to "simpler" products.

The project was nominated in the category Innovation within Sustainable Healthcare prior to the premier of Nordic Conference on Sustainable Healthcare in February 2017. Three actors, in three different categories, was awarded for showing – via their sustainability work – that it is possible to make a difference.

At the conference the PM was also invited to speak, which she did in the seminar section B:4 Projects that push the envelope.

Constant incremental improvements are not always enough – sometimes a paradigm shift is necessary. The session highlights projects in the Nordic region that represent real progress: a new hospital, a strategy for comprehensive energy-efficient renovations of existing building stock, and much more to inspire new thinking.

- Gustav Eriksson, environment director, New Karolinska Solna University Hospital
- Kristina De Geer, environmental strategist, EU LIFE+ project Climate Friendly Health and Care, CLIRE
- Lena Stigh, project manager, PVCfreeBloodBag
- Hulda Steingrimsdottir, Environmental Coordinator Landspitali /The National University Hospital of Iceland

The project has also been mentioned as the forefront as the only project working for a safer blood bag without PVC. European Blood Alliance invited PM and a representative from Haemotronic to a meeting to present the project because of that.

PM has been invited to speak at a conference about Medical Device in November 2017 and will attend the workshop about medical devices at the EP the 6th of November.

6. Comments on the financial report

The overall total in the budget remains the same, but the original budget is changed following Amendment 2. The foreseen costs per beneficiary has changed.

There has been a change in personnel regarding the financial officers at Coordinating Beneficiary. Linda Andersson was the financial officer until August 2015 and when she left the organisation Maria Arnstål was assigned as financial officer. Arne Nilsson as supervisor has been responsible for the whole project period.

6.1. Summary of Costs Incurred

PROJECT COSTS INCURRED				
	Cost category	Budget according to the grant agreement*	Costs incurred within the project duration	%**
1.	Personnel	1 342 551	1 365 444,68	101,71%
2.	Travel	112 230	41 289,52	36,79%
3.	External assistance	205 365	139 171,9	67,77%
4.	Durables: total non-depreciated cost	115 000		
	- Infrastructure sub-tot.			
	- Equipment sub-tot.		33 333,00	28,99%
	- Prototypes sub-tot.			
5.	Consumables	235 867	77 808,40	32,99%
6.	Other costs	49 234	9 854,57	20,02%
7.	Overheads	144 217	115 516,47	80,10%
	TOTAL	**2 204 464**	**1 782 418,90**	80,85%

– *) If the Commission has officially approved a budget modification indicate the breakdown of the revised budget Otherwise this should be the budget in the original grant agreement.
– **) Calculate the percentages by budget lines: e.g. the % of the budgeted personnel costs that were actually incurred

6.2. Accounting system

The coordinating beneficiary Region Jämtland Härjedalen uses two systems to manage the economy. For salaries and other costs incurred by the staff, i.e. subsidies and other, the system employed is called Heroma. For other costs, the Region Jämtland Härjedalen uses Raindance accounting system. Accounting information is transferred into Raindance from Heroma every month when the salaries are paid.

To manage invoices, Raindance uses a web-based application for viewing, approving and post costs. This allows only the superiors to approve invoices and it is possible to follow an invoice from the arrival to Region Jämtland Härjedalen to the actual payment date. It's easy to search an invoice by supplier, date, invoiced amount etc. The portal allows the staff to view and follow up on the economy in their own area of work.

All suppliers to the project are encouraged to mark their invoices with the reference LIFE10 ENV/ SE/ 000037- PVCFreeBloodBag. Region Jämtland Härjedalen employ invoice scanning and our routines demand for our supplier to use a special invoice address to our scanning supplier and mark the invoice with our reference.

Region Jämtland Härjedalen runs many different projects at the same time. Therefor we use a unique internal project code for every project, it allows us to follow up on all our different project at all times. PVCfreeBloodBag's internal code is 4563 and that is searchable in Raindance and in the portal.

Time reports are written every month by the employee and later approved and signed by the superior in question. The administration will thereafter post the salary cost into the project code in the economic system. We use manual time reports on paper that are archived every month.

6.3. Partnership arrangements

The partnership agreements were delivered to the Commission on 12 July 2012. The revised agreement (based on the Grant Agreement amendment approved on 6 December 2013; the inclusion of the Primo Co. as a new partner) was delivered to the Commission on 24 March 2014.

The project has a project management group with participants from all beneficiaries.

There are no financial transactions between the beneficiaries. The coordination beneficiary transferred the beneficiaries' share of the first advance payment and the second payment after Mid-term report was approved.
The partnership agreement says that timesheets shall be delivered according to instructions regularly.

In general originals are kept at each beneficiary and they are traceable to the project. Scanned timesheets and copies of invoices are sent to coordinating beneficiary.
The financial officer at coordinating beneficiary are compiling financial data for each beneficiary.

There has been delays in the financial reporting from some of the beneficiaries. The coordinating beneficiary has repeatedly sent remainders to those concerned, with various result. If we would have applied for a project like this once more, we would arrange the partnership arrangements differently. Some of the private beneficiaries have expressed that it would have been easier to invest money in the project instead of time. There is absolutely no lack of commitment from the companies, but they want to focus on solving problems instead of doing the paper work. A lot of their input in the project is not visible in the financial reports since they rather do things than report them.

6.4. Auditor's report/declaration

The CB's auditor of choice has after procurement been Ernst & Young. Request for Offer and Agreement is found in Annex 7.2.2-3
The independent audit report is attached as 8.22

The auditor firm visited Coordinating Beneficiary in Östersund, Melitek in Denmark and Wipak in Finland.

7.Annexes

7.1 Administrative annexes

7.1.1 A list of administrative annexes already submitted to EC
7.1.2 Gant scheme: Action time plan
7.1.3 Agreement and Offer regarding Organisation of First seminar Action 6, 2012
7.1.4 Assignment Economic Feasibility Study
7.1.5 Agreement Economic Feasibility Study
7.1.6 Request for Offer LCA 2 Dnr RUN/322/2016
7.1.7 Agreement LCA 2
7.1.8 Agreement Critical Review of LCA 2
7.1.9 Offer from WEZUPPORT Dnr RUN/353/2017
7.1.10 Agreement Final webinar Dnr RUN/353/2017
7.1.11 Request for Offer Audit
7.1.12 Agreement Audit
7.1.13 Action list from PMG meetings
7.1.14 Agreement between Haemotronic and Alice Ravizza

7.2 Technical annexes

7.2.1 List of keywords and abbreviations used
7.2.2 First Life Cycle Assessment 2012– submitted before as a Deliverably on 30/03/2012
7.2.3 Life Cycle Assessment April 2017
7.2.4 Critical Review of LCA
7.2.5 Monitoring of blood transfusions operation in EU-countries October 2015
7.2.6 Checklist User tests
7.2.7 Compilation of user test result
7.2.8 Vox Sanguinis (2017) 112, 33–39
7.2.9 Pre-audit report Gap analysis of CE marking
7.2.10 Economic feasibility study

7.3 Dissemination annexes

7.3.1 A list of dissemination annexes submitted before final report
7.3.2 Layman report in English
7.3.3 Layman report in Spanish
7.3.4 Layman report in Italian
7.3.5 Layman report in Danish
7.3.6 Layman report in Swedish
7.3.7 Layman report in German
7.3.8 Layman report in Polish
7.3.9 Layman report in French
7.3.10 Layman report in Finnish

7.3.11 YouTube PVCfreeBloodBag, January 2016
https://www.youtube.com/watch?v=ckGj1yKaZzw&feature=youtu.be
7.3.12 Recordings of presentations at seminar Östersund, September 2016
https://vimeopro.com/user8683870/pvcfreebloodbag
7.3.13 Moving pictures: User tests https://vimeo.com/199819084
7.3.14 Webinar together with HCWH, October 2015 link https://noharm-europe.org/issues/europe/edcs-pvcfree-blood-bag-webinar
7.3.15 Webinar Jesper Laursen Melitek, November 2016 https://noharm-europe.org/issues/europe/webinar-new-medical-devices-regulation-engine-edc-substitution
7.3.16 Final webinar 30 May 2017 link: http://www.pvcfreebloodbag.eu/?page_id=1276

7.3.17 Newsletter 4 April 2016
7.3.18 Newsletter 5 Jan 2017
7.3.19 Abstract Italian congress 6-8 April 2017
7.3.20 Presentation held at NCSH February 2017
7.3.21 Poster WHO Geneva 10th of May 2017
7.3.22 Presentation held at HCWH AGM 4-5 May 2017
7.3.23 Programme Final seminar Östersund
7.3.24 Programme B4 Seminar 20 Oct 2016 at CleanMed Europe Conference
7.3.25 Picture Collage Östersund
7.3.26 Picture Collage Copenhagen
7.3.27 Pictures from Düsseldorf
7.3.28 After Life Communication plan
7.3.29 Press release 23Sep 2016
7.3.30 Press release 18Oct 2016
7.3.31 Handout 2016
7.3.32 Handout Result
7.3.33 Poster Result
7.3.34 A list with news published on the website

7.4 Output Indicator Table