LIFE10 ENV/SE/037

MIDTERM Report
Covering the project activities from 01/09/2011 to 31/08/2014

Reporting Date
30/09/2014

LIFE+ PROJECT NAME or Acronym
PVCfreeBloodBag

Project Data

Project location	Sweden, Finland, Denmark, Poland, Italy
Project start date:	01/09/2011
Project end date:	31/03/2016 **Extension date:** n/a
Total Project duration	55 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/ Regional Council of Jämtland
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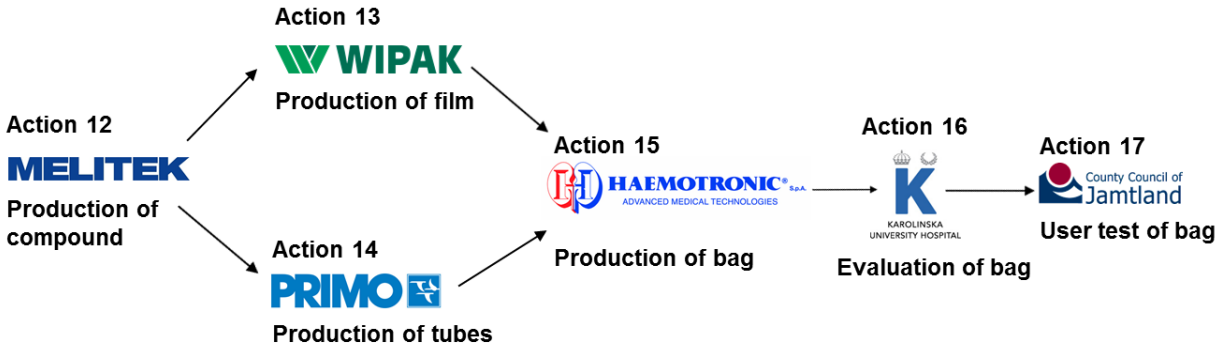
1. List of contents

2. Executive Summary

The project will demonstrate that is possible to produce a PVC-free blood bag that fulfils requirement specification, including CE-labelling. Four companies representing the links in the supply chain are producing the new bag and Karolinska University Hospital is responsible for evaluating the bag.



Melitek in Denmark are making the compound which is needed in both film and tubings. The compound is delivered to Wipak in Finland who have produced film in both trials and regular production. Primo Profile in Poland are producing tubings from the same quality of compound. Wipak has delivered film to Haemotronic in Italy and Primo will send redesigned tubings to Haemotronic in June. Haemotronic has produce the first prototype of a blood bag. The prototype bag has then been re-designed to be better adopted to the in vitro evaluation. The evaluation is ready to start, but some minor obstacles have to be solved before it could start.

To facilitate market introduction of the new bag an increased demand is necessary. This will be achieved through cooperation and dissemination of information within European healthcare.

The life cycle assessment presented at the kick-off seminar highlighted the benefits of a fictive polyolefin bag compared to a bag made of PVC and DEHP. The Scientific Committee on Emerging and Newly Identified Health Risks requested a new scientific opinion “On the safety of medical devices containing DEHP (di (2-ethylhexyl) phthalate) plasticized PVC on groups possibly at risk.” with a reference to the LCA. Hans Gulliksson from Karolinska was invited as a member of the expert committee.

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.

The first two of the six milestones in the project was achieved in time, but the following three milestone will be not achieved in time. 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 estimated milestone “A non-PVC blood bag tested and approved according to the Requirements Specifications” was expected to be achieved by 01/07/2014. The most recent estimated date for an approved prototype bag is 01/03/2015 which means a delay of 8 months.

Production and evaluation of five prototypes were planned for, but a shortcut is possible if the project succeed in reaching the milestone with one or two prototypes. 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 shortcut will also reduce the amount of money spent on production and evaluation.
If the milestone of an approved bag is reach there are different possibilities to direct budget resources to different activities.

- Investigate different opportunities for clinical testing to enhance and facilitate market introduction of a PVC-free blood bag. There might be a project to apply that encourage clinical testing of medical device. This option is suitable for the companies in the supply chain and should be led by Haemotronic.
- Increase the effort to create a big buyers group in European healthcare.
- Act more in dissemination of information on why and how to demand non-toxic products. For example more visits to healthcare organisations together with beneficiaries.

The project’s objectives are still intact and the prerequisites for success remain in place.

As explained above the duration of the project depends on how many prototypes we need to evaluate before a satisfying prototype is found. The full consequences of the delays to the project are yet not known yet, but we will apply for a prolongation of 6-12 months. The status will be more apparent after the first bag evaluation and the decision to apply for an amendment to prolong the project will thus be made later.

When we apply for prolongation of the project a fast response would facilitate the planning of the final workshops. Setting the dates in a long period before the actual workshops is of outmost importance to achieve high attendance and hence dissemination of information.

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 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 consist 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 prestudy, 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 by 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 by blood storage studies by Karolinska University Hospital. Jämtland county council is 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 expect to have a PVC-free prototype bag that fulfils requirement specification, including CE-labelling.
An economic feasibility study and estimate of the benefits of a 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.

Additional objectives is to open up for the use of the new material in other medical applications and also an alternative material for food contact applications.

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

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.

4. Administrative part

4.1 Description of the management system

Regional council of Jämtland is responsible for administration. The project manager together with communication officer, economist and support from IT and administration take care of management and dissemination of information including documentation and contact with public bodies. Coordinating beneficiary monitor the progress of the project and report to the commission.

Documents regarding procurement, agreements, grants and similar are archived in the diary and other documents at the servers for Regional council of Jämtland. The project web site www.pvcfreebloodbag.eu is used as a project platform for all documents except working documents and technical reports from beneficiaries to CB. Instructions on how to report costs and time are on the web site as well as minutes from meetings. They have been revised and updated once after remarks from the EC.
Examples of a timesheets are attached as Annex 7.1.5.

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. Expected is that the project will work according to plan and budget and that deviations are acted on. A monitoring visit by EC was made 4 April 2014.

The project management group (PMG) consist of representatives from all beneficiaries and have 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. There have been 13 PMG meetings so far. Due to problems with the on-line meetings regular telephone meetings have been held from meeting number 8 and onward. Operations manager, Maria Tengvall Linder and unit manager of Transfusion Medicine Karolinska, Beatrice Aspevall Diedrich, will follow the progress of the project via the PMG meetings from June 2014.

The Partnership Agreement was signed on 15 May 2012 and the shares were distributed according to the partnership agreement. One amendment to the Grant Agreement has been approved an additional beneficiary to take over responsibility of making the tubings. The partnership agreement has therfor been revised in the beginning of 2014 and is valid from 01 January 2013. This revised Partnership agreement was submissioned to the commission 24 March 2014.

The project manager have visited three of the beneficiaries so far to learn more about their business and activities in the project. The companies representing the first steps in the supply chain, Melitek, Totax/Primo and Wipak was visited first. PM visited Melitek in October 2012, Totax/Primo in November 2012 and Wipak in March 2014. On the visits project-related issues of reporting time and costs are discussed. PM look at the production facilities including monitoring, quality control and waste management.

PM visited Karolinska in order to present the project to new project members at Transfusion Medicin and to discuss how to best replace Inger Johed who retired in April 2014.

The former monitor Diderick Velthoen visited CB on 24 May 2012 and the new monitor, Pekka Hänninen has visited Östersund on 22 August 2012, 4 November 2013 and 4 April 2014.

There are 23 actions in the project and 15 of these have started. The seven actions highlighted in green are the projects core actions.

Nr	Action	Status
1	Project management	On-going
2	Web site and media work	On-going
3	Notice boards and dissemination of project information	On-going
4	Project meetings for the Project Management Group	4 times per year
5	Monitoring the project's progress	On-going
6	Organisation of first seminar Action 7	√
7	First seminar – Kick- off in Copenhagen	7 Feb 2012
8	Networking with other projects	On-going
9	Audit	Start in July 2015
10	Increase demand	On-going
11	Production of brochures, reports, posters, invitations etc	On-going
12	Production of compounds for film and tubes used in blood bags	Delivery On-going
13	Production of film for the blood bags	Delivery,on-going
14	Production of tubes to be used in blood bags	Started
15	Production of a PVC-free blood bag	Started
16	Evaluation and monitoring of blood bags by Karolinska	Delayed
17	User test including economic feasibility study of PVC-free blood bag	Delayed
18	After-LIFE Communication plan	Start in Oct 2014
19	Final layman's report	Start in Oct 2014
20	Technical publication based on the evaluation results of blood bags	Delayed
21	Organisation of concluding workshops action 22	Not started
22	Concluding workshops	Delayed
23	Final project report	Delayed

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.

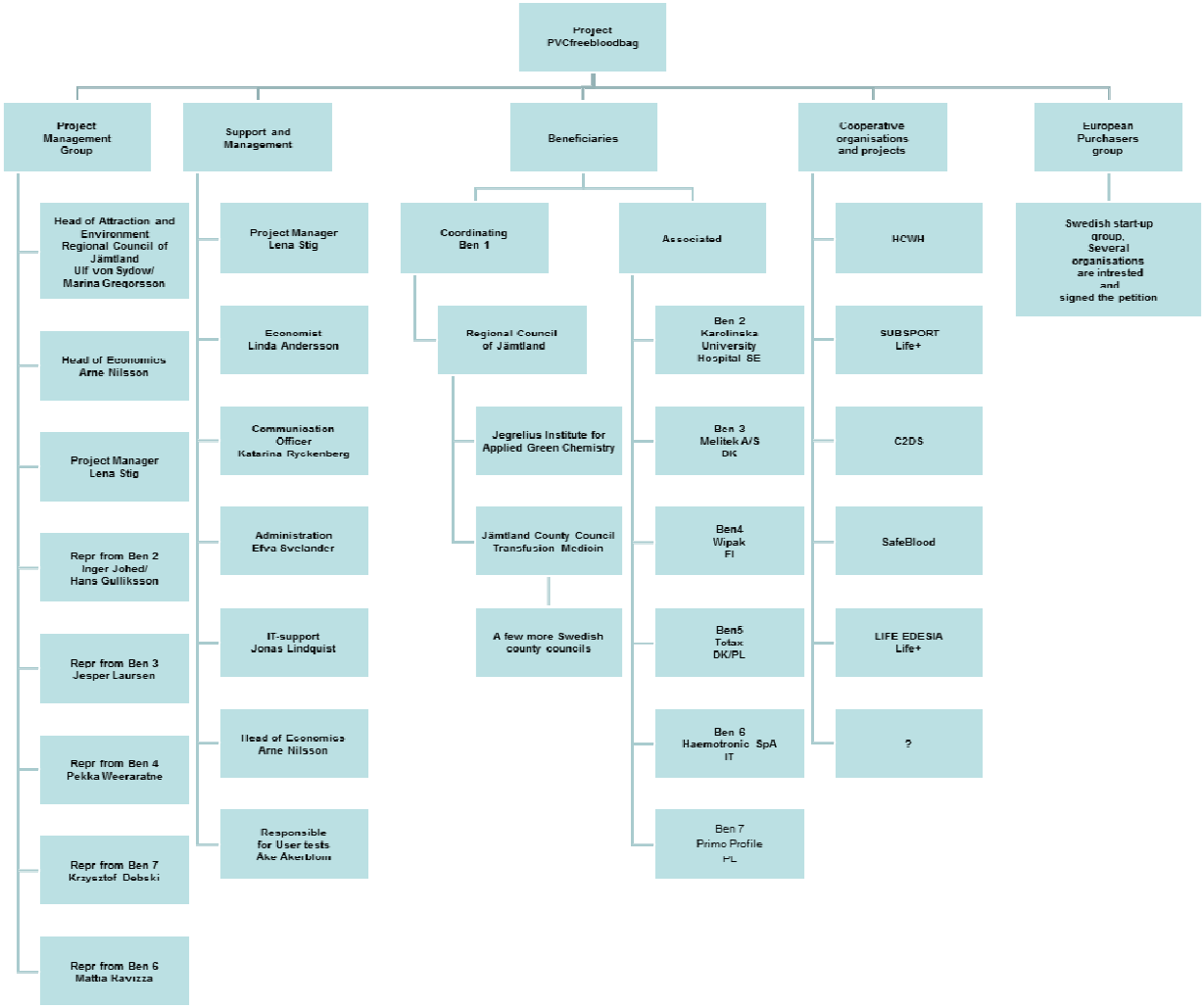
The requested amendment changing the delivery of the Mid-term report from 30/10/2013 to 30/04/2014 was approved by EC. Due to the postponed delivery of the MidTerm report we suggest that the next progress reports delivery date is postponed to 01/11/2015.

Deliveries	Delivered	Original deadline
– Project website	21/10/2011	(01/10/2011)
– Notice Boards	18/11/2011	(01/11/2011)
– A plan for the implementation phase		(01/12/2011)
– Monitoring protocol	27/03/2012	(01/12/2011)
– Initial Report	21/03/2012	(30/11/2011)

- LCA of PVC blood bag* 23/03/2012
- Presentation of the LCA 08/02/2012
- Inception Report 30/03/2012 (01/04/2012)
- Progress Report 30/09/2012 *not to EC* (01/08/2012)
- Progress Report 1 01/02/2013 (01/02/2013)
- Mid-term Report 30/09/2014 30/10/2013
- Progress Report new suggestion 31/12/2014
- Audit result 01/10/2015
- Technical report 01/01/2016
- Publication of the technical report 01/01/2016
- Final Layman's report 01/03/2016
- Final Report 01/03/2016

* This is an additional deliverable to support Action 6 and 16

The project organisation



Organogram of project organisation

The management team consists of

Project Manager	Lena Stig
Head of Economics	Arne Nilsson
Economist	Linda Andersson
Administrator	Efva Svelander
Communication Officer	Katarina Ryckenberg
IT Support	Jonas Lindquist

Responsible for User Test: Åke Åkerblom at Jämtland County Council

The PMG consists of
Head of Attraction and Environment/Region Council of Jämtland,
Ulf von Sydow/Marina Gregorsson (shared leadership)
Head of Economics Arne Nilsson
Project Manager Lena Stigh
Hans Gulliksson and Maria Tengvall Linder represent Beneficiary 2, Karolinska
Jesper Laursen represents Beneficiary 3, Melitek
Pekka Weeraratne and Jouni Vikman represent Beneficiary 4, Wipak
Krzysztof Debski represents Beneficiary 7, Primo
Mattia Ravizza and Ettore Ravizza represents Beneficiary 6, Haemotronic

The European Buyers Group/ Demand Group
This group originates from the Swedish group of healthcare organisations and will expand through activities in Action 10 – Increase Demand.

Cooperation organisations
HCWH, Health Care Without Harm
Life+ Project SubsPort with Swedish representation from ChemSec.
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
LIFE-EDESIA, LIFE+12 ENV/IT/000633

From 1 January 2015 The Regional Council of Jamtland will merge together with Jamtland County Council into the new Region Jämtland Härjedalen. The management team will be the same, but the organisation number will be changed.

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 changes the economic system and routines, which means 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 have visited CB on three occasions and been of great support regarding administrative details in the project.

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.

The lead times for getting information both from associated beneficiaries and the commission have sometime 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.

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.

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.

5. Technical part

5.1. Technical progress

The core actions in the project is production of the bag divided in four steps followed by the evaluation of the bag. To increase demand is also a core action, but a part of dissemination of project information as well and therefore dealt with in section 5.2.

5.1.1 Action 12 Production of compound

Expected result in this action is a non-PVC compound suitable for production of blood bag according to ISO 3826-1:2003. A price estimate for the compound in industrial scale will be calculated. When the final compound is choosen environmental data will be collected to make a simplified life cycle assessment of the new bag compared with the existing PVC/DEHP bag.

In order to produce compound assessment of raw material, planning and preparing trial and production-scale compound manufacturing is needed. The compound is beeing 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. Wipaks 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.

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. This also makes flexibility and small scale tests necessary.

Most activities and indicators of progress are under control. Melitek made an effort to find good quality compound with lowest price possible. When the final compound have been selected a technical data sheet will be prepared, a collection of environmental data completed and a cost estimation made.

5.1.2 Action 13 Production of film for blood bags

A reproducible film with mechanical and barrier properties suitable for a blood bag is expected. Expected is also a cost estimate for the industrial scale product as well as a collection of environmental data. 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 had to be 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 correspond to the material composition. Later project manager 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 have decreased due 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 have a PVC-free policy.

Activities left to do are analysing monitoring results for preparing technical data sheet, external testing of film to fulfil regulatory requirements , a cost estimation of and collection of environmental data.

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

Expected result is reproducible non-PVC tubings that fulfill regulatory requirements. A price estimate for the tubings at an industrial scale and environmental data of the production is also expected.
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 Poland in November 2012 to go through the changes and get confirmation of their commitment. Krzystof Debski and Primo Profile was very interesting in taking over 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.

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 is going to be made. After additional design discussions of the bag in April and June 2014 further changes of the tubings were made.
First delivery of tubes to Hamotronic for production of bags will be in September 2014.

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.

Krzystof Debski visited CB in Östersund in 8 January 2014 where he met PM and the project economist Linda Andersson to go through time sheets and he was the first to sign the revised partnership agreement. The production activities started are reception and storage of raw material, pre-production activities as planning, preparing and purging, extrusion for reaching stable production process conditions and QC. Next activities are delivery of the first tubes to Haemotronic, 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.

5.1.4 Action 15 Production of a PVC-free blood bag

Blood bags that fulfil CE criteria are expected as well as a price estimate based on data from Melitek, Primo and Wipak. Environmental data for the life cycle assessment is also expected.
Before production of the bag take place product and quality requirements are defined. The best methods for welding and general manufacturing has to be set.
The prototype bag is produced of the film from Wipak and tubing from Primo. Prototype bags are sent to Karolinska for evaluation. The bag is 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.

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 fulfill delayed obligations to customers.

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 are first priority. Chemical and physical properties have to be 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 in June. Alice Ravizza visited Karolinska University Hospital the 13 May 2014 to verify the design of the bag. The scope of the production was changed and different options were investigated in parallel in May, June and July. There have 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.

PM will visit Haemotronic when production of the prototype has started in full scale. However, the monitor Pekka Hänninen paid Haemotronic a visit in 2013 monitoring their time and cost reports.

5.1.5 Action 16 Evaluation and monitoring of blood bags

Expected result is one or two prototype bags suitable for storing blood components and recommended for testing CE-criteria. The result will be compiled for a technical report. The evaluation means storage tests using blood and standardized laboratory techniques. Two prototypes may be tested simulaneously.

Method work and promising tests have been performed, but tests on the actual prototypes have been delayed as a consequence of the delays in actions 12-15.

Pre-laboratory work and training has started. Preparation for in vitro red cell storage studies in blood bags manufactured from non-PVC plastic has been performed. Trained members of laboratory staff are available.
An agreement with external company (Fenwal Inc) regarding supply of specific red cell storage solution has been signed. CB helped out by providing legal help concerning the agreement between Karolinska and the company delivering the storage solution. PM wanted to secure that the agreement was in compliance with Common Provision, Grant agreement, Partnership Agreement and Public Procurement Act.

Delivery of bags for first trial evaluation is estimated to take place in September. Some technical issues have to be solved before the in-vitro studies start. First in-vitro evaluation has therfore been moved to January 2015. This means that the first results may be available in March 2015. Personell who was going to perform the in-vitro tests will be on maturnity leave. New personell will be recruited for the task.

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.

5.1.6 Action 17 User test including economic feasibility study

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 also expected.

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

Jämtland County Council will perform and be responsible of the user tests. They will start to set up user test protocols with other county councils in Sweden as soon as the evaluation is within reach. The protocol from the user tests will be circulated for approval from other Swedish county councils that are willing to do tests. Uppsala, Värmland and Region Skåne are among those that are interested.

PM is responsible for the economic feasibility study.

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.

5.2.2 Action 2 Website and media work

More than 50 000 visits on the web site is expected and that is tracked using Google analytics. Articles in newspapers or magazines are expected as well as press releases in each of the beneficiaries' countries. The target audience group is in the medical sector in particular in transfusion medicine and plastic industry.
The project's web site www.pvcfreebloodbag.eu is used for communication and documentation. Press releases, reports, news, information and minutes are examples of 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 web site and all beneficiaries have information about the project on their own web sites.
Haemotronic has launched a new and improved company website as well as Primo.
Wipak have sent out a newsletter including project information,

The software Joomla was chosen for the web page in order to get support from Regional council of Jämtland. The web site have been hacked several times from the autumn 2012 the web site is being transformed to WordPress and placed in a web hotel.

News published on the website are listed below

- Final report from the pre-study
- Project web site launched 2011
- Sucessful Kick-off seminar 2012
- Attendance innovation day, Sundsvall
- Presentations at regional transfusion medicine days in Örebro, Sweden
- Life Cycle Assessment of PVC blood bag ready
- PVCfreeBloodBag will take part in CleanMed in Malmö
- Visit from monitor 24 May
- Life+ 20 years! Celebrate and walk with us
- Meet us at CleanMed Europe
- The project included in a publication by the Danish eco council
- Our comments on the LCA
- CleanMed SUBSPORT workshop
- CleanMed PVC replacement strategies in healthcare
- Project presentation for a non-toxic environment
- Article in Medical Plastic News
- Melitek presented by the Danish Ministry for Science, Innovation and higher Education.
- France bans the use of tubing containing DEHP in certain hospital wards
- Important movie release 2013

- Briefing article about substitution
- Project Manager invited to the European Parliament
- New study from Baltimore on storage of blood
- Towards non-toxic healthcare – Brussels meeting
- Newsletter Nr 2
- Poster at CleanMed 2013
- Well visited poster presentation in Oxford
- Collaboration with C2DS
- Procurement with environmental and social focus
- Looking forward meeting LIFE-EDESIA
- Victory-European Parliament favours a ban on hazardous chemicals in medical devices
- Krzystof Debski visits Östersund
- Visit to Finland
- Monitoring visit from the European Commission

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 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. We agreed on that the study and the results only complement the SCHENIR report (Scientific Committee on Emerging and Newly Identified Health Risks) and that the study is in line with project objectives.
http://www.pvcfreebloodbag.eu/index.php?option=com_content&view=article&id=165:our-comments-on-the-lca&catid=19:nyheter&Itemid=28

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 requested a new scientific opinion "On the safety of medical devices containing DEHP (di (2-ethylhexyl) phthalate) plasticized PVC on groups possibly at risk." with a reference to the LCA. Hans Gulliksson from Karolinska University Hospital/Beneficiary 2 was invited and became a member of the expert committee.

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. A link to the article is among the news.

Media activities by Melitek have resulted in a part of a publication from the Danish eco-council about the substitution of hazardous substances. 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 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 is being produced for education at nursing schools. Both blood bags and the hazardous PVC/DEHP are topics covered in the film.

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 made through action 2,6,7,8,10 and 11 so far and later in action 18- 23.
The notice boards describe the project and are disseminated to public bodies, institutions, organisation and at conferences.
Communication channels have been seminars, press releases, mail, telephone, LinkedIn and the website. We target the Red Cross, European Blood Alliance and the NHS.

All beneficiaries have had project information on their web sites. Haemotronic and Primo has launched new and improved company websites which will make it easier to disseminate information.

Beneficiary 2/Karolinska:
http://www.karolinska.se/en/Departments/Administration/The-Department-of-Environment/PVC-free-blood-bags/
Beneficiary 3/Melitek:
http://www.melitek.com/PVCfreebloodbags
Beneficiary 4/Wipak:
http://www.winnovations.wipak.com/project/non-pvc-bloodbags

On a regional level PM attended an 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.
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, 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.

In CleanMed Europe 2013 we attended with a poster about the benefits of a new blood bag.

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.

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 softeners.

Two newsletters have been sent out. The first one targeting healthcare with a survey of estimation of the number of blood bags and number of transfusions made in Europe attached. This will also give more input to the mapping of European healthcare and those organisations that buy blood bags.

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.

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.
Copenhagen was chosen and a survey of suitable conference facilities was made.
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 was held at the National museum of Copenhagen the 8 Feb 2012.
The programme is attached as 7.3.5. Monitor 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.

There were over 50 participants at the seminar and among them representatives from the plastic industry indicating interest of our project. However 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 ourselves. In public organisations plans for conferences often have to be taken 6 month in advance. During the time around the seminar the number of visits on the web site increased. The presentations from all speakers are provided at the website.

5.2.6 Action 8 Networking with other projects

Expected result is an exchange of information and cooperation with four identified Life+ projects.

CleanMed made new opportunities for networking with other projects. PM and CO attended the Life +SUBSPORT workshop.
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 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 try to change to other softeners, Canada avoid it as much as possible.

PM was invited as a speaker to the Kick-off in October 2013 for a Life+ project with similar objectives. 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 will be part of the panel following the project.

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 Devises.

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.
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 will continue. 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, 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 are initially targeting the Red Cross, European Blood Alliance and the NHS. A working document with countries, organisations and contact information is being used and updated. Statistics from WHO and EC have been searched for, but so far results are scarce.

Around 500 000 blood bag units are purchased every year in Sweden
In Finland the number of bags are 250 000.

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

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 Katarina Ryckenberg, Communication Officer, Jegrelius Institute for Applied Green Chemistry.
The five lectures which also are on our web site 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"

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.
CleanMed gave contacts with United Nations Development Programme, WHO, Ecological Physicians Society/German Affilitae of ISDE, along with some others.

The LCA gave general information about the difference between PVC and Polyethylene in the disposal phase, but we are searching for more statistics on the number of purchased blood bags in Europe and the number of blood transfusions carried out.

The LCA resulted in media attention.

The EC mentioned the LCA as one of the reasons for getting a new scientific opinion on DEHP in medical devices. Hans Gulliksson was invited and accepted to be a member of the committee.

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 22 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.
http://www.pvcfreebloodbag.eu/index.php?option=com_content&view=article&id=188:victory-european-parliament-favors-a-ban-on-hazardous-chemicals-in-medical-devices&catid=19:nyheter&Itemid=28

The project will continue 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.

5.2.2 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.
The CleanMed presentation is on the website..
Material is attached as annexes 7.3.1 to 7.3.18

5.2.3 Actions to come - Action 18-23

Next action to start with, action 21, is the planning and organisation of the concluding workshops. As learned from the First seminar it is important to set a date early to get high attendance. Professionals will be 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 will be discussed in PMG meetings. Setting the dates in a long period before the actual workshops is of outmost importance of the attendance, and hence dissemination of information. When we apply for prolongation of the project a fast response will facilitate the planning of the workshops.

In action 22 there will be four workshops and possibilities to attend the workshops virtually will be looked into. We will also aim for the concluding workshops to be in adjacent to meeting or conferences held by health care for example together with European Blood Alliance. The objective is to disseminate awareness and increase demand for a PVC-free blood bag. Project result, lesson learned and how to, via clinical testing, further introduce the new blood bag into the global market will be presented. One of the workshops will be held in Sweden.

The result from evaluation of the blood bag by Karolinska will be reported as a technical report, action 20, and if sufficient quality is obtained it will be published in an adequate scientific journal.

As action 18, an After-Life communication plan will be written with the objective to disseminate project experiences about removing the barrier to introduction of the new blood bag. PM will do a desk survey including how to disseminate how to procure a new product, how to get clinical testing started and national strategies for the introduction of

PVC- free blood bags. The continuation of dissemination by all beneficiaries and through the projects web site as well as newsletters will be regarded.
The content in the After-Life communication plan will be presented in concluding workshops and will be included in the final project report action 23. The actions in the plan are not included in project budget.

As action 19 a 5-10 pages Final layman's report for the general public will be made. Expected is a report in pdf format with limited printed editions for the concluding workshops. The layman's report will be translated into beneficiaries' languages as well as into German, French and Spanish.

Finally the last action 23 is the Final project report of maximum 56 pages in English. The report will be written by the project manager with input from every beneficiary. The report will also be reviewed by members of the European purchasers group. The port will be submitted no later than three months before the end of the project.

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, but the following three milestone (Production of the first PVC-free prototype, First Evaluation of a prototype performed and First Evaluation of a protype performed) will not be achieved in time mostly explained by administrative reasons and organisation changes.

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. The newest estimated date for an approved prototype bag is 01/03/2015 that is a delay of 8 months.
Production and evaluation of five prototypes were planned for, but a shortcut to gain time is possible if the project succeed in reaching the milestone with one or two prototypes. 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.

Below is a list of activities from the action list discussed at the PMG meetings. Most of them are already presented in the section 5.1 and 5.2

Action	**Activity**	**Foreseen in revised proposal and plans**	**Achieved**	**Evaluation comments**
1	*Partnership agreement Revision due to additional beneficiary*	*28/10/2011*	*Signed 15/05/2012*	*Delayed Revised 10/03/2014*
1	*Instructions on how to report time*	*26/09/2011*	*26/09/2011*	*Later revised*
1	*Reports from AB*	*Within 2 weeks after end of each month*	*partly*	*Late from some AB*
1	*Initial Report*	*Deadline 30/11/2011*	*21/03/2012*	*Was attached to inception report*
1	*A detailed plan for the implementation phase*	*01/12/2011*		*Implementation described in the Inception report*
1	*Instructions for reports to CB*	*19/02/2012*	*24/02/2012*	
1	*Procure LCA consultant*	*New activity*	*13/12/2011*	*Received two good offers despite shortage of time*
1	*Inception report to EC*	*01/04/2012*	*30/03/2012*	
1	*Pre Progress report*	*01/08/2012*	*30/09/2012*	*EC did not want the planned report.*
1	*Respond to feed-back about Inception reports*		*14/09/2012*	
1	*Visit by monitor*	*CB described project management and the project very thorough the first*	*24/05/2012 22/08/2012 04/11/2013*	*The change of monitor was unexpected.*
1	*Visit to AB*	*The visits were planned to take place when each beneficiary were active with their main action.*	*Oct 2012 Nov 2012 March 2014*	*PM have visited the three first companies in the supply chain. Melitek, Primo and Wipak.*

Action	Activity	Foreseen in revised proposal and plans	Achieved	Evaluation comments
1	*Visit Melitek*		*15/05/2014*	*Financial discussions by economist*
1	*Visit Karolinska*		*19/05/2014*	*PM introduce new members and discuss replacement of retired member*
1	*Revision of time table.*		*30/09/2012 30/01/2013*	
1	*Progress report 1*	*01/02/2013*	*31/01/2013*	
1	*Amendment about postponed Mid-term report*	*Not foreseen*	*31/01/2013*	*Approved by EC in April 2013*
1	*Amendment Ben 7*	*Not foreseen*		*Sent June 2013 Approved 6 Dec2014*
2	*Send beneficiaries Logos for the web page*	*30/09/2011*	*yes*	
2	*Launch PVCfreeBloodBag.eu*	*01/10/2011*	*14/10/2011*	*Great teamwork of four people*
2	Update with pictures and information			Continuously
2	Link to project web site from beneficiaries web site			*Renewel due to two new web pages*
2	*Make correction on map concerning Totax, Melitek and Primo*		*16/12/2011 Jan 2014*	
2	*Add text to side of Life logotype*		*13/08/2012*	
2	Media activities		Continuously	*See monitoring protocol at web site*
2	Secure web site	Not foreseen Hacked several times		*Will be transformed into new format*
2&3	*Inform those who signed the petition and letter of intent about the web page.*	*15/10/2011*	*yes*	
3	*first Notice board set-up*	*01/11/2011*	*14/10/2011*	
3	Disseminate more Noticeboards and project information			Continuously

Action	Activity	Foreseen in revised proposal and plans	Achieved	Evaluation comments
3 (and 10)	*Attend HCWH meeting in Malmö to disseminate project information and take a part in planning CleanMed 2012 in Europe*	*09/12/2011*	*09/12/2011*	*By attending the meeting we managed to get our own seminar about PVC substitution*
3	*Communication plan first draft*		*14/05/2012*	
3	*Prezi project presentation*		*29/11/2012*	
3	*Send abstract to ISBT conference in the Netherlands*		*03/Mar/2013*	*It was not approved because of its content*
3	*Send abstract to CleanMed Europe*		*08/05/2013*	*It was approved*
3	*Attend CleanMed 17-19 Sept 2013*		*19/09/2013*	
3	Newsletter		May2013	Two newsletter so far
3	Presentation about how to get a non-toxic product, Procurement conference	Not foreseen Invited	10/10/2013	
4	*Send headsets, recommended by our It-support, to all PMG members.*	*10/10/2011*	***yes***	
4	*Individual "OpenMeetings" will be arranged between project manager and all members together with IT support.*		*31/10/2011*	*Yes*
4	*Set dates for PMG meetings annualy*		*15/10/2011 04/12/2012*	*Decide on meeting or by mail*
4	*Extra meeting for those that could not attend; Wipak, Totax, Melitek*		*31/10/2011*	*N/A*
4	*Arrange next PMG the 8 Feb in Copenhagen. After Kick-off.*		*02/02/2012*	
5	*Monitor protocol*	*01/12/2011*	*27/03/2012*	
5	*Monitoring visit by EC*		*04/04/2014*	*Feed back 29/07*
6	*Set date and place for the first seminar –*	*2011*	*2011*	*Date set in Oct place in early Nov*

Action	Activity	Foreseen in revised proposal and plans	Achieved	Evaluation comments
6	*Procure Kick-off facilities, food and refreshments*	*20/12/2011*	*18/12/2011*	*Karolinska*
6	*Make registration set-up at web page*	*16/12/2011*	*16/12/2011*	*Help from IT-support*
6	*Write and send out invitation*	*16/12/2011*	*16/12/2011*	
6	*Arrange agreements with external lecturers and moderator*	*20/12/2011*	*12/01/2012*	*Time consuming*
6	*Set final program*	*31/01/2012*	*20/01/2012*	
6	*Produce handouts /info material for seminar*	*08/02/2012*	*03/02/2012*	
7	*Update web site with presentations*	*12/02/2012*	*10/02/2012*	
8	Contact other projects	Continuously		Mail to all listed in application has
8	*Kick-off LIFE-EDESIA*	*Invited as speaker*	*14/10/2013*	
8	Act as stakeholder in LIFE-EDESIA			
10	*Preparation CleanMed Malmö*	*CB invited as member of HCWH*	*26/09/2012*	
10	Plan buyer group meeting	Increase the Swedish buyers group	No	Not reached target group
10	Inventory of buyers of blood bags in Europe			More difficult than expected
10	Survey # blood bags and # blood transfusion			Survey via newsletter, student
10	Influence on EU-legislation regarding EDC	Not foreseen	*Oct 2013*	*Best result in increasing demand*
12	*Delivery of first compound to Wipak*	*01/01/2012*	*20/11/2012*	*delayed*
12	*Gather material for workshop below*		*yes*	
12	*Workshop "Material Specifications"*		*08/02/2012*	
12	*Set "material Specification"*		*01/06/2012*	
12	*Delivery of compound to Primo*		*Nov 2013*	
13	*Start of action*	*01/01/2012*	*01/10/2012*	*Delayed*
13	*Delivery of film to Haemotronic*		*yes*	*yes*
14	Start of production		01/01/2012	

Action	Activity	Foreseen in revised proposal and plans	Achieved	Evaluation comments
14	Delivery of tubings			Sep 2014
15	*Start of production*			*May 2013*
15	Production of first prototype bag			March 2014
15	Design discussions Visit Karolinska		*12-14/05/2014*	
16	Start of evaluation			Nov 2014
16	Find Ingers suceessor	Yes Inger retired		Aug 2014
17	Test protocol user tests		Est 2014	
17	*New start-up meeting*		*27/02/2013*	

5.4 Analysis of long-term benefits

Expected long-term benefits are

- minimised patient exposure to potentially hazardous substances,
- a better working environment for both manufacturers and hospital employees
- 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
- no need to clean smoke from waste combustion means less contribution to climate change.

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.

The project have 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

The project will demonstrate how to drive innovations towards non-toxic healthcare.

The long-term benefits will be analysed in detail in the Final report.

6. Comments on the financial report

The original budget stays valid up to this date with only one change. Since there's a new beneficiary in the project, Primo Co, Primo Co will take on the budget of the former partner Totax AS. The foreseen costs per beneficiary has changes as a result, but the overall total remains the same. This has already been clarified by the Commission.

Regarding the verification of costs representing consumables in action 12, production of compound. The used material is traceable on the invoices by lot number and thus the external invoices could be checked by an audit.

The Regional Council has received the letter of the Commission dated 29 July 2014. Points have gratefully been taken into consideration and will be respected in the future.

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	1367686	628042	46%
2.	Travel	127250	20819	16%
3.	External assistance	192210	53584	28%
4.	Durables: total non-depreciated cost			
	- Infrastructure sub-tot.			
	- Equipment sub-tot.			
	- Prototypes sub-tot.	174000	33333	19%
5.	Consumables	146867	32566	22%
6.	Other costs	52234	4947	9%
7.	Overheads	**144217**	**53293**	37%
	TOTAL	**2204464**	**826584**	37%

- *) 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 Regional Council of Jamtland uses two systems to manage the economy. For salaries and other costs incurred by the staff, e g subsidies and other, the system employed is called Heroma. For other costs, the Regional Council 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 Regional Council 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. Regional Council of Jamtland 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.

Regional Council of Jamtland 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 has been some delays in the financial reporting from some of the beneficiaries. The coordinating beneficiary has repeatedly sent remainders to those concerned, with various result. This is something to pay close attention to ahead.

There are no financial transactions between the beneficiaries. The coordination beneficiary transferred the beneficiaries' share of the first advance payment so far.
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 economist at coordinating beneficiary are compiling financial data for each beneficiary.

6.4. Auditor's report/declaration

The CB's auditor of choice will be Majvor Enström, Box 654, SE-831 27 Östersund, majvor.enstrom@jll.se, +46 63 147500
The auditor is employed as Revision Director by the County Council of Jämtland which is one of the owning organisations of Regional Council of Jämtland.

6.5 Summary of costs per action

Action no.	Short name of action	1. Personnel	2. Travel and subsistence	3. External assistance	4.a Infra-structure	4.b Equip-ment	4.c Prototype	5. Purchase or lease of land	6. Consumables	7. Other costs	TOTAL
1	Project Management	133814	1375	1136					355	581	137261
2	Web &Media Work	45149		1588							46737
3	Project information	30776	1846	798					327	397	34144
4	Meeting	13000	345						239		13584
5	Monitoring	8276	2529						231		11036
6	Org first seminar	3874								1620	5494
7	First seminar	11286	4241	7849					92	540	24008
8	Networking	5421	550								5971
9	Audit										0
10	Increase demand	8245	2740	2271						128	13384
11	Brochyres ets			233						1681	1914
12	Production	49400	3555						23223		76178
13	Film	25741	134	290					6590		32755
14	Tubes	2055									2055
15	Bag	281664	1541	26616			33333		1509		344662
16	Evaluation	9341	1963	12803							24107
17	Usertest										
Over-heads											53293
	TOTAL	628042	20819	53584	0	0	33333	0	32566	4947	826854

7. Annexes *The same annexes as reported 30 May 2014*

7.1 Administrative annexes

7.1.1 Partnership agreement revised, delivered to EC on 24 March 2014
7.1.2 Amendment No 1 to Grant agreement
7.1.3 Time report instruction
7.1.4 Cost report instruction
7.1.5 Example of a timesheet

7.2 Technical annexes

7.2.1 List of keywords and abbreviations used
7.2.2 Life cycle assessment – submitted before as a Deliverably on 30/03/2012

7.3 Dissemination annexes

7.3.1 First Banner
7.3.2 Hand-out General
7.3.3 Press release before First seminar
7.3.4 Invitation to First seminar
7.3.5 Programme First seminar
7.3.6 Calling cards/business cards
7.3.7 Name tags
7.3.8 Poster CleanMed Sep 2012
7.3.9 Poster 15 Oct 2012
7.3.10 Poster CleanMed Sep 2013
7.3.11 Handout Benefits
7.3.12 Handout Wanted
7.3.13 Notebook
7.3.14 Output indicator table
7.3.15 Newsletter 1
7.3.16 Newsletter 2
7.3.17 Short presentation about challenges to bring a new blood bag to the market
7.3.18 Presentation held at Finnish Red Cross March 2013

8. Financial report and annexes

The financial part of the Mid-term report sent as a separate volume contains the following tables:

Payment request
Consolidated Cost Statement
Financial Statement Wipak
Financial Statement Melitek
Financial Statement Haemotronic
Financial Statement Primo
Financial Statement Karolinska
Financial Statement Regional Council of Jamtland

The financial report in excel format is enclosed in a memory stick/USB key.