LIFE10 ENV/SE/037

Progress Report 2
Covering project activities from 01/09/2014 to 31/01/2015 and budget from 01/09/2011 to 31/12/2015

Reporting Date
28/02/2016

LIFE+ PROJECT NAME and Acronym
Public healthcare and plastic makers demonstrate how to remove barriers to PVC-free blood bags in the spirit of REACH
PVCfreeBloodBag

Data Project

Project location	Sweden, Finland, Denmark, Italy, Poland
Project start date:	01/09/2011
Project end date:	31/03/2017
Total budget	€2,204,464
EC contribution:	€1,091,040
(%) of eligible costs	49.49%

Data Beneficiary

Name Beneficiary	Jegrelius Institute for Applied Chemistry/ Region Jämtland Härjedalen
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Project Website	www.pvcfreebloodbag.eu

1. Table of contents

2. List of abbreviations

PMG – Project Management Group
CB – Coordinating Beneficiary
PM – Project Manager
EC – European Commission
CO – Communication Officer
OpenMeeting – The platform/software used for PMG virtual meetings
Karolinska – Karolinska University Hospital, Beneficiary 2
HCWH – Health Care Without Harm
EBA – European Blood Alliance
PVC – PolyVinylChloride
DEHP – Dietyl Hydroxi Phtlalate, plasticizer
LCC – Life Cycle Cost
LCA – Life Cycle Assessment. A method for analysing the impact on health and environment from a product's lifecycle.
C2DS – Comité pour le Développement Durable en Santé
ECVM – European Council of Vinyl Manufacturers
SCENIHR – The Scientific Committee on Emerging and Newly Identified Health Risks
NHS – National Health Services (UK)
NCSH – Nordic Center of Sustainable Healthcare
EDC - Endocrine Disruptive Chemicals

3. Executive summary

3.1 General progress

The crucial in-vitro evaluation of the blood bags capability to store red blood cells has started and will be ready in the end of March 2016. The set of three, totally PVC-free, bags is made up from material from the whole supply chain; action 12, 13, 14 and 15, including filter and needle from an external source.

Communication activities to disseminate information, network and increase demand have been intensified with webinar, short movie, meeting with EBA and planning of final workshops.

3.2 Assessment as to whether the project's objectives and work plan are still viable.

The project has been prolonged with one year. The amendment to the Grant Agreement approved on 10/11/2015. The new end date is 31/03/2017.
This prolongation makes the project's objectives, despite delays in action 13-16, still possible to achieve. The objectives are intact and the prerequisites for success remain in place. There is one delay in the project regarding the user tests in action 17.

3.3 Problems encountered

Problems encountered in the project have mostly 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 have caused delays effecting the production and evaluation of the prototype bag. The amendment tackled this problem with a prolongation of 12 months and some changes of technical character in action 15, production and some budget changes.

The quality of the blood bag set was sufficient enough to perform the in-vitro tests, but it was revealed that improvements were needed before validation of the bags and the user-tests can be performed. Two different optimisation scenarios are planed that involves Primo, Haemotronic and maybe Wipak. Validation and user tests go hand in hand, but validation of the bags in action 15 has a higher priority than user tests in action 17.

The worst case scenario would be difficulties in proving that the blood bag fulfil the criteria for CE-labelling in action 15. Read in section 5.2.12 how we are minimising the risks.

The situation at CB has been troublesome for several reasons.
Our IT-manager passed away unexpectedly in the summer of 2015, and thus the person supporting our project with IT-related issues took over his duties in the autumn. The family situation for our communication officer has been severe and she has not been able to work full time since her husband were diagnosed with brain tumour. He passed away in cancer in December 2015.
To cover for these lack of resources two external consultants has been employed for two assignments. One photographer, Andreas Johansson, instead of Katarina Ryckenberg, covering the start of the in-vitro tests and one person regarding film production instead of our IT-support Jonas Lindquist. The film production is described in section 5.2.8.
Both our communication officer and IT-support is now working with their ordinary employments.

Karolinska has been on stand-by, waiting for bags to evaluate, and during this postponement new personell repeatadly had to be trained. In September 2015 Karolinska strengthened their effort in the project by adding MD, PhD and professor Petter Höglund. He will together with HansGulliksson be responsible for the in-vitro evaluation and Peter Höglunds group will perform the in-vitro studies in action 16.

4. Administrative part

The legal status of the coordinating beneficiary has been changed from Regional council of Jämtland to Region Jämtland Härjedalen. This means a larger organisation, including the healthcare organisation, which we applied this Life+ project with. The hospital within Region Jämtland Härjedalen is responsible for the user tests in the project.
The financial officer Linda Andersson ended her employment in September 2015 and the responsibility for the project was taken by Head of Economics Arne Nilsson. Maria Arnstål at administration have been introduced to the financial tasks.

4.1 Project organisation

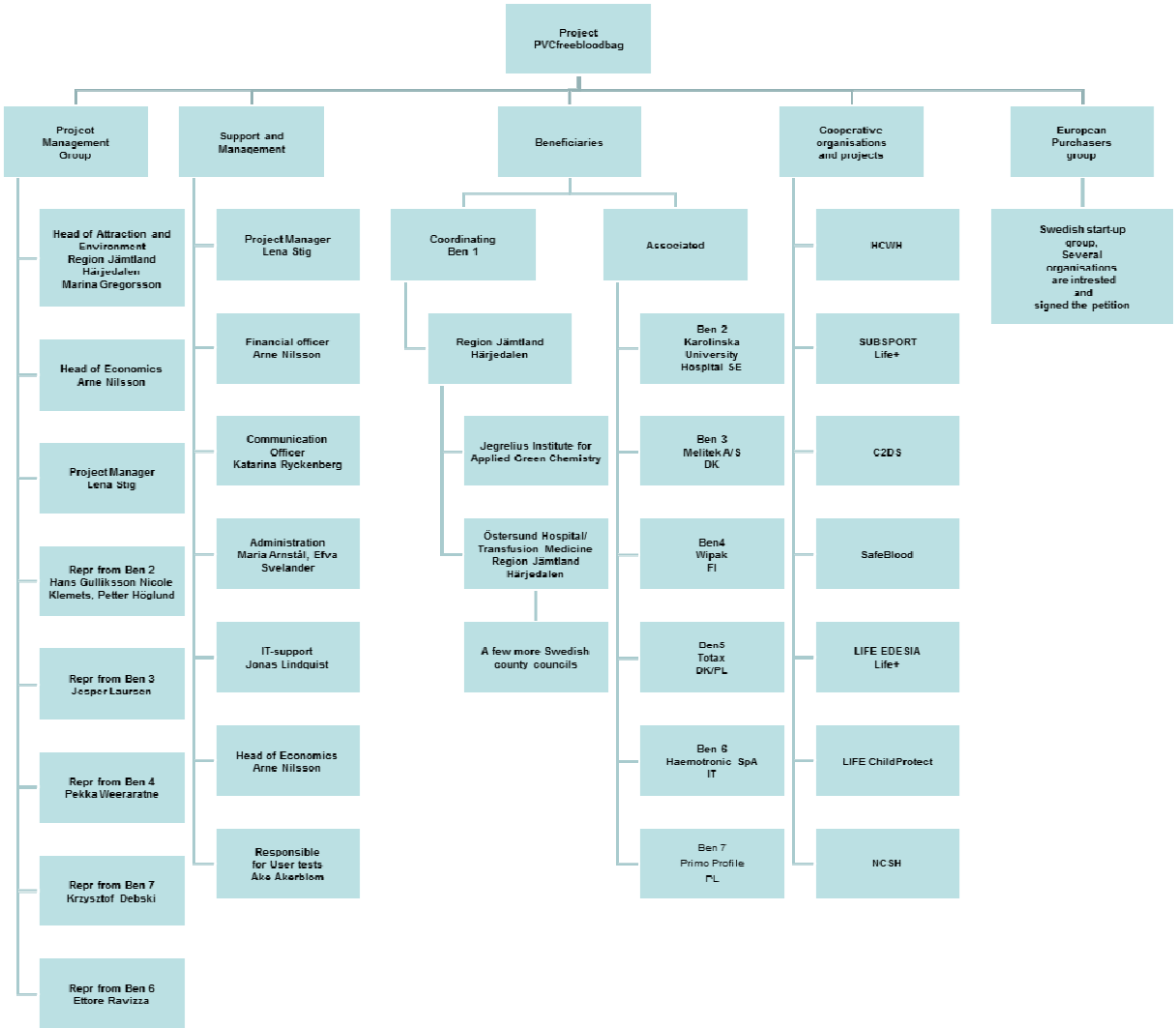


Figure 1. Project organisation

The management team consists of

Project Manager	Lena Stig
Head of Economics	Arne Nilsson
Financial Officer	Arne Nilsson
Administrators	Maria Arnstål, Efva Svelander
Communication Officer	Katarina Ryckenberg
IT Support	Jonas Lindquist

Responsible for User Test Åke Åkerblom, Östersund Hospital

The PMG consists of

Head of Attraction and Environment/ Region Jämtland Härjedalen	Marina Gregorsson
Head of Economics	Arne Nilsson
Project Manager	Lena Stigh
Communication Officer	Katarina Ryckenberg

Hans Gulliksson, Petter Höglund, Nicole Klemets represents Beneficiary 2, Karolinska
Jesper Laursen represents Beneficiary 3, Melitek
Pekka Weeraratne and Jouni Vikman represent Beneficiary 4, Wipak
Krzysztof Debski and Daniel Jaworski represents Beneficiary 7, Primo
Ettore Ravizza and Alice 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 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

4.2 Description of project management activities

Activities are presented in more detail in section 5.2. The Partnership Agreement has been updated and signed. The MidTerm report was approved followed by delivering of the associated beneficiaries' shares.
PMG meetings are held regularly and protocols and instructions are published on the project's web site. The last PMG meeting was held the 17th of February. The internal communication in the project has increased, since there have been activities in all the core actions.
A second request for amendment to the grant agreement was after clarification and correction approved.
The third monitor Inta Dũce visted us in Östersund 3 September 2015.

Instructions regarding reporting times and costs have been revised and updated.

PM now visited all beneficiaries, Beneficiary 2 in Sweden several times and Beneficiary 6 in Italy 05 Nov 2014.

4.3 Completed Deliverables

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)
– Pre 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	
– Monitoring of blood transfusion operations Oct 2015 Annex 7.4		

The deliverables next to come are listed in section 5.4.

5. Technical part - Actions and activities

In the attached revised form of part C, are deliverable products, milestones, activity reports foreseen and the timetable C3. Annex 7.1.1

Below is the picture describing the core actions in the project. It describes how the supply chain interact to produce the set of bag in action 16, followed by the evaluation and user tests.

To increase demand in healthcare is, besides production and evaluation, a core action as well.

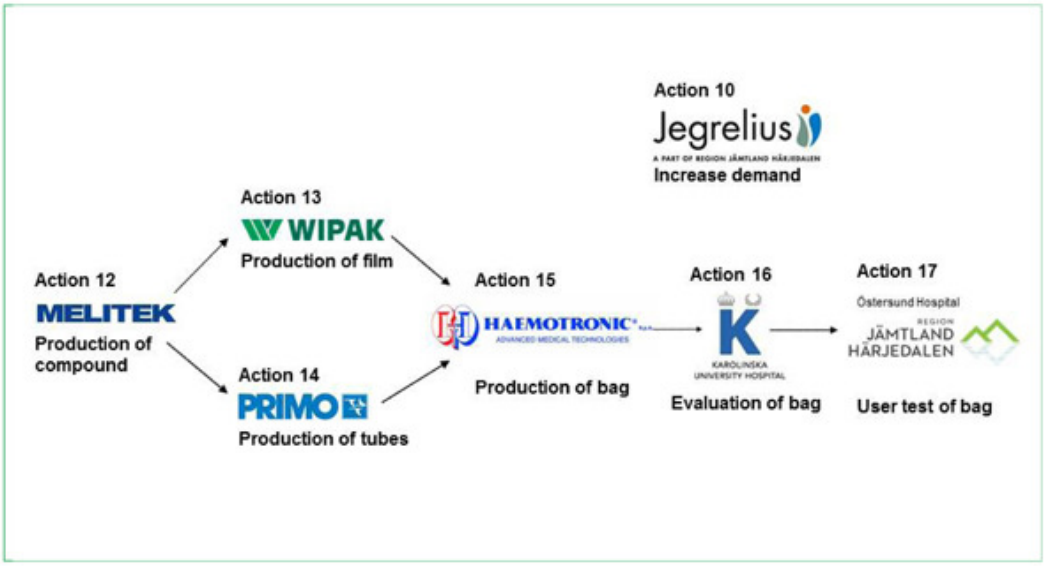


Figure 2 The core actions.

The responses to the technical issues raised in the EC letter 3 November 2015

Issue 1

Task 11 – Production of brochures, reports, films, visitors map etc.

The status of this task was not clarified during the external monitoring visit on 3 September 2015, therefore please provide a clear information and supporting material with your next progress report. Including the number of the copies

Reply 1

This is reported below in section 5.2.8 The Output Indicator in annex 7.2 give an overall picture of the statistics.

Issue 2

Technical tasks 11-15

I urge you to speed up the implementation of the key technical actions 11, 12, 13, 14 and 15 in order to overcome significant delays in the project affecting other related activities. Please also describe the CE-marking (indicating the compliance with the EU legislation) procedures for the new blood bags (task15) and provide detailed information in this respect in your next progress report. Please ensure that the EC common standards are respected and the marking is completed by the end of the project as foreseen in the Grant Agreement. The relevant proofs should be provided with your Final Report at the latest in order to have the related costs eligible for the EC co-funding.

Reply 2

The speed of the core actions 12-16 has increased, resulting in evaluation in action 16. The evaluations analytical phase will be ended in March.

Progress in each core action will be described below in corresponding section 5.2.9 to 5.2.12. The CE-labelling issues will be described in detail in action 15 section 5.2.11

Issue 3

Task 16- Evaluation and monitoring of blood bags

Please speed up the implementation of this action and deliver the summary of the test results and conclusions with your next progress report. The final scientific report containing the results of all the tests done and final results should be delivered with the Final report at the latest.

Reply 3

According to the updated project description the deadline of the milestone of “A non-PVC blood bag tested and approved according to Requirements Specification” has been changed to 30/03/2016. Details about the action is described in section 5.

5.1 Action list

The action list has been revised after the approval of the second amendment, where the project was prolonged one year.
All beneficiaries are involved in actions marked in green. Core actions are marked in pink.

Nr	Ben	Action	Start	End	Comments
1	CB	Project management	Sep2011	Mar2017	
2	CB	Website and media work	Oct2011	Mar2017	
3	CB	Notice boards and the dissemination of project information	Oct2011	Dec2016	
4	CB	Project meetings for the Project Management Group	Sep2011	Mar2017	
5	CB	Monitoring the project's progress	Oct2011	Mar2017	
6	Karolinska	Organisation of First Seminar Action 7	Oct2011	Dec2011	Completed
7	Karolinska	First Seminar	Jan2012	Mar2012	Completed
8	CB	Networking with other projects	Apr2012	Jun2016	
9	CB	Audit	Jul2015	Sep2016	
10	CB	Increase demand	Jan2012	Dec2016	Start Dec 2011
11	CB	Production of brochures, reports, posters, invitations etc	Oct2011	Mar2017	
12	Melitek	Production of compounds for films and tubes used in blood bags	Oct2011	Mar2014	Start Dec 2011
13	Wipak	Production of film for the blood bags	Jan2012	Mar2016	Start Dec 2012
14	Primo	Production of tubes to be used in blood bags	Jan2012	Apr2016	Start Feb 2013
15	Haemotronic	Production of a PVC-free blood bag	Apr2012	May2016	Start Jan 2013
16	Karolinska	Evaluation and monitoring of blood bags	Jul2012	Mar2016	
17	CB	User test including economic feasibility study of PVC-free blood bags	Apr2013	July2016	Delayed
18	CB	After-LIFE Communication plan	Oct2014	Sep2016	
19	CB	Final layman's report	Oct2014	Mar2017	
20	Karolinska	Technical publication based on the evaluation results of blood bags	Apr2014	Mar2017	Start Feb2016
21	CB	Organisation of Concluding Workshops action 22	Jan2014	Sep2016	Start Oct 2014
22	CB	Concluding Workshops	Apr2015	Nov2016	Start Sep 2016
23	CB	Final project report	Jan2015	Mar2017	Start Sep 2016

As seen in the table above, there is one delay of concern regarding action 17.

5.2 Actions

5.2.1 Action 1 Project Management

The mid-term 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.

1 June 2015 the projects second request amendment was sent to the Commission. It included a request for a prolongation, a change of organisation, technical changes and changes in budget. A letter of clarification was later, 27/07/2015, sent to the monitor. Our request was formally approved with signatures from EC the 18th of November.

PMG meetings are held regularly and minutes are placed on the project's website. At total of 23 PMG meetings have been held so far. The last meeting last year was the 23rd of November.

The projects third monitor, Inta Dũce, visited CB on 3 September 2015.
She met PM, financial officer Linda Andersson and head of economics Arne Nilsson.
At that moment the financial officer was about to leave her employment at CB and the responsibility for the financial issues was been taken over by the Head of Economics. Maria Arnstål from administration has been introduced to the project and been working on transferring all data from existing excel sheets into the new template from September 2015. She is also checking all supporting documents from the beneficiaries.

PM presented the project, progress in all actions, except those regarding financial issue that Linda presented. Inta Dũce informed us about the changes in the monitoring system from 2015 and we went through the questions and concerns from her.

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 are presented in section 6.1

PM visited Beneficiary 6 /Haemotronic the 5th of November 2014 in both Mirandola and Carbonara. PM was shown the production facilities and we discussed production in detail.
A visit report was written by PM.

PM also visited Beneficiary 2 a second time to meet Petter Höglund and Erik Stenholm.
On both visits we went through project-related issues of reporting time and costs.

The additional deliverable named "LCA of a PVC-free blood bag" will be procured with the same procedure as the former LCA and based on the real materials used in this project. The benefits of this deliverable was discussed when the EC visited CB in April 2014. The purpose is to strengthen the environmental arguments for the new bag and thus facilitate market introduction.

5.2.2 Action 2 Website and Media Work

The necessary switch of website format was launched the 11 March 2015.
News published on the website since the mid-term report is as follows.

- Project member Primo – Medical tubing is a rapidly expanding business area
- Visit to Italy
- New project contact
- Making the world's first PVC-free Blood Bags
- Project Movie in Progress
- Non-toxic Healthcare: Alternatives to Phtalates and Bisphenol A in Medical Devices
- Newsletter Nr 1 2015 (the third)
- Attention to risks with DEHP in healthcare - in Norwegian media
- How to bring safer blood bags into healthcare – Webinar
- The project invited to European Blood Alliance meeting

- The in vitro tests have started at Karolinska University Hospital
- Webinar recording available
- The project prolonged one year
- A short movie about the project
- Report about blood transfusion operations in EU-countries

Press release 5 Nov 2014 was launched before visiting Italy. Annex 7.3.2
Another press release was launched the 5 October 2015 along with the start of the in-vitro evaluation. Annex 7.3.3
The PR resulted, amongst other, an announcement by HCWH Europe and Life+ Communication team.

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. Annex 7.3.5
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. You may watch the webinar from here https://noharm-europe.org/content/europe/webinar-how-bring-safer-blood-bags-healthcare

A short video about the project has been launched. The video is targeting healthcare organisations with the purpose to increase demand. The film was launched in January 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.

The project have also been 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. They also interviewed Head of Environment at Karolinska University Hospital, Gustav Eriksson. The program has not been sent yet.

In January 2016 the Project started a Twitter account.

5.2.3 Action 3 Notice boards and the dissemination of project information

Activities in action 3 are performed in parallel with actions 10, 2 and 8.
Communication channels have been seminars, press releases, mail, telephone, LinkedIn, The website, Twitter and other organisations.
The third newsletter was launched 28/05/2015. Annex 7.3.1

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.

Other implementations of dissemination of information are presented in Annex 7.3
Additional dissemination materials have been produced. See section 5.2.8

All beneficiaries have had project information on their website. However, some of them changed their websites. Primo promotes the project on their web site the 16th of April 2015.

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/MELITEK---Specialist-in-medical-technologies/PVCfreebloodbags
Beneficiary 4/Wipak:
http://www.winnovations.wipak.com/project/non-pvc-bloodbags
Beneficiary 7/Primo
http://www.primo.com/news/latest-news?Action=1&NewsId=120&M=NewsV2&PID=45190

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.

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 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 have also been sent to Mid Sweden European Office in Brussels.

5.2.4 Action 4 Project Meetings for the PMG 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 Attraction and Environment.

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.
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 23 meetings so far and all minutes include an updated action plan.
See the meeting's minutes on the website under Documents/Minutes.

5.2.5 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 is attached as Annex 7.2 It provide all statistics.

Action 6 and 7 were completed in 2012.

5.2.6 Action 8 Networking with other projects

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.
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.
http://childprotectfromchemicals.eu/

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.

5.2.7 Action 10 Increase Demand

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*? (Vox Sanguinis (2014) 106-176-195), 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.
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. 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. Marco Goldoni from Haemotronic joined her at the meeting. Annex 7.3.6
The presentation was followed by questions and discussions. The opinions varied in the group whether or not 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.

Mapping of European organisations and surveys to obtain more statistics has been performed by Erik Stenholm, employed by Karolinska during the summer of 2015. The report was launched 28 January 2016 on the website. 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.

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.

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

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.
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 explained in section 3.3.
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 is 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 7.4

New dessimination material is attached in annexes 7.3.

The additional deliverable named "LCA of a PVC-free blood bag" should also be a report prepared for printout with ISBN-number. Print costs are in budget for 19, 23 and action 11 referring to action 3, 8, 10 and 22.

Hans Gulliksson and Petter Höglund at Karolinska, who are responsible for the in-vitro evaluation of the bag in action 16 and the technical publication in action 20, will present result from the evaluation at lectures at additional occasions. This will be in action 22, the final workshops.

5.2.9 Action 12 Production of compounds

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 have also been searching for 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.

5.2.10 Action 13 Production of films for the blood bags

Wipak has produced six runs of film so far. 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 was 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 is 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 is now shipped to Haemotronic.
Wipak is also planning for one more improvement in case the improved bags for the user tests are not satisfying enough.

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

A new tool has been produced in order to produce tubings according to design requests from Haemotronic and Karolinska. The technical requirements on the properties of the tubings are higher than estimated in beginning and more consumables are 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. This new quality control is part of the increase in costs described in the new budget version. No verification of the increased costs have been sent to CB.

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 will be changed in the coming production run of the tubings. There will not be a change in the inner surface that are in contact with blood and solutions. These tubings will be produced in March and sent to Haemotronic for the production in action 15 in April-May.

5.2.12 Action 15 Production of a PVC-free blood bag

The scope of production of a PVC-free blood has 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 have to be outsourced by Beneficiary 6. This corresponding activities caused by the change in scope are described in the updated part C. Annex 7.1.1

Design discussion were held at Karolinska 12-14 May 2014. The physical properties of a complete set of bags was checked first time at Karolinska 20-21st of January 2015. This set of three bags was 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 whole action has been updated as part of the amendment and is describing the actual situation. A more detailed description of action 15 is found in the revised Part C that is now approved and on the web site. Annex 7.1.1

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 with the in-vitro tests. However, before scaling up production for the user tests, improvements are needed. There are different technical scenarios to choose from.
PM met Alice Ravizza the 29th of September 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-labelling.
As written in the description of action 15, the bags will be tested for fulfilment of CE marking acceptability, including technical and dimensional features. All tests will be performed for the final set suitable for blood collection and blood processing in action 16.

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 can draft a full technical file.
Annex I is the list of essential requirements for safety which is mandatory for all medical devices. Haemotronic will give 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 this annex II.

In the budget Haemotronic have budget posts for external assistance for example for validation according to ISO-standards and production consultant.

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.
We suggest a pre-audit from a Notified body to prove this. A pre-audit on annex 1 requirements 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 are as explained needed before scale up, user tests and validation according to methods described in action 15 in part C. Annex 7.1.1
The plan is 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 will be 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 remain valid.

5.2.13 Action 16 Evaluation and monitoring of blood bags

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.

Second tests with water was performed in June after improvement of the bag.

In September 2015 the working group was strengthen by physician and professor Petter Höglund, who together with Hans Gulliksson, is 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. The final result will be ready in the end of March.
The results will be presented in a separate report intended for publication. Action 20: Technical publication based on the evaluation results of blood bags.
Both Petter Höglund and Hans Gulliksson will present the result as part of action 22. Concluding workshops.

5.2.14 Action 17 User test including economic feasibility study

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 have sent out questions to health care organizations in Sweden, regarding the user tests, and the interest to participate is still there. We are aiming at 5 hospitals involvement in the user tests.
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 have been delayed and will not be able to start the user test until June 2016.
The good thing is that the user tests only require a period of 2-3 weeks.
Besides improved sets of bags clamps/clamp tools and plastic sealer will be required for all five hospitals performing the user tests.

The economic feasibility study will be reported as a separate delivery and PM is looking into the possibilities to procure external expertise for this feasibility study. The report will be delivered 01/01/2017.

5.2.15 Action 21 Organisation of Concluding Workshops action 22

We have decided that one of the final workshops will be in Östersund in September in adjacent to the UNESCO conference 2015.
The planning started in October 2014 and one activity has been a webinar survey. What kind of virtual presentations and seminars are most suitable for as to use in the final workshops.

Our IT-support Jonas Lindquist has together with Nicole Klemets at Karolinska and the communication officer started looking 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.

A second workshop to reach a big audience with European healthcare is planned in adjacent to CleanMed 2016. The date has not been set by the organiser HCWH, but autumn 2016 is most likely.

Other suggestions are presentations presenting the in-vitro evaluation at two international conferences targeting Transfusion Medicine.
- An expert meeting of BEST (Biomedical Excellence for Safer Transfusion) in October
- International Society of Blood Transfusion (ISBT) conference in September

A seminar or oral presentation at Medica/Compamed in November 2015 has also been suggested. This is a conference with high attendance from the industry.

In March the date for the workshop in Östersund will be set and distributed in next Newsletter as well as on the web site.

5.4 Envisaged progress until next report.

During this last period of the project, we will deliver result in form of audit certificate, publications, final workshops and reports. Action 9, 17,18,19,20, 22 and 23.

Next in time will be validation of the bag, user tests, organisation of workshops, procuring external assistance for the final LCA and start the economic feasability study.

The audit of the the project's expenditure in action 9 will start. The internal auditor of Region Jämtland Härjedalen will be responsible for the audit certificate. The other beneficiaries send approved certificates to the the auditor. All the private beneficaries have a post for external audit in the budget.

Technically the quality of the set of bags is being improved. The production of the sets of bags for validation and user tests are planned to take place in April to May in Haemotronic, followed by final validation. The user tests are planned to start in June in Östersund and end in August 2016.

The deliverables to come are.

	Deliveries	Action	deadline
–	Economic feasibility study	17	01/01/2017
–	Audit result	9	01/10/2016
–	Final layman's report	19	01/03/2017
–	Technical report	20	01/01/2017
–	Publication of technical report	20	01/01/2017
–	LCA of the new PVC-free bag	22,11	01/03/2017
–	After-LIFE communication plan	18	01/02/2017
–	Final report with payment request	23	01/03/2017

5.5 Impact:

Environmental Policy & Governance: 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 for a stronger legislation regarding harmful chemicals in medical devices.

Information and Communication: The awareness of the target audience, healthcare organisations in Europe, is increasing. The project has received attention via media activities, newsletters, a webinar and a short movie.

Indirect impacts: The project is a good example of long-term work on how to drive innovation towards non-toxic healthcare.

5.6 Outside LIFE:

The dissemination of information and the cooperation with other organisations as HCWH, C2DS have been increased the awareness of EDC's in medical devices and blood bags in particular. In the article *Should DEHP be eliminated in blood bags*? Vox Sanguiunis (2014) 106-176-195, Sweden and the project is mentioned as the only country among those represented in International forum, that have 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.

6. Financial part

In letters dated 29 July 2014, 6 February 2015 and 3 November EC raised concern about specific technical and financial issues. The financial issues are addressed below and the technical issues in section 5.
The same headlines as in the letters are used and specific issues are listed in order.

6.1 The responses to the financial issues raised in the EC letter 29 July 2014

Issue 1 General issues
Please be reminded about Article 6.1 of the Common Provisions where the coordinating beneficiary must retain copies of the supporting documents for all the associated beneficiaries. It was noted that the associated beneficiaries according to the partnership agreements should submit their financial documents each month, but except for you and Karolinska, no financial reports were up to date, i.e. latest entries were beginning of 2013. Please be reminded that in order for you to be able to monitor the financial implementation of the project effectively your associated beneficiaries must submit their financial data to you on a regular basis. If the beneficiary only have a few monthly financial transactions, it may not be necessary to submit the transaction each month, but each 3rd month should be sufficient or exceptionally each 6th necessarily have to update the financial report in the excel work book, as the coordinating beneficiary you can offer your associated beneficiaries to do so on their behalf as long as they sign their respective financial statements. Please inform your associated beneficiaries accordingly.

Reply 1
As CB we remind all beneficiaries repeatedly that all supporting documents should be sent to CB, preferable every month, according to the Partnership agreement and Article 6.1 in Common Provision. All beneficiaries have sent signed timesheets for 2015.
CB is updating financial reports on behalf of each beneficiary in an excel workbook. The new template from September 2015 is used.

Issue 2 Reference to the project on the invoices
In some of the invoices checked during visit the reference to the project was made by using a stamp. You and all your associate beneficiaries are, therefore, informed that the stamp should be on the original invoice and it is not sufficient if it is on the copy of the invoice you receive from your associated beneficiaries. Using a stamp is an acceptable way of making the reference on the invoice and in some cases it may even be the only way to include the project reference in the invoice. However, the reference is supposed to be included in the invoice by the subcontractor/supplier and you and your associated beneficiaries are therefore encouraged to continue to insist that they include such a reference to in all the invoices they issue to your project. It is always useful to include the project reference in the postal address which is provided to the suppliers/subcontractors, as that way it automatically appears on their invoices. Please be reminded that the recommended reference is the project number and the acronym, LIFE10 ENV/SE/000035 SLIDE IN.

Reply 2
In the project instruction on how to report costs, has from the start of the project been stated that “All invoices shall also include a clear reference to the project LIFE10/ENV/SE/000037

PVCfreeBloodBag and you have to inform the suppliers and subcontractors accordingly." All beneficiaries should also provide sufficiently detailed explanation of the costs. CB is filling in the description box of all cost transactions in the excel sheets and if the supporting documents are missing some information, we send them back for updating.
CB has informed the beneficiaries that incomplete cost transactions in the final report will be ineligible. An example of an invoice with a clear invoice Annex 7.1.4

Issue 3 During the examination of the payment proof of Haemotronic it was discussed that it would be very helpful if the beneficiaries explained how the invoice is identified in the payment proof.

Reply 3
Haemotronic has sent a payment proof from the subcontractor of the prototype stating that they confirm the payment of the invoice. See section 6.4 issue 11.

Issue 4
All beneficiaries should annex an extract from the analytical accounting system showing the projects costs booked on the specific cost account. Please provide the costs per sub cost category the costs reported in your accounting system and please explain if the costs differ to the costs in the financial report.

Reply 4
All beneficiaries, except Melitek, will send us an extract from the analytical accounting system showing the project costs booked on the specific cost account/project code.
More information provided in section 6.3. Extract from Haemotronic, CB and Karolinska is found in Annex 7.1.3

Issue 5 Personnel costs – annual personnel costs
The annual personnel costs for your organisation are extrapolated to a 12 month period on the basis of the monthly gross salary per employee duly adjusted by obligatory social charges and a holiday allowance of around 12% times 12. As your staff receives salary during holiday, it is incorrect to increase the monthly salary by the holiday allowance and your personnel costs are therefore overstated by around 12%. Please be informed that the personnel costs should be calculated on the basis of the actual annual gross salary and the obligatory social charges. The annual gross salary should be the actual annual gross salary received per calendar year per employee according to the salary slips (or extracted from the pay roll register). If the salary slip contains accumulated yearly figures the annual gross salary can be obtained from the December salary slip, alternatively from the yearly report (Kontrolupgift) sent to the tax authorities. The latter is also very useful to cross check the annual gross salary started on the December salary slip. The annual personnel costs reported by Heamotronic seem to be understated because no obligatory social charges appear to be included. The supporting documentation provided by the associated beneficiary Heamotronic seem to contain the relevant data for calculating the annual personnel costs correctly, but Heamotronic should in the final report, at the latest, explain in detail the source of this documentation and identify the elements to be included in the annual personnel costs. The annual personnel costs are calculated the following way:

Item	Text
1	Annual gross salary including 13th and 14th salaries, if applicable.
+ 2	Holiday allowance, if not included in #1 above
+ 3	Obligatory/compulsory social charges imposed by law, such as pension schemes, health schemes, insurance schemes, contribution to labour market funds, etc
+ 4	Pension schemes according to general trade union agreements
+ 5	Company specific pension schemes (that existed before the submission of project proposal) if offered to all employees in a non-discriminatory manner
- 6	Compensation received from insurance or other schemes in case of sickness, maternity leave, re-employment schemes to reactivate unemployed people, etc
=	Annual personnel cost (sum of 1-5 minus 6)

Bonus is not an eligible salary element, so if beneficiaries operate with bonus, the individual salary slips should be checked in order to ensure that the annual gross salary does not include any bonus. Please recalculated the annual personnel costs and update the financial report accordingly. You and your associated beneficiaries could insert additional columns in the financial report next to the column "Annual Personnel Costs" specifying the elements of annual gross salary and the obligatory social charges. With regard to the personnel costs of Hans Gulliksson from Karolinska, as he is employed purely on an hourly basis the personnel costs could be calculated on the basis of the hourly rate plus the obligatory social charges and the columns "Annual personnel costs" and "annual productive hours" could exceptionally be left blank. Please also inform/instruct your associated beneficiaries how to calculate the annual personnel costs correctly.

Reply 5

The instruction for reporting time provided for the beneficiaries follow the same instructions as EC provide in their letters since October 2012.
http://www.pvcfreebloodbag.eu/wp-content/uploads/2015/12/Time-report-instruction-Dec2015.pdf
Haemotronic has provided an excel sheet that identify all the elements to be included in the annual personnel costs for all personnel reporting time in 2011-2015. In the headings are:
Name
RETR.LM. – Gross Salary (monthly)
RETR. LA (CX13) – Gross Salary (yearly with 13 monthly gross salary)
TFR (it's a like a pension. The worker will get the sum of this amount he earned through the years when he finishes to work for Haemotronic according to national law.)
CONTr (Social charges)
Total
ORE LAV (hours worked in the year)

They also verified personnel costs with December salary slip for 2014 and 2015 for all employees.

Issue 6 Personnel costs – annual productive hours

The reported number of annual productive hours have varied between 1488 and 1927 hours. It is the actual working time that is reported, that is absence as holidays, bank holidays, flexitime compensation, weekends and sickness. It is accepted to report calculated and statutory hours in the financial report, but if the actual productive hours are higher, this number should be used. The actual annual productive hours can be obtained from the timesheets or the time registration records by adding the hours worked on all activities, i.e. the hours actually worked on the LIFE project plus other activities. If the annual productive hours are not recorded a default number of annual productive hours of 1720 can be used. For more details please refer to the annex of the circular Note on Timesheets on the following web site: http://ec.eurona.eu/environment/lile/toolkit/nmtools/lifeplus/timcshects.htm·

Reply 6

See Reply 5 and section 6.3 Issue 3

Issue 7 Personnel costs – 2% rule

Please be reminded that the public beneficiaries, i.e. your organisation and Karolinska, must respect the 2% rule, which mean your financial contribution should cover at least 102% of the cost of your permanent staff, which was not the case in the version of the financial report available at the project visit. In order to assess this rule correctly you should clearly indicate if the staff is permanent or temporary. Please be reminded that in order to be considered temporary staff the contracts should not start before the date of signature of the grant agreement and expire before the end date of the project and the contract should mention the LIFE project specifically. The contract of Hans Gulliksson from Karolinska do not mention the LIFE project, see the following paragraph.

Reply 7

We are well aware of the 2% rule applicable to public bodies. Region Jämtland Härjedalen and Karolinska's total own contribution will be at least 2% higher than the reported cost of permanent staff. This will be reported in the Final Report.

Issue 8 Personnel costs – specifically seconded

During the project visit, the issue "specifically seconded" was not discussed. Referring to Article 25.2 of the Common Provisions, please be informed that the staff of public bodies should be specifically seconded to the project, i.e. their contract and personnel file must show that the member of staff concerned have been working for x weeks/months on the project. In this context I would like to inform you that the contract of Katarina Ryckenberg comply with this condition because it is indicated that she should work 35% of her time for the LIFE project. Please ensure that the personnel files of all public staff contain such an instruction. It also apply for the contract for Hans Gulliksson from Karolinska.

Reply 8

At CB project manager, communication officer and financial officer have wordings in their contracts that show what role and commitment to the project they have.
In Lena Stigh's contract says that she is project manager in LIFE10 ENV/SE/037 and in Katarina Ryckenbergs contract states that she works 35% of a full time in the project as a communication officer. For Arne Nilsson, please see copy from our personnel file. Annex 7.1.5

At Karolinska they fulfilled this by a reference in the individual employment contracts or on a separate paper in the same manner as CB.

Issue 9 Externable assistance/durable goods

All beneficiaries are being reminded about the provisions of Article 25.1 of the Common Provisions 3 rd bullet point where costs to be considered eligible should be reasonable and comply with the principles of sound financial management, in particular in terms of value for money and cost effectiveness. This means that even if national tender rules do not apply to non-public beneficiaries, they still have to able to explain how the rules of the aforementioned Article have been observed. The non-public beneficiaries should provide 6 these explanations in the final report at the latest. All the beneficiaries that report durable goods should in the final report describe their depreciation policy and should provide supporting accounting evidence of the depreciated values declared in the financial report. It also applies to the costs reported as prototype

Reply 9

CB and Karolinska as public beneficiaries follow national tender rules and either use existing frame agreements or procure according to public procurement legislation.
See examples on section 6.4 Issue 10 and 11.

Issue 10 Prototype

Heamotronic explained that the equipment developed to produce the PVC free blood bags are only used in connection with the special compound for the PVC free blood bags and cannot be used in connection with the foil for the conventional blood bags. However, please be informed that the equipment classified as prototype cannot be used for commercial purposes in the project period and during a 5 year period after the project end date, i.e. in a commercial production of PVC free or conventional blood bags. The eligibility of the prototype costs will not be affected if the equipment is used for further tests and/or research and development during the same period. The eligibility of the prototype costs are not affected if all the prototype equipment is dismantled after the project end date and not used at all.
In order to prove the respect of Article 13.8 of the Common Provisions, please annex to the Final Report at the latest photo documentation of the project equipment where the LIFE logo is clearly visible.

Reply 10

Haemotronic is aware of that equipment classified as prototype cannot be used for commercial purposes in the project period and during a 5 year period after the project end. Haemotronic has sent an extract from their accounting system for the amortization of the prototype from supplier PIEFFE (invoice 33,333€). The extract shows that the PIEFFE invoice has been booked in Haemotronic ASSET BOOK with the ID number 211120130007 and it is following an amortization plan of 4,166.67 Eur/year (7.5 years total period) as per Italian rules.

The supplier PIEFFE made a modification to the tube inserting station and the cutting station to be able to produce the bag prototypes. A photos of the equipment with the LIFE logo on is in Annex 7.1.9

Wipak has still not any prototypes.

6.2 The responses to the financial issues raised in the EC letter 6 February 2015

The first two issues have been responded upon according to request in our letter dated 27 February 2015, followed by a responding letter from EC dated 10 March 2015.

Issue 3.
Please explain why your associated beneficiary Karolinska has reported approximately the same number of hours for the project for the administrative staff the expert/chemist.

Reply 3
Karolinska has reported approximately the same number of hours for the administrative staff as the expert/chemist for several reasons. The delay of the evaluation postponed the working time and the decreased time needed for evaluation opened an opportunity to increase activities to increase demand. The person replacing Inger Johed, who was listed as administrative staff, was selected because of her communication skills and because she had a permanent employment at the same department as Inger. The Environmental Department in Karolinska that are responsible for the project internally.

Issue 4.
I am very concerned that no financial information has been reported by the associated beneficiary Primo which has been included in the project implementation since January 2013. Please explain the financial status of this beneficiary.

Reply 4
Primos activities regarding producing of the tubings depend on design decisions made by Haemeotronic and Karolinska. The major production work started in June 2014.
Primo now reported time for three persons in 2014 and 2015.

6.3 The responses to the financial issues raised in the EC letter 3 November 2015

Issue 1 Project management
I kindly ask you to take necessary steps to improve the financial and administrative management of the project and ensure that all the project related information (for the project's associated beneficiaries including) as stated in the Common Provisions article 6.1 is always available at your office at the time of the yearly visits of the external monitoring team. Please instruct the associated beneficiaries accordingly. Please note that the quality of the overall management of the project may affect the amount of the final (balance) payment to your project. To improve the project management and reporting performance, please consult the "Guidance for the financial management and reporting" that is available on LIFE homepage, Toolkit section: http://ec.europa.eii/environment/life/toolkit/pmtools/lifeplus/reporting.htm

Reply 1
As CB we remind all beneficiaries repeatedly that all supporting documents should be sent to CB, preferable every month, according to the Partnership agreement and Article 6.1 in Common Provision.
CB is updating financial reports on behalf of each beneficiary in an excel workbook. The new template from September 2015 is used.

1) Issue 2

Please provide with your next progress report detailed information as listed below for your organisation and for each of the associated beneficiaries of the project:
a) A clear and detailed information regarding the cost accounts in the analytical accounting system - cost account and/or a project code (for all beneficiaries).
b) An extract from the analytical accounting system of the costs actually registered/booked under this project account/project code, preferably with sub accounts;
c) A detailed information regarding the method of calculation and reimbursement of travel costs: tickets, fuel, allowances etc.;
d) A description of the methods applied for selection of subcontractors with references to the relevant national rules.

Reply 2

a) For each beneficiaries all costs related to the project are separated from other costs. All beneficiaries, except Melitek, have provided the cost account or project code which identifies the project costs in the analytical accounting system. Melitek's all transaction regarding the project are tagged and traceable. See section 6.4 issue13.

Short name of beneficiary	Cost account (code name or number)	Name / function of person authorising expenditure (e.g. purchase order)	Name / function of person authorising payment	Name / function of person responsible for financial project management (e.g. accounting, reporting etc.)
CB, Jegrelius	4563	Lena Stig Project Manager	Marina Gregorsson Head of Attraction & Env.	Arne Nilsson Head of Economics
Karolinska	91803/102814	Gustav Eriksson, Head of Env. Dep	Gustav Eriksson, Head of Env. Dep	Ragne Jönsson, Controller
Melitek	See explanation above	Jesper Laursen /Director	Jesper Laursen /Director	Jesper Laursen /Director
Wipak	30473	Jouni Vikman / Director Health	Simo Harju / Financial Manager Nordic	Kristiina Turunen / Solution Expert Finance
Haemotronic	LIFE ENV/SE/037	Renato Ravizza, Moreno de Tomi, Ettore Ravizza, Angelo Poletti	The same persons as on the left. They are all managers.	Mr. Claudio Cona
Primo		Aleksandra Trzeciak-Krysta (Purchasing specialist)	Marcin Śliż (Financial Manager)	Krzysztof Dębski (General Manager).

Wipak is monitoring the project according to their internal costs monitoring system utilizing the financial tools that are in use and available. Project code LIFE10 ENV/SE/037
At Karolinska they have an internal project account and archive all documents as invoices and time sheets.
b) All beneficiaries, except Melitek and Primo, have sent us an extract from the analytical accounting system showing the project costs booked on the specific cost account/project code. Primo will send on Monday 29 Feb 2016. Examples Haemotronic , CB in Annex 7.1.3
c) See section 6.4 issue 9
d) CB and Karolinska as public beneficiaries follow national tender rules and either use existing frame agreements or procure according to public procurement legislation.
See section 6.4 Issue 10, 11

2) Issue 3

The timesheets inspected by the monitor complied with the provisions of the common provisions. However, the staff of the associated beneficiary Haemotronic is only recording the time worked for the project and not on other activities. Please be informed that in case time on other activities are not registered, the personnel costs are based on a default number of 1,720 productive hours.

Reply 3

In timesheets the time worked other than is recorded. An example of timesheets from Haemotronic provided as annex 7.1.2

3) Issue 4

The latest project related invoices available for inspection by the monitor dated back to 2013 and the other accounting documents dated back to 2014. In this context please be reminded again that the copies of the project beneficiaries' documentation must be retained at the coordinating beneficiary's offices and must be collected on a regular basis - monthly according to the requirements of the project's partnership agreement. It is in your interest as coordinating beneficiary ensure that your associated beneficiaries comply with the provisions of the partnership agreement. You should also ensure that all information is available at the occasion of the yearly monitoring visits.

Reply 4

As CB we remind all beneficiaries repeatedly that all supporting documents should be sent to CB, preferable every month, according to the Partnership agreement and Article 6.1 in Common Provision.
All beneficiaries have provided time sheets for 2015 and most of the supporting documents. When transferring all posts into the new excel templates from Sept 2015 all supporting documents are looked into. Insufficient documents have been sent back for adjustments.

4) Issue 5

The reference to the project on the invoices inspected by the monitor was not always in accordance with the Common Provisions, for more guidance please refer to guidance on this issue contained in previous correspondence from the Commission.

Reply 5

In the project instruction on how to report costs, has from the start of the project been stated that “All invoices shall also include a clear reference to the project LIFE10/ENV/SE/000037 PVCfreeBloodBag and you have to inform the suppliers and subcontractors accordingly.”
CB have informed the beneficiaries that incomplete cost transactions in the final report will be ineligible.

6.4 The responses to the financial issues raised in the EC letter 10 March 2015

Some issues have already been regarded in the above section 6.1-6.3 and some issues will be regarded in the Final Report.

Issue 7

Wipak it was explained that the high salary rate of Mr Weijo was explained by his retirement during 2013 and that the holiday allowance due was paid to him at this point of time. However no explanation on the high salary rates reported for Nieminen and Wikman

compared to the rates quoted in the budget (approximately 100% higher) was provided. Please explain and justify.

Reply 7
Mr Vikman high salary rate is explained by his high expertise and specific role in the project. Mr Jouni Vikman is the Director of Wipak Health and the supervisor and spokesman for the project. He proceeded Mr Weijo in the project.
Mr Nieminen was a legal advisor working in administration. He is no longer working in the project. Both their hours reported are limited in the project and thus the cost impact low.

Issue 9 Travel costs
Please be reminded to include information of the duration in describing the purpose of the travel. This applies in particular to Melitek, Regionsforbundet and Wipak.

Reply 9
CB has reminded the beneficiaries about what details are needed and ask for more details if necessary. CB also requested from the beneficiary to describe how travel expenses are handled.
At CB travel expenses can be handled in two different ways, either:

- through personal expenses that are regulated in a travel expenses form and payed along with the salary or
- purchase from the procured traveling agency.

Costs reimbursed through the travel expense in the salary system is usually about traveling with your own car. The reimbursements is made according to a fixed price per kilometre (SEK 2.90). It can also apply to minor outlay for connections such as bus or taxi. Travel expenses are always attested by the supervisor.

All other trips are ordered from the procuring agency and billed by them to the CB. The invoice is attested by the supervisor

Issue 10 External assistance Regionsforbundet
Please provide copy of invoice 162 of 2 April 2012 and the corresponding payment proof. Please also explain the selection procedure employed when selecting “Eco2Win” as subcontractor.

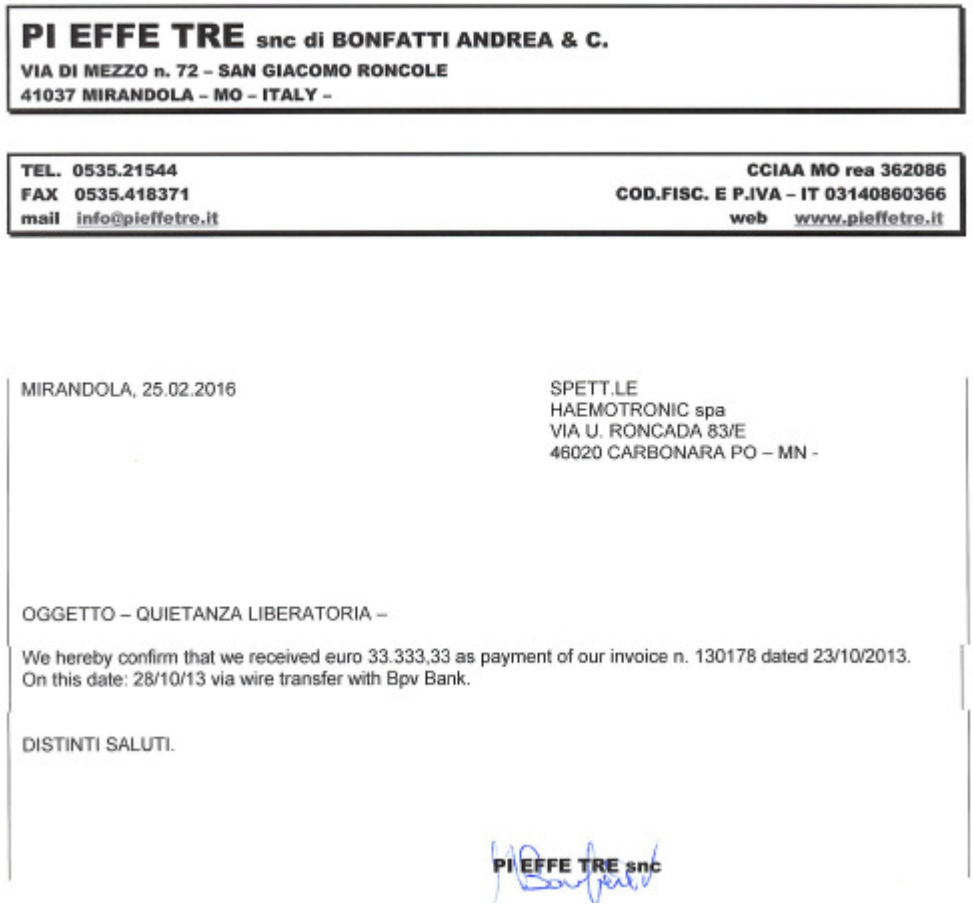
Reply 10
CB provide a copy of invoice 162 of 2 April 2012 and the corresponding proof in annex 7.1.6
The procedure used to procure subcontractor Eco2win was following the organisations public procurement routines. The procedure depend on the expected total sum of the contract. In this case a request for offer was sent to three companies with the lifecycle assessment skills. Two of them, Miljögiraff AB and Eco2win, sent in equally qualified offers and we selected Eco2win.
As reported in inception report the expertise in performing the LCA as well as presenting the result in the Kick-off was procured and an agreement was signed. The three documents; Guidance data, Request for offer and Agreement are in the diary of Regional council of Jämtland with registration number 2011-479. The diary and numbers are still valid in the new organisation.

Issue 11 Prototype Haemotronic

Please provide copy of invoice 130178 of 10 October 2013 and the corresponding payment proof. Please also explain the selection procedure employed when selecting "PIEFFE TRE" as subcontractor.

Reply 11

Haemotronic has provided a copy of invoice 130178 of 10 October and corresponding payment proof. The invoice is in Annex 7.1.7 and the payment proof is below.



PI EFFE TRE snc di BONFATTI ANDREA & C.
VIA DI MEZZO n. 72 – SAN GIACOMO RONCOLE
41037 MIRANDOLA – MO – ITALY –

TEL. 0535.21544
FAX 0535.418371
mail info@pieffetre.it

CCIAA MO rea 362086
COD.FISC. E P.IVA – IT 03140860366
web www.pieffetre.it

MIRANDOLA, 25.02.2016

SPETT.LE
HAEMOTRONIC spa
VIA U. RONCADA 83/E
46020 CARBONARA PO – MN -

OGGETTO – QUIETANZA LIBERATORIA –

We hereby confirm that we received euro 33.333,33 as payment of our invoice n. 130178 dated 23/10/2013.
On this date: 28/10/13 via wire transfer with Bpv Bank.

DISTINTI SALUTI.

PI EFFE TRE snc

The selection procedure employed selecting PI EFF TRE as a subcontractor is explained here: The best offer in terms of time/quality/money between 2 subcontractors are selected. This is the usual procedure for selecting a subcontractor and also applied here.

Issue 12 Consumables Regionsforbundet

Cost related to use of mobile phone, head sets and chocolate box' are considered having a character as overheads and should be removed from this cost category.

Reply12

Costs related to use of mobile phone are considered as overhead and those costs that by mistake been specified otherwise have been. Removed.
As requested by EC the head sets required for all PMG members to perform on-line meetings in action 4 have been moved to overhead, as well as the ecological chocolate boxes for the speakers in the PVC-replacement seminar the projected hosted at CleanMed Europe 2012.

Issue 13 Consumables Wipak&Melitek
Please improve the description all transactions purchased internally. Please also quote the unit rate and number of units included in the internal invoice. Please also provide a detailed specification of the unit rate in order to ensure that the unit costs only represent actual costs. Please also explain why the costs are purchased internally and not from an external source.

Reply 13
When producing the compund at Melitek, high quality and reproducibility is of outmost importance. Melitek produces all their compounds in line with a dedicated medical service concept which guarantees full lot traceability, change control management and extensive line clearance procedures to ensure high uniform quality. The quality system is certified in accordance to ISO 9001:2008 to ensure superior product control.

The raw material in one compound batch may origin from different suppliers and different lot-numbers. A commercial internal invoice is simpler and more accurate since it includes the real costs for the specific compound.
The commercial invoices, see annex 7.1.8, from Melitek are provided with lot-numbers, material specifications and are traceable to the external suppliers and raw material.

Below is an example of a cost break down from Melitek.

Cost breakdown - example

Order no.	203456
Invoice no.	704406
Ship date	13.03.13
Type	R21166A
Qty (kg)	700
Cost (EUR/kg)	8,00

Costs	**EUR/KG**	
Production prep	0,596	
Production kosts	2,310	incl electricity, water, line time, maintanace
Packaging	0,053	
QC release cost	0,198	
Raw materials	4,846	incl production waste and surcharge for LTL shipment
TOTAL (EUR/kg)	**8,003**	

Earlier before the project was approved a cost estimation of compound was sent to EC upon request. Both an estimate for compound for film and for tubing. Both PM and the financial officer have visited Melitek at two separate occasions and found documentation in order.

Issue 14 Other costs Regionsforbundet
Costs related to use of mobile phone from the service provider Telia are considered having a character as overheads and should be removed from this cost category.

Reply 14
Costs related to use of mobile phone have by mistake been registered in other costs. We are aware of these costs are regarded as overheads. They have been removed from this cost category.

6.5 Costs incurred

Budget breakdown categories	Total cost in € According to Form FA	Costs incurred from the start date to 31.12.2015in €	% of total costs
1. Personnel	1 342 551	891 785	66,42%
2. Travel and subsistence	112 230	26 056	23,22%
3. External assistance	205 365	54 968	26,77%
4. Durable goods			
Infrastructure	0	0	
Equipment	0	0	
Prototype	115 000	33 333	28,99%
5. Land purchase / long-term lease			
6. Consumables	235 867	65 082	27,59%
7. Other Costs	49 234	12 082	24,54%
8. Overheads	144 217	75 831	52,58%
TOTAL	2 204 464	1 159 137	52,58%

The costs for Travel and subsistence will increase in action 22 when we have the final seminars and in the cost category Other costs we have printed matter that also will increase towards the end of the project.

When looking at the table in next page we have exceeded the foreseen costs with 31 132 € in action 1, 2, 3 and 8. At the same time we have an excess from action 6 and 7 with 44 306 € and there also seems to be an excess in action 4 and 5 with around 56 000 €.

One reason for more costs in project management is time needed to solve administrative problems and apply for two amendments. The prolongation will also require some time in managing the project, even though the project manager will spend a majority of time in action 10, 17, 21, 22 and 23.

In the column for projected final costs, the estimated excess from action 4 and 5 have been moved to action 1.

The actions regarding dissemination of information and an increased awareness; action 2,3, 7, 8,10 and the coming 21 and 22 have the same overall objectives.
Since action 6 and 7, regarding the first seminar are completed and the excess could be transferred to actions were there are more activities to come. In action 2, 3, 8 there will be activities related to the final seminars in action 22. In action 11 we estimate a higher cost for printing reports and material for the final seminars.

In 2015 there was a cost from external assistance regarding production of the film, Action11. The cost of 2670 € is however registered in February 2016. Annex 7.1.4

In action 17 we added costs for external assistance. The economic feasibility study may like the second Life cycle assessment be performed by an independent assessor.

In action 13, the production of tubings, the costs have been higher, but Primo has not provided any verification of that yet.

Form FB of the proposal contains the projected final costs:

Action number and name	Foreseen costs	Spent so far	Remaining	Projected final cost
Action 1 Project Management	166 290	187 516	- 21 226	222 290
Action 2 Web sites and media work	66 942	73 075	- 6 133	76 942
Action 3 Notice boards and dissemination of project information	43 556	46 304	- 2 748	48 556
Action 4 Project meetings for the PMG	28 301	17 379	10 922	22 301
Action 5 Monitoring the project's progress	74 375	11291	63 084	24 375
Action 6 Org of First seminar action 7	9 040	5 494	3 546	5 494
Action 7 First Seminar	64 768	24 008	40 760	24 008
Action 8	8 756	9 781	- 1 025	10 756
Action 9 Audit	37 373	0	37 373	37 373
Action 10 Increase Demand	32 697	16 419	16 278	32 697
Action 11 Production of brochures, reports, posters, invitations	36 437	4 479	31 958	42 437
Action 12	183 290	127 725	55 565	183 290
Action 13	172 421	51 385	121 036	172 421
Action 14	90 195	62 569	27 626	90 195
Action 15	613 520	407 952	205 568	613 520
Action 16	138 542	34 432	104 110	138 542
Action 17	7 533	410	7 123	21 533
Action 18	0	0		0
Action 19	16 855	0	16 855	16 855
Action 20	16 490	0	16 490	16 490
Action 21	25 770	3 087	22 683	25 770
Action 22	190 433	0	190 433	197 739
Action 23	36 663	0	36 663	36 663
TOTAL	2 060 247	1 083 306	976 941	2 060 247

7. Annexes

7.1 Financial and administrative issues

7.1.1 Updated part C

7.1.2 Example of time sheet - Haemotronic

7.1.3 Extract from accounting system

7.1.4 Example of an invoice with detailed description

7.1.5 Verification of specifically seconded employment

7.1.6 Copy of invoice 162 of April 2012

7.1.7 Copy of invoice 130178 of 10 October

7.1.8 Commercial invoice from Melitek

7.1.9 Picture with equipment with logotype from Haemotronic

7.2 Output indicator table

7.3 Dissemination material

7.3.1 Third Newsletter

7.3.2 Press release 5 November 2014

7.3.3 Press release 22 October 2015

7.3.4 Handout updated

7.3.5 Invitation to webinar

7.3.6 Presentation 16th of October 2015

7.4 Delivery: Monitoring of blood transfusion operations