

*LIFE 10 ENV/SE037*

## **Action 4: Project meetings for the Project Management Group**

The 30th PMG meeting. The updated action plan is at the end of the notes.

### **Minutes**

**17 Jan 2017**

#### **Attendees**

Coordinating beneficiary:

Lena Stig (PM), Katarina Ryckenberg, Åke Åkerblom, Arne Nilsson

Karolinska: Hans Gulliksson,

Haemotronic: Alice Ravizza

Primo: Krzysztof Debski

#### **Not attending**

Karolinska; Beatrice Aspevall Diedrich/ Maria Matl, Gustav Eriksson, Linda Nilsson,  
Petter Höglund

Melitek: Jesper Laursen

Wipak: Pekka Weeraratne

#### **Agenda**

- Administration and economy
- User tests in Trollhättan, Jönköping, Östersund and Uppsala
- The Life Cycle Assessment
- pre-audit for CE-labelling in March
- Translators for the Layman report
- Update from other actions

#### **The meeting**

##### **1. Administration and economy**

We still haven't received the official approval of the prolongation of the project. PM mailed the EC before Christmas, because we wanted to know prior to next newsletter.

Maria still misses financial documents from most of you. It is urgent to make the financial update in order to plan this last few months' activities and prepare for audit; annual income, pensions, time sheets and invoices regarding action 22. For example we need to know how much is left for external assistance regarding LCA and whether or not we could make some complementary assessments of the new bag. It would also be valuable to let someone from outside do the economic feasibility study.

Since we have completed the final seminars it is important that everyone report time, invoices and participation related to this action - Action 22.

Krzysztof will contact Maria separate.

## 2. Action 17 User tests

Haemotronic delivered 500 set of bags during 13-15<sup>th</sup> of December. Östersund, Trollhättan, Jönköping and Uppsala all received 125 sets each. Åke and PM had a dialogue with Linda Larsson in November about how to improve the tests. The short instruction movie was sent to the three hospitals and we hold a telephone meeting the 14<sup>th</sup> of December. Åke sent test protocols intended for the hospitals and both Jönköping and Trollhättan started with the user tests in December using metal clips. Due to problems with the centrifuge, Östersund is starting today and as soon as they are ready the sealer will be sent to Uppsala. The new sealer is working fine even though it is a bit clumsy. Alice appreciated that there are a lot of pictures taken.

An economic feasibility study is also included in action 17 and is listed as a separate delivery to EC. PM is responsible, but need help from you in estimating the costs for producing a set of PVC-free blood bags as well as the estimated price for a buyer. Alice informed us that they made an estimation at Haemotronic and Ettore is the one who knows.

As the title of report reveals feasibility is the main issue.

## 3. The Life Cycle Assessment

There are still some data missing, regarding sterilization and the production of compound. PM sent mail to Alice and Jesper earlier about additional information. Alice will try to get hold of more data. Ettore is working in US at the moment. A new dead-line for the LCA is March and that includes an external audit. An extra audit of the LCA would be valuable, since there was criticism of the LCA presented at the Kick-off.

This budget cost is one example that we would need to know the coverage of as soon as possible. We have a name a suitable third part, that not been involved in either of the LCA's.

## 4. Action 15 Pre-audit for CE-labelling

One third part body has been selected and will visit Haemotronic the 24<sup>th</sup> of March at the Carbonara plant.

As required by the notifying body PM will be available for questions during the visit and the inspection will be held in English.

A technical file of the device according to the current Directive, required by the notified body, about the set of blood bag, will be completed by Alice before the inspection.

In order to complete the Technical File Alice need some very important information from the project partners.

From MELITEK: updated list of raw materials and their regulatory, technical and MSDS documents

From PRIMO and WIPAK: technical drawings of their products

From HANS and/r PETTER: availability to review the Clinical Evaluation report and availability to a conference call on the topic in early March

From ÅKE AND ALL HOSPITALS: user testing reports as detailed as possible.

## 5. Action 19 The Final layman's report

The Layman report, a 5-10 page report with pictures, will be translated into Swedish, Danish, Finnish, Italian, Polish, German, French and Spanish.

Who will perform the translations?

Krzysztof said that Primo could provide translation from English to Polish and from English to German.

PM expects that Melitek, Wipak and Haemotronic could provide for the translation into their native languages. PM consults the projects two proof readers about Spanish and French.

## 6. Update from other actions

### Action 2, 3, 10

A Newsletter is prepared and ready to be launched as soon as we get the official approval about the prolongation.

The presentations from the seminar have been cut by Jonas and will soon be on the web.

The short version of the user tests, the one PM used in Copenhagen, has been provided with a speaker's voice and will also be on the web soon.

PM will present the result from the project at Nordic Conference on Sustainable Healthcare, 15 February 2017, in Stockholm. There are several opportunities for networking since HCWH, C2DS and representatives from Nordic healthcare organisations are attending.

Krzysztof has presented the project in a conference in Warsaw with healthcare as target group. He will send more information of the event to Katarina.

Action 20 The manuscript for the publication in Vox Sanguinis has been accepted and is available on-line.

### Action 21,22

There will be one extra webinar presenting all results after the CE-labelling is completed and then will probably also the layman report to present.

What dates in April or May do you prefer?

The project also talked about future scenarios and if there are possibilities to provide sets of bags for a Dutch organization that are interesting in testing new storage solutions.

Cooperation is a success factor. Cooperation of organizations with different competences as product development, evaluation and demand.

Future scenarios should be described in both the After Life+ communication plan and in the final report.

## 7. Next PMG meeting

4th of April 13-14 CET

**ACTION PLAN**

<b>Action</b>	<b>Activity</b>	<b>Take action</b>	<b>Deadline</b>	<b>Delivered</b>
1	1. Coordinating beneficiary (CB) will write a draft of a Partnership agreement. The draft will be sent out to all beneficiaries.	Jegrelius	14/10/2011	11/11/2011
1	2. Set the Partnership agreement	All beneficiaries	28/10/2011	24/04/2012
1	3. Send out templates for time reports and calculating Daily personal costs.		26/09/2011	26/09/2011
1	4. Report time according to time sheet	All project personnel	Within two weeks after end of each month	
1	5. Initial Report Will be attached to inception report	Jegrelius	30/11/2011	21/03/2012
1	6.A detailed plan for the implementation phase	All beneficiaries	01/12/2011	Implementation described in the Inception report
1	7. Sign Partnership agreement	All		15/05/2012
1	8. Instructions for rest of reports to CB	Jegrelius	19/02/2012	24/02/2012
1	9. Procure LCA consultant	Jegrelius	12/12/2011	13/12/2011
1	10. Time reports including Feb2012	All project members	01/03/2012	yes
1	11. Inception report to EC	Jegrelius	01/04/2012	30/03/2012
1	12. Plan for action 12-17	All		Updated several times
1	13. Report costs according to instructions.	All beneficiaries	Within two weeks after end of each month	
1	14. Pre Progress report	Jegrelius	01/08/2012	30/09/2012
1	15. Respond to feed-back about Inception reports	Jegrelius	14/09/2012	
1,5	16. Visit by monitor	Jegrelius		24/05/2012 22/08/2012 04/11/2013 16/10/2014 3/09/2015 20/09/2016

1	17. Visit Melitek	Jegrelius	Oct 2012	22/10/2012
1	18. Visit Totax/Primo	Jegrelius	Nov 2012	06/11/2012
1	19. Revision of time table. Has to be made again.	Jegrelius	30/09/2012 30/01/2013	30/09/2012
1	20. Progress report 1	Jegrelius	01/02/2013	31/01/2013
1	21. Visit Wipak	Jegrelius	2013	11/03/2014
1	22. Visit Haemotronic	Jegrelius	2013	05/11/2014
1	23. Visit Karolinska	Jegrelius	2014	2015
1	24. Amendment about postponed Mid-term report	Jegrelius		31/01/2013
1	25. Amendment request Ben 7	Jegrelius, Krzysztof		Sent June 2013 Approved 6 Dec2014
1	26. Revised Partnership Agreement from 2013	Jegrelius		15/05/2014
1	27. Mid-Term Report	Jegrelius	30/04/2014	30/05/30
1	28. EC visits CB	Jegrelius, Karolinska, Haemotronic	04/04/2014	04/04/2014
1	29. Follow up on remarks from EC	Jegrelius	In progress report 2	28/02/2016
1	30. Progress report 2	Jegrelius	28/02/2016	28/02/2016
1	31. Visit Melitek	Jegrelius/ Linda		15/05/2014
1	32. Visit Karolinska to present project and discuss personel	Jegrelius		19/05/2014
1	33. Revised Mid-Term report	Jegrelius	30/09/2014	30/09/2014
1	34. Apply for prolongation	Jegrelius	May 2015	01/06/2015
1	35. Amendment request new legal status of CB	Jegrelius	May 2015	01/06/2015
1	36. Change of financial officer	Jegrelius		14/09/2015
1	37. Amendment approved	Jegrelius		18/11/2015
1	38. Revise partnership agreement	Jegrelius		
1	39. Amendment request no 3	Jegrelius		25/11/2016
1	40. Visit Haemotronic to assist during CE-labelling audit	Jegrelius	March 2017	
1	41. Final report with payment request	Jegrelius	01/03/2017 Will be changed	
2	1. Send beneficiaries Logos for the web page	All beneficiaries	30/09/2011	yes
2	2. Launch PVCfreeBloodBag.eu	Jegrelius	01/10/2011	14/10/2011
2	3. Inform those who signed the petition and letter of intent about the web page.	Jegrelius	15/10/2011	Yes
2	4. Update with pictures and information	Jegrelius	Continuously	

2	5. Link to project web site from beneficiaries web site	All		<i>A few renewal is needed</i>
2	6. Make correction on map concerning Totax and Melitek	Jegrelius		16/12/2011
2	7. Add text to side of Life logotype	Jegrelius		13/08/2012
2	8. Media activities		Continuously	See monitoring protocol at web site
2	9. Secure web site, Transform to new format	Jegrelius	April-Maj 2014	11/03/2015
2	10. Update "map" with Primo Profile	Jegrelius		Jan 2014
2	11. Press release	Jegrelius/ Haemotronic		05/11/2014
2	12. Press release when in-vitro starts	Jegrelius/ Karolinska	Sep 2015	22/10/2015
2	13. Identify media channels	Jegrelius/ Karolinska		
2	14. Launch Web site in Word press format	Jegrelius		11/03/2015
2	15. Short project movie recording 5/05/2015	Jegrelius/ Karolinska	April-June 2015	19/01/2016
2	16. Involvement in Dutch TV-programm Radar	Jegrelius/Karo linska		March 2016
2	17. Record the user tests	CB		Sept 2016
2	18. Presentation at HCWH webinar	Melitek		09/11/2016
2	19. Launch short user test clip with Speaker's voice	Jegrelius	Jan 2017	
3	1. first Notice board set-up	Jegrelius	01/11/2011	14/10/2011
3	2. Disseminate more Noticeboards and project information	Jegrelius, All	Continuously	
3 (and 10)	3. Attend HCWH meeting in Malmö to disseminate project information and take a part in planning CleanMed 2012 in Europe	Jegrelius	09/12/2011	09/12/2011
3	4. Communication plan -first draft	Jegrelius		14/05/2012
3	5. Prezi project presentation	Jegrelius		29/11/2012
3	6. Send abstract to ISBT conference in the Netherlands	Jegrelius	03/Mar/2013	

3	7. Send abstract to CleanMed Europe	Jegrelius		08/05/2013
3	8. Attend CleanMed 17-19 Sept 2013	Jegrelius		19/09/2013
3	9. Newsletters	Jegrelius	Dec 2016	May2013 Aug 2013 May 2015 April 2016
3	10. Presentation about how to get a non-toxic product, Procurement conference	Jegrelius		10/10/2013
3	11. Dialogue meeting at Swedish Chemical Agency	Jegrelius	16/06/2014	16/06/2014
3	12. Presentation to Stockholm County Council	Karolinska	09/09/2014	09/09/2014
3	14. Webinar with HCWH	Jegrelius/ Karolinska/ Melitek	22 Oct 2015	22/10/2015
3.	15. Presentation at kick-off NCSH	Jegrelius		28/05/2015
3.	16. National Procurement meeting about medical devices	Jegrelius, Karolinska		29/09/2015
3	17. Twitter account opened	Melitek/Jegrelius		Jan 2016
3.	18. Presentation of project and progress	Jegrelius/Karolinska	12/05/2016	12/05/2016
3.	19. Project presentation NCSH	Jegrelius	15/02/2017	
4	1. Send headsets, recommended by our It-support, to all PMG members.	Jegrelius	10/10/2011	yes
4	2. Individual "OpenMeetings" will be arranged between project manager and all members together with IT support.	Jegrelius PMG members	31/10/2011	Yes
4	3. Set dates for PMG meetings next year2012	PMG members	15/10/2011	yes
4	4. Extra meeting for those that could not attend; Wipak, Totax, Melitek	Jegrelius	31/10/2011	N/A
4	5. Arrange next PMG the 8 Feb in Copenhagen.	Jegrelius		02/02/2012
4.	6. Set dates for PMG meetings 2013	Jegrelius	04/12/2012	
5	1. Monitor protocol	Jegrelius	01/12/2011	27/03/2012
5.	2. Outcome Indicator database	Jegrelius	29/04/2016	29/04/2016

6	2. Set date and place for the first seminar – Date decided in Oct and place in early Nov	Karolinska	2011	yes
6	3. Procure Kick-off facilities, food and refreshments	Karolinska	20/12/2011	18/12/2011
6	4. Make registration set-up at web page	Jegrelius	16/12/2011	16/12/2011
6	5. Write and send out invitation	Jegrelius/Karolinska	16/12/2011	16/12/2011
6	6. Arrange agreements with external lecturers and moderator	Karolinska/Jegrelius	20/12/2011	12/01/2012
6	7. Set final program	Karolinska/Jegrelius	31/01/2012	20/01/2012
6	8. Produce handouts /info material for seminar	Karolinska Jegrelius	08/02/2012	03/02/2012
7	Update web site with presentations	Jegrelius	12/02/2012	10/02/2012
8	1. Contact other projects	Jegrelius	Continuously	
8	2. Kick-off LIFE-EDESIA	Jegrelius		14/10/2013
8	3. Act as stakeholder in LIFE-EDESIA	Jegrelius		
8	4. Attend HCWH AGM	Jegrelius		06/11/2014
8	5. Contact Life Childprotect	Jegrelius		Dec 2014
8	6. Seminar Swetox	Jegrelius		28/01/2015
8	7. Invite other project to final seminars	Jegrelius		Yes
8	8. Attend HCWH AGM	Jegrelius		20/10/2016
9.	1. Audit CB	Jegrelius	01/10/2016	
10	1. Preparation CleanMed Malmö	Jegrelius		26/09/2012
10	2. Plan buyer group meeting	Jegrelius		
10	3. Inventory of buyers of blood bags in Europe	Jegrelius/ Karolinska		
10	4. Survey # blood bags and # blood transfusion	Jegrelius/ Karolinska		Oct 2015
10	5. Influence on EU-legislation regarding EDC	Jegrelius, HCWH		Oct 2013
10	6. Visit to Finnish Red Cross			10/04/2014
10	7. Present project on EBA meeting	Karolinska/ Jegrelius		16/10/2015
10	8. Project presentation “Nordic Center sustainable healthcare”	Jegrelius	28 May 2015	28/05/2015
10	9. Webinar with HCWH	Karolinska/Me litek/CB		22/10/2015
10	10. Telephone meeting UNDP	Jegrelius		2/06/2016
12	1. Delivery of first compound to Wipak	Melitek	01/01/2012 will be rev	20/11/2012



12	2. Gather material for 12.3	Melitek		yes
12	3. Workshop "Material Specifications"	All beneficiaries	08/02/2012	08/02/2012
12	4. Set "material Specification"	Melitek		01/06/2012
12	5. Delivery of compound to Primo	Melitek		Nov 2013
13	1. Start of action, delayed due to 12.1 and 12.4	Wipak	01/01/2012	01/10/2012
13	2. Delivery of film to Haemotronic	Wipak		yes
14	1. Start of production	Totax/ Primo	01/01/2012	01/11/2013
14.	2. Delivery of tubings	Primo		Oct 2014
14.	3. Make new tool	Primo		May 2014
14.	4. Delivery of new tubings	Primo	April 2016	
15	1. Start of production	Haemotronic		May 2013
15	2. First prototype bag	Haemotronic		March 2014
15	3. Design discussion Visit Karolinska	Haemotronic	April 2014	12-14 May 2014
15.	4. Delivery of bags to Karolinska for evaluation	Haemotronic	Before summer 2014	
15.	5. Physical properties First trial	Haemotronic/ Karolinska		20-21 jan 2015
15.	6. Verification of bag Second tests	Haemotronic/ Karolinska	8-9 June 2015	
15.	7. Delivery of bags for in-vitro evaluation	Haemotronic		Sept 2015
15.	8. Verification of bags for user test	Haemotronic	May 2016	3/05/2016
15.	9. Delivery of bags for user tests	Haemotronic		Sept 2016
15.	10. Second delivery of bags for user tests	Haemotronic	Nov 2017	Dec 2017
15.	11. Prepare Technical File	Haemotronic	Feb 2017	
15	12. Verification of CE-labelling	Haemotronic	March 2017	
16	1. Start of evaluation	Karolinska	Aug 2014	
16	2. Replace Inger	Karolinska	April 2014	Sep 2014
16	3. Recruit new BMA	Karolinska		Jan 2015
16	4. Start of in-vitro study	Karolinska	Sep 2015	Oct 2015
16	5. New staff	Karolinska		Sep 2015
16	6. End in-vitro evaluation	Karolinska		Mar 2016
17	1. Test protocol user tests	Jämtland County Council	2014	
17	2. New start-up meeting	Jegrelius/Jämtl and County Council	27/02/2013	
17	3. Discussion with Alice regarding user tests	Östersund Hospital		02/02/2015

17	4. Attend trial tests	Åke Åkerblom, Östersund Hospital	08/06/2015	
17	5. User tests Östersund	Jegrelius		Sept2016
17	6. Second user tests in Östersund	Jegrelius	Dec 2016	Jan 2017
17	7. User tests Trollhättan	Jegrelius		
17	8. User tests Jönköping	Jegrelius		
17	9. User tests Uppsala	Jegrelius	Jan 2017	Feb 2017
17	6. Economic feasibility study	Jegrelius		
18.	1. After-Life Communication plan	Jegrelius		
19	1. Layman report in English	Jegrelius	Mar 2017	
19.	2. Translate to Swedish	Jegrelius	Mar 2017	
19	3. Translate to Danish	Melitek	Apr 2017	
19	4. Translate to Polish	Primo	April 2017	
19	5. Translate to Finnish	Wipak	April 2017	
19	6. Translate to Italian	Haemotronic	April 2017	
19	7. Translate to German	Primo	April 2017	
19	8. Translate to Spanish	Jegrelius	April 2017	
19	9. Translate to French	Jegrelius	April 2017	
20.	1. Write manuscript for publication	Karolinska		yes
20.	2. Send manuscript	Karolinska		June 2016
20	3. Edit manuscript	Karolinska		Yes
20	4. Manuscript approved	Karolinska		Oct 2016
20	5. In-vitro study publiced	Karolinska		15Jan 2017
21	1. Start planning	Jegrelius, Karolinska	01/03/2014	Oct 2014
21	2. Set dates	Jegrelius/Karolinska		Yes
21	3. Webinar survey start	Katarina, Nicole, Jonas		25/11/2014
21	4. Östersund Arrange seminar	Jegrelius	September	
21	5. Copenhagen/CleanMed Dialogue HCWH	Jegrelius/Katarina	19-20 Oct	Yes Planning
21	6. Düsseldorf	Supply chain	Nov 2017	
21	7. Orlando – send abstract	Hans		Approved speaker
21	8. Procure second LCA	Jegrelius		25/07/2016
21	9. Plan final webinar			
22	1. Final workshops- Östersund	Jegrelius	01/07/2015	28/09/2016
22	2. Orlando	Karolinska/ Hans		20/10/2016
22	3. Copenhagen	Jegrelius		20/11/2016
22	4. Düsseldorf		Nov 2017	14-17 Nov
22	5. Final Webinar	Jegrelius	April 2017?	
23	1. Final project report	Jegrelius		


