

LIFE 10 ENV/SE037

Action 4: Project meetings for the Project Management Group

The 31st PMG meeting. The updated action plan is at the end of the notes.

Minutes

4 April 2017

Attendees

Coordinating beneficiary: Lena Stig (PM), Katarina Ryckenberg, Maria Arnstål
Karolinska: Hans Gulliksson
Haemotronic: Alice Ravizza

Not attending

Coordinating beneficiary: Åke Åkerblom
Karolinska; Beatrice Aspevall Diedrich/ Maria Matl, Linda Nilsson, Petter Höglund
Melitek: Jesper Laursen
Wipak: Pekka Weeraratne
Primo: Krzysztof Debski

Agenda

- Administration and economy
- Outcome of the pre-audit for CE-labelling
- Decide date for the final webinar; 23rd or 30th of May
- Italian conference 6-8 April
- HCWH AGM in Berlin 4-5 May
- WHO Global Forum on Medical devices 10th of May in Geneva
- After-Life promotion activities
- Layman report
- The Life Cycle Assessment
- Update from other actions

The meeting

Unfortunately there was problem with the meeting service. The meeting code was not working and the meeting became delayed with 40 minutes. Åke and Pekka could thus not attend as planned.

1. Administration and economy

The project has received the official approval of the prolongation of the project. The new end date is the 30th of June.

Maria still misses financial documents from most of the members. It is urgent to make the financial update in order to plan this last few months' activities and prepare for the audit; **annual income, pensions, time sheets and invoices**. Maria have sent out separate reminders to all beneficiaries. Maria would like everyone to confirm when they sent everything, by sending her an e-mail.

Krzysztof will contact Maria separate. - Note from last meeting.

Due to lack of resources in form of available personnel, the auditor at Region Jämtland Härjedalen will not perform the audit. An external auditor for **Action 9** will be procured by Region Jämtland Härjedalen. PM and the procurement unit are preparing the request for offer together with the internal auditors.

2. Action 15 Outcome of the pre-audit for CE-labelling

A technical file of the device according to the current directive, required by the notified body, was completed by Alice before the inspection. Christian Vendramin and Tomaso Villa from the notified body Italcert s.r.l. visited the Mirandola plant at Haemotronic the 24th of March together with project manager Lena Stig. Alice Ravizza was the host. The pre-audit confirmed the Gap-analysis made by Alice with one minor addition. The notified body will deliver an official report in English at the end of April.

3. Decide date for the final webinar

The meeting decided on the 30th of May for the final webinar. The plan is to launch the Layman report at the same day. Katarina and PM will start planning together with Jonas.

4. Italian conference 6-8 April

Alice's abstract regarding "Human factors engineering and user friendly design in the PVCfreebloodbag project" was accepted in the Italian Biomedical Engineering summit. She will represent and present the project at the national congress in Genua.

At the XVII Convegno Nazionale AIIC Genova- Italy 6-8 April she will present a poster about the innovative blood bag and also present the project orally. The conference is one of the Italian most important conferences with approximate 1500 attendees. The Ministry of health will attend.

This conference will also be an opportunity to get in contact with a hospital for a complementary user test.

Katarina will add information about the conference on the web.

5. HCWH AGM Berlin 4-5 May

PM Lena Stig and communication officer Katarina Ryckenberg will participate in the meeting in Berlin and probably arrange a workshop focusing on the demand side. Is it possible to initiate a joint procurement or other activities regarding demand?

PM will contact Gustav to know if they as member will attend the meeting.

6. WHO Global Forum on Medical devices 10th of May in Geneva

Alice have applied with an abstract to the WHO Forum and will, according to the conference web site, get a response the 7th of April. Even if the abstract is not accepted Alice will attend. PM Lena Stig would like her to represent the project and disseminate information as the expert on medical devices.

Hans will consider going, depending on if people important for after-Life activities will attend. Alice will send list of participations to Hans, Lena and Katarina.

PM might go for one day if the abstract is accepted.

7. After Life promotion activities

Earlier there have been discussions regarding 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 one important success factor. Cooperation of organizations with different competences as product development, evaluation and demand.

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

What other promotion activities could we arrange besides the webinars and the above conferences and meetings?

8. Action 19 The Final layman's report

A first draft in English is out-lined by PM and a few lines are written about the outcome of the pre-audit for the CE-labelling and also the LCA will be included.

The Layman report will then be sent for proof reading and translated into Swedish, Danish, Finnish, Italian, Polish, German, French and Spanish.

Are there anyone within the PM-group that would like to 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 has sent a request to procure translators for Spanish and French.

The plan is to have the English version ready in the end of April and the translated versions ready to launch at the webinar the 30th of May.

9. The Life Cycle Assessment

PM received a final draft on Friday the 31th of March. This report will be reviewed by Jesper and PM.

An critical review of the LCA will be performed by the third part in April. The result from the LCA and the critical review will be presented at the webinar 30th of May

10. Update from other actions

Action 2, 3, 10

A Newsletter has been launched. In connection with this a site for registration to the Webinar 30th of May was created. Please register and promote the Webinar to colleges and customers.

Most of the presentations from the seminar in September have been cut by Jonas and placed on the web.

The 2-minute version of the user tests, the one PM used in Copenhagen, has been provided with a speaker's voice and is on the web.

PM presented the result from the project at Nordic Conference on Sustainable Healthcare, 15 February 2017, in Stockholm.

Krzysztof presented the project in a conference in Warsaw with healthcare as target group. He will send more information of the event to Katarina. These are notes from last meeting. Have you got information Katarina? – No I have not received any notes/Kr

Action 17 User tests

The user tests in the 4 Swedish hospitals have been finalized. Åke has sent protocols and pictures to Alice for the pre-audit. He also sent a box with failure bags.

There are also unused sets of bags that would be very valuable for Haemotronic to use. They was sent to Italy at the same shipping as the failure bags, but Haemotronic have not received them yet.

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. **This is a note from last meeting.**

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

11. Next PMG meeting

An invitation will be sent for a meeting in June.

There will also be a couple of meetings prior to the webinar the 30th of May.

ACTION PLAN

Action	Activity	Take action	Deadline	Delivered
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. Amendment request no 3 approved officially			
1	41. Visit Haemotronic to assist during CE-labelling audit	Jegrelius	March 2017	24/03/2017
1	42. 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/Karolinska		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	20/01/2017
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	15/02/2017
3.	20. Poster accepted for WHO			
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
8	9. Attend HCWH AGM	Jegrelius	May 2017	
9.	1. Audit CB	Jegrelius	Aug 2017	
9	2. Write Request for Offer	Jegrelius	April 2017	
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/Melitek/CB		22/10/2015
10	10. Telephone meeting UNDP	Jegrelius		2/06/2016
10	11. Workshop Berlin	Jegrelius	May 2017	
10	12. WHO Geneva Med dev	Haemotronic	May 2017	
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	March 2017
15	12. Pre-audit CE-labelling	Haemotronic	March 2017	24Mar2017
15	13. Pre-audit report			
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	CB/Åke	2014	2016
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		Feb 2017
17	8. User tests Jönköping	Jegrelius		Feb 2017
17	9. User tests Uppsala	Jegrelius	Jan 2017	Feb 2017
17	6. Economic feasibility study	Jegrelius	May 2017	
18.	1. After-Life Communication plan	Jegrelius		
19	1. Layman report in English	Jegrelius	April 2017	
19.	2. Translate to Swedish	Jegrelius	April 2017	
19	3. Translate to Danish	Melitek	May 2017	
19	4. Translate to Polish	Primo	May2017	
19	5. Translate to Finnish	Wipak	May2017	
19	6. Translate to Italian	Haemotronic?	May2017	
19	7. Translate to German	Primo	May2017	
19	8. Translate to Spanish	Jegrelius	May2017	
19	9. Translate to French	Jegrelius	May 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/Karo linska		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/Kata rina	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	Jegrelius		
21	10. Critical review of LCA	Jegrelius	April 2017	

21	<i>11.LCA ready</i>	<i>Jegrelius</i>	<i>May 2017</i>	
22	<i>1. Final workshops- Östersund</i>	<i>Jegrelius</i>	<i>01/07/2015</i>	<i>28/09/2016</i>
22	<i>2. Orlando</i>	<i>Karolinska/ Hans</i>		<i>20/10/2016</i>
22	<i>3.Copenhagen</i>	<i>Jegrelius</i>		<i>20/11/2016</i>
22	<i>4.Düsseldorf</i>	<i>Ben 3-7</i>	<i>Nov 2017</i>	<i>14-17 Nov</i>
22	<i>5. Final Webinar</i>	<i>Jegrelius</i>	<i>30May2017</i>	
22	<i>6. Italian conference</i>	<i>Haemotronic</i>	<i>April 2017</i>	
23	<i>1.Input from Hans</i>	<i>Jegrelius</i>		<i>March 2017</i>
23	<i>2. First draft</i>	<i>Jegrelius</i>	<i>June 2017</i>	