BiomarCaRE Biomarker for Cardiovascular Risk Assessment in Europe
7th Framework Programme Collaborative Project, Grant Agreement No. HEALTH-F2-2011-278913

BiomarCaRE Third Period Report (01 October 2014 to 31 March 2016 and Final Report (01 October 2011 to 31 March 2016)

Reporting Guide: Procedure and Responsibilities

(status 14 April 2016 – please contact the project manager for any questions: erik.werner@rns4u.com)

Contents

(A) Overview

The project ended on March 31st 2016. Documents to submit include:

(1) The **periodic report** for the 3rd reporting period (October 2014 to March 2016). Scientific progress report covering the last reporting period, including milestones and deliverables.

(2) The **final report** covering the complete runtime of the project (October 2011 to March 2016). A summary of project results and impact.

You are:	you need to do:	by when:	using:
Workpackage CONTRIBUTOR	PERIODIC REPORT: provide your contribution to the WP coordinator (cc Erik)	27 Apr 2016	periodic workpackage template
	FINAL REPORT: upon request of the WP coordinator		
Workpackage COORDINATOR	PERIODIC REPORT: complete the WP progress report, send to Erik	09 May 2016	periodic workpackage template
	FINAL REPORT: complete the WP summary report, send to Erik	09 May 2016	final workpackage template
PRINCIPAL INVESTIGATOR	PERIODIC REPORT: provide details on collaborations and dissemination to Erik	03 Nov 2014	collaboration/dissemination template
	FINAL REPORT: provide input related to questionnaire to Erik	09 May 2016	questionnaire template
Responsible for a DELIVERABLE	PERIODIC REPORT: report on the delivery, send to Erik	09 May 2016	deliverable template
FINANCIAL OFFICER, CFS	complete financial statement online, sign electronically, submit to coordinator	16 May 2016	online, Participant Portal

Please note:

- Not providing any reporting contributions is equivalent to no work done; in this case, no costs can be accepted!
- Failing to provide financial statements within the deadlines given above will mean that no costs can be claimed for this reporting period. A future amendment is not possible after the end of the project, so the budget is most likely lost!

(B) Structure of the Report

PERIODIC REPORT: Scientific Progress Report

1. Publishable summary • summary description of the project context and the main objectives • description of the work performed since the beginning of the project and the main results • description of the expected final results and their potential impacts		Stefan, Tanja and Erik – based on the workpackage progress reports***; *completed online*
2. Core of the report		*to be uploaded as single pdf*
	Project objectives for the period	Stefan, Tanja and Erik
	Work progress and achievements during the period	***Workpackage Coordinators, based on the contributions of researchers involved in this WP**
	Project management during the period	Erik – based on the contributions from all principal investigators (collaboration/dissemination template)
3. Deliverables and milestones tables		Erik – *completed online* based on the work progress reports***

Deliverables	extra document provided by the responsible scientist (deliverables template); uploaded online
Publications	authors, complete in the collaboration/dissemination template; Erik to complete online
Dissemination Activities	principal investigator, complete in the collaboration/dissemination template; Erik to complete online
Patents/Exploitable Results	please get in touch with Erik
Financial statement	Financial officer of each institution, complete online, including justification of resources; sign electronically and submit online
Certificate on the financial statement	Financial officer, attach to signed original financial statement (uploade pdf; if accumulated EC contribution >375k €)

FINAL REPORT

(a) Publishable summary report [1]	*all completed online*
executive summary	Stefan, Tanja and Erik
summary description of project context and objectives	Stefan, Tanja and Erik
description of the main S&T results[2]	*workpackage coordinators, for the WP*
potential impact (including socio-economic impact and wider social implications of the project so far)	*workpackage coordinators, for the WP*
main dissemination activities and exploitation of results[3]	*workpackage coordinators, for the WP*
address of website	*Erik*
project logo, diagrams or photographs illustrating the work of the project[2] (including videos, etc….), list of beneficiaries with corresponding contact names	*to be uploaded as pdf (Erik), collected from the workpackage coordinators from section "main results" above*
(b) Plan for use and dissemination of foreground [4]	*list of publications, other dissemination and exploitation activities, to be completed online (Erik) based on the lists of the periodic reports*
(c) Report covering the wider societal implications of the project[5] • Ethics • Workforce statistics • Gender aspects • Synergies with Science Education • Interdisciplinary • Engaging with civil society and policy makers • Use and dissemination • Media and communication to the general public	*questionnaire to be completed online (Erik), based on the information provided by the partner in the questionnaire template*

NOTES

(1) All content of the final report part (a) is going to be public. If your content is confidential, please anonymise it or leave it out (or describe it without giving confidential details).

(2) The major content of the final report needs to be in text form that is uploaded into an online form without formatting possibility. You can still refer to images/graphics or tables in the text but those need to be provided as extra files, which then get uploaded separately.

(3) Do not replicate complete lists of publications but highlight major dissemination and exploitation activities.

(4) Plans for exploitation of foreground need to be marked confidential in order for them NOT to be made publicly available.

(5) Each partner is asked to complete the questionnaire template for the own institution. The information will then be compiled and submitted online by Erik. Should an answer require extra information, text needs to be provided to be included in the appropriate section of the reports.

(C) Submission procedure: Templates and ECAS

Scientific Workpackage Periodic Progress and Final Reports

The contributions to the scientific workpackage progress report are added to doc-file templates and provided as email-attachment.

The templates:	***and Who is using them:***
BiomarCaRE_RP3_PeriodicWorkpackage.docx	by **every Principal Investigator** (to send contributions to the WP coordinator by 27 April 2016; could be formless as well) by the **WP Coordinator** (to send the complete WP report to Erik by 09 May 2016)
BiomarCaRE_Deliverable.docx	by the **PI responsible** for this Deliverable (to send to Erik by 09 May 2016)
BiomarCaRE_FinalReport_Workpackage.docx	by the **WP Coordinator** (to send the complete WP report to Erik by 09 May 2016)
BiomarCaRE_RP3_CollaborationDissemination.docx	by **every Principal Investigator** (to send to Erik, for the compilation of the management report by 09 May 2016)
BiomarCaRE_FinalReport_Questionnaire.docx	by **every Principal Investigator** (to send to Erik, for the compilation of the online questionnaire; by 09 May 2016)

Financial statements

The financial statements ("Forms C") usually are completed by the financial officer of the beneficiary. If more than one research group of the same beneficiary has a project share, only one financial statement is to be provided. However, the split between the groups shall be sent to Erik as well.

The financial statement also includes the ***"justification of resources"*** part. Each entry (personnel costs, other direct costs, major cost items) needs to be described and allocated to a workpackage. Researcher and financial officer need to communicate about this. **The number of person months per workpackage/task needs to be obvious from this entry.**

The submission procedure:

- complete the financial statement in the participant portal (see below), including the justification
- via the online tool, the "Project Financial Signatory"* needs to sign the financial statement electronically
- submit electronically to the Coordinator by 09 May 2016
- this needs to be accompanies by a certificate on the financial statement ("audit certificate") if the accumulated EC contribution exceeds 375.000 Euro (to be uploaded as pdf within the financial statement).

***Project Financial Signatory (PFS)**

A colleague with the role "Participant Contact" needs to give someone the project role of an PFS. To do this, find BiomarCaRE in your list of projects at the Participant Portal and click on the PC icon  (Project Consortium). Find your institution and click "edit roles". Click the button "Add roles" and select "Project Financial Signatory" in the drop down "Role" menu. There, a number of people should be listed who were nominated by the administration. Contact the LEAR / your administration if no one is listed there. Select the person who shall sign the financial statements electronically and confirm with "OK".

Please contact Erik if you need any further help with roles or with completing the financial statement.

(D) Responsibilities: who needs to provide which contribution

The table below indicates, which contributions are expected from each project group and institution (F: Financial/administrative officer; please name the correct contact for your institution if he/she is not listed below and cc'd in the request email).

As a **Workpackage Coordinator**, you take responsibility for ALL aspects of a work package. Please request contributions from other involved groups ON YOUR OWN (even though everybody does receive this table!) and do so way in advance of the **internal deadline (09 May 2016)**.

If you are **contributor** to a workpackage (but not coordinator), provide your contributions as soon as possible, even if not asked again specifically! This is especially important if you are the **lead beneficiary of a milestone or deliverable!** The WP Coordinator needs to have your contribution **by 27 April 2016**.

A researcher **responsible for a Deliverable** needs to provide the completed Deliverable template.

To clarify for **Cohort Centres**: the data harmonisation and analysis is reported in WP7, communicate with Kari Kulasmaa (THL); sample related issues and biomarker measurements are reported in WP6, communicate with Tanja Zeller (UKE).

The responsible Principal Investigator of a **Subproject** needs to report a short summary of the subproject (approach, goals, progress, (expected) results. Send to Erik by May 9th 2016.

Every Principal Investigator needs to report on collaboration and dissemination activities and complete the final report questionnaire.

As a **financial/administrative officer** or contact person, you are expected to complete all figures and forms in time so that the respective Principal Investigator can complete the work package distribution and, together with you, the explanation for the use of resources.

If you believe that the table is not correct or if you have nothing to contribute, please tell the project manager. The justification of resources and the scientific reporting need to be consistent (no report means no eligible costs!).

IMPORTANT:

- If no Form C is provided and submitted to the Coordinator within the deadline, the coordinator will submit to the EC without your Form C. This will mean that your institution will not receive any payment. As this is the last report of the project, the amount is going to be lost.
- If you do not contribute to any scientific report, you also cannot claim any costs and any respective cost claims in Form C will be denied by the coordinator. Even if you have done some work: "no report" needs to be interpreted as "no work done"!
- If you had no costs during the reporting period, still complete a financial statement and claim "0" everywhere.

Table colour code:

- **light green**: send contribution to work package coordinator (based on the person month planning in Annex I; if you have no contribution, let the work package coordinator and the project manager know; if you have a contribution but the field is not coloured, still send it in time!.
- **red** : responsible for this work package, milestone or deliverable – collect, compile and submit to the project manager
- **blue**: contributions to be submitted to the project manager or online by EVERY institution and/or group

Institution/Group	Resources		Collaboration/dissemination	Questionnaire	Milestones RP1	Deliverables RP1	Work package reports										
	Form C	Justif.					1	2	3	4	5	6	7	8	9	10	11
01 UKE – Hoffmann/Kees (F)																	
01 UKE – Blankenberg/Zeller/Schnella					MS12, 13, 21, 25, 27	D5.1, 6.1											
02 THL – Talponen (F)																	
02 THL – Kuulasmaa/Salomaa					MS14, 17, 23, 24, 26	D7.1											
03 CAVADIS - Dijkshoorn (F)																	
03 CAVADIS – Breek/Agustiandari																	
04 UMC – Krol/Laaper-Ertmann (F)																	
04 UMC – Pasterkamp																	
05 HMGU – Ries/Ertel (F)																	
05 HMGU – Peters/Thorand																	
06 BIOCRATES - Schwab (F)																	
06 BIOCRATES – Röhring					MS15												
07 UHSH – Schatton (F)																	
07 UHSH – Ziegler/Schillert																	
08 UMIT – Luwitsch/Moesl/Papp(F)																	
08 UMIT – Conrads-Frank					MS22, 28	D9.1											
09 MHH – Hess/Kaul (F)																	
09 MHH – Wollert																	
10 FLEET - Wilkinson (F)																	
10 FLEET – Dent					MS11	D11.1											
12 RNSL - Werner (F)																	
12 RNSL – Werner						D10.3											
13 UMCM – Tschauder/Gürtler /Flessa/Gertler (F)																	
13 UMCM – Wild																	
14 UIT - Fismen(F)																	
14 UIT – Njorstad/Mathiesen																	
15 UCSC – Leone (F)																	

Institution/Group	Resources		Collaboration/dissemination	Questionnaire	Milestones RP1	Deliverables RP1	Work package reports										
	Form C	Justif.					1	2	3	4	5	6	7	8	9	10	11
15 UCSC – Biasucci																	
16 EMAUG - Völker (F)																	
16 EMAUG – Völzke																	
17 UCL – Borg-Carbott/Hertel (F)																	
17 UCL – Bobak																	
18 QUB – Spence/Bennett (F)																	
18 QUB – Kee																	
19 IPL – Jean (F)																	
19 IPL – Dallongevielle																	
20 ICCC – Escobar (F)																	
20 ICCC – Pardo/Sans																	
21 UMU – Wikman/Näslund (F)																	
21 UMU – Söderberg																	
22 UTARTU – Leego (F)																	
22 UTARTU – Metspalu																	
23 RCPH – Fogelberg (F)																	
23 RCPH – Jorgensen/Linneberg																	
24 UIV – Barbierei (F)																	
24 UIV – Ferrario																	
25 UDUN – Peek/Williamson/Kidd (F)																	
25 UDUN – Tunstall-Pedoe																	
26 USB – Gruberski (F)																	
26 USB – Müller/Twerenbold																	
27 UULM – Gleixner (F)																	
27 UULM – König						D8.1											
29 USYD – Taylor/Smyth/Homan (F)																	
29 USYD - Sims																	

(E) Annex: List of tasks, milestones and deliverables

Milestones (Mi, in green) and Deliverables (D, in magenta) are listed for each work package with their due date (project month Mx and calendar month), chronological. Those due in Reporting Period 3 are in ***bold and highlighted in yellow****. Milestones in grey are reported in another Workpackage.* **Basis is the amended Description of Work from September 2015!**

WP 1 Selection of existing and emerging biomarkers related to cardiovascular disease

Task 1.1: Selection of existing and emerging biomarkers related to cardiovascular disease.
Task 1.2: Selection of emerging biomarkers that are disclosed by the SMEs or academic partners based on -omics technologies

- MS1 Relevant marker selection data (M4-Jan12) - achieved
- MS3 Biomarker eligibility criteria (M5-Feb12) - achieved
- ❖ D1.1 List of selected biomarkers (M5-Feb12) - delivered

WP 2 Assay development: exosome

Task 2.1: Optimization of exosome extraction and normalization protocol.
Task 2.2: Assay development for prediction of primary events.
Task 2.3: Assay development for prediction of secondary event
Task 2.4: Manufacturing and validation of multiplex assay.

- MS2 Exosome extraction and normalization method defined (M4-Jan12) - achieved
- MS3 Biomarker eligibility criteria (M5-Feb12) – WP1, achieved
- MS5 Identification of exosome protein biomarker panels for primary and secondary events (M8-May12) - achieved
- MS10 Two exosome protein multiplex assays transferred (M18-Mar13; forecast M21-Jun13) - achieved
- ❖ D2.1 Immunoassays (M18-Mar13; forecast M21-Jun13) - delivered

WP 3 Assay development: transcriptome

Task 3.1: Assay development for transcriptomics-derived biomarkers.
Task 3.2: Manufacturing of transcriptomics-derived biomarker assay reagents.
Task 3.3: Transfer of transcriptomics-derived biomarker assay reagents.

- MS3 Biomarker eligibility criteria (M5-Feb12) – WP1, achieved
- **MS11 Transcriptome immuno assays transferred to Participants 1 (UKE) (M45-Jun15)**
- ❖ **D3.1 Immunoassays for transcriptome biomarkers (M54-Mar16)** – delivered

WP 4 Assay development: metabolomics

Task 4.1: Acquisition of materials for the manufacture of 125 kits
Task 4.2: Preparation of assay components (FIA/MS-MS and LC/MS-MS)
Task 4.3: Manufacturing of the 125 Absolute IDQ p180 kits
Task 4.4: Manufacturing and delivery of remaining 125 kits to Partner 5

- MS3 Biomarker eligibility criteria (M5-Feb12) – WP1
- MS4 FIA/LC/MS-MS assay (M6-Mar12) - achieved
- MS8 Absolute IDQ p180 kits, first set (M29-Feb14)
- **MS15 Absolute IDQ p180 kits, second set (M39-Dec14)**
- ❖ D4.1 Metabolomics assays (M39-Dec14) – delivered

WP 5 Assay development: miRNA

Task 5.1: Project initiation
Task 5.2: Proof of principle assay design
Task 5.3: Multiplexing
Task 5.4: Sample prep requirements
Task 5.5: Workflow proof of principle
Task 5.6: Design and development of dedicated multiplex assay
Task 5.7: Assay transfer

- MS3 Biomarker eligibility criteria (M5-Feb12) – WP1
- MS9 Concept multiplex assay (M15-Dec12) - achieved
- ~~MS18 Transfer of final miRNA assay (M30-Mar14)~~ – deleted (GA amendment)
- **D5.1 miRNA assay (M54-Mar16)**

WP 6 Measurements of biomarkers in population based and clinical samples

Task 6.1: Logistics of sample transfer from Cohort Centres to the BiomarCare laboratories
Task 6.2: Acquisition of biomarker levels in the BiomarCaRE laboratories and quality control
Task 6.3: Laboratory sample and data management
Task 6.4: Transfer of biomarker results to Data Centres for analyses

- MS7 Phase 1 samples (M12-Sep12; forecast M16-Jan13) - achieved
- MS8 Absolute IDQ p180 kits, first set (M12-Sep12) – WP4
- MS10 Two exosome protein multiplex assays transferred (M18-Mar13) – WP2
- MS11 Transcriptome immuno assays transferred to Participants 1 (UKE) and 5 (HMGU) (M18-Mar13) – WP3
- **MS12 Phase 1 biomarker data (M46-Jul15)**
- **MS13 Phase 2 samples (M43-Apr15)**
- MS15 Absolute IDQ p180 kits, second set (M24-Sep13) – WP4
- MS18 Transfer of final miRNA assay (M30-Mar14) - WP5
- **MS21 Phase 2 biomarker data (M53-Feb16)**
- **MS25 Samples of clinical trials (M39-Dec14)**
- MS27 BiomarCaRE Panel data in clinical trial (M51-Dec15) – WP8
- D6.1 Biomarker data (M54-Mar16)

WP 7 Data harmonization and statistical analysis

Task 7.1: Harmonization of cohort data
Task 7.2: Analysis of lifestyle, socio-economic and imaging data
Task 7.3: Risk model development
Task 7.4: Risk model validation

- MS12 Phase 1 biomarker data (M20-May13) – WP6
- **MS14 Selection of biomarkers for Phase 2 laboratory analysis (M45-Jun15)**
- **MS17 Risk estimation models (M53-Feb16)**
- MS21 Phase 2 biomarker data (M34-Jul14) – WP6
- **MS23 Selection of biomarkers for the BiomarCaRE Panel (M45-Jun15)**
- **MS24 Feasibility of a multi-marker panel for the diagnosis or prognosis of cardiovascular diseases (M50-Nov15)**
- **MS26 Statistical analysis plan (M53-Feb16)**
- MS27 BiomarCaRE Panel data in clinical trial (M51-Dec15) – WP8
- **D7.1 BiomarCaRE panel and impact (M54-Mar16)**

WP 8 Retrospective application of the European BiomarCaRE panel in biobanks of clinical trials

Task 8.1: Sample transfer, selection of biomarkers, acquisition of biomarker levels, quality control and laboratory sample and data management
Task 8.2: Transfer of biomarker results to Clinical Trial Data Centres
Task 8.3: Strategies for statistical analyses of the clinical trial data.

- MS23 Selection of biomarkers for the BiomarCaRE Panel (M45-Jun15) – WP7
- MS24 Feasibility of a multi-marker panel for the diagnosis or prognosis of cardiovascular diseases (M50-Dec15) – WP7
- MS26 Statistical analysis plan (M53-Feb16) – WP7
- **MS27 BiomarCaRE Panel data in clinical trial (M51-Dec15)**
- **D8.1 Biomarker data analysis (M54-Mar16)**

WP 9 Economic assessment of the BiomarCaRE panel

Task 9.1: Development of a decision-analytic model to assess the long-term effectiveness of strategies guided by the BiomarCaRE panel.
Task 9.2: Compilation of a cost data base and assessment of the cost-effectiveness of strategies guided by the BiomarCaRE panel
Task 9.3: Selection of potentially cost-effective strategies and test cut-offs for a clinical trial

- MS1 Relevant marker selection data (M4-Jan12) – WP1
- MS12 Phase 1 biomarker data (M46-Jul15) – WP6
- MS17 Risk estimation models (M53-Feb15) – WP7
- MS20 Draft of model structure with health states and events completed (M32-May14) - achieved
- MS21 Phase 2 biomarker data (M53-Feb16) – WP6
- **MS22 Implementation of the model and technical debugging finished (M54-Mar16)**
- MS23 Selection of biomarkers for the BiomarCaRE Panel (M45-Jun15) – WP7
- MS27 BiomarCaRE Panel data in clinical trial (M51-Dec15) – WP8
- **MS28 Cost data included in model cost-effectiveness analysis can be performed (M54-Mar16)**
- **D9.1 Economic biomarker assessment (M54-Mar16)**

WP 10 Project Management

Task 10.1: Support of the scientific and administrative coordination
Task 10.2: Development and maintenance of the project website

- D10.1 Project website online (M3-Dec11) - delivered
- D10.2 Ethical approvals (M5-Feb12) - delivered
- MS6 Interim report for reporting period 1 (M10-Jul12) - achieved
- MS16 Interim report for reporting period 2 (M28-Jan14) - achieved
- **D10.3 Final management report (M54-Mar16)**

WP 11 Dissemination , Exploitation and Training

Task 11.1: Prepare and execute dissemination plans for biomarker assessment and validation
Task 11.2: Prepare and execute exploitation plans for the novel platform technologies and novel biomarker assays developed in WPs 2 to 5.
Task 11.3: Organise students training and exchange

- MS19 Training, dissemination and exploitation plans (M30-Mar14) - achieved
- **D11.1 Final impact report (M54-Mar16)**