European Malaria Vaccine Initiative

MoM OPTIMALVAC Kick-Off Meeting

Room X7, WHO building, 20 Avenue Appia, Geneva
7-8th May 2009

Delegates		Initials	Organisation	Contact details
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AGENDA

Day 1

Schedule	Topic	Speaker	No	Document Name
9:30-9:35	Welcome	ODL		
9:35-9:40	Approval of agenda	All		
9:40-9:45	Introduction of the participants	All		
9:45-9:55	Meeting objectives and brief introduction	ROV		
9:55-10:20	**WP1: Recognition of parasite proteins** - Presentation of objectives and work plan	DAC		
10:20-10.45	**Discussion**	All		
10:45-11:05	Coffee			
11:05-11:30	**WP2: Cell dependent parasite inhibition assays** - Presentation of objectives and work plan	PAD		
11:30-11:55	**Discussion**	All		
11:55-12.20	**WP3: Assays assessing cell-mediated immune (CMI) responses** - Presentation of objectives and work plan	PAD		
12.20-12:45	**Discussion**	All		
12:45-13:45	Lunch - WHO restaurant (cash only accepted, Swiss francs required)			
13:45-14:10	**WP4 Repository of Resources** - Presentation of objectives and work plan	DAC		
14:10-14:35	**Discussion**	All		
14:35-14:55	Coffee			
14:55-15:20	**WP5 Data Management, Statistical Analysis and Dissemination** - Presentation of objectives and work plan	EDR		
15:20-15:45	**Discussion**	All		
15:45-15:50	Close	ODL		
15:50-16:00	Pause			
16:00-17:00	OPTIMALVAC Steering Committee Meeting	DAC, VAM, PAD, EDR, BAI, (OLY-Coordinator)		

Day 2

Schedule	Topic	Speaker	No	Document Name
9:30-9:35	Welcome	ODL		
9:35-9:40	Approval of agenda	All		
9:40-10:00	**WP6 Regulatory and Ethical Considerations** - Presentation of objectives and work plan	BAI		
10:00-10:20	**Discussion**	All		
10:20-10:40	Coffee			
10:40-11:00	**WP7 Project Coordination and Management** - Management structure, current state of EC negotiation, consortium agreement, website & communication. **Finances** - Overall budget, flexibility, scientist / financial manager cooperation, FORCE reporting tool	ROV & STL		
11:00-11:20	**Discussion**	All		
11:20-11:40	**WP8 Global Project Coordination and Management** - Presentation of objectives and work plan	VAM		
11:40-12:00	**Discussion**	All		
12:00-13:00	Lunch - WHO restaurant (cash only accepted, Swiss francs required)			
13:00-15:00	**WP2 Scientific Session**	PAD		
15:00-15:20	Coffee			
15:20-17:20	**WP3 Scientific Session**	PAD		
17:20-17:25	Close	PAD		

Abbreviations:

MoM	Minutes of meeting
CT	Clinical trial
SC	Steering committee
SOP	Standard operating procedure
WPL	Workpackage leader

European Malaria Vaccine Initiative

Item	Discussion	Action by	Due Date
Welcome	ODL welcomed all participants and thanked VAM for his contribution to the organisation of the meeting.		
Approval of agenda	Approved.		
Introduction of the participants	The participants introduced themselves.		
Meeting objectives and brief introduction	ROV discussed the format of the meeting, its objectives, and gave a very brief introduction to the OPTIMALVAC project.		
WP1: Recognition of parasite proteins	See DAC WP1 presentation.		
Discussion	Planning and deliverables are OK. TA should be amended to reflect the work plan. The allocation of person-months should be amended, as it is not realistic for RUNMC and UEDIN. WP leader should send Doodle link to schedule the first work meeting with workpackage members (teleconference). All project participants will have access to the website holding SOPs. The website will hold the history of the SOP, with a history of what was altered and why. As much as possible, each WP will actively involve other OPTIMALVAC project members working in other WPs. Having an agreed standard would be major progress. DAC has a monoclonal, but needs permission from the owner to distribute it. MVI is also funding a monoclonal Ab which could be used. Acquiring an agreed standard is a key step in this WP. Permission to use these antibodies should be requested. Training of Africans: procedure for selecting candidates should be put in place Need a SOP for selection of trainees.	DAC DAC/EML DAC/PAD/ROV	25 May 2009 29 May 2009 1 Dec 2009
WP2: Cell dependent parasite inhibition assays	See PAD WP2 presentation		
Discussion	WP leader should send Doodle link to schedule the first work meeting with workpackage partners (teleconference). Reagents for harmonisation will be stored at NIBSC, so will be freely distributed. Reagents will only be available to people within the project, and registration will be required for access.	PAD	25 May 2009

Item	Discussion	Action by	Due Date
	Amendments are required to the DoW. A two-track approach was proposed and agreed by the WP members (second track details to be discussed and agreed later). D2.5 to be deleted (2.4 completed already). 2.5 should be maintained if new sera are considered (issue with informed consent for exsiting reagents). Timelines for D2.1 , D2.2, D 2.3 and D2.8 to be modified. Timelines for M2.1, M2.2 and M2.3 to be modified (see above) PAD to investigate making PID/KLB's protocols available for the WP members. WPL should provide terms of reference for the SC to develop endemic region trainee selection SOP	PAD PAD PAD	
WP3: Assays assessing cell-mediated immune (CMI) responses	See PAD WP3 presentation		
Discussion	WP leader should send Doodle link to schedule the first work meeting with workpackage partners (teleconference). For T Cell assays three panels are agreed as suitable for harmonisation. First two panels available in November 2009. Current NIBSC ICS standard + new ICS standard tailored to needs of the project will be tested. WPL should provide terms of reference for the SC to develop endemic region trainee selection SOP. Extended CEF is the preferred choice and the availability should be investigated as well as confirmation that samples from the same batch are obtainable. Cryo-shippers agreed as ideal to transport PBMC panels but are costly. Partners to investigate if possible to get funds for this. Dry ice maybe the alternative option. Need to identify reliable shippers. For PBMC panels, the more labs that participate the better.	PAD DAC/PAD PAD Steering committee + all	25 May 2009 15 June 2009 15 June 2009 31 August 2009

Item	Discussion	Action by	Due Date
WP4 Repository of Resources	See DAC WP4 presentation		
Discussion	WP leader should send Doodle link to schedule the first work meeting with workpackage partners (teleconference).	DAC	25 May 2009
	Amend www.malariaresearch.eu website to be FP7 and OPTIMALVAC orientated, and link it to the OPTIMALVAC and EMVDA web pages. A secure intranet section will be established to upload large data files. SOPs can hold a contact name and number. A guest log in will be provided for project members who need to log in. DAC to host the website.	DAC	30 Nov 2009
	Amendment required to the GANTT chart as one deliverable is missing.	ROV	14 June 2009
	BPRC Rabbit Ab probably available with MTA. EDR to investigate and discuss findings with DAC.	EDR	14 June 2009
	How to track shipments? Need to develop a form for sample recipients (temperatures, condition of sample, any issues, when it was sent etc.). Implement a form on the website so that people can upload their data and then it can be made available for administrators to see.	WPL	30 Nov 2009
WP5 Data Management, Statistical Analysis and Dissemination	See EDR WP5 presentation		
Discussion	WP leader should send Doodle link to schedule the first work meeting with workpackage members (teleconference).	EDR	25 May 2009
	Once the data is generated it will be sent to BPRC for all assays.		
	The cost of NIBSC (independent) doing analysis to be investigated. Ask NIBSC to do the data analysis? We need to cover their expenses for doing this. If cost prohibitive then another option is BPRC.	EDR	14 June 2009
WP6 Regulatory and Ethical Considerations	See BAI WP6 presentation		
Discussion	BAI to liaise with VMO as necessary for workpackage activities.		
	Deliverable 6.3 needs amendment.	BAI	15 June 2009
	BAI to request the necessary documents from project participants to initiate the development of the necessary	BAI	15 Aug 2009

Item	Discussion	Action by	Due Date
	forms. A questionnaire could also be prepared to collect the necessary information from the labs. It may be advisable to bring in expert outside help for this. BAI to decide best course of action and implement. One option is to collect fresh blood from donors in Europe so that there are no issues of informed consent. Deliverable 6.3 considered unrealistic. To be merged with 6.2. PAD to forward email from NIBSC about the issues on sample transfer from Kenya and share with BAI + issues on informed consent. ADL and PID to inquire about getting ethics approval for Gabon and Ivory Coast samples. ODL to discuss with Peter Kremsner about approaching Gabon ethics for approval. Perhaps organise new study at zero cost? Give CAD details of samples needed so she can inquire about running study in Mozambique.	ROV PAD PID/ODL PAD	15 June 2009 Done 15 Aug 2009 31 Aug 2009
WP7 Project Coordination and Management - Finances	See STL WP7 and ROV WP7 presentations		
Discussion	**Finance** Partners should review their project finances and STL WP7 presentation with their institution's finance administrator and send any questions to STL. STL to clarify if those not getting money have to fill in form C. Partners to let STL know if EU requests an audit. Daily time sheets are required in FP7 but the format is flexible eg excel sheet with project no, person name, WP number, and how many hours worked. DAC to share his time sheets with consortium? **Management** WP leaders to amend DOW and return to ROV with tracked changes.	All STL DAC WPL	ASAP 15 June 2009 29 May 2009 15 June 2009

Item	Discussion	Action by	Due Date
	Partners to propose TAC members to SC and WHO/EU but final decision lies with SC.	All Partners	22 May 2009
	James Beeson proposed by WHO. PAD to ask AERAS if they have an expert. Also proposed are pneumococcal group eg- Bob Alan	PAD	Before 22 May 2009
	Email to all partners requesting that they propose TAC names in next seven days.	ROV	Done
	WP groups to meet at least quarterly. Monthly TCs recommended. Face to face depends on your budget. WPL responsible for scheduling and minutes. The OPTIMALVAC project manager should be copied on emails indicating the scheduling of meetings so that the secretariat can keep a record of all OPTIMLAVAC meetings.	All	
	Blog to aid inter WP communication to be established. WP leaders to provide text, ROV to maintain.	ROV/WPL	18 June 2009
	ROV to send consortium agreement template and final DoW with minutes.	ROV	Done
	Investigate if project reporting can be aligned with financial reporting. STL to be contacted should any financial amendments be required.	ROV	15 June 2009
	All communications should initially be directed to WPL, not to project manager or coordinator (unless circumstances dictate otherwise).		
	Need formal approval from other partners to include new "unofficial partners" (hereafter referred to as "affiliates") – confidentiality agreements should be signed prior to participation (obtainable from ROV).		
	When new affiliates (e.g. Carole Long) are identified for inclusion in project activities, a brief dossier of the partner and their proposed involvement should be sent to the secretariat for distribution to the current partners for time-constrained comment.	Contact ROV when necessary	
WP8 Global Project Coordination and	See VAM WP8 presentation		

Item	Discussion	Action by	Due Date
Management			
Discussion	All to articulate importance of exploratory research into assays. There has long been a need to document in overview the approaches to reducing variability in assay performance for agreed immunological outcomes in malaria vaccine development. It would be beneficial if this could occur during the course of OPTIMALVAC although it is not a deliverable. Approach suggested to write a manuscript for publication. Note a similar manuscript written by the TB vaccine community. WHO invites partners to communicate with WHO about synergies so they can identify possibilities of linking with other groups. One example is Barcelona, who plan to harmonise immunology aspect of Phase III RTS,S trial. Good contacts in other fields like cancer, HIV and TB are needed so WHO can investigate how to link and update funders group. Re- phrase deliverable of funding for establishment of reference centre to assess suitability/appropriateness of reference or service centres.	All PAD for first draft VAM	 30 Sep 2009 15 June 2009
Close	ODL thanked the participants for a constructive and interesting meeting. ODL to communicate contract signature as soon as done.	ODL	When possible

Meeting Objectives

OPTIMALVAC Kick-Off Meeting

- Through a series of presentations and discussions:
  - Understand the main aims of OPTIMALVAC
  - Establish each WP group, identify participants, and agree on the next WP meeting
  - Clarify and discuss the work involved
  - Understand the INYVAX project managerial structure as well as the financial aspects

Structure of the Meeting

- Eight presentations and two scientific sessions
- Each WP will be introduced by a presentation
- Each presentation will be followed by open discussion
- Minutes of the meeting will be taken and distributed for comment
- Scientific sessions

Introduction to OPTIMALVAC

OPTIMALVAC

- Initiative on optimising malaria vaccine lab assays evaluation
- Official starting date April 1st 2009

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OPTIMALVAC Aims

- Harmonise and optimise:
  - Humoral, Functional and Cell mediated immunity assays
- Establish:
  - Repositories for protocols and SOPs
  - Repositories for standards and reagents for specific assays
  - Data management and statistical analysis plans
  - Training, transfer and trouble-shooting capacity
  - Regulatory and ethical considerations
  - Project and global coordination

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WP1: Recognition of parasite proteins

Beneficiary Number	Beneficiary Name	Beneficiary Short Name	Country	Start month	End month
1	European Malaria Vaccine Initiative/Statens Serum Institut	EMVI/SSI	Denmark	M1	M36
2	Institut Pasteur	UPBM	France	M1	M36
3	Biomedical Primate Research Centre	BPRC	The Netherlands	M1	M36
4	Stockholm University	SU	Sweden	M1	M36
5	University of Edinburgh	UEDIN	United Kingdom	M1	M36
6	University of Oxford	UOXF	United Kingdom	M1	M36
7	Radboud University Nijmegen	RUNMC	The Netherlands	M1	M36
8	World Health Organisation	WHO	Switzerland	M1	M36
9	ImmunoVac Consulting	IVC	Belgium	M1	M36
10	Malaria Vaccine Initiative (PATH)	MVI	United States	M1	M36
11	Barcelona Centre for International Health Research	CRESIB	Spain	M1	M36
12	National Institute for Biological Standards and Control	NIBSC	United Kingdom	M1	M36
13	Centre for diseases control	CDC	United States	M1	M36

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WP1: Recognition of parasite proteins

Workpackage number	1	Start date or starting event:			Month 1	
Workpackage title	Recognition of parasite proteins					
Activity type	Coordination					
Participant number	UEDIN	BPRC	RUNMC	WHO	MVI	
Person-months per participant	18	18	24	2	5	

Objectives

To identify suitable parasite protein assays and harmonize them
Task 1: Evaluate different options for detection of parasite proteins
Task 2: Compare methods for detection of parasite protein and identify key issues
Task 3: Select method and SOPs for further development and identify optimal detection reagents
Task 4: Perform intra and inter laboratory assay variability tests

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WP1: Recognition of parasite proteins

Standardised methods to evaluate and measure antibody reactivity against parasite proteins.

Assays
- antibodies from malaria-exposed humans
  - purified
  - sera
- antibodies from immunised animals
  - polyclonal
  - monoclonal

Abs raised by immunisation not always:
a) similar or identical to those elicited by natural infection
b) capable of recognising the natural parasite antigen as displayed by the parasite itself.

Confirm reactivity with parasite Ags by:
- Immunofluorescence (IFA)
- Western blotting (WB),

Aims: Develop, establish and disseminate standardised assays which are easily reproducible.

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WP1: Recognition of parasite proteins

Key tasks

- Select methods for detecting parasite antigens, such as IFA and WB.
  Priority: easy to use and reproducible
- Compare methods for detection and identification of key issues
- Select one method to be developed as a reference assay
- Identify reagents suitable for detection of parasite proteins.
  Dependent on assays selected
- Produce positive and negative controls
- Standard SOP to be optimized and harmonized
- Assay harmonization
  intra- and inter- laboratory assay variability
- Inter-laboratory training,
  training of 1-2 African scientists in AIA network

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WP1: Recognition of parasite proteins

Description of work

Task 1: Evaluate different options for detection of parasite proteins
Compare different options for detection of parasite proteins (including fluorescence based assay and western blotting)
Identify parasite strains employed
Selection of approaches which take into account issues such as distribution of standard preparations, availability of equipment and harmonization issues
Identify positive and negative controls used as first stage reference preparations
Define optimal assay performance

Task 2: Compare methods for detection of parasite protein and identify key issues
Exchange reagents used in different labs
Perform selected assays in parallel in blinded manner
Compare results obtained in different labs
Identify key issues

Task 3: Select method and SOPs for further development and identify optimal detection reagents
Select optimal detection reagents
Draft common SOPs for detection of parasite proteins

Task 5: Perform intra and inter laboratory assay variability tests
Perform intra laboratory assay variability tests
Perform inter laboratory assay variability tests
Compare coded results

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WP1: Recognition of parasite proteins – IFA and WB

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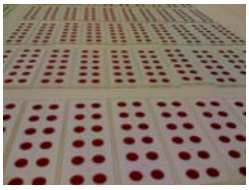
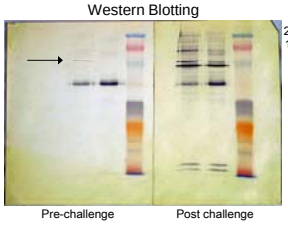
Recognition of parasite proteins – IFA and WB

IFA



Western Blotting



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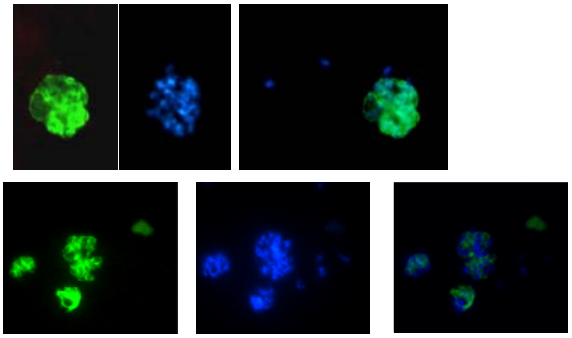
Recognition of parasite proteins -IFA



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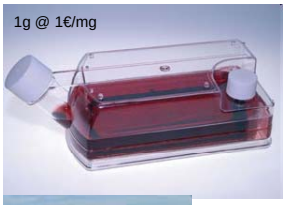
Recognition of parasite proteins – production of standards

Monoclonal and polyclonal antibody production and purification

1g @ 1€/mg



1.4L serum

(7g total IgG @€900)

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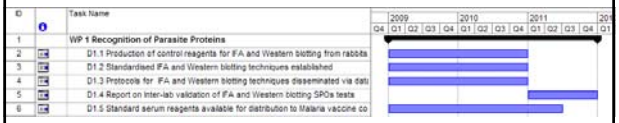
WP1: Recognition of parasite proteins - deliverables



Deliverables		
D1.1	Production of control reagents for IFA and Western blotting from rabbits immunised with AMA-1 and MSP-1 constructs	Month 0-24
D1.2	Standardised IFA and Western blotting techniques established	Month 0-24
D1.3	Protocols for IFA and Western blotting techniques disseminated via database website	month 0-24
D1.4	Report on Inter-lab validation of IFA and Western blotting SPOs tests	month 24-36
D1.5	Standard serum reagents available for distribution to Malaria vaccine community	month 0-30
Milestones		
M1.1	Control reagents and harmonized protocols available.	Month 24
M1.2	Report/publication interlaboratory of IFA and WB assays variability	Month 36

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Action points

- Decisions on reagents, standards, methodology
- Decisions on labs to do testing and exchange of reagents
- Distribution of existing SOPs and agreement on harmonised single assay system(s)

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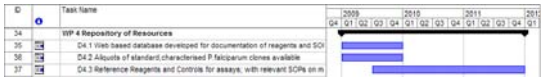
WP4: Repository of resources

Workpackage number	4	Start date or starting event:			1			
Workpackage title	Repository of Resources							
Participant id	UEDIN	WHO	BPRC					
Person-months per participant	14	2	2					



Deliverables		
D4.1	Web based database developed for documentation of reagents and SOPs.	Month 0-12
D4.2	Aliquots of standard, characterised *P. falciparum* clones available.	Months 0-16
D4.3	Reference Reagents and Controls for assays; with relevant SOPs on maintenance and care produced and information stored on database	Months 6-24
D4.4	Repository of facilities and materials resources (reagents: serum samples, antigens and antibodies) for the conduct of assays.	Month 6-28
Milestones		
M4.1	Database and repository(ies) of facilities and material resources available	Months 0-28

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WP4: Repository of resources

WP4: Repository of resources

This WP will focus on establishing common standard reagents and protocols on a global scale, a repository which the malaria vaccine community can utilise as a source of reference, to increase harmonisation of assays would be an invaluable resource. This work package will produce such a resource, initially in a virtual form, but over the lifetime of the project the aim will be to produce physical resources, such as standard, well-characterised parasite clones, antibody preparations, monoclonal antibodies and purified antigens, stored under agreed conditions at several sites, for dissemination on request. Without such a resource, comparisons between laboratories and methods will be difficult. The aim of producing such a resource is that intra- and inter-laboratory comparisons will be more robust. Maintenance and management of this resource will be imperative to ensure that standard reagents remain uniform and of high quality throughout and beyond the timescale of this project.

The key activities include:

• Development of standard preparations which can be used for the recognition of parasite proteins will be provided as reference to participating labs. This may include fixed parasite infected erythrocytes, or western blot of electrophoresed parasite extracts. It may also include positive and negative antibody controls. As much as possible existing antibody preparations will be used as standards.

• A standard preparation (rabbit anti-AMA1) is currently being developed by the EMVDA consortium and will be used as a standard in activities related to WP2. This will therefore not be covered in this workpackage. However, two standard antibody preparations for other antigens (MSP1, MSP3 or GLURP) will have to be identified or generated as part of this work package. In addition, reference parasite strains will be identified and distributed to labs participating in WP2.

• A standard preparation which can be used in harmonizing the cell dependent parasite inhibition assays will be established using existing pools of sera from malaria endemic regions. At least two such pools with demonstrated activity could be available from participating labs. The selected pool(s) will be aliquoted and stored for distribution to the participating labs provided they meet ethical requirements. Parasite strains as well as human cell lines or blood cells which can be used in harmonizing the cell dependent parasite inhibitions assays will be distributed to participating labs.

• Standards used in harmonizing T cell assays include an existing staining, acquisition and analysis standard developed by NIBSC which is currently available. In addition, the need to develop PBMC standards which can be used for optimising stimulation conditions will be evaluated and developed under WP4 if deemed necessary. There seems to be no need to develop antigen standards as peptides derived from common pathogen such as EBV, CMV and Flu are commercially available and should be sufficient for the activities in WP3.

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WP4: Repository of resources

Objectives
Establishment and maintenance of repository facilities and function for the conduct of optimization and harmonization activities for key assays

Description of work
• Conduct an initial inventory of resources declared available for use for activities of the CA.
• Categorize and define quality of collection methods as well as parameters of storage.
• For key assays, develop and maintain an inventory of available reagents with defined conditions of storage and distribution.
• Agree and designate repository sites for specific resources, conditions and process of submission, processing, storage and distribution of reagents for harmonization and validation.

Deliverables		
D4.1	Web based database developed for documentation of reagents and SOPs.	Month 0-12
D4.2	Aliquots of standard, characterised P. falciparum clones available.	Months 0-16
D4.3	Reference Reagents and Controls for assays; with relevant SOPs on maintenance and care produced and information stored on database	Months 6-24
D4.1	Repository of facilities and materials resources (reagents: serum samples, antigens and antibodies) for the conduct of assays.	Month 6-28
Milestones		
M4.1	Database and repository(ies) of facilities and material resources available	Months 0-28

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WP4: Repository of resources

Edinburgh *Plasmodium* spp. culture database 2006

-~270 *P. falciparum* isolates – W.H.O. funded (1986-?)

-~>7,000 ampoules

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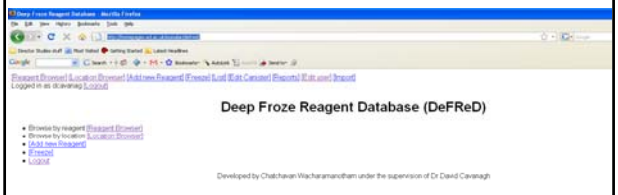
WP4: Repository of resources

Edinburgh *Plasmodium* spp. culture database 2008



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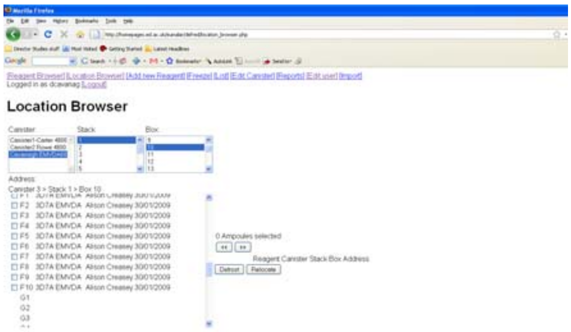
WP4: Repository of resources

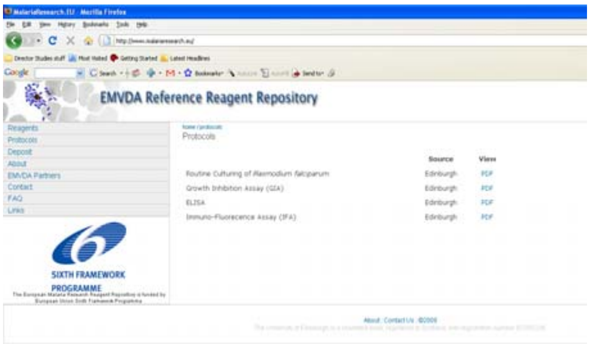
OPTIMALVAC WP4: Repository of resources



OPTIMALVAC WP4: Repository of resources

www.malariaresearch.eu

OPTIMALVAC WP4: Repository of resources



www.malariaresearch.eu

OPTIMALVAC WP4: Repository of resources

www.malariaresearch.eu

OPTIMALVAC WP4: Repository of resources – new culture labs 2007

OPTIMALVAC WP4: Repository of resources – new storage vessels 2007

OPTIMALVAC

WP4: Repository of resources

Web based database developed for documentation of reagents and SOPs Ongoing
Aliquots of standard, characterised *P. falciparum* clones available - Ongoing
Reference Reagents and Controls for assays; with relevant SOPs on maintenance and care produced and information stored on database – Decision on creation of standards?
Repository of facilities and materials resources (reagents: serum samples, antigens and antibodies) for the conduct of assays – Some ready, some in production, some to be obtained

OPTIMALVAC

WP2

Cell dependent parasite inhibition assays including ADCI/GIM

WP2 will focus on the optimization and harmonization of selected assay(s) in terms of assay performance criteria, development and selection of a common SOP, IgG or plasma preparation and storage methods, optimal parasite culture conditions (including strain selection and speed of growth), threshold of positive response and perform intra and inter-laboratory assay variability tests using coded samples and standards.

WP2

Cell dependent parasite inhibition assays including ADCI/GIM

Key activities:

- **Identifying optimal conditions for preparation of purified IgG and/or handling and storage of serum samples**
- **Identification of optimal parasite strains and culture conditions**
- **Identification of an ADCI effective cell line, production of Master and Working Cell Banks and Identification of Markers to characterize the biologically effective phenotype**

WP2

Cell dependent parasite inhibition assays including ADCI/GIM

- **Optimizing cell dependent parasite inhibition assay protocols**
- **Drafting common SOPs**
- **Optimizing of assay(s) components**
- **Developing and testing reference reagents**
- **Perform intra and inter laboratory assays variability tests**
- **Inter-laboratory training, training of 1-2 African scientists in the Afro-Immuno-Assay network**

WP2

Cell dependent parasite inhibition assays including ADCI/GIM

Workpackage number	2	Start date or starting event:		1					
Workpackage title	Cell dependent parasite inhibition assays								
Participant id	8	2	4	12	7	9	3	10	13
Person-months per participant	6	30	30	10	24	2	2	5	2

Objectives

To optimize, and harmonize the cell dependent parasite inhibition assays
Task 1: Compare different protocols for cell dependent assays parasite inhibition assays
Task 2: Optimize and standardize selected protocol
Task 3: Establishing reference parasite strains culture conditions, and appropriate controls
Task 4: Conduct intra and inter-laboratory assay variability tests

WP2

Cell dependent parasite inhibition assays including ADCI/GIM

Description of work

Task 1: Compare different protocols for cell dependent parasite inhibition assays
Compare protocols for cell dependent parasite inhibition assays, including ADCI, GIM, and Phagocytosis
Identify key parameters for optimising and harmonizing cell dependent parasite inhibition assays

WP2

Cell dependent parasite inhibition assays including ADCI/GIM

Task 2: Optimize and harmonize the cell dependent parasite inhibition assays

Compare results obtained using blood monocytes or cell lines and select optimal for use in assay. Identification of an ADCI effective cell line, production of Master and Working Cell Banks.
Identification of Markers to characterize the biologically effective phenotype.
Identification of the optimal read-out technique through comparison of read-out techniques (^{3}H-hpx incorporation, Flow cytometry, LDH-Ag detection, microscopy)
Optimize assay using purified IgG or serum stored under defined conditions, compare different methods of IgG purification, with emphasis on the handling of small volumes.
Definition of reagents and controls and of conditions for their optimal maintenance
Definition of conditions allowing the maximal efficacy and definition of the threshold of positivity.
Identify and select sources of reagents and equipment.

WP2

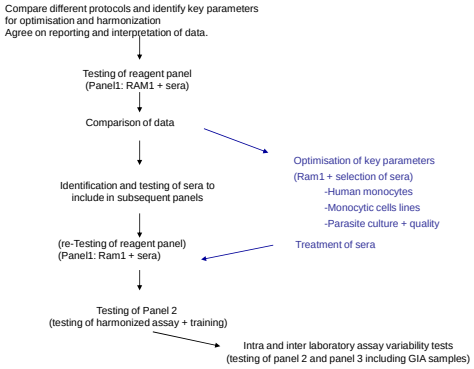
Cell dependent parasite inhibition assays including ADCI/GIM

Task 3: Establishing standard reference parasite strains

Establishment of criteria for selection of reference parasite strains, depending on the target antigen.
Establishment of a Master cell Bank of effective cells.
Production and full characterization of reference sera and IgG.
Testing of reference parasite strains for reactivity with sera, IgG fractions and monoclonal antibodies of defined specificity.
Side by side comparison of reference parasite strains using standard IgG reference reagent.
Establishment of inhibition activity with serum reference reagent.

Task 4: Conduct intra and inter-laboratory assay variability tests

Run intra laboratory assay variability tests.
Run inter laboratory assay variability tests in blinded manner.
Conduct hands-on teaching sessions (Two series of 2-3 weeks).
Compare coded results.



WP2

Cell dependent parasite inhibition assays including ADCI/GIM

Deliverables		
D2.1	First consensus SOP for ADCI/GIM assays.	Months 0-12 (⇨24)
D2.2	Report on the development and rationale of acceptance criteria for assay performance.	Months 0-12 (⇨18)
D2.3	Report on the determination and rationale behind minimal requirements and conditions for key assay components	Months 0-12 (⇨20)
D2.4	Sera from endemic and non endemic areas identified or collected.	Months 0-16
D2.5	IgG fractions characterized for reactivity to different Malaria antigens. ?	Months 8-16
D2.6	Condition for preparation sera and / or IgG preparations identified.	Month 1-20
D2.7	Standard IgG reagents available for distribution to Malaria vaccine community	Months 6-24
D2.8	Reference Reagents and Controls; with relevant SOPs on maintenance and care	Months 20-26 Months 6-26
D2.9	Practical training activities.	Months 16-26
D2.10	Intra and inter laboratory assay variability tests completed	Months 26-36
D2.11	Report/publication inter-laboratory assay variability test.	Month 33-36

Milestones		
M2.1	Consensus SOP for ADCI/GIM available.	Month 12 (⇨24)
M2.2	Acceptance criteria for assay performance and requirements for key components identified.	Month 12 (⇨20)
M2.3	Standard reagents, sera and IgG fractions available for distribution and testing.	Month 24
M2.4	Report/publication inter-laboratory assay variability test.	Month 36

WP3

This WP will focus on harmonizing T cell-mediated immune assays in the context of malaria vaccine development. Activities will include identifying key parameters in Elispot and ICS which are relevant to malaria vaccine evaluation. WP3 will benefit from experience gained by other groups including the HIV and TB communities which are or have been involved in harmonization of these assays. The optimization and harmonization of the T cell assays will be done in close consultation with the HIV and TB vaccine communities. It will also participate in ongoing global efforts in T cell assay harmonization sponsored by the Malaria Vaccine Initiative.

WP3
CMI assays

Key activities include:

- Identifying key parameters and relevant T cell assay or assays suited to malaria vaccine evaluation
- Harmonizing protocols for detection of T cell responses
- Harmonizing staining, acquisition and data analysis procedures using the existing fixed cell standard available at NIBSC (currently applies to the ICS assay but could be extended to Elispot during year 2)
- Harmonizing data analysis procedures
- Performing intra and inter laboratory assay variability
- Inter-laboratory training, training of 1-2 African scientists in the Afro-Immuno-Assay network

WP3
CMI assays

Deliverables		
D3.1	Report identification of key parameters and optimal approaches for evaluating T cell responses in pre-erythrocytic and blood-stage vaccinations.	Months 1-4
D3.2	Report on the development and rationale of acceptance criteria for assay performance.	Month 4-9
D3.3	Identification of source of activation and detection standards reagent.	Months 1-9
D3.4	Identification of reference cell preparations.	Months 1-9
D3.5	Repository site/sites for standard reagents and controls identified and established.	Month 9-15
D3.6	SOPs harmonized and available to all participants	Months 9-15
D3.7	Proficiency panel for training and evaluation of operators	Months 16-18
D3.8	Training of personnel	Months 18-23
D3.9	Results of intra and inter laboratory assay variability.	Month 23-32
D3.10	Report on intra and inter-laboratory assay variability tests	Month 30-36

WP3
CMI assays

Milestones		
M3.1	Key parameters, acceptance criteria reference cell preparations and reagents identified.	Month 9
M3.2	Repository of cells and reagents established.	Month 15
M3.3	Harmonized SOP available to all participants.	Month 15
M3.4	Training of personnel completed.	Month 23
M3.5	Results of intra and inter laboratory assay variability test available.	Month 36

WP3
CMI assays

Issues

- **Supply of antigens**
  - **TT (no cost)**
  - **CEF peptides (budget ???)**
- **Shipment of PBMC panels (dry ice >< cryoshippers + cost issues)**

Optimalvac WP5

WP5

- Harmonizing protocol and SOP formats and publication of harmonized protocols and SOPs on the web space (EMVDA)
- Setting up a protocol and SOP database for open access to all participants
- Provision of open-source software tools for the calculation of assay read-outs for the assays described in WP1-3 (BPRC)
- Harmonizing the data report format for each assay (BPRC)
- Setting up a web space where participants can upload data obtained during assay optimization and harmonization, and download SOPs, software tools and analysis results. The web space will also provide general information (e.g. clinical trials information, links to relevant sites etc), as well as a forum with questions and answers relating to malaria assays (EMVDA)
- Harmonize statistical analyses of data obtained with each of the assays described in WP 1-4 and provision of software tools to perform these analyses (BPRC)
- An agreed statistical analysis plan for the identification of factors influencing assay performance in both an inter- and intra- laboratory context (BPRC)
- Performance and reporting of central statistical analyses of assay data (BPRC)

Deliverables

D5.1	Web space for communication between partners
D5.2	Harmonised protocols and SOPs
D5.3	Harmonised data report formats
D5.4	Definition how the data audit trail is to be kept
D5.5	Methods for calculating assay read outs and data management
D5.6	Validated software tools for the calculation of assay read-outs
D5.7	Methods for statistical analyses
D5.8	Validated software tools for harmonised statistical analyses
D5.9	Access to data emerging from the assay performance efforts for the partners
D5.10	Report on factors influencing assay variation and correlations between the outcomes of the assays in WP1-4
D5.11	Access to software tools and SOPs for partners and third parties
D5.12	Finalised protocols and SOPs

Project Connections

- Assay package in EMVDA
- WHO / EMVI / MVI assay standardisation (Sienna meeting December 2007)
- Ongoing GIA comparison NIH, WRAIR & BPRC

WP5

Workpackage number 5 **Start date or starting event:** 1

Workpackage title Data Management, Statistical Analysis and Dissemination

Participant id	BPRC	WHO
Person-months per participant	5	2

Objectives

To develop and utilize standard and appropriate data management tools that fully support assay validation

To develop and utilize standard statistical analysis plans appropriate and valid for analysis of data from standardization and validation efforts

To set up a web-based tool that allows access to information, SOPs and results, communication between partners and dissemination of deliverables

WP5

- **Description of work**
- Establishment and maintenance of open source database/ data management tools to collect, maintain, record all data and relevant documentation in accordance with GLP requirements
- Define specifications for computer programs required for calculation of assay read-outs
- Define how data audit trail is kept
- Define output formats for calculation programs, allowing easy data retrieval
- Provide an open-source Excel-based application to convert GIA and or ADCI/GIM pLDH OD data into growth inhibitions.
- Provide an open-source Excel-based application to convert Elisa OD data into units.
- Definition and provision of software tools for the assays other than GIA, ADCI, Elisa.

WP5

- Agreed statistical analysis plans for the following topics
- Identification of factors influencing assay performance in both an inter- and intra-laboratory context.
- Correlations between the outcomes of the various assays in WP1-3.
- Between participating laboratories comparisons for results obtained with the assays in WP1-3.

WP5

- Establishment and maintenance of a Web-based tool for communication and dissemination of data and develop the following functionalities:-
- Catalogue of available SOP's
- Catalogue of available reagents (Sera, IgG, Antigens, Parasite strains)
- Forum with questions and answers on malaria assays
- Clinical trials information
- Information on statistical analysis and data management
- Electronic repository with validation data, reagent fact sheets etc.
- Download page with programs for calculating Elisa and programs for data management and statistical analysis
- Members area with upload functionality

WP5

Data protection

- All activities will be compliant with national and European regulations and directives with regard to the banking distribution and maintenance of databases for materials of biological origin.
- Databases published on the website will be locked and checked for integrity on a regular basis. In the event a database was modified without authorisation, it will be replaced by a back-up copy.

Timing

E.M.V.I.

OPIMALVAC WP 6
Regulatory and Ethical Considerations

Egeruan Babatunde Imoukhuede
OPTIMALVAC KoM Geneva
07-08 May 2009

E.M.V.I.

Outline

- Description of WP
- Partners
- Deliverables, milestones
- Finances
- Progress

E.M.V.I.

Description of Work 1/2

- Identification of potential RA issues or questions by the WP teams
- Identification of Ethical issues by the WP teams
- Compiling current informed consent templates from partners

E.M.V.I.

Description of Work 2/2

- Considering the relevant issues in the process to enable ethical use of left-over samples for relevant analysis
- Discussion with IRB experts and Ethics authorities on the issues of use of left-over samples
- Ensure adherence to ethical and normative guidelines

E.M.V.I.

Partners

- European Malaria Vaccine Initiative
- World Health Organization

E.M.V.I.

Deliverables, Milestones

- **D6.1**: Report on potential regulatory and ethical issues
- **D6.2**: Report on ethical consideration around utilisation of leftover sample specimen
- **D6.3**: Proposed informed consent template to be modified that could allow for utilisation of leftover samples without breaching ethical guidelines

➢ *Month 0-12*

Finances

7

Progress to date

- Consultation to begin with WHO on strategy
- Proposal for topic to be introduced as a working group topic at the next VSCR 'Ethical Aspects of Clinical Research Course' – Vienna Jun 2009
- Are partners likely to use samples from Clinical Trials in Africa?

8

ISSUES 1 / 2

- Ensuring appropriate informed consent process before and during collection of samples – presumed consent, blanket approvals, case-by-case
- Ensuring the quality and security of stored samples
- Protection of confidentiality of CT participants

9

ISSUES 2 / 2

- Shipment of samples between sites (within Europe/ between Europe/Africa) – legal context, procedures
- Use of samples by investigators for tests/assays other than those stipulated in the approved CTP
- Ensuring appropriate research access to samples for public health good

10

Thank you….God Bless

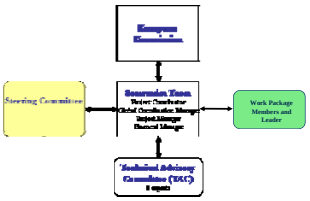
11

E.M.V.I.

Project Coordination and Management

E.M.V.I.

Management Structure



E.M.V.I.

Coordinator

- Official communication between the partnership and the EC
- Is responsible for the distribution of the EC financial contribution
- Member of the steering committee

E.M.V.I.

Secretariat

- Handles all day to day communication with the EC
- Responsible for the daily management of the initiative
- Monitor actual work progress against the planned implementation
- Maintains transparency and accountability for the decisions made at each level of the partnership
- Manages EC reporting

E.M.V.I.

Steering Committee

- Chair, vice-chair, work package leaders, coordinator and EC observer
- The committee will be responsible for:
  - Taking the decisions needed to effectively implement the work programme and achieve deliverables
  - Changes and additions to the partners in the initiative
  - Discussion on financial allocation and distribution of resources according to the proposed work programme
  - Be the main and final decision-making body for the partnership
  - Consult the TAC as necessary

E.M.V.I.

Work Package Leaders

- Each work group will be led by a work package leader (WPL). The WPL will:
  - Be responsible for convening group meetings and maintain efficient communication
  - Chair meetings and discussions regarding decision-making, work plans, coordination and follow-up of activities and prioritise activities
  - Present work group decisions to the steering committee
  - Preparing minutes of meetings
  - Technical and financial reporting

Work Group

- Should meet minimum every three months to schedule and formulate key activities
- The work groups are responsible for:
  - - Formulating detailed work plan of activity and proposing allocation of tasks and resources to achieve the work plan objectives.
  - - Identify and discuss potential difficulties and barriers associated with achieving the objectives
  - - Highlight and present any difficult issues that need the arbitration of the secretariat
  - - Technical and administrative/financial reporting on the progress of the work plan
- Decisions will be taken by the group collectively and presented to the secretariat by the workgroup leader. Should there be any dissent that the workgroup leader cannot resolve, this will be presented to the secretariat who will be the arbitrating authority

External Advisory Committees

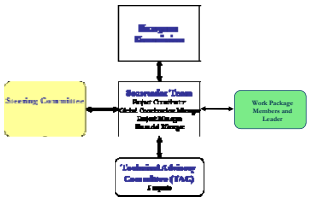
- The Technical Advisory Committee (TAC)
- Maximum 5 experts
- Advise on: 1) the strategic plan, 2) its technical orientation, 3) the work programme of the initiative and the progress being achieved, and 4) regulatory issues that require specific expertise identified by the Steering Committee.
- Three experts will be nominated by WHO and EU and two by the Steering Committee. The procedure of nomination will take place at the kick-off meeting.
- On an ad-hoc basis, external experts could be called

Miscellaneous

- Reporting
- Current status of negotiation with EC
- Consortium agreement
- Website
- Communication – wp run by wpl not me or odile
- Next WP meeting and frequency of meetings

E.M.V.I.

Management Structure



E.M.V.I.

OPTIMALVAC Kick Off

Finance Agenda

1. Current Issues
2. Overall budget
3. Flexibility in FP7
4. Scientist & Financial manager cooperation
5. FORCE reporting tool
6. Pre-financing & Cash Flow
7. Audit

2

E.M.V.I.

New Financial Guidelines

4th April 2009

- If the method for determining indirect **costs** in funding schemes with RTD activities **is actual costs or the 20% standard flat rate** then the indirect **costs** for the participation in the CSA are determined according to the same method.
- If the method for determining indirect **costs** in funding schemes with RTD activities **is the 60% transitional flat rate**, then the indirect **costs** for the participation in the CSA are determined according to the standard flat rate method (i.e. 20% of direct costs minus subcontracting, not 60%)
- Does not affect EU Contribution ! - It's mathematics

3

E.M.V.I.

OPTIMALVAC Budget

Work package	WP1	WP2	WP3	WP4	WP5	WP6	WP7	WP8	TOTAL per Beneficiary
1. EMVI/SSI						12	66	30	108
2. UPBM		30	25						55
3. BPRC	18	2	4	2	5				31
4. SU		30							30
5. UEDIN	18			14					32
6. UOXF			23						23
7. RUNMC	24	24	24						72
8. WHO	2	6	2	2	2	2	12	7	35
9. IVC		(2)	(10)						(12)
10. MVI	(5)	(5)	(5)					(32)	(47)
11. CRESIB			28						28
12. NIBSC		(10)	(10)						(20)
13. CDC		(2)							(2)
TOTAL	67	111	131	18	7	14	78	69	495

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E.M.V.I.

OPTIMALVAC Overall Budget

WP Activity	WP 1 IFA*	WP 2 ADC*	WP 3 CMI*	WP7 & 8 Management & Global Coordination	Total Budget	EU contribution	Complimentary contribution
1. EMVI/SSI	10,681	10,681	10,681	314,479	346,522	308,982	-
2. UPBM	-	67,289	44,860	-	112,149	100,000	-
3. BPRC	41,928	8,650	11,356	-	61,934	55,224	-
4. SU	-	61,682	-	-	61,682	55,000	-
5. UEDIN	89,720	-	-	-	89,720	80,000	-
6. UOXF	-	-	45,751	-	45,751	40,794	-
7. RUNMC	48,598	48,599	48,598	-	145,795	130,000	-
8. WHO	9,626	59,253	9,626	123,364	201,869	180,000	-
9. IVC	-	4,342	100,253	-	104,595	-	104,595
10. MVI	43,276	43,276	43,276	276,972	406,800	-	406,800
11. CRESIB	-	-	56,074	-	56,074	50,000	-
12. HPA	-	25,000	25,000	-	50,000	-	50,000
13. CDC	-	30,000	-	-	30,000	-	30,000
TOTAL Budget	243,829	358,772	395,475	714,815	1,712,891	----------	----------
TOTAL EU Requested	123,121	219,024	273,468	418,982	----------	1,000,000	----------
Complimentary	43,276	102,618	168,529	276,972	----------	----------	591,395

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E.M.V.I.

OPTIMALVAC Flexibility

•The transfer of budget between activities and beneficiaries is allowed without the need for an amendment of the GA. However, a condition for this is that the work can be carried out as foreseen

•The coordinator verifies this on a case-by-case basis in close collaboration with our EU Project Officer Andreas Holtel.

	Type of Activity			
	Coordination / Support (A)	Management (B)	Other (C)	Total A+B+C
Personnel costs	0.00	0.00	0.00	0.00
Subcontracting	0.00	0.00	0.00	0.00
Other direct costs	0.00	0.00	0.00	0.00
Indirect costs	0.00	0.00	0.00	0.00
Maximum reimbursement Indirect costs at	0.00	0.00	0.00	0.00
Total costs	0.00	0.00	0.00	0.00
Maximum allowable EC contribution	0.00	0.00	0.00	0.00
Requested EC contribution	0.00	0.00	0.00	0.00
Receipts				0.00

An amendment to the GA will be necessary in all cases if the budget transfer arises from a significant change. Significant change refers to a change that affects the technical work as foreseen in DoW, including subcontracting of a task meant to be carried out by a beneficiary.

6

OPTIMALVAC Scientist & Financial manager cooperation

1. Understanding between Scientist and Financial Manager and a close working relationship required
2. EU audits will reveal all weaknesses – disqualification of costs.

Recommendations:

- Keep daily time sheets (control) of staff paid on the project
- Avoid excessive expenditure: paying significantly more for products, services or personnel than the prevailing market rates, resulting in an avoidable financial loss to the project.
- Avoid reckless expenditure: failing to exercise care in the selection of products, services or personnel resulting in an avoidable financial loss to the project
- Designated Financial Manager & Scientist collaboration strongly recommended - mutual understanding technically & economically.

7

OPTIMALVAC FORCE

- Web based tool to edit and submit Forms C, both for FP-6 and FP-7 (access via SESAM)
- FP-7: only 1 way to submit Forms C
  - Web based application FORCE
- Only coordinators have access (in a later version individual beneficiaries will be able to view, edit and print their own Form C – May 2009 ?)

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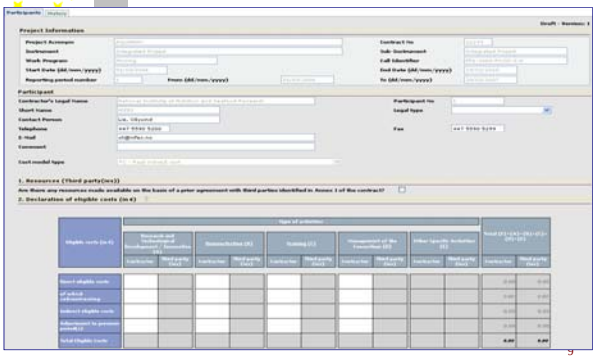
OPTIMALVAC Force



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OPTIMALVAC Reporting

Key elements

- The preparation of **FP6 FORMS C and FP-7 FORMS C** with updated and correct contract/grant information of each beneficiary participating in the project/grant
- Electronic submission of **FORMS C** to the Commission (signed paper version to be sent afterwards)
- Possible Correction of **Forms C** after refusal by Commission
- First Financial reporting 18 Months midterm. 1st February 2009 - 31st July 2010. **Once completed EU has 105 days to evaluate and make the next payment!**
- Finance review of budget and Person months after one year !!!

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OPTIMALVAC Pre-financing

•There is **only one** pre-financing payment (advance payment) during the life of the project.
•It will be received by the coordinator at the beginning of the project and in any case within 45 days of the entry into force of the grant agreement.

•Estimation of Pre Financing (Based on Financial guidelines 4th April 2009)

• OPTIMALVAC running over 2 reporting periods with **EUR 1,000,000** EC contribution

Pre-financing (usually 75% of **EUR 1,000,000**) Interval 60%-80% = **EUR 750,000**
Contribution to Guarantee Fund: 5% of total EU funding: **1,000,000** x 5% = **EUR – 50,000**
Net amount transferred to Coordinator3: **EUR 800,000 – EUR 50,000** = **EUR 700,000**

= 70 % !

It may reach 80% in which case pre-financing are equal to EUR 750,000 or 75%.

•75% (or 80% in which case pre-financing are equal to EUR 750,000 or 75%) of beneficiaries via the coordinator at the moment of the final payment, at the end of the project.
•10 % are withheld until the final payment including the guarantee funds. Meaning the interim payment will be as an example 75% - 90% = 15 % or equal to EUR 150,000 depending of reported expenditures.

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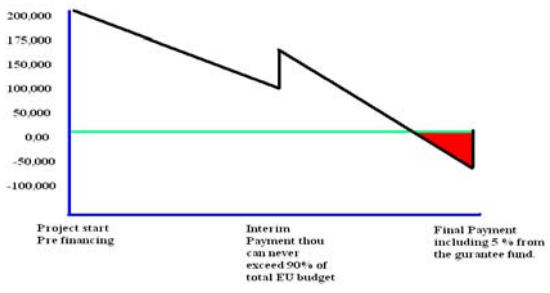
OPTIMALVAC Cash Flow



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OPTIMALVAC Audit issue

•A Certificate on CFS is mandatory for every claim (interim or final) in the form of reimbursement of costs whenever the amount of the EC contribution is equal or superior to EUR 375.000

•This means that no partners in OPTIMALVAC will be required to submit audits (Certification of Costs) during and after the project duration only the Form C's are required.

•Please observe that this does not affect the EU right to demand audits of your institution up to 5 years after the closure of OPTIMALVAC. (WHO exemption)

•If, for safety reasons, you prefer to have your accounting audited then it is on your own expenses.

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The EU - Audits may cover:

- Financial aspects (If suspicions – measured agains DoW.)
- Systemic aspects including the minutes of meetings & travel justifications (verifying staff travel)
- Aspects such as Internal controlling, accounting principles and management principles.

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OPTIMALVAC

Questions and comments regarding OPTIMALVAC Financial Issues:

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+45 32 68 35 60

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WP8

Global Coordination

Malaria Vaccine Funders Group

- EMVI
- EDCTP
- EC
- Wellcome
- BMGF
- NIH
- USAID
- MVI
- WHO

Malaria Vaccine Funders Group

- Meets twice a year (though varies)
- Informal interactions between subgroups of members through year

Malaria Vaccine Funders Group: Agreed Priority Areas

- Assay harmonization agreed as one of the roadmap priorities

"Develop a standard set of immunological assays with standardized procedures and reagents to enable comparisons of the immune responses of vaccines"

- Individual funders have different priority assignments to this field
- Importance of the "evaluation technologies" increasingly recognised

Related roadmap priority

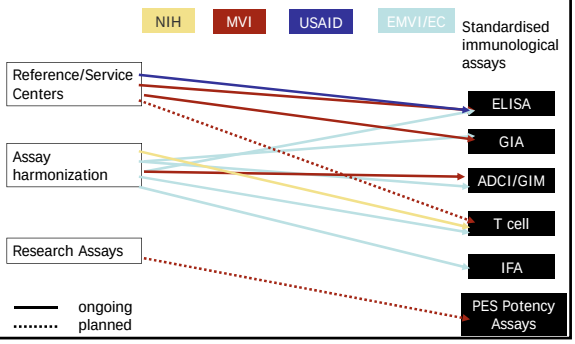
"Develop web-based information-sharing tools to strengthen connections between the laboratory and the clinic."

Immunoassays and Malaria Vaccine Development

Three-pronged approach:

- **Assay harmonization**
- **Reference/Service Centers**
- Research assays

Assay Activities



Key Activities for WP8

- Establishing links, identifying synergy and fostering collaboration with ongoing or future assay development and harmonization efforts.
- Integrating the activities of OPTIMALVAC with the global strategy for malaria vaccine development.
- Coordinating strategies for the establishment of future assay reference centres.

Already undertaken

- Update of global assay harmonization activities presented to MVFG Dec 2008
- Disseminated through funders group website
- Clarity of involvement of various funders in activities

Synergies to be identified

- Proactively through IVR involvement in assay harmonization outside OPTIMALVAC
- OPTIMALVAC Partners to inform IVR of potential synergies identified – malaria, HIV and TB
- Presentations at MVFG when appropriate

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Deliverable 1 – 12 months

- Contacts with laboratories outside OPTIMALVAC established
- For T cell assays what is WHO's role in linking with HIV and TB T cell assay work
- Input sought as to other contacts necessary

Deliverable 2 – 24 months

- Synergies between OPTIMALVAC activities and other assay harmonization efforts identified

36 month deliverables

- Contacts between the relevant assay WPs and the Tb and HIV vaccine communities established.
- OPTIMALVAC activities integrated in the global strategy for malaria vaccine development
  - Web-based tool lends itself to a role for the global community if developed with this in mind?
- Needs, strategies and sources of funding for the establishment of reference centres identified.
- ?change to evaluation of appropriateness of establishment of reference/service centre(s) for each assay

Thank you

- Keep Stefan and I informed
- wageners@who.int