

The VEGF Consortium

Founding Parties:

1. UMR INSERM U1122; IGE-PCV – Sophie VISVIKIS-SIEST
2. Queen Mary University of London (QMU) – Panos DELOUKAS
3. Boston University (BU) - Sudha SESHADRI
4. Randox Laboratories Limited – John LAMONT
5. Univerza V Ljubljani – Janja MARC
6. Università degli studi di Roma (UniRoma1) - Maurizio SIMMACO
7. European Society of Pharmacogenomics and Personalised Therapy (ESPT) - Gérard SIEST † / Ron van Schaik (president of ESPT since October 2016)
8. Biobanking and Biomolecular Resources Research Infrastructure (BBMRI) / INSERM US 13, BIOBANQUES – Georges DAGHER
9. University Medical Center of Groningen (UMCG) – Behrooz ALIZADEH
10. Genetics of Complex Traits Laboratory at IGB- National Research Council of Italy (CNR) – Marina CIULLO

Additional core Parties:

1. Institut de Cancérologie de Lorraine – Biopathology Department, CNRS UMR7039 CRAN, Université de Lorraine – Jean-Louis MERLIN
2. University of Luxembourg, Luxembourg Centre for Systems Biomedicine – Jochen SCHNEIDER
3. University of North Carolina at Chapel Hill, NC, USA - Federico INNOCENTI

CONSORTIUM AGREEMENT

THIS CONSORTIUM AGREEMENT is based upon REGULATION (EU) No 1290/2013 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 11 December 2013 laying down the rules for the participation and dissemination in “Horizon 2020 – the Framework Programme for Research and Innovation (2014-2020)” (hereinafter referred to as “the Rules”), and the European Commission Multi-beneficiary General Model Grant Agreement and its Annexes, and is made on 23/06/2015, hereinafter referred to as the Effective Date

BETWEEN:

**UMR INSERM U1122; IGE-PCV,
Principal Investigator and the Coordinator: Sophie VISVIKIS-SIEST**

**Queen Mary University of London (QMU)
Principal Investigator: Panos DELOUKAS**

**Boston University (BU)
Principal Investigator: Sudha SESHADRI**

**Randox Laboratories Limited
Principal Investigator: John LAMONT**

**Univerza V Ljubljani
Principal Investigator: Janja MARC**

**Universita degli studi di Roma (UniRoma1)
Principal Investigator: Maurizio SIMMACO**

**European Society of Pharmacogenomics and Personalised Therapy (ESPT)
Principal Investigator: Gérard SIEST† / Ron van Schaik (president of ESPT since October 2016)**

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Principal Investigator: Marina CIULLO**

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Principal Investigator: Jean-Louis MERLIN**

**University of Luxembourg, Luxembourg Centre for Systems Biomedicine (ULUX)
Principal Investigator: Jochen SCHNEIDER**

**University of North Carolina at Chapel Hill, NC, USA
Principal Investigator: Federico INNOCENTI**

hereinafter, jointly or individually, referred to as "Parties" or "Party"

relating to the Action entitled

The VEGF Consortium

Herein after referred to as "Project"

WHEREAS:

The Parties, having considerable experience in the field concerned, will

- Conduct collaborative projects (hereinafter referred to as "Consortium Bodies" or "Consortium Body") and
- Submit proposals for the Project to the Funding Authority as part of the Horizon 2020 – the Framework Programme for Research and Innovation (2014-2020) and to other Funding Bodies

The Parties wish to specify or supplement binding commitments among themselves.

The Parties are aware that this Consortium Agreement is based upon the DESCAs model consortium agreement.

WHEREAS The VEGF Consortium aims to develop a transnational collaborative network dedicated to large integrative and multidisciplinary genomic studies of the Vascular Endothelial Growth Factor in order to generate practicable knowledge for medical practice.

AS AGREED the objectives are as follows:

- To combine data from multiple cohorts in order to identify VEGF '-omics' profiling in health and non-communicable diseases
- To elucidate the pivotal role of VEGF in the pathophysiology of non-communicable diseases
- To demonstrate the patients' stratification potential of VEGF '-omics' profiling
- To implement the research results into clinical practice and establish the role of VEGF as a predictive, preventive, diagnostic and prognostic biomarker
- To provide information on the effect of VEGF '-omics' profiling in side effects and response to therapy through pharmacogenomics studies
- To propose implementation strategies and European guidelines involving VEGF '-omics' profiling for the management of non-communicable diseases
- To share methodologies, data and knowledge in the field of '-omics' management and innovative statistics
- To develop standardized teaching and evaluation methods practiced and validated by the Consortium

NOW, THEREFORE, IT IS HEREBY AGREED AS FOLLOWS:

Section 1: Definitions

1.1 Definitions

Words beginning with a capital letter shall have the meaning defined either herein or in the Rules.

1.2 Additional Definitions

"Consortium Plan"

Consortium Plan means the description of the action and the related agreed budget as first defined and which may be updated by the General Assembly.

“Defaulting Party”

Defaulting Party means a Party which the General Assembly has identified to be in breach of this Consortium Agreement as specified in Section 4.2 of this Consortium Agreement.

“Needed”

means:

For the implementation of the Project:

Access Rights are Needed if, without the grant of such Access Rights, carrying out the tasks assigned to the recipient Party would be impossible, significantly delayed, or require significant additional financial or human resources.

For exploitation of own Results:

Access Rights are Needed if, without the grant of such Access Rights, the Exploitation of own Results would be technically or legally impossible.

“Software”

Software means sequences of instructions to carry out a process in, or convertible into, a form executable by a computer and fixed in any tangible medium of expression.

Section 2: Purpose

The purpose of this Consortium Agreement is to specify with respect to the Project the relationship among the Parties, in particular concerning the organisation of the work between the Parties, the management of the Project and the rights and obligations of the Parties concerning inter alia liability, Access Rights and dispute resolution.

Section 3: Entry into force, duration and termination

3.1 Entry into force

An entity becomes a Party to this Consortium Agreement upon signature of this Consortium Agreement by its Principal Investigator.

This Consortium Agreement shall have effect from the Effective Date identified at the beginning of this Consortium Agreement.

An entity becomes a Party to the Consortium Agreement upon signature of the accession document by the new Party and the Coordinator. Such accession shall have effect from the date identified in the accession document.

3.2 Duration and termination

This Consortium Agreement shall continue in full force and effect until complete fulfilment of all obligations undertaken by the Parties under this Consortium Agreement.

However, this Consortium Agreement or the participation of one or more Parties to it may be terminated in accordance with the terms of this Consortium Agreement.

3.3 Survival of rights and obligations

The provisions relating to Access Rights and Confidentiality, for the time period mentioned therein, as well as for Liability, Applicable law and Settlement of disputes shall survive the expiration or termination of this Consortium Agreement.

Termination shall not affect any rights or obligations of a Party leaving the Consortium incurred prior to the date of termination, unless otherwise agreed between the General Assembly and the leaving Party. This includes the obligation to provide all input, deliverables and documents for the period of its participation.

Section 4: Responsibilities of Parties

4.1 General principles

Each Party undertakes to take part in the efficient implementation of the Project, and to cooperate, perform and fulfil, promptly and on time, all of its obligations under this Consortium Agreement as may be reasonably required from it and in a manner of good faith.

Each Party undertakes to notify promptly, in accordance with the governance structure of the Project, any significant information, fact, problem or delay likely to affect the Project.

Each Party shall promptly provide all information reasonably required by a Consortium Body or by the Coordinator to carry out its tasks.

Each Party shall take reasonable measures to ensure the accuracy of any information or materials it supplies to the other Parties.

4.2 Breach

In the event that a responsible Consortium Body identifies a breach by a Party of its obligations under this Consortium Agreement (e.g. improper implementation of Consortium Bodies), the Coordinator or, if the Coordinator is in breach of its obligations, the Party appointed by the General Assembly, will give formal notice to such Party requiring that such breach will be remedied within 30 calendar days.

If such breach is substantial and is not remedied within that period or is not capable of remedy, the General Assembly may decide to declare the Party to be a Defaulting Party and to decide on the consequences thereof which may include termination of its participation.

4.3 Involvement of third parties

A Party that enters into a subcontract or otherwise involves third parties (including but not limited to Affiliated Entities) in the Project remains responsible for carrying out its relevant part of the Project and for such third party's compliance with the provisions of this Consortium Agreement. It has to ensure that the involvement of third parties does not affect the rights and obligations of the other Parties under this Consortium Agreement.

Section 5: Liability towards each other

5.1 No warranties

In respect of any information or materials (incl. Results and Background) supplied by one Party to another under the Project, no warranty or representation of any kind is made, given or implied as to the sufficiency or fitness for purpose nor as to the absence of any infringement of any proprietary rights of third parties.

Therefore,

- the recipient Party shall in all cases be entirely and solely liable for the use to which it puts such information and materials, and
- no Party granting Access Rights shall be liable in case of infringement of proprietary rights of a third party resulting from any other Party (or its Affiliated Entities) exercising its Access Rights.

5.2 Limitations of contractual liability

No Party shall be responsible to any other Party for any indirect or consequential loss or similar damage such as, but not limited to, loss of profit, loss of revenue or loss of contracts, provided such damage was not caused by a wilful act or by a breach of confidentiality.

A Party's aggregate liability towards the other Parties collectively shall be limited to once the Party's share of the total costs of the Consortium Bodies as such damage was not caused by a wilful act or gross negligence.

The terms of this Consortium Agreement shall not be construed to amend or limit any Party's statutory liability.

5.3 Damage caused to third parties

Each Party shall be solely liable for any loss, damage or injury to third parties resulting from the performance of the said Party's obligations by it or on its behalf under this Consortium Agreement or from its use of Results or Background.

5.4 Force Majeure

No Party shall be considered to be in breach of this Consortium Agreement if it is prevented from fulfilling its obligations under the Consortium Agreement by Force Majeure.

Each Party will notify the competent Consortium Bodies of any Force Majeure without undue delay. If the consequences of Force Majeure for the Project are not overcome within 6 weeks after such notification, the transfer of tasks - if any - shall be decided by the competent Consortium Bodies.

Section 6: Governance structure

6.1 General structure

The organisational structure of the Consortium shall comprise the following Consortium Bodies:

General Assembly as the ultimate decision-making body of the consortium

Executive Board as the supervisory body for the execution of the Project which shall report to and be accountable to the General Assembly

The Coordinator is the legal entity acting as the intermediary between the Parties. The Coordinator shall, in addition to its responsibilities as a Party, perform the tasks assigned to it as described in this Consortium Agreement.

The Management Support Team assists the Executive Board and the Coordinator.

6.2 General operational procedures for all Consortium Bodies

6.2.1 Representation in meetings

Any Party which is a member of a Consortium Body (hereinafter referred to as "Member"): should be represented at any meeting of such Consortium Body; may appoint a substitute or a proxy to attend and vote at any meeting; and shall participate in a cooperative manner in the meetings.

6.2.2 Preparation and organisation of meetings

6.2.2.1 Convening meetings:

The chairperson of a Consortium Body shall convene meetings of that Consortium Body.

	Ordinary meeting	Extraordinary meeting
General Assembly	At least once a year	At any time upon written request of the Executive Board or 1/3 of the Members of the General Assembly
Executive Board	At least quarterly	At any time upon written request of any Member of the Executive Board

6.2.2.2 Notice of a meeting:

The chairperson of a Consortium Body shall give notice in writing of a meeting to each Member of that Consortium Body as soon as possible and no later than the minimum number of days preceding the meeting as indicated below.

	Ordinary meeting	Extraordinary meeting
General Assembly	45 calendar days	15 calendar days
Executive Board	14 calendar days	7 calendar days

6.2.2.3 Sending the agenda:

The chairperson of a Consortium Body shall prepare and send each Member of that Consortium Body a written (original) agenda no later than the minimum number of days preceding the meeting as indicated below.

General Assembly	21 calendar days, 10 calendar days for an extraordinary meeting
Executive Board	7 calendar days

6.2.2.4 Adding agenda items:

Any agenda item requiring a decision by the Members of a Consortium Body must be identified as such on the agenda.

Any Member of a Consortium Body may add an item to the original agenda by written notification to all of the other Members of that Consortium Body up to the minimum number of days preceding the meeting as indicated below.

General Assembly	14 calendar days, 7 calendar days for an extraordinary meeting
Executive Board	2 calendar days

6.2.2.5 During a meeting the Members of a Consortium Body present or represented can unanimously agree to add a new item to the original agenda.

6.2.2.6 Any decision may also be taken without a meeting if the Coordinator circulates to all Members of the Consortium Body a written document which is then agreed by the defined majority (see Section 6.2.3.) of all Members of the Consortium Body. Such document shall include the deadline for responses.

6.2.2.7 Meetings of each Consortium Body may also be held by teleconference or other telecommunication means.

6.2.2.8 Decisions will only be binding once the relevant part of the Minutes has been accepted according to Section 6.2.5.

6.2.3 Voting rules and quorum

6.2.3.1 Each Consortium Body shall not deliberate and decide validly unless two-thirds (2/3) of its Members are present or represented (quorum).

If the quorum is not reached, the chairperson of the Consortium Body shall convene another ordinary meeting within 15 calendar days. If in this meeting the quorum is not reached once more, the chairperson shall convene an extraordinary meeting which shall be entitled to decide even if less than the quorum of Members are present or represented.

6.2.3.2 Each Member of a Consortium Body present or represented in the meeting shall have one vote.

6.2.3.3 Defaulting Parties may not vote.

6.2.3.4 Decisions shall be taken by a majority of two-thirds (2/3) of the votes cast.

6.2.4 Veto rights

6.2.4.1 A Member which can show that its own work, time for performance, costs, liabilities, intellectual property rights or other legitimate interests would be severely affected by a decision of a Consortium Body may exercise a veto with respect to the corresponding decision or relevant part of the decision.

6.2.4.2 When the decision is foreseen on the original agenda, a Member may veto such a decision during the meeting only.

6.2.4.3 When a decision has been taken on a new item added to the agenda before or during the meeting, a Member may veto such decision during the meeting and within 15 calendar days after the draft minutes of the meeting are sent.

6.2.4.4 In case of exercise of veto, the Members of the related Consortium Body shall make every effort to resolve the matter which occasioned the veto to the general satisfaction of all its Members.

6.2.4.5 A Party may not veto decisions relating to its identification as a Defaulting Party. The Defaulting Party may not veto decisions relating to its participation and termination in the consortium or the consequences of them.

6.2.4.6 A Party requesting to leave the consortium may not veto decisions relating thereto.

6.2.5 Minutes of meetings

6.2.5.1 The chairperson of a Consortium Body shall produce written minutes of each meeting which shall be the formal record of all decisions taken. He shall send the draft minutes to all Members within 10 calendar days of the meeting.

6.2.5.2 The minutes shall be considered as accepted if, within 15 calendar days from sending, no Member has sent an objection in writing to the chairperson with respect to the accuracy of the draft of the minutes.

6.2.5.3 The chairperson shall send the accepted minutes to all the Members of the Consortium Body and to the Coordinator, who shall safeguard them.

If requested the Coordinator shall provide authenticated duplicates to Parties.

6.3 Specific operational procedures for the Consortium Bodies

6.3.1 General Assembly

In addition to the rules described in Section 6.2, the following rules apply:

6.3.1.1 Members

6.3.1.1.1 The General Assembly shall consist of one representative of each Party (hereinafter General Assembly Member).

6.3.1.1.2 Each General Assembly Member shall be deemed to be duly authorised to deliberate, negotiate and decide on all matters listed in Section 6.3.1.2. of this Consortium Agreement.

6.3.1.1.3 The Coordinator shall chair all meetings of the General Assembly, unless decided otherwise in a meeting of the General Assembly.

6.3.1.1.4 The Parties agree to abide by all decisions of the General Assembly. This does not prevent the Parties to submit a dispute to resolution in accordance with the provisions of Settlement of disputes in Section 11.8.

6.3.1.2 Decisions

The General Assembly shall be free to act on its own initiative to formulate proposals and take decisions in accordance with the procedures set out herein. In addition, all proposals made by the Executive Board shall also be considered and decided upon by the General Assembly.

The following decisions shall be taken by the General Assembly:

Content, finances and intellectual property rights

- Changes to the Consortium Plan
- Additions to List of Third Parties for simplified transfer according to Section 8.2.2
- Additions to Identified Affiliated Entities

Evolution of the consortium

- Entry of a new Party to the consortium and approval of the settlement on the conditions of the accession of such a new Party
- Withdrawal of a Party from the consortium and the approval of the settlement on the conditions of the withdrawal

- Identification of a breach by a Party of its obligations under this Consortium Agreement
- Declaration of a Party to be a Defaulting Party
- Remedies to be performed by a Defaulting Party
- Termination of a Defaulting Party's participation in the consortium and measures relating thereto
- Proposal to the Funding Authority for a change of the Coordinator
- Proposal to the Funding Authority for suspension of all or part of the Project
- Proposal to the Funding Authority for termination of the Project and the Consortium Agreement

Appointments

The appointment if necessary of:

Executive Board Members

6.3.2 Executive Board

In addition to the rules in Section 6.2, the following rules shall apply:

6.3.2.1 Members

The Executive Board shall consist of the Coordinator and the Parties appointed by the General Assembly (hereinafter Executive Members).

The Coordinator shall chair all meetings of the Executive Board, unless decided otherwise by a majority of two-thirds.

6.3.2.2 Minutes of meetings

Minutes of Executive Board meetings, once accepted, shall be sent by the Coordinator to the General Assembly Members for information.

6.3.2.3 Tasks

6.3.2.3.1 The Executive Board shall prepare the meetings, propose decisions and prepare the agenda of the General Assembly according to Section 6.3.1.2.

6.3.2.3.2 It shall seek a consensus among the Parties.

6.3.2.3.3 The Executive Board shall be responsible for the proper execution and implementation of the decisions of the General Assembly.

6.3.2.3.4 The Executive Board shall monitor the effective and efficient implementation of the Project.

6.3.2.3.5 In addition, the Executive Board shall collect information at least every 6 months on the progress of the Project, examine that information to assess the compliance of the Project with the Consortium Plan and, if necessary, propose modifications of the Consortium Plan to the General Assembly.

6.3.2.3.6 The Executive Board shall:

- agree on the Members of the Management Support Team, upon a proposal by the Coordinator
- support the Coordinator in preparing meetings, related data and deliverables
- prepare the content and timing of press releases and joint publications by the consortium.
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6.3.2.3.7 In the case of abolished tasks as a result of a decision of the General Assembly, the Executive Board shall advise the General Assembly on ways to rearrange tasks and budgets of the Parties concerned. Such rearrangement shall take into consideration the legitimate commitments taken prior to the decisions, which cannot be cancelled.

6.4 Coordinator

6.4.1 The Coordinator shall be the intermediary between the Parties and shall perform all tasks assigned to it as described in this Consortium Agreement.

6.4.2 In particular, the Coordinator shall be responsible for:

- monitoring compliance by the Parties with their obligations
- keeping the address list of Members and other contact persons updated and available
- collecting, reviewing to verify consistency and submitting reports, other deliverables (including financial statements and related certifications)
- transmitting documents and information connected with the Project to any other Parties concerned
- administering the financial contribution of the Parties and fulfilling the financial tasks described in Section 7.3
- providing, upon request, the Parties with official copies or originals of documents which are in the sole possession of the Coordinator when such copies or originals are necessary for the Parties to present claims.

If one or more of the Parties is late in submission of any project deliverable, the Coordinator may nevertheless submit the other parties' project deliverables and all other necessary documents.

6.4.3 If the Coordinator fails in its coordination tasks, the General Assembly may propose to the Funding Authority to change the Coordinator.

6.4.4 The Coordinator shall not be entitled to act or to make legally binding declarations on behalf of any other Party or of the consortium, unless explicitly stated otherwise in this Consortium Agreement

6.4.5 The Coordinator shall not enlarge its role beyond the tasks specified in this Consortium Agreement.

6.5 Management Support Team

The Management Support Team shall be proposed by the Coordinator. It shall be appointed by the Executive Board and shall assist and facilitate the work of the Executive Board and the Coordinator for executing the decisions of the General Assembly as well as the day-to-day management of the Project.

6.6 External Expert Advisory Board (EEAB)

An External Expert Advisory Board (EEAB) will be appointed and steered by the Executive Board. The EEAB shall assist and facilitate the decisions made by the General Assembly. The Coordinator is authorised to execute with each member of the EEAB a non-disclosure agreement, which terms shall be not less stringent than those stipulated in this Consortium Agreement, no later than 30 calendar days after their nomination or before any confidential information will be exchanged, whichever date is earlier. The Coordinator shall write the minutes of the EEAB meetings and prepare the implementation of the EEAB's suggestions. The EEAB members shall be allowed to participate in General Assembly meetings upon invitation but have not any voting rights.

Section 7: Financial provisions

7.1 General Principles

7.1.1 Distribution of Financial Contribution

Until the obtention of a specific Grant from any Funding Body, Parties's financial contributions, bilateral exchanges of personnel and budget will allow the functioning of the Consortium and the completion of its tasks.

Upon the obtention of specific grants, the financial contributions to the Project shall be distributed by the Coordinator according to:

- the Consortium Plan and
- the provisions of payment in Section 7.3.

A Party shall be funded only for its tasks carried out in accordance with the Consortium Plan.

7.1.2 Justifying Costs

In accordance with its own usual accounting and management principles and practices, each Party shall be solely responsible for justifying its costs with respect to the Project. Neither the Coordinator nor any of the other Parties shall be in any way liable or responsible for such justification of costs.

7.1.3 Funding Principles

A Party which spends less than its allocated share of the budget as set out in the Consortium Plan or – in case of reimbursement via unit costs - implements less units than foreseen in the Consortium Plan will be funded in accordance with its actual duly justified eligible costs only.

A Party that spends more than its allocated share of the budget as set out in the Consortium Plan will be funded only in respect of duly justified eligible costs up to an amount not exceeding that share.

7.1.4 Financial Consequences of the termination of the participation of a Party

A Party leaving the consortium shall refund all payments it has received except the amount of contribution accepted. Furthermore a Defaulting Party shall, within the limits specified in Section 5.2 of this Consortium Agreement, bear any reasonable and justifiable additional costs occurring to the other Parties in order to perform its and their tasks.

7.2 Budgeting

The budget set out in the Consortium Plan shall be valued in accordance with the usual accounting and management principles and practices of the respective Parties.

7.3 Payments

7.3.1 Payments to Parties are the exclusive tasks of the Coordinator.

In particular, the Coordinator shall:

- notify the Party concerned promptly of the date and composition of the amount transferred to its bank account, giving the relevant references
- perform diligently its tasks in the proper administration of any funds and in maintaining financial accounts

- undertake to keep the Community financial contribution to the Project separated from its normal business accounts, its own assets and property, except if the Coordinator is a Public Body or is not entitled to do so due to statutory legislation.

Section 8: Results

8.0 Ownership of Results

Results are owned by the Party that generates them.

8.1 Joint ownership

Unless otherwise agreed:

In case of joint ownership, each of the joint owners shall be entitled to Exploit the joint Results as it sees fit, and to grant non-exclusive licences, without obtaining any consent from, paying compensation to, or otherwise accounting to any other joint owner, unless otherwise agreed between the joint owners.

The joint owners shall agree on all protection measures and the division of related cost in advance.

8.2 Transfer of Results

8.2.1 Each Party may transfer ownership of its own Results.

8.2.2 It may identify specific third parties it intends to transfer the ownership of its Results to. The other Parties hereby waive their right to prior notice and their right to object to a transfer to listed third parties.

8.2.3 The transferring Party shall, however, at the time of the transfer, inform the other Parties of such transfer and shall ensure that the rights of the other Parties will not be affected by such transfer.

8.2.4 The obligations above apply only for as long as other Parties still have - or still may request - Access Rights to the Results.

8.3 Dissemination

8.3.1 Dissemination of own Results

8.3.1.1 During a Consortium Body and for a period of 1 year after the end of the Consortium Body, the dissemination of own Results by one or several Parties including but not restricted to publications and presentations, shall be governed by the following provisions.

Prior notice of any planned publication shall be given to the other Parties at least 45 calendar days before the publication. Any objection to the planned publication shall be made in writing to the Coordinator and to the Party or Parties proposing the dissemination within 30 calendar days after receipt of the notice. If no objection is made within the time limit stated above, the publication is permitted.

8.3.1.2 An objection is justified if

(a) the protection of the objecting Party's Results or Background would be adversely affected

(b) the objecting Party's legitimate academic or commercial interests in relation to the Results or Background would be significantly harmed.

The objection has to include a precise request for necessary modifications.

8.3.1.3 If an objection has been raised the involved Parties shall discuss how to overcome the justified grounds for the objection on a timely basis (for example by amendment to the planned publication and/or by protecting information before publication) and the objecting Party shall not unreasonably continue the opposition if appropriate measures are taken following the discussion.

The objecting Party can request a publication delay of not more than 90 calendar days from the time it raises such an objection. After 90 calendar days the publication is permitted, provided that Confidential Information of the objecting Party has been removed from the Publication as indicated by the objecting Party.

8.3.2 Dissemination of another Party's unpublished Results or Background

A Party shall not include in any dissemination activity another Party's Results or Background without obtaining the owning Party's prior written approval, unless they are already published.

8.3.3 Cooperation obligations

The Parties undertake to cooperate to allow the timely submission, examination, publication and defence of any dissertation or thesis for a degree which includes their Results or Background subject to the confidentiality and publication provisions agreed in this Consortium Agreement.

8.3.4 Use of names, logos or trademarks

Nothing in this Consortium Agreement shall be construed as conferring rights to use in advertising, publicity or otherwise the name of the Parties or any of their logos or trademarks without their prior written approval.

8.4 Exclusive licenses

Where a Party wishes to grant an exclusive licence to its Results and seeks the written waiver of the other Parties, the other Parties shall respond to the requesting Party within 45 calendar days of the request. Any Party's failure to respond (whether in the negative or the positive) to the request within such 45 calendar days shall be deemed to constitute written approval of the waiver by the non-responding Party.

Section 9: Access Rights

9.1 Background

Defined as "data, know-how or information that is needed to implement the action or exploit the results".

9.1.1 The Parties have identified and agreed on the Background for the Project and have also, where relevant, informed each other that Access to specific Background is subject to legal restrictions or limits.

Anything not identified shall not be the object of Access Right obligations regarding Background.

9.1.2 Any Party can propose to the General Assembly to modify its Background.

9.2 General Principles

9.2.1 Each Party shall implement its tasks in accordance with the Consortium Plan and shall bear sole responsibility for ensuring that its acts within the Project do not knowingly infringe third party property rights.

9.2.2 Any Access Rights granted expressly exclude any rights to sublicense unless expressly stated otherwise.

9.2.3 Access Rights shall be free of any administrative transfer costs.

9.2.4 Access Rights are granted on a non-exclusive basis.

9.2.5 Results and Background shall be used only for the purposes for which Access Rights to it have been granted.

9.2.6 All requests for Access Rights shall be made in writing.

The granting of Access Rights may be made conditional on the acceptance of specific conditions aimed at ensuring that these rights will be used only for the intended purpose and that appropriate confidentiality obligations are in place.

9.2.7 The requesting Party must show that the Access Rights are Needed.

9.3 Access Rights for implementation

Access Rights to Results and Background Needed for the performance of the own work of a Party under the Project shall be granted on a royalty-free basis, unless otherwise agreed for Background.

9.4 Access Rights for Exploitation

9.4.1 Access Rights to Results if Needed for Exploitation of a Party's own Results shall be granted on Fair and Reasonable conditions.

Access rights to Results for internal research activities shall be granted on a royalty-free basis.

9.4.2 Access Rights to Background if Needed for Exploitation of a Party's own Results, including for research on behalf of a third party, shall be granted on Fair and Reasonable conditions.

9.4.3 A request for Access Rights may be made up to twelve months after the end of the Project or, in the case of Section 9.7.2.1.2, after the termination of the requesting Party's participation in the Project.

9.5 Access Rights for Affiliated Entities

Access Rights must be requested by the Affiliated Entity from the Party that holds the Background or Results. Alternatively, the Party granting the Access Rights may individually agree with the Party requesting the Access Rights to have the Access Rights include the right to sublicense to the latter's Affiliated Entities. Access Rights to Affiliated Entities shall be granted on Fair and Reasonable conditions and upon written bilateral agreement.

Affiliated Entities which obtain Access Rights in return fulfil all confidentiality and other obligations accepted by the Parties under this Consortium Agreement as if such Affiliated Entities were Parties.

Access Rights may be refused to Affiliated Entities if such granting is contrary to the legitimate interests of the Party which owns the Background or the Results.

Access Rights granted to any Affiliated Entity are subject to the continuation of the Access Rights of the Party to which it is affiliated, and shall automatically terminate upon termination of the Access Rights granted to such Party.

Upon cessation of the status as an Affiliated Entity, any Access Rights granted to such former Affiliated Entity shall lapse.

Further arrangements with Affiliated Entities may be negotiated in separate agreements.

9.6 Additional Access Rights

For the avoidance of doubt any grant of Access Rights not covered by this Consortium Agreement shall be at the absolute discretion of the owning Party and subject to such terms and conditions as may be agreed between the owning and receiving Parties.

9.7 Access Rights for Parties entering or leaving the consortium

9.7.1 New Parties entering the consortium

As regards Results developed before the accession of the new Party, the new Party will be granted Access Rights on the conditions applying for Access Rights to Background.

9.7.2 Parties leaving the consortium

9.7.2.1 Access Rights granted to a leaving Party

9.7.2.1.1 Defaulting Party

Access Rights granted to a Defaulting Party and such Party's right to request Access Rights shall cease immediately upon receipt by the Defaulting Party of the formal notice of the decision of the General Assembly to terminate its participation in the consortium.

9.7.2.1.2 Non-defaulting Party

A non-defaulting Party leaving voluntarily and with the other Parties' consent shall have Access Rights to the Results developed until the date of the termination of its participation. It may request Access Rights within the period of time specified in Section 9.4.3.

9.7.2.2 Access Rights to be granted by any leaving Party

Any Party leaving the Project shall continue to grant Access Rights pursuant to the Consortium Agreement as if it had remained a Party for the whole duration of the Project.

9.8 Specific Provisions for Access Rights to Software

For the avoidance of doubt, the general provisions for Access Rights provided for in this Section 9 are applicable also to Software.

Parties' Access Rights to Software do not include any right to receive source code or object code ported to a certain hardware platform or any right to receive respective Software documentation in any particular form or detail, but only as available from the Party granting the Access Rights.

Section 10: Non-disclosure of information

10.1 All information in whatever form or mode of communication, which is disclosed by a Party (the "Disclosing Party") to any other Party (the "Recipient") in connection with the Project during its implementation and which has been explicitly marked as "confidential" at the time of disclosure, or when disclosed orally has been identified as confidential at the time of disclosure

and has been confirmed and designated in writing within 15 calendar days from oral disclosure at the latest as confidential information by the Disclosing Party, is “Confidential Information”.

10.2 The Recipients hereby undertake in addition and without prejudice to any commitment of non-disclosure, for a period of 4 years after the end of the Consortium Body:

- not to use Confidential Information otherwise than for the purpose for which it was disclosed;
- not to disclose Confidential Information to any third party without the prior written consent by the Disclosing Party;
- to ensure that internal distribution of Confidential Information by a Recipient shall take place on a strict need-to-know basis; and
- to return to the Disclosing Party on demand all Confidential Information which has been supplied to or acquired by the Recipients including all copies thereof and to delete all information stored in a machine readable form. The Recipients may keep a copy to the extent it is required to keep, archive or store such Confidential Information because of compliance with applicable laws and regulations or for the proof of on-going obligations.

10.3 The Recipients shall be responsible for the fulfilment of the above obligations on the part of their employees or third parties involved in the Project and shall ensure that they remain so obliged, as far as legally possible, during and after the end of the Project and/or after the termination of the contractual relationship with the employee or third party.

10.4 The above shall not apply for disclosure or use of Confidential Information, if and in so far as the Recipient can show that:

- the Confidential Information becomes publicly available by means other than a breach of the Recipient’s confidentiality obligations;
- the Disclosing Party subsequently informs the Recipient that the Confidential Information is no longer confidential;
- the Confidential Information is communicated to the Recipient without any obligation of confidence by a third party who is to the best knowledge of the Recipient in lawful possession thereof and under no obligation of confidence to the Disclosing Party;
- the disclosure or communication of the Confidential Information is foreseen by specific provisions;
- the Confidential Information, at any time, was developed by the Recipient completely independently of any such disclosure by the Disclosing Party; or
- the Confidential Information was already known to the Recipient prior to disclosure or
- the Recipient is required to disclose the Confidential Information in order to comply with applicable laws or regulations or with a court or administrative order, subject to the provision Section 10.7 hereunder.

10.5 The Recipient shall apply the same degree of care with regard to the Confidential Information disclosed within the scope of the Project as with its own confidential and/or proprietary information, but in no case less than reasonable care.

10.6 Each Party shall promptly advise the other Party in writing of any unauthorised disclosure, misappropriation or misuse of Confidential Information after it becomes aware of such unauthorised disclosure, misappropriation or misuse.

10.7 If any Party becomes aware that it will be required, or is likely to be required, to disclose Confidential Information in order to comply with applicable laws or regulations or with a court or administrative order, it shall, to the extent it is lawfully able to do so, prior to any such disclosure

- notify the Disclosing Party, and
- comply with the Disclosing Party’s reasonable instructions to protect the confidentiality of the information.

Section 11: Miscellaneous

11.1 Inconsistencies and severability

In case the terms of this Consortium Agreement are in conflict with the terms of a Grant Agreement, the terms of the latter shall prevail.

Should any provision of this Consortium Agreement become invalid, illegal or unenforceable, it shall not affect the validity of the remaining provisions of this Consortium Agreement. In such a case, the Parties concerned shall be entitled to request that a valid and practicable provision be negotiated which fulfils the purpose of the original provision.

11.2 No representation, partnership or agency

Except as otherwise provided in Section 6.4.4, no Party shall be entitled to act or to make legally binding declarations on behalf of any other Party or of the consortium. Nothing in this Consortium Agreement shall be deemed to constitute a joint venture, agency, partnership, interest grouping or any other kind of formal business grouping or entity between the Parties.

11.3 Notices and other communication

Any notice to be given under this Consortium Agreement shall be in writing to the addresses and recipients as listed in the most current address list kept by the Coordinator.

Formal notices:

If it is required in this Consortium Agreement (Sections 4.2, 9.7.2.1.1, and 11.4) that a formal notice, consent or approval shall be given, such notice shall be signed by an authorised representative of a Party and shall either be served personally or sent by mail with recorded delivery or telefax with receipt acknowledgement.

Other communication:

Other communication between the Parties may also be effected by other means such as e-mail with acknowledgement of receipt, which fulfils the conditions of written form.

Any change of persons or contact details shall be notified immediately by the respective Party to the Coordinator. The address list shall be accessible to all concerned.

11.4 Assignment and amendments

Except as set out in Section 8.2, no rights or obligations of the Parties arising from this Consortium Agreement may be assigned or transferred, in whole or in part, to any third party without the other Parties' prior formal approval.

Amendments and modifications to the text of this Consortium Agreement not explicitly listed in Section 6.3.1.2 require a separate written agreement to be signed between all Parties.

11.5 Mandatory national law

Nothing in this Consortium Agreement shall be deemed to require a Party to breach any mandatory statutory law under which the Party is operating.

11.6 Language

This Consortium Agreement is drawn up in English, which language shall govern all documents, notices, meetings, arbitral proceedings and processes relative thereto.

11.7 Applicable law

This Consortium Agreement shall be construed in accordance with and governed by the laws of each Party excluding its conflict of law provisions.

11.8 Settlement of disputes

The parties shall endeavour to settle their disputes amicably.

Nothing in this Consortium Agreement shall limit the Parties' right to seek injunctive relief in any applicable competent court.

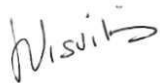
Section 12: Signatures

AS WITNESS:

The Parties have caused this Consortium Agreement to be duly signed by the undersigned Principal Investigators in separate signature pages the day and year first above written.

UMR INSERM U1122; IGE-PCV (Coordinator) Principal Investigator

Signature(s)



Name(s) Sophie VISVIKIS-SIEST
Title(s) Director of Research INSERM, Director of UMR U1122
Date 23/06/2015

Queen Mary University of London (QMU) Principal Investigator

Signature(s)



Name(s) Panos DELOUKAS
Title(s) Professor of Cardiovascular Genomics
Date 04/01/2016
**Boston University (BU)
Principal Investigator**

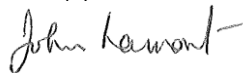


Signature(s)

Name(s) Sudha SESHADRI
Title(s) Professor
Date 02/01/2016

Randox Laboratories Limited
Principal Investigator

Signature(s)



Name(s) John LAMONT
Title(s) Chief Scientist
Date 10/12/2015

Univerza V Ljubljani
Principal Investigator

Signature(s)



Name(s) Janja MARC
Title(s) Professor
Date 10/12/2015

Universita degli studi di Roma (UniRoma1)
Principal Investigator

Signature(s)



Name(s) Maurizio SIMMACO
Title(s) MD, Full Professor of Molecular Biology
Date 22/12/2015

**European Society of Pharmacogenomics and Personalised Therapy (ESPT)
Principal Investigator**

Signature(s)

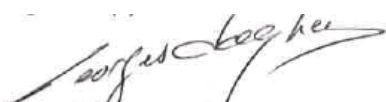


Name(s) Gérard SIEST†
Title(s) President of ESPT
Date 15/12/2015

Name(s) Ron Van Schaik
Title(s) President of ESPT since October 2016
Date

**Biobanking and Biomolecular Resources Research Infrastructure (BBMRI) / INSERM US
13, BIOBANQUES
Principal Investigator**

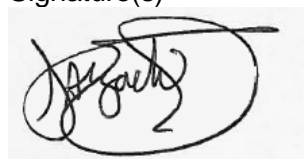
Signature(s)



Name(s) Georges DAGHER
Title(s) Director INSERM US13
Date 21/12/2015

**University Medical Center of Groningen (UMCG)
Principal Investigator**

Signature(s)



Name(s) Behrooz ALIZADEH
Title(s) MD, MSc, PhD
Date 07/01/2016

**Genetics of Complex Traits Laboratory at IGB- National Research Council of Italy (CNR)
Principal Investigator**

Signature(s)



Name(s) Marina CIULLO
Title(s) Ph.D
Date 22/12/2015

**Institut de Cancérologie de Lorraine, Université de Lorraine (ICL)
Principal Investigator**

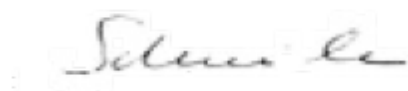
Signature(s)



Name(s) Jean-Louis MERLIN
Title(s) Professor
Date 22/12/2015

**University of Luxembourg, Luxembourg Centre for Systems Biomedicine (ULUX)
Principal Investigator**

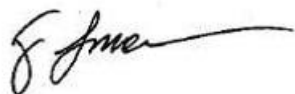
Signature(s)



Name(s) Jochen SCHNEIDER
Title(s) Professor Dr. med.
Date 8.3.2017

University of North Carolina at Chapel Hill, NC, USA
Principal Investigator

Signature(s)

A handwritten signature in black ink, appearing to read 'F. Innocenti', with a long horizontal flourish extending to the right.

Name(s) Federico INNOCENTI
Title(s) Associate Professor
Date February 10, 2016