

## ANNEXII OF MODEL GRANT AGREEMENT OF THE IMI JOINT UNDERTAKING

### II.1. Definitions

1. "*access rights*" means the rights to use;
2. "*affiliated entity*" means any legal entity that is under the direct or indirect control of a *beneficiary*, under the same direct or indirect control as a *beneficiary*, or is directly or indirectly controlling a *beneficiary*, control taking any of the following forms: (a) the direct or indirect holding of more than 50% of the nominal value of the issued share capital in the legal entity concerned, or of a majority of the voting rights of the shareholders or associates of that entity; (b) the direct or indirect holding, in fact or in law, of decision-making powers in the legal entity concerned.
3. "*associated country*" means a *third country* which is party to an international agreement with the *Union*, under the terms or on the basis of which it makes a financial contribution to all or part of the Seventh Framework Programme;
3. "*background*" means information, including data and know-how which is held by a *beneficiary* prior to the accession to this agreement, as well as copyrights or other intellectual and industrial property rights pertaining to such information, and which is necessary for carrying out the project and identified in the *project agreement*;
4. "*confidential information*" means any and all written information communicated between the *beneficiaries* in the framework of the *project* clearly identified or marked as being confidential at the moment of its disclosure, except for the information which the receiving party can prove (a) is, at the time of communication, in the public domain, (b) after the communication, becomes part of the public domain by publication or otherwise, except by breach of this agreement by the receiving party, (c) is obtained from a third party not in breach of any obligation of confidentiality, (d) is known by the receiving party prior the date of the communication, (e) is required to be disclosed by the receiving party pursuant to any applicable law or judicial or governmental order, provided that the receiving party shall give immediate written notice of such requirement to the disclosing party with the view to agreeing the timing and the content of such disclosure. Whenever *confidential information* is communicated orally, its confidential nature shall be confirmed in writing by the disclosing party within thirty (30) days after such disclosure;
5. "*direct exploitation*" means to develop for commercialization or to commercialize *foreground* itself;
6. "*dissemination*" means disclosure by any appropriate means other than that resulting from the formalities for protection, and including the publication in any medium;
7. "*fair and reasonable terms*" means appropriate conditions including financial terms (where appropriate) taking into account the actual or potential value of the *foreground* or *background* to which access is requested and other characteristics of the *research use* envisaged;
8. "*managing entity of the IMI JU funding*" means the *beneficiary* n°2 acting as *managing entity of the IMI JU funding* in accordance to article II.2.3.

9. “*foreground*” means the results, including data, know how and information, whether or not they can be protected, which are generated under the project and excluding *sideground*. Such results include rights related to copyright; design rights; patent rights; or similar forms of protection;

10. “*irregularity*” means any infringement of a provision of *European Community* and *European Union* law or any breach of obligation resulting from an act or omission by a *beneficiary* which has, or would have, the effect of prejudicing the budget of the *IMI JU* or of the *European Union* through unjustified expenditure;

11. “*project*” means the research activities carried out by the *beneficiaries* as defined in Annex I of this agreement;

12. “*project agreement*” means the agreement between the *beneficiaries* for the implementation of the *project*. The *project agreement* shall be consistent with this *grant agreement*; In case of contradiction between the *project agreement* and the *grant agreement*, the *grant agreement* provisions shall prevail.

13. “*project objectives*” means the objectives which are defined in the Annex I. The *project objectives* shall not include direct development and/or commercialization of marketable pharmaceutical or diagnostic products;

14. “*non-profit public body*” means any legal entity established as such by national law. This term includes also those entities that may make profit but are not permitted to distribute such profits otherwise than in the furtherance of public interest purposes and which carry out scientific and technological research among their main activities;

15. “*research organisation*” means a legal entity established as *non-profit* organisations which carry out research or technological development as one of its main objectives;

16. “*SMEs*” mean micro, small and medium-sized enterprises within the meaning of Recommendation 2003/361/EC in the version of 6 May 2003;

17. “*third country*” means a State that is not a Member State;

18. “*third party*” means any legal entity which is not a *beneficiary*;

19. “*research use*” means the use of *foreground* or *background* necessary to use *foreground* for all purposes other than for completing the project or for *direct exploitation*;

20. “*sideground*” means the results, including data, know how and information, whether or not they can be protected, which are generated by a *beneficiary* under the *project* but outside of the *project objectives* and which are not needed for undertaking and completing the *project* or the *research use* of *foreground*.

21. “*non-profit qualified patient organisation*” means a non-profit organisation representing the interests of certain patient groups and which complies with the guiding principles with regards to transparency established by the European Union Health Policy Forum: ([http://ec.europa.eu/health/ph\\_overview/health\\_forum/policy\\_forum\\_en.htm](http://ec.europa.eu/health/ph_overview/health_forum/policy_forum_en.htm))

## **Part A IMPLEMENTATION OF THE PROJECT**

### **SECTION 1 – GENERAL PRINCIPLES**

#### **II.2. Organisation of the consortium and respective roles of coordinator and of managing entity of the IMI JU funding**

1. All the *beneficiaries* together form the *consortium*. *Beneficiaries* are represented towards the *IMI JU* by the *coordinator*, who shall be the intermediary for any communication between the *IMI JU* and any *beneficiary*, with the exceptions foreseen in this grant agreement.
2. The *IMI JU financial contribution* to the *project* shall be paid to the *managing entity of the IMI JU funding* who receives it on behalf of the *beneficiaries* eligible to receive *IMI JU* funding. The payment of the *IMI JU financial contribution* to the *managing entity of the IMI JU funding* discharges the *IMI JU* from its obligation on payments.
3. The *coordinator* shall:
  - a) instruct the *managing entity of the IMI JU funding* to administer the *IMI JU financial contribution* regarding its allocation and distribution between *beneficiaries* eligible to receive *IMI JU* funding and activities, in accordance with this *grant agreement* and the decisions taken by the *consortium*;
  - b) review the reports to verify consistency with the *project* tasks before transmitting them to the *IMI JU*;
  - c) monitor the compliance by *beneficiaries* with their obligations under this *grant agreement*.

The *managing entity of the IMI JU funding* shall:

- a) keep the records and financial accounts making it possible to determine at any time what portion of the *IMI JU financial contribution* has been paid to each *beneficiary* eligible to receive *IMI JU* funding for the purposes of the *project*,
- b) inform the *coordinator* and the *IMI JU* of the distribution of the *IMI JU* financial contribution and the date of transfers to the *beneficiaries* eligible to receive *IMI JU* funding, when required by this *grant agreement* or by the *IMI JU* or by the *coordinator*;
- c) ensure that all the appropriate payments are made to the *beneficiaries* eligible to receive *IMI JU* without unjustified delay;

Neither the *coordinator* nor the *managing entity of the IMI JU funding* may subcontract the above-mentioned tasks.

4. *Beneficiaries* shall fulfil the following obligations as a *consortium*:

- a) provide all detailed data requested by the *IMI JU* for the purposes of the proper administration of this *project*;
- b) carry out the *project* jointly and severally vis-à-vis the *IMI JU*, taking all necessary and reasonable measures to ensure that the *project* is carried out in accordance with the terms and conditions of this *grant agreement*.

c) make appropriate internal arrangements consistent with the provisions of this *grant agreement* to ensure the efficient implementation of the *project*. These internal arrangements shall take the form of a written *project agreement* (the "*project agreement*"). The *project agreement* governs *inter alia* the following:

i. the internal organisation of the *consortium* including the decision making procedures;

ii. rules on dissemination and use, and access rights;

iii. the distribution of the *IMI JU financial contribution*;

iv. the settlement of internal disputes, including cases of abuse of power;

v. liability, indemnification and confidentiality arrangements between the *beneficiaries*.

d) engage, whenever appropriate, with actors beyond the research community and with the public in order to foster dialogue and debate on the research agenda, on research results and on related scientific issues with policy makers and civil society; create synergies with education at all levels and conduct activities promoting the socioeconomic impact of the research.

e) allow the *IMI JU* to take part in meetings concerning the *project*.

### **II.3. Specific performance obligations of each *beneficiary***

Each *beneficiary* shall:

a) carry out the work to be performed, as identified in Annex I. However, where it is necessary for the implementation of the *project* it may call upon third parties to carry out certain elements, according to the conditions established in Article II.7 or any special clause in Article 7. The *beneficiary* may use resources that are made available by third parties in order to carry out its part of the work;

b) ensure that any agreement or contract related to the project, entered into between the *beneficiary* and any third party contain provisions that this third party, including the auditor providing the certificate on the financial statements, shall have no rights vis-à-vis the *IMI JU* under this *grant agreement*;

c) ensure that the rights of the *IMI JU* to carry out financial audits and on-the-spot checks, as well as the right of the *Commission* and the Court of Auditors to carry out on-the-spot-checks among the *beneficiaries* eligible to receive *IMI JU* funding, are extended to the right to carry out any such audit or on-the-spot check on any third party whose costs are reimbursed in full or in part by the *IMI JU financial contribution*, on the same terms and conditions as those indicated in this *grant agreement*;

d) ensure that the conditions applicable to it under Articles II.4.4, II.10, II.11, II.12, II.13 and II.21 are also applicable to any third party whose costs are claimed under the *project* according to the provisions of this *grant agreement*;

e) ensure that the tasks assigned to it are correctly and timely performed;

f) inform the other *beneficiaries* and the *IMI JU* through the *coordinator* in due time of:

the names of the person(s) who shall manage and monitor its work, and its contact details as well as any changes to that information;

- any event which might affect the implementation of the *project* and the rights of the *IMI JU*;
  - any change in its legal name, address and of its legal representatives, and any change with regard to its legal, financial, organisational or technical situation including change of control and, in particular, any change of status as regards *non-profit public bodies*, secondary and higher education establishments, *research organisations*, non-profit qualified patients organisations and *SMEs*;
  - any circumstance affecting the conditions of participation in the *IMI Regulation*, the *IMI Financial Rules* or of any requirements of the *grant agreement*, especially if and when any eligibility criteria cease(s) to be met during the duration of the *project*.
- g) provide the *IMI JU* (for all *beneficiaries*) and the *Commission* including the European Anti-Fraud Office (OLAF) and Court of Auditors (only for the *beneficiaries* eligible to receive *IMI JU* funding) directly with all information requested in the framework of on the spot check and audits;
- h) take part in meetings concerning the supervision, monitoring and evaluation of the *project* which are relevant to it;
- i) take all necessary steps to avoid commitments that are incompatible with the obligations provided for in this *grant agreement* and inform the other *beneficiaries* and the *IMI JU* of any unavoidable obligations which may arise during the duration of the *grant agreement* which may have implications for any of its obligations under the *grant agreement*;
- j) ensure that it complies with the provisions of the state aid framework;
- k) carry out the *project* in accordance with fundamental ethical principles;
- l) endeavour to promote equal opportunities between men and women in the implementation of the *project*;
- m) have regard to the general principles of the Commission Recommendation of 11 March 2005 on the European Charter for Researchers and the Code of Conduct for the Recruitment of Researchers, in particular concerning the working conditions, transparency of recruitment processes, and career development of the researchers recruited for the *project*;
- n) take every necessary precaution to avoid any risk of conflict of interest relating to economic interests, political or national affinities, family or emotional ties or any other interests liable to influence the impartial and objective performance of the *project*.

## **SECTION 2 – REPORTING AND PAYMENTS**

### **II.4. Reports and deliverables**

1. The *coordinator* shall submit a **periodic report** to the *IMI JU* for each reporting period within 60 days after the end of each respective period. The reporting shall comprise:

- a) an overview, including a publishable summary, of the progress of work towards the objectives of the *project*, including achievements and attainment of any milestones and deliverables identified in Annex I. This report should include the differences between work expected to be carried out in accordance with Annex I and that actually carried out,

- b) an explanation of the use of the resources, and
- c) a financial statement (including a Form C) from each *beneficiary*, together with a certificate on this financial statement when required in paragraph 4,
- d) a summary financial report, jointly prepared by the *managing entity of the IMI JU funding* and the *coordinator*, consolidating the claimed *IMI JU* contribution of all the *beneficiaries* eligible to receive *IMI JU* funding in an aggregate form, based on the information provided in Form C by each *beneficiary* eligible to receive *IMI JU* funding,
- e) a summary financial report, prepared by the *coordinator*, based on the information provided in Form C by each beneficiary, consolidating the project costs incurred by all beneficiaries not eligible to receive *IMI JU* funding, which meet the conditions established in article II.13.1 and exclude costs set in paragraph (a) to (g) of article II.13.3, to which are added the financial contributions made by *beneficiaries* not eligible to receive *IMI JU* funding to *beneficiaries* eligible to receive *IMI JU* funding in order to reimburse part of their eligible costs. This, in an aggregate form, constitutes the overall in-kind contribution of all *beneficiaries* not eligible to receive *IMI JU* funding..

2. The *coordinator* shall submit a **final report** to the *IMI JU* within 60 days after the end of the *project*. The report shall comprise:

- a) a final publishable summary report covering results, conclusions and socioeconomic impact of the *project*,
- b) a report covering the plan for research use by beneficiaries and dissemination of foreground as well as the wider societal implications of the *project*, including where appropriate gender equality actions, ethical issues, efforts to involve other actors and spread awareness.

3. The *managing entity of the IMI JU funding* shall submit a report on the distribution of the *IMI JU* financial contribution between *beneficiaries* eligible to receive *IMI JU* funding. This report must be submitted 30 days after receipt of the final payment.

4. A **certificate on the financial statements** shall be submitted by each *beneficiary* at least every two reporting periods or when the amount of costs claimed is equal to or superior to EUR 200 000, when cumulated with all previous cost statements for which a certificate on the financial statements has not been submitted and in any case at the end of the *project* for any amount not previously certified. This certificate must be forwarded in the form of a detailed description verified as factual by its external auditor (Form D – Annex VI).

Certificates on the financial statements shall certify that the costs claimed and the receipts declared during the period for which they are provided (as well as the declaration of the interest yielded by the pre-financing) meet the conditions required by this *grant agreement*.

Where third parties' costs are claimed under the *grant agreement*, such costs shall be certified in accordance with the provisions of this Article. The auditor shall include in its certificate that no conflict of interest exists between itself and the *beneficiary* in establishing this certificate.

Certificates on the financial statements shall be prepared and certified by an external auditor and shall be established in accordance with the terms of reference attached as annex VI to this *grant agreement*. Each *beneficiary* is free to choose any qualified external

auditor, including its usual external auditor, provided that the cumulative following requirements are met:

- i) the auditor must be independent from the *beneficiary*;
- ii) the auditor must be qualified to carry out statutory audits of accounting documents in accordance with national legislation implementing the Council Directive on statutory audits of annual accounts and consolidated accounts<sup>1</sup> or any *European Community* or *European Union* legislation replacing this Directive. *Beneficiaries* established in *third countries* shall comply with national regulations in the same field and the certificate on the financial statement provided shall consist of an independent report of factual findings based on procedures specified by the *IMI JU*.

*Public bodies*, secondary and higher education establishments, intergovernmental organisations, legal entities established under European Community or European Union law, *research organisations* and non profit qualified patient organisations may opt for a competent public officer to provide their certificate on the financial statements, provided that the relevant public authorities have established the legal capacity of that competent public officer to audit that entity and that the independence of that officer, in particular regarding the preparation of the financial statements, can be ensured.

Certificates by external auditors according to this Article do not affect the liability of *beneficiaries* nor the rights of the *IMI JU* arising from this *grant agreement*.

5. The *consortium* shall transmit the reports and other deliverables through the *coordinator* to the *IMI JU* by electronic means. In addition, Form C must be signed by the authorised person(s) within the *beneficiary's* organisation, and the certificates on the financial statements must be signed by an authorised person of the auditing entity, and the originals shall be sent to the *IMI JU*.

6. The layout and content of the reports shall conform to the instructions and guidance notes established by the *IMI JU*.

7. The reports submitted to the *IMI JU* for publication should be of a suitable quality to enable direct publication and their submission to the *IMI JU* in publishable form indicates that no confidential material is included therein.

8. Deliverables identified in Annex I shall be submitted as foreseen therein.

9. The *IMI JU* may be assisted by external experts, submitted to confidentiality obligations, in the analysis and evaluation of the reports and deliverables.

## **II.5. Approval of reports and deliverables, time-limit for Payments**

1. At the end of each reporting period, the *IMI JU* shall evaluate project reports and deliverables required by the provisions of Annex I and disburse the corresponding payments within 105 days of their receipt unless the time-limit, the payment or the project has been suspended.

---

<sup>1</sup> Directive 2006/43/EC of the European Parliament and of the Council of 17 May 2006 on statutory audits of annual accounts and consolidated accounts, amending Council Directives 78/660/EEC and 83/349/EEC and repealing Council Directive 84/253/EEC

2. Payments shall be made after the *IMI JU's* approval of reports and/or deliverables. The absence of a response from the *IMI JU* within this time-limit shall not imply its approval. However, the *IMI JU* should send a written reply to the *consortium* in accordance with paragraph 3. The *IMI JU* may reject reports and deliverables even after the time-limit for payment. Approval of the reports shall not imply recognition of their regularity or of the authenticity of the declarations and information they contain and do not imply exemption from any audit or review.

3. After reception of the reports the *IMI JU* may:

a) approve the reports and deliverables, in whole or in part or make the approval subject to certain conditions.

b) reject the reports and deliverables by giving an appropriate justification and, if appropriate, start the procedure for termination of the *grant agreement* in whole or in part.

c) suspend the time limit if one or more of the reports or appropriate deliverables have not been supplied, or are not complete or if some clarification or additional information is needed or there are doubts concerning the eligibility of costs claimed in the financial statement and/or additional checks are being conducted. The suspension will be lifted from the date when the last report, deliverable or the additional information requested is received by the *IMI JU*, or where the *IMI JU* decides to proceed with an interim payment in part in accordance with paragraph 4. The *IMI JU* shall inform the *consortium* in writing via the *coordinator* of any such suspension and the conditions to be met for the lifting of the suspension. Suspension shall take effect on the date when notice is sent by the *IMI JU*.

d) suspend the payment at any time, in whole or in part for the amount intended for the *beneficiary(ies)* concerned:

- if the work carried out does not comply with the provisions of the *grant agreement*;
- if a *beneficiary* eligible to receive *IMI JU* funding has to reimburse to its national state an amount unduly received as state aid;
- if the provisions of the *grant agreement* have been infringed or if there is a suspicion or presumption thereof, in particular in the wake of any audits and checks provided for in Articles II.21 and II.22.;
- if there is a suspicion of *irregularity* committed by one or more *beneficiary(ies)* eligible to receive *IMI JU* funding in the performance of the *grant agreement*;
- if there is a suspected or established *irregularity* committed by one or more *beneficiary(ies)* eligible to receive *IMI JU* funding in the performance of another *grant agreement* funded by the *IMI JU* budget, the general budget of the European Union or by budgets managed by them. In such cases, suspension of the payments will occur where the *irregularity* (or suspected *irregularity*) is of a serious and systematic nature which is likely to affect the performance of the current *grant agreement*.

When the *IMI JU* suspends the payment the *consortium* shall be duly informed of the reasons why payment in whole or in part will not be made.

4. The *IMI JU* may proceed with an interim payment in part if some reports or deliverables are not submitted as required, or only partially or conditionally approved. The reports and deliverables due for one reporting period which are submitted late will be evaluated together with the reports and deliverables of the next reporting period.



5. On expiry of the time-limit for approval of the reports and payments, and without prejudice to suspension by the *IMI JU* of this time-limit, the *IMI JU* shall pay interest on the late payment, according to the conditions foreseen in the *Financial Rules*, at the rate applied by the European Central Bank for its main refinancing operations in euros, plus three and a half points. The reference rate to which the increase applies shall be the rate in force on the first day of the month of the final date for payment, as published in the C series of the Official Journal of the European Union.

This provision shall not apply to *beneficiaries* that are *public bodies* of the Member States of the European Union. Interest on late payment shall cover the period from the final date of the period for payment, exclusive, up to the date when the payment is debited to the *IMI JU's* account, inclusive. The interest shall not be treated as a *receipt* for the *project* for the purposes of determining the final grant. Any such interest payment is not considered as part of the *IMI JU* financial contribution.

6. The suspension of the time-limit, of payment or of the project by the *IMI JU* may not be considered as late payment.

7. At the end of the *project*, the *IMI JU* may decide not to make the payment of the corresponding *IMI JU financial contribution* subject to one month's written notice of non-receipt of a report, of a certificate on the financial statements or of any other *project* deliverable.

8. The *IMI JU* shall inform the *coordinator* of the amount of the final payment of the *IMI JU financial contribution* and shall justify this amount. The *coordinator* shall have two months from the date of receipt to give reasons for any disagreement. After the end of this period such requests will no longer be considered and the consortium is deemed to have accepted the *IMI JU's* decision. The *IMI JU* undertakes to reply in writing within two months following the date of receipt, giving reasons for its reply. This procedure is without prejudice to the beneficiary's right to appeal against the *IMI JU's* decision.

## **II.6. Payment modalities and cost reporting**

1. The *IMI JU* shall make the following payments:

- a) a pre-financing in accordance with Article 6,
- b) for *projects* with more than one reporting period, the *IMI JU* shall make interim payments of the *IMI JU financial contribution* corresponding to the amount accepted for each reporting period.
- c) the *IMI JU* shall make a final payment of the *IMI JU financial contribution* corresponding to the amount accepted for the last reporting period plus any adjustment needed.

Where the amount of the corresponding *IMI JU financial contribution* is less than any amount already paid to the *consortium*, the *IMI JU* shall recover the difference.

Where the amount of the corresponding *IMI JU financial contribution* is more than any amount already paid to the *consortium*, the *IMI JU* shall pay the difference as the final payment within the limit of Articles 5.1

In accordance with the *IMI JU financial rules*, the pre-financing may be subject to a verification of the financial capacity of the *managing entity of the IMI JU funding* and/or

of *beneficiaries* eligible to receive *IMI JU* funding as well as to the taking of any required protective measures, including the submission of guarantees.

2. The total amount of the pre-financing and interim payments shall not exceed 90% of the maximum *IMI JU financial contribution* defined in Article 5.

3. Payments by the *IMI JU* shall be made in Euro.

4. Costs shall be reported in Euro. *Beneficiaries* with accounts in currencies other than the Euro shall report costs by using, either the conversion rate published by the European Central Bank that would have applied on the date that the actual costs were incurred, or its rate applicable on the first day of the month following the end of the reporting period. *Beneficiaries* with accounts in Euro shall convert costs incurred in other currencies according to their usual accounting practice.

5. The bank account mentioned in Article 5.3 shall allow that the *IMI JU* financial contribution and related interest are identified. Otherwise, the accounting methods of the beneficiaries or intermediaries must make it possible to identify the *IMI JU* financial contribution and the interest or other benefits yielded.

6. Any payment may be subject to an audit or review and may be adjusted or recovered based on the results of such audit or review.

7. Payments by the *IMI JU* shall be deemed to be effected on the date when they are debited to the *IMI JU's* account.

## **SECTION 3 – IMPLEMENTATION**

### **II.7. Subcontracting**

1. A *subcontractor* is a third party which has entered into an agreement on business conditions with one or more *beneficiaries*, in order to carry out part of the work of the *project* without the direct supervision of the *beneficiary* and without a relationship of subordination.

Where the *beneficiary* enters into a subcontract to carry out some parts of the tasks related to the *project*, it remains bound by its obligations to the *IMI JU* and the other *beneficiaries* under the *grant agreement* and retains sole responsibility for carrying out the *project* and for compliance with the provisions of the *grant agreement*.

Provisions of this *grant agreement* applying to *subcontractors* shall also apply to external auditors who certify financial statements.

2. Where it is necessary for the *beneficiaries* to subcontract certain elements of the work to be carried out, the following conditions must be fulfilled:

- subcontracts may only cover the execution of a limited part of the *project* such as services for data processing for example. Such services may only be subcontracted if it is a more efficient means for that participant to deliver the required service.
- subcontracted work must be conducted in European Member States or countries associated to the 7<sup>th</sup> Framework Programme. Exceptions may only be accepted on a case-by-case basis, based on scientific or technical justification.

- recourse to the award of subcontracts must be duly justified in Annex I having regard to the nature of the *project* and what is necessary for its implementation;
- recourse to the award of subcontracts by a *beneficiary* may not affect the rights and obligations of the *beneficiaries* regarding *background* and *foreground*;
- Annex I must indicate the tasks to be subcontracted and an estimation of the costs; However, if a need for additional subcontracting is identified during the course of a *project*, Annex I will be updated accordingly through an amendment to the Grant Agreement following approval of the IMI JU and the tasks will be subcontracted in accordance with the conditions mentioned above and following agreement among the *beneficiaries* on condition that this does not increase the project costs.

Any subcontract, the costs of which are to be claimed as an eligible cost, must be awarded according to the principles of best value for money (best price-quality ratio), transparency and equal treatment. Subcontracts concluded on the basis of framework contracts entered into between a *beneficiary* and a *subcontractor*, prior to the beginning of the *project* in accordance with the *beneficiary's* usual management principles may also be accepted.

3. *Beneficiaries* may use external support services for assistance with minor tasks that do not represent per se *project* tasks as identified in Annex I.

## **II.8. Suspension of the *project***

1. The *coordinator* shall immediately inform the *IMI JU* of any event affecting or delaying the implementation of the *project*.

2. The *coordinator* can propose to suspend the whole or part of the *project* if *force majeure* or exceptional circumstances render its execution excessively difficult or uneconomic. The *coordinator* must inform the *IMI JU* without delay of such circumstances, including full justification and information related to the event, as well as an estimation of the date when the work on the *project* will begin again.

3. After having given the consortium through the coordinator a delay to make observations, the *IMI JU* may suspend the whole or part of the *project* where it considers that the *consortium* is not fulfilling its obligations according to this *grant agreement*. The *coordinator* shall be informed without delay of the justification for such an event and the conditions necessary to reinstate the work again. The *coordinator* shall inform the other *beneficiaries*. This suspension takes effect 10 days after the receipt of the notification by the *coordinator*.

4. During the period of suspension, no costs may be charged to the *project* for carrying out any part of the project that has been suspended.

5. The suspension of the whole or part of the *project* may be lifted once the parties to the *grant agreement* have agreed on the continuation of the project and, as appropriate, any necessary modification, including extension of the duration of the *project*, has been identified by means of a written amendment.

## **II.9. Confidentiality**

1. During the *project* and for a period of five years after its completion or any other period thereafter as established in the *project agreement*, the *beneficiaries* undertake to preserve the confidentiality of *confidential information*. The *IMI JU* undertakes to preserve the

confidentiality of *confidential information* until five years after the completion of the *project*. Upon a duly substantiated request by a *beneficiary*, the *IMI JU* may agree to extend this period regarding specific *confidential information*.

2. The *beneficiaries* undertake to use such *confidential information* only in relation to the execution of the *project* unless otherwise agreed with the disclosing party.

3. Notwithstanding the preceding paragraphs, the treatment of data, documents or other material which are classified (“*classified information*”) or subject to security restrictions or export- or transfer- control, must follow the applicable rules established by the relevant national and *European Community* or *European Union* legislation for such information, including the *Commission's* internal rules for handling *classified information*<sup>2</sup>. Where a *beneficiary* is established in a *third country*, any security agreements between that *third country* and the *Union* shall also apply.

## **II.10. Communication of data for evaluation, impact assessment and standardisation purposes**

1. *Beneficiaries* shall provide, at the request of the *IMI JU*, the data necessary for:
- the review of the specific *IMI JU* programme and the Seventh Framework Programme;
  - the evaluation and impact assessment of *IMI JU* activities, including the *research use* and *dissemination of foreground*.

Such data may be requested throughout the duration of the *project* and up to five years after the end of the *project*. The data collected may be used by the *IMI JU* in its own evaluations but will not be published other than on an anonymous basis.

2. Without prejudice to the provisions regarding protection of *foreground* and confidentiality, the *beneficiaries* shall, where appropriate, during the *project* and for two years following its end, inform the *IMI JU* and the European standardisation bodies about *foreground* which may contribute to the preparation of European or international standards.

## **II.11. Information and communication**

1. The *beneficiaries* shall, throughout the duration of the *project*, use their reasonable efforts to engage with the public and the media about the *project* and to highlight the Union (*IMI JU*) financial support. Unless the *IMI JU* requests otherwise, any publicity, including at a conference or seminar or any type of information or promotional material (brochure, leaflet, poster, presentation etc), must specify that the *project* has received Union (*IMI JU*) research funding and display the *IMI JU* logo and the European emblem. This obligation to use the *IMI JU* logo and the European emblem in respect of *projects* to which the European Union (*IMI JU*) contributes implies no right of exclusive use. It is subject to general third-party use restrictions which do not permit the appropriation of the European emblem or the logo, or of any similar trademark or logo, whether by registration or by any other means. Under these conditions, *beneficiaries* are exempted from the obligation to obtain prior permission from the *Commission* and the *IMI JU* to use the logo and the European emblem. Further detailed information on the EU emblem can be found on the Europa web page. Any publicity made by the *beneficiaries* in respect of the *project*, in whatever form and on or by whatever medium, must specify that it reflects only the author's views and that neither the

---

<sup>2</sup> Commission Decision 2001/844/EC, ECSC, Euratom of 29 November 2001 OJ L 317, 3.12.2001, p. 1 (as last amended by Decision 2006/548/EC, Euratom, OJ L 215, 5.8.2006, p. 38)

*IMI JU* nor the *Commission* is liable for any use that may be made of the information contained therein

2. The *IMI JU* and/or the *Commission* shall be authorised to publish, in whatever form and on or by whatever medium, the following information:

- the name of the *beneficiaries*;
- contact addresses of *beneficiaries*;
- the general purpose of the *project* in the form of a non confidential summary provided by the *consortium*;
- the amount and rate of the *IMI JU financial contribution* granted to the *project*;
- the estimated amount and rate of the *IMI JU financial contribution* foreseen for each *beneficiary* eligible to receive *IMI JU* funding in the table of the estimated breakdown of costs in Annex I; and after the final payment, the amount and rate of the *IMI JU financial contribution* accepted by the *IMI JU* for each *beneficiary* eligible to receive *IMI JU* funding.
- the geographic location of the activities carried out;
- the list of *dissemination* activities and/or of patent (applications) relating to *foreground*;
- the details/references and the abstracts of scientific publications relating to *foreground* and the published version or the final manuscript accepted for publication;
- the publishable reports submitted to it;
- any picture or any audiovisual or web material provided to the *IMI JU* in the framework of the *project*.

The *consortium* shall ensure that all necessary authorisations for such publication have been obtained and that the publication of the information by the *IMI JU* and/or the *Commission* does not infringe any rights of third parties.

Upon a duly substantiated request by a *beneficiary*, the *IMI JU* and/or the *Commission* may agree to forego such publicity if disclosure of the information indicated above would risk compromising the *beneficiary's* security, academic or commercial interests.

## **II.12. Processing of personal data**

1. All personal data contained in the *grant agreement* shall be processed in accordance with Regulation (EC) No 45/2001 of the European Parliament and of the Council on the protection of individuals with regard to the processing of personal data by the *Community* institutions and bodies and on the free movement of such data. Such data shall be processed by the *IMI JU* solely in connection with the implementation and follow-up of the *grant agreement* and the evaluation and impact assessment of *Union* and *IMI JU's* activities, including the *research use* and *dissemination* of *foreground*, without prejudice to the possibility of passing the data to the bodies in charge of a monitoring or inspection task in accordance with *European Community* and *European Union* legislation and this *grant agreement*.

2. *Beneficiaries* may, on written request, gain access to their personal data and correct any information that is inaccurate or incomplete. They should address any questions regarding the processing of their personal data to the *IMI JU*. *Beneficiaries* may lodge a complaint against the processing of their personal data with the European Data Protection Supervisor at any time.

3. For the purposes of this *grant agreement*, the Controller identified in Article 8.4 shall be the contact person for the *IMI JU*

## **Part B FINANCIAL PROVISIONS**

### ***SECTION 1 – GENERAL FINANCIAL PROVISIONS***

#### **II.13. Eligible costs of the *project***

1. Costs incurred for the implementation of the *project* shall meet the following conditions in order to be considered eligible:

- a) they must be actual;
- b) they must be incurred by the *beneficiary* who is claiming them;
- c) they must be incurred during the duration of the *project*, with the exception of costs incurred in relation to final reports and reports corresponding to the last period as well as certificates on the financial statements and final reviews if applicable, which may be incurred during the period of up to 60 days after the end of the *project* or the date of termination whichever is earlier;
- d) they must be determined in accordance with the usual accounting and management principles and practices of the *beneficiary*. The accounting procedures used in the recording of costs and *receipts* shall respect the accounting rules of the State in which the *beneficiary* is established. The beneficiary's internal accounting and auditing procedures must permit direct reconciliation of the costs and receipts declared in respect of the *project* with the corresponding financial statements and supporting documents;
- e) they must be used for the sole purpose of achieving the objectives of the *project* and its expected results, in a manner consistent with the principles of economy, efficiency and effectiveness;
- f) they must be recorded in the accounts of the *beneficiary* who is claiming them; in the case of any contribution from third parties, they must be recorded in the accounts of the third parties;
- g) they must be incurred for prospective research conducted in a Member State or country associated to the FP7;
- h) they must be indicated in the estimated overall budget in Annex I.

2. Costs incurred by third parties in relation to resources they make available free of charge to a *beneficiary*, can be declared by the *beneficiary* provided they meet the conditions established in paragraphs 1 and 3, *mutatis mutandis* and are claimed in conformity with Article II.16

3. The following costs shall be considered as non-eligible and may not be charged to the *project*:

- a) identifiable indirect taxes including value added tax,
- b) duties,
- c) interest owed,
- d) provisions for possible future losses or charges,
- e) exchange losses, cost related to return on capital,

- f) costs declared or incurred, or reimbursed in respect of another *Union* or Euratom *project*,
- g) debt and debt service charges, excessive or reckless expenditure.

## II.14. Identification of direct and indirect costs

1. Direct costs are all those eligible costs which can be attributed directly to the *project* and are identified by the *beneficiary* as such, in accordance with its accounting principles and its usual internal rules.

With regard to personnel costs, only the costs of the actual hours worked by the persons directly carrying out work under *the project* may be charged. Such persons must:

- be directly hired by the *beneficiary* in accordance with its national legislation,
- work under the sole technical supervision and responsibility of the latter, and
- be remunerated in accordance with the normal practices of the *beneficiary*.

Costs related to parental leave for persons who are directly carrying out the *project* are eligible costs, in proportion to the time dedicated to the *project*, provided that they are mandatory under national law

2. Indirect costs are all those eligible costs which cannot be identified by the *beneficiary* as being directly attributed to the *project* but which can be identified and justified by its accounting system as being incurred in direct relationship with the eligible direct costs attributed to the *project*. They may not include any eligible direct costs.

By way of derogation to article II.13, indirect costs shall be identified by a flat rate of 20% of the *beneficiary's* total direct eligible costs, excluding its direct eligible costs for subcontracting and the costs of resources made available by third parties which are not used on the premises of the *beneficiary*.

## II.15. Upper funding limits

1. For **research and technological development activities**, the *IMI JU* financial contribution may reach a maximum of 75% of the total eligible costs for the *beneficiaries* eligible to receive *IMI JU* funding.

If a *beneficiary* loses its status as an entity eligible to receive *IMI JU* funding during the life of the *project*, the reimbursement rate shall be applicable up to the moment it loses its status and no further funding shall be paid for the work to be performed from that moment on.

2. For **other activities** not covered by paragraph 1, *inter alia*, management and training, the *IMI JU* financial contribution may reach a maximum of 100% of the total eligible costs for the *beneficiaries* eligible to receive *IMI* funding.

Paragraphs 1 to 2 shall apply also in the case of *projects* where flat rate financing or lump sum financing is used for the whole or for part of the *project*.

3. **Management** of the *consortium* activities includes:

- maintenance of the *project agreement*,
- the overall legal, ethical, financial and administrative management including, for each of the *beneficiaries* eligible to receive *IMI JU* funding, the obtaining of the certificates on the financial statements and costs relating to financial audits and technical reviews,
- any other management activities foreseen by the annexes, except coordination of research and technological development activities

4. For **training activities**, the salary costs of those being trained are not eligible costs under this activity.

## **II.16. Receipts of the *project***

*Receipts* of the *project* may arise from:

- a) Resources made available by third parties to the *beneficiary* by means of financial transfers or contributions in kind which are free of charge:
  - i. shall be considered a *receipt* of the *project* if they have been contributed by the third party specifically to be used on the *project*;
  - ii. shall not be considered a *receipt* of the *project* if their use is at the discretion of the *beneficiary's* management.
- b) Income generated by the *project*:
  - i. shall be considered a *receipt* for the *beneficiary* when generated by actions undertaken in carrying out the *project* and from the sale of assets purchased under the *grant agreement* up to the value of the cost initially charged to the *project* by the *beneficiary*;
  - ii. shall not be considered a *receipt* for the *beneficiary* when generated from the *research use* or *direct exploitation* of *foreground* resulting from the *project*.
- c) Financial contributions made by *beneficiaries* not eligible to receive *IMI JU* funding to the *beneficiaries* eligible to receive *IMI JU* funding in accordance to article II.4.1 (e).

## **II.17. IMI JU financial contribution**

1. The "*IMI JU financial contribution*" to the *project* shall be determined by applying the upper funding limits indicated in Article II.15, per activity and per *beneficiary* eligible to receive *IMI JU* funding to the actual eligible costs and/or to the flat rates and/or lump sums accepted by the *IMI JU*.

2. The *IMI JU financial contribution* shall be calculated by reference to the cost of the project as a whole and its reimbursement shall be based on the accepted costs of each *beneficiary* eligible to receive *IMI JU* funding.

3. The *IMI JU* financial contribution cannot give rise to any profit for any *beneficiary*. For this purpose, at the time of the submission of the last financial statement, the final amount of the *IMI JU* financial contribution will take into account any receipts of the project received by each *beneficiary* eligible to receive *IMI JU* funding. For each *beneficiary* eligible to receive *IMI JU* funding, the *IMI JU* financial contribution cannot exceed the eligible costs minus the receipts for the project.

4. The total amount of payments by the *IMI JU* shall not exceed in any circumstances the maximum amount of the *IMI JU* financial contribution referred to in Article 5.

5. Without prejudice to the right to terminate the *grant agreement* under Article II.37, and without prejudice to the right of the *IMI JU* to apply the penalties referred to in Articles II.23 and II.24 if the *project* is not implemented or is implemented poorly, partially or late, the *IMI JU* may reduce the grant initially provided for in line with the actual implementation of the *project* on the terms laid down in this *grant agreement*



## **II.18. Interest yielded by pre-financing provided by the IMI JU**

1. *Pre-financing* remains the property of the *IMI JU* until the final payment
2. The *IMI JU* shall recover from the *managing entity of the IMI JU funding*, for each reporting period following the implementation of the agreement, the amount of interest generated when such pre-financing exceeds the amount fixed in the *Financial Rules*

## **SECTION 2 – FINANCIAL RESPONSIBILITY AND RECOVERIES**

### **II.19 Financial responsibility**

The financial responsibility of each *beneficiary* shall be limited to its own debt.

### **II.20 Reimbursement and recovery**

1. If any amount is unduly paid to a *beneficiary* or if recovery is justified under the terms of this *grant agreement*, the *beneficiary* undertakes to repay the *IMI JU* the sum in question following a written request by the *IMI JU*.
2. Where, following this request from the *IMI JU*, a *beneficiary* in an on-going grant agreement does not reimburse to the *IMI JU* any requested amount at the latest 30 days after receipt of the request, the *IMI JU* may recover the amount due from that beneficiary by any appropriate means, including invoking any guarantees. No prior consent of the beneficiary is required.
3. If the obligation to pay the amount due is not honoured by the date set by the *IMI JU*, the sum due shall bear interest at the rate applied by the European Central Bank for its main refinancing operations in euros, plus three and a half points. The reference rate to which the increase applies shall be the rate in force on the first day of the month of the final date of payment, as published in the C series of the Official Journal of the European Union. Interest on late payment shall cover the period between the date set for payment, exclusive and the date on which the *IMI JU* receives full payment of the amount owed in full, inclusive. Any partial payment shall first be entered against charges and interest on late payment and then against the principal.
4. Each *beneficiary* hereby accepts that any pending payment excluding *pre-financing* due by the *IMI JU* to the said *beneficiary*, irrespective of its origin, is assigned to the payment of that *beneficiary's* debt towards the *IMI JU*.
5. Bank charges occasioned by the recovery of the sums owed to the *IMI JU* shall be borne solely by the beneficiary

## **SECTION 3 – CONTROLS AND SANCTIONS**

### **II.21. Financial audits and controls**

1. The *IMI JU* may, at any time during the implementation of the *project* and up to five years after the end of the *project*, arrange for financial audits to be carried out, by external auditors, or by the *IMI JU's* services themselves. The audit procedure shall be deemed to be initiated on the date of receipt of the relevant letter sent by the *IMI JU*. Such audits may

cover financial, systemic and other aspects (such as accounting and management principles) relating to the proper execution of the *grant agreement*. They shall be carried out on a confidential basis.

2. The *beneficiaries* shall make available directly to the *IMI JU* all detailed information and data that may be requested by the *IMI JU* or any representative authorised by it, with a view to verifying that the *grant agreement* is properly managed and performed in accordance with its provisions and that costs have been charged in compliance with it. This information and data must be precise, complete and effective.

3. The *beneficiaries* shall keep the originals or, in exceptional cases, duly authenticated copies – including electronic copies - of all documents relating to the *grant agreement* for up to five years from the end of the *project*. These shall be made available to the *IMI JU* where requested during any audit under the *grant agreement*.

4. In order to carry out these audits, the *beneficiaries* shall ensure that the *IMI JU's* services and any external body(ies) authorised by it have on-the-spot access at all reasonable times, notably to the *beneficiaries' offices*, to its computer data, to its accounting data and to all the information needed to carry out those audits, including information on individual salaries of persons involved in the *project*. They shall ensure that the information is readily available on the spot at the moment of the audit and, if so requested, that data be handed over in an appropriate form.

5. On the basis of the findings made during the financial audit, a provisional report shall be drawn up. It shall be sent by the *IMI JU* or its authorised representative to the *beneficiary* concerned, which may make observations thereon within one month of receiving it. The *IMI JU* may decide not to take into account observations conveyed or documents sent after that deadline. The final report shall be sent to the *beneficiaries* of *IMI JU* funding concerned within two months of expiry of the aforesaid deadline.

6. On the basis of the conclusions of the audit, the *IMI JU* shall take all appropriate measures which it considers necessary, including the issuing of recovery orders regarding all or part of the payments made by it and the application of any applicable sanction.

7. The Commission including OLAF<sup>3</sup> and the Court of Auditors shall have the same rights as the *IMI JU* among the *beneficiary* eligible to receive *IMI JU* funding and the agent responsible for allocating it, including right of access, for the purpose of on-spots-checks and audits.

## **II.22. Technical audits and reviews**

1. The *IMI JU* may initiate a technical audit or review at any time during the implementation of the *project* and up to up to five years after the end of the *project*. The aim of a technical audit or review shall be to assess the work carried out under the *project* over a certain period, *inter alia* by evaluating the *project* reports and deliverables relevant

---

<sup>3</sup> In addition to Council Regulation (Euratom, EC) No 2185/96 of 11 November 1996 concerning on-the-spot checks and inspections carried out by the *Commission* in order to protect the European Communities' financial interests against fraud and other irregularities (OJ L 292, 15.11.1996, p.2) and Regulation (EC) No 1073/1999 of the European Parliament and of the Council of 25 May 1999 concerning investigations conducted by the European Anti-Fraud Office (OLAF)<sup>9</sup> Council Regulation (Euratom) No 1074/1999 of 25 May 1999 concerning investigations conducted by the European Anti-Fraud Office (OLAF) (OJ L 136, 31.5.1999).

to the period in question. Such audits and reviews may cover scientific, technological and other aspects relating to the proper execution of the *project* and the *grant agreement*.

2. With respect to the Description of Work (Annex I), the audit or review shall objectively assess the following:

- the degree of fulfilment of the *project* work plan for the relevant period and of the related deliverables;
- the continued relevance of the *project objectives* and breakthrough potential with respect to the scientific and industrial state of the art;
- the resources planned and utilised in relation to the achieved progress, in a manner consistent with the principles of economy, efficiency and effectiveness;
- the management procedures and methods of the *project*;
- the *beneficiaries'* contributions and integration within the *project*;
- the expected potential impact in economic, competition and social terms, and the *beneficiaries'* plan for the *research use* and *dissemination* of *foreground*.

3. Audits and reviews shall be deemed to be initiated on the date of receipt by the *beneficiary(ies)* of the relevant letter sent by the IMI JU.

4. Any such audit or review shall be carried out on a confidential basis.

5. The IMI JU may be assisted in technical audits and reviews by external scientific or technological experts. Prior to the carrying out of the evaluation task, the IMI JU shall communicate to the *beneficiaries* the identity of the appointed experts. The *beneficiary(ies)* shall have the right to refuse the participation of a particular external scientific or technological expert on grounds of commercial confidentiality.

6. Audits and reviews may be carried out remotely at the expert's home or place of work or involve sessions with *project* representatives either at the IMI JU premises or at the premises of *beneficiaries*. The IMI JU or the external scientific or technological expert may have access to the locations and premises where the work is being carried out, and to any document concerning the work.

7. The *beneficiaries* shall make available directly to the IMI JU all detailed information and data that may be requested by it or the external scientific or technological expert with a view to verifying that the *project* is being/has been properly implemented and performed in accordance with the provisions of this *grant agreement*.

8. A report on the outcome of the audits and reviews shall be drawn up. It shall be sent by the IMI JU to the *beneficiary* concerned, who may make observations thereon within one month of receiving it. The IMI JU may decide not to take into account the observations conveyed after that deadline.

9. On the basis of the experts' formal recommendations the IMI JU will inform the *coordinator* of its decision:

- to accept or reject the deliverables;
- to allow the *project* to continue without modification of Annex I or with minor modifications;
- to consider that the *project* can only continue with major modifications;
- to initiate the termination of the *grant agreement* or of the participation of any *beneficiary* according to Article II. 37;

- to issue a recovery order regarding all or part of the payments made by the *IMI JU* and to apply any applicable sanction.

10. An ethics audit may be undertaken at the discretion of the *IMI JU* services up to five years after the end of the *project*. Paragraphs 3, 4, 5, 6, 7, 8 and 9 shall apply *mutatis mutandis*.

### **II.23. Liquidated damages**

1. A *beneficiary* that is found to have overstated any amount and which has therefore received an unjustified financial contribution from the *IMI JU* shall, without prejudice to any other measures provided for in this *grant agreement*, be liable to pay damages, hereinafter "*liquidated damages*". *Liquidated damages* are due in addition to the recovery of the unjustified *IMI JU* financial contribution from the *beneficiary*. In exceptional cases the *IMI JU* may refrain from claiming *liquidated damages*.

2. Any amount of *liquidated damages* shall be proportionate to the overstated amount and the unjustified part of the *IMI JU financial contribution*. The following formula shall be used to calculate *liquidated damages*:

***Liquidated damages* = unjustified *IMI JU financial contribution* x (overstated amount/total *IMI JU financial contribution* claimed)**

The calculation of any *liquidated damages* shall only take into consideration the reporting period(s) relating to the *beneficiary's* claim for the *IMI JU financial contribution* for that period. It shall not be calculated in relation to the entire *IMI JU financial contribution*

3. The *IMI JU* shall inform the *beneficiary* which it considers liable to pay liquidated damages in writing of its claim by way of a registered letter with acknowledgement of receipt. The *beneficiary* shall have a period of 30 days to answer *the IMI JU's* claim.

4. The procedure for repayment of unjustified *IMI JU financial contribution* and for payment of *liquidated damages* will be determined in accordance with the provisions of Article II.20. *Liquidated damages* will be deducted from any further payment or will be subject to recovery by the *IMI JU*.

5. The *IMI JU* shall be entitled to *liquidated damages* in respect of any overstated amount which comes to light after the end of the project, in accordance with the provisions of paragraphs 1 to 4

### **II.24. Financial penalties**

1. A *beneficiary* eligible to receive *IMI JU* funding that has made false declarations or has seriously failed to meet its obligations under this grant agreement shall be liable to financial penalties of between 2% and 10% of the value of the *IMI JU* financial contribution received or of the value of the in-kind contribution claimed by that beneficiary. The rate may be increased to between 4% and 20% in the event of a repeated offence within five years following the first infringement.

2. In the cases of paragraph 1, said *beneficiaries* shall be excluded from all *IMI JU* grants for a maximum of two years from the date the infringement has been established.

3. The provisions in this Article shall be without prejudice to any additional financial sanction that may be imposed on any defaulting *beneficiary* eligible to receive *IMI JU*

funding in accordance with the *IMI JU Financial Rules* or to any other civil remedy to which the *IMI JU* or any other *beneficiary* may be entitled. Furthermore, these provisions shall not preclude any criminal proceedings which may be initiated by the Member States' authorities.

4. The *IMI JU* shall give the beneficiary concerned the opportunity to present its observations before imposing any financial penalties.

## **Part C INTELLECTUAL PROPERTY RIGHTS, USE AND DISSEMINATION**

### ***SECTION 1: IDENTIFICATION, OWNERSHIP AND TRANSFER***

#### **II.25. Background**

1. Each *beneficiary* shall remain the exclusive owner of its *background*.
2. The *background* to be included in the *project* shall be identified in the *project agreement*.

The *beneficiaries* shall identify in the *project agreement* any legal restrictions which exist relating to the use of such *background* for *research use* or for completing the *project*, and of which they are aware. The *IMI JU* shall be informed of any such restrictions prior to execution of the *grant agreement* and shall consider the impact of any such restrictions in achieving the *project objectives* and the objectives of the *IMI JU* as described in the *IMI JU Statutes*.

*Beneficiaries* shall be entitled but not obliged to introduce into the *project* and to designate as *background* information as well as copyrights or other intellectual property rights pertaining to such information and which is generated or held or acquired by a *beneficiary* after the accession to the *grant agreement*.

3. Each *beneficiary* shall remain free to license, assign or otherwise dispose of its ownership rights in *background*, subject to any rights and obligations of the *grant agreement* and the *project agreement*.

Where a *beneficiary* transfers ownership of *background*, it shall pass on its obligations regarding that *background*, as defined in the *grant agreement* and *project agreement*, to the assignee including the obligation to pass those obligations on to any subsequent assignee.

Notwithstanding the above, a *beneficiary* may - without the permission of the other *beneficiaries*, but provided that other *beneficiaries* are informed and that the assignee agrees in writing to be bound by the *grant agreement* and the *project agreement* - assign its *background* to (i) its *affiliated entity*; or (ii) any purchaser of all or substantially all of its assets; or (iii) any successor entity resulting from the merger or consolidation of such party with or into such entities.

#### **II.26. Foreground**

1. Ownership of the *foreground* belongs in the first instance to the *beneficiary(ies)* who generated it.

*Beneficiary(ies)* may agree on a different allocation of ownership in the *project agreement*.

If employees or any party working on behalf of a *beneficiary* are entitled to claim rights to *foreground*, the *beneficiary* shall ensure that it is possible to exercise those rights in a manner compatible with its obligations under the *grant agreement* and *project agreement*.

2. Where several *beneficiaries* have jointly carried out work generating *foreground* and where no individual *beneficiary* can be identified as its owner, such *beneficiaries* shall, unless otherwise agreed in the *project agreement*, have joint ownership of such *foreground*.

In case of joint ownership, unless otherwise agreed in the *project agreement*, each joint owner shall have the right to use such jointly owned *foreground*, including the right to grant non-exclusive licenses, with the following conditions:

- Prior notice must be given to any other joint owner(s);
- *Fair and reasonable* compensation must be provided to the other joint owner(s).

3. Each *beneficiary* shall remain free to license, assign or otherwise dispose of its ownership rights in *foreground*:

- Either as expressly permitted in the Annex I of the *grant agreement* and/or in the *project agreement*;
- Or after obtaining the consent of all *beneficiaries*, which may only be withheld where they can demonstrate that their rights would be adversely affected.

Where a *beneficiary* transfers ownership of *foreground*, it shall pass on its obligations regarding that *foreground*, as defined in the *grant* and *project agreements*, to the assignee including the obligation to pass those obligations on to any subsequent assignee.

Notwithstanding the above, a *beneficiary* may - without the permission of the other *beneficiary* but provided that other *beneficiaries* are informed and that the assignee agrees in writing to be bound by the *grant agreement* and the *project agreement* - assign its *foreground* to (i) its *affiliated entity*; or (ii) any purchaser of all or substantially all of its assets; or (iii) any successor entity resulting from the merger or consolidation of such party with or into such entities;

4. Patent applications relating to *foreground*, filed by or on behalf of a *beneficiary* must include the following statement to indicate that said *foreground* was generated with the assistance of financial support from the *IMI JU*:

**The work leading to this invention has received funding from the European Union's Seventh Framework Programme (FP7/2007-2013) for the Innovative Medicine Initiative under grant agreement n° [xxxxxx].<sup>4</sup>**

Furthermore, all patent applications relating to *foreground* filed shall be reported in the plan for the *research use* and *dissemination* of *foreground*, including sufficient details/references to enable the *IMI JU* to trace the patent (application). Any such filing arising after the final report must be notified to the *IMI JU* including the same details/references.

---

<sup>4</sup> This statement will have to be translated into the language of the patent filing.

5. All publications or any other *dissemination* relating to *foreground* shall include the following statement to indicate that said *foreground* was generated with the assistance of financial support from the *IMI JU*:

**The research leading to these results has received funding from the European Union's Seventh Framework Programme (FP7/2007-2013) for the **Innovative Medicine Initiative** under *grant agreement* n° [xxxxxx].**<sup>5</sup>

Any *dissemination* activity shall be reported in the plan for the *research use* and *dissemination of foreground*, including sufficient details/references to enable the *IMI JU* to trace the activity. With regard to scientific publications relating to *foreground* published before or after the final report, such details/references and an abstract of the publication must be provided to the *IMI JU* at the latest two months following publication. Furthermore, an electronic copy of the published version or the final manuscript accepted for publication shall also be provided to the *IMI JU* at the same time for the purpose set out in Article II.11.2 if this does not infringe any rights of third parties.

## **II.27. Sideground**

Ownership of the *sideground* belongs in the first instance to the *beneficiary* (ies) who generated it.

The *beneficiaries* may agree on a different allocation of ownership in the *project agreement*.

## **SECTION 2 – ACCESS RIGHTS**

### **II.28. Principles**

1. All requests for *access rights* shall be made in writing, unless otherwise agreed in the *project agreement*

2. 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

3. The termination of the participation of a *beneficiary* shall in no way affect the obligation of that *beneficiary* to grant *access rights* to the remaining *beneficiaries* and *third parties*

4. Unless otherwise agreed by the owner of the *foreground* or *background*, *access rights* shall confer no entitlement to grant sub-licences. However, any person to whom rights for completing the *project* or for *research use* have been made available under this *grant agreement* may authorise another party to exercise those rights on its behalf providing that that person shall be liable for the acts of that party as if those acts have been performed by this person.

---

<sup>5</sup> This statement will have to be translated into the language of the dissemination activity.

## **II.29. Access rights to the beneficiaries for completing the project**

*1. Foreground.* During the *project*, *beneficiaries* shall enjoy *access rights* to the *Foreground* of the other *beneficiaries* solely for the purpose and to the extent necessary for undertaking and completing the project.

Such *access rights* shall be granted on a royalty-free basis

*2. Background.* During the *project*, the *beneficiaries* shall, unless prevented or restricted from doing so by obligations to others which exist at the date of accession to the *project agreement*, as identified in II.25.2, enjoy *access rights* to the *background* of the other *beneficiaries* solely for the purpose and to the extent necessary for undertaking and completing the *project*.

Such *access rights* shall be granted on a royalty-free basis

## **II.30. Access rights to the beneficiaries and affiliated entities for research use**

*1. Foreground.* During and after completion of the *project*, *beneficiaries* and their *affiliated entities* shall enjoy *access rights* to the *foreground* of the other *beneficiaries* for *research use*.

Such *access rights* shall be granted on a non-exclusive basis under *fair and reasonable terms* or royalty-free, as determined in the *project agreement*

*2. Background.* During and after completion of the *project*, *beneficiaries* and their *affiliated entities* shall enjoy *access rights* to the *background* of the other *beneficiaries*, but only to the extent reasonably required for and only for the purpose of the *research use* of *foreground*.

Such *access rights* shall be granted on a non-exclusive basis under *fair and reasonable terms* or royalty-free, as determined in the *project agreement*

## **II.31. Access rights to third parties for research use**

*1. Foreground.* After the completion of the *project*, *third parties* shall have the right to request and receive under licence *access rights* to the *foreground* of the *beneficiaries* for *research use*.

Such *access rights* shall be granted on a non-exclusive basis under *fair and reasonable terms*, as determined in the *project agreement*

*2. Background.* After the completion of the *project*, *third parties* shall have the right to request and receive under licence *access rights* to the *background* of the *beneficiaries*, but only to the extent reasonably required for and only for the purpose of the *research use* of *foreground*.

Such *access rights* shall be granted on a non-exclusive basis under *fair and reasonable terms*, as determined in the *project agreement*.

3. The terms for providing *access rights* under paragraphs 1 and 2 shall be included in the *project agreement*.

4. Before execution of the *grant agreement*, a *beneficiary* may identify specific elements of the *background* and provide a reasoned request to the *IMI JU* that such elements shall be wholly or partially excluded from the obligations referred to in this section. The *IMI JU* shall only grant such request in exceptional circumstances and in making its decision shall consider the objectives of IMI as described in the IMI JU Statutes. It may grant such



request on such conditions as it may agree with the *beneficiary*. Any exceptions shall be included in the *grant agreement* and cannot be changed unless such change is permitted in the *grant agreement*.

### **II.32. Access rights for direct exploitation**

1. *Beneficiaries* may use, exploit, sublicense or otherwise commercialise their *foreground*, *background* and *sideground* as they see fit beyond the *research use* rights
2. Where *direct exploitation* by a *beneficiary* or *third party* requires *foreground* or *background* necessary to use *foreground* owned by another *beneficiary*, the *access rights* will be negotiated between the parties involved as they see fit.  
*Beneficiaries* may agree on such *access rights* in the *project agreement*

### **II.33. Confidential information**

1. In accordance to section II.9, the *beneficiaries* covenant not to disclose and not to use the *confidential information* received from other *beneficiaries* except as provided in and for the purposes of the *project agreement* and *grant agreement*.
2. Unless otherwise agreed in the *project agreement*, each *beneficiary* may disseminate (through journals, lectures, or otherwise) information relating to *foreground*, provided that a copy of the proposed dissemination shall have been provided to the other *beneficiaries* at least thirty (30) days prior to the submission of any written publication or any oral dissemination to allow the *beneficiaries* to determine whether any invention or *confidential information* would be disclosed.

The reviewing *beneficiaries* shall have the right to (a) require a delay in publication or presentation in order to protect patentable information, (b) require modifications to the publication for patent reasons or (c) require that *confidential information* be maintained as a trade secret.

The delay required by the reviewing *beneficiaries* in publication or presentation in order to protect patentable information shall not exceed three months, unless agreed in the *project agreement*.

### **II.34 Dissemination of foreground**

1. The *beneficiaries* undertake to disseminate the *foreground* (as described in the *project objective*) as soon as reasonably practicable but not later than one (1) year after the termination or expiry of the Project.
2. The *project agreement* shall include a description of the material which must be disseminated in accordance with the *grant agreement*.
3. If the *beneficiaries* do not disseminate within such time periods without good reason, the *IMI JU* has the right to disseminate such results in a manner consistent with the *grant agreement*.

## FINAL PROVISIONS

### II.35. Requests for amendments and termination at the initiative of the *consortium*

1. Amendments to this *grant agreement* may be requested by any of the parties. Requests for amendments and termination shall be signed by the legal representative of the parties and submitted in accordance with Article 8. Any request or acceptance by the *consortium* or a *beneficiary(s)* shall be submitted by the *coordinator*. The *coordinator* is deemed to act on behalf of all *beneficiaries* when signing a request, an acceptance or rejection letter concerning an amendment as well as when requesting a termination. The *coordinator* shall ensure that adequate proof of the *consortium's* agreement to such an amendment or termination exists and is made available in the event of an audit or upon request of the *IMI JU*.

2. In the case of change of *coordinator* without its agreement, the request shall be submitted by all other *beneficiaries* or by one of them representing the others.

3. A request for amendment including more than one modification to the agreement shall be considered a package that cannot be separated into several requests and shall be approved or rejected by the other party as a whole, except where the request explicitly states that it contains separate requests that can be approved independently.

4. Requests for the addition of a new *beneficiary* shall include a completed Form B, duly signed by such new entity. Any addition is subject to the conditions required by the related call for proposals and the *IMI JU Financial Rules*. Such additional entity shall assume the rights and obligations of *beneficiaries* as established by the *grant agreement* with effect from the date of its accession specified in the signed Form B.

5. The amendments may not have the purpose or the effect of making changes to the agreement which might call into question the decision awarding the grant or result in unequal treatment of the *beneficiaries*.

6. Requests for termination of the participation of one or more *beneficiaries* shall include:

- the *consortium's* proposal for reallocation of the tasks and budget of that *beneficiary*,
- the reasons for requesting the termination,
- the proposed date on which the termination shall take effect,
- a letter containing the opinion of the *beneficiary* whose participation is requested to be terminated and
- the reports and deliverables referred to in Article II.4, relating to the work carried out by this *beneficiary* up to the date on which the termination takes effect, together with a comment of the *coordinator* on behalf of the *consortium* on these reports and deliverables, as well as a declaration on distribution of payments to this *beneficiary* (in case it is eligible to receive *IMI JU* funding) by the *coordinator* and *managing entity of the IMI JU funding*.

In the absence of receipt of such documents, the request shall not be considered as a valid request.

The letter containing the opinion of the *beneficiary* concerned can be substituted by proof that this *beneficiary* has been requested in writing to express its opinion on the proposed termination of its participation and to send the reports and deliverables but failed to do so within the time-limit established by that notification. This time-limit shall not be inferior to one month. In this case, if no reports have been submitted with the request for termination,

the *IMI JU* shall not take into account any further cost claims of that *beneficiary* and shall not make any further reimbursement for it (in case it is a *beneficiary* eligible to receive *IMI JU* funding).

Unless otherwise agreed with the *IMI JU*, all the tasks of the *beneficiary* whose participation is terminated must be reallocated within the *consortium*.

Requests for termination of the *grant agreements* shall provide the justification for termination and the reports and deliverables referred to in Article II.4 relating to the work carried out up to the date on which the termination takes effect.

### **II.36. Approval of amendments and termination requested by the consortium**

1. The parties to this *grant agreement* undertake to approve or reject any valid request for an amendment or termination within 45 days of its receipt. The absence of a response within 45 days of receipt of such a request shall be considered as a rejection.

2. By derogation to paragraph 1, when the *consortium* requests the addition or the termination of the participation of a *beneficiary*, the absence of a response from the *IMI JU* within 30 days of receipt of such a request constitutes approval.

Changes in the composition of the consortium associated with proposals for other changes to the *grant agreement* which are not directly related to the change in composition shall be subject to written approval by the *IMI JU*.

3. The *IMI JU*'s approval of the requested amendment or termination shall be notified to the *coordinator*, which receives it on behalf of the *consortium*. In case of termination of the participation of one or more *beneficiaries*, the *IMI JU* shall send a copy to the *beneficiary* concerned.

4. Amendments and terminations shall take effect on the date agreed by the parties; where there is no date specified they shall take effect on the date of the *IMI JU*'s approval.

### **II.37. Termination of the grant agreement or of the participation of one or more beneficiaries at the IMI JU's initiative**

1. The *IMI JU* may terminate the *grant agreement* or the participation of a *beneficiary* in the following cases:

- a) where one or more of the legal entities identified in Article 1 does not accede to this *grant agreement*.
- b) in case of non-performance or poor performance of the work or breach of any substantial obligation imposed by this *grant agreement* that is not remedied following a written request to the *consortium* to rectify the situation within a period of 30 days;
- c) where the *beneficiary* has deliberately or through negligence committed an *irregularity* in the performance of any *grant agreement* with the *IMI JU*;
- d) where the *beneficiary* has contravened fundamental ethical principles;
- e) where the required reports or deliverables are not submitted or the *IMI JU* does not approve the reports or deliverables submitted;
- f) for major technical or economic reasons substantially adversely affecting the completion of the *project*;

- g) if the potential *research use* of the *Foreground* diminishes to a considerable extent;
- h) where a legal, financial, organisational or technical change or *change of control* of a *beneficiary* calls into question the decision of the *IMI JU* to accept its participation;
- i) where any such change identified in h) above or termination of the participation of the *beneficiary(s)* concerned substantially affects the implementation of the *project*, or the interests of the *Union*, or calls into question the decision to grant the *IMI JU* contribution;
- j) in case of *force majeure* notified in conformity with Article II.39, where any reactivation of the *project* after suspension is impossible;
- k) where the conditions for participation in the *project* established by Council Regulation (EC) 73/2008 or the call for proposals to which the *project* was submitted are no longer satisfied, unless the *IMI JU* considers that the continuation of the *project* is essential to the implementation of the work programme;
- l) where a *beneficiary* is found guilty of an offence involving its professional conduct by a judgment having the force of *res judicata* or if it is guilty of grave professional misconduct proven by any justified means;
- m) where further to the termination of the participation of one or more *beneficiaries*, the *consortium* does not propose to the *IMI JU* an amendment to the *grant agreement* with the necessary modifications for the continuation of the *project* including the reallocation of task of the *beneficiary* whose participation is terminated within the time limit determined by the *IMI JU*, or where the *IMI JU* does not accept the proposed modifications.
- n) where a *beneficiary* is declared bankrupt or is being wound up.

2. The *IMI JU* shall notify the *beneficiary (ies)* whose participation is intended to be terminated with a copy to the *coordinator* and both shall have the opportunity to make their observations. Termination of the participation of the *beneficiary (ies)* at the *IMI JU's* initiative shall take effect on the date indicated in the notification and at the latest 30 days after its receipt by the *beneficiary*.

The *IMI JU* shall inform the *consortium* of the effective date of termination.

The *IMI JU* shall notify the *coordinator* of its intent to terminate the grant agreement and the *consortium* shall have the opportunity to make its observations through the coordinator. In the case of termination of the *grant agreement*, the *coordinator* shall be notified, who shall in turn notify all the other *beneficiaries* and the termination shall become effective 45 days after receipt by the *coordinator*.

3. Within 45 days after the effective date of termination, the *beneficiary(s)* whose participation is terminated shall submit (through the *coordinator*) all required reports and deliverables referred to in Article II.4 relating to the work carried out up to that date. In the absence of receipt of such documents within the above time-limits, the *IMI JU* may, after providing 30 days notice in writing of the non-receipt of such documents, determine not to take into account any further cost claims and not to make any further reimbursement (in case the *beneficiary* is a *beneficiary* eligible to receive *IMI JU* funding) and, where appropriate, require the reimbursement of any *pre-financing* due by the *beneficiary (ies)*.

4. If the *beneficiary* is eligible to receive *IMI JU* funding, the consortium has up to 30 days after the effective date of termination of the *beneficiary's* participation to provide the *IMI*

*JU* with information on the share of the *IMI JU* contribution that has been effectively transferred to such *beneficiary* since the beginning of the project.

5. In the absence of receipt of such information within the time-limits, the *IMI JU* shall consider that the *beneficiary* whose participation is terminated owes no money to the *IMI JU* and that the *IMI JU* contribution already paid is still at the disposal of the *consortium* and under its responsibility.

6. Based on documents and information referred to in the paragraphs above, the *IMI JU* shall establish the debt owed by the *beneficiary* whose participation is terminated.

7. Where the participation of one or more *beneficiaries* who are eligible to receive *IMI JU* funding is terminated, the *beneficiary(ies)* whose participation is terminated shall reimburse the amount due to the *IMI JU* or transfer it to the *managing entity of the IMI JU funding* as requested by the *IMI JU*, within 30 days. The *IMI JU* shall send a copy of such a request to the *coordinator* and to the *managing entity of the IMI JU funding*. In the latter case, the *managing entity of the IMI JU funding* shall inform the *IMI JU* at the latest 10 days after the end of this time-limit whether the amount has been transferred to it.

8. Where the *grant agreement* is terminated, the *IMI JU* shall establish the debt owed by the *consortium* and notify it to the *coordinator* and to the *managing entity of the IMI JU funding*.

### **II.38. Financial contribution after termination and other termination consequences**

1. In the event of termination any financial contribution from the *IMI JU* is limited to those *eligible costs* incurred and accepted up to the effective date of such termination and of any legitimate commitments taken prior to that date, which cannot be cancelled.

2. By derogation to the above paragraph:

- in the case of Article II.37.1.a), no costs incurred by the *consortium* under the *project* can be approved or accepted as eligible by the *IMI JU*. Any *pre-financing* provided to the *consortium* and any interest generated by the *pre-financing* must be returned in full to the *IMI JU*.

- in the case of Article II.37.1.b), any financial contribution from the *IMI JU* is limited to those eligible costs incurred up to the date of receipt of the written request to rectify the breach.

3. In addition, in the cases of Article II.37.1.b), c), d), e), l) and m) the *IMI JU* may require reimbursement of all or part of the *IMI JUs* financial contribution. In the case of Article II.37.1.b) and m) the *IMI JU* shall take into account the nature and results of *the work* carried out and its usefulness to the *IMI JU* in the context of the specific objectives concerned.

4. Reports and deliverables submitted in the framework of a termination are deemed to be submitted at the end of the corresponding reporting period.

5. Where the *IMI JU* makes a payment after the termination of the participation of a *beneficiary* eligible to receive *IMI JU* funding or after termination of the *grant agreement*, this payment shall be considered as a final payment in relation to such *beneficiary(ies)* or the *project*, respectively and in any case shall be done through the *managing entity of the IMI JU funding*.

Notwithstanding the termination of the *grant agreement* or the participation of one or more *beneficiaries*, the provisions identified in Articles II.9, II.10, II.11, II.20, II.21, II.22, II.23, II.24, II.34, II.35, II.37, II.40, II.41 and Part C of Annex II continue to apply after the termination of the *grant agreement* or the termination of the participation of such *beneficiary(s)*.

### **II.39. Force majeure**

1. *Force majeure* shall mean any unforeseeable and exceptional event affecting the fulfilment of any obligation under this *grant agreement* by the parties, which is beyond their control and cannot be overcome despite their reasonable endeavours. Any default of a product or service or delays in making them available for the purpose of performing this *grant agreement* and affecting such performance, including, for instance, anomalies in the functioning or performance of such product or service, labour disputes, strikes or financial difficulties do not constitute *force majeure*.

2. If any of the *beneficiaries* is subject to *force majeure* liable to affect the fulfilment of its obligations under this *grant agreement*, the *coordinator* shall notify the *IMI JU* without delay, stating the nature, likely duration and foreseeable effects.

3. If the *IMI JU* is subject to *force majeure* liable to affect the fulfilment of its obligations under this *grant agreement*, it shall notify the *coordinator* without delay, stating the nature, likely duration and foreseeable effects.

4. No party shall be considered to be in breach of its obligation to execute the *project* if it has been prevented from complying by *force majeure*. Where *beneficiaries* cannot fulfil their obligations to execute the *project* due to *force majeure*, remuneration for accepted eligible costs incurred may be made only for tasks which have actually been executed up to the date of the event identified as *force majeure*. All necessary measures shall be taken to limit damage to the minimum.

### **II.40. Assignment**

The *beneficiaries* shall not assign any of the rights and obligations arising from the grant agreement except those cases provided for in Article II.26.3 (transfer of foreground), without the prior and written authorisation of the *IMI JU* and the other *beneficiaries*.

### **II.41. Liability**

1. The *IMI JU* cannot be held liable for any acts or omissions of the *beneficiaries* in relation to this *grant agreement*. It shall not be liable for any defaults of any products, processes or services created on the basis of *foreground*, including, for instance, anomalies in the functioning or performance thereof

2. Each *beneficiary* fully guarantees the *IMI JU*, and agrees to indemnify it, in case of any action, complaint or proceeding brought by a third party against the *IMI JU* as a result of damage caused, either by any of its acts or omissions in relation to this *grant agreement*, or by any products, processes or services created by it on the basis of *foreground* resulting from the *project*. In the event of any action brought by a third party against a *beneficiary* in connection with the performance of this *grant agreement*, the *IMI JU* may assist the latter

upon written request. The costs incurred by the *IMI JU* in this connection shall be borne by the *beneficiary* concerned.

3. Each *beneficiary* shall bear sole responsibility for ensuring that their acts within the framework of this *project* do not infringe third parties rights.

4. The *IMI JU* cannot be held liable for any consequences arising from the proper exercise of the rights of the *IMI JU* under the *European Community* and *European Union* acts relating to the *IMI JU*, the *IMI JU* financial rules or this *grant agreement*.

#### **II.42. Limitation of entitlements**

Any entitlements of the *IMI JU* against a *beneficiary* or of a *beneficiary* against the *IMI JU* shall be subject to a limitation period of five years. The provisions of the Implementing rules of the Financial Regulation applicable to the general budget of the European Union shall apply regarding the date for calculating the limitation period and the conditions for interrupting this period.