

IMI JOINT UNDERTAKING MODEL GRANT AGREEMENT CORE

IMI Joint Undertaking GRANT AGREEMENT No _____

PROJECT TITLE [ACRONYM]

The IMI Joint Undertaking (the "*IMI JU*"), represented for the purposes of this agreement by [forename, name], its Executive Director or her/his duly authorised representative, of the **one part**,

and (name of the coordinator and legal form) (national registration number if any), established in (*full address city/state/province/country*), represented by (name of legal representative), (function) [and/or (name of legal representative), (function)], or her/his/their authorised representative, the *participant* acting as *coordinator* of the consortium (the "**coordinator**"), ("*participant no. XXX*"),

and (name of the managing entity of the IMI JU funding and legal form) (national registration number if any), established in (*full address city/state/province/country*), represented by (name of legal representative), (function) [and/or (name of legal representative), (function)], or her/his/their authorised representative, the *participant* acting as *managing entity of the IMI JU funding* (the "**managing entity of the IMI JU funding**"), ("*participant no. XXX*"), of the **other part**

HAVE AGREED to the following terms and conditions including those in the following annexes, which form an integral part of this *grant agreement* (the "*grant agreement*").

Annex I - Description of Work

Annex II - General conditions

Annex III - Form A - Accession of *participants* to the *grant agreement*

Annex IV - Form B - Request for accession of a new *participant* to the *grant agreement*

Annex V - Form C - Financial statement

Annex VI - Form D – Terms of reference for the certificate on the financial statements

Article 1 – Accession to the *grant agreement* of the other *participants*

1. The *coordinator* shall endeavour to ensure that each legal entity identified below accedes to this *grant agreement* as a *participant*, assuming the rights and obligations established by the *grant agreement* with effect from the date on which the *grant agreement* enters into force, by signing Form A in three originals, countersigned by the *coordinator*.

- (full name and legal form of the *participant*) (national registration number if any) established in (*full address city/state/province/country*), represented by (name of legal representative) (function), [and/or (name of legal representative), (function)], or her/his/their authorised representative ("*participant no. XXX*"),

- (full name and legal form of the *participant*) (national registration number if any) established in (*full address city/state/province/country*), represented by (name of legal representative) (function), [and/or (name of legal representative), (function)], or her/his/their authorised representative ("*participant no. XXX*"),

- (...)

All the *participants* together form the *consortium* (the "*consortium*").

2. The *coordinator* shall send to the *IMI JU* one duly completed and signed Form A per *participant* at the latest 45 calendar days after the entry into force of the *grant agreement*. The two remaining signed originals shall be kept, one by the *coordinator* to be made available for consultation at the request of any *participant*, and the other by the *participant* concerned.

3. Should any legal entity identified above, fail or refuse to accede to the *grant agreement* within the deadline established in the previous paragraph, the *IMI JU* is no longer bound by its offer to the said legal entity(ies). The *consortium* may propose to the *IMI JU*, within the time-limit to be fixed by the latter, appropriate solutions to ensure the implementation of the *project*. The procedure established in Annex II for amendments to this *grant agreement* will apply.

4. The *participants* are deemed to have concluded a project agreement (the "*project agreement*") regarding the internal organisation of the *consortium*.

5. In accordance with the provisions of the Council Regulation (EC) No 73/2008 of 20 December 2007, the following *participants* only are *beneficiaries*:

- (full name of the *participant*), *participant no. XXX*

- (full name of the *participant*), *participant no. XXX*

- (...)

Article 2 – Scope

The *IMI JU* has decided to grant a financial contribution for the implementation of the *project* as specified in Annex I, called [*project title (Acronym)*] (the "*project*") under the conditions laid down in this *grant agreement*.

Article 3 – Duration and start date of the *project*

The duration of the *project* shall be [*insert number*] months from [the first day of the month after the entry into force of the *grant agreement*] [*insert fixed start date*¹] [the effective starting date notified by the *coordinator* which must be within [*insert number*] months from the date the *grant agreement* enters into force] (hereinafter referred to as the "*start date*").

¹ In cases where the start date of the project is before the grant agreement is signed by both parties, i.e. before it has entered into force, according to Article 99 of the IMI JU Financial rules, it is required that the consortium can demonstrate the need to start the action before the agreement is signed. In any case, the start date of the project cannot be prior to the submission of the proposal.

Article 4 – Reporting periods and language of reports

The *project* is divided into reporting periods of the following duration:

- P1: from month 1 to month X
- P2: from month X+1 to month Y
- P3: from month Y+1 to month Z
- (...)
- [final]: from month [N+1] to the last month of the *project*

Any report and deliverable, when appropriate, required by this *grant agreement* shall be in English.

Article 5 – Estimated budget and maximum IMI JU financial contribution

1. The maximum *IMI JU* financial contribution to the *project* shall be EUR **[insert amount] ([insert amount in words] EURO)**. The actual *IMI JU* financial contribution shall be calculated in accordance with the provisions of this *grant agreement*.

2. Details of the estimated budget of the *project* are contained in Annex I to this *grant agreement* which includes:

- a table of the estimated breakdown of budget per activity to be carried out by each of the *participants* under the *project*, including the estimated *IMI JU* financial contribution per *beneficiary*. *Participants* are allowed to transfer budget between different activities and between themselves in so far as the work is carried out as foreseen in Annex I.

- [a table per *beneficiary* specifying the budget to be covered by a lump sum or flat-rate financing. *Beneficiaries* are not allowed to transfer *IMI JU* financial contribution to the part to be covered by a lump sum or flat-rate financing.]²

3. The bank account of the *managing entity of the IMI JU funding* to which all payments of the *IMI JU* financial contribution shall be made is:

Name of account holder:

Name of bank:

Account reference: IBAN/sort code and number

Article 6 – Pre-financing

A *pre-financing* of EUR **[insert amount] ([insert amount in words]³ EURO)** shall be paid to the *managing entity of the IMI JU funding* within 45 days following the date of entry into force of this *grant agreement*. The *managing entity of the IMI JU funding* shall distribute, in accordance with the *coordinator's* instructions, the *pre-financing* only to the *beneficiaries* who have acceded to the *grant agreement* and after the minimum number of *participants* as detailed in the Call for proposals to which the *project* is related, have acceded to the *grant agreement*.

² This indent only appears when part of the grant is reimbursed as lump sum, flat rate (other than indirect costs)(including scale of unit costs) or a combination of those.

³ As an indication, for projects with more than 2 periods, this amount could be around 160% of the average funding per period (Average = total *IMI JU* financial contribution / nr of periods). For projects with 2 periods or less, this amount should be fixed in accordance with the needs of the project and could be between 60-80% of the total maximum *IMI JU* financial contribution.

Article 7 – Special clauses

[No special clauses apply to this *grant agreement*.]

[The following special clauses apply to this *grant agreement*:]

Article 8 – Communication

1. Any communication or request concerning the *grant agreement* shall identify the *grant agreement* number, the nature and details of the request or communication and be submitted to the following addresses:

For the *IMI JU*: IMI Joint Undertaking

[Name]

[Address]

For the *coordinator*: [name of contact person]

[Contact address]

For the *managing entity of the IMI JU funding* [name of contact person]

[Contact address]

2. For information or documents to be transferred by electronic means, the following addresses shall be used:

For the *IMI JU*:

For the *coordinator*:

For the *managing entity of the IMI JU funding*:

3. In case of refusal of the notification or absence of the recipient, the *participant* or the *consortium*, as the case may be, is deemed to have been notified on the date of the latest delivery, if notification to the *coordinator* has been sent to one of the addresses mentioned in paragraphs 1 and 2 and to their legal representative. Other *participants* are deemed to have been notified if notification has been sent to the address mentioned in Article 1.1, or, for the *managing entity of the IMI JU funding*, to the address mentioned in Article 8.1 above.

4. Any communication or request relating to the processing of personal data (Article II.12) shall be submitted, using the address(es) for the *IMI JU* identified in paragraphs 1 and 2, to the *IMI JU* controller responsible for the processing (the Executive Director of the *IMI JU*).

Article 9 – Applicable law and competent Court

The *IMI JU* financial contribution is a contribution from the *IMI JU*'s budget with the aim to implement the 7th Research Framework Programme (FP7). Accordingly, this *grant agreement* shall be governed by the terms of this *grant agreement*, Council Regulation (EC) No 73/2008 on the establishment of the *IMI JU*, the *IMI JU* financial rules, as well as other European Community and European Union law and, on a subsidiary basis, by the law of Belgium.

The General Court, or on appeal, the Court of Justice of the European Union, shall have sole jurisdiction to hear any dispute between the *IMI JU* and any *participant* concerning the interpretation, application or validity of this *grant agreement*.

Article 10 – Application of the *grant agreement* provisions

Any provision of this core part of the *grant agreement*, shall take precedence over the provisions of any of the Annexes. The provisions of Annex II shall take precedence over the provisions of Annexes I, III, IV, V and VI. The special clauses set out in Article 7 shall take precedence over any other provisions of this *grant agreement*.

Article 11 – Entry into force of the *grant agreement*

This *grant agreement* shall enter into force after its signature by the *coordinator*, the *managing entity of the IMI JU funding* and the *IMI JU*, on the day of the last signature.

Done in English, in three originals.

For the *coordinator* done at [insert place]:

Name of the legal entity:

Name of legal representative:

Stamp of the organisation (if applicable):

Signature of legal representative:

Date:

For the *IMI JU* done at Brussels

Name of legal representative:

Signature of legal representative:

Date:

For the *managing entity of the IMI JU funding* done at [insert place]:

Name of the legal entity:

Name of legal representative:

Stamp of the organisation (if applicable):

Signature of legal representative:

Date:

IMI JOINT UNDERTAKING MODEL GRANT AGREEMENT

ANNEX II – GENERAL CONDITIONS

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 *participant*, under the same direct or indirect control as a *participant*, or is directly or indirectly controlling a *participant*, 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 *European Union*, under the terms or on the basis of which it makes a financial contribution to all or part of the Seventh Framework Programme;
4. "*background*" means information, including data and know-how which is held by a *participant* 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*;
5. "*beneficiary*" means a *participant* eligible to receive *IMI JU* financial contribution in accordance with the *IMI JU* Statutes annexed to Council Regulation (EC) No 73/2008 on the establishment of the *IMI JU* of 20 December 2007;
6. "*confidential information*" means any and all written information communicated between the *participants* 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, to the extent legally and reasonably possible, 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;
7. "*coordinator*" means the *participant* designated as such under this *grant agreement*;
8. "*direct exploitation*" means to develop for commercialisation or to commercialise *foreground* itself;
9. "*dissemination*" means disclosure by any appropriate means other than that resulting from the formalities for protection, and including the publication in any medium;
10. "*EFPIA*" means European Federation of Pharmaceutical Industries and Associations;

11. "*EFPIA company*" means a *participant* which is a research based pharmaceutical company that is member of EFPIA; Where reference to work to be performed by an *EFPIA company* is made in Annex I, it shall be understood as referring to work to be performed by the *EFPIA company* or any of its *affiliated entities*, without these *affiliated entities* becoming *participants*;
12. "*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;
13. "*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;
14. "*in kind contribution*" means contributions to the *project* by *EFPIA companies* and their *affiliated entities*, with resources such as personnel, equipment, consumables, declared in accordance with Articles II.4, II.13 and II.14;
15. "*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 *participant* which has, or would have, the effect of prejudicing the budget of the *IMI JU* through unjustified expenditure;
16. "*managing entity of the IMI JU funding*" means the *beneficiary* designated as such under this *grant agreement*;
17. "*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;
18. "*non-profit qualified patient organisation*" means an organisation considered as non-profit by national or international law, 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/archive/ph_overview/health_forum/docs/euhpf_principles_en.pdf);
19. "*participant*" means a legal entity being a party of the *consortium*, contributing to the *project* and having rights and obligations with regard to the *IMI JU* under the terms of this *grant agreement*;
20. "*project*" means the research activities carried out by the *participants* as defined in Annex I of this *grant agreement*;
21. "*project agreement*" means the agreement between the *participants* 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;
22. "*project objectives*" means the objectives which are defined in the Annex I. The *project objectives* shall not include direct development and/or commercialisation of marketable pharmaceutical or diagnostic products;

23. "*research organisation*" means a legal entity established as an organisation which carries out research or technological development as one of its main objectives, and is considered as non-profit by national or international law;

24. "*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*;

25. "*sideground*" means the results, including data, know how and information, whether or not they can be protected, which are generated by a *participant* 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*;

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

27. "*third country*" means a State that is not a Member State;

28. "*third party*" means any legal entity which is not a *participant*.

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 *participants* together form the *consortium*. *Participants* are represented towards the *IMI JU* by the *coordinator*, who shall be the intermediary for any communication between the *IMI JU* and any *participant*, 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*. 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* 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 *participants* 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* 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*, 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* without unjustified delay.

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

4. *Participants* 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* governs *inter alia* the following:

- i. the internal organisation of the *consortium* including the decision making procedures notably in case of new or departing *participants*;
 - 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 *participants*.
- 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 *participant*

Each *participant* 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 *participant* 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 *participant* 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 among the *participants* are extended to the right to carry out any such audit or on-the-spot check, on the same terms and conditions as those indicated in this *grant agreement*, on any *affiliated entity* of an *EFPIA company* or any *third party* making its resources available free of charge as referred to in Article II.13.5 and *third party* linked to a *participant* whose costs are declared under the *project* according to the provisions of this *grant agreement*;
 - the rights of the European Commission and the Court of Auditors to carry out on-the spot-checks among the *beneficiaries* are extended to the right to carry out any such audit or on-the-spot check, on the same terms and conditions as those indicated in this *grant agreement*, on any *third party* whose costs are reimbursed in full or in part by the *IMI JU* financial contribution or any *third party* linked to a *beneficiary* whose costs are declared under the *project* according to the provisions of 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 reimbursed in full or in part by the *IMI JU* financial contribution or any *third party* linked to a *beneficiary* whose costs are declared 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 *participants* 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 *participants*) and the European Commission including the European Anti-Fraud Office (OLAF) and Court of Auditors (only for the *beneficiaries*) 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 *participants* 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 European 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 *project objectives*, 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 (Annex V - Form C) from each *participant*, together with a certificate on this financial statement when required in Article II.4.4; and
- d) a summary financial report, jointly prepared by the *managing entity of the IMI JU funding* and the *coordinator*, consolidating, in an aggregate form, based on the information provided in Form C by each *participant*:
 - i. the eligible costs of the *beneficiaries*, as defined in Articles II.13 and II.14, and the requested *IMI JU* financial contribution of the *beneficiaries*;
 - ii. the *in kind contribution* made by the *EFPIA companies*, corresponding to the sum of the eligible costs of the *EFPIA companies*, as defined in Article II.13 and II.14, and of the financial contributions made by the *EFPIA companies* to *beneficiaries* costs or to *participants* which are neither a *beneficiary* nor an *EFPIA company* in order to reimburse part of their eligible costs;
 - iii. when applicable, the eligible costs of the *third parties* linked to a *participant* as defined in Articles II.13 and II.14 and/or the costs declared by *participants*, which are neither a *beneficiary* nor an *EFPIA company*.

For the purposes of point (c) and (d), *in kind contribution* made by *affiliated entities* of an *EFPIA company* can be declared by this *EFPIA company* as its own *in kind contribution*, provided they are in accordance with the point (ii) above, *mutatis mutandis*.

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 *participants* 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*. 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 *participant* when the amount of costs claimed is equal to or superior to EUR 375,000, 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 (Annex VI - Form D).

Certificates on the financial statements shall certify that the costs claimed and, for *beneficiaries*, 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 *participant* 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 *participant* 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 *participant*;
- 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 accounts¹ or any *European Community* or *European Union* legislation replacing this Directive. *Participants* 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*.

Non-profit and *for-profit 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 *participants* nor the rights of the *IMI JU* arising from this *grant agreement*.

5. The requirement to provide a certificate on the financial statements shall be waived for those *participants* that declare personnel and indirect costs on the basis of a certified methodology approved by the European Commission within the Seventh Framework Programme in accordance with Article II.13.2, except for the final reporting period.

The requirement to provide a certificate on the financial statements shall be waived for those *EFPIA companies* that declare costs on the basis of a certified methodology in accordance with Article II.13.4, except for the final reporting period.

6. 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 *participant'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*.

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

8. 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.

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

¹ 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

10. 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.

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 Article II.5.3. 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 Article II.5.4. 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* 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)* in the performance of the *grant agreement*;
 - if there is a suspected or established *irregularity* committed by one or more *beneficiary(ies)* 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 *coordinator* and the *managing entity of the IMI JU funding* shall be duly informed of the reasons why payment in whole or in part will not be made. The *coordinator* shall inform the other *participants*.

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 *IMI JU* 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 authorities 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 of the final accepted *in kind contribution*, and shall justify these amounts. 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 *participant'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* 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 5.1.

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

4. Costs shall be reported in Euro. *Participants* with accounts in currencies other than 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. *Participants* 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 *participants*, in order to carry out part of the work of the *project* without the direct supervision of the *participant* and without a relationship of subordination.

Where the *participant* 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 *participants* 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 *participants* 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 *associated countries*. Exceptions may only be accepted by the *IMI JU* 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 *participant* may not affect the rights and obligations of the *participants* 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 *participants*.

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 *participant* and a subcontractor, prior to the beginning of the *project* in accordance with the *participant's* usual management principles may also be accepted.

3. *Participants* 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 *participants*. 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 *participants* 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 *participant*, the *IMI JU* may agree to extend this period regarding specific *confidential information*.

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

3. Notwithstanding Article II.9.1 and 2, 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 European Commission's internal rules for handling *classified information*². Where a *participant* is established in a *third country*, any security agreements between that *third country* and the *European Union* shall also apply.

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

1. *Participants* 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 *participants* 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 *participants* 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 European Union (*IMI JU*) financial support and *EFPIA companies' in kind contribution*. 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 support from *EFPIA companies* and the European Union (*IMI JU*) and display the *IMI JU* and *EFPIA* logos and the European emblem. This obligation to use the *IMI JU* and *EFPIA* logos and the European emblem in respect of *projects* to which the European Union (*IMI JU*) and *EFPIA companies* contribute implies no right of exclusive use. It is subject to general third-party use restrictions which do not permit the appropriation of the *IMI JU* and *EFPIA* logos and the European emblem or the logo, or of any similar trademark or logo, whether by registration or by any other means. Under these conditions, *participants* are exempted from the obligation to obtain prior permission from the European Commission, *EFPIA* and the *IMI JU* to use the logos and the European emblem. Further detailed information on the EU emblem can be found on the Europa web page. Any publicity made by the *participants* 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

² European 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 *EFPIA* nor the European Commission is liable for any use that may be made of the information contained therein.

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

- the name of the *participants*;
- contact addresses of *participants*;
- 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* 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*;
- the amount of the *EFPIA companies' in kind contribution* to the *project*, and *EFPIA companies'* contributions from outside Europe;
- 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 European Commission and/or *EFPIA* does not infringe any rights of *third parties*.

Upon a duly substantiated request by a *participant*, the *IMI JU* and/or the European Commission and/or *EFPIA* may agree to forego such publicity if disclosure of the information indicated above would risk compromising the *participant'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 European 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. *Participants* 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. *Participants* 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 *participant* 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 *participant*. The accounting procedures used in the recording of costs and receipts shall respect the accounting rules of the State in which the *participant* is established. The *participant'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 *participant* 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 *associated country*;
- h) they must be indicated in the estimated overall budget in Annex I.

2. Notwithstanding point a) of Article II.13.1, *participants* may opt to declare average personnel cost if the following cumulative criteria are fulfilled:

- a) The average personnel cost methodology shall be the one declared by the *participant* as its usual cost accounting practice; as such it shall be consistently applied to all the participations of the *participant* related to implementation of the Seventh Framework Programme;

- b) The methodology shall be based on the actual personnel costs of the *participant* as registered in its statutory accounts, without estimated or budgeted elements;
- c) The methodology shall exclude from the average personnel rates any ineligible cost item as referred to in Article II.13.6 and any costs claimed under other costs categories in order to avoid double funding of the same costs;
- d) The number of productive hours used to calculate the average hourly rates shall correspond to the usual management practice of the *participant* provided that it reflects the actual working standards of the *participant*, in compliance with applicable national legislation, collective labour agreements and contracts and that it is based on auditable data.

A certified methodology submitted by a *participant* and approved by the European Commission within the Seventh Framework Programme shall be deemed to comply with the criteria referred to in points (a) to (d) of this Article II.13.2, provided that the methodology has not changed.

Average personnel costs charged on the basis of methodologies which comply with the criteria referred to in points (a) to (d) of this Article II.13.2 shall be deemed not to differ significantly from actual costs.

3. *SME* owners who do not receive a salary and other natural persons who do not receive a salary shall charge as personnel costs a flat rate based on the ones used in the People Specific Programme for researchers with full social security coverage, adopted by Council Decision No 2006/973/EC, and specified in the European Commission's annual Work Programme of the year of the publication of the call to which the proposal has been submitted.

The value of the personal work of those *SME* owners and natural persons shall be based on a flat rate to be determined by multiplying the hours worked in the *project* by the hourly rate to be calculated as follows:

{Annual living allowance corresponding to the appropriate research category published in the 'People' Work Programme of the year of the publication of the call to which the proposal has been submitted / standard number of annual productive hours} multiplied by {country correction coefficient published in the 'People' Work programme of the year of the publication of the call /100}

The standard number of productive hours is equal to 1 575. The total number of hours claimed for European Union projects in a year cannot be higher than the standard number of productive hours per *SME* owner/natural person.

The value of the personal work shall be considered as a direct eligible cost of the *project*.

4. Notwithstanding point a) of Article II.13.1, *EFPIA companies* may opt to declare costs if based on a certified methodology on *in kind contribution* that fulfils the following cumulative criteria:

- a) The methodology is based on the usual cost accounting practices of the *EFPIA company*; as such it shall be consistently applied to all participations of the *EFPIA company* in *IMI JU projects*;
- b) The methodology is based on the costs of the *EFPIA company* as registered in its statutory accounts or on costs as accepted for reimbursement by the *EFPIA company's* national authorities under comparable funding schemes; it may include accounting estimates if these are part of normal cost accounting policy;

- c) Costs declared according to the methodology exclude any ineligible cost item as referred to in Article II.13.6 and any cost already declared under another cost category, so that the methodology ensures avoidance of double funding of the same costs.

Such a methodology on *in kind contribution*, to be accepted by the *IMI JU*, shall be certified by an external auditor fulfilling the requirements set out in Article II.4.4 i) and ii), and shall confirm that the criteria referred to in points (a), (b) and (c) of this Article II.13.4 are fulfilled.

Costs declared by *EFPIA companies* on the basis of methodologies which comply with the criteria referred to in points (a), (b) and (c) of this Article II.13.4 shall be deemed eligible for the purpose of evaluating their *in kind contribution*, without prejudice to compliance of these costs with the other conditions defined in points (b) to (h) of Article II.13.1.

5. Costs incurred by *third parties* in relation to resources they make available free of charge to a *participant*, can be declared by the *participant* provided they meet the conditions established in Article II.13.1 and they are not non-eligible in accordance with Article II.13.6, *mutatis mutandis* and are claimed in conformity with Article II.16.

6. 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 European Union, Euratom or *IMI JU 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 *participant* 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 *participant* 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 *participant*.

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 *participant* 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.

Indirect costs shall represent a fair apportionment of the overall overheads of the organisation.

They may be identified according to one of the following methods:

- a) Based on actual indirect costs for those *participants* which have an analytical accounting system to identify their indirect costs as indicated above. For this purpose, a *participant* is allowed to use a simplified method of calculation of its full indirect eligible costs at the level of its legal entity if this is in accordance with its usual accounting and management principles and practices. Use of such a method is only acceptable where the lack of analytical accounting or the legal requirement to use a form of cash-based accounting prevents detailed cost allocation. The simplified approach must be based on actual costs derived from the financial accounts of the last closed accounting year;
- b) *Participants* may opt for a flat rate of 20% of their total direct eligible costs, excluding their direct eligible costs for subcontracting and the costs of resources made available by *third parties* which are not used on the premises of the *participant*.

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 of the *beneficiaries*.

2. For **other activities** not covered by Article II.15.1, *inter alia*, management and training, the *IMI JU* financial contribution may reach a maximum of 100% of the total eligible costs of the *beneficiaries*.

3. Article II.15.1 and 2 shall apply also in the case of *projects* where flat rate financing or lump sum is used for the whole or for part of the *project*.

However, Article II.15.1 and 2 shall not apply for the whole duration of the *project* if the *beneficiary* has lost its status as an entity eligible to receive *IMI JU* funding and entered under the control of an *EFPIA company*. In this case, and from the date the *beneficiary* entered under the control of an *EFPIA company*, its eligible costs claimed shall be considered as *in kind contribution*.

4. **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*, 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.

5. 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 to the *beneficiaries* made by *EFPIA companies* and/or their *affiliated entities* or made by *participants* which are neither a *beneficiary* nor an *EFPIA company*.

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* 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*.
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*. For each *beneficiary*, 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 5.1.
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 *grant agreement*, the amount of interest generated when such pre-financing exceeds the amount fixed in the *IMI JU 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 *participants* 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 *participants* 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 *participants* shall ensure that the *IMI JU*'s services and any external body(ies) authorised by the *IMI JU* have on-the-spot access at all reasonable times, notably to the *participants* offices, to their computer data, to their 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 *participant* 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 *participants* 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 to the *beneficiaries* by the *IMI JU* and the application of any applicable sanction.

7. The European Commission including OLAF³ and the Court of Auditors shall have the same rights as the *IMI JU* among the *beneficiaries* and the agent responsible for allocating it, including right of access, for the purpose of on-the-spots-checks.

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 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;

³ 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 European 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)⁹ 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).

- 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 *participants'* contributions and integration within the *project*;
- the expected potential impact in economic, competition and social terms, and the *participants'* 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 *participant(s)* 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 *participants* the identity of the appointed experts. The *participant(s)* 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 *participants*. 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 *participants* 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 *participant* 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 *participant* according to Article II.37;
- to issue a recovery order regarding all or part of the payments made to the *beneficiaries* 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*. Article II.22.3 to 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 *liquidate damages* in respect of any overstated amount which comes to light after the end of the *project*, in accordance with the provisions of Article II.23.1 to 4.

II.24. Financial penalties

1. By virtue of the *IMI JU* Financial Rules, any *beneficiary* declared to be in serious breach of its obligations shall be liable to financial penalties of between 2% and 10% of the value of the *IMI JU* financial contribution received, with due regard for the principle of proportionality. The rate may be increased to between 4% and 20% in the event of a repeated breach within five years following the establishment of the first sanction that may be imposed on any defaulting *beneficiary* in accordance with the *IMI JU* Financial Rules. This provision shall be without prejudice to any other civil remedy to which the *IMI JU* or any other *participant* may be entitled. Furthermore, these provisions shall not preclude any criminal proceedings which may be initiated by the Member States' authorities.

2. In the cases of Article II.24.1, 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 *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 *participant* 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 *participants* 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.

Participants 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 *participant* after the accession to the *grant agreement*.

3. Each *participant* 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 *participant* 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 *participant* may - without the permission of the other *participants*, but provided that other *participants* 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 *participant(s)* that generated it.

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

If employees or any party working on behalf of a *participant* are entitled to claim rights to *foreground*, the *participant* 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 *participants* have jointly carried out work generating *foreground* and where no individual *participant* can be identified as its owner, such *participants* 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 *participant* 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 *participants*, which may only be withheld where they can demonstrate that their rights would be adversely affected.

Where a *participant* 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 *participant* may - without the permission of the other *participants* but provided that other *participants* 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 *participant* 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 support from the Innovative Medicines Initiative Joint Undertaking under *grant agreement* n° [xxxxxx], resources of which are composed of financial contribution from the European Union's Seventh Framework Programme (FP7/2007-2013) and EFPIA companies' in kind contribution.⁴

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.

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 support from the Innovative Medicines Initiative Joint Undertaking under *grant agreement* n° [xxxxxx], resources of which are composed of financial contribution from the European Union's Seventh Framework Programme (FP7/2007-2013) and EFPIA companies' in kind contribution.⁵

⁴ This statement will have to be translated into the language of the patent filing.

⁵ This statement will have to be translated into the language of the dissemination activity.

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 *participant(s)* that generated it.

The *participants* 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 *participant* shall in no way affect the obligation of that *participant* to grant *access rights* to the remaining *participants* 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.

II.29. Access rights to the *participants* for completing the *project*

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

1. *Foreground*. During and after completion of the *project*, *participants* and their *affiliated entities* shall enjoy *access rights* to the *foreground* of the other *participants* 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*, *participants* and their *affiliated entities* shall enjoy *access rights* to the *background* of the other *participants*, 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 *participants* 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 *participants*, 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 Articles II.31.1 and II.31.2 shall be included in the *project agreement*.

4. Before execution of the *grant agreement*, a *participant* 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 *participant*. 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. *Participants* 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 *participant* or *third party* requires *foreground* or *background* necessary to use *foreground* owned by another *participant*, the *access rights* will be negotiated between the parties involved as they see fit.

Participants may agree on such *access rights* in the *project agreement*.

II.33. Confidential information

1. In accordance with section II.9, the *participants* covenant not to disclose and not to use the *confidential information* received from other *participants* except as provided in and for the purposes of the *project agreement* and *grant agreement*.

2. Unless otherwise agreed in the *project agreement*, each *participant* 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 *participants* at least thirty (30) days prior to the submission of any written publication or any oral dissemination to allow the *participants* to determine whether any invention or *confidential information* would be disclosed.

The reviewing *participants* 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 *participants* 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 *participants* 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 *participants* 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 *participant(s)* shall be submitted by the *coordinator*. The *coordinator* is deemed to act on behalf of all *participants* 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 *participants* 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 *participant* 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 *participants* 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 *participants*.

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

- the *consortium's* proposal for reallocation of the tasks and budget of that *participant*;
- the reasons for requesting the termination;
- the proposed date on which the termination shall take effect;
- a letter containing the opinion of the *participant* 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 *participant* 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 *participant* (in case it is a *beneficiary*) 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 *participant* concerned can be substituted by proof that this *participant* 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 statements of that *participant* and shall not make any further reimbursement for it (in case it is a *beneficiary*).

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

Requests for termination of the *grant agreement* 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 Article II.36.1, when the *consortium* requests the addition or the termination of the participation of a *participant*, 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 *participants*, the *IMI JU* shall send a copy to the *participant* 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 *participants* at the *IMI JU*'s initiative

1. The *IMI JU* may terminate the *grant agreement* or the participation of a *participant* 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 *participant* has deliberately or through negligence committed an *irregularity* in the performance of any *grant agreement* with the *IMI JU*;
- d) where the *participant* 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 *participant* 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 *participant(s)* concerned substantially affects the implementation of the *project*, or the interests of the *European Union*, or calls into question the decision to grant the *IMI JU* financial 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 IMI Research Agenda;

- l) where a *participant* 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 *participants*, 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 *participant* 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 *participant* is declared bankrupt or is being wound up.

2. The *IMI JU* shall notify the *participant(s)* 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 *participant(s)* 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 *participant*.

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 *participants* and the termination shall become effective 45 days after receipt by the *coordinator*.

3. Within 45 days after the effective date of termination, the *participant(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 statements and not to make any further reimbursement (in case the *participant* is a *beneficiary*) and, where appropriate, require the reimbursement of any *pre-financing* due by the *beneficiary(ies)*.

4. In case the *participant* is a *beneficiary*, 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 Article II.37.1 to 5 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* 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 Article II.38.1:

- 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 JU* 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* or after termination of the *grant agreement*, this payment shall be considered as a final payment in relation to such *beneficiary(ies)* or to 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 *participants*, 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 *participant(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 *participants* 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 *participants* cannot fulfil their obligations to execute the *project* due to *force majeure*, eligible costs may be accepted 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 *participants* 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 *participants*.

II.41. Liability

1. The *IMI JU* cannot be held liable for any acts or omissions of the *participants* 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 *participant* 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 *participant* 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 *participant* concerned.

3. Each *participant* 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 *participant* or of a *participant* 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.

II. 43. Competitive calls

1. When required by the relevant call for proposals and/or the terms of Annex I, the *consortium* shall, following a competitive call in accordance with the provisions of this Article, identify and propose to the *IMI JU* the participation of new *beneficiaries*.

2. The *consortium* shall publish the competitive call at least in one international journal and in three different national newspapers in three different Member States or *associated countries*. It shall also be responsible for advertising the call widely using specific information support, particularly Internet sites on the IMI JU, the specialist press and brochures and through the national contact points set up by Member States and *associated countries*. In addition, the publication and advertising of the call shall conform to any instructions and guidance notes established by the *IMI JU*. The *consortium* shall inform the *IMI JU* of the call and its content at least 30 days prior to its expected date of publication.

3. The competitive call shall remain open for the submission of proposals by interested parties for a period of at least five weeks.

4. The *consortium* shall evaluate applications received in the light of the criteria that governed the *IMI JU*'s evaluation and selection of the *project*, defined in the relevant call for proposals, and with the assistance of at least two independent experts appointed by the *consortium* on the basis of the criteria described in the IMI Rules for submission, evaluation and selection of expressions of interest and full project proposals.

5. The *consortium* shall notify the *IMI JU* of the proposed accession of a new *beneficiary(ies)* in accordance with Article II.35. At the same time, it will inform the *IMI JU* of the means by which the competitive call was published and of the names and affiliation of the experts involved in the evaluation. The *IMI JU* may object to the accession of any new *beneficiary* within 30 days of the receipt of the notification in accordance with Article II.36.